



Bioprocess Catalogue Products and Solutions for the Biopharmaceutical Industry

ssflow (sum- t

Crossflow Systems

Membrane Chroma-

Virus Filter

Disposable Liquid Hand-

> Cartridge Housings

grity Testing Systems

FACTS

biological Control





#### **About Sartorius**

Sartorius is an internationally leading process technology supplier covering the segments of biotechnology and mechatronics. The Goettingen-based company founded in 1870 currently employs a good 3,660 persons. Its biotechnology segment focuses on filtration and separation applications, fermenters and proteomics. The mechatronics segment particularly consists of products for weighing, measurement and automation technology in laboratory and industrial applications.

Sartorius key customers are from the pharmaceutical, chemical and food and beverage industries and from numerous research and educational institutes of the public sector.

Sartorius has its own production facilities in Europe, Asia and America, as well as sales subsidiaries and local commercial agencies in more than 110 countries.





#### **About this Catalogue**

This process catalogue offers you several options for selecting the optimal product for your application or process.

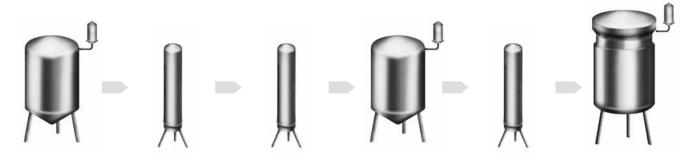
In the first chapter, you will find our offer of product solutions for individual application areas all along the process chain, and the corresponding references to the product pages. The thumbnail tabs will help guide you to the section you need to find.

Alternatively, you can use our Bioprocess Product Finder on page 8. It will assist you in choosing the recommended products for your application.

The following subjects that cover more than one application are listed below: Housings, page 201 Integrity Testing, page 209 Microbiological Testing, page 231 Services, page 223

If you know the name of the product of your choice, just check the name index at the back of the catalogue to find the page number right away.

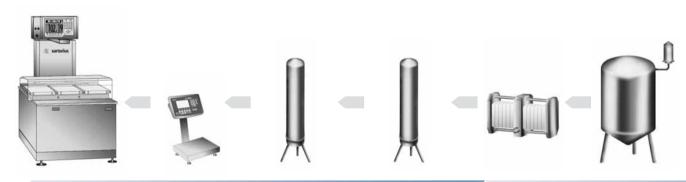
# **Bioprocess Product Finder**



#### Media | Buffer Preparation

Cell Culture & Fermentation

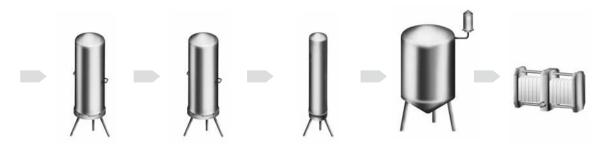
Holding Tank	Prefiltration	Sterile Filtration	Holding Tank	Sterile Filtration	Fermentation
Fluid Handling Bags   178  Fluid Mixing Systems   186  Sartofluor GA*   56  Sartopure GA*   68  Level Control   286  Load Cells   285  Indicators   283	Sartopore 2 0.45 µm*   106 Sartobran P 0.45 µm*   92 Sartopure GF Plus*   72 Sartopure PP2*   70 Sartoclean CA*   78 Sartoclean GF*   76	Sartopore 2 0.2 μm*   96 Sartobran P 0.2 μm*   84	Fluid Handling Bags   178  Fluid Mixing Systems   186  Sartofluor GA*   56  Level Control   286  Load Cells   285  Indicators   283	Sartopore 2 0.2 µm*   96 Sartobran P 0.2 µm*   84	Engineering   229 Fermenter   33 Sartofluor GA*   56 Level Control   286 Load Cells   285 Indicators   283 Scales   280 Platforms   288



#### Form & Fill

Controlling	Filling	Sterile Filtration	Prefiltration	Concentration स Diafiltration	Holding Tank
Checkweighers   292 Scales   280 Platforms   288 Indicators   283	Combics   281 Scales   280 Platforms   288 Load Cells   285 Indicators   283	Sartopore 2 0.2 µm*   96 Sartobran P 0.2 µm*   84	Sartopore 2 0.45 µm*   106 Sartobran P 0.45 µm*   92 Sartopure PP2*   70 Sartoclean CA*   78	Crossflow Ultrafilters*   136 Crossflow Systems   147	Fluid Handling Bags   178  Fluid Mixing Systems   186  Sartofluor GA*   56  Level Control   286  Load Cells   285  Indicators   283

<sup>\*</sup>Also in disposable technology available.



#### Capturing

**Cell Harvest** Sartoclear P\* | 118 Crossflow Microfilters\* | 128 Crossflow Systems | 147 Sartopure GF Plus\* | 72 Sartofine\* | 80

## Clarification

Sartoclear P\* | 118 Crossflow Microfilters\* | 128 Crossflow Systems | 147 Sartopure GF Plus\* | 72 Sartofine\* | 80 Sartoclean\* GF | 76

#### Sterile Filtration

Sartopore 2 0.2 μm\* | 96 Sartobran P  $0.2~\mu\text{m}^*\mid 84$ 

#### **Holding Tank**

Fluid Handling Bags | 178 Fluid Mixing Systems | 186 Sartofluor GA\* | 56 Level Control | 286 Load Cells | 285 Indicators | 283

#### Concentration & Diafiltration

Crossflow Ultrafilters\* | 136 Crossflow Systems | 147

Purification











Polishing

# **Purification**

Membrane Chromatography Polishing	Virus Filtration	Membrane Filtration	Membrane Chromatography Capturing & Purification	Membrane Filtration
Sartobind SingleSep*   162	Virosart CPV   166	Sartopore 2 0.1 μm*   104 Sartobran 0.1 μm*   90	Sartobind re-usable   160	Sartopore 2 0.2 μm*   96 Sartobran P 0.2 μm*   84





# Bioprocessing Competence

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#### **Creating Value by Integrated Biomanufacturing**

Sartorius offers the most comprehensive technology, product and service portfolio worldwide, which ranges from the discovery of active ingredients to production all the way to compliance with the accompanying regulatory steps. Featuring special filters, fermenters and bioreactors, products for membrane chromatography, bags, containers and mixing systems for fluid media handling as well as an extensive service portfolio, Sartorius serves all production steps in the biopharmaceutical industry.

Technology from Sartorius makes production processes more reliable, accurate and predictable. Sartorius offers not only products for individual production steps, but also technologically and economically optimized solutions developed together with the customer for complete upstream and downstream processing.

Sartorius thinks in processes and therefore focuses on the factors that are critical to success:

- Time to Market
- Regulatory Compliance
- Production Costs
- Production Capacities

As a result, Sartorius offers its customers the unique benefits of a total solution provider.

#### Scale-Up

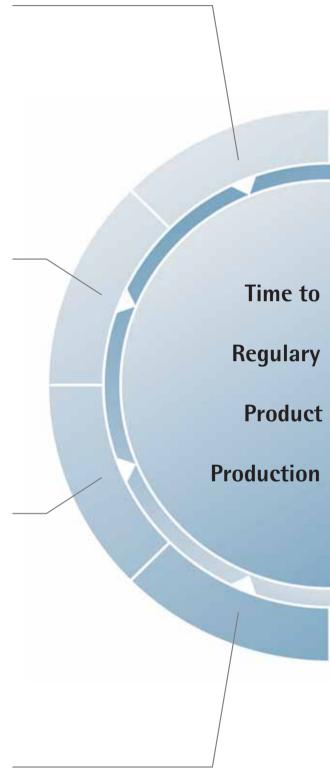
Sartorius technologies are scalable so that the customer can generate increasing quantities of a substance within a short time throughout all phases, from discovery up to commercial production and with optimal yield.

#### **Disposable Technology**

Disposable technology is decisive for the speed and efficiency of processes, while ensuring maximum security and reliability in preventing cross-contamination. For all process steps and volumes, Sartorius offers the advantages of powerful and cost-efficient disposable technology.

## **Regulatory Services**

Along with the BioPharmAlliance jointly founded with KMI | Parexel, Sartorius customers have access to the entire wealth of expertise of the market leader in validation and regulatory compliance.



## **Validation and Training**

Sartorius won't go when the going gets tough. Sartorius' experienced and highly knowledgeable experts help customers with process validation and training.



#### **Process Optimization**

Together with our customers, we analyze processes and optimize them in terms of increasing yield as well as saving time and costs. As a result, Sartorius creates genuine added value for its customers.

# Cell Culture | Fermentation

Together with Sartorius BBI Systems, Sartorius offers the product and service portfolio of the market leader in cell culture and fermentation, and is focusing on the optimal interaction between fermentation | cell cultures and downstream processing.

## **Engineering**

Sartorius engineering expertise covers customized design, production, installation, automation, integration and validation of bioreactors, fermenters and peripheral systems.

## Weigh | Detect | Control

Sartorius offers a truly wide product and service portfolio for hopper weighing, fill-by-weight level control, average weight control of prepackages, completeness checks and quality assurance.



# Fermentors | Bioreactors | Integrated Solutions from Research Through Production

Sartorius BBI Systems GmbH has for more than 35 years provided a range of innovative bioreactor products (BIOSTAT®) and support services to major biotechnology and pharmaceutical companies worldwide. In this position, Sartorius BBI Systems is the worldwide leading supplier of biotechnology systems.

The BIOSTAT®line of fermentation and bioreactor equipment spans the full operational spectrum – from benchtop and pilot systems to custom process skids.

The core areas of expertise of Sartorius BBI Systems are in the development and production of fermenters and bioreactors for applications in the laboratory, in production and in the corresponding automation and controlling units.

As part of the Biotechnology Division of Sartorius AG the product portfolio now also includes crossflow filtration equipment in upstream and downstream processing.

#### Our capabilities

Operating internationally, we are always close to our customers around the world. Our closely meshed network of agencies, each with its own service team, enables us to provide direct, individualized support to our clients, from the planning stage to operation. This "concept to completion" approach keeps our clients at the forefront of scientific and technical developments.

Our engineers all over the world tailor systems and whole plants, realizing specific solutions across the spectrum of customer applications. Units developed and tested in the laboratory are scaled up to industrial size in an elaborate and painstaking process. With the aid of special 3D CAD planning procedures, we can show the client their plant at each stage of development.

With a workforce of a good 500 persons, the company is represented with its production sites in Germany, Italy, the U.S, and India, and with sales companies in more than 50 countries.

#### Practical solutions at every level

Our portfolio of capabilities spans all areas of customer support. From technical consultation to project planning, in areas such as laboratory automation, industrial poduction, validation support and after sales service, we handle it all.

Sartorius BBI Systems is a valuable partner for companies in the pharmaceutical and biotech market where cGMP requirements and FDA guidelines must be followed. Equipment and plants supplied by Sartorius BBI Systems are fully documented "as built."

Discover our capabilities on page 33.



#### **Cell Removal | Clarification**

Within the biotech industry, cell culture and microbial fermentation are today's key processes for the production of therapeutic proteins. Key technologies relevant in the upstream and downstream processing of cell culture and microbial fermentation mainly involve filtration and purification.

Purification steps such as chromatography are very cost-intensive. Chromatography performance depends significantly on the prior removal of particulate matter, especially cell and cell debris, as well as colloidal compounds from the fermentation media.

Sartorius has developed depth filter technologies that effectively meet these requirements, applying the Sartoclear® P direct flow technology.

Effective removal of cell and cell debris, as well as contaminants by Sartoclear® P, allow for the design of economic and reliable filtration systems for such biopharmaceutical applications.

The Sartoclear® P direct flow technology combines excellent cell harvest & clarification capabilities with highest throughput of fermentation media.

The filter media of Sartoclear® P consist of cellulose fibers combined with inorganic filter aids, which offer most valuable benefits:

- Excellent clarification effect with highest capacity for retaining particles and colloidal compounds
- Particles and colloidal compounds smaller than the nominal retention rating of the filter media are captured by adsorption due to the positive-charged filter media

Discover our capabilities on page 117.

Discover our capabilities on page 65.



# Capturing | Purification Chromatography of Highly Diluted Proteins, Large Proteins and Viruses

Chromatography is the most important purification method for biopharmaceuticals as it offers the highest selectivity and product purity. It is used mainly in columns filled with gel beads having disadvantages such as long processing times, size exclusion effects due to small pore size of the beads and low throughput at 100–150 cm/h, only. Care has to be taken when handling columns, as the gel bed is susceptible to breakage, channelling and inclusion of air. Column packing and its validation can be time-consuming and costly. Investment in hardware is high and cleaning and storage conditions as well as the complex use, influence the overall process economy.

#### Membrane chromatography

To overcome these disadvantages Sartorius has developed a number of innovative chromatography membranes, including ion exchangers such as quaternary amine (Q), sulfonic acid (S), diethylamine (D) and carboxylic acid(C), metal chelate iminodiacetic acid (IDA) and affinity membranes such as a protein A and a Blue 3-GA membrane, benzamidine as well as membranes for creating your own affinity supports, such as aldehyde and epoxy membranes.

They feature a macroporous structure with a pore size of > 3 and 0.45–0.35  $\mu$ m. That means they have many times more area than do conventional chromatographic gel matrices. The pores allow large molecules and even viruses to access the binding sites within the porous structure of the membrane support by direct fluid convection, instead of being dependent on diffusion and a sieving effect of small pores in chromatography resins.

These membrane adsorbers add new options for the downstream processing, as they come ready-to-use, fully scaleable, and are usable at several times higher flow rates compared to columns.

#### "Innovation pure"

A single membrane and a single module cannot address all the different needs for purification. Therefore, Sartorius has developed the largest variety of chromatographic membranes and modular systems for large-scale membrane chromatography on the market.

#### Approved technology

In 2001 Campath®\* received FDA approval. This monoclonal antibody is polished by application of Sartobind ion exchange Q modules in flow-through mode (DNA | endotoxin | leached protein A | virus removal). It was the first time that a membrane adsorber had been accepted in the production of a therapeutic protein. This shows not only Sartorius' position as the pioneer in adsorptive membrane chromatography, but also displays that this technology is proven and tested.

Sartobind® membrane adsorbers display major advantages when using very diluted protein solutions or large volumes to be processed in a very short time.

# Typical capturing applications for Sartobind

- Purification of highly diluted proteins
- Purification of viruses
- Purification of large proteins
- High-speed purification of labile biomolecules

**Sartobind** modules can be reused hundreds of times. They are designed to achieve high binding capacity for large molecules and viruses at the highest throughput.

**Sartorius** has the experience and the products to optimize your membrane-based chromatographic process to improve your throughput, yield and budget.

Discover our capabilities on page 159.

<sup>\*</sup> Campath is a trademark of ILEX Pharmaceuticals



# Polishing Virus Clearance Technologies

The risk of viral contamination is a feature common to all biotechnological products derived from human or animal plasma and mammalian cell lines. Modern manufacturing processes employ complementary viral clearance technologies, frequently combining active virus removal with virus inactivation steps.

Among the various technologies available for viral clearance, three robust and orthogonal technologies have been integrated into the Sartorius virus clearance technology platform.

This platform comprises virus filtration with Virosart® CPV, virus inactivation with UVivatec UVC-light and Virus adsorption with Sartobind® Q Membrane Chromatography.

These individual elimination steps depend on different physical principles and address typical properties of the relevant virus classes, such as size, presence of a lipid envelope and type of the nucleic acid.

Whether you target the production of therapeutic proteins derived from cell lines or animal human plasma, Sartorius has the product range that provides you with a total process solution meeting your needs in terms of security, reliability, GMP compliance and cost effectiveness. The three-step viral clearance technology platform ensures maximum process safety in your manufacturing scheme.

#### Virosart® CPV

Polyethersulfone filters for state of the art virus retention according to highest safety standards, with more than 4  $\log_{10}$  for PPV and more than 6  $\log_{10}$  for retroviruses.

Discover our capabilities on page 165.

#### **UVivatec**

Effective UV irradiation at 254 nm through a novel spiral flow UVivatec module. Highly efficient product mixing and evenly delivered UVC dose for homogeneous and shorter residence time. Ideal for small non-enveloped viruses like PPV.

#### Sartobind® Q

Sartobind® membrane adsorbers disposable formats for the purification of therapeutic proteins, antibodies and clearance of viruses, as well as for the removal of contaminants such as DNA, endotoxins or host cell proteins.

Discover our capabilities on page 159.







# Disposable Bioprocess Components for Optimized Process Economy in Biopharmaceutical Production

#### Disposable technology

In biopharmaceutical production, disposable technology and single-use concepts are established satisfactorily during product discovery, early development phases, and also in late clinical phase time lines. Disposable components are being increasingly used in cGMP manufacturing steps from fermentation to initial recovery, purification and polishing steps. Single-use concepts eliminate the need for cleaning, ease the validation, and influence the economical situation in a positive way. Sartorius offers a wide range of disposable components: Bags, Capsules, Slice Disposable, Membrane Chromatography

#### **Bags**

Disposable bioprocessing systems have been widely applied to media preparation, filtration, storage and delivery processes. Disposable storage bags may be fitted with a variety of connectors that allow for aseptic or sterile connection to the bioreactor. In addition to the typical process scenario above, other disposable schemes are also commonly applied to the media preparation area. Due to its enormous advantages, sterile fluid handling bags have become increasingly important to numerous other process steps along the entire process chain. Typical applications include bioreactor and fermentation harvest, diafiltration, waste collection, transport, storage and mixing of bulk intermediate and final product. Together with its cooperation partners TC Tech (Bag Technology) and LevTech® (Sanitary Mixing). Sartorius provides integrated solutions for biopharmaceutical fluid handling. Discover our capabilities on page 171.

Sartorius offers a complete line of disposable filter elements made of the same materials and mode of construction as our large scale filter cartridges.

#### MidiCaps

Our unique MidiCaps disposable capsule design offers multiple advantages for the user in the biopharmaceutical industry:

- GMP compliant vent and drain valve design with integral hose barb for optimal fluid containment during the venting process
- Imprinted, easy to read labelling including filter type, pore size or retention rating, lot-no., piece-no., operating parameters and direction of use for optimal traceability
- Broad range of connector styles for flexible integration into any process
- Overall optimised capsule design for reduced dead volume, maximized flow and enhanced mechanical stability

#### **MaxiCaps**

The use of disposable filter elements in the past was limited to laboratory- and small production scale. MaxiCaps incorporate standard 10", 20" and 30" cartridges in a disposable format. The implementation of MaxiCaps into your production processes allows to benefit

from the advantages of disposable technologies in large scale processing. Reduced cleaning validation, elimination of SIP and CIP cycles as well as higher flexibility in your overall production processes are typical advantages associated with the use of MaxiCaps in our production.

#### SartoScale

For filterability trials, to determine the ideal membrane material or combination of prefilter and final filter ideally suited for your application, we recommend to use our SartoScale disposable filter units. The self-contained, ready to use filter disposables contain 47 mm filter discs of original filter cartridge material sealed into a polypropylene housing for reliable scale-up and scale down filtration trials. Standard filter and bag assemblies have been developed by Sartorius, Gammasart BioSystem™, to help customers implement disposable technology faster and more economically. The following Sartorius filter types are available in capsule formats:

Title types are available	III Caps
– Sartobran P	(523)
<ul> <li>Sartopore 2</li> </ul>	(544)
<ul> <li>Sartopore 2 Gamma</li> </ul>	(544
<ul><li>Sartolon</li></ul>	(510)
<ul> <li>Sartofluor GA</li> </ul>	(518)
<ul> <li>Sartoclean CA</li> </ul>	(562)
<ul> <li>Sartoclean GF</li> </ul>	(560)
<ul> <li>Sartopure PP2</li> </ul>	(559)
- Sartopure GF Plus	(555)

These filters are suitable for the same applications as the larger filtration area filter cartridges. These filters are available in a variety of effective filtration areas: 150 cm² | 0.15 ft², 300 cm² | 0.3 ft², 500 cm² | 0.5 ft², 1000 cm² | 1 ft², 2000 cm² | 2 ft², 4500 cm² | 5 ft² ln order to accommodate various processing systems, these filters are available with the following inlet and outlet connectors: 1 ½" sanitary flange, ¾" sanitary flange, ½" single stepped hose barb, Multiple stepped hose barb (DN 6-12) **Discover our capabilities on page 83.** 

#### Slice disposable

Crossflow slice disposable units are designed for single-use applications. Membrane types are available in Polyethersulfone and Hydrosart. **Discover our capabilities on page 127.** 

#### Membrane chromatography

For capturing high-value products and contaminant removal (i.e. DNA or host cell protein; endotoxins & viruses) novel technologies enter the arena for disposable bioprocess components. Membrane chromatography modules are integrated in plastic housings for ready-to-use applications. With "SingleSep" membrane chromatography disposables, the need for dedicated purification equipment can be eliminated.

Discover our capabilities on page 159.



#### **Integrity Testing | Filter Management Systems**

In 1980, Sartorius launched the first automated integrity tester, Sartocheck 1000. Beginning with this milestone, Sartorius creative innovations entered the market. Some examples prove this innovation force, e.g., WIT (Water Intrusion Test) which is today's standard filter integrity test method for hydrophobic filters, EPS-External Pressure Sensor technology which allows the user to easily overcome distances between integrity tests and filter housing.

Filter integrity testing is more than using "stand-alone-units," only. The market constantly calls for increasingly enhanced and faster technology in order to meet the customers' demands. These demands are the driving force for our research and development as well as for our system engineers to develop innovative solutions. There are no limits in terms of technical feasibility. Sartorius can offer a broad range of filter integrity test solutions - beginning with our Sartocheck Junior series, Sartocheck 3 and the latest version Sartocheck 4, our integrated built-in concept "integrity within", WIT-Trolley and finally customized filter management systems.

#### Sartocheck Junior BP+

The Sartocheck Junior BP+ is designed as an easy and independent filter integrity tester with a rechargeable battery, which meets the requirements for small production and public labs. The filter integrity test is microprocessor-controlled, however the record data have to be entered manually.

#### Sartocheck 3 and Sartocheck 3 EPS

Both Sartocheck 3 and Sartocheck 3 EPS, the most successful filter integrity testers still, fulfill the technical requirements. It does whether matter the filter is used in the laboratory for small scale filtration or in the process for filtering high volumes on media. The technology based on the well-established and highly precise pressure decay measurement gives the user 100% security in his filter integrity testing.

#### Sartocheck 4

Sartocheck 4 enables you to step into the world of electronic records and electronic signatures. The system is designed to meet the requirements in GAMP guidelines in order to comply with 21CFR Part 11. The reason for the compliance with regard to data management, user handling and audit trails is to ensure 100% tracebility. Furthermore, Sartocheck 4 is able to communicate via a standard network connection with an FTP server. This feature, which was requested by the industry, enables the data to be easily archived on a general file server.

#### Within concept

The built-in concept allows the user to integrity-test the filter inside the machine without connecting an external integrity tester, e.g. Sartocheck 3 or Sartocheck 4. The within concept utilizes the existing hardware and software platform in order to install and program the filter integrity test. The control function, as well as the mathematical algorithms, are directly integrated into the PC or PLC software as a subroutine.

#### WIT-Trolley

The WIT-Trolley contains the whole equipment for carrying out the WIT on a filter housing. A water reservoir inside the Trolley brings the test water under controlled conditions to the filter housing. Temperature probes ensure that the water temperature does not exceed the limits. The water level switch monitors and controls a sufficient water level inside the tank in order to perform the next test.

#### Filter management system

This is a new approach that not only focuses on filter integrity testing, but comprises all stages of the filter handling. The revolutionary concept makes the filter handling procedures independent of the point-of-use of the filter. After filtration has been completed, the filter housing has to be taken from the filtration line and brought to the filter management system. The filtration line can be cleaned and sanitized before a new filter housing, which is sterile and integrity tested, can be reconnected.

Discover our capabilities on page 209.



#### FACTS - Program Added Value for Your Business

#### Facts® program

Get the FACTS® with Fully Advanced Customer Total Support. This comprehensive service program represents our professional pledge to you to go above and beyond in customer support by paying particular attention to the many ways in which we can make a difference.

As a total solution provider, Sartorius offers a platform of innovative products and technologies, as well as an extensive service portfolio along our customer's value chain in the pharma | biotech industry, which is highly regulated and confronted with ever-changing compliance parameters.

We focus on what is of major importance to our customers. Our business strategy very clearly addresses the critical success factors like time-to-market, regulatory compliance, cost of goods and production capacities.

The service philosophy of the Sartorius FACTS® program means added value for your business through optimization, validation, compliance and training support.

Helping you transform the complexity of cost efficiency and regulatory compliance into a balanced situation is the goal of the FACTS® program and the BioPharm-Alliance, which has extended our performance spectrum. The alliance with Parexel Consulting, an independent supplier and market leader in the sector of validation and regulatory compliance, was established in 2003.

The FACTS® and BioPharm-Alliance Program is divided into four service categories:

#### **DISCOVER®**

Our audit and survey services:

- Compliance audits
- Regulatory inspection readiness
- Plant | Process surveys
- Validation surveys
- Quality system surveys
- Technical studies

#### **INCREASE®**

Our optimization services:

- Corrective actions guidance
- Process optimization and development support
- Design review and technology transfer
- Documentation and submittal optimization
- Regulatory guidance

#### **CONFIDENCE®**

Our validation services:

- Validation designs
- Pre-approval inspection preparation
- Post-approval change support
- CFR 21 Part 11 GAMP compliance
- Regulatory liaison
- Equipment qualification
- Filter | Cleaning | Process validation
- Extractables Leachables testing

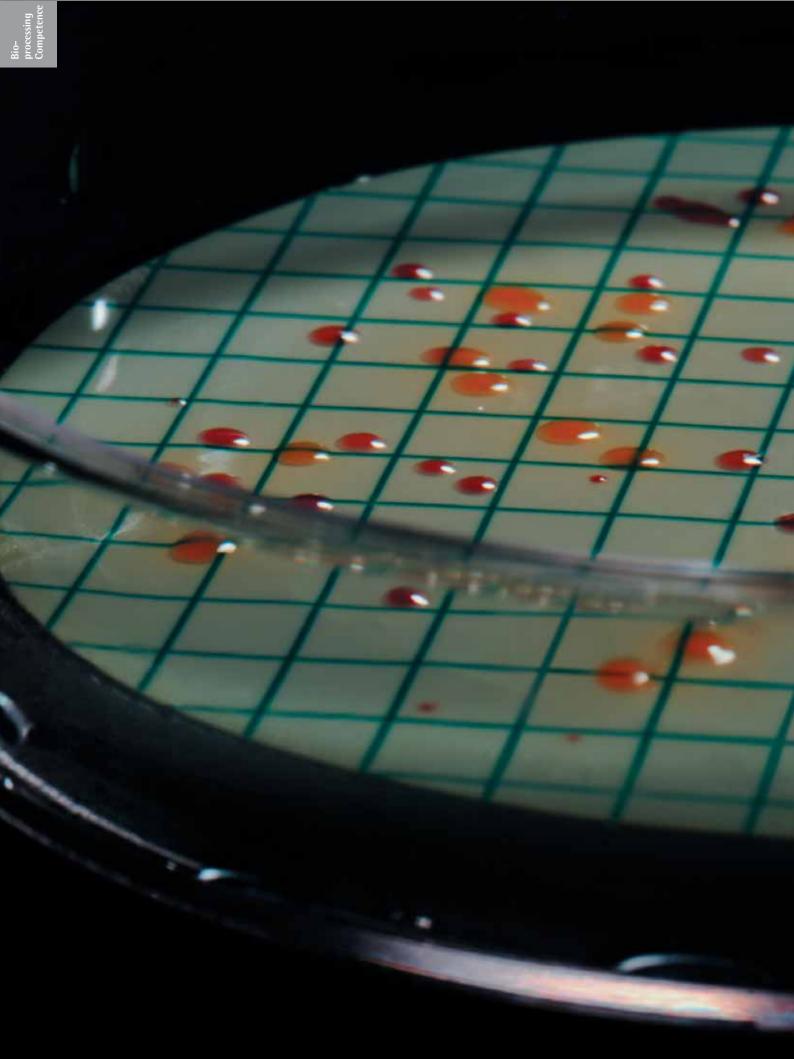
#### **EXPAND®**

Our training services:

- FDA risk-based approach
- Regulatory inspection
- CFR 21 Part 11 GAMP
- Aseptic processing
- Upstream | Downstream processing
- Process validation
- Cell culture | Fermentation
- Integrity testing
- Quality control and quality assurance

These services are provided by experienced experts in collaboration with our BioPharm-Alliance partner.

Discover our capabilities on page 223.



#### **Microbiological Quality Control**

#### **Colony counts**

The requirements for a practical microbiological test method are that it permits quantitative and reproducible detection of trace contamination, and that it can be performed efficiently and economically under routine conditions. These requirements are optimally fulfilled by the membrane filter method.

The sample is filtered through a membrane filter, which is then rinsed, placed on a culture medium and incubated. The resulting colonies are counted and related to the filtered volume.

Individually packed, gridded membrane filters are manufactured specifically for this application. They are ready-for-use, quality-controlled for colony growth and packed in

application. They are ready-for-use, qualitycontrolled for colony growth and packed in easily opened envelopes, each clearly marked with product identification and lot number.

**Nutrient pads** are a further simplification. They are culture media in dry form, sterile-packed in Petri dishes, easy to stock and of consistent high quality, ready-for-use after simply wetting with water. Typical colonies grown on the various types are shown on page 250. The wide range of media includes types for food, beverage and pharmaceutical industries.

#### Other water testings

142 mm diameter polyamide membranes of 0.2  $\mu$ m or 0.45  $\mu$ m pore size are specified in a method for the collection of legionella organisms.

A method using a Sartocon Crossflow system with 100,000 cut-off polyethersulfone cassettes for the recovery of bacteriophages from water has shown very good results.

#### Airborne bacteria and viruses

Gelatine membrane filters are routinely used to quantitatively collect airborne microorganisms for clean-room and isolator monitoring. Their effectiveness for the collecton of viruses has also been demonstrated. The gelatine appears to have a protective effect on the captured viruses and can be dissolved in buffer or medium for subsequent virus detection.

A recent publication describes their use for the routine monitoring of bacteriophages in the ambient air of milk-processing facilities.

For quicker and simpler sample filtration Sterile, single-use funnels and monitors to replace stainless steel funnels of vacuum holders.

#### **Biosart 250 funnels**

250 ml funnels which eliminate the need for time-consuming sterilization between samples. Their large inner base diameter ensures shortest filtration times.

#### **Biosart 100 monitors**

100 ml capacity units with filters available in different pore sizes, filter colors and diameters. The completely sterile units have to be used in connection with various culture media. Lid and base form a Petri dish after the culture medium has been added.

Discover our capabilities on page 231.



#### **Industrial Process Weighing**

Under the umbrella of the Sartorius Group, the Process Weighing & Control business area is represented in a global network – for sales and distribution, technical service and research.

We combine a wide range of products and services for process industries; from heavy duty platforms and precision scales to in-line checkweighers, from load cells and batch controllers to metal detectors.

As a specialist for solutions in the areas of industrial weighing, particle detection and process control, we see ourselves as a partner to help optimize the performance of your processes. From Goods In to Goods Out, from Production to Quality Control.

At Sartorius we provide more than just products. We are at your disposal to provide consultancy during specification and design right through start-up, commissioning and the day-to-day operation of your plant. Your individual solution is at the very heart of all our efforts at Sartorius. Our sales and service experts, with all their application and process know-how, are there to help you.

#### Sartorius paint mixing systems

Sartorius has demonstrated its design expertise with numerous technological highlights throughout our 130-year-plus history. Today, Sartorius customers continue to profit from the benefits of a head start in development – including in the design of paint-mixing systems – that puts us ahead of the rest.

Sartorius has the widest array of products offered anywhere in the field of paint-mixing equipment, from simple paint-mixing scales to complex network-capable systems. With outstanding product features like the recalculation function, Sartorius systems deliver practical solutions to virtually any problem. Our policy of ongoing development, integrating valuable input from the real world, ensures our global leadership in this market.

Discover our capabilities on page 279.





# Fermentation | Cell Culture

Bioprocess Automation	34
Biostat® A plus	36
Biostat® B plus	38
Photohioreactor Riostat® PRR	50

#### Platforms for Biotechnology - Bioprocess Automation







We at Sartorius can offer a broad range of bioprocess automation solutions – from teaching, research and development through process development to production in GMP environment with advanced software solutions.

#### Creating bench-top control

Since the introduction of our first digital fermentor controller (DCU), we have delivered several thousand systems to leading pharmaceutical and biotech companies worldwide. Use of a modular system design has enabled us to offer a range of cost-effective solutions for new users, as well as providing an upgrade platform for existing installations.

Our key platform to automation is based on the use of flexible Digital Control Systems (Micro-DCU and DCU), which are specifically tailored for fermentation and cell culture applications. First level automation is available using the Micro-DCU platform, which is delivered, together with our standard range of fermenters, in preconfigured versions according to the type and size of the fermentor.

When combined with our MFCS/win Supervisory Control and Data Acquisition (SCADA) system, this solution provides the most costeffective platform for small- to medium-scale research and pilot plant applications.

#### Process automation at a single touch

Sartorius BBI Systems' DCU fermentor control system utilizes 'state of the art' technologies and software which have been specifically developed for use in biotech equipment control.

Incorporating an intuitive touch panel operator interface for ease of use, DCU can be supplied in bench top or control panel mounted versions, complete with integrated amplifiers for all standard measurements.

Standard DCU firmware provides full functionality for execution of all basic control tasks (i.e. calibration, alarm monitoring, control loops and sequences) and can be configured according to individual process requirements. A range of advanced control features (e.g. gravimetric flow controllers in combination with high precision Sartorius balances) can also be realized at this level.

#### Retrofitting made easy

Hardware expansion plus software configuration capabilities are combined with Sartorius BBI Systems' experience in bioprocess control to make DCU the ideal platform for replacing older fermentor control systems. Customized control panels or interface boxes ensure trouble-free integration with existing fermenters, ranging from laboratory to production scale.

With classification as GAMP Category 4 (Configurable System), DCU is a validatable local control system, which can also be used in regulated cGMP production environments.

A range of supporting functions, including multi-level password and operator logs, are standardly provided together with comprehensive documentation for validated systems.

Connection of DCU controllers via Ethernet/TCP-IP to MFCS/win SCADA software provides a range of extended control and evaluation facilities including:

- Recipe-based batch processing (ISA-S88 standard)
- Visualization
- Data acquisition, evaluation, storage and reporting
- Advanced control algorithms.

#### Servicing your automation needs

With options ranging from dedicated local controllers to high-level system integration using PLC/SCADA or DCS control systems, our expertise is available to ensure the optimum solution to any demanding biotech production process .

We provide standardized PLC control systems for both fermentation and crossflow filtration package units. These controllers, in combination with SCADA systems, are based on platforms offered by leading European and US PLC vendors in satisfying the 'in house' standards of our customers.

For full-scale automation of complete biotech production facilities, DCS systems are the preferred choice for performing batch control according to ISA-S88 standard.

Our involvement in providing automation solutions, together with leading automation system suppliers and system integrators, has focussed on specification and commissioning, resulting in the realization of a number of successful projects world-wide.

#### **Experience the support**

Expertise gained through long-term cooperation with pharmaceutical and biotech companies has been used to develop and refine a comprehensive range of validation support services. The scope of these services includes validation of computerized systems, as well as the qualification of automated process equipment.

In addition to the generation of comprehensive 'as built' documentation, our team of experienced engineers has developed an extensive library of qualification protocols for Installation Qualification (IQ) and Operational Qualification (OQ).

For projects requiring validation, the key factor to successful realization is through expertise in project management. Sartorius BBI Systems, with well-established methods for defined project execution according to GAMP guideline and S88 models for batch control, is today uniquely placed to guarantee delivery on schedule and within budget.

#### MFCS/win SCADA

MFCS/win, the 5th generation of Sartorius BBI Systems Supervisory Control and Data acquisition software package can be considered as the 'de facto' standard for SCADA in the field of bioprocess applications. Based on standard PC hardware and operating under Windows 2000 and Windows XP, MFCS/win can be supplied as a single-user system, or integrated in a local area network (LAN) environment.

MFCS/win functionality is specifically designed for bioprocess applications involving data acquisition and storage, sample data management, on-line calculations, process visualization and batch reporting. Supplied preconfigured and "ready-to-use", the configuration can easily be adapted by the user to any change in process requirements.

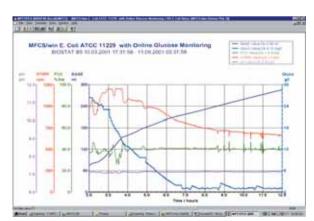
MFCS/win is designed as an open system, with an OPC (OLE for process control) interface, resulting in simple connectivity to third-party software packages for expanding the functionality of an entire system. Current versions incorporate batch management features, compliant with ISA-S88, allowing utilization of procedural batch control already on small systems, resulting in consistent process operation.

Fully validatable according to GAMP Category 4 (Configurable System), MFCS/win has all the necessary functionality for operation in a regulated cGMP production environment and supports 21 CFR Part 11 compliance for electronic records and signatures.

A comprehensive driver library and OPC Client functionality are included for easy connection to all brands of fermenters and auxiliary process instrumentation, making MFCS/win the ideal choice for laboratory or pilot plant automation retrofit projects.



Supervisory control of multiple process units



Comprehensive plot and report functions

#### Biostat® A plus Economy Fermentor | Bioreactor Benchtop System







#### Biostat®A plus... plug in and grow

The BIOSTAT®A plus is a compact, auto-clavable fermentor | bioreactor system specially designed for educational use and preliminary or investigational R&D applications. The single housing design concept with integrated measurement and control hardware, pumps, temperature, gassing and motor systems, saves valuable laboratory bench space.

The application-driven, configured packages for microbial and cell culture include everything needed for to get started immediately. The BIOSTAT®A plus is available with 1 L, 2 L, or 5 L working volume single wall culture vessel. Just select the size that meets your needs today – it can be interchanged for another vessel, if needed. Each system also includes a powerful Notebook PC with local control software, as well as our MFCS/DA software package for simultaneous control and data collection.

#### The BIOSTAT®A plus is ideal for:

- Microbial culture growth of bacteria, yeast and fungi
- Cell culture growth of animal, insect and plant cells
- Transition from shake or tissue culture flasks
- Small-scale protein expression
- For education and research

#### **Features**

- Ready-to-use packages for microbial or cell culture applications
- Inclusive Notebook PC for operation
- Control of temperature, pH, DO, stirrer speed, gas mixing, Foam | Level and substrate
- Configurable 2-stage DO controller via stirrer speed, gas mixing or substrate
- In-line pH calibration
- Trend display
- 4-gas mixing system with individual gas flow path for cell culture packages
- Oxygen enrichment capability for microbial packages
- Interchangeable culture vessels with
   1 L, 2 L or 5 L working volume
- Industry proven hardware
- Powerful PC operating software capable of handling up to four units
- MFCS/DA data storage and plotting software package
- Easy to follow step by step installation and user guide

#### **Specifications**

#### **Technical specifications**

Basic housing (dimensions W×H×D [mm])	210 × 455 × 425 mm (81/2 × 181/4 × 17 in)			
Space requirements per culture vessel (inner autoclave dimension Diameter × Height)	1 L 2 L 5 L	220×500* mm (9×20* in) 250×550* mm (10×22* in) 280×700* mm (111/4×28* in)		

#### **Utilities**

Power supply	120 VAC or 230 VAC
Gases	Controlled @ 1.5 barg; dry, particle and oil-free
Water	Controlled @ 2 barg
Drain	gravity drain with zero backpressure required

<sup>\*</sup> Optional flexible adaptor for the exhaust cooler (8844593) is available to reduce autoclave height requirement

## **Specifications**

#### Ordering information

Description	BIOSTAT®/ Microbial			BIOSTAT®A plus Cell culture packages		
Culture vessel	1 L	2 L	5 L	1 L	2 L	5 L
Cat. No. 120 VAC	8843815	8843817	8843819	8843823	8843825	8843827
Cat. No. 230 VAC	8843814	8843816	8843818	8843822	8843824	8843826
Culture Vessel						
Total volume [L]	1.6	3.0	6.6	1.6	3.0	6.6
Working volume [L]	0.4-1.0	0.6-2.0	0.4-5.0	0.4-1.0	0.6-2.0	0.4-5
Culture vessel tripod	•	•	•	•	•	•
Stirrer shaft with sealing	•	•	•	•	•	•
6-blade disk impeller (Rushton impeller)	2	2	2	_	_	_
3-blade pitched impeller (Marine type)	_	-	_	1	1	1
Agitation [rpm]	20-1200	20-1200	20-800	20-1200	20-1200	20-800
Baffle cage	8846375	8846812	8846820	8846375	8846812	8846820
Storage bottle 250 mL	3	3	1	3	3	1
Storage bottle 500 mL	_	_	2	_	_	2
Bottle rack	8846464	8847428	8847436	8846464	8847428	8847436
Air inlet and exhaust filter	2	2	2	3	3	3
Aeration tube with ring-sparger	•	•	•	_	_	_
Aeration tube with µ-sparger	_	_	_	•	•	•
Inoculation port	•	•	•	•	•	•
Exhaust cooler	•	•	•	•	•	•
4-way addition fitting	•	•	•	•	•	•
Fitting for overlay aeration	_	_	_	•	•	•
Sample Harvest pipe	•	•	•	•	•	•
Manual sampler	•	•	•	•	•	•
Cooling finger	•	•	•	8846456	8847819	8847827
Heating blanket	•	•	•	•	•	•
pH Electrode, cable	•	•	•	•	•	•
DO Electrode, cable	•	•	•	•	•	•
Temperature sensor with pocket	•	•	•	•	•	•
Foam Level probe, cable	•	•	•	•	•	•
Spare parts kit	34090422	34090424	34090426	34090422	34090424	34090426
Basic unit						
Digital controller	•	•	•	•	•	•
Control capabilities for temperature, pH, DO (2 stage cascade), stirrer speed, combined Level   Foam controller, substrate*	•	•	•	-	-	-
Rotameter for air [I/min]	0.16-1.6	0.42-4.2	1.3-13	-	-	-
02 Enrichment	•	•	•	•	•	•
Gassing with individual gas flow path, control valve and rotameter; N2 without automatic control valve						
Air & N2 [ml/min]	-	-	-	16-166	33-333	50-500
02 & C02 [ml/min]	-	-	_	3.3-33	16-166	33-333
Peristaltic pumps (integrated)	3	3	3	3	3	3
Balance for weight measurement of culture vessel	8843513	8843513	8843513	8843513	8843513	8843513
Tubing, O-Ring spare set	•	•	•	•	•	•
Control PC and Software						
Notebook PC for operation	•	•	•	•	•	•
PC operation software package	•	•	•	•	•	•
SCADA Software MFCS/DA	•	•	•	•	•	•

<sup>• =</sup> included, - = not included, Cat. No. = option
\* Functionality only with optional system extensions

#### Biostat® B plus Laboratory Fermentor | Bioreactor Benchtop System...







#### BIOSTAT® B plus integrated system solutions...

BIOSTAT® B plus are designed to become the new benchtop systems standard in research fermentors and bioreactors, worldwide. Application-driven preconfigured packages for microbial culture and cell culture can be delivered ready-to-use right "out of the box."

A comprehensive range of preconfigured packages are available to satisfy the demands of both microbial & cell culture applications.

#### Basic unit comprising...

- Stainless steel housing
- Digital controller
- Operating interface
- Gassing system with rotameter, solenoid valves or mass flow controller
- Motor with controller
- Thermostat system with circulation pump or dry heating with controlled cooling water valve
- Up to 4 peristaltic pumps
- Integrated amplifier

#### Culture vessel equipped with...

- Sensors for temperature, pH, DO, foam and level
- Stirrer shaft with industrial sealing
- Impeller
- Aeration tube with sparger, sterile filters and exhaust cooler
- Storage bottles, sample/harvest pipe, blind plugs
- Tube, O-ring and tool kit

... and optionally, a full range of accessories to meet your future needs.

#### **Features**

#### (Single or Twin configuration)

- Graphical user interface with touch screen
- Trend display with up to 6 process values
- Direct balance connection
- 1 L-10 L UniVessel® culture vessel with storage bottle tray, lifting handles and sampling system
- High-performance stirrer motor for all applications and UniVessel® sizes
- Up to 4 integrated peristaltic pumps, 2 external pump connections
- Application-driven integrated gassing system, choice of:
  - Microbial culture
  - 0<sub>2</sub> enrichment

  - Gas flow ratio controlCell culture | dual use
  - Exclusive flow
  - Cell culture
    - Additive low flow
- Integrated thermostat or dry-heating system
- Space for Redox and turbidity measurement (Single only)
- Preconfigured software for system extensions

#### Space requirement

Required bench size approx. $W \times H \times D$ (mm)	Single	Twin	
BIOSTAT® B plus / 1 L	560 × 730 × 565	800 × 730 × 565	
BIOSTAT® B plus / 2 L	590 × 730 × 565	860 × 730 × 565	
BIOSTAT® B plus / 5 L	620 × 730 × 565	920 × 730 × 565	
BIOSTAT® B plus / 10 L	670 × 820 × 565	1040 × 820 × 565	
Required inner autoclave dimension $\varnothing \times H$ [mm]	]		
UniVessel® 1 L	240 × 500 *		
UniVessel® 2 L	270 × 550 *		
UniVessel® 5 L	300 × 700 *		
UniVessel® 10 L	350 × 820 *		
Utility lines	Customer supply		
Power supply	230 VAC or 120 AC		
Gases	Controlled @ 1.5 barg; dry, particle and oil-free		
Water	Controlled @ 2 barg		
Drain	@ 0 barg		

<sup>\*</sup> Height reducible via flexible adaptor

## ...Ready to Use Packages for Your Drug Discovery and Small-Scale-Production

#### MFCS/DA software

To accelerate your research activities, a powerful supervisory software MFCS/DA for extended visualization, data acquisition and trend display is included.

#### Digital controller

BIOSTAT® B plus controller created for the needs of today's bioprocess applications.

- Single and Twin control capability
- Graphical user interface with color display and touch screen
- Integrated amplifiers for temperature, pH, DO, foam & level
- Twin combined level | foam controller
- Space for Redox and turbidity amplifier, Single only
- Integrated digital control loops for temperature, pH, DO, agitation, gas mixing, air flow and 2x substrate
- Level control via probe or balance
- Multi-stage DO cascade control
- Totalizer with digital calibration for probes and pumps
- In-process pH-recalibration
- Trend display for up to 6 process values
- Balance connection
- Developed according to GAMP guidelines

#### **Temperature control system**

Choice of dry-heating or thermostat system for precise temperature control with rapid heating and cooling rates.

#### Thermostat system

- Integrated in basic unit
- Powerful heater (1 kW)
- Automatically controlled cooling water valve
- Circulation pump
- Temperature range 8 °C above cooling water up to 80 °C.

#### Dry heating system

- Integrated in basic unit
- Plug connector for heating blanket
- Automatically controlled cooling water valve for optional cooling unit
- For temperatures up to 60°C

#### Gassing

Integrated culture vessel protection via safety valve

#### O<sub>2</sub> Enrichment

- For microbial cultures
- Automatic gas mixing of air and O<sub>2</sub>
- Solenoid valve for O<sub>2</sub>-Enrichment capability
- Controlled via DO controller
- Exchangeable rotameter
- Optional mass flow controller

#### **Gas Flow Ratio Control**

- For microbial cultures
- Gasmixing of Air and O<sub>2</sub>
   via Gas Flow Ratio Controller
- Two integrated massflow controller for Air and O<sub>2</sub>
- Controlled via DO controller
- Exchangeable Rotameter

#### **Exclusive Flow**

- For cell culture or multipurpose use
- Sparger and Overlay gas outlet
- Automatic gasmixing of Air, O<sub>2</sub>, N<sub>2</sub>, CO<sub>2</sub> for Sparger aeration
- Air for Overlay aeration
- 2 exchangeable rotameters
- Controlled via pH/DO controller
- Optional massflow controller

#### **Additive Low Flow**

- For cell cultures
- Sparger and Overlay gas outlet
- Automatic gasmixing of O<sub>2</sub>, N<sub>2</sub>, CO<sub>2</sub> for Sparger gassing
- Air for Overlay gassing
- 4 exchangeable rotameters
- Controlled via pH/DO controller
- Optional mass flow controller for total Sparger and Overlay flow

#### Pumps

Controlled via BIOSTAT® B plus controller for precise media conditioning, feeding and harvest.

- Up to 4 integrated pumps
- Configurable substrate controller
- Up to 2 external or internal feed pumps
- Watson Marlow pump heads

#### **Culture vessel**

UniVessel® autoclavable culture vessels. Developed with over 40 years experience in sterile design.

- 1 L 10 L jacketed or single wall culture vessels
- Pre-configured for microbial or cell culture application
- Stirrer shaft with single mechanical seal
- Polished head plate for highest sanitary conditions
- Vertical lifting handles for easy handling
- Head plate with maximized numbers of ports
- Removable addition bottle support
- Minimized autoclave space requirement
- 316 L stainless steel for medium contact parts
- Real O-ring sealing, no compressed
   O-rings
- Full range of accessories for microbial and cell culture applications

#### Stirrer drive

High-performance servo drive combines low shear agitation for cell cultures with high-speed mixing for microbial high-cell density fermentations.

- Speed range 20-2.000 rpm
- Maintenance-free
- High torque
- Easy handling

## The following BIOSTAT® B plus benchtop systems are available:

- BIOSTAT® B plus Gas flow ratio control Page 40
- BIOSTAT® B plus
   Additive low flow single wall
   Page 42
- BIOSTAT® B plus Additive low flow Page 44
  BIOSTAT® B plus O<sub>2</sub> Enrichment
- Page 46

   BIOSTAT® B plus
  Exclusive flow
  Page 48
- Accessories Page 52

## BIOSTATERA



#### BIOSTAT® B plus Gas Flow Ratio Control

The BIOSTAT® B plus with the integrated Gas Flow Ratio Control (GFRC), and two integrated mass flow controllers for air and oxygen, controlled via DO control loop allows advanced process control and easy gas balancing. The GFRC strategy enables highest oxygen transfer for high-cell density cultures, as well as for sheer stress sensitive gassing for filamentous organisms. It combines two operation modes for advanced gassing control of air and O<sub>2</sub>.

- Constant flow: percentage alteration
- Constant ratio: alteration of flow rates

#### **Digital controller**

- Graphical user interface with color display and touch screen operation
- Measurement and control for temperature, pH, DO, agitation, foam & level (Twin: combined foam | level control)
- Multi-stage DO cascade control
- 2× feed controller per vessel
- Gas flow ratio controller
- Level control via Level probe or balance
- Space for Redox and Turbidity amplifier (Single only)
- Totalizers with digital calibration for pumps
- In-process pH recalibration
- Trend display for up to 6 process values
- Up to 2 direct balance connections

#### "Gas Flow Ratio Control" gassing system

- Gas mixing of air and  $\ensuremath{\text{O}}_2$
- Mass flow controllers for air and O<sub>2</sub> controlled via DO controller

#### Pumps

- Up to 4 integrated pumps per side
- Configurable to substrate controller
- Up to 2 external feed pumps per side
- Optional integrated speed-controlled pump

#### **Temperature system**

- Powerful heater (1 kW)
- Integrated controlled cooling water valve
- Circulation pump
- Temperature range 8°C above cooling; water up to 80°C.

#### **Agitation system**

- Speed range 20 up to 2,000 rpm
- Maintenance-free
- High torque for powerful mixing
- Gear-free for quiet operation

#### **Culture vessel**

Jacketed culture vessel fully equipped with:

- Probes for temperature, DO, pH, foam and level
- Stirrer shaft with single mechanical seal
- Rushton impeller
- Baffle assembly
- Aeration tube with ring sparger, sterile filters and exhaust cooler
- Manual sampler with sampling pipe
- Removable addition bottle support
- Addition bottles with stainless steel head component and sterile filters
- Inoculation | addition port
- Four-way addition port
- Tube, O-ring and tool kit

#### SCADA Software MFCS/DA

- Plug and Play configuration
- Online data acquisition
- Sample data management
- Enhanced Plotting
- Export functions
- Easy-to-use programming interface

## The BIOSTAT® B plus GFRC packages are applicable for

- Culture of microorganisms
- Batch, fed batch and continuous culture
- Small-scale cell mass and protein production
- High-cell density culture
- Culture of filamentous microorganism
- Anaerobic | microaerophilic culture, on request

#### **Key features**

- Single or Twin configuration
- Independent vessel control
- Small footprint
- Mass flow controller for air and oxygen
- Gas Flow Ratio control strategy
- Graphical user interface with touch screen operation
- Totalizers with digital calibration for valves and pumps
- One high-performance stirrer motor for all UniVessel® sizes
- Trend display with up to 6 process values
- Direct balance connection
- Preconfigured firmware for system extensions

Description		BIOSTAT® B plus-MO GFRC with jacketed UniVessel®			BIOSTAT® B plus-TWIN-MO GFRC with 2× jacketed UniVessel®			
	1 L	2 L	5 L	10 L	1 L	2 L	5 L	10 L
Cat. No. 230 VAC	8843489	8843491	8843493	8843497 8843495	8843750	8843752	8843754	8843758 8843756
Cat. No. 120 VAC	8843490	8843492	8843494	8843498 8843496	8843751	8843752	8843755	8843760 8843757
Culture Vessel listing per vessel	Jacketed	UniVessel®						
Total volume [L]	1.6	3	6.6	13	1.6	3	6.6	13
Working volume [L]	0.4–1	0.6-2	0.4-5	1.5–10 5–10	0.4-1	0.6-2	0.4	1.5–10 5–10
Culture vessel tripod	•				•			
Stirrer shaft with Single Mechanical Seal	•				•			
6-blade disk impeller	2	2	2	3	2	2	2	3
200-watt servo motor (rpm)	20-2000	20-2000	20-1500	20-800	20-2000	20-2000	20-1500	20-800
Storage bottle 250 mL	3	3	_	_	3	3	_	_
Storage bottle 500 mL	_	_	3	3	_	_	3	3
Air Inlet and Exhaust filter	2				2			
Aeration tube with Ring-sparger	•				•			
Inoculation   addition port	•				•			
Exhaust Cooler	•				•			
4-Way addition fitting	•				•			
Sample-   Harvest pipe	•				•			
Manual sampler	•				•			
Baffles	•				•			
pH Electrode, cable	•				•			
DO Electrode, cable	•				•			
Level sensor, cable	•				•			
Foam sensor, cable	•				•			
Temperature sensor Pt 100	•				•			
Basic unit								
Digital controller color display with touch screen	•				•			
Control capabilities listing per ves	ssel							
Temperature, pH, DO (2 stage cascade), Stirrer speed	•				•			
Level and Foam via probe	•				Combined	Level   Foan	n controller	
Level via balance	•				•			
Substrate A and Substrate B	•				•			
Gasmixing (integrated)	Gas Flow	Ratio Contro	ol via MFC fo	or Air and O <sub>2</sub>				
Rotameter [I/min]	0.16-1.6	0.42-4.2	1.3-13	2-20	0.16-1.6	0.42-4.2	1.3-13	2-20
Gas Flow Ration Control Air MFC [I/min] Ration Control O <sub>2</sub> MFC [I/min]	0.06-3 0.06-3	0.06-3 0.06-3	0.4-20 0.4-20	0.4-20 0.4-20	0.06-3 0.06-3	0.06-3 0.06-3	0.4-20 0.4-20	0.4-20 0.4-20
Peristaltic pumps (integrated)	4				3 per side			
Feed pump (integrated) speed controlled	o <b>-</b>				8843468			
Thermostat system (integrated)	•				•			
Tubing, O-Ring spare set	•				•			
MFCS/DA	•				•			
Balance for culture vessel	0 8843475				8843475			
Turbidity measurement	° 8843472	8843473	8843474	8843474				
Redox measurement	o 8843469	8843470	8803471	8843471				



#### BIOSTAT® B plus Additive Low Flow | Single Wall

The BIOSTAT® B plus Additive Low Flow packages with single wall culture vessels are specially configured for cell culture. The integrated automatically controlled gas mixing system provides Sparger and Overlay gassing. Air is routed to Overlay,  $O_2$ ,  $N_2$  and  $CO_2$  are routed to Sparger, automatically controlled via DO and pH controller. Each gas has its own rotameter for individual flow rate adjustment.

#### Digital controller

- Graphical user interface with color display and touch screen operation
- Integrated amplifiers for Temperature, pH, DO, combined Foam | Level amplifier
- Space for Redox and Turbidity amplifier (single only)
- Integrated digital control loops for Temperature, pH, DO, agitation, gas mixing, total Sparger flow, total Overlay flow and 2× substrate
- Level control via Level probe or balance
- Multi-stage DO cascade control
- Totalizers with digital calibration for valves and pumps
- In-process pH-recalibration
- Trend display for up to 6 process values
- Up to 2 direct balance connections

#### Additive low flow gassing system

- Sparger and Overlay gas outlet
- Gasmixing of O<sub>2</sub>, N<sub>2</sub>, CO<sub>2</sub> for Sparger gassing
- Air for Overlay gassing
- Controlled via pH/DO controller
- Optional mass flow controllers for total Sparger flow and Overlay flow

#### **Pumps**

- 2× integrated pumps per side
- Configurable to substrate controller
- Up to 2 external feed pumps per side
- Optional integrated speed controlled pump

#### **Temperature system**

- Heating blanket
- Integrated controlled cooling water valve
- Temperature range up to 60°C.
- Optional cooling finger

#### Agitation system

- Speed range 20 up to 2,000 rpm
- Maintenance free
- Gear-free for quite operation

#### **Culture vessel**

Single wall culture vessel fully equipped with:

- Probes for Temperature, DO, pH, Foam and Level
- Stirrer shaft with single mechanical seal
- 3-blade segment impeller
- Aeration tube with micro Sparger, Overlay aeration fitting, sterile filters and exhaust cooler
- Manual sampler with sampling pipe
- Removable addition bottle support
- Addition bottles with stainless steel head piece and sterile filters
- Inoculation | addition port
- Four way addition port
- Tube, O-ring and tool kit

#### SCADA Software MFCS/DA

To accelerate your research activities, a powerful supervisory software MFCS/DA for extended visualization, data acquisition and trend display is included.

- Plug and Play configuration
- Batch oriented software package
- Online data acquisition
- Sample Data Management
- Enhanced Plotting
- Export functions
- Easy to use programming interface

## The BIOSTAT® B plus Additive Low Flow packages are applicable for

- Cell culture of insect and mammalian cells
- Batch, fed batch and continuous culture
- Easy upgrade to perfusion operation
- Small scale cell mass, protein, MAb & vaccine production
- High cell density culture
- Suspension and micro carrier cultures

#### **Key features**

- Single or Twin configuration
- Independent vessel control
- Small footprint
- Automatically controlled gas mixing
- Sparger and Overlay gassing
- Graphical user interface with touch screen operation
- Totalizers with digital calibration for valves and pumps
- One high performance stirrer motor for all UniVessel® sizes
- Trend display with up to 6 process values
- Direct balance connection
- Pre-configured firmware for system extension

Description	Additive	B plus-CC Low Flow le wall UniV	essel®		Additive I	B plus-TW Low Flow ingle wall U		
	1 L	2 L	5 L	10 L	1 L	2 L	5 L	10 L
Cat. No. 230 VAC	8843730	8843732	8843734	8843738 8843736	8843792	8843794	88433796	8843800 8843798
Cat. No. 120 VAC	8843731	8843733	8843735	8843739 8843737	8843793	8843795	8843797	8843801 8843799
Culture Vessel listing per vessel	Single wa	II UniVessel®						
otal volume [L]	1.6	3	6.6	13	1.6	3	6.6	13
Vorking volume [L]	0.4-1	0.6-2	0.4-5	1.5–10 5–10	0.4–1	0.6-2	0.4	1.5–10 5–10
Culture vessel tripod	•				•			
Stirrer shaft with Single Mechanical Seal	•				•			
Magnetic coupling	0 8847339				8847339			
B-blade segment impeller	1				1			
200-watt servo motor (rpm)	20-2000	20-2000	20-1500	20-800	20-2000	20-2000	20-1500	20-800
storage bottle 250 mL	3	3	_		3	3	_	
torage bottle 500 mL			3	3			3	3
Air Inlet and Exhaust filter	3				3			
eration tube with μ-sparger	•				•			
noculation port	•				•			
xhaust Cooler	•				•			
-Way addition fitting	•				•			
Iniversal Adaptor 3.2 mm or overlay aeration	•				•			
ample-   Harvest pipe	•				•			
lanual sampler	•				•			
H Electrode, cable	•				•			
00 Electrode, cable	•				•			
evel sensor, cable	•				•			
oam sensor, cable	•				•			
emperature sensor Pt 100	•				•			
Basic unit								
Digital controller color display vith touch screen	•				•			
Control capabilities listing per ve	essel							
emperature, pH, DO (2 stage ascade), Stirrer speed	•				•			
combined Level   Foam controller	r •				•			
evel via balance	•				•			
ubstrate A and Substrate B	•				•			
asmixing	Additive I	ow Flow						
otameter Sparger [I/min]	O <sub>2</sub> : 0.002-0.0	N <sub>2</sub> : 056 0.002		) <sub>2</sub> : 002-0.056	O <sub>2</sub> : 0.002-0.0	N <sub>2</sub> : 56 0.002	CO -0.056 0.0	<sub>2</sub> : 02-0.056
otameter for Overlay [I/min]	Air: 0.010	-0.270			Air: 0.010	-0.270		
utomatic gasmixing	•				•			
MFC (Sparger total flow)	0.03-0.15				0.03-0.15			
AFC (Overlay flow)	0.06-0.3	[l/min]			0.06-0.3 [	l/min]		
eristaltic pumps (integrated)	2				2 per side			
eed pump speed controlled integrated)	o <b>–</b>				8843468			
emperature system with leating blanket	•				•			
ubing, O-Ring spare set	•				•			
MFCS/DA	•				•			
alance for culture vessel	0 8843475				8843475			
urbidity measurement	0 8843510	8843511	8843512	8843512				
Redox measurement	0 8843469	8843470	8803471	8843471				

# S TAYLOR OF THE STATE OF THE ST



#### BIOSTAT® B plus Additive I ow Flow

The BIOSTAT® B plus Additive Low Flow packages are specially configured for cell culture applications. The integrated, automatically controlled gas mixing system provides Sparger and Overlay gassing. Air is routed to Overlay.  $O_2$ ,  $N_2$  and  $CO_2$  is routed to Sparger, automatically controlled via DO and pH controller. Each gas has its own rotameter for individual flow rate adjustment.

#### Digital controller

- Graphical user interface with color display and touch screen operation
- Measurement and control for Temperature, pH, DO, agitation, combined Foam | Level control
- Multi-stage DO cascade control
- 2× feed controller per side
- Level control via Level probe or balance
- Space for Redox and Turbidity amplifier (Single only)
- Totalizers with digital calibration for pumps and valves
- In-process pH-recalibration
- Trend display for up to 6 process values
- Up to 2 direct balance connections

#### "Additive Low Flow" gassing system

- Sparger and Overlay gas outlet
- Gasmixing of O<sub>2</sub>, N<sub>2</sub>, CO<sub>2</sub> for Sparger gassing
- Air for Overlay gassing
- Controlled via pH/DO controller
- Optional mass flow controller for total Sparger and Overlay flow

#### **Pumps**

- 2× integrated pumps per side
- Configurable to substrate controller
- Up to 2 external feed pumps per side
- Optional integrated speed controlled pump

#### **Temperature system**

- Powerful heater 1 kW
- Integrated cooling valve
- Circulation pump
- Temperature range 8°C above cooling water up to 80°C.

#### Agitation system

- Speed range 20 up to 2,000 rpm
- Maintenance free
- Gear-free for quite operation

#### **Culture vessel**

Jacketed culture vessel fully equipped with:

- Probes for Temperature, DO, pH, Foam and Level
- Stirrer shaft with single mechanical seal
- 3-blade segment impeller
- Aeration tube with micro Sparger, Overlay aeration fitting, sterile filters and exhaust cooler
- Manual sampler with sampling pipe
- Removable addition bottle support
- Addition bottles with stainless steel head plates and sterile filters
- Inoculation | addition port
- Four way addition port
- Tube, O-ring and tool kit

#### SCADA Software MFCS/DA

- Plug and Play configuration
- Online data acquisition
- Sample Data Management
- Enhanced Plotting
- Export functions
- Easy to use programming interface

## The BIOSTAT® B plus Additive Low Flow packages are applicable for

- Cell culture of insect and mammalian cells
- Batch, fed batch and continuous culture
- Easy upgrade to perfusion operation
- Small scale cell mass, protein, MAb & vaccine production
- High cell density culture
- Suspension and micro carrier cultures

#### **Key features**

- Single or Twin configuration
- Independent vessel control
- Small footprint
- Individual gas flow rate adjustment
- Automatically controlled gas mixing
- Sparger and Overlay gassing
- Graphical user interface with touch screen operation
- Totalizers with digital calibration for valves and pumps
- One high performance stirrer motor for all UniVessel® sizes
- Trend display with up to 6 process values
- Direct balance connection
- Pre-configured firmware for system extensions

Description	BIOSTAT® B plus-CC Additive Low Flow with jacketed UniVessel®			BIOSTAT® B plus-TWIN Additive Low Flow with 2× jacketed UniVessel®				
	1 L	2 L	5 L	10 L	1 L	2 L	5 L	10 L
Cat. No. 230 VAC	8843710	8843712	8843714	8843718 8843716	8843771	8843773	884377	6 8843780 8843778
Cat. No. 120 VAC	8843711	8843713	8843715	8843719 8843717	8843772	8843774	884377	7 8843781 8843779
Culture Vessel listing per vessel	Jacketed L	IniVessel®						
otal volume [L]	1.6	3	6.6	13	1.6	3	6.6	13
Norking volume [L]	0.4–1	0.6-2	0.4-5	1.5–10 5–10	0.4-1	0.6-2	0.4	1.5–10 5–10
Culture vessel tripod	•				•			
Stirrer shaft with Single Mechanical Seal	•				•			
Magnetic coupling $\circ$	8847339				8847339			
3-blade segment impeller	1				1			
200-watt servo motor (rpm)	20-2000	20-2000	20-1500	20-800	20-2000	20-2000	20-150	0 20-800
Storage bottle 250 mL	3	3	_	_	3	3	_	_
Storage bottle 500 mL	_	_	3	3	_	_	3	3
Air Inlet and Exhaust filter	3				3			
Aeration tube with μ-sparger	•				•			
noculation port	•				•			
Exhaust Cooler	•				•			
1-Way addition fitting	•				•			
Jniversal Adaptor 3.2 mm for overlay aeration	•				•			
Sample-   Harvest pipe	•				•			
Manual sampler	•				•			
oH Electrode, cable	•				•			
00 Electrode, cable	•				•			
evel sensor, cable	•				•			
oam sensor, cable	•				•			
emperature sensor Pt 100	•				•			
Basic unit								
Digital controller color display with touch screen	•				•			
Control capabilities listing per vess	el							
emperature, pH, DO (2 stage cascade), Stirrer speed	•				•			
Combined Level   Foam controller	•				•			
evel via balance	•				•			
Substrate A and Substrate B	•				•			
Gasmixing	Additive L	ow Flow						
Rotameter Sparger [I/min]	O <sub>2</sub> : 0.002-0.0	N <sub>2</sub> : 56 0.002-		20 <sub>2</sub> : 0.002-0.056	O <sub>2</sub> : 0.002-0.0	N <sub>2</sub> : 56 0.002		CO <sub>2</sub> : 0.002-0.056
Rotameter for Overlay [I/min]	Air: 0.010-	-0.270			Air: 0.010-	-0.270		
Automatic gasmixing	•				•			
MFC (Sparger total flow)	0.03-0.15	O [I/min]			0.03-0.150	0 [l/min]		
MFC (Overlay flow)	0.06-0.3 [	/min]			0.06-0.3 [	l/min]		
Peristaltic pumps (integrated)	2				2 per side			
hermostat system	•				•			
ubing, O-Ring spare set	•				•			
MFCS/DA	•				•			
און כאווי								
Balance for culture vessel	8843475				8843475			

# BIOSTATE



## BIOSTAT® B plus O<sub>2</sub> Enrichment

The BIOSTAT® B plus with integrated  $O_2$ –Enrichment gassing capability enables high oxygen transfer for high cell density cultures as well as for sheer stress sensitive gassing for filamentous organisms. Furthermore, it may help to solve foaming problems due to reduced gassing rates.

#### Digital controller

- Graphical user interface with color display and touch screen operation
- Measurement and control for Temperature, pH, DO, agitation, Foam & Level (Twin: combined Foam | Level control)
- Multi-stage DO cascade control
- 2× feed controller per vessel
- Level control via Level probe or balance
- Totalizers with digital calibration for valves and pumps
- In-process pH-recalibration
- Trend display for up to 6 process values
- Up to 2 direct balance connections
- Space for internal Redox and Turbidity amplifier (Single only)

#### "O2 Enrichment" gassing system

- Gas mixing of Air and O<sub>2</sub>
- O<sub>2</sub> Enrichment capability controlled via DO controller
- Optional mass flow controller for total flow

#### **Pumps**

- Up to 4 integrated pumps per side
- Configurable to feed controller
- Up to 2 external feed pumps per side
- Optional integrated speed controlled pump

#### **Temperature system**

- Powerful heater (1 kW)
- Integrated controlled cooling water valve
- Circulation pump
- Temperature range 8°C above cooling water up to 80°C.

#### Agitation system

- Speed range 20 up to 2,000 rpm
- Maintenance free
- High torque for power full mixing
- Gear-free for quiet operation

#### **Culture vessel**

Jacketed culture vessel fully equipped with:

- Probes for Temperature, DO, pH, Foam and Level
- Stirrer shaft with single mechanical seal
- Rushton impeller
- Baffle assembly
- Aeration tube with ring Sparger, sterile filters and exhaust cooler
- Manual sampler with sampling pipe
- Removable addition bottle support
- Addition bottles with stainless steel head piece and sterile filters
- Inoculation | addition port
- Four-way addition port
- Tube, O-ring and tool kit

#### SCADA Software MFCS/DA

- Plug and Play configuration
- Online data acquisition
- Sample Data Management
- Enhanced Plotting
- Export functions
- Easy to use programming interface

## The BIOSTAT® B plus O<sub>2</sub> Enrichment packages are applicable for

- Culture of microorganisms
- Batch, fed batch and continuous culture
- High cell density culture
- Culture of filamentous microorganism
- Small scale cell mass and protein production
- Anaerobic | microaeriphilic culture, on request

#### **Key features**

- Integrated system design
- Single or Twin configuration
- Independent vessel control
- Small footprint
- Automatically controlled O<sub>2</sub> Enrichment
- Graphical user interface with touch screen operation
- Totalizers with digital calibration for valves and pumps
- One high performance stirrer motor for all UniVessel® sizes
- Trend display with up to 6 process values
- Direct balance connection
- Pre-configured firmware for system extensions

Description	O <sub>2</sub> -Enrich	B plus-MO ment with UniVessel®			O <sub>2</sub> -Enrich	B plus-TWI ment with ed UniVess		
	1 L	2 L	5 L	10 L	1 L	2 L	5 L	10 L
Cat. No. 230 VAC	8843479	8843481	8843483	8843487 8843485	8843740	8843742	8843744	8843748 8843746
Cat. No. 120 VAC	8843480	8843482	8843484	8843488 8843486	8843741	8847343	8843745	8843749 8843747
Culture Vessel listing per vessel	Jacketed l	JniVessel®						
Total volume [L]	1.6	3	6.6	13	1.6	3	6.6	13
Working volume [L]	0.4-1	0.6-2	0.4-5	1.5–10 5–10	0.4-1	0.6-2	0.4	1.5-10 5-10
Culture vessel tripod	•				•			
Stirrer shaft with single mechanical seal	•				•			
6-blade disk impeller	2	2	2	3	2	2	2	3
200-watt servo motor (rpm)	20-2000	20-2000	20-1500	20-800	20-2000	20-2000	20-1500	20-800
Storage bottle 250 mL	3	3			3	3		
Storage bottle 500 mL	_	_	3	3	_	_	3	3
Air Inlet and Exhaust filter	2				2			
Aeration tube with Ring-sparger	•				•			
Inoculation   addition port	•				•			
Exhaust Cooler	•				•			
4-Way addition fitting	•				•			
Sample-   Harvest pipe	•				•			
Manual sampler	•				•			
Baffles	•				•			
pH Electrode, cable	•				•			
DO Electrode, cable	•				•			
Level sensor, cable	•				•			
Foam sensor, cable	•				•			
Temperature sensor Pt 100	•				•			
Basic unit								
Digital controller color display with touch screen	•				•			
Control capabilities listing per vess	el							
Temperature, pH, DO (2 stage cascade), Stirrer speed	•				•			
Level and Foam via probe	•				Combined	Level   Foam	controller	
Level via balance	•				•			
Substrate A and Substrate B	•				•			
Gasmixing (integrated)	O <sub>2</sub> -Enrich	ment						
Rotameter [I/min]	0.16-1.6	0.42-4.2	1.3-13	2-20	0.16-1.6	0.42-4.2	1.3-13	2-20
Solenoid Valve for O <sub>2</sub> -Enrichment	•				•			
Mass Flow Controller	0.06–3 [l/i 8847770	min]	0.4–20 [l/l 8847797	min]	0.06-3 [l/r 8847770	min]	0.4-20 [l/r 8847797	nin]
Peristaltic pumps (integrated)	4				3 per side			
Feed pump (integrated) speed controlled	) _				8843468			
Thermostat system (integrated)	•				•			
Tubing, O-Ring spare set	•				•			
MFCS/DA	•				•			
Balance for culture vessel	8843475	8843475						
Turbidity measurement	8843472	8843473	8843474	8843474				
Redox measurement	8843469	8843470	8803471	8843471				

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#### BIOSTAT® B plus Exclusive Flow

The BIOSTAT® B plus Exclusive Flow packages are configured for cell culture. The integrated automatically controlled four gas mixing system, with provides Overlay and Sparger gassing. Air is roated to Overlay. Air, O<sub>2</sub>, N<sub>2</sub> and CO<sub>2</sub> is roated to Sparger. By an easy upgrade of culture vessel components and rotameter flow range the system can be also used for microbial cultures. Separate rotameters for gas to the Sparger and Overlay makes adjusting the flow rate easy. The gas composition is automatically controlled via DO and pH controller.

#### Digital controller

- Graphical user interface with color display and touch screen operation
- Measurement and control for Temperature, pH, DO, agitation, Foam & Level (Twin: combined Foam | Level control)
- Multi-stage DO cascade control
- 2× feed controller per side
- Level control via Level probe or balance
- Space for Redox and Turbidity amplifier (Single only)
- Totalizers with digital calibration for pumps and valves
- In-process pH-recalibration
- Trend display for up to 6 process values
- Up to 2 direct balance connections

#### "Exclusive Flow" gassing system

- Sparger and Overlay gas outlet
- Gasmixing of Air, O<sub>2</sub>, N<sub>2</sub>, CO<sub>2</sub> for Sparger gassing
- Air for Overlay gassing
- Controlled via pH/DO controller
- Optional mass flow controller for total Sparger and Overlay flow

#### Pumps

- Up to 4 integrated pumps per side
- Configurable to substrate controller
- Up to 2 external feed pumps per side
- Optional integrated speed controlled pump

#### **Temperature system**

- Powerful heater (1 kW)
- Integrated controlled cooling water valve
- Circulation pump
- Temperature range 8°C above cooling water up to 80°C.

#### Agitation system

- Speed range 20 up to 2,000 rpm
- Maintenance free
- Gear-free for quite operation

#### **Culture vessel**

Jacketed culture vessel fully equipped with:

- Probes for Temperature, DO, pH, Foam and Level
- Stirrer shaft with single mechanical seal
- 3-blade segment impeller
- Aeration tube with micro Sparger, Overlay aeration fitting, sterile filters and exhaust cooler
- Manual sampler with sampling pipe
- Removable addition bottle support
- Addition bottles with stainless steel head piece and sterile filters
- Inoculation | addition port
- Four-way addition port
- Tube, O-ring and tool kit

#### SCADA Software MFCS/DA

- Plug and Play configuration
- Batch oriented software package
- Online data acquisition
- Sample Data Management
- Enhanced Plotting
- Export functionso
- Easy to use programming interface

## The BIOSTAT® B plus Exclusive Flow packages are applicable for

- Cell culture of insect, mammalian and plant cells
- Microbial culture by easy upgrade
- Batch, fed batch and continuous culture
- Easy upgrade to perfusion operation
- Small scale cell mass, protein, MAb & vaccine production
- High cell density culture
- Suspension and micro carrier cultures

#### **Key features**

- Single or Twin configuration
- Independent vessel control
- Easy multipurpose use upgrade
- Small footprint
- Automatically controlled gas mixing
- Sparger and Overlay gassing
- Graphical user interface with touch screen operation
- Totalizers with digital calibration for valves and pumps
- One high performance stirrer motor for all UniVessel® sizes and application
- Trend display with up to 6 process values
- Direct balance connection
- Pre-configured firmware for system extensions

Description	BIOSTAT® B plus-CC Exclusive Flow with jacketed UniVessel®			BIOSTAT® B plus- TWIN Exclusive Flow with 2× jacketed UniVessel®				
	1 L	2 L	5 L	10 L	1 L	2 L	5 L	10 L
Cat. No. 230 VAC	8843499	8843501	8843503	8843507 8843505	8843761	8843763	8843765	8843769 8843767
Cat. No. 120 VAC	8843500	8843502	8843504	8843508 8843506	8843762	8843764	8843766	8843770 8843768
Culture Vessel listing per vessel	Jacketed L	JniVessel®						
otal volume [L]	1.6	3	6.6	13	1.6	3	6.6	13
Norking volume [L]	0.4–1	0.6-2	0.4-5	1.5–10 5–10	0.4–1	0.6-2	0.4	1.5–10 5–10
Culture vessel tripod	•				•			
Stirrer shaft with Single Mechanical Seal	•				•			
Magnetic coupling	o 8847339				8847339			
3-blade segment impeller	1				1			
200-watt servo motor (rpm)	20-2000	20-2000	20-1500	20-800	20-2000	20-2000	20-1500	20-800
Storage bottle 250 mL	3	3	_	_	3	3	_	_
Storage bottle 500 mL	_	_	3	3	_	_	3	3
Air Inlet and Exhaust filter	3				3			
Aeration tube with μ-sparger	•				•			
noculation port	•				•			
xhaust Cooler	•				•			
I-Way addition fitting	•				•			
Jniversal Adaptor 3.2 mm or overlay aeration	•				•			
ample-   Harvest pipe	•				•			
Manual sampler	•				•			
oH Electrode, cable	•				•			
00 Electrode, cable	•				•			
evel sensor, cable	•				•			
oam sensor, cable	•				•			
emperature sensor Pt 100	•				•			
Basic unit Digital controller color display	•				•			
vith touch screen								
Control capabilities listing per ves								
emperature, pH, DO (2 stage ascade), Stirrer speed	•				•	ı de	. "	
evel and Foam via probe	•					Level   Foam	controller	
evel via balance	•				•			
Substrate A and Substrate B	Exclusive I	low			•			
Rotameter Sparger [I/min]	0.016-	0.016-	0.05-0.5	0.1-1.0	0.016-	0.016-	0.05-0.5	0.1-1.0
	0.166	0.166			0.166	0.166		
Rotameter for Overlay [I/min]	0.1-1	0.16-1.6	0.42-4.2	0.8-8.3	0.1-1	0.16-1.6	0.42-4.2	0.8-8.3
Automatic gasmixing		l 004775	. 4				. 4	
AFC (Overlay flow)		nin] 884775 nin] 884778				nin] 884775 nin] 884778		
MFC (Overlay flow) Peristaltic pumps (integrated)	0.2-10 [l/r	mmj 884778	) J		3 per side	mmj 884//8	າປ	
eed pump (integrated) peed controlled	0 -				8843468			
hermostat system	•				•			
ubing, O-Ring spare set	•				•			
MFCS/DA	•				•			
Balance for culture vessel	o 8843475				8843475			
urbidity measurement	<ul><li>8843510</li></ul>	8843511	8843512	8843512				
Redox measurement	· 8843469	8843470	8803471	8843471				

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#### Photobioreactor Biostat® PBR Photosynthesis lights the way









#### Photobioreactor BIOSTAT® PBR

The new models of photobioreactor BIOSTAT® PBR are designed especially for the cultivation of phototrophic organisms, e.g. micro algae and other phototrophe single cell organisms.

The well-known and proven quality of Sartorius BBI Systems measurement and control equipment is combined with long experience of building photo bioreactors.

The standard model range consists of bioreactors of different size. A small and autoclavable unit in lab scale and two in-situ sterilizable units in different size of pilot scale offer a qualified start in a cultivation of phototrophe organisms - under sterile conditions.

All bioreactors are designed for GMP conform reproduction of either defined organisms or generation of valuable intracellular or extracellular substances.

#### Photosynthetic module

The autoclavable start-up model BIOSTAT® PBR 2 S is a special edition for all lab scale experiments. The BIOSTAT® PBR 20 S is the in-situ sterilizable laboratory fermenter the BIOSTAT® PBR 100 AS completes the standard series:

- Double wall vessel or unit for tempering
- Vessel for gas exchange holds probes for measuring pH, pO2, temperature and turbidity
- Glass tubing in an external loop in the illumination unit
- Effective lighting unit for controlled illumination
- Lightening may be controlled by measured parameter
- Specific measuring and control cabinet with adapted display

The start-up BIOSTAT® PBR is designed to fit in common lab autoclaves. All other models have small footprint and need not more space than a standard microbial fermenter.

BIOSTAT® PBR 2 S meets the requirements of higher capacity. By modular combination bigger volume needs can be realised.

#### Features and benefits

- The BIOSTAT® PBR is a new model range for fermentation of phototrophic organisms in lab scale to pilot and production size
- The range of sterilizable fermenters is designed especially for photosynthetic organisms
- GMP conform fermentation
- Effective illumination by the photosynthetic module for optimal growth conditions
- The specific design follows the fundamental demands for cultivation of photosynthetic organisms
- Space saving construction
- Approved measuring and control equipment (DCU) from our type series BIOSTAT
- Optional SCADA/MFCS/win software for monitoring, control and documentation
- Software is compliant to FDA21 CFR Part 11

#### BIOSTAT PBR® 2 S

The autoclavable model BIOSTAT® PBR 2 S is the special edition for all lab scale fermentation with pure culture.

- Double wall glass vessel with connectors for tempering
- Vessel lid for air input and exhaust, for probes for measuring pH, pO2, temperature and OD
- Tubing for external loop in the illumination unit
- Lighting unit for installation after sterilisation

This combination has a small footprint and is designed to fit in common lab autoclaves. After sterilization the fermenter is completed by the illumination unit, which is compact and easy to be mounted.

#### **BIOSTAT PBR® 20 S**

The in-situ sterilizable pilot-scale photobioreactor is high efficient and thus designated for optimal cultivation under defined and controlled conditions.

The measuring and control cabinet with its micro DCU (Digital Control Unit) is proved in numerous BIOSTAT® fermenters. The stainless steel double wall vessel is connected to a strong circulation pump and the photosynthetic module.

Fluorescent tubes installed in between illuminate a combination of glass tubes and bends in the tubing unit.

#### **BIOSTAT PBR 100 AS**

This photo bioreactor is a very space saving unit with its vertical arrangement of the tubing in the photosynthetic module. The total volume of 100 litres is realized in the combination of vessel and glass tubing. The liquid movement in this model is managed by an air-lift system (AS) where the liquid speed range is ruled by the variable airflow.

In the head space the streams of all tubes are mixed and the gas exchange is realized. The temperature control is done via the vessel unit in the base of the photosynthetic module.

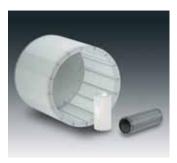
This photo bioreactor model – as well as the BIOSTAT® PBR 20 S – allows the production under GMP conditions of single cell organisms using photosynthesis.

Light intensity can be dimmed in correlation to the measured optical density of the culture. All other parameters are shown on the LCD and can be monitored by the Sartorius BBI Systems MFCS/win software which includes multiple correlation analysis and documentation. All demands of CFR part 11 are fulfilled.

	BIOSTAT® PBR 2 S	BIOSTAT® PBR 20 S	BIOSTAT® PBR 100 AS
Max. working volume (L)	3	25	100
Footprint W × L (mm)	400 × 600	1500 × 800	3000 × 2000
Total Height (mm)	700	1300	3600
Sterilisation	Autoclave	In-situ	In-situ
Photosynthetic unit	1	1	1
Photosynthetic area (m²)	0.5	1.8	3.0
Number of lamps	8	14	24
Wattage (W)	18	16	58
Circulation pump (I/min)	1 - 15	10 - 30	Airlift system
Volume of Gas + Heat exchange vessel (L)	1	10	50
pH sensor	+	+	+
PO2 sensor	+	+	+
OD sensor	On request	+	+
Rotameter	2	2	2
Thermostat system	yes	yes	yes
Steam generator	-	Option	Option
MFCS software	Option	Option	Option
Power supply request	230 V/50 Hz 115 V/60 Hz 208 V/60 Hz	230 V/50 Hz on request	400 V/50 Hz 115 V/60 Hz on
Total power input (kW)	2.0	1.8	2.0

<sup>\*</sup> Technical data are subject to change prior notice

#### Accessories for Today's and Future Bioprocessing Needs



#### Perfusion system: Internal spinfilter The Internal Spinfilter is a scalable perfusion system which is applicable for continuous medium exchange for long-term cultivation. It can be used for suspension or micro carrier

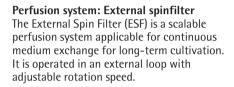
cultivations and is available in stainless steel or disposable design.

It is directly mounted on the stirrer shaft, resulting in easy sterile handling and operation.



#### Sterile couplings: STT couplings

STT-Sterile quick connectors provide sterile connection of tubings. Due to the use of a replaceable slot membranes STT couplings provide a re-usable sterile environment.











#### SuperSpinner

The SuperSpinner is a incubator-based cell cultivation system. It combines a traditional spinner bottle with a patented bubble free aeration | stirrer system. SuperSpinners are used for seed cultivations and micro scale production and are applicable for suspension and micro carrier cultures. Due to the disposable design of the aeration | stirrer system constant cultivation results are assured.

#### **Bubble free aeration**

Bubble free aeration is recommended for extremely shear stress sensitive cells, such as primary mammalian cells. Shear forces caused by bursting bubbles can be avoided and, in addition foam production is prevented.

## Turbidity measurement system: FUNDALUX® II

FUNDALUX® II is an absorption-based photometric probe, designed for use with fermentors | bioreactors.

By continuously measuring cell growth | biomass as a function of light absorption, the process operator can gain real-time knowledge to optimize the process control.





## Air Filter

Sartofluor GA	5
Aerosart	5
Midisart® 2000	6
Sartosteel	6

#### Sartofluor GA Air Filter Cartridges for Bio-Pharmaceutical Applications



#### Description

Sartofluor GA filter cartridges, manufactured with permanently hydrophobic PTFE membranes, are specially designed for sterile venting and gas applications where adherence to cGMP's is a must. Due to their permanent hydrophobicity, Sartofluor GA cartridges offer the highest process security, even with high volume gas streams, extreme humidity and stringent in-line steam sterilizations.

#### **Applications**

Sartofluor GA cartridges are ideally suited for application requiring a sterile, hydrophobic gas filter such as:

- Fermenter and bioreactor inlet gases
- Fermenter and bioreactor vents
- Autoclave vents
- Lyophilizer vents
- Purified water system storage tank vents
- In process storage tank vents
- Filling equipment process air

#### Performance

PTFE is the most hydrophobic of all membranes used in sterile filtration of gases. The inherent hydrophobicity of the PTFE membrane remains unaffected by repeated autoclaving or steaming. The sterile filtration of dry or moist gases is guaranteed. The unique single layer design is optimized for high flow rates at low differential pressures with short blow down times.

#### **Stability**

Sartofluor GA can withstand high differential pressures in either the forward or reverse direction of flow. The mechanical stability and membrane structure are not affected by pulsation or high flow rates.

#### Water Intrusion Test (WIT) | Water Flow Test (WFT)

A Sartorius development, the WFT offers the first and only correlated in-situ integrity testing system for hydrophobic vent filters. WFT not only eliminates downstream intervention and preflushing, more importantly, it does not require a single drop of alcohol.

#### Quality control

Each individual element is tested for integrity prior to released assuring absolute reliability.

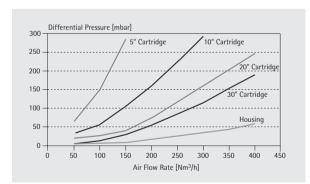
#### **Documentation**

Sartofluor GA cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

#### **Related products**

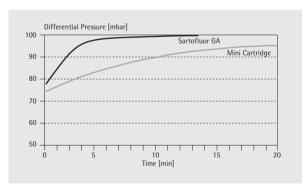
Sartopure GA, page 68

#### Air Flow Chart Sartofluor GA 0.2 μm



Under atmospheric pressure conditions

#### Blow-Down Time after WIT



Differential pressure after steam sterilization measured at 200 mbar

#### Pore size

0.2 μm 0.1 μm

#### Available sizes | Filtration area

Size 1	10"	0.75 m <sup>2</sup>   8.1 ft <sup>2</sup>
Size 2	20"	1.5 m <sup>2</sup>   16.1 ft <sup>2</sup>
Size 3	30"	2.25 m <sup>2</sup> 24.2 ft <sup>2</sup>

#### Available adapters cartridges

25

#### **Extractables**

Sartofluor GA filter cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

#### Regulatory compliance

100% Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test.

Non-pyrogenic according to USP Bacterial Endotoxins

Meets USP Plastics Class VI biological reactivity test, in vivo

Non-fiber releasing according to 21 CFR

#### Sterilization

#### In-line steam sterilization

 $134^{\circ}$ C, 20 min. at max differential pressure of 0.5 bar | 7 psi

#### Autoclaving

134°C, 2 bar | 29 psi, 30 min

#### Sterilization cycles

In-line sterilization: min 150 (in direction and in reverse direction of filtration)

#### **Technical references**

Validation Guide SPK 5711-e

#### Materials

Membrane	PTFE
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
0-Rings	Silicone (EPDM or Viton optional)

#### Operating parameters

Max. allowable differential	5 bar   75 psi at 20°C
Pressure	0.5 bar   7 psi at 140°C
Max. allowable back pressure	3 bar   43.5 psi at 20°C

#### Ordering information

Size	Pore size [µm]
1	0.1
2	0.1
3	0.1
1	0.2
2	0.2
3	0.2
	Size  1 2 3 1 2 3 1 2 3

## Aerosart Airfilter Cartridge for Industrial Applications



#### Description

Aerosart high performance air filter cartridges can significantly reduce operating costs. The Aerosart is a high flow rate, low differential pressure, hydrophobic membrane filter. The unique single layer filter construction also reduces Blow-Down-time. Both the high flow rate and the short Blow-Down-time lowers the energy cost of air supply operations.

#### **Applications**

The Aerosart is designed for large-scale fermentation inlet and exhaust gas filtration.

#### Microbiological safety

Aerosart filter cartridges have been tested and passed aerosol bacterial and viral challenge tests. Tests were conducted using MS-2 coli phages (NCIMB 10 108) and B. subtils var. niger spores (NCTC 10073) at a challenge level of greater than 2.5 × 107 under worst case conditions of greater than 90% RH. No MS-2 coli phages or B. subtilis spores were detected on the downstream side of the Aerosart filter cartridges.

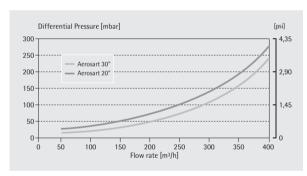
#### Performance

The unique single layer pleated filter construction of the highly hydrophobic PTFE membrane provides low differential pressures, excellent flow rates and the fastest blow down times of any gas service filter.

#### Long service life time

The mechanical and thermal stresses experienced during steam in place sterilization pose the highest risk to any filter cartridge. In many cases, Aerosart filter cartridges will be used for more the 120 steaming cycles. Tests have shown Aerosart cartridges to pass integrity tests with greater than 150 steaming cycles.

#### Air flow rates Aerosart



Air flow rate for Aerosart filter cartridges (0.2  $\mu m)$  in relation to the filter cartridge heights at atmosphere pressure condition.

#### Pore size

0.2 μm

#### Available sizes | Filtration area

Size 2 20" 1.5 m<sup>2</sup> | 16.1 ft<sup>2</sup> Size 3 30" 2.25 m<sup>2</sup> | 24.2 ft<sup>2</sup>

#### Available adapters

25

#### **Packaging**

6 cartridges per box

#### Regulatory compliance

Qualified for retention of aerosolized bacterial spores and viruses (coli-phages) in air

Non pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non fiber releasing according to 21 CFR

#### Sterilization

#### In-line steam sterilization

134°C, 20 min. at a maximum differential pressure of 0.5 bar | 7 psi

#### Sterilization cycles

Minimum of 150 in-line sterilization cycles

#### Materials

Filter membrane	PTFE
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	EPDM

#### Operating parameters

Max. allowable differential pressure	5 bar   75 psi at 20°C 0.5 bar   7 psi at 134°C
Max. allowable back pressure	3 bar   43.5 psi at 20°C 0.5 bar   7 psi at 134°C

#### **Ordering information**

Order code	Size	Pore size [µm]	
5152507T2EC	2	0.2	
5152507T3EC	3	0.2	

#### Midisart® 2000 The Ready-to-use Filter for Sterilizing Gases and Venting







Midisart 2000 filtration units are ideal tools in biotechnology, the pharmaceutical industry, research institutes and anywhere you need sterile vents, bioisolation or sterile air and gases.

Midisarts are excellent for

- sterile venting of filling vessels and fermentation carboys, including culture vessels and CO<sub>2</sub> incubators (6 to 120 liters)
- venting of holding tanks for sterile, distilled water and liquid culture media
- autoclave venting
- in-line sterilization of and particulate removal from air and gases, such as sterilization of air for small fermenters

Midisart 2000 filtration units have been specially designed for maximum handling ease and safety. Tapered hose barbs ensure a simple and secure hold for 6- to 12-mm inner diameter tubing. Midisart is lightweight – only 20 g – so it will not weigh down or kink tubing.

#### User benefits

#### 1. Maximum handling ease

 Midisart 2000 comes individually packaged and presterilized – it's ready to connect!

#### 2. Extra reliability and safety

- Midisart 2000 is integrity testable and delivers reproducible results.
- The membrane is reinforced with polypropylene gauze, giving the Midisart unit added stability and making it pressure resistant up to 3 bar (approx. 44 psi).
- Midisart 2000 entirely eliminates moisture breakthrough because of its inherently hydrophobic PTFE material.
- In addition, Midisart is biosafe because all materials of construction meet the requirements of the current USP Plastics Class VI testing.
- Midisart 2000 units easily withstand at least 20 autoclaving cycles with no loss in performance. The convenient Memory Discs supplied with each Midisart 2000 in UPNcoded boxes enable you to keep track of the number of autoclaving cycles by marking or clipping off each cycle. This feature is key in complying with GLP and ISO standards for traceable documentation.

#### 3. Quality control certificate

- Each unit is automatically tested 100% for housing and membrane sealing during manufacture as part of our zero-defect quality control testing.
- The lot number and the individual unit number are imprinted on the top part of each Midisart 2000 housing to ensure complete traceability.

Midisart 2000 units are visually inspected before they are packaged.

In addition to 100% leak testing, random samples taken from each lot undergo the following tests to assure compliance with Sartorius' stringent in-house quality assurance standards:

- Housing burst pressure test
- Pressure-hold test
- Bubble point test
- Pyrogen test
- Sterile filtration capability
- Flow rate test
- Sterility test

#### Performance

- With a diameter measuring just 64 mm, Midisart incorporates a filter area of 20 cm², which means that it is "packed" with high flow rate performance power!
- Midisarts multiply filtration performance in more ways than one. They can be autoclaved at least 20 times at 134°C!

#### Chemical compatibility

The materials used in Midisart (PTFE and polypropylene) give it excellent compatibility with the solvents and other chemicals listed on the right. However, its compatibility can be affected by various factors, such as temperature, concentration, composition, etc. We therefore recommend that you perform a trial filtration run to test whether Midisart is compatible with the particular medium you wish to filter.

Midisart 2000 can also be used to filter aqueous solutions. In this case, it must be first wetted with alcohol to overcome the membrane's hydrophobicity.

- Acetic acid (concentrated), acetone, acetonitrile
- n-butanol
- Cellosolve (ethyl), chloroform
- Diethylacetamide, dimethyl formamide, dimethyl sulfoxide, dioxane
- Ethanol, ethyl acetate, ethylene glycol
- Freon TF
- Gasoline
- 1 N hydrochloric acid, hexane
- Isobutanol, isopropanol
- Methanol, methylene chloride, methyl ethyl ether, methyl ethyl ketone
- Sodium hydroxide (5%)
- Pentane
- Tetrahydrofuran, toluene, trichloroacetic acid, trichloroethane
- Water
- Xylene





Lechnical	specifications

Filter material	PTFE – reinforced with polypropylene gauze		
Housing material	Polypropylene		
Filtration area	20 cm <sup>2</sup>		
Housing diameter	64 mm		
Priming volume	Approx. 3 ml		
Maximum operating pressure	300 kPa (3 bar = 44 psi)		
Water penetration point (breakthrough)	0.2 μm – approx. 400 kPa 0.45 μm – approx. 300 kPa		
Max. autoclaving temperature	134°C		
Max. autoclave cycles	20		
Hold-up volume	Before the bubble point After the bubble point	approx. 1.0 ml approx. 0.5 ml	
Biosafety	USP Plastics Class VI		
Bubble point with isopropanol (60%)	0.45 μm 0.2 μm	≥ 0.9 bar (~13.1 psi) ≥ 1.1 bar (~16 psi)	
Flow rate for air at $\Delta p = 0.1$ bar (1.45 psi) (1 bar = 100 kPa = 14.5 psi)	0.2 μm pore size 0.45 μm pore size	5.0 l/min 8.5 l/min	

#### Order information

Order numbers	Pore size	Mem- brane	Connectors E A	Pieces/ Case	Sterile
17804 E	0.45 μm	PTFE	Olive Olive	12	Yes
17804 G	0.45 μm	PTFE	Olive Olive	25	Yes
17804 NPE	0.45 μm	PTFE	1/8" 1/8" NPT	12	Yes
17804 NPG	0.45 μm	PTFE	1/8" 1/8" NPT	25	Yes
17839 UNN	0.45 μm	PTFE	Luer Lock female   Olive	100	No
17805 E	0.2 μm	PTFE	Olive Olive	12	Yes
17805 G	0.2 μm	PTFE	Olive Olive	25	Yes
17805 NPE	0.2 μm	PTFE	1/8" 1/8" NPT	12	Yes
17805 NPG	0.2 μm	PTFE	1/8" 1/8" NPT	25	Yes
17805 UPN	0.2 μm	PTFE	Olive Olive	100	No
17809 UNN	0.2 μm	PTFE	1/8" 1/8" NPT	100	No
17812 UNN	0.2 um	PTFE	1/8" Olive	100	No

In the interest of further development of Sartorius products, we reserve the right to make changes without notice.

#### Sartosteel Removing Particles from Liquids, Gas and Steam



#### Description

Sartosteel are especially developed for removing particles from liquids, gas and steam.

#### **Applications**

Sartosteel is applied in biopharmaceutical process such as:

- Steam filtration
- Condensate filtration
- Water filtration

#### **Further applications**

Chemical Industrie

- Polymer filtration (from 3 μm)
- Catalyst retention (10 μm)
- Gas filtration (≥ 80°C)
- Cleaning agents

#### Performance

Sartosteel stainless steel depth filter catridges contain sintered, homogeneous, 0.4 mm thick non woven stainless steel mesh layers, which are reinforced on both sides by mesh supports. These filters are used for removing particles from liquids and gases (steam). Sartosteel filter cartridges offer the user maximum security along with low filtration costs.

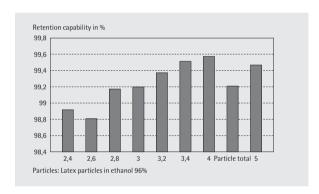
#### **Product benefits**

- High dirt-handling capacity
- High mechanical stability
- Homogeneous material construction
- Absolutely leak-proof connections between end caps and filter unit

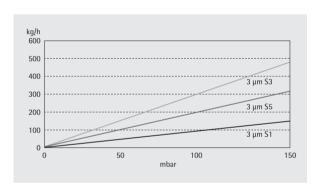
#### **Quality control**

Sartocell are designed, developed and manufactured in accordance with a DIN ISO 9001 certified Quality Management System.

#### Particle retention rating 3 µm Sartosteel



Sartosteel – sarturated steam  $(T = 121^{\circ}C, P = 1 \text{ bar system pressure})$ 



#### **Retention rates**

3 µm

#### Filter area

10" element: 500 cm<sup>2</sup> (effective filter area)

#### **Operation parameters**

Max. differential pressure:

≤ 20 bar, in the direction of filtration ≤ 1 bar, opposite to the direction

of filtration

Resistance | Compatibility thermal up to 200°C (not with

silicone sealing)

chemical

inert to caustic solutions, solvents not compatible with aggressive and relatively high concentrations of acid (≥ 5%)

#### Materials

Sintered non woven stainless steel media, reinforced on both sides with sintered-on mesh

Filter media	AISI 316 L
Support mesh	AISI 304/316 L
Outer support	AISI 304/316 L
Core	AISI 304/316 L
End caps	AISI 304/316 L
Gaskets	silicone*

<sup>\*</sup> standard: also availabe in Viton and EPDM

#### Order information

#### Cartriges

Order code	Adapter type	Retention rate [μm]	Height
570 02S1	25, 28	3	10"
570 02S5	25, 28	3	20"
570 02S3	25, 28	3	30"

<sup>■ :</sup> Please replace the blanks with the appropriate two-letter combination for the adapter type.





## Pre-|Depth Filter

Jumbo Star	66
Sartopure GA	68
Sartopure PP2	70
Sartopure GF Plus	72
Sartopure GF2	74
Sartoclean GF	76
Sartoclean CA	78
Sartofine PP	80

#### Jumbo Star The New Filter Generation



#### Features and benefits

- Highest flow rates
- Highest dirt holding capacity improved
- Modular filter design for easy adaptation and handling
- Improved filter construction for highest thermal and mechanical stability
- Able to handle a broad range of flow requirements



The large filter area and proprietary pleat design of Jumbo Star provides highest flow rates and total throughputs. Capable of flow rates ranging from 10.000 to 40.000 liter per hour. Sartorius Jumbo Star filters are especially designed to match requirements for any large volume filtration process. Sartorius Jumbo Star filters feature up to 46 m<sup>2</sup> of filter area and thus can replace up to twenty four standard filter cartridges. The new modular filters are available in 10", 20", 30" and 40" height allow for easy adaptation into the system.

The rugged construction of Jumbo Star features unique combinations of polypropylene and glass fiber filter layers. This prevents breakthrough of particles, colloids and bio burden - providing maximum protection for downstream standard filters.

The unique, modular construction of the Jumbo Star filter requires much less set-up work and time than standard filter cartridges technology.

The closed filter system of Sartorius Jumbo Star allows ease of use and hygienic processing. Product losses and oxidation are also minimized as a result of this design.



#### Structual integrity

In addition to ease of handling, the new Jumbo construction provides better mechanical stability of the filter system and can withstand back-flushing. The adapter joints between the modules are constructed to meet the most stringent requirements of Food and Beverage applications.

#### Jumbo filter and FDA approval

All materials used for the construction of Jumbo filters meet FDA requirements for use in food and beverage applications. You can choose a wide selection of filters for both applications.

#### **Applications**

- Filtration of food & beverage products
- Filtration of water
- Filtration of large volume fluid

#### Quality from start to finish

All Sartorius filter cartridges are required to pass stringent in-process quality control tests.

Completely traceable documentation of the entire manufacturing process of Jumbo cartridges is guaranteed by our stringent quality assurance policy that is certified for compliance with ISO 9001. This results in consistently high product quality ranging from raw materials to the finished product. Establishing a good partnership with our customers is our No. 1 priority. That's why Sartorius offers not only excellent products, but also an international customer support service network that will make your daily work easy.

Our experienced engineers are ready to assist you in solving your filtration problems.









#### Ordering information

Cartridge type	Adapter type	Retention rating (μm)	1-high (10")	2-high (20")
Sartoclean SC	40	1.20	5634003J1	5634003J2
	40	3.00	5634002J1	5634002J2
Sartopure PP2	40	0.65	5594005J1	5594005J2
	40	1.20	5594003J1	5594003J2
	40	3.00	5594002J1	5594002J2
	40	8.00	5594001J1	5594001J2
	40	20.00	5594020J1	5594020J2
Sartopure GF Plus	40	0.65	5554005J1	5554005J2
•	40	1.20	5554003J1	5554003J2
Sartopure GA	40	0.20	5594007J1GA	5594007J2GA
Cartridge type	Adapter type	Retention rating (µm)	3-high (30")	4-high (40")
Sartoclean SC	40 40	1.20 3.00	5634003J3 5634002J3	5634003J4 5634002J4
Sartopure PP2	40	0.65	5594005J3	5594005J4
•	40	1.20	5594003J3	5594003J4
	40	3.00	5594002J3	5594002J4
	40	8.00	5594001J3	5594001J4
	40	20.00	5594020J3	5594020J4

0.65 1.20

Sartopure GF Plus 40

5554005J3 5554003J3 5554005J4

5554003J4

#### Sartopure GA Superior Venting Filter Cartridges



#### Description

Sartopure GA and Sartofluor GA are the ideal choice for air filtration in the biopharmaceutical industry. Sartopure GA filters expand the service life time of sterilizing grade air filter systems by removal of particles from the air stream. In addition they can be used for all venting purposes that do not necessarily require an integrity testable membrane filter. Sartopure GA offers an outstanding flow rate at low differential pressure.

#### **Applications**

Typically applications for Sartopure GA air filters are:

- Prefiltration in front of Sartofluor GA membrane filters or any other membrane air filter
- Venting of non pressure resistant vessels
- Particle removal from air streams, e.g. pressure supplies

#### Retention efficiency

The excellent retention and therefore superior protection for stored products has been proven by particle retention filtration and bacteria challenge tests performed under worst case conditions. Sartopure GA retained 10 million Bacillus subtilis var niger spores per cm² filtration area. Featuring a retention of 0.2 µm for gas, Sartopure GA efficiently protects stored products, e.g. water, liquid sugar, oral solutions etc., in the pharmaceutical industry as well as the food and beverage industry.

#### Flow rate

Due to the larger filter area of  $0.7 \text{ m}^2 \mid 10^{\circ}$ , Sartopure GA delivers a flow rate of nearly  $40 \text{ m}^2/\text{h}$  at a differential pressure of 10 mbar. This means Sartopure GA is the preferred product for high performance filling or draining of tanks | vessels.

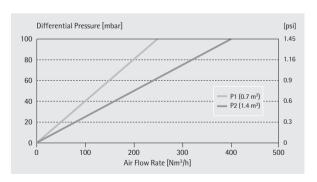
#### Optimized filter material

Sartopure GA's hydrophobic material guarantees an air flow recovery of 60–80% within 30 seconds after the filter has been wetted with water. The water prevents high differential pressures, ensuring fast recovery of air flow rate e. g. after cleaning the tank with hot water agents.

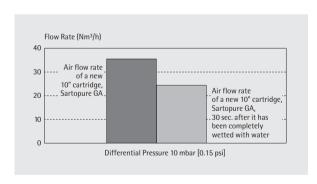
#### **Documentation**

Sartopure GA cartridges are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System.

#### Air Flow Rates for 10" and 20" Cartridges



#### Air Flow Recovery



0.2 µm (nominal in Gases)

#### Available sizes | Filtration area

Size 1	10"	0.7 m <sup>2</sup>   7 ft <sup>2</sup>
Size 2	20"	1.4 m <sup>2</sup> 14 ft <sup>2</sup>
Size 3	30"	2.1 m <sup>2</sup> 21 ft <sup>2</sup>

#### Available adapters cartridges

25 28

#### Regulatory compliance

Filter material bacteria challenge tested with Bacillus subtilis var niger spores

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

#### Sterilization

#### In-line steam sterilization

 $134^{\circ}$ C, 20 min. at max differential pressure of 0.5 bar | 7 psi

#### Autoclaving

134°C, 2 bar | 29 psi, 30 min

#### Sterilization cycles

In-line sterilization: Min. 50

#### Materials

Filter material	Hydrophobic Glass Fiber
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone (EPDM or Viton optional)

#### Pore size

#### **Operating parameters**

Max. allowable differential pressure	5 bar   75 psi at 20°C 2 bar   29 psi at 80°C
Max. allowable back pressure	2 bar   29 psi at 20°C

#### **Ordering information**

Order code	Size	Pore size [µm]
559**07P1GA	1	0.2
559**07P2GA	2	0.2
559**07P3GA	3	0.2

## Sartopure PP2 Particle & Bioburden Reduction Filter Cartridges



#### Description

Sartopure PP2 cartridges were optimized for the wide range of prefiltration. Retention of particles and reduction of bioburden from liquids as well as gases is ensured through fractionated defined depth filtration. Sartopure PP2 filters combine multiple layers of progressively finer pleated polypropylene depth filter material. They are ideally suited for clarification and prefiltration prior to membrane filtration.

#### **Applications**

Typical applications for Sartopure PP2 filters are particle removal from various media like:

- Plasma Fractions
- Vaccines
- MAB
- Diagnostics
- Purified Protein Solutions
- Biological Fluids
- Ophtalmics
- Solutions containing Preservatives
- WFI

#### Security

The Sartopure PP2 filter elements ensure the selective, effective and defined particle retention. It is a valuable protection for the final filter. The all polypropylene construction offers a broad chemical compatibility.

#### Performance

The Sartopure PP2 filter elements combine high dirt loading capacities with long service life and extremely high flow rates.

#### **Economical results**

Considering all features and benefits, Sartopure PP2 filters guarantee the maximum in process profitability.

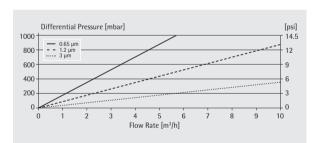
#### Flexibility

Sartopure PP2 filters are available as standard filter cartridges, mini cartridges, MaxiCaps, capsules and in various sizes to allow for broadest choice and highest process flexibility.

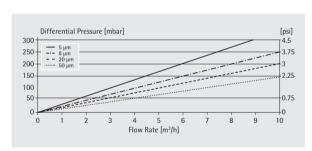
#### **Documentation**

Sartopure PP2 cartridges are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

#### Water Flow Rates for 10" Cartridges and MaxiCaps



#### Water Flow Rates for 10" Cartridges



#### **Retention rates**

 $0.65~\mu\text{m},\,1.2~\mu\text{m},\,3~\mu\text{m},\,5~\mu\text{m},\,8~\mu\text{m},\,20~\mu\text{m},\,50~\mu\text{m}$ 

#### Available sizes | Filtration area

#### Cartridges | MaxiCaps

Size 1	10"	0.6 m <sup>2</sup> 6 ft <sup>2</sup>
Size 2	20"	1.2 m <sup>2</sup> 12 ft <sup>2</sup>
Size 3	30"	1.8 m <sup>2</sup> 18 ft <sup>2</sup>

#### Capsules | Mini Cartridges

0.05 m <sup>2</sup> 0.5 ft <sup>2</sup>
0.1 m <sup>2</sup>   1 ft <sup>2</sup>
0.2 m <sup>2</sup> 2 ft <sup>2</sup>
0.45 m <sup>2</sup>   5 ft <sup>2</sup>
(only Capsules)

#### Available adapters cartridges

21, 25, 27, 28

### **Available adapter Mini Cartridges**

## **Available connectors capsules | MaxiCaps** SS, SO, 00

#### Extractables

Sartopure PP2 cartrides, MaxiCaps and Capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

#### Regulatory compliance

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

#### Sterilization

#### In-line steam sterilization

 $134^{\circ}$ C, 20 min. at max differential pressure of 0.5 bar | 7 psi

#### Note

Capsules and MaxiCaps cannot be in-line steam sterilized!

#### Autoclaving

134°C, 2 bar | 29 psi, 30 min

#### Sterilization cycles

In-line sterilization	Min. 25
(only cartridges)	
Autoclaving	Min. 25

#### **Technical references**

Validation Guide SPK 5717-e Extractables Guide SPK 5719-e

#### Materials

Filter material	Multiple Polypropylene layers
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

#### Operating parameters

Max. allowable differential pressure	5 bar   75 psi at 20°C (Cartridges) 4 bar   58 psi at 20°C (Capsules) 3 bar   43.5 psi at 20°C (MaxiCaps) 2 bar   29 psi at 80°C (Cartridges and Capsules)
Max. allowable back pressure	2 bar   29 psi at 20°C

#### Order information

Order code	Pore size [µm]	
Cartridges		
559**05PX	0.65	
559**03PX	1.2	
559**02PX	3	
559**42PX	5	
559**01PX	8	
559**20PX	20	
559**50PX	50	

## Sartopure GF Plus The New Generation of Adsorptive Depth Filters





#### Description

Sartopure GF Plus adsorptive depth filters are designed for removal of contaminants like colloids, lipids, protein aggregates (Host Cell Protein) and particles from biopharmaceutical fluids. They are used for protection of membrane filters, chromatography columns and ultrafiltration systems in pharmaceutical and biotechnological production processes.

#### **Applications**

Sartopure GF Plus adsorptive depth filters are the ideal choice for prefiltration and clarification of:

- Cell Culture fluids after cell harvest
- Fermentation broths
- Serum free or serum containing cell culture media
- Serum
- Highly viscous opthalmic and LVP solutions
- All media containing lipids and colloids as contaminants

#### **Effective clarification**

Sartopure GF Plus adsorptive depth filters feature highly charged glass fiber layers for effective clarification of fluid streams based on the combination of adsorptive and mechanical retention.

#### **Economic prefiltration**

The 3-dimensional filter matrix of Sartopure GF Plus adsorptive depth filters assures outstanding total throughput performance of the filters thus ensuring most economic design of your prefiltration scheme.

#### Reliable operation

The high and defined particle retention capability of Sartopure GF Plus allows reliable operation and reproducible results from batch to batch even under varying process conditions.

#### Cost saving

The efficient protection of downstream membrane filters and purification equipment saves filter costs and helps to increase the yield of biotech production processes.

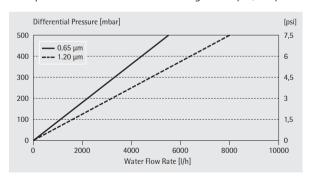
#### Flexibility

Sartopure GF Plus filters are available as standard cartridges and MaxiCaps. Cartridges are strong and robust and designed for maximum pressure differentials and multiple steaming cycles. Disposable MaxiCaps are designed for single use and are integral component of disposable manufacturing lines.

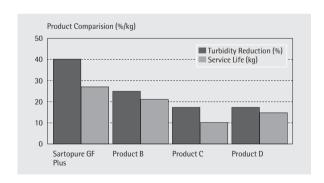
#### **Documentation**

Sartopure GF Plus adsorptive depth filters are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for Sartopure GF Plus Sartopure GF Plus 10" Standard Cartridges 0.65 μm, 1.2 μm



**Product Comparision Data** 



#### **Retention rates**

0.65 μm, 1.2 μm

## Available sizes | Filtration area Cartridges and MaxiCaps

Size 1	10"	0.6 m <sup>2</sup> 6 ft <sup>2</sup>
Size 2	20"	1.2 m <sup>2</sup> 12 ft <sup>2</sup>
Size 3	30"	1.8 m <sup>2</sup> 18 ft <sup>2</sup>

#### Available adapters cartridges

21, 25, 27, 28

#### Available connectors MaxiCaps

SS, SO, 00

#### **Extractables**

Sartopure GF Plus cartridges and MaxiCaps meet, or exceed the requirements for WFI quality standards set by the current USP.

#### Regulatory compliance

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber relesaing according to 21 CFR

#### Sterilization

#### In-line steam sterilization

 $134^{\circ}\text{C}$ , 20 min. at max differential pressure of 0.5 bar

#### Note

MaxiCaps cannot be in-line steam sterilized!

#### Autoclaving

134°C, 2 bar, 30 min

#### Sterilization cycles

In-line sterilization

(only cartridges) Min. 25 Autoclaving Min. 25

#### **Technical references**

Validation Guide SPK5753-e

#### Materials

Filter material	Glass Fiber fleeces
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

#### **Operating parameters**

Max. allowable differential pressure	5 bar   75 psi at 20°C (Cartridges) 2 bar   29 psi at 80°C (Cartridges) 4 bar   58 psi at 20°C (MaxiCaps) 3 bar   43.5 psi at 50°C (MaxiCaps)
Max. allowable back pressure	2 bar   29 psi at 20°C (Cartridges and MaxiCaps)

#### **Order information**

Order code	Pore size [µm]	
Cartridges		
555**05PX	0.65	
555**03PX	1.2	
MaxiCaps		
5551305PX■■	0.65	
5551303PX■■	1.2	

\*\* = Adapter 21, 25, 27, 28

X = Height 10", 20", 30", 40"

= Inlet and outlet connectors

(0 = Hosebarb 1" inner diameter

 $S = 1\frac{1}{2}$ " Sanitary flange)

# Sartopure GF2 Adsorptive High Capacity Filter Cartridges





#### Description

Sartopure GF2 cartridges are optimized for the protection of downstream membrane filter systems and clarification in biopharmaceutical production processes. Due to their high adsorptive power by glass fiber fleeces, they are the ideal solution for removal of colloids and lipids from bio-pharmaceutical fluids

# **Applications**

Sartopure GF2 are ideal for the prefiltration of:

- Fermentation Broths
- Cell Debris solutions
- Serum
- Plasma
- LVP
- Colloid containing solutions
- Lipid containing solutions

#### High adsorption

Based on electrostatic forces of attraction, the negatively charged glass fiber material retains positively charged, small particles that would otherwise pass through the filter. These particles can even be smaller than the nominal filter retention rate.

#### **Defined retention rates**

The key feature of Sartopure GF2 cartridges is their defined and accurate retention rating >99.9%!

# High profitability

The cartridges' high flow rates at a low differential pressure reduce overall costs as less energy is used. Moreover, a high total throughput guarantees the maximum in process profitability.

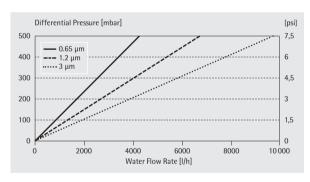
#### **Flexibility**

Sartopure GF2 filters are available as standard filter cartridges, mini cartridges, capsules and in various sizes to allow for broadest choice and highest process flexibility.

#### **Documentation**

Sartopure GF2 cartridges are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for Sartopure GF2 10" Standard Cartridges 0.65  $\mu\text{m},\,1.2~\mu\text{m},\,3~\mu\text{m}$ 



# **Retention rates**

0.65 μm, 1.2 μm, 3 μm

# Available sizes | Filtration area

Ca	rtr	id	q	es

Size 1	10"	$0.6 \text{ m}^2$	6 ft <sup>2</sup>
Size 2	20"	1.2 m <sup>2</sup>	12 ft <sup>2</sup>
Size 3	30"	1.8 m <sup>2</sup>	18 ft <sup>2</sup>

# Capsules | Mini Cartridges

Size 7	0.05 m <sup>2</sup> 0.5 ft <sup>2</sup>
Size 8	0.1 m <sup>2</sup>   1 ft <sup>2</sup>
Size 9	0.2 m <sup>2</sup> 2 ft <sup>2</sup>
Size 0	0.45 m <sup>2</sup> 5 ft <sup>2</sup>
	(only Capsules)

# Available adapters cartridges

21, 25, 27, 28

# Available connectors capsules

SS, SO, 00

#### **Extractables**

Sartopure GF2 cartrides and capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

# Regulatory compliance

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR  $\,$ 

# Sterilization

#### In-line steam sterilization

134°C, 20 min. at max differential pressure of 0.5 bar  $\mid$  7 psi

#### Note

Capsules cannot be in-line steam sterilized!

# Autoclaving

134°C, 2 bar | 29 psi, 30 min

# Sterilization cycles

In-line sterilization Min. 25

(only cartridges)

Autoclaving Min. 25

# **Technical references**

Validation Guide SPK 5717-e

# Materials

Filter material	Glass Fiber fleeces
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
0-Rings	Silicone (optional EPDM or Viton)

## Operating parameters

Max. allowable differential pressure	5 bar   75 psi at 20°C (Cartridges) 4 bar   58 psi at 20°C (Capsules) 2 bar   29 psi at 80°C (Cartridges and Capsules)
Max. allowable back pressure	2 bar 29 psi at 20°C

Order code	Pore size [µm]	
Cartridges		
557**05PX	0.65	
557**03PX	1.2	
557**02PX	3	
Mini Cartridges		
5571505PXB	0.65	
5571503PXB	1.2	
5571502PXB	3	
Capsules		
5571305PX**#	0.65	
5571303PX**#	1.2	
5571302PX**#	3	

# Sartoclean GF Adsorptive Membrane Filter for Colloid and Bioburden Reduction





## Description

Sartolclean GF filter cartridges combine absolute retention performance by membrane filtration with high adsorptive power by glass fiber fleeces. Therefore Sartoclean GF are ideally suited for removal of colloids and lipids as well as defined particle retention and bioburden reduction for a broad range of bio-pharmaceutical applications.

## **Applications**

Sartoclean GF filter cartridges are widely used for prefiltration in biotech manufacturing processes to protect subsequent downstream processing equipment. Typical applications include bioburden reduction as well as effective colloid and lipid removal from:

- Fermentation broths
- Serum
- Cell Culture Media
- Colloid and Lipid containing solutions

# **Process safety**

The removal of colloidal contaminants and lipids by adsorption allows an effective downstream processing and bioburden reduction by membrane filtration avoids formation of pyrogenes during the process resulting in an increased process safety especially for biotech derived fluids.

#### Performance

The combination of adsorptive glass fiber fleeces with membrane filters assures optimal total throughput performance and allow for economic filtration system design.

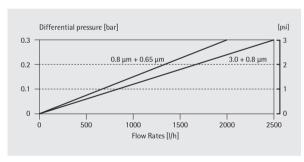
## **Flexibility**

Sartoclean GF filters are available as standard filter cartridges, mini cartrides and capsules offering broadest choice for scale-up and easiest adoption to varying process volumes.

#### **Documentation**

Sartoclean GF cartridges are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

# Water Flow Rates for 10" Sartoclean GF Cartridges



Standardized at 20°C

# Pore sizes

 $0.8 + 0.65 \, \mu m$   $3.0 + 0.8 \, \mu m$ 

# Available sizes | Filtration area

# Cartridges

Size 1	10"	0.6 m <sup>2</sup> 6 ft <sup>2</sup>
Size 2	20"	1.2 m <sup>2</sup> 12 ft <sup>2</sup>
Size 3	30"	1 8 m <sup>2</sup> 18 ft <sup>2</sup>

#### Capsules | Mini Cartridges

Size 7	0.05 m <sup>2</sup> 0.5 ft <sup>2</sup>
Size 8	0.1 m <sup>2</sup> 1 ft <sup>2</sup>
Size 9	0.2 m <sup>2</sup> 2 ft <sup>2</sup>
Size 0	0.45 m <sup>2</sup> 5 ft
	(only Capsules)

# Available adapters cartridges

21, 25, 27, 28

# Available adapter Mini Cartridges

15

# Available connectors capsules

SS, SO, 00

#### **Extractables**

Sartoclean GF cartrides, mini cartridges and capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

# Regulatory compliance

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

## Sterilization

#### In-line steam sterilization

 $134\,^{\circ}\text{C}\text{, }20$  min. at max differential pressure of 0.5 bar  $|\,7$  psi

#### Note

Capsules cannot be in-line steam sterilized!

#### Autoclaving

134°C, 2 bar | 29 psi, 30 min

# Sterilization cycles

In-line sterilization Min. 25 (only cartridges)

Autoclaving Min. 25

# **Technical references**

Validation Guide SPK5718-e

#### Materials

Prefilter membrane	Cellulose Acetate
Endfilter membrane	Cellulose Acetate
Filter active fleece	Glass Fiber
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

# **Operating parameters**

Max. allowable differential pressure	5 bar   75 psi at 20°C (Cartridges) 4 bar   58 psi at 20°C (Capsules) 2 bar   29 psi at 80°C (Cartridges and Capsules)
Max. allowable back pressure	2 bar   29 psi at 20°C

Order code	Pore size [µm]	
Cartridges		
560**05GX	0.65	
560**04EX	0.8	
Capsules		
5601305GX**#	0.65	
5601304EX**#	0.8	
Mini Cartridges		
5601305GXB	0.65	
5601304EXB	8.0	

# Sartoclean CA Particle & Bioburden Reduction Filter Cartridges



#### Description

Sartoclean CA filter cartridges are the ideal choice for a broad range of prefiltration applications in the biopharmaceutical industry from particle removal to bioburden reduction. They offer a defined retention performance by size exclusion. The use of Sartoclean CA prefilters avoids early blockage of downstream sterilizing grade membrane filters and contributes significantly to an economical design of your filtration system.

# Performance

Sartoclean CA filters with heterogeneous double layer construction (3.0 | 0.8  $\mu m$  &t 0.8 | 0.65  $\mu m$ ) offer highest total throughput performance due to the "build-in prefiltration" to avoid filter change during filtration and assure economical system design. Single layer Sartoclean CA filters (0.45  $\mu m$  &t 0.2  $\mu m$ ) offer highest flow rates for microbe retentive filtration.

The reinforcement of the membrane results in

increased mechanical and thermal resistance,

especially of interest in applications with high

differential pressure and with repeated steam

#### **Applications**

Featuring ultra low binding cellulose acetate membranes, Sartoclean CA filters are typically used for membrane prefiltration of:

- Plasma Fractions
- Vaccines
- MAB
- Diagnostics
- Purified Protein Solutions
- Biological Fluids
- Solutions containing Preservatives

# **Flexibility**

Mechanical strength

sterilization of the filters.

Sartoclean CA filters are available as standard filter cartridges, mini cartrides, capsules and MaxiCaps offering broadest choice for scale-up and easiest adoption to varying process volumes.

# High product yield

Throughout the years the cellulose acetate membranes of the Sartoclean CA filters have proven to be the membrane material with lowest unspecific binding capabilities, assuring highest protein yields and rapid preservative recovery enhancing your process efficiency.

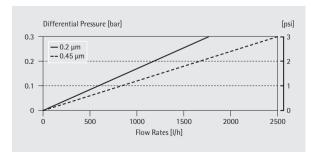
## Documentation

Sartoclean CA cartridges are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.



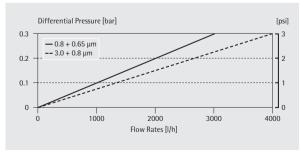


#### Water Flow Rates for Sartoclean CA 10" cartridges



Standardized at 20°C

#### Water Flow Rates for Sartoclean CA 10" cartridges



Standardized at 20°C

# Pore sizes

 $\begin{array}{l} 3.0 + 0.8 \; \mu m \\ 0.8 + 0.65 \; \mu m \\ 0.45 \; \mu m \\ 0.2 \; \mu m \end{array}$ 

## Available sizes | Filtration area

# Cartridges | MaxiCaps

Size 1	10"	0.74 m <sup>2</sup> 7.4 ft <sup>2</sup>
Size 2	20"	1.5 m <sup>2</sup>   15 ft <sup>2</sup>
Size 3	30"	2.2 m <sup>2</sup> 22 ft <sup>2</sup>

# Capsules | Mini Cartridges

Size 7	0.08 m <sup>2</sup>   0.8 ft <sup>2</sup>
Size 8	0.16 m <sup>2</sup> 1.6 ft <sup>2</sup>
Size 9	0.3 m <sup>2</sup> 3 ft <sup>2</sup>
Size 0	0.6 m <sup>2</sup> 6 ft <sup>2</sup>
	(only Capsules)

# Available adapters cartridges

21, 25, 27, 28

# Available adapter Mini Cartridges

# **Available connectors capsules | MaxiCaps** SS, SO, 00

#### **Extractables**

Sartoclean CA cartrides, MaxiCaps and Capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

# Regulatory compliance

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

## Sterilization

#### In-line steam sterilization

134°C, 20 min. at max differential pressure of 0.5 bar  $\mid$  7 psi

#### Note

Capsules and MaxiCaps cannot be in-line steam sterilized!

## Autoclaving

134°C, 2 bar | 29 psi, 30 min

#### Sterilization cycles

In-line sterilization (only cartridges)
Autoclaving Min. 25
Min. 25

## **Technical references**

Validation Guide SPK5718-e

#### Materials

Prefilter membrane	Cellulose Acetate	
Endfilter membrane	Cellulose Acetate	
Support fleece	Polypropylene	
Core	Polypropylene	
End caps	Polypropylene	
O-Rings	Silicone (optional EPDM or Viton)	

#### Operating parameters

Max. allowable differential pressure	5 bar   75 psi at 20°C (Cartridges) 4 bar   58 psi at 20°C (Capsules) 3 bar   43.5 psi at 20°C (MaxiCaps) 2 bar   29 psi at 80°C (Cartridges and Capsules)
Max. allowable back pressure	2 bar   29 psi at 20°C

Order code	Pore size [µm]
Cartridges	
562**07AX	0.2
562**06AX	0.45
562**05GX	0.65
562**04EX	0.8
MaxiCaps	
5621305GX**	0.65
5621304EX**	0.8
Capsules	
5621307AX**#	0.2
5621306AX**#	0.45
5621305GX**#	0.65
5621304EX**#	0.8
Mini Cartridges	
5621505GXB	0.65
5621504EXB	0.8
0021001EX	0.0

# Sartofine PP Particle & Bioburden Reduction Filter Cartridges



#### Description

Sartofine filter cartridges contain no pleated filter layers. For application purposes, they feature a 14 mm thick multilayer, consisting of 4 to 7 different filter zones. The number of zones depends on the type of cartridge. Each zone, made up of polypropylene filter layers is a homogeneous depth filter itself. The nominal retention rating of the respective filter zones becomes increasingly finer in the direction of filtration. Therefore Sartofine PP filters are ideally suited for all applications requirering exceptional high dirt holding capacities with added benefit of high total throughput.

#### **Applications**

Whether in the bio-pharmaceutical or chemical industry, Sartofine PP filter cartridges are used wherever liquids with a wide range of particle sizes need to be prefiltered or clarified. You can choose from 7 different retention ratings (0.5  $\mu m$  to 40  $\mu m$ ), depending on the size of the particles to be removed. This variety allows you to select the filter type which best suits your particular application.

# Efficiency

Particle removal by fractionated depth filtration ensures optimal use of the entire multiplayer which results in a long service life of the filter. The filtration efficiency is enhanced by the filter cake that can be build up within the depths of each filter zone. This filter cake allows colloids to be retained in the finer filter zones.

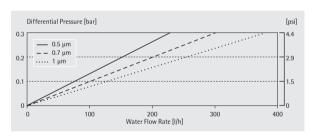
## Mechanical stability

Sartofine PP filter cartridges have been designed for daily routine use. Our special production method of wrapping the filter layers tightly around the supportive core of the cartridge provides high mechanical stability and eliminates the common problem of breakthrough right from the start. The thermally bonded exterior layer and our special welding technique for joining filter layers and end caps allow you to easily backflush the cartridges during cleaning at a pressure up to 2 bar (29 psi).

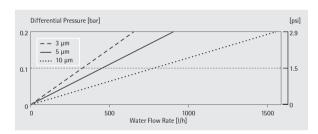
#### Documentation

Sartofine PP cartridges are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

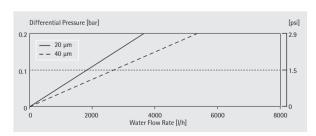
Sartofine 10" Standard Cartridges, 0.5 µm, 0.7 µm, 1 µm



Sartofine 10" Standard Cartridges, 3 μm, 5 μm, 10 μm



Sartofine 10" Standard Cartridges, 20 µm, 40 µm



# **Retention rates**

 $0.5~\mu m$  ,  $0.7~\mu m$  ,  $1~\mu m$  ,  $3~\mu m$  ,  $5~\mu m$  ,  $10~\mu m$  ,  $15~\mu m$  ,  $20~\mu m$  ,  $40~\mu m$ 

# Available sizes | Filtration area

# Cartridges

Size 1	10"	0.05 m <sup>2</sup> 0.5 ft <sup>2</sup>
Size 2	20"	0.1 m <sup>2</sup>   1 ft <sup>2</sup>
Size 3	30"	0.15 m <sup>2</sup>   1.5 ft <sup>2</sup>
Size 4	40"	0.2 m <sup>2</sup> 2 ft <sup>2</sup>

## Available adapters cartridges

00, 03, 05, 07, 08

#### **Extractables**

Sartofine PP cartrides meet, or exceed the requirements for WFI quality standards set by the current USP.

# Regulatory compliance

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

#### Sterilization

## In-line steam sterilization

134°C, 20 min. at max differential pressure of 0.5 bar  $\mid$  7 psi

# Autoclaving

134°C, 2 bar | 29 psi, 30 min

# Sterilization cycles

In-line sterilization Min. 25 (only cartridges)
Autoclaving Min. 25

## **Technical references**

Validation Guide SPK 5707-e

# Materials

Filter material	Multiple Polypropylene layers	
Support fleece	Polypropylene	
Core	Polypropylene	
End caps	Polypropylene	
O-Rings	Silicone (optional EPDM or Viton)	

# Operating parameters

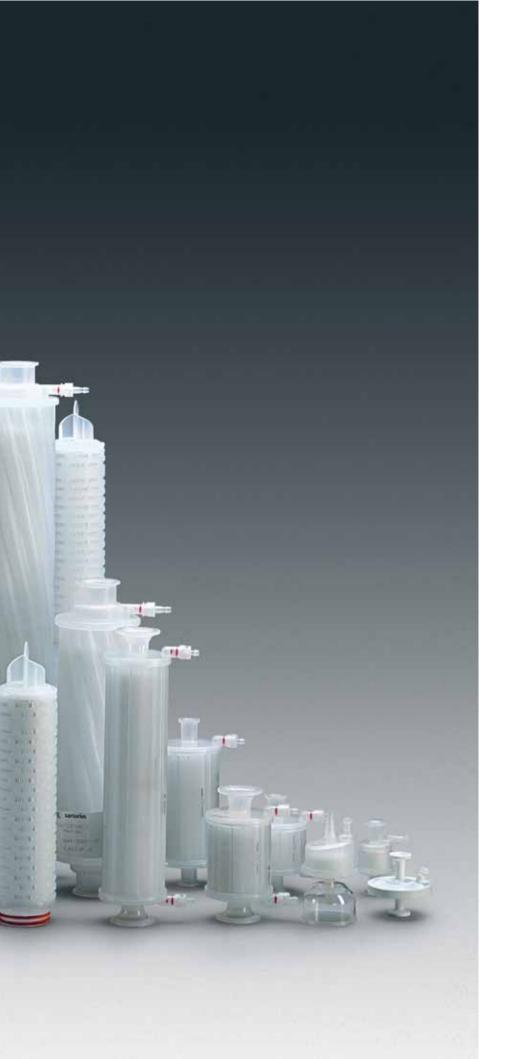
Max. allowable differential pressure	5 bar   75 psi at 20°C 2 bar   29 psi at 80°C
Max. allowable back pressure	2 bar 29 psi at 20°C

#### **Order information**

Order code	Pore size [µm]	
Cartridges		
558**06WX	0.5	
558**05WX	0.7	
558**03WX	1	
558**02WX	3	
558**42WX	5	
558**10WX	10	
558**15WX	15	
558**20WX	20	
558**40WX	40	

# Legende

\*\* = Adapter X = Size



# Sterile Liquid Filters

Sartobran P	84
Sartopore 2	90
Sartolon	112
Sartofluor I G MaxiCans	114

# Sartobran P 0.2 μm Sterilizing Grade Filter Cartridges and Mini Cartridges





#### Description

Sartobran P sterilizing grade filter cartridges have proven throughout the years to be the first choice in the bio-pharmaceutical industry for all applications requiring low adsorption capabilities. The unique ultra low unspecific binding capacity of the cellulose acetate membranes assures highest protein yield and rapid preservative recovery. Sartobran P filters are ideally suited for processing high value biological solutions like dilute protein solutions and pharmaceuticals sensitive to adsorption like dilute preservative solutions.

# **Applications**

Sartobran P filters are ideally suited for all applications that require highest product recovery rates like:

- Coagulation Factors, Albumine, IgG
- Bacterial and Viral Vaccines
- MAB's
- Bio-processed Pharmaceuticals
- Diagnostics
- Purified Protein Solutions
- Biological Fluids
- Solutions containing Preservatives

#### Highest product yield

The Sartobran P's cellulose acetate membrane provides the lowest unspecific adsorption of any membrane material available, ensuring the highest product recovery rates.

#### Performance

Due to the "built-in prefiltration" by a 0.45  $\mu m$  membrane, Sartobran P 0.2  $\mu m$  filters provide excellent total throughputs and higher flow rates at low differential pressure for gentle product treatment.

# **Flexibility**

Sartobran P 0.2 µm filters are available in traditional cartridge formats and disposable capsules from 150 cm<sup>2</sup> to 1.8 m<sup>2</sup> for simple linear scale up and process flexibility.

# Microbiological retention

Sartobran P 0.2 µm rated filter cartridges are fully validated as sterilizing grade filter elements according to HIMA and ASTM F-838-83 guidelines.

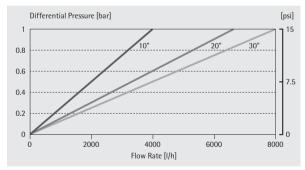
## **Quality control**

Each individual element is integrity tested by diffusion and bubble point test prior to release, assuring absolute reliability.

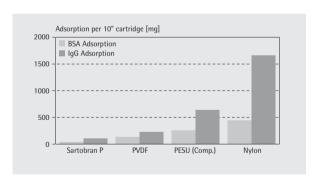
#### Documentation

Sartobran P cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

## Water Flow Rates for Standard Cartridges and MaxiCaps



Standardized at 20°C



10" Cartridge format

#### Pore size

 $0.45 \mu m + 0.2 \mu m$ 

#### Available sizes | Filtration area

Cartridges
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Size 1	10"	0.6 m <sup>2</sup> 6.5 ft <sup>2</sup>
Size 2	20"	1.2 m <sup>2</sup> 12.9 ft <sup>2</sup>
Size 3	30"	1.8 m <sup>2</sup> 19.4 ft <sup>2</sup>

# Mini Cartridges

Size 7	5	0.05 m <sup>2</sup> 0.54 ft <sup>2</sup>
Size 8		0.1 m <sup>2</sup> 1.1 ft <sup>2</sup>
Size 9		0.2 m <sup>2</sup> 2.2 ft <sup>2</sup>

# Available adapters cartridges

21, 25, 27, 28

# **Available adapter Mini Cartridges** 15, 18

#### **Extractables**

Sartobran P 0.2  $\mu$ m rated filter cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

# Regulatory compliance

100% Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

# Sterilization

## In-line steam sterilization

134°C, 20 min. at max differential pressure of 0.5 bar  $\mid$  7 psi

#### Note

Capsules and MaxiCaps cannot be in-line steam sterilized.

# Autoclaving

134°C, 2 bar | 29 psi, 30 min

## Sterilization cycles

In-line sterilization Min. 25 Autoclaving Min. 25

#### **Technical references**

Validation Guide SPK5726-e Extractables Guide SPK5720-e

#### Materials

Prefilter membrane	Cellulose Acetate	
Endfilter membrane	Cellulose Acetate	
Support fleece	Polypropylene	
Core	Polypropylene	
End caps	Polypropylene	
O-Rings	Silicone (optional EPDM or Viton)	

#### **Operating parameters**

Max. allowable differential pressure	5 bar   75 psi at 20°C 2 bar   29 psi at 80°C
Max. allowable back pressure	2 bar 29 psi at 20°C

Order code	Size	Pore size [µm]	
Cartridges			
523**07H1P	1	0.2	
523**07H2P	2	0.2	
523**07H3P	3	0.2	
Mini Cartridges			
5231507H7B	7	0.2	
5231507H8B	8	0.2	
5231507H9B	9	0.2	

# Sartobran P 0.2 μm Sterilizing Grade MidiCaps and MaxiCaps





#### Description

Sartobran P membrane filter MidiCaps and MaxiCaps are self contained, ready to use, sterile filter units for sterilizing grade filtration in the pharma | biotech industry. The extremely low unspecific adsorption of their cellulose acetate membranes assures highest protein yields and rapid preservative recovery.

# **Applications**

Sartobran P filter elements have proven throughout the years to be the first choice for all applications in the biopharmaceutical industry requiring low adsorption capabilities. They are typically used for sterilizing grade filtration of:

- Coagulation Factors, Albumin, IgG
- Bacterial & Viral Vaccines
- MAB
- Bio-processed Pharmaceuticals
- Diagnostics
- Purified Protein Solutions
- Biological Fluids
- Fluids containing preservatives

#### Easy to use

Sartobran P MidiCaps and MaxiCaps are delivered as individually packed sterile units. On site, pre-use sterilization can be eliminated.

#### **Flexibility**

Sartobran P 0.2  $\mu$ m MidiCaps and MaxiCaps are available with various filtration areas from 500 cm<sup>2</sup> | 0.5 ft<sup>2</sup> up to 1.8 m<sup>2</sup> | 18 ft<sup>2</sup> for easy adoption to any filtration process independent from the batch size.

#### **Scalability**

Consistent and predictable scale-up and down trials can reliably be performed as all Sartobran P MidiCaps and MaxiCaps are produced with the same type of membrane and identical materials of construction.

#### Cost saving

The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

# Microbiological retention

Sartobran P MidiCaps and MaxiCaps 0.2  $\mu$ m rated are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-83 guidelines.

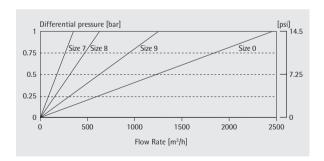
#### **Quality control**

Each individual element is tested for integrity by B.-P. and Diffusion-Test prior to be released assuring absolute reliability.

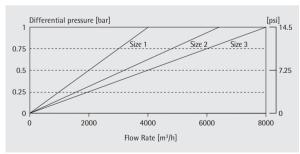
#### **Documentation**

Sartobran P MidiCaps and MaxiCaps are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for MidiCaps with SS inlet and outlet



Water Flow Rates for MaxiCaps



Standardized at 20°C

#### Pore size

 $0.45 \mu m + 0.2 \mu m$ 

# Available sizes | Filtration area

## MidiCaps

Size 7 0.05 m<sup>2</sup> | 0.5 ft<sup>2</sup> Size 8 0.1 m<sup>2</sup> | 1 ft<sup>2</sup> Size 9 0.2 m<sup>2</sup> | 2 ft<sup>2</sup> Size 0 0.45 m<sup>2</sup> | 5 ft<sup>2</sup>

#### **MaxiCaps**

Size 1 0.6 m<sup>2</sup> | 6 ft<sup>2</sup> Size 2 1.2 m<sup>2</sup> | 12 ft<sup>2</sup> Size 3 1.8 m<sup>2</sup> | 18 ft<sup>2</sup>

## Available connectors MidiCaps

SS, SO, OO, FF, FO, HH (only size 7)

# Available connectors MaxiCaps

SS, SO, 00

S: 11/2" Tri-Clamp (Sanitary)

O: Hose Barb

F: 3/4" Tri-Clamp (Sanitary)

H: Small, multiple stepped hose barb (with filling bell at the outlet)

#### **Extractables**

Sartobran P 0.2 µm rated filter MidiCaps and MaxiCaps meet, or exceed the requirements for WFI quality standards set by the current USP.

#### Regulatory compliance

Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

#### Sterilization

# Autoclaving

134°C, 2 bar, 30 min

No in-line steam sterilization

#### Sterilization cycles

Autoclaving Min. 25

# **Technical references**

Validation Guide

- SPK5760-e (MidiCaps)
- SPK5726-e (MaxiCaps)

## Extractables Guide

- SPK5720-e

#### Materials

Prefilter membrane	Cellulose Acetate
Endfilter membrane	Cellulose Acetate
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule housing	Polypropylene
O-Rings	Silicone
Filling Bell	Polycarbonate

# **Operating parameters**

Max. allowable differential pressure	5 bar   72.5 psi at 20°C (MidiCaps) 2 bar   29 psi at 80°C (MidiCaps) 4 bar   58 psi at 20°C (MaxiCaps) 3 bar   43.5 psi at 20°C (MaxiCaps)
Max. allowable back pressure	2 bar   29 psi at 20°C

Order code	Pore size [μm]	Pack size [Pieces]	Test pressure [bar   psi]	Max. diffusion [ml/min]	Min. Bubble Point [bar psi]
MidiCaps					
5235307H7**A	0.2	4	2.5   36	3	3.2   46
5235307H8**A	0.2	4	2.5 36	4	3.2   46
5235307H9**A	0.2	4	2.5   36	5	3.2   46
5235307H0**V	0.2	2	2.5   36	10	3.2   46
MaxiCaps					
5231307H1**	0.2	1	2.5   36	15	3.2   46
5231307H1	0.2	1	2.5 36	30	3.2   46
5231307H3**	0.2	1	2.5   36	45	3.2   46

<sup>\*\*:</sup> Connector Styles

# Sartobran P 150 & 300 0.2 µm Sterilizing Grade Filter Capsules



The Sartobran 150 & 300 are disposable, sterile ready-to-use membrane filter capsules. They are designed for use in small-scale production of high value pharmaceutical and biotech products, due to the ultra low binding of their cellulose acetate membrane for proteins and preservatives. The Sartobran 150 and 300 feature the same materials and type of construction as any other Sartobran P filter element, for easy scale-down and scale-up, making them perfect for R&D Labs in pharmaceutical development.

#### **Applications**

Typical applications include sterilizing grade filtration of any solution sensitive to adsorption like:

- Therapeutics
- Bioprocessed Pharmaceuticals
- Serum
- Injectables
- Media
- Buffers

#### Performance

The unique pleated filter construction and the "built-in-prefiltration" offers excellent flow rates and superior total throughput performance, especially in comparison to conventional stacked disc filter systems.

#### High product yield

The highest product yields are realized by the combination of extremely low residual volume in the capsule housing and ultra low unspecific adsorption of the cellulose acetate membrane.

## **Automatic venting**

A hydrophobic PTFE vent filter membrane positioned at the highest point upstream allows easy venting of the capsule and prevents product loss during the venting process.

## Scalability

Featuring the same materials and type of construction as any other Sartobran P filter element, Sartobran P 150 & 300 are ideally suited for R&D Labs in pharmaceutical development. Filtration trials can be performed using extremely small volumes of high value products .

## Microbiological retention

Sartobran P 0.2  $\mu$ m rated 150 & 300 capsules are fully validated as sterilizing grade filter elements according to HIMA and ASTM F-838-83 guidelines .

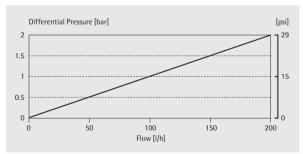
#### **Quality control**

Each individual element is integrity tested by diffusion and bubble point test prior to release, assuring absolute reliability.

#### **Documentation**

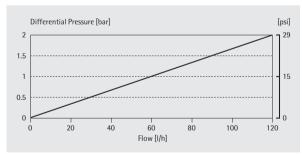
Sartobran P 150 & 300 capsules are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

## Water Flow Rate Sartobran 300



Standardized at 20°C

## Water Flow Rate Sartobran 150



Standardized at 20°C

#### Pore size

 $0.45 \mu m + 0.2 \mu m$ 

# Available sizes | Filtration area

Size 4 0.015 m<sup>2</sup> | 0.16 ft<sup>2</sup> Size 5 0.03 m<sup>2</sup> | 0.32 ft<sup>2</sup>

#### **Available connectors**

SS, SO, 00 (Type 150) 00 (Type 300)

# Extractables

Sartobran P 0.2 µm rated 150 & 300 filter capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

# Regulatory compliance

100% Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

#### Sterilization

# **Autoclaving**

134 °C, 2 bar | 29 psi, 30 min

No in-line steam sterilization

# Sterilization cycles

Autoclaving Min. 25 (Type 300) Max. 3 (Type 150)

# **Technical references**

Validation Guide SPK5726-e Extractables Guide SPK5720-e

# Materials

Prefilter membrane	Cellulose Acetate
Endfilter membrane	Cellulose Acetate
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Housing	Polypropylene

#### **Operating parameters**

Max. allowable differential pressure	4 bar   58 psi at 20°C 2 bar   29 psi at 80°C
Max. allowable back pressure	2 bar   29 psi at 20 °C

Order code	Pore size [µm]	
Sartobran 150		
5231307H400B	0.2	
5231307H4SOB	0.2	
5231307H4SSB	0.2	
Sartobran 300		
5231307H500B	0.2	

# Sartobran P 0.1 µm Sterilizing Grade Filter Cartridges and Capsules



#### Description

Sartobran P 0.1 µm rated, high-flow filter elements are designed to give enhanced sterility assurance for applications with microorganisms present that can pass through 0.2 µm rated sterilizing grade filters. The Sartobran P's cellulose acetate membrane offers ultra low binding properties for proteins and preservatives, making Sartobran P filters the ideal choice for filtration of high value bio-pharmaceutical products.



#### **Applications**

All applications which require sterilizing grade filtration with retention finer than conventional 0.2 µm sterilizing grade filters for removal of unusually small microorganisms. This typically includes:

- Bio-processed pharmaceuticals
- Long term filling operations
- Filtration in pharmaceutical water systems

Any other application requiring sub 0.2 µm filtration for enhanced sterility assurance.



#### Flow rates

Higher flow rates than other 0.1 µm rated filters provide short filtration time and gentle product treatment, even if replacement of conventional 0.2 µm rated filters is necessary.



Due to the "built-in prefiltration" by a 0.45 um membrane. Sartobran P 0.1 um filters provide higher total throughputs than any other 0.1 µm rated filter for economical process design.

## Highest product vield

The ultra low adsorption characteristic of the Sartobran P's cellulose acetate membrane provides the highest product yield - especially important for high value proteins.

Sartobran  $\stackrel{.}{P}$  0.1  $\mu m$  filters are available in traditional cartridge formats and disposable capsules from 150 cm<sup>2</sup> to 1.8 m<sup>2</sup> for simple linear scale up and process flexibility.

## Quality control

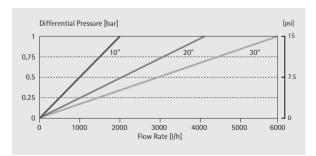
Each individual element is integrity tested by diffusion and bubble point test prior to release, assuring absolute reliability.

#### Documentation

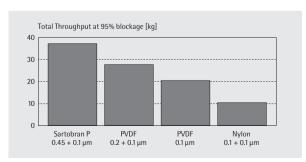
Sartobran P cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.



#### Water Flow Rates for 10", 20" and 30" Cartridges



Standardized at 20°C



10" Cartridge format

#### Pore size

 $0.45 \, \mu m + 0.1 \, \mu m$ 

# Available sizes | Filtration area

## Cartridges | MaxiCaps

Size 1	10"	0.6 m <sup>2</sup> 6 ft <sup>2</sup>
Size 2	20"	1.2 m <sup>2</sup> 12 ft <sup>2</sup>
Size 3	30"	1.8 m <sup>2</sup> 18 ft <sup>2</sup>

#### Capsules | Mini Cartridges

Size 7	0.05 m <sup>2</sup> 0.5 ft
Size 8	0.1 m <sup>2</sup>   1 ft <sup>2</sup>
Size 9	0.2 m <sup>2</sup> 2 ft <sup>2</sup>

# Available adapters cartridges

21, 25, 27, 28

# **Available adapter Mini Cartridges** 15

**Available connectors MaxiCaps | Capsules** SS, SO, OO

#### **Extractables**

Sartobran P  $0.1~\mu m$  rated filter cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

#### Regulatory compliance

100% Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test.

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

#### Sterilization

# In-line steam sterilization

134°C, 20 min. at max differential pressure of 0.5 bar  $\mid$  7 psi

## Note

Capsules cannot be in-line steam sterilized.

# Autoclaving

134°C, 2 bar | 29 psi, 30 min

# Sterilization cycles

In-line sterilization Min. 25 (only cartridges)

Autoclaving Min. 25

#### **Technical references**

Validation Guide SPK5726-e Extractables Guide SPK5720-e

#### Materials

Prefilter membrane	Cellulose Acetate
Endfilter membrane	Cellulose Acetate
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

#### Operating parameters

Max. allowable differential pressure	5 bar   75 psi at 20°C (Cartridges) 4 bar   58 psi at 20°C (Capsules) 2 bar   29 psi at 80°C (Cartridges and Capsules)
Man allandala la almana	2     20   -+ 20%

Max. allowable back pressure 2 bar | 29 psi at 20°C

Order code Size		Pore size [µm]
Standard Cartridges		
523**58H1P	1	0.1
523**58H2P	2	0.1
523**58H3P	3	0.1
Mini Cartridges		
5231558H7B	7	0.1
5231558H8B	8	0.1
5231558H9B	9	0.1
MaxiCaps		
5231358H1**	1	0.1
5231358H2**	2	0.1
5231358H3**	3	0.1
Capsules		
5231358H7**B	7	0.1
5231358H8**B	8	0.1
5231358H9**A	9	0.1

# Sartobran P 0.45 μm Bioburden and Particle Reductive Filter Cartridges





#### Description

Sartobran P 0.45 µm rated filter cartridges are ideally suited for bioburden and particle removal from bio-pharmaceutical solutions for protection of subsequent downstream processing equipment or sterilizing grade filters. The unique low unspecific binding capacity of the cellulose acetate membranes assures highest protein yield and rapid preservative recovery.

# **Applications**

Sartobran P filters are ideally suited for prefiltration of high value biological solutions and pharmaceuticals sensitive to adsorption as well as for final filtration of LVP's and Buffers. Typical applications are filtration of:

- Coagulation Factors, Albumine, IgG
- Bacterial and Viral Vaccines
- MAB's
- Bio-processed Pharmaceuticals
- Diagnostics
- Purified Protein Solutions
- LV P
- Buffers

#### Highest product yield

The cellulose acetate membrane of the Sartobran P filters provides the lowest unspecific adsorption of all membrane materials available for highest product recovery rates.

#### Performance

Due to the "built-in prefiltration" by a 0.65  $\mu$ m membrane, Sartobran P 0.45  $\mu$ m filters provide excellent total throughputs and higher flow rates at low differential pressure for gentle product treatment.

# **Flexibility**

Sartobran P 0.45 µm filters are available in traditional cartridge formats and disposable capsules from 150 cm<sup>2</sup> to 1.8 m<sup>2</sup> for simple linear scale up and process flexibility.

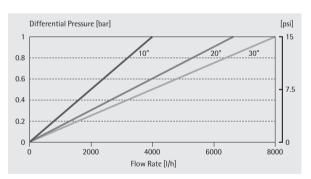
#### **Quality control**

Each individual element is tested for integrity by diffusion and bubble point test prior to be released assuring absolute reliability.

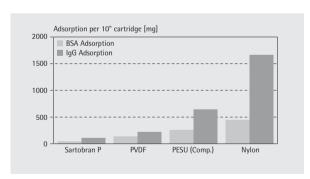
#### **Documentation**

Sartobran P cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

## Water Flow Rates for Standard Cartridges and MaxiCaps



Standardized at 20°C



10" Cartridge format

#### Pore size

 $0.65 \mu m + 0.45 \mu m$ 

#### Available sizes | Filtration area

Size 1	10"	$0.6 \text{ m}^2$	6.5 ft <sup>2</sup>
Size 2	20"	1.2 m <sup>2</sup>	12.9 ft <sup>2</sup>
Size 3	30"	1.8 m <sup>2</sup>	19.4 ft <sup>2</sup>

# Mini Cartridges

Size 7	$0.05~{\rm m}^{2}$	² 0.5 ft²
	0.1 m <sup>2</sup>	
Size 9	0.2 m <sup>2</sup>	2.2 ft <sup>2</sup>

# Available adapters cartridges

21, 25, 27, 28

# **Available adapter Mini Cartridges** 15

#### **Extractables**

Sartobran P 0.45  $\mu m$  rated filter cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

# Regulatory compliance

100% Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

# Sterilization

## In-line steam sterilization

134°C, 20 min. at max differential pressure of 0.5 bar  $\mid$  7 psi

#### Note

Capsules and MaxiCaps cannot be in-line steam sterilized.

# Autoclaving

134°C, 2 bar | 29 psi, 30 min

# Sterilization cycles

In-line sterilization Min. 25 Autoclaving Min. 25

#### **Technical references**

Validation Guide SPK 5726-e Extractables Guide SPK5720-e

#### Materials

Prefilter membrane	Cellulose Acetate	
Endfilter membrane	Cellulose Acetate	
Support fleece	Polypropylene	
Core	Polypropylene	
End caps	Polypropylene	
O-Rings	Silicone (optional EPDM or Viton)	

#### Operating parameters

Max. allowable differential pressure	5 bar   75 psi at 20°C 2 bar   29 psi at 80°C
Max. allowable back pressure	2 bar 29 psi at 20°C

Order code	Size	Pore size [µm]	
Standard Cartridges			
523**06D1P	1	0.45	
523**06D2P	2	0.45	
523**06D3P	3	0.45	
Mini Cartridges			
5231506D7B	7	0.45	
5231506D8B	8	0.45	
5231506D9B	9	0.45	

# Sartobran P 0.45 μm Bioburden and Particle Retentive MidiCaps and MaxiCaps





#### Description

Sartobran P membrane filter MidiCaps and MaxiCaps 0.45 µm rated are ideally suited for bioburden and defined particle reduction from bio-pharmaceutical solutions. They can be used for protection of sterilizing grade membrane filters or subsequent downstream processing equipment in biotech production processes.

#### **Applications**

Featuring extremely low adsorptive cellulose acetate membranes, Sartobran P filter elements are ideally suited for filtration of highly valuable protein solutions or solutions containing preservatives. They assure highest protein yield and rapid preservative recovery.

Typical applications include:

- Coagulation Factors, Albumin, IgG
- Bacterial & Viral Vaccines
- \_ MAR
- Bio-processed Pharmaceuticals
- Diagnostics
- Purified Protein Solutions
- Biological Fluids
- Fluids containing preservatives

#### Easy to use

Sartobran P MidiCaps and MaxiCaps are delivered as individually packed sterile units. On site, pre-use sterilization can be eliminated.

#### **Flexibility**

Sartobran P 0.45  $\mu$ m MidiCaps and MaxiCaps are available with various filtration areas from 500 cm² | 0.5 ft² up to 1.8 m² | 18 ft² for easy adoption to any filtration process independent from the batch size.

#### **Scalability**

Consistent and predictable scale-up and down trials can reliably be performed as all Sartobran P MidiCaps and MaxiCaps are produced with the same type of membrane and identical materials of construction.

#### Cost saving

The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

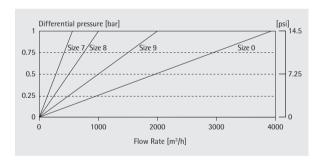
#### Quality control

Each individual element is tested for integrity by B.-P. and Diffusion-Test prior to be released assuring absolute reliability.

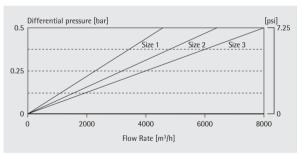
#### **Documentation**

Sartobran P MidiCaps and MaxiCaps are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for MidiCaps with SS inlet and outlet



Water Flow Rates for MaxiCaps



Standardized at 20°C

## Pore size combination

 $0.65 \ \mu m + 0.45 \ \mu m$ 

# Available sizes | Filtration area

## MidiCaps

Size 7  $0.05 \text{ m}^2 | 0.5 \text{ ft}^2$ Size 8  $0.1 \text{ m}^2 | 1 \text{ ft}^2$ Size 9  $0.2 \text{ m}^2 | 2 \text{ ft}^2$ Size 0  $0.45 \text{ m}^2 | 5 \text{ ft}^2$ 

#### **MaxiCaps**

Size 1 0.6 m<sup>2</sup> | 6 ft<sup>2</sup> Size 2 1.2 m<sup>2</sup> | 12 ft<sup>2</sup> Size 3 1.8 m<sup>2</sup> | 18 ft<sup>2</sup>

#### Available connectors MidiCaps

SS, SO, OO, FF, FO, HH (only size 7)

#### Available connectors MaxiCaps

SS, SO, 00

S: 11/2" Tri-Clamp (Sanitary)

O: Hose Barb

F: 3/4" Tri-Clamp (Sanitary)

H: Small, multiple stepped hose barb (with filling bell at the outlet)

#### **Extractables**

Sartobran P 0.45  $\mu m$  rated filter MidiCaps and MaxiCaps meet, or exceed the requirements for WFI quality standards set by the current USP.

# Regulatory compliance

Individually integrity tested

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

## Sterilization

#### Autoclaving

134°C, 2 bar, 30 min

No in-line steam sterilization

# Sterilization cycles

Autoclaving Min. 25

#### **Technical references**

Validation Guide

- SPK 5760-e (MidiCaps)
- SPK 5726-e (MaxiCaps)

#### Extractables Guide

- SPK5731-e

#### Materials

Prefilter membrane	Cellulose Acetate
Endfilter membrane	Cellulose Acetate
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule housing	Polypropylene
O-Rings	Silicone
Filling Bell	Polycarbonate

#### **Operating parameters**

Max. allowable differential pressure	5 bar   72.5 psi at 20°C (MidiCaps) 2 bar   29 psi at 80°C (MidiCaps) 4 bar   58 psi at 20°C (MaxiCaps) 3 bar   43.5 psi at 20°C (MaxiCaps)
Max. allowable back pressure	2 bar 29 psi at 20°C

Order code	Pore size [μm]	Pack size [Pieces]	Test pressure [bar   psi]	Max. diffusion [ml/min]	Min. Bubble Point [bar psi]
MidiCaps					
5235306D7**A	0.45	4	1.5   22	3	2.0   29
5235306D8**A	0.45	4	1.5 22	4	2.0 29
5235306D9**A	0.45	4	1.5   22	5	2.0 29
5235306D0**V	0.45	2	1.5   22	10	2.0   29
MaxiCaps					
5231306D1**	0.45	1	1.5   22	15	2.0   29
5231306D2**	0.45	1	1.5   22	30	2.0   29
5231306D3**	0.45	1	1.5   22	45	2.0   29

<sup>\*\*:</sup> Connector Styles

# Sartopore 2 0.2 μm Sterilizing Grade Filter Cartridges and Mini Cartridges





#### Description

Sartopore 2 0.2 µm rated sterilizing grade filter cartridges are designed for filtration of a broad range of pharmaceutical products where compliance with cGMP requirements has to be fulfilled. Sartopore 2 cartridges feature a unique hydrophilic heterogeneous double layer Polyethersulfone membrane with broad chemical compatibility, high thermal resistance and higher throughput arld flow-rate than any other sterilizing grade filter cartridge.

#### **Applications**

Typical applications include sterilizing grade filtration of:

- Therapeutics
- Biological Fluids
- Opthalmics
- SVPs, LVPs
- Antibiotics
- WFI
- Chemicals
- Cleaning and sanitizing agents
- Bulk pharmaceutical products

#### Compatibility

The polyethersulfone membrane is compatible with a pH range from pH 1 to pH 14 and unaffected by steam sterilization cycles making Sartopore 2 cartridges ideal for filtration of solutions with high|low pH and for SIP|CI P-cycles.

#### Performance

Sartopore 2 cartridges provide an exception ally high total throughput by fractionated filtration due to the "built-in prefiltration" of the 0.45  $\mu$ m membrane. The asymmetric pore structure of the polyethersulfone membrane provides high flow rates at low pressure drops.

#### Wettability

Sartopore 2 cartridges can be easily wetted out for integrity testing even after drying at 80°C for 12 hours.

# Microbiological retention

Sartopore 2 filter cartridges are fully validated as sterilizing grade filter elements according to HIMA and ASTM F-838-83 quidelines.

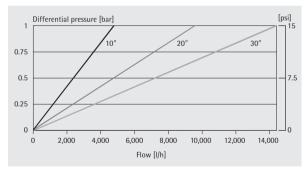
#### **Quality control**

Each individual element is integrity tested by diffusion and bubble point test prior to release, assuring absolute reliability.

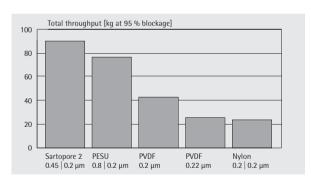
#### Documentation

Sartopore 2 cartridges are designed, devel oped and manufactured in accordance with an ISO 9001 certified Quality Management System. AValidation Guide and Extractables Guide are available for compliance with regulatory requirements.

## Water Flow Rates for 10", 20" and 30" Cartridges



Standardized at 20°C



10" Cartridge format

#### Pore size

 $0.45 \mu m + 0.2 \mu m$ 

# Available sizes | Filtration area

#### Standard cartridges

Size 0	5"	0.3 m <sup>2</sup>   3 ft <sup>2</sup>
Size 1	10"	0.6 m <sup>2</sup> 6 ft <sup>2</sup>
Size 2	20"	1.2 m <sup>2</sup>   12 ft <sup>2</sup>
Size 3	30"	1.8 m <sup>2</sup> 18 ft <sup>2</sup>

#### Mini Cartridges

Size 7	0.05 m <sup>2</sup> 0.5 ft <sup>2</sup>
Size 8	0.1 m <sup>2</sup>   1 ft <sup>2</sup>
Size 9	0.2 m <sup>2</sup> 2 ft <sup>2</sup>

#### **Available connectors**

21, 25, 27, 28

#### Extractables

Sartopore 2 0.2 µm rated filter cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

# Regulatory compliance

- Individually integrity tested
- Integrity test correlated to HIMA/ASTM
   F 838-83 Bacteria Challenge Test
- Non pyrogenic according to USP Bacterial Endotoxins
- Passes USP Plastic Class VI Test
- Non fiber releasing according to 21 CFR

#### Sterilization

## In-line steam sterilization

134°C, 20 min. at max differential pressure of 0.5 bar |7.25~psi>

# Autoclaving

134°C, 2 bar 29 psi, 30 min

#### Sterilization cycles

In-line sterilization Min. 25 Autoclaving Min. 25

#### **Technical references**

Validation Guide SPK5732-e Extractables Guide SPK5731-e

#### Materials

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule housing	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

# Operating parameters

Max. allowable differential pressure	5 bar   58 psi at 20°C 2 bar   29 psi at 80°C
Max. allowable back pressure	2 bar   29 psi at 20°C

# Integrity test limits

Maximum allowable diffusion at 2.5 bar 36 psi at 20°C

Cartridge size	Maximum diffusion	Minimum Bubble Point
Size 0	10 ml   min	3.2 bar   46 psi
Size 1	18 ml   min	3.2 bar   46 psi
Size 2	36 ml   min	3.2 bar   46 psi
Size 3	54 ml   min	3.2 bar   46 psi
Size 7	4 ml   min	3.2 bar   46 psi
Size 8	5 ml min	3.2 bar   46 psi
Size 9	7 ml min	3.2 bar   46 psi

Order code	Pore size [μm]	Test pressure [bar   psi]	Max. diffusion [ml/min]	Min. B.P. [bar   psi]
544**07H1	0.2	2.5   36	18	3.2   46
544**07H2	0.2	2.5 36	36	3.2 46
544**07H3	0.2	2.5   36	54	3.2   46

# Sartopore 2 0.2 µm Sterilizing Grade MidiCaps and MaxiCaps





#### Description

Sartopore 2 0.2 µm membrane filter MidiCaps and MaxiCaps are self contained, ready to use, sterile filter units for sterilizing grade filtration in the pharma | biotech industry. Made of a unique hydrophilic heterogeneous double layer Polyethersulfone membrane, Sartopore 2 capsules are designed for convenient sterile filtration of a broad range of pharmaceutical products.

#### **Applications**

Typical applications include sterilizing grade filtration of:

- Therapeutics
- Biological Fluids
- Injectables
- Media
- Buffers
- Chemicals
- Cleaning and sanitizing agents

#### Compatibility

The polyethersulfone membrane is compatible with a pH-range from pH 1 to pH 14 making Sartopore 2 MidiCaps and MaxiCaps ideal for filtration of solutions with high low pH.

#### Easy to use

Sartopore 2 MidiCaps are delivered as individually packed sterile units. On site, pre-use sterilization can be eliminated.

#### **Flexibility**

Sartopore 2 0.2  $\mu m$  MidiCaps and MaxiCaps are available with various filtration areas from 500 cm $^2$  | 0.5 ft $^2$  up to 1.8 m $^2$  | 18 ft $^2$  for easy adoption to any filtration process independent from the batch size.

## **Scalability**

Consistent and predictable scale-up and down trials can reliably be performed as all Sartopore 2 MidiCaps and MaxiCaps are produced with the same type of membrane and materials and identical construction.

#### Cost saving

The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

# Microbiological retention

Sartopore 2 filter MidiCaps and MaxiCaps 0.2 µm rated are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-83 guidelines.

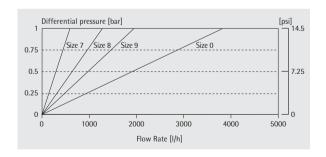
#### **Quality control**

Each individual element is tested for integrity by B.-P. and Diffusion-Test prior to be released assuring absolute reliability.

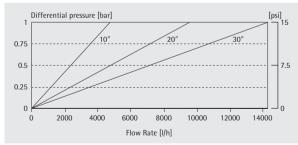
#### **Documentation**

Sartopore 2 MidiCaps and MaxiCaps are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for MidiCaps with SS inlet and outlet



Water Flow Rates for MaxiCaps



Standardized at 20°C

#### Pore size

 $0.45 \mu m + 0.2 \mu m$ 

# Available sizes | Filtration area

#### MidiCaps

Size 7  $0.05 \text{ m}^2 | 0.5 \text{ ft}^2$ Size 8  $0.1 \text{ m}^2 | 1 \text{ ft}^2$ Size 9  $0.2 \text{ m}^2 | 2 \text{ ft}^2$ Size 0  $0.45 \text{ m}^2 | 5 \text{ ft}^2$ 

#### **MaxiCaps**

Size 1 0.6 m<sup>2</sup> | 6 ft<sup>2</sup> Size 2 1.2 m<sup>2</sup> | 12 ft<sup>2</sup> Size 3 1.8 m<sup>2</sup> | 18 ft<sup>2</sup>

# Available connectors MidiCaps

SS, SO, OO, FF, FO, HH (only size 7)

# **Available connectors MaxiCaps** SS, SO, OO

S: 11/2" Tri-Clamp (Sanitary)
O: Single stepped hose barb
F: 3/4" Tri-Clamp (Sanitary)

H: Small, multiple stepped hose barb (with filling bell at the outlet)

#### Extractables

Sartopore 2 0.2 µm rated filter MidiCaps and MaxiCaps meet, or exceed the requirements for WFI quality standards set by the current USP.

#### Regulatory compliance

- Individually integrity tested
- Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test
- Non pyrogenic according to USP Bacterial Endotoxins
- Pass USP Plastic Class VI Test
- Non fiber releasing according to 21 CFR

# Sterilization

#### Autoclaving

134°C, 2 bar, 30 min

No in-line steam sterilization

## Sterilization cycles

Autoclaving Min. 25

#### **Technical references**

Validation Guide

- SPK5751-e (MidiCaps)
- SPK5732-e (MaxiCaps)

Extractables Guide

- SPK5731-e

#### Materials

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule housing	Polypropylene
O-Rings	Silicone
Filling Bell	Polycarbonate

#### **Operating parameters**

Max. allowable differential pressure	5 bar   58 psi at 20°C (MidiCaps) 3 bar   43.5 psi at 20°C (MaxiCaps) 2 bar   29 psi at 80°C
Max. allowable back pressure	2 bar   29 psi at 20°C

Order code	Pore size [µm]	Pack size [Pieces]	Test pressure [bar psi]	Max. diffusion [ml/min]	Min. Bubble Point [bar psi]
MidiCaps					
5445307H7**A	0.2	4	2.5   36	4	3.2   46
5445307H8**A	0.2	4	2.5 36	5	3.2 46
5445307H9**A	0.2	4	2.5   36	7	3.2   46
5445307H0**V	0.2	2	2.5   36	14	3.2   46
MaxiCaps 5441307H1** 5441307H2** 5441307H3**	0.2 0.2 0.2	1 1 1	2.5   36 2.5   36 2.5   36	18 36 54	3.2   46 3.2   46 3.2   46

<sup>\*\*:</sup> Connector Styles

# Sartopore 2 HF 0.2 µm Sterilizing Grade Filter Cartridges



#### Description

Sartopore 2 High Flow sterilizing grade filter cartridges are developed for filtration of water based pharmaceutical formulations. Sartopore 2 HF cartridges feature a unique single layer, hydrophilic polyethersulfone membrane. This membrane is characterized by broadest chemical compatibility, highest thermal resistance, increased mechanical stability and higher flow-rates than any other sterilizing grade filter cartridge offers.

#### **Applications**

Typical applications include sterilizing grade filtration of:

- Large Volume Parenterals (LVP)
- Buffers
- WFI
- Cleaning and sanitizing agents
- Bulk pharmaceutical products
- Each application requiring exceptional high flow rates

#### Compatibility

The polyethersulfone membrane is compatible with a pH-range from pH 1 to pH 14 and to multiple steam sterilization cycles making Sartopore 2 HF cartridges ideal for filtration of solutions with high|low pH and for SIPICIP-cycles.

#### Performance

The increased effective filtration area of Sartopore 2 HF filter cartridges allows for highest flow rates and assures thereby most economic design of filtration systems.

## Wettability

Sartopore 2 HF cartridges can be easily wetted out for integrity testing even after drying cycles with 80°C for 12 hours.

# Microbiological retention

Sartopore 2 HF filter cartridges 0.2 µm rated are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-83 quidelines.

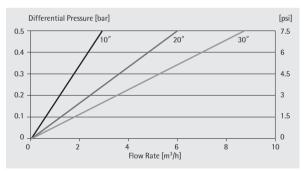
#### Quality control

Each individual element is tested for integrity by B.-P. and Diffusion-Test prior to release, assuring absolute reliability.

#### **Documentation**

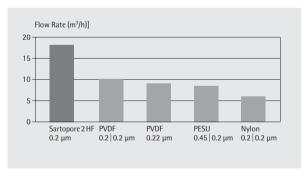
Sartopore 2 HF cartridges are designed, developed and manufactured in accordar with a ISO 9001 certified Quality Manage ment System. A Validation Guide and an Extractables Guide are available for compliance with regulatory requirements.

#### Water Flow Rates for 10", 20" and 30" Cartridges



Standardized at 20°C

#### Flow Rate Comparison



30" Filter cartridges at 1 bar | 14.5 psi differential pressure (20°C)

#### Pore size

0.2 μm

#### Available sizes | Filtration area

Size 1	10"	$0.7 \text{ m}^2$	7ft <sup>2</sup>
Size 2	20"	1.4 m <sup>2</sup>	14ft <sup>2</sup>
Size 3	30"	2.1 m <sup>2</sup>	21ft <sup>2</sup>

#### Available adapters

25

#### Extractables

Sartopore 2 HF 0.2  $\mu m$  rated filter cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

# Regulatory compliance

- Individually integrity tested
- Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test
- Non pyrogenic according to USP Bacterial Endotoxins
- Pass USP Plastic Class VI Test
- Non fiber releasing according to 21 CFR

#### Sterilization

#### In-line steam sterilization

 $134^{\circ}\text{C}$ , 20 min. at max differential pressure of 0.5 bar | 7 psi

#### Autoclaving

134°C, 2 bar, 30 min

# Sterilization cycles

in-line sterilization	IVIIN. 25
Autoclaving	Min. 25

# **Technical references**

Validation Guide SPK 5741-e Extractables Guide SPK 5742-e

# Materials

Filter membrane	Polyethersulfone, asymmetric	
Support fleece	Polypropylene	
Core	Polypropylene	
End caps	Polypropylene	
O-Rings	Silicone	

# **Operating parameters**

Max. allowable differential pressure	5 bar   75 psi at 20°C 2 bar   29 psi at 80°C
Max. allowable back pressure	2 bar   29 psi at 20°C

# Integrity test limits

Maximum allowable diffusion at 2.5 bar 36 psi at 20°C

Cartridge size	Maximum diffusion	Minimum Bubble Point
Size 1	21 ml min	3.2 bar   46 psi
Size 2	42 ml   min	3.2 bar   46 psi
Size 3	63 ml   min	3.2 bar   46 psi

Order code	Pore size [μm]	Test pressure [bar psi]	Max. diffusion [ml/min]	Min. B.P. [bar   psi]
544**07H1	0.2	2.5   36	18	3.2   46
544**07H2	0.2	2.5   36	36	3.2   46
544**07H3	0.2	2.5   36	54	3.2   46

# Sartopore 2 150 0.2 µm Sterilizing Grade Filter Capsule



## Description

Sartopore 2 150 is a disposable, sterile, ready-to-use membrane filter capsule for convenient sterilizing grade filtration. Sartopore 2 150 capsules are made with a unique hydrophilic Polyethersulfone membrane providing outstanding total throughput, flow rate, low extractables and broadest chemical compatibility.

#### **Applications**

Typical applications include sterilizing grade filtration of:

- Therapeutics
- Biological Fluids
- Injectables
- Purified Water
- Media
- Buffers

# Compatibility

The polyethersulfone membrane is compatible with a pH range from pH 1 to pH 14 making Sartopore 2 150 ideal for filtration of solutions with high | low pH.

#### Performance

The unique pleated filter construction combined with the highly asymmetric pore structure of the polyethersulfone membrane offers excellent flow rates and superior total throughput performance, especially in comparison to conventional stacked disc filter systems.

# Easy to use

Sartopore 2 150 capsules are available with hose barb, ¼ inch NPT-thread or ½ inch Tri-Clamp connectors for simple installation in your filtration system. The Tri-Clamp connection assures secure and reliable integrity testing.

## **Automatic venting**

The new vent design enables easy access to the venting valve. A hydrophobic PTFE membrane positioned on the highest point upstream allows an easy venting of the capsule and prevents product loss during the venting process.

## Scalability

Featuring the same materials and type of construction as any other Sartopore 2 filter element, Sartopore 2 150 is ideally suited for R&D Labs in pharmaceutical development. Filtration trials can be performed using extremely small volumes of high value products.

#### Microbiological retention

Sartopore 2 150 0.2 µm rated capsules are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-83 quidelines.

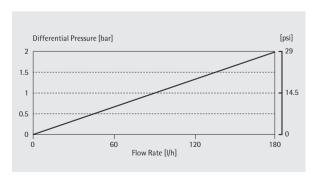
#### Quality control

Each individual element is integrity tested by diffusion and bubble point test prior to release, assuring absolute reliability.

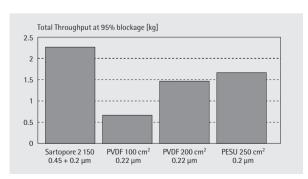
#### **Documentation**

Sartopore 2 150 capsules are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide is available for compliance with regulatory requirements.

#### Water Flow Rate



Standardized at 20°C



At 0.5 bar | 7.25 psi differential pressure

# Pore size

 $0.45 \mu m + 0.2 \mu m$ 

# Available sizes | Filtration area

Size 4 0.015 m<sup>2</sup> | 0.15 ft<sup>2</sup>

# **Available connectors**

SS, SO, 00

# Extractables

Sartopore 2 150 filter capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

# Regulatory compliance

- 100% Individually integrity tested
- Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test
- Non-pyrogenic according to USP Bacterial Endotoxins
- Meets USP Plastics Class VI biological reactivity test, in vivo
- Non-fiber releasing according to 21 CFR

#### Sterilization

#### Autoclaving

134°C, 2 bar | 29 psi, 30 min

No in-line steam sterilization

# **Technical references**

Validation Guide SPK5732-e Extractables Guide SPK5731-e

#### Materials

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Housing	Polypropylene

#### **Operating parameters**

Max. allowable differential pressure	4 bar   58 psi at 20°C 2 bar   29 psi at 80°C
Max. allowable back pressure	2 bar 29 psi at 20°C

Order code	Pore size [µm]
5441307H400B	0.2
5441307H4SOB	0.2
5441307H4SSB	0.2

# Sartopore 2 0.1 μm Sterilizing Grade and Mycoplasma Retentive Filter Cartridges



## Description

Sartopore 2 0.1 µm rated filter cartridges are especially developed for validated sterile filtration and reliable mycoplasma removal from any media likely to contain it such as those originating from animal sources. In addition these elements are ideally suited for removal of unusually small microorganisms that have been shown to pass through a 0.2 µm rated sterilizing grade filter.

#### **Applications**

Typical applications include sterilizing grade filtration and Mycoplasma removal from:

- Animal Sera
- Cell Culture Media
- Media Components
- Bioprocessed Pharmaceuticals
- Biological Fluids

Any other application requiring sub  $0.2 \mu m$  filtration for enhanced sterility assurance.

#### Compatibility

Featuring a unique hydrophilic polyethersulfone membrane, Sartopore 2 0.1 µm cartridges are compatible from pH 1 to pH 14 and to numerous steam sterilization cycles. Therefore they are also ideally suited for filtration of solutions with high low pH and for multiple SIP | CIP cycles.

#### Performance

Sartopore 2 0.1  $\mu$ m cartridges provide exceptionally high flow rates, resulting in economical sizing of filtration systems. Due to the "built-in prefiltration" by a 0.2  $\mu$ m membrane, Sartopore 2 0.1  $\mu$ m rated cartridges achieve outstanding total throughputs.

#### Wettability

Sartopore 2 cartridges can be easily wetted out for integrity testing even after drying at 80°C for 12 hours

## Microbiological retention

Sartopore 2 0.1 µm rated filter cartridges are validated as sterilizing grade filters according to ASTM F 838-83 standard and for Mycoplasma removal with a Log Reduction Value (LRV) of 7 for Acholeplasma laidlawii.

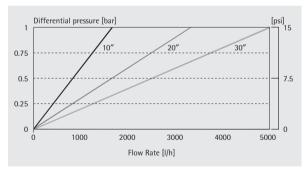
#### Quality control

Each individual element is tested for integrity by diffusion test prior to be released assuring absolute reliability.

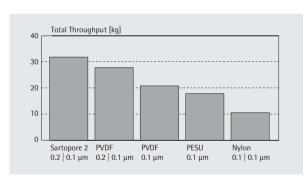
#### **Documentation**

Sartopore 2 0.1 µm rated cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

# Water Flow Rates for 10", 20" and 30" Cartridges



Standardized at 20°C



10" Cartridge format

#### Pore size

 $0.2 \mu m + 0.1 \mu m$ 

#### Available sizes | Filtration area

Size 1	10"	0.6 m <sup>2</sup>   6 ft <sup>2</sup>
Size 2	20"	1.2 m <sup>2</sup> 12 ft <sup>2</sup>
Size 3	30"	1.8 m <sup>2</sup> 18 ft <sup>2</sup>

# Available adapters

21, 25, 27, 28

#### **Extractables**

Sartopore 2 0.1  $\mu m$  rated filter cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

# Regulatory compliance

Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test and Mycoplasma removal.

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

#### Sterilization

# In-line steam sterilization

134°C, 20 min. at max differential pressure of 0.5 bar  $\mid$  7.25 psi

## Autoclaving

134°C, 2 bar | 29 psi, 30 min

# Sterilization cycles

In-line sterilization Min. 25 Autoclaving Min. 25

# **Technical references**

Validation Guide SPK5735-e Extractables Guide SPK5731-e

#### Materials

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

#### **Operating parameters**

Max. allowable differential pressure	5 bar   75 psi at 20°C 2 bar   29 psi at 80°C
Max. allowable back pressure	2 bar   29 psi at 20°C

Order code	Pore size [µm]	
544**58K1	0.1	
544**58K2	0.1	
544**58K3	0.1	

# Sartopore 2 0.45 μm Bioburden & Particle Reductive Filter Cartridges



## Description

Sartopore 2 0.45  $\mu m$  rated filter cartridges are designed for bioburden reduction and particle removal from a broad range of pharmaceutical products. They offer extremely high flow rates and total throughputs and are therefore ideally suited for membrane prefiltration of aqueous solutions and highly viscous, difficult to filter pharmaceutical products.

#### **Applications**

Typical applications include bioburden reduction and particle removal from:

- Buffers
- Biological Fluids
- Opthalmics
- I VP
- Antibiotics
- Bulk pharmaceutical products

#### Compatibility

Featuring a unique hydrophilic polyethersulfone membrane, Sartopore 2 0.45  $\mu m$  cartridges are compatible with solutions from pH 1 to pH 14 and are unaffected by numerous steam sterilization cycles. They are ideally suited for filtration of solutions with high low pH and for multiple SIP | CIP cycles.

#### Performance

Sartopore 2 0.45 µm cartridges provide exceptional high flow rates, resulting in economical sizing of filtration systems. Due to the "built-in prefiltration" by a 0.8 µm membrane, Sartopore 2 0.45 µm rated cartridges offer outstanding total throughputs.

#### Wettability

Sartopore 2 cartridges can be easily wetted out for integrity testing even after drying at 80°C for 12 hours.

#### Microbiological retention

Sartopore 2 0.45  $\mu$ m rated filter cartridges are validated for removal of Serratia marcessens with a Log Reduction Value (LRV) of 7 according to HIMA and ASTM F-838-83 guidelines.

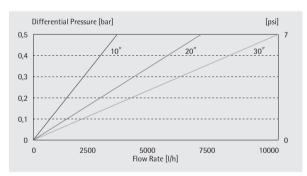
## **Quality control**

Each individual element is integrity tested by diffusion and bubble point test prior to release, assuring absolute reliability.

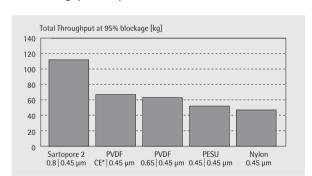
#### **Documentation**

Sartopore 2 cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

#### Water Flow Rates for Standard Cartridges



Standardized at 20°C



10" Cartridges

<sup>\*</sup> Cellulose Ester prefilter

#### Pore size

 $0.8 \mu m + 0.45 \mu m$ 

#### Available sizes | Filtration area

Size 1	10"	$0.6 m^{2}$	6.5 ft <sup>2</sup>
Size 2	20"	1.2 m <sup>2</sup>	12.9 ft <sup>2</sup>
Size 3	30"	1.8 m <sup>2</sup>	19.4 ft <sup>2</sup>

#### Available adapters

21, 25, 27, 28

#### **Extractables**

Sartopore 2 0.45  $\mu m$  rated filter cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

# Regulatory compliance

100% Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test using Serratia marcescens

Non-pyrogenic according to USP Bacterial Endotoxins

Meets USP Plastics Class VI biological reactivity test, in vivo

Non-fiber releasing according to 21 CFR

## Sterilization

## In-line steam sterilization

134°C, 20 min. at max differential pressure of 0.5 bar  $\mid$  7.25 psi

# Autoclaving

134°C, 2 bar | 29 psi, 30 min

# Sterilization cycles

In-line sterilization Min. 25 Autoclaving Min. 25

# **Technical references**

Validation Guide SPK 5732-e Extractables Guide SPK 5731-e

#### Materials

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

#### **Operating parameters**

Max. allowable differential pressure	5 bar   75 psi at 20°C 2 bar   29 psi at 80°C
Max. allowable back pressure	2 bar 29 psi at 20°C

Order code	Pore size [µm]
544**06G1	0.45
544**06G2	0.45
544**06G3	0.45

# Sartopore 2 0.2 $\mu$ m Sterilizing Grade $\gamma$ -Irradiatable Filter Capsules



## Description

Sartopore 2- $\gamma$ -Capsules are 0.2  $\mu$ m rated sterilizing grade filter capsules designed for connection to flexible-bag-container-systems prior to sterilization by gamma-irradiation.

# **Applications**

Typical applications include sterilizing grade filtration of:

- Pharmaceuticals
- Biologicals
- Cell Culture Media
- Culture Media Components
- Serum
- Buffers
- Diagnostic Reagents

#### Compatibility

Sartopore  $2-\gamma$ -Capsules are designed for sterilization by gamma irradiation  $\leq 50$  kGy irradiation dosage. The polyethersulfone membrane of the Sartopore  $2-\gamma$ -Capsules offers a broad chemical compatibility from pH 1 to pH 14 making them ideally suited for a broad range of applications in the Pharma | Biotech field.

#### Performance

Due to the superior construction including a "build-in prefiltration" by a 0.45  $\mu$ m membrane Sartopore 2- $\gamma$ -Capsules offer outstanding total throughputs and excellent flow rates.

## **Flexibility**

Sartopore  $2-\gamma$ -Capsules are available with filtration areas from 0.015  $m^2 \mid 0.15$  ft<sup>2</sup> up to 0.45  $m^2 \mid 5$  ft<sup>2</sup> for easy use in any bag-filtration process independent of the batch size.

# Microbiological retention

Sartopore 2-\(\gamma\)-Capsules 0.2 \(\mu\) m rated are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-83 guidelines.

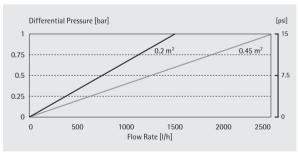
## **Quality control**

Each individual element is integrity tested by diffusion and bubble point test prior to release, assuring absolute reliability.

#### **Documentation**

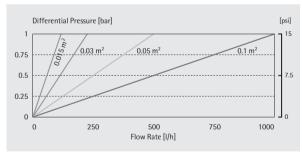
Sartopore 2 Gamma capsules are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

Water Flow Rates for 0.2 m<sup>2</sup> and 0.45 m<sup>2</sup> Capsules



Standardized at 20°C

Water Flow Rates for 0.015  $m^2$ , 0.03  $m^2$ , 0.05  $m^2$  and 0.1  $m^2$  Capsules



Standardized at 20°C

#### Pore size

 $0.45 \mu m + 0.2 \mu m$ 

#### Available sizes | Filtration area

Size 4	0.015 m <sup>2</sup>   0.15 ft <sup>2</sup>
Size 5	0.03 m <sup>2</sup>   0.3 ft <sup>2</sup>
Size 7	0.05 m <sup>2</sup> 0.5 ft <sup>2</sup>
Size 8	0.1 m <sup>2</sup>   1 ft <sup>2</sup>
Size 9	0.2 m <sup>2</sup> 2 ft <sup>2</sup>
Size 0	0.45 m <sup>2</sup>   5 ft <sup>2</sup>

#### **Available connectors**

SS, SO, 00

# Extractables

Sartopore- $\gamma$ -Capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

# Regulatory compliance

100% Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastic Class VI Test

Non-fiber releasing according to 21 CFR

# Sterilization

 $\gamma$ - irradiation  $\leq$  50 kGy irradiation dosage

#### Autoclaving

134°C, 2 bar | 29 psi, 30 min

No in-line steam sterilization

# Sterilization cycles

γ- Irradiation	Max. 1
Autoclaving	Max. 3

## **Technical references**

Validation Guide SPK5734-e Extractables Guide SPK5740-e

# Materials

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule housing	Polypropylene

# **Operating parameters**

Max. allowable differential pressure	4 bar   58 psi at 20 °C 2 bar   29 psi at 80 °C
Max. allowable back pressure	2 bar   29 psi at 20 °C

Order code	Pore size [µm]
5441307H4G**B	0.2
5441307H5G00B	0.2
5441307H7G**B	0.2
5441307H8G**B	0.2
5441307H9G**A	0.2
5441307H0G**	0.2

# Sartopore 2 0.1 μm Sterilizing Grade and Mycoplasma Retentive γ-Irradiatable Filter Capsules



#### Description

Sartopore 2 0.1  $\mu$ m rated  $\gamma$ -irradiatable filter capsules are designed for sterilizing grade filtration and Mycoplasma removal in bag filtration processes. Prior or after connection to flexible-bag-container-systems they can be sterilized by  $\gamma$ -irradiation  $\leq$  50 kGy.

#### **Applications**

Typical applications for Sartopore 2-γ-Capsules include combined sterilizing grade filtration and mycoplasma removal from

- Cell Culture Media
- Culture Media Components
- Serum

They are ideally suited for bioprocessed pharmaceuticals and any other applications requiring sub 0.2  $\mu$ m filtration for enhanced sterility assurance.

#### Compatibility

Sartopore  $2-\gamma$ -Capsules are designed for sterilization by gamma irradiation  $\leq 50$  kGy irradiation dosage. The Polyethersulfone membrane of the Sartopore  $2-\gamma$ -Capsules offers a broad chemical compatibility from pH 1 to pH 14 making them ideally suited for a broad range of applications in the Pharma | Biotech field.

#### Performance

Due to the superior construction including a "build-in" prefiltration by a heterogeneous double layer membrane Sartopore 2-γ-Capsules achieve outstanding total throughputs and excellent flow rates.

#### **Flexibility**

Sartopore  $2-\gamma$ -Capsules are available with filtration areas from 0.03 m² | 0.3 ft² up to 0.45 m² | 5 ft² for easy adaption to any bag-filtration process independent from the batch size.

# Microbiological retention

Sartopore  $2-\gamma$ -Capsules 0.1  $\mu$ m rated are validated as sterilizing grade filters according to ASTM F 838-83 standard and for Mycoplasma removal with a Lock Reduction Value (LRV) of 7 for Acholeplasma laidlawii.

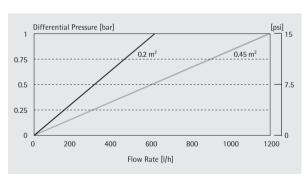
#### Quality control

Each individual element is tested for integrity by Diffusion-Test prior to be released assuring absolute reliability.

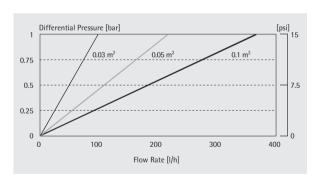
#### **Documentation**

Sartopore 2 Gamma capsules are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for 0.2 m<sup>2</sup> and 0.45 m<sup>2</sup> Capsules



Water Flow Rates for 0.03 m<sup>2</sup>, 0.05 m<sup>2</sup> and 0.1 m<sup>2</sup> Capsules



#### Pore size

 $0.2 \mu m + 0.1 \mu m$ 

#### Available sizes | Filtration area

Size 5	0.03 m <sup>2</sup>   0.3 ft <sup>2</sup>
Size 7	0.05 m <sup>2</sup> 0.5 ft <sup>2</sup>
Size 8	0.1 m <sup>2</sup>   1 ft <sup>2</sup>
Size 9	0.2 m <sup>2</sup>   2 ft <sup>2</sup>
Size 0	0.45 m <sup>2</sup>   5 ft <sup>2</sup>

#### **Available connectors**

SS, SO, 00

#### **Extractables**

Sartopore- $\gamma$ -Capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

# Regulatory compliance

Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

# Sterilization

γ-irradiation ≤ 50 kGy irradiation dosage

#### Autoclaving

134°C, 2 bar | 29 psi, 30 min

No in-line steam sterilization

# Sterilization cycles

γ-Irradiation	•	Max.	1
Autoclaving		Max.	3

#### **Technical references**

Validation Guide SPK5734-e Extractables Guide SPK5740-e

#### Materials

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule housing	Polypropylene

# **Operating parameters**

Max. allowable differential pressure	4 bar   58 psi at 20 °C 2 bar   29 psi at 80 °C
Max. allowable back pressure	2 bar 29 psi at 20 °C

#### **Order information**

Order code	Pore size [µm]
5441358K5G-00B	0.1
5441358K7G-**B	0.1
5441358K8G-**B	0.1
5441358K9G-**A	0.1
5441358K0G-**	0.1

<sup>\*\*</sup> Inlet | Outlet connectors

# Sartolon Sterilizing Grade Filter Cartridges and MaxiCaps







#### Description

Sartolon sterilizing grade filter cartridges, MaxiCaps and capsules are designed for broad chemical compatibility for specific applications in the pharmaceutical and chemical industry. Their superior filtration performance compared to competitive nylon membrane filters allow more economical design of your filtration process.

#### **Applications**

Featuring a unique hydrophillic nylon membrane, Sartolon filters are ideally suited for sterilizing grade filtration of:

- Solvents
- Antibiotics
- Bulk Pharmaceutical Chemicals
- LVP

#### Compatibility

Sartolon filter elements are ideal for filtration of a broad range of solvents and liquids containing solvents. The Nylon membrane material provides a broad chemical compatibility especially for aggressive solvent solutions.

#### Performance

Sartolon filter elements offer higher total throughputs than any other sterilizing grade Nylon filter element on the market. The heterogeneous double layer construction provides higher total throughputs than homogeneous double layer types due to the "built-in prefiltration".

#### Microbiological retention

Sartolon 0.2 µm rated filter elements are fully validated as sterilizing grade filter elements according to HIMA and ASTM F-838-83 guidelines.

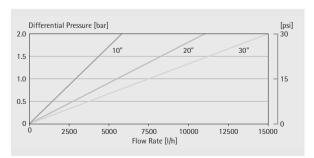
#### **Quality control**

Each individual element is integrity tested by Diffusion and Bubble-Point-Test prior to release, assuring absolute reliability.

#### **Documentation**

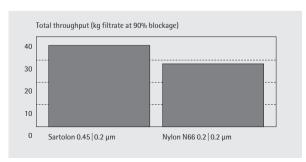
Sartolon filter elements are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

#### Water Flow Rates for 10", 20" and 30" Cartridges



Standardized at 20°C

#### **Total Throughput Comparison**



10" Cartridge format

#### Pore size

 $0.45 \mu m + 0.2 \mu m$ 

#### Available sizes | Filtration area

#### Cartridges | MaxiCaps

Size 1	10"	0.6 m <sup>2</sup> 6 ft <sup>2</sup>
Size 2	20"	1.2 m <sup>2</sup> 12 ft <sup>2</sup>
Size 3	30"	1.8 m <sup>2</sup> 18 ft <sup>2</sup>

#### Mini Cartridges | Capsules

Size 9  $0.2 \text{ m}^2 | 2 \text{ ft}^2$ 

#### Available adapters cartridges

21, 25, 27, 28

# Available adapter Mini Cartridges

15

# **Available connectors capsules** | MaxiCaps SS, SO, OO

#### **Extractables**

Sartolon cartridges, MaxiCaps and capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

#### Regulatory compliance

100% Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

#### Sterilization

#### In-line steam sterilization

 $134\,^{\circ}\text{C}\text{, }20$  min. at max differential pressure of 0.5 bar  $|\,7$  psi

#### Note

Capsules and MaxiCaps cannot be in-line steam sterilized!

#### Autoclaving

134°C, 2 bar | 29 psi, 30 min

#### Sterilization cycles

In-line sterilization Min. 25 (only cartridges)

Autoclaving Min. 25

#### **Technical references**

Validation Guide SPK5716-e Extractables Guide SPK5729-e

#### Materials

Prefilter membrane	Nylon
Endfilter membrane	Nylon
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

#### **Operating parameters**

Max. allowable differential pressure	5 bar   75 psi at 20°C (Cartridges) 4 bar   58 psi at 20°C (Capsules) 3 bar   43.5 psi at 20°C (MaxiCaps) 2 bar   29 psi at 80°C (Cartridges and Capsules)
M. II. II. I	2 bar   29 psi at 80 C (Cartridges and Capsules)

Max. allowable back pressure 2 bar 29 psi at 20°C

#### Ordering information

Order code	Size	Pore size [µm]
Cartridges		
510**07H1	1	0.2
510**07H2	2	0.2
510**07H3	3	0.2
MaxiCaps		
5101307H1**	1	0.2
5101307H2**	2	0.2
5101307H3**	3	0.2
Capsules		
5101307H9**A	4	0.2
Mini Cartridges		
5101507H9B	4	0.2
310130/113D	4	0.2

# Sartofluor LG MaxiCaps Membrane Filtration of Aggressive Media



#### Description

MaxiCaps are a unique new housing design concept from Sartorius that brings the benefits of single use filter elements to process scale. The incorporation of standard filter cartridges into self contained, high, quality polypropylene housings makes it possible to operate large scale filter installations without the need for filter housings.

#### **Applications**

Sartofluor LG MaxiCaps improve the process security of sterile filtration of aggressive media (acids and bases) and solvents. There is no need to open the filter housing after filtration. The capsule design allows filtration of such media without any handling of the contaminated filter cartridge post use.

# Speed of operation

MaxiCaps are ready-to-use, saving time and money. No more backup filtration rigs to prepare. MaxiCaps can be easily replaced should any operational difficulties occur.

#### **Process security**

By relying on established process validation data for standard cartridge elements, MaxiCaps can easily be implemented into current filtration processes.

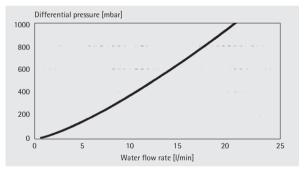
#### Cleaning validation

As these capsules are single use filter elements, there is no need to spend time and money for validating the efficiency of your cleaning procedure for filter housing.

#### Cost

Sartofluor LG MaxiCaps remove the need for investment in stainless steel or PVDF filter housings and an inventory of spare parts such as valves and O-rings.

Water Flow Rates\* for Sartofluor LG MaxiCaps 0.2  $\mu m$  with Sanitary Flanges



<sup>\*</sup> Prewetted with IPA | water

#### Pore size

0.2 μm

#### Available sizes | Filtration area

Size 1	10"	0.5 m <sup>2</sup> 5.4 ft <sup>2</sup>
Size 2	20"	1.0 m <sup>2</sup> 10.8 ft <sup>2</sup>
Size 3	30"	1.5 m <sup>2</sup> 16.1 ft <sup>2</sup>

### Available adapters connectors

SS, SO, 00

#### Extractables

Sartofluor LG MaxiCaps meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory compliance 100% Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Meets USP Plastics Class VI biological reactivity test, in vivo

Non-fiber releasing according to 21 CFR

#### Sterilization

#### Autoclaving

134°C, 2 bar | 29 psi, 30 min

No in-line steam sterilization

#### Sterilization cycles

Autoclaving min 25

#### Materials

Filter membrane	PTFE
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	EPDM (Viton as accessory in the package)

# **Operating parameters**

Max. allowable differential pressure	3 bar   43.5 psi at 20°C
Max. allowable back pressure	2 bar 29 psi at 20°C

#### **Ordering information**

Order code	Size	Pore size [µm]	
Capsules			
5181307T1**	1	0.2	
5181307T2**	2	0.2	
5181307T3**	3	0.2	



# Clarification Filters

Depth Filter Capsules – Sartoclear® P 1	18
Depth Filter Capsules – Sartoclear® P MaxiCaps 1	20
Sartoclear® P Depth Filter Modules 1	22
Sartoclear® P Depth Filter Sheets 1	24

# Sartoclear® P Depth Filter Capsules for Bench Scale Trials



Sartoclear® P Caps are especially developed to serve small scale volumes in cell harvest and clarification applications. The product features encapsulated cellulose based depth filter media with highest dirt holding capacity. Sartoclear® P Caps are being manufactured using the advantage of the unique and closed Sartoscale system.

#### **Applications**

Sartoclear® P Caps are being used as single use capsules for bench scale trials, scale up trials and small scale manufacturing.

#### Filter area

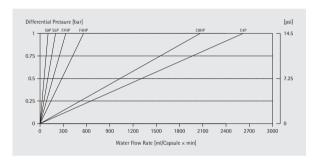
Each Sartoclear® P Cap contains an effective filter area of 25 cm<sup>2</sup>.

#### **Product benefits**

Sartoclear® P Caps are completely disposable capsules. This technology provides highest flexibility for disposable small scale manufacturing and scale up work. Sartoclear® P Caps can be simply and directly connected to the downstream processing line or disposable bags. The integrated teflon vent valve features unique venting procedure and eliminates contamination of the laboratory environment.

#### **Flexibility**

Sartoclear® P Caps can be used for small volume processing from 50 ml up to 1.000 ml.



# **Retention rates**

8 µm
4 µm
1.5 µm
1 μm
0.3 μm
0.1 μm

#### Filtration area

 $25 \text{ cm}^2$ 

#### Sterilization

1 cycle of wet autoclaving 121°C at 1 bar for 30 min Sartoclear® P Caps may not be in line steam sterilized!

#### **Extractables**

The depth filter media of Sartoclear® P meets the requirements for WFI quality standards set by the USP 26.

- Non pyrogenic according to USP Bacterial Endotoxins after a flush of 50I/m<sup>2</sup> WFI
- LAL level < 0.125 UE/ml
- Pass USP Plastic Class VI Test

#### Metal extractables

(Please see validation guide of Sartoclear® P Depth Filter Module)

Non fiber releasing according 21 CFR

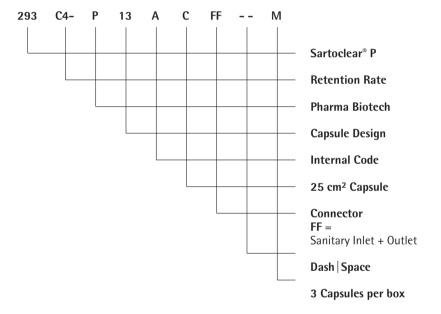
#### Materials

Depth filter media	Cellulosic depth filter media with inorganic filter aids
Core	Polypropylene
Capsule housing	Polypropylene

#### **Operating parameters**

Max. allowable system pressure	5.5 bar   80 psi at 20°C
Max. allowable pressure differential	2.0 bar   29 psi
Max. allowable back pressure	0.03 bar   0.4 psi

#### Order information



# Sartoclear® P MaxiCaps® Depth Filter MaxiCaps® for the Biopharmaceutical Industry



#### Description

Sartoclear® P MaxiCaps® are especially developed for cell harvest and clarification of cell culture and microbial fermentation media in biopharmaceutical applications. The products feature cellulose based depth filter media with highest dirt holding capacity and electrocinetic adsorption combined with the advantage of the unique and closed MaxiCap® system.

#### **Applications**

Sartoclear® P MaxiCaps® are applied in biopharmaceutical processes such as:

- Cell harvest & clarification of cell culture and other fermentation media
- Upstream filtration of growth media
- Particle and colloid removal from serum & plasma
- Removal of cryoprecipitants

#### Performance

At 1.100 cm<sup>2</sup> filter area each 10" MaxiCap® element contains more filter area than any comparable capsules on the market – offering you maximum benefits in terms of costs & speed of operation.

#### **Product benefits**

Sartoclear® P MaxiCaps® are completely disposable filters, which provides you the flexibility you need for modern disposable manufacturing. These disposable filters do not need stainless steel filter housing and thus eliminate cleaning validation. Sartoclear® P MaxiCaps® can be simply and directly connected to the downstream processing line or disposable bags. This minimizes direct contact of product with the operator and thus improves operator safety.

#### **Flexibility**

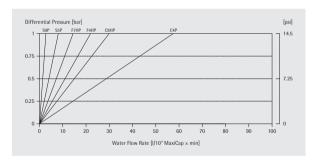
Sartoclear® P MaxiCaps® are available with various filtration areas from 0.11 m² to 0.22 m² for ease of use in any depth filtration processes from batch sizes of 500 ml to 100 liter.

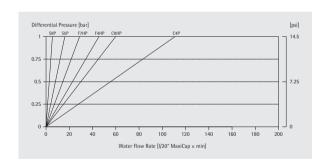
#### Scale up

Sartoclear® P MaxiCaps® provide highest scale-up security for either small scale manufacturing or large scale production.
Scale up from a small 25 cm² Sartoclear® P Cap capsule to a full scale production design will be optimized by employing an intermediary scale up step with Sartoclear® P MaxiCaps®.

#### Quality control

Each individual MaxiCap® undergoes a pressure hold test during manufacture to guarantee product stability.





#### **Retention rates**

C4P	8 μm
C8HP	4 µm
F4HP	1.5 μm
F7HP	1 μm
S5P	0.3 μm
S9P	0.1 μm

#### Filtration area

10" MaxiCap® | 1.100 cm² 20" MaxiCap® | 2.200 cm²

#### **Extractables**

Sartoclear® P MaxiCaps® meet the requirements for WFI quality standards set by the current USP.

Non pyrogenic according to USP Bacterial Endotoxins after a flush of 8 I WFI per 10" MaxiCap® and 16 liter per 20" MaxiCap®. LAL level < 0.125 UE/ml

Pass USP Plastic Class VI Test

#### Metal extractables

(Please see validation guide of Sartoclear® P MaxiCaps®) Non fiber releasing according 21 CFR

#### Sterilization

1 cycle of wet autoclaving 121°C at 1 bar for 30 min MaxiCaps® may not be in line steam sterilized!

#### **Technical references**

Brochure 85030-519-85 Validation Guide 85030-519-88

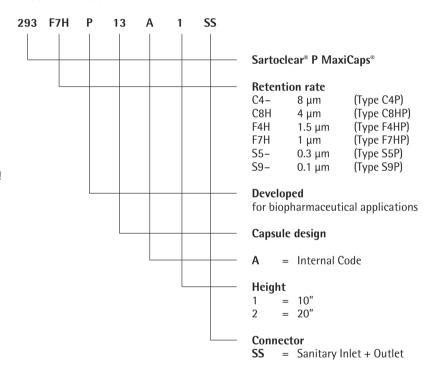
#### Materials

Depth filter media	Cellulosic depth filter media with inorganic filter aids
Sealing media	Silicone
Core	Polypropylene
End caps	Polypropylene
Capsule housing	Polypropylene

#### **Operating parameters**

Max. allowable differential pressure	2.0 bar   29psi
Max. allowable back pressure	0.03 bar   0.4 psi

#### **Order information**



# Sartoclear® P Depth Filter Modules Depth Filter Modules for the Biopharmaceutical Industry



#### Description

Sartoclear® P depth filter modules are especially developed for use in the biopharmaceutical industry. They feature cellulose based depth filtration media with highest dirt holding capacity and electrokinetic adsorption combined with the advantage of a closed filtration system.

#### **Applications**

Sartoclear® P depth filter modules are applied in biopharmaceutical processes such as:

- Cell harvest & clarification of cell culture and other fermentation media
- Upstream filtration of growth media
- Particle and colloid removal serum and plasma
- Removal of cryoprecipitants

Typical process volumes for Sartoclear® P depth filter modules are regulary higher than 100 liters. Smaller volumes are being filtered by Sartoclear® P MaxiCaps.

#### Performance

Sartoclear® P depth filter modules provide an excellent total throughput and enhanced clarification. They provide economical upstream- and downstream filtration when retention of both, high particle load and colloidal contamination have to be realised.

#### **Product benefits**

- The vertical modular system ensures totally enclosed process design
- Modular system optimises handling costs due to easy and quick handling
- Maximum product yield
- No droplet losses or contamination

#### Using Sartoclear® P depth filter modules

Sartoclear® P depth filter modules are being used in vertical filter housings which can be easily adapted to the batch volumes and process conditions on sight.

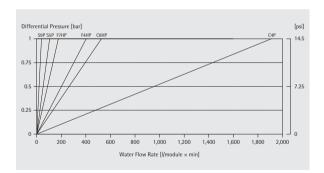
#### Scalability

For bench scale and scale up trials Sartoclear® P capsules (from 50 ml to 1.000 ml) and Sartoclear® P MaxiCaps (from 1.000 ml to 100 Liter) are being used. Scale up trials can be optimized applying the Zero T test system.

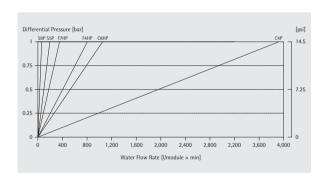
#### **Validation**

Sartoclear® P filter modules have been validated according to the USP 26. A Validation Guide is available with detailed data for compliance with regulatory requirements.

Water Flow Rates for Sartoclear® P 12" Depth Filter Module



Water Flow Rates for Sartoclear® P 16" Depth Filter Module



#### **Retention rates**

 $\begin{array}{ccc} \text{C4P} & 8 \ \mu\text{m} \\ \text{C8HP} & 4 \ \mu\text{m} \\ \text{F4HP} & 1.5 \ \mu\text{m} \\ \text{F7HP} & 1 \ \mu\text{m} \\ \text{S5P} & 0.3 \ \mu\text{m} \\ \text{S9P} & 0.1 \ \mu\text{m} \\ \end{array}$ 

#### Filtration area

12" module | 1.8 m² 16" module | 3.6 m²

#### **Extractables**

Sartoclear® P depth filter modules meet the requirements for WFI quality standards set by the USP 26.

Non pyrogenic according to USP Bacterial Endotoxins

LAL level < 0,124 EU/ml

#### Metal extractables

Please see validation guide of Sartoclear® P depth filter modules

Pass USP Plastic Class VI Test

#### Sterilization

Steam 121°C, 30 or 60 min

#### **Technical references**

Brochure SR-1501-e Validation Guide SR-5700-e

#### Materials

Resin binder

Polypropylene

EPDM o-rings

Cellulose

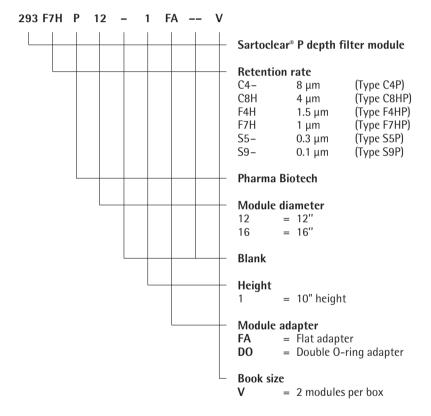
Diatomaceous earth

Perlite

#### **Operating parameters**

Max. allowable differential Pressure	2.0 bar   29 psi
Max allowable back pressure	0.03 har 0.4 nsi

#### **Order information**



# Sartoclear® P Depth Filter Sheets for the Biopharmaceutical Industry



#### Description

Sartoclear P filter sheets are especially developed for use in the biopharmaceutical industry. They feature cellulose based depth filtration media with highest dirt holding capacity and electrokinetic adsorption.

#### **Applications**

Sartoclear P filter sheets are applied in biopharmaceutical processes such as:

- Upstream filtration of growth media
- Downstream filtration of fermentation media (removal of cells or cell debris)
- Particle removal from chemical bulk ware
- Particle removal from serum and plasma
- Filtration of plasma derived products
- Separation of precipitants
- Endotoxin removal

#### Performance

Sartoclear P filter sheets provide an excellent total throughput and enhanced clarification. They provide economical upstream- and downstream filtration when retention of both, high particle load and colloidal contamination have to be realised.

### **Using Sartoclear P**

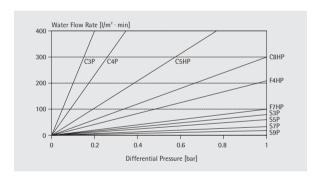
Sartoclear P filter sheets are being used in horizontal filter presses which can be easily adapted to the batch volumes and process conditions on sight.

#### Scalability

For scale up trials 60 mm Sartoclear P filter pads are available which can be used together with the Zero T test. Filtration trials can then be performed using small volumes of products.

#### Quality control

Sartoclear P filter sheets are designed, developed and manufactured in accordance with a DIN ISO 9001 certified Quality Management System. A Validation Guide is available with detailed data for compliance with regulatory requirements.



# Retention rate

C4P	8 µm
C8HP	4 μm
F4HP	1.5 μm
F7HP	1 μm
S5P	0.3 μm
S9P	0.1 µm

#### Filtration area

40	×	40	cm	0.16	$m^2$
60	×	60	cm	0.36	${\sf m}^2$

#### Extractables

Sartoclear P filter sheets meet the requirements for WFI quality standards set by the current USP.

Non pyrogenic according to USP Bacterial Endotoxins LAL level < 0,124EU/ml

#### Metal extractables

Please see brochure of Sartoclear P | Sartocell P

Pass USP Plastic Lass VI Test

#### Sterilization

Steam: 121°C, 30 min

#### **Technical references**

Brochure SR-1501-e Validation Guide SR-5700-e

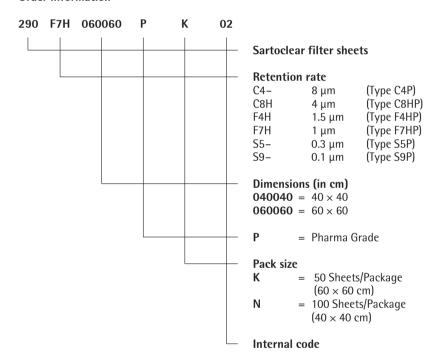
#### Materials

iviatchiais	
Cellulose	
Diatomaceous earth	
Perlite	
Resin binder	

#### **Operating parameters**

- p			
Max. allowable differential pressure	C4P C8HP F4HP F7HP	2.5 bar   36 psi at 20°C 2.5 bar   36 psi at 20°C 2.0 bar   29 psi at 20°C 2.0 bar   29 psi at 20°C	
	S5P S9P	1.5 bar   21 psi at 20 °C 1.5 bar   21 psi at 20 °C	

#### **Order information**





# Crossflow Consumables

Polyethersulfone Mirofiltration	
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# Polyethersulfone Microfiltration Cassettes Cell Removal and Mycoplasma Reduction





#### Description

#### The polyethersulfone membrane

The polyethersulfone membrane (PESU) is a membrane polymer that is well established in the biotechnological and pharmaceutical industries. The PESU membrane is a stable polymer that features a broad pH and temperature range. Its wide temperature range makes it possible to sterilize the membrane by either steam or autoclaving. Membrane regeneration, storage and depyrogenation can be accomplished by using NaOH even at elevated temperatures. Because of these features, the PESU membrane is ideally suited for biotechnological applications. PESU cassettes are available in 0.1 µm.

#### Application

Polyethersulfone membranes are designed for applications in the biotechnological and pharmaceutical industries. They can be used to remove the following cells from liquids:

- mammalian cells
- clostridia
- yeasts
- salmonella
- mycoplasma reduction

#### **Product profile**

Polyethersulfone can withstand in-line steam sterilization without any loss of integrity or changes in membrane retention. Membrane retention is unaffected by repeated re-use.

Feature	Benefits
Low adsorption	Minimal loss of proteins
Low protein-binding	High product yield
Wide pH and a wide variety of temperature range	Chemicals can be used for the removal of foulants
High flow rates	Economical filtration runs
Self sealing cassette	No gaskets needed
Silicone sealing compound	No glue
Enlarged inlet and outlet holes	Lower pressure drop

#### Pore size | Retention rate

PESU microfiltration cassettes are available in a choice of 0.1 µm pore size.

#### Available sizes

Sartorius Crossflow Cassettes are available in **Standard Cassette** size for pilot-|production scale and in **Sartocon Slice** format for reduced volume handling.

#### Available filterholder

Sartorius Crossflow Cassettes are designed for Sartorius filter holders like SartoconSlice (0.1 m<sup>2</sup> Cassettes only), Sartocon, Sartocon 2 Plus, Sartocon 3, and different Sartoflow holder.

#### Filtration area

Filter area Sartocon Cassette 0.6 m<sup>2</sup> Filter area Sartocon Slice Cassette 0.1 m<sup>2</sup>

#### Sterilization

121°C, 30 min, steaming 121°C, 40 min, autoclaving

# Regulatory compliance

All materials have passed the current USP Biological Test. The filtrate meets or exeeds USP and EP requirements for Sterile Water for Injection with respect to total solids, oxidizable substances, particulate matter, ammonia, chloride, nitrate, sulfate and heavy metals.

#### **Quality control**

Each filter cassette is individually assigned a serial number, integrity tested and certified.

It complies with cGMP requirements for non-fiber-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available upon request.

If you use holding devices from other suppliers, please contact our Applications Department. A different torque might be needed due to specific variations in design.

#### **Technical references**

Validation Guide Publication No.: SPC5701-e

Publication No.: SPC6001-a

Directions for Use (Sartocon Cassettes and Sartocon Slice Cassettes)

#### Materials of construction

Membrane	Polyethersulfone
Gaskets	PVDF
Spacer	Polypropylene
Sealing compound	Silicone

#### **Operating parameters**

Feed pressure, P <sub>in</sub>	58 psi 4 bar maximum
Operating temperature	50°C maximum
pH stabilty	1–14
Air diffusion rates at $P_{in} = 15 \text{ psi}  \big   1 \text{ bar}$	15 ml air/min for 0.6 m <sup>2</sup> filter area 5 ml air/min for 0.1 m <sup>2</sup> filter area
Cleaning	NaOH Sodium hydroxide, 1M, max. 40°C
Disinfection	NaOH, 1 M, max. 50°C, 30 min
Storage	NaOH, 0.1 M

#### Typical flux for water

71		
Permeate*	1300 l/h/m <sup>2</sup>	

<sup>\*</sup> Feed pressure,  $P_{in} = 29 \text{ psi} \mid 2.0 \text{ bar}$ ; retentate pressure,  $P_{out} = 7 \text{ psi} \mid 0.5 \text{ bar}$ 

#### Retention coefficient

Marker	Retention (static conditions)	
Mycoplasmen	LRV ≥ 7	
Brevundimonas diminuta	LRV > 7	

#### **Order information**

Туре	Filter area	Pore size	Order No.
Sartocon Cassettes	0.6 m <sup>2</sup>	0.1 μm	302 154 58 06 W-SG
Sartocon Slice Cassettes	0.1 m <sup>2</sup>	0.1 μm	305 154 58 01 W-SG

# Hydrosart® Microfiltration Cassettes Cell Harvest and Bacteria Concentration





#### Description

#### The Hydrosart® membrane

Hydrosart is a stabilized cellulose derivative membrane polymer that has been optimized for the biotechnological and pharmaceutical industries. The Hydrosart membrane is a stable polymer that features a broad pH and temperature range. Hydrosart is also extremely hydrophilic, making it non-protein-binding and virtually non-fouling. As a result, it has extremely high flux. Hydrosart's wide temperature range makes it possible to sterilize the membrane by either steam or autoclaving. Membrane regeneration, storage and depyrogenation can be accomplished by using NaOH even at elevated temperatures.

#### **Product profile**

Hydrosart has minimal adsorption of proteins, viruses, etc. Membrane retention is unaffected by repeated re-use. Hydrosart has been validated to withstand in-line steam sterilization without any loss of integrity or changes in membrane retention.

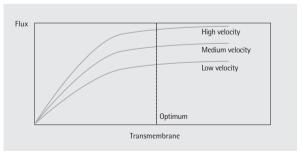
#### **Applications**

Hydrosart membranes are designed for use in the biotechnological and pharmaceutical industries. They can be used to remove the following from liquids:

- Mammalian cells CHO BHK
- BacteriaE. coliPasteurellaC. diphtheria
- Yeasts
- Cell lysates

Feature	Benefits
Non-adsorptive No loss of proteins, easy to c sustained flux	
Non-protein-binding	High product yield
Wide pH and temperature range	More choices in sanitizing agents
High flow rates	Economical filtration runs
Steam-resistant polymer	Withstands repeated steam-sterilization cycles
Self sealing cassette	No gaskets needed
Silicone sealing compound	No glue
Enlarged inlet and outlet holes	Lower pressure drop

Because of these features, Hydrosart is ideal for biological applications.



Effect of Transmembrane Pressure (TMP) and crossflow velocity on flux rates

Hydrosart<sup>®</sup> Microfiltration Cassettes

# **Specifications**

#### Pore size | Retention rate

Hydrosart Microfilter Cassettes are available in a choice of 0.2 µm and 0.45 µm pore sizes.

#### Available sizes

Sartorius Crossflow Cassettes are available in Standard Cassette size for pilot- production scale and in Sartocon Slice format for reduced volume handling.

#### Available filter holder

Sartorius Crossflow Cassettes are designed for Sartorius filter holders like SartoconSlice (0.1 m<sup>2</sup> Cassettes only), Sartocon, Sartocon 2 Plus, Sartocon 3, and different Sartoflow holder.

#### Filtration area

Filter area Sartocon Cassette  $0.6 \, m^2$ Filter area Sartocon Slice Cassette  $0.1 \, \text{m}^2$ 

#### Sterilization

Sterilization 121°C, 30 min, steaming 121°C, 30 min, auloclaving

#### Regulatory compliance

All materials have passed the current USP Biological Test. The filtrate meets or exeeds USP and EP requirements for Sterile Water for Injection with respect to total solids, oxidizable substances, particulate matter, ammonia, chloride, nitrate, sulfate and heavy metals.

#### Quality control

Each filter cassette is individually assigned a serial number, integrity tested and certified.

It complies with cGMP requirements for non-fiber-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available upon request.

If you use holding devices from other suppliers, please contact our Applications Department. A different torque might be needed due to specific variations in design.

#### **Technical references**

Validation Guide

Publication No.: SPC5701-e

Directions for Use (Sartocon Cassettes and Sartocon Slice Cassettes) Publication No.: SPC6001-a

#### Materials of construction

Membrane	Hydrosart (stabilized cellulose based membrane)
Gaskets	PVDF
Spacer	Polypropylene
Sealing compound	Silicone

#### **Operating parameters**

Feed pressure, P <sub>in</sub>	58 psi   4 bar maximum
Operating temperature	50°C maximum
pH stability	2–14
Air diffusion rates at P <sub>in</sub> = 15 psi (1 bar)	50 ml air/min for 0.6 m <sup>2</sup> filter area 15 ml air/min for 0.1 m <sup>2</sup> filter area
Cleaning	P3 Ultrasil 11, 1%, pH 13, max. 50°C, 30 min P3 Ultrasil 53, 1.5%, pH 8, 50°C, 60 min P3 Ultrasil 62/60a, 1%, ph 6.5; max. 50°C, 30 min Sodium hydroxide, 1 M; 40°C, 60 min
Disinfection	NaOH, 1 M, max. 50°C, 30 min
Storage	NaOH, 0.1 M

#### Examples of flux for water

Pore size	Sartocon Cassettes 0.6 m <sup>2</sup> filter area Permeate*	Sartocon Slice Cassettes 0.1 m <sup>2</sup> filter area Permeate*
0.2 μm	2,100 l/h/m <sup>2</sup>	1,350 l/h/m <sup>2</sup>
0.45 μm	2,300 l/h/m <sup>2</sup>	1,855 l/h/m <sup>2</sup>

<sup>\* (</sup>Feed pressure,  $P_{in} = 29 \text{ psi} \mid 2.0 \text{ bar}$ ; retentate pressure,  $P_{out} = 7 \text{ psi} \mid 0.5 \text{ bar}$ )

#### Retention coefficient

Marker	Retention
Bacteria	>99%
Mammalian cells	>99%

#### **Order information**

Туре	Filter area	Pore size	Order No.
Sartocon Cassettes	0.6 m <sup>2</sup>	0.2 μm	302 186 07 06 W-SG
Sartocon Cassettes	0.6 m <sup>2</sup>	0.45 μm	302 186 06 06 W-SG
Sartocon Slice Cassettes	0.1 m <sup>2</sup>	0.2 μm	305 186 07 01 W-SG
Sartocon Slice Cassettes	0.1 m <sup>2</sup>	0.45 μm	305 186 06 01 W-SG

# Polypropylene Microfiltration Cassettes Cell Harvest and Bacteria Concentration



#### Description

#### The Polypropylene membrane

The Polypropylene membrane is a stable polymer that features a broad pH and temperature range. Polypropylene wide temperature range makes it possible to sterilize the membrane by either steam or autoclaving. Membrane regeneration, storage and depyrogenation can be accomplished by using NaOH even at elevated temperatures. Because of these features, Polypropylene is ideal for biological applications. Polypropylene cassettes are available in 0.2 µm.

### **Applications**

Polypropylene membranes are designed for use in the biotechnological and pharmaceutical industries. They can be used to remove the following from liquids:

- mammalian cells
- clostridia
- yeasts
- salmonella

#### **Product profile**

Polypropylene can withstand in-line steam sterilization without any loss of integrity or changes in membrane retention. Membrane retention is unaffected by repeated re-use.

Feature	Benefits
Low adsorption	Minimal loss of proteins
Low protein-binding	High product yield
Steam stable polymer	Withstands repeated steam-sterilization cycles
Wide pH and a wide variety of temperature range	Chemicals can be used for the removal of foulants
High flow rates	Economical filtration runs
Self sealing cassette	No gaskets needed
Silicone sealing compound	No glue
Enlarged inlet and outlet holes	Lower pressure drop

Polypropylene Microfiltration Cassettes

# **Specifications**

#### Pore size | Retention rate

PP microfiltration cassettes are available in a choice of 0.2 μm pore size.

#### Available sizes

Sartorius Crossflow Cassettes are available in **Standard Cassette** size for pilot-|production scale.

#### Available filterholder

Sartorius Crossflow Cassettes are designed for Sartorius filter holders like Sartocon, Sartocon 2 Plus, Sartocon 3, and different Sartoflow holder.

#### Filtration area

Filter area Sartocon Cassette 0.6 m<sup>2</sup>

#### Sterilization

121°C, 30 min, steaming 121°C, 110 min, autoclaving

#### Regulatory compliance

All materials have passed the current USP Biological Test. The filtrate meets or exeeds USP and EP requirements for Sterile Water for Injection with respect to total solids, oxidizable substances, particulate matter, ammonia, chloride, nitrate, sulfate and heavy metals.

#### **Quality control**

Each filter cassette is individually assigned a serial number, integrity tested and certified.

It complies with cGMP requirements for non-fiber-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available upon request.

If you use holding devices from other suppliers, please contact our Applications Department. A different torque might be needed due to specific variations in design.

#### **Technical references**

Validation Guide

Publication No.: SPC5701-e

Directions for Use (Sartocon Cassettes and Sartocon Slice Cassettes)
Publication No.: SPC6001-a

#### Materials of construction

Membrane	Polypropylene
Gaskets	PVDF
Spacer	Polypropylene
Sealing compound	Silicone

#### **Operating parameters**

Feed pressure, P <sub>in</sub>	58 psi   4 bar maximum
Operating temperature	50°C maximum
pH stabilty	1–14
Air diffusion rates at P <sub>in</sub> = 15 psi   1 bar	15 ml air/min for 0.6 m <sup>2</sup> filter area
Cleaning	P3 Ultrasil 91, (2-4%), pH 13; max. 50°C; Sodium hydroxide, 1 M; 40°C
Disinfection	NaOH, 1 M, max. 50°C, 30 min
Storage	NaOH, 0.1 M

#### **Examples of flux for water**

Permeate*	0.2 μm	1000 l/h/m <sup>2</sup>

<sup>\*</sup> Feed pressure,  $P_{in} = 29 \text{ psi} \mid 2.0 \text{ bar}$ ; retentate pressure,  $P_{out} = 7 \text{ psi} \mid 0.5 \text{ bar}$ 

#### **Retention coefficient**

Marker	Retention	
Bacteria	>99%	
Mammalian cells	>99%	

#### **Order information**

Pore size	Sartocon Cassettes 0.6 m <sup>2</sup> filter area			
0.2 μm	302 175 07 06 W-SG			

# **Sartocon® Single-Use Cassettes Protein Purification, Concentration and Diafiltration**



#### Description

#### The polyethersulfone membrane

The polyethersulfone membrane (PESU) is a membrane polymer that is well established in the biotechnological and pharmaceutical industries. The PESU membrane is a stable polymer that features a broad pH and temperature range. Its wide temperature range makes it possible to sterilize some of the membrane by either steam or autoclaving. Because of these features, the PESU membrane is ideally suited for biotechnological applications. Polyethersulfone membranes are designed for Single Use applications use in the biotechnological and pharmaceutical industries.

They can be used for the following applications:

- IaG
- Blood factors
- Enzymes
- Peptides

#### **Product profile**

The polyethersulfone membrane in Sartocon® Single-Use Cassettes has minimal adsorption of proteins, viruses, etc. Membrane retention is unaffected by always out of the box performance. Some PESU ultrafiltration cassettes have been validated to withstand in-line steam sterilization without any loss or changes in membrane retention.

Feature	Benefits
New Filter-Cassette in each production run	Reproducability  - Consistent process economics  "Ready to use   easy to use conditions"  - High Target  Protein rejection "Consistent Yield"  - Sustained Performance (Lot-to-Lot)  - Batch-to-Batch Consistency  "Always out of the box performance"
Single use	Eliminate cleaning Validation Reduced down time
Alcohol   Glycerol storage	Consistently low TOC limits
Consistent performance	Minimal processing time
Self sealing cassette	No gaskets required
Silicone sealing internal external	No glue No Polyurethane extractables
Opimized Cassette construction	Lower pressure drop across the Cassette

Sartocon® Single-Use Cassettes

# **Specifications**

#### Pore size | Retention rate

PESU ultrafiltration cassettes are available in a choice of the following nominal molecular weight cut offs: 1kD, 5kD, 8kD, 10kD, 30kD, 50 kD, 300 kD.

#### Available sizes

Sartorius Sartocon® Single-Use Crossflow Cassettes are available in Standard Cassette format size for pilot- production scale.

#### Available filterholder

Sartorius Sartocon® Single-Use Crossflow Cassettes are designed for Sartorius filter holders like Sartocon, Sartocon 2 Plus, Sartocon 3, and different Sartoflow holder.

#### Filtration area

Filter area Sartocon Cassette

 $0.7 m^{2}$ 

#### Sterilization

only 30 kD | 100 kD | 300 kD, 121°C, 30 min., steaming; 121°C, 110 min, autoclaving

#### Regulatory compliance

All materials have passed the current USP Biological Test. The filtrate meets or exeeds USP and EP requirements for Sterile Water for Injection with respect to total solids, oxidizable substances, particulate matter, ammonia, chloride, nitrate, sulfate and heavy metals.

#### Quality control

Each filter cassette is individually assigned a serial number, integrity tested and certified.

It complies with cGMP requirements for non-fiber-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available upon request.

If you use holding devices from other suppliers, please contact our Applications Department. A different torque might be needed due to specific variations in design.

#### **Technical references**

Validation Guide

Publication No.: SPC5701-e

Directions for Use

Publication No.: SPC6001-a

#### Materials of construction

Membrane	Polyethersulfone
Gaskets	PVDF
Spacer	Polypropylene
Sealing compound	Silicone
Operating parameters	
Feed pressure, P:	58 psi 4 bar maximum

Feed pressure, P <sub>in</sub>	58 psi   4 bar maximum
Operating temperature	50°C maximum
Air diffusion rates at P <sub>in</sub> = 15 psi   1 bar	1 k–300 k: 50 ml 50 ml air/min for 0.7 m² filter area
att <sub>in</sub> – 13 pst   1 dat	15 ml air/min for 0.1 m <sup>2</sup> filter area

#### **Retention rates Polyethersulfone**

Substance	Approx. Mol. wt	1 kD	5 kD	8 kD	10 kD	30 kD	50 kD	100 kD	300 kD
Vitamin B12	1.200	>70	>50	<45	-	-	-	-	-
Inulin	5.000	>85	>70	-	-	-	-	-	-
Cytochrome C	12.400	-	>99	>99	>95	>60	-	-	-
Myoglobin	17.000	-	-	-	>99	>98	>95	<80	_
Albumin	67.000	-	-	-	>95	-	-	-	-
γ-Globulin	169.000	-	-	-	-	-	>99	>98	<70
Dextran	2,000.000	-	-	-	-	-	-	-	>95

#### Typical water flux release data

Cutoff	Sartocon <sup>®</sup> Single-Use Cassettes 0.7 m <sup>2</sup> filter area [I/h]	
1 kD	9	
5 kD	21	
8 kD	125	
10 kD	160	
30 kD	280	
50 kD	460	
100 kD PESU	530	
300 kD	630	

<sup>\* (</sup>Feed pressure,  $P_{in}$  = 22 psi | 1.5 bar; Retentate pressure,  $P_{out}$  = closed valve;  $P_{Filtrate}$ = open valve)

#### Order information

Cutoff	Sartocon <sup>®</sup> Single-Use Cassettes, 0.7 m <sup>2</sup> filter area
1 kD	3021460907ESUD
5 kD	3021462907ESUD
8 kD	3021463407ESUD
10 kD	3021463907ESUD
30 kD	3021465907ESUD
50 kD	3021465007ESUD
100 kD	3021466807ESUD
300 kD	3021467907ESUD

# Polyethersulfone Ultrafiltration Cassettes Protein Purification, Concentration and Diafiltration





#### Description

#### The polyethersulfone membrane

The polyethersulfone membrane (PESU) is a membrane polymer that is well established in the biotechnological and pharmaceutical industries. The PESU membrane is a stable polymer that features a broad pH and temperature range. Its wide temperature range makes it possible to sterilize some of the membrane by either steam or autoclaving. Membrane regeneration, storage and depyrogenation can be accomplished by using NaOH even at elevated temperatures. Because of these features, the PESU membrane is ideally suited for biotechnological applications. Polyethersulfone membranes are designed for use in the biotechnological and pharmaceutical industries.

They can be used for the following applications:

- IgG
- Blood factors
- Enzymes
- Peptides

#### **Product profile**

The polyethersulfone membrane has minimal adsorption of proteins, viruses, etc. Membrane retention is unaffected by repeated re-use. PESU ultrafiltration cassettes have been validated to withstand in-line steam sterilization without any loss or changes in membrane retention.

Feature	Benefits			
Low adsorption	Minimal loss of proteins			
Low protein-binding	High product yield			
pH Wide pH and a wide variety of temperature range	Chemicals can be used for the removal of foulants			
High flow rates	Economical filtration runs			
Self sealing cassette	No gaskets needed			
Silicone sealing compound	No glue			
Enlarged inlet and outlet hole	Lower pressure drop			

#### Pore size | Retention rate

PESU ultrafiltration cassettes are available in a choice of the following nominal molecular weight cut offs: 1kD, 5kD, 8kD, 10kD, 30kD, 50kD, 300kD.

#### Available sizes

Sartorius Crossflow Cassettes are available in **Standard Cassette** size for pilot-|production scale and in **Sartocon Slice** format for reduced volume handling.

#### Available filterholder

Sartorius Crossflow Cassettes are designed for Sartorius filter holders like SartoconSlice (0.1 m² Cassettes only), Sartocon, Sartocon 2 Plus, Sartocon 3, and different Sartoflow holder.

#### Filtration area

Filter area Sartocon Cassette 0.7 m<sup>2</sup> Filter area Sartocon Slice Cassette 0.1 m<sup>2</sup>

#### Sterilization

only 30 kD | 100 kD | 300 kD, 121°C, 30 min., steaming; 121°C, 110 min, autoclaving

#### Regulatory compliance

All materials have passed the current USP Biological Test. The filtrate meets or exeeds USP and EP requirements for Sterile Water for Injection with respect to total solids, oxidizable substances, particulate matter, ammonia, chloride, nitrate, sulfate and heavy metals.

#### Quality control

Each filter cassette is individually assigned a serial number, integrity tested and certified.

It complies with cGMP requirements for non-fiber-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available upon request.

If you use holding devices from other suppliers, please contact our Applications Department. A different torque might be needed due to specific variations in design.

#### **Technical references**

Validation Guide

Publication No.: SPC5701-e

Directions for Use (Sartocon Cassettes and Sartocon Slice Cassettes)
Publication No.: SPC6001-a

#### Materials of construction

Membrane	Polyethersulfone
Gaskets	PVDF
Spacer	Polypropylene
Sealing compound	Silicone
Operating parameters	
Feed pressure, P <sub>in</sub>	58 psi 4 bar maximum
Operating temperature	50°C maximum
Air diffusion rates at $P_{in} = 15 \text{ psi}   1 \text{ bar}$	1 k-300 k: 50 ml 50 ml air/min for 0.7 m² filter area   15 ml air/min for 0.1 m² filter area
Cleaning	P3 Ultrasil 91, (2-4%), pH 13; max. 50°C; Sodium hydroxide, 1 M; 40°C
Disinfection	NaOH, 1 M, max. 50°C, 30 min
Storage	NaOH, 0.1 M

#### **Retention rates Polyethersulfone**

Substance	Approx. Mol. wt	1 kD	5 kD	8 kD	10 kD	30 kD	50 kD	100 kD	300 kD
Vitamin B12	1.200	>70	>50	<45	-	-	-	-	-
Inulin	5.000	>85	>70	-	-	-	-	-	-
Cytochrome C	12.400	-	>99	>99	>95	>60	-	-	_
Myoglobin	17.000	-	-	-	>99	>98	>95	<80	-
Albumin	67.000	-	-	-	>95	-	-	-	-
γ-Globulin	169.000	-	-	-	-	-	>99	>98	<70
Dextran	2,000.000	-	-	-	-	-	-	-	>95

### Typical water flux release data

Cutoff	Sartocon Cassettes 0.7 m <sup>2</sup> filter area [I/h]	Sartocon Slice Cassettes 0.1 m <sup>2</sup> filter area, permeate* [l/h]
1 kD	9	3
5 kD	21	5
8 kD	125	25
10 kD	160	38
30 kD	280	70
50 kD	460	90
100 kD PESU	530	100
300 kD	630	120

#### Order information

Cutoff	Sartocon Cassettes, 0.7 m <sup>2</sup> filter area	Sartocon Slice Cassettes, 0.1 m <sup>2</sup> filter area
1 kD	3021460907E-SG	3051460901E-SG
5 kD	3021462907E-SG	3051462901E-SG
8 kD	3021463407E-SG	3051463401E-SG
10 kD	3021463907E-SG	3051463901E-SG
30 kD	3021465907E-SG	3051465901E-SG
50 kD	3021465007E-SG	3051465001E-SG
100 kD	3021466807E-SG	3051466801E-SG
300 kD	3021467907E-SG	3051467901E-SG

<sup>\* (</sup>Feed pressure,  $P_{in} = 22 \text{ psi} \mid 1.5 \text{ bar}$ ; Retentate pressure,  $P_{out} = \text{closed valve}$ ;  $P_{Filtrate} = \text{open valve}$ )

# Sartocube<sup>™</sup> – Hydrosart<sup>®</sup> Ultrafilter Cassette Protein purification, concentration and diafiltration



#### Description

#### The Hydrosart® Membrane

Hydrosart is a stabilized cellulose based membrane that has been optimized for the biotechnological and pharmaceutical industry. The Hydrosart membrane is a stable polymer that features a broad pH range. Hydrosart is also extremely hydrophilic, making it non-protein binding, virtually nonfoul, and has extremely high flux. Membrane regeneration, storage and depyrogenation can be accomplished by using NaOH even at elevated temperatures. These features make Hydrosart an ideal membrane for biological applications. Hydrosart ultrafiltration Sartocube™ cassettes are available in the following nominal molecular weight cutoffs: 10 kD 30 kD

#### **Applications**

Hydrosart ultrafiltration membranes are designed for use in the biotechnological and pharmaceutical industries. They can be used for the following applications:

- Oligonucleotide
- Proteins
   Albumin, even with 40% EtOH Hemoglobin
- Coagulation factors Factor VIII Factor III
- Vaccines Tetanus Diphteria
- Monoklonal Antibodies

#### **Product profile**

Hydrosart shows minimal adsorption of proteins, viruses, etc. Membrane retention is unaffected by repeated re-use.

The Hydrosart ultrafiltration membrane can be re-used without any less cleaning loss of integrity or performance.

Feature	Benefits
Non-adsorptive	No loss of proteins, easy to clean, sustained flux
Non-protein binding	High product yield
Wide pH and temperature range	More choices in sanitizing agents
High flow rates	Economical filtration runs
Self sealing cassette	No gaskets needed
Silicone sealing compound	No glue
Enlarged inlet and outlet holes	Lower pressure drop

Better solvent resistance than Polyethersulfone and Cellulose Triacetate

#### Pore size | Retention rate

Hydrosart ultrafiltration cassettes are available in a choice of the following nominal molecular weight cut offs: 10 kD | 30 kD

#### Available sizes

Sartorius Crossflow Cassettes are available in **Standard Cassette** size for pilot-|production scale and in **Sartocon Slice** format for reduced volume handling.

#### Available filterholder

Sartorius Crossflow Cassettes are designed for Sartorius filter holders like, Sartocon, Sartocon 2 Plus, Sartocon 3, and different Sartoflow holder.

#### Filtration area

Filter area Sartocube™ Cassette is 3.0 m<sup>2</sup>

#### Sterilization

NaOH, 1 M, 40 °C, 30 min

#### Regulatory compliance

All materials have passed the current USP Biological Test. The filtrate meets or exeeds USP and EP requirements for Sterile Water for Injection with respect to total solids, oxidizable substances, particulate matter, ammonia, chloride, nitrate, sulfate and heavy metals.

#### Quality control

Each filter cassette is individually assigned a serial number, integrity tested and certified.

It complies with cGMP requirements for non-fiber-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available upon request.

If you use holding devices from other suppliers, please contact our Applications Department. A different torque might be needed due to specific variations in design.

For further assistance, please contact your local Sartorius field engineer or our Goettingen- based Applications Department in Germany.

#### **Technical references:**

Validation Guide

Publication No.: SPC5704-e

Directions for Use (Sartocube™ Cassettes)

Publication No.: SPC6018-a

#### Materials of construction

Membrane	Hydrosart (stabilized cellulose based membrane)
Gaskets	PVDF
Spacer	Polypropylene
Sealing compound	Silicone

#### **Operating parameters**

1 31		
Feed pressure, P <sub>in</sub>	58 psi 4 bar maximum	
Operating temperature	50°C maximum, at 20°C	
Max. air diffusion rates at $P_{in} = 15 \text{ psi}   1 \text{ bar}$	50 ml air/min for 3.0 m <sup>2</sup> filter area	
Cleaning	NaOH, 1 M, 40°C	
Disinfection	NaOH, 1 M, 40°C, 30 min	
Storage	NaOH, 0.1 M	

#### Typical water flux release data\*

Nominal molecular weight cutoff (kD)	Sartocube™ Cassettes 3.0 m² filter area Permeate* [I/h]
10 kD	190
30 kD	600

#### Retention rates Hydrosart®

Substance	Approx. Mol. Wt.	2 kD	5 kD	10 kD	30 kD	100 kD
Vitamin B12	1.200	≥88%	-	-	_	
Inulin	5.000	-	>97%	-	_	
Cytochrome C	12.400	-	-	>97,5%	-	
Albumin	67.000	-	-	-	>97,5%	≤60%
γ Globulin	169.000	-	-	-	>97,5%	≥96%

#### **Order information**

Туре	Filter area	Cut off	Order no.
Sartocon Cassettes	$3.0 \; m^2$	10 kD	302 144 39 30 E-BSW
Sartocon Cassettes	3.0 m <sup>2</sup>	30 kD	302 144 59 30 F-BSW

# Hydrosart® Ultrafiltration Cassettes Protein Purification, Concentration and Diafiltration





#### Description

#### The Hydrosart® membrane

Hydrosart is a stabilized cellulose based membrane that has been optimized for the biotechnological and pharmaceutical industry. The Hydrosart membrane is a stable polymer that features a broad pH range. Hydrosart is also extremely hydrophilic, making it non-protein binding, virtually nonfoul, and has extremely high flux. Membrane regeneration, storage and depyrogenation can be accomplished by using NaOH even at elevated temperatures. These features make Hydrosart an ideal membrane for biological applications. Hydrosart ultrafiltration cassettes are available in the following nominal molecular weight cutoffs: 2 kD 5 kD | 10 kD | 30 kD | 100 kD

#### **Applications**

Hydrosart ultrafiltration membranes are designed for use in the biotechnological and pharmaceutical industries. They can be used for the following applications:

- Oligonucleotide
- Proteins Albumin, even with 40% EtOH Hemoglobin
- Coagulation factors Factor VIII Factor III
- VaccinesTetanusDiphteria
- Monoklonal Antibodies

#### **Product profile**

Hydrosart shows minimal adsorption of proteins, viruses, etc. Membrane retention is unaffected by repeated re-use.

The Hydrosart ultrafiltration membrane can be re-used without any less cleaning loss of integrity or performance.

Feature	Benefits
Non-adsorptive	No loss of proteins, easy to clean, sustained flux
Non-protein binding	High product yield
Wide pH and temperature range	More choices in sanitizing agents
High flow rates	Economical filtration runs
Self sealing cassette	No gaskets needed
Silicone sealing compound	No glue
Enlarged inlet and outlet holes	Lower pressure drop

Better solvent resistance than Polyethersulfone and Cellulose Triacetate

#### Pore size | Retention rate

Hydrosart ultrafiltration cassettes are available in a choice of the following nominal molecular weight cut offs: 2 kD | 5 kD | 10 kD | 30 kD | 100 kD

#### Available sizes

Sartorius Crossflow Cassettes are available in **Standard Cassette** size for pilot-|production scale and in **Sartocon Slice** format for reduced volume handling.

#### Available filterholder

Sartorius Crossflow Cassettes are designed for Sartorius filter holders like SartoconSlice (0.1 m² Cassettes only), Sartocon, Sartocon 2 Plus, Sartocon 3, and different Sartoflow holder.

#### Filtration area

Filter area Sartocon Cassette 0.6 m<sup>2</sup> Filter area Sartocon Slice Cassette 0.1 m<sup>2</sup>

#### Sterilization

NaOH, 1 M, 40°C, 30 min

#### Regulatory compliance

All materials have passed the current USP Biological Test. The filtrate meets or exeeds USP and EP requirements for Sterile Water for Injection with respect to total solids, oxidizable substances, particulate matter, ammonia, chloride, nitrate, sulfate and heavy metals.

#### Quality control

Each filter cassette is individually assigned a serial number, integrity tested and certified.

It complies with cGMP requirements for non-fiber-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available upon request.

If you use holding devices from other suppliers, please contact our Applications Department. A different torque might be needed due to specific variations in design.

#### **Technical references**

Validation Guide Publication No.: SPC5701-e

Directions for Use (Sartocon Cassettes

and Sartocon Slice Cassettes)
Publication No.: SPC6001-a

#### \* (Feed pressure, $P_{in} = 22 \text{ psi} \mid 1.5 \text{ bar}$ ; Retentate pressure, $P_{out} = \text{closed valve}$ ; $P_{Filtrate} = \text{open valve}$ )

#### Materials of construction

Membrane	Hydrosart (stabilized cellulose based membrane)	
Gaskets	PVDF	
Spacer	Polypropylene	
Sealing compound	Silicone	
Operating parameters		
Feed pressure, P <sub>in</sub>	58 psi   4 bar maximum	
Operating temperature	50°C maximum, at 20°C	
Max. air diffusion rates at P <sub>in</sub> = 15 psi   1 bar	15 ml air/min for 0.6 m² filter area 5 ml air/min for 0.1 m² filter area	
Cleaning	NaOH, 1 M, 40°C	
Disinfection	NaOH, 1 M, 40°C, 30 min	
Storage	NaOH, 0.1 M	

#### Typical water flux release data\*

Nominal molecular weight cutoff (kD)	Sartocon Cassettes 0.6 m <sup>2</sup> filter area permeate* [I/h]	Sartocon Slice Cassettes 0.1 m <sup>2</sup> filter area permeate* [I/h]
2 kD	7	1.5
5 kD	12	3
10 kD	35	8
30 kD	120	25
100 kD	340	70

#### Retention rates Hydrosart®

Substance	Approx. Mol. Wt.	2 kD	5 kD	10 kD	30 kD	100 kD
Vitamin B12	1.200	≥88%	-	-	-	
Inulin	5.000	-	>97%	-	-	
Cytochrome C	12.400	-	-	>97,5%	-	
Albumin	67.000	-	-	-	>97,5%	≤60%
γ Globulin	169.000	_	-	_	>97,5%	≥96%

#### Order information

Туре	Filter area	Cutoff	Order No.
Sartocon Cassettes	0.6 m <sup>2</sup>	2 kD	302 144 19 06 ESG
Sartocon Cassettes	0.6 m <sup>2</sup>	5 kD	302 144 29 06 ESG
Sartocon Cassettes	0.6 m <sup>2</sup>	10 kD	302 144 39 06 ESG
Sartocon Cassettes	0.6 m <sup>2</sup>	30 kD	302 144 59 06 ESG
Sartocon Cassettes	0.6 m <sup>2</sup>	100 kD	302 144 68 06 ESG
Sartocon Slice Cassettes	0.1 m <sup>2</sup>	2 kD	305 144 19 01 ESG
Sartocon Slice Cassettes	0.1 m <sup>2</sup>	5 kD	305 144 29 01 ESG
Sartocon Slice Cassettes	0.1 m <sup>2</sup>	10 kD	305 144 39 01 ESG
Sartocon Slice Cassettes	0.1 m <sup>2</sup>	30 kD	305 144 59 01 ESG
Sartocon Slice Cassettes	0.1 m <sup>2</sup>	100 kD	305 144 68 01 ESG

# **Cellulose Triacetate Ultrafiltration Cassettes Protein Purification, Concentration and Diafiltration**



#### Description

#### Cellulose triacetate membrane

The cellulose triacetate membrane is a membrane polymer that is well established in the biotechnological and pharmaceutical industries. The cellulose triacetate membrane is extremely hydrophilic, making it virtually non-protein-binding. These features make cellulose triacetate membranes ideally suited for biotechnological applications. Cassettes with cellulose triacetate membranes are available in a choice of the following nominal molecular weight cutoffs:

- 5 kD
- 20 kD

# **Applications**

Cellulose triacetate membranes are designed for use in the biotechnological and pharmaceutical industries. For example, these membranes can be used to separate or concentrate the following from liquids:

- Blood fractions
- Enzymes
- Proteins
- Peptides
- Antibodies

#### **Product profile**

The cellulose triacetate membrane shows minimal adsorption of proteins, viruses, etc. Membrane retention is unaffected by repeated re-use. The cellulose triacetate membrane can be re-used without any loss of integrity or performance.

Feature	Benefits
Non-adsorptive	No loss of proteins, easy to clean, sustained flux
Non-protein binding	High product yield
High flow rates	Economical filtration runs
Self sealing cassette	No gaskets needed
Silicone sealing compound	No glue
Enlarged inlet and outlet holes	Lower pressure drop

**Cellulose Triacetate Ultrafiltration Cassettes** 

# **Specifications**

#### Pore size | Retention rate

CTA ultrafiltration cassettes are available in a choice of the following nominal molecular weight cut offs: 5 kD, 20 kD

#### Available sizes

Sartorius Crossflow Cassettes are available in Standard Cassette size for pilot- production

#### Available filter holder

Sartorius Crossflow Cassettes are designed for Sartorius filter holder like Sartocon, Sartocon 2 Plus, Sartocon 3, and different Sartoflow holder.

#### Filtration area

Filter area Sartocon Cassette 0.7 m<sup>2</sup>

#### Sterilization

2-3% formaldehyde, 20°C, 30 min

#### Regulatory compliance

All materials have passed the current USP Biological Test. The filtrate meets or exeeds USP and EP requirements for Sterile Water for Injection with respect to total solids, oxidizable substances, particulate matter, ammonia, chloride, nitrate, sulfate and heavy metals.

#### Quality control

Each filter cassette is individually assigned a serial number, integrity tested and certified.

It complies with cGMP requirements for non-fiber-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available upon request.

If you use holding devices from other suppliers, please contact our Applications Department. A different torque might be needed due to specific variations in design.

#### Technical references

Validation Guide

Publication No.: SPC5701-e

Directions for Use (Sartocon Cassettes and Sartocon Slice Cassettes) Publication No.: SPC6001-a

#### Materials of construction

Membrane	Cellulose triacetate
Gaskets	Polyester
Spacer	Polypropylene
Sealing compound	Silicone

#### **Operating parameters**

operating parameters	
Feed pressure, P <sub>in</sub>	58 psi   4 bar maximum
Operating temperature	50°C maximum
pH stability	4-8
Air diffusion rates at P <sub>in</sub> = 15 psi   1 bar	15 ml air/min for 0.7 m <sup>2</sup> filter area
Cleaning	P3 Ultrasil 53, 1,5%, pH 8; 35°C; Sodium tetraborate (5g/l) + citric acid, free of tensides and proteases (2.5 g/l), pH 8; 40°C Calgonit CMR™ (1%), pH 4; 40°C
Disinfection	Formaldehyde, 2–3%, 20–30°C, 30 min Sodium azide, 0.1%, 20–30°C, 15 min
Storage	Formaldehyd 2–3% Sodium disulfite, 0.1%, pH 4 Ethanol, 20%

#### Examples of flux for water

	5 kD	20 kD
Permeate*	12 l/h/m <sup>2</sup>	200 l/h/m <sup>2</sup>

<sup>\* (</sup>Feed pressure, P<sub>in</sub> = 29 psi | 2.0 bar; Retentate pressure, P<sub>out</sub> = 7 psi | 0.5 bar; Permeate= Valve open)

#### Retention coefficient

Marker	5 kD	20 kD	
Inulin	>80%		
Cytochrome C	>99%	<75%	
Myoglobin		>85%	
Albumin		>99%	

#### **Order information**

Cutoff	Order No.	
5 kD	302 145 29 07 E-SG	
20 kD	302 145 49 07 E-SG	

# New Albumin Ultrafiltration Cassettes "PESU-MAX" Albumin Concentration





#### Description

#### The PESU-MAX membrane

The PESU-MAX membrane is made out of polyethersulfone (PESU). This membrane polymer is well established in the biotechnological and pharmaceutical industries. The PESU-MAX cassette, is designed for use in the blood market specially for ALBUMIN rejectable applications. The PESU-MAX membrane is a stable polymer that features a broad pH and temperature range. Membrane regeneration, storage and depyrogenation can be accomplished by using NaOH even at elevated temperatures. Because of these features, the PESU membrane is ideally suited for blood market applications.

#### **Product profile**

The polyethersulfone membrane has minimal adsorption of proteins, viruses, etc. Membrane retention is unaffected by repeated re-use. PESU ultrafiltration cassettes have been validated to withstand in-line steam sterilization without any loss or changes in membrane retention.

The Sartorius design "Stress test" as an indication of cassette cleaning cycles

#### **Purpose**

The goal of this test is to establish that Sartorius Cassette is resistent to NaOH exposure as is recommended in this Guide for cleaning and storage.

#### Test procedure

PESU-MAX Sartocon® Cassette (Mat. No. 302146AL07K--SW) are tested under stress test conditions according to demonstrate compatibility with caustic. The test conditions are: feed pressure in 4 bar; retentate pressure 0 bar and permeate open; pH is 14 with 1 N NaOH at above 50°C for minimum 200 hours.

#### Results

All released and published Sartocon® cassettes are validated according to this procedure. All cassettes passed the integrity test after minimum 50 hours.

Feature	Benefits
Low adsorption	Minimal loss of proteins
Low protein-binding	High product yield
Wide pH and a wide variety of temperature range	Chemicals can be used for the removal of foulants
High flow rates	Economical filtration runs
Self sealing cassette	No gaskets needed
Silicone sealing compound	No glue
Enlarged inlet and outlet hole	Lower pressure drop

#### Pore size | Retention rate

PESU-MAX ultrafiltration cassette is available in a retention rate of >99.99% for Albumin.

#### Available sizes

Sartorius Crossflow Cassettes are available in **Standard Cassette** size for pilot-|production scale and in **Sartocon Slice** format for reduced volume handling.

#### Available filterholder

Sartorius Crossflow Cassettes are designed for Sartorius filter holders like SartoconSlice (0.1m² Cassettes only), Sartocon, Sartocon 2 Plus, Sartocon 3, and different Sartoflow holder.

#### Filtration area

Filter area Sartocon Cassette 0.7 m<sup>2</sup> Filter area Sartocon Slice Cassette 0.1 m<sup>2</sup>

#### Sterilization

Sterilization NaOH, 1 M, max. 50°C, 30 min

#### Regulatory compliance

All materials have passed the current USP Biological Test. The filtrate meets or exeeds USP and EP requirements for Sterile Water for Injection with respect to total solids, oxidizable substances, particulate matter, ammonia, chloride, nitrate, sulfate and heavy metals.

#### Quality control

Each filter cassette is individually assigned a serial number, integrity tested and certified. It complies with cGMP requirements for non-fiber-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available upon request.

If you use holding devices from other suppliers, please contact our Applications Department. A different torque might be needed due to specific variations in design.

#### **Technical references**

Validation Guide Publication No.: SPC5701-e Directions for Use (Sartocon Cassettes and Sartocon Slice Cassettes) Publication No.: SPC6001-a

#### Materials of construction

Membrane	Polyethersulfone
Gaskets	PVDF
Spacer	Polypropylene
Sealing compound	Silicone white

#### **Operating parameters**

Feed pressure, P <sub>in</sub>	58 psi   4 bar maximum
Operating temperature	50 °C maximum
Air diffusion rates at P <sub>in</sub> = 14,5 psi   1 bar	20 ml air/min for 0.7 m² filter area   5 ml air/min for 0.1 m² filter area
Cleaning	Sodium hydroxide, 1M, 40 °C, 60 min
Disinfection	NaOH, 1 M, max. 50 °C, 30 min
Storage	NaOH, 0.1 M

#### **Operating parameters**

Feed pressure, P <sub>in</sub>	58 psi   4 bar maximum
Operating temperature	50°C maximum
Air diffusion rates at P <sub>in</sub> = 14,5 psi   1 bar	50 ml air/min for 0.7 m² filter area   15 ml air/min for 0.1 m² filter area
Cleaning	P3 Ultrasil 53TM, 1.5%, 50°C, 60 min, pH 8 P3 Ultrasil 11 (1%), 50°C, 30 min, pH 13 Sodium hydroxide, 1M, 40°C, 60 min
Disinfection NaOH, 1 M, max. 50°C, 30 min	
Storage	NaOH, 0.1 M

An Example of Flux Rates for Water

#### **Permeate**

I/h/m²	per Cassette 0.7 m <sup>2</sup>	per Cassette 0.1 m <sup>2</sup>	
approx. 350	250	50	
$(P_{in} = 29 \text{ psi}   2.0 \text{ bar}, P_{out} = 7 \text{ psi}   0.5 \text{ bar})$			

#### **Retention rates PESU-MAX**

Polyethersulfone

#### Retention coefficient

Marker	Retention
Albumin	>99.99%

#### Ordering information

Cutoff	Sartocon Cassettes 0.7 m <sup>2</sup> filter area	Sartocon Slice Cassettes 0.1 m <sup>2</sup> filter area
Albumin	302146AL07KSW	305146AL01KSW





## Crossflow Holders & Systems

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## Sartocon® 2Plus Stainless Steel Holder Crossflow Holder for Sartocon® Cassettes



#### Description

#### Sartocon 2Plus holder

The Sartocon 2Plus stainless steel holder is optimized for the use with up to ten Sartocon production scale Crossflow cassettes (max. 7 m²). It is designed for applications from 30 l to 1000 l volume.

#### Target use:

- process development
- preclinical trials
- clinical trials
- pilot lots

Sartocon cassettes with a filter area of up to 0.7 m<sup>2</sup> each, are available with Polyethersulfone, Hydrosart, Polypropylene and Cellulose Triacetate membrane types.

The Sartocon 2Plus system covers the whole range of pharmaceutical and biotechnological crossflow applications like concentration and diafiltration of proteins, vaccines, viruses, antibodies, oligo nucleotides, endotoxin removal etc. The system is also suitable for cell harvesting and clarification processes. The family of Sartorius Crossflow holders feature the latest advances in crossflow design:

- vertical orientation of cassettes
- self draining systems
- autoclavable and inline steamable
- no welds
- minimized hold up volume

The Sartocon 2Plus holding device is part of a modular micro- and ultrafiltration system and fits up to ten Sartocon filter cassettes. It is designed for process development and pilot scale production in pharmaceutical and biotechnology applications. Easy handling design and high quality materials make this holder the perfect tool.

The Sartocon cassettes are placed between filter and clamping plate without a need for additional gaskets. It's not even necessary to remove the clamping plate for installation of the cassettes. Just place the cassettes on the guide rods and close the holder with a torque wrench.

The vertical positioning of the cassettes allows complete draining of retentate and permeate channels by gravity during harvesting and steaming procedures.

Thermal sterilisation in an autoclave or steaming in place even with cassettes installed is possible. A special pressure compensation tool was designed to allow thermal sterilisation of Sartocon filter cassettes in the Sartocon 2Plus device.

The Sartocon 2Plus's flow distribution plate is machined from a single piece of stainless steel. It's sanitary 1½" tri-clamp connections are not welded but machined from the same plate. This eliminates potentially problems associated with welds and ensures long service life and safe and reliable connection to other equipment.

The feed and retentate connectors are located on one side of the plate. This allows easy integration into any skid design and assures a compact system with low minimum working volume.

Port locations on the distribution plate are situated to eliminate potential air locks and to assure thorough cleaning and total product recovery.

The Sartocon 2Plus device is available in a grinded and an electro polished surface version.

Feature	Benefits
Cassettes in vertical position	Self draining
Tri-clamp connectors	Safe fit of accessories
No welds	No corrosion
Steamable	No cross contamination
Fits up to ten Sartocon cassettes	High flexibility for up to 1000 l working volume

#### Materials of construction

Filter and Clamping plate	316L (1.4404) Stainless steel
Connectors	1"-11/2" sanitary Tri Clamp flange (DN25)
Nuts for tie rods	Nickel coated bronze
Other components	316L Stainless steel

#### Technical data

Surface finish	Ra ≤ 0.6 μm
Maximum number of cassettes	10 Sartocon cassettes
Dimensions (L×W×H)	371×270×348 mm
Weight	approx. 50 kg

#### Ordering informations and accessories

<b>9</b>	
Sartocon 2Plus stainless steel holder, grinded	17546002
Sartocon 2Plus microfiltration set	17546201
Sartocon 2Plus ultrafiltration set	17546202
Sartocon 2Plus stainless steel holder, electro polished	17546E002
Torque wrench for Sartocon 2Plus holder	17128
Socket, 27 mm	6986135
Pressure gauge,0-6 bar, 1-11/2" autoclavable	17546003
Diaphragm valve,1–11/2"	17546005
Silicone gasket (FDA), 1–11/2"	17546012
Clamp for 1–11/2" Tri Clamp	17033
Sartocon 2Plus manifold for permeate outlet	17546016
Hose connector to 1–11/2" Tri Clamp flange	17546018
Pressure compensation tool for steaming and autoclaving	17625

Available Sartocon® cassettes are described in Chapter "Crossflow Consumables" on page 127.

#### Sartoflow® 10 Stainless Steel Holder Hydraulic Crossflow Holder for Sartocon® Cassettes



#### Description

#### Sartoflow10 holder

The Sartoflow10 stainless steel holder is optimized for the use with up to ten Sartocon production scale Crossflow cassettes (max. 7 m²). It is designed for applications from 30 l to 1000 l volume.

#### Target use:

- process development
- preclinical trials
- clinical trials
- pilot lots

Sartocon cassettes with a filter area of up to 0.7 m<sup>2</sup> each, are available with Polyethersulfone, Hydrosart, Polypropylene and Cellulose Triacetate membrane types.

The Sartoflow10 system covers the whole range of pharmaceutical and biotechnological crossflow applications like concentration and diafiltration of proteins, vaccines, viruses, antibodies, oligo nucleotides, endotoxin removal etc. The system is also suitable for cell harvesting and clarification processes. The family of Sartorius Crossflow holders feature the latest advances in crossflow design:

- vertical orientation of cassettes
- self draining systems
- autoclavable and inline steamable
- no welds
- minimized hold up volume

The Sartoflow10 holding device is part of a modular micro- and ultrafiltration system and fits up to ten Sartocon filter cassettes. It is designed for process development and pilot scale production in pharmaceutical and biotechnology applications.

The Sartocon cassettes are placed between filter and clamping plate without a need for additional gaskets. It's not even necessary to remove the clamping plate for installation of the cassettes. Just place the cassettes on the guide rods and close the holder with the manual driven oil hydraulic pump. The crossflow holder and the hand oil hydraulic pump are mounted on a stainless steel skid for easy handling.

The clamping pressure can be controlled by an integrated oil pressure gauge. This allows very accurate and reproducable clamping conditions. Defined clamping conditions are essential, especially for steaming in place applications but it is also very valueable when cassettes have to be changed frequently. The Sartoflow10 holder offers high performance production scale technology for every process development and small scale production facility.

The vertical positioning of the cassettes allows complete draining of retentate and permeate channels by gravity during harvesting and steaming procedures.

The Sartoflow10 flow distribution plate is machined from a single piece of stainless steel. It's sanitary 1½" tri-clamp connections are not welded but machined from the same plate. This eliminates potentially problems associated with welds and ensures long service life and safe and reliable connection to other equipment. The feed and retentate connectors are located on one side of the plate. This allows easy integration into any skid design and assures a compact system with low minimum working volume.

Port locations on the distribution plate are situated to eliminate potential air locks and to assure thorough cleaning and total product recovery.

Feature	Benefits
Cassettes in vertical position	Self draining
Tri-clamp connectors	Safe fit of accessories
No welds	No corrosion
Steamable	No cross contamination
Fits up to ten Sartocon cassettes	High flexibility for up to 1000 I working volume
Hydraulic closure	Precise and reproducible clamping conditions

#### Materials of construction

Filter and Clamping plate	316L (1.4435) Stainless steel, grinded
Connectors	1"-1½" sanitary Tri Clamp flange (DN25)
Other components	316L Stainless steel
Skid	1.4301 stainless steel, grinded

#### Technical data

Surface finish, grinded	Ra ≤ 0.6 µm
Hydraulic hand pump	Enerpac P-392
Closure	Lukas Hydraulic ram ACM 10/150
Oil pressure gauge	0–400 bar   0–6000 psi
Pressure limit	430 bar
Maximum number of cassettes	10 Sartocon cassettes
Dimensions (L×W×H)	680×420×508 mm
Weight	approx. 70 kg

#### Ordering informations and accessories

Sartoflow10 stainless steel holder, grinded	179015301
Pressure gauge, 0-6 bar, 1–1 1/2"	17546003
Diaphragm valve,1–11/2"	17546005
Silicone gasket (FDA), 1–1 ½"	17546012
Clamp for 1–11/2" Tri-clamp	17033
Sartocon manifold for permeate outlet	17546016
Hose connector to 1–1½" Tri-clamp flange	17546018

Available Sartocon® cassettes are described in Chapter "Crossflow Consumables" on page 127.

#### Sartoflow<sup>®</sup> 20 Stainless Steel Holder Hydraulic Crossflow Holder for Sartocon<sup>®</sup> Cassettes



#### Description

#### Sartoflow20 holder

The Sartoflow20 stainless steel holder is optimized for the use with up to twenty Sartocon production scale Crossflow cassettes (max. 14 m²). It is designed for applications from 200 I to 2500 I volume.

#### Target use:

- process development
- preclinical trials
- clinical trials
- pilot lots

Sartocon cassettes with a filter area of up to 0.7 m<sup>2</sup> each, are available with Polyethersulfone, Hydrosart, Polypropylene and Cellulose Triacetate membrane types.

The Sartoflow20 system covers the whole range of pharmaceutical and biotechnological crossflow applications like concentration and diafiltration of proteins, vaccines, viruses, antibodies, oligo nucleotides, endotoxin removal etc. The system is also suitable for cell harvesting and clarification processes. The family of Sartorius Crossflow holders feature the latest advances in crossflow design:

- vertical orientation of cassettes
- self draining systems
- autoclavable and inline steamable
- no welds
- minimized hold up volume

The Sartoflow20 holding device is part of a modular micro- and ultrafiltration system and fits up to twenty Sartocon filter cassettes. It is designed for process development and pilot scale production in pharmaceutical and biotechnology applications.

The Sartocon cassettes are placed between filter and clamping plate without a need for additional gaskets. It's not even necessary to remove the clamping plate for installation of the cassettes. Just place the cassettes on the guide rods and close the holder with the oil hydraulic system. Manual driven hydraulic pump and automatic hydraulic pumps are available.

The clamping pressure can be controlled by an oil pressure gauge of a manual or automatic hydraulic pump. This allows very accurate and reproducable clamping conditions. Defined clamping conditions are essential, especially for steaming in place applications but it is also very valueable when cassettes have to be changed frequently. The Sartoflow20 holder offers high performance production scale technology for every pilot and production scale facility.

The vertical positioning of the cassettes allows complete draining of retentate and permeate channels by gravity during harvesting and steaming procedures.

The Sartoflow20 flow distribution plate is machined from a single piece of stainless steel. It's sanitary 1½" tri-clamp connections are not welded but machined from the same plate. This eliminates potentially problems associated with welds and ensures long service life and safe and reliable connection to other equipment. The feed and retentate connectors are located on one side of the plate. This allows easy integration into any skid design and assures a compact system with low minimum working volume.

Port locations on the distribution plate are situated to eliminate potential air locks and to assure thorough cleaning and total product recovery.

Feature	Benefits
Cassettes in vertical position	Self draining
Tri-clamp connectors	Safe fit of accessories
No welds	No corrosion
Steamable	No cross contamination
Fits up to twenty Sartocon cassettes	High flexibility for up to 2500 l working volume
Hydraulic closure	Precise and reproducible clamping conditions

#### Materials of construction

Filter and Clamping plate	316L (1.4435) Stainless steel, electro polished
Connectors	1"-1½" sanitary Tri-clamp flange (DN35: feed, retetate, DN25: permeate)
Other components	316L Stainless steel

#### Technical data

Surface finish, grinded	Ra ≤ 0.6 μm
Closure	Lukas Hydraulic ram ACM 10/150
Maximum number of cassettes	20 Sartocon cassettes (max. 14 m²)
Dimensions (L×W×H)	933×270×348 mm
Weight	approx. 80 kg

#### Ordering informations and accessories

Sartoflow20 stainless steel holder, electro polished, to be completed with hydraulic pump system

Manual and automatic hydraulic pumps are available on request.

Available Sartocon® cassettes are described in Chapter "Crossflow Consumables" on page 127.

#### Sartoflow® Alpha DL Crossflow System Crossflow System with Datalogger (DL) for Sartocon® Slice Cassettes





#### Description

The family of Sartoflow Alpha benchtop systems feature the latest advances in crossflow technology from Sartorius. It is designed to fulfill all requirements of small scale crossflow filtration systems for Microand Ultrafiltration in pharmaceutical and biotech applications. It is mainly used in cGMP facilities to run Scale-Up and Scale-Down trials as well as clinical trial and small scale production lots. The system is designed to accomodate up to 5 Sartorius Sartocon Slice Cassettes (max. 0.5 m² membrane area). The design and engineering of this modular system is equivalent to large scale production systems.

Sartoflow Alpha DL features digital display and 21CFR Part11 compliant acquisition of the process parameters via a digital data recorder. Log-In functions and password protection for user mapping are included. The audit trail and all process data are securely transferred to an external computer for read out and data storage. Data transfer via serial interface or PCMCIA data storage card is possible.

The modular Sartoflow Alpha DL system allows a large variety of options to fulfill all needs of cGMP production processes. Even automatic diafiltration with an external peristaltic pump controlled by a platform balance is possible.

All Sartoflow Alpha DL systems can use Sartorius recirculation bags instead of stainless steel tanks.

The basic features of all Sartoflow Alpha DL systems are:

- 21CFR Part11 compliant data recorder
- Rotary lobe pump for shear sensitive and reliable operation (500 l/h at 4 bar, 1 cP, 20°C)
- Sartocon Slice filter holder for up to 5 Sartocon Slice Cassettes (0.5 m² membrane area)
- Min. working volume < 400 ml (depending on filter area and accessories)
- Tubular, zero dead leg, pressure gauges
- Magnetic flow meter
- Sanitary membrane valves and Tri-clamp connectors
- Overpressure protection
- Self draining, zero dead leg piping
- Qualified material in contact with product: 316L (1.4404/1.4435) stainless-steel,
   Surface finish Ra: < 0.8 μm</li>
- Gaskets: EPDM (FDA)
- Small footprint benchtop system
- Documentation package for easy start-up

Sartocon Slice cassettes (0.1 m² each) utilize the same parallel leaf design and materials like the Sartocon production scale cassettes (up to 0.7 m² each). This provides the user with predictable performance for large scale processes.

Weight

Dimensions  $(L \times W \times H)$ 

## Materials of construction Product wetted components

316L (1.4404/1.4435) Stainless steel
Ra < 0.8 μm
³/4" sanitary Tri-clamp flange
500 l/h @ 4 bar   60 psi
0.5 m <sup>2</sup>
4 bar   60 psi
< 400 ml (depending on the accessories)

600×480×580 mm

60 kg (depending on the accessories)

(depending on the accessories)

#### Ordering informations and accessories

ordering informations and accessories		
Sartoflow Alpha DL System Sartocon Slice holding device, three pressure indicators magnetic flow meter (permeate) over pressure protection 21CFR Part11 compliant digital data recorder		179SFG-02-00-22 179SFG-02-00-11
Sartoflow Alpha DL-Retentate Flow meter Sartocon Slice holding device Three pressure transducers two magnetic flow meters (permeate and retentate) 21CFR Part 11 compliant digital data recorder		179SFG-02-02-22 179SFG-02-02-11
Sartoflow Alpha DL-Conductivity Sartoflow Slice holding device Three pressure transducers magnetic flow meter (permeate) Conductivity probe (permeate) Temperature probe 21CFR Part11 compliant digital data recorder		179SFG-02-06-22 179SFG-02-06-11
Sartoflow Alpha DL-Diafiltration Sartoflow Slice holding device Three pressure transducers Magnetic flow meter (permeate) Conductivity probe (permeate) Temperature probe Platform balance for recirculation vessel or ba External diafiltration peristaltic pump 21CFR Part11 compliant digital data recorder	110 V 60 Hz:	179sfg-02-07 179SFG-02-07-22 179SFG-02-07-11
2 I jacketed tank with interconnection piping and zero dead leg harvest valve		179sfzt01
10 l jacketed tank with interconnection piping and zero dead leg harvest valve		179sfzt02

Complete IQ | OQ package and additional options on request

Available Sartocon® cassettes are described in Chapter "Crossflow Consumables" on page 127.

#### Sartoflow® Beta Crossflow System Crossflow System for Sartocon® Cassettes



#### Description

The Family of manual and semi automatic Sartoflow Beta Crossflow Systems feature the latest advances in crossflow technology from Sartorius. The Sartoflow Beta is a compact and movable Crossflow filtration system for Micro- and Ultrafiltration in pharmaceutical and biotech applications. It is mainly used in cGMP facilities to run development, clinical trial and production lots. The system is designed to accomodate up to 10 Sartorius Sartocon Cassettes (7 m<sup>2</sup> membrane area). The Sartoflow Beta system covers the whole range of pharmaceutical and biotechnological crossflow applications like concentration and diafiltration of proteins, vaccines, viruses, antibodies, oligo nucleotides, endotoxin removal etc. The system is also suitable for cell harvesting and clarification processes.

The modular design allows a large variety of options to fulfill all needs of cGMP production processes. The basic features of all Sartoflow Beta systems are:

- Rotary lobe pump for shear sensitive and reliable operation (7.000 l/h at 4 bar, 1 cP, 20°C)
- Crossflow filter holder for up to 10
   Sartocon Cassettes (7 m² membrane area)
- Min. working volume < 5.000 ml (depending on filter area and accessories)
- Tubular, zero dead leg, pressure gauges
- Sanitary membrane valves and Tri-clamp connectors
- Overpressure and dry run protection
- Self draining, zero dead leg piping
- Qualified material in contact with product: 316L (1.4404/1.4435) stainless steel, Surface finish Ra: < 0.8 μm</li>
- Gaskets: EPDM (FDA)
- Movable system on casters
- Documentation package for easy start-up

Sartoflow Beta systems with digital 21CFR Part 11 compliant data recorder feature digital display and acquisition of the process pressures and flow rates. The audit trail and all process data are securely transferred to an external computer for read out and data storage. Data transfer via serial interface or PCMCIA data storage card is possible.

Log-In functions and password protection for user mapping are included.

The Sartoflow10 crossflow filter holder gives an additional security feature: A safety pressure switch controls the pressure of the hydraulic closure system and shuts down the system if the holder is not closed tightly. The clamping pressure can be controlled by an integrated oil pressure gauge. This allows very accurate and reproducible clamping conditions. Defined clamping conditions are essential, especially for steaming in place applications but it is also very valueable when cassettes have to be changed frequently.

The semi automatic Sartoflow Beta sps system is designed to run predefined process steps automatically. A set of parameters can be defined and controlled for each step. A process step once activated from the operator will run with the predefined feed and retentate pressure and stop automatically when the end of the process step is indicated. The feed pressure is controlled by the pump speed, the retentate pressure is controlled by a motor driven membrane valve.

Process steps will end automatically after a predefined time, a predefined permeate volume or when a predefined conductivity is triggered in the permeate.

Automatic diafiltration is possible with the optional 40 I vessel with integrated level probe and additional peristaltic diafiltration pump. Activation and end of each process step is indicated in the audit trail of the digital data recorder.

Steaming options for aseptic operations are available on request.

#### Materials of construction

Product wetted components	316L (1.4404/1.4435) Stainless steel
Surface finish	Ra < 0.8 μm
Connectors	1"-11/2" sanitary Tri-clamp flange

#### **Specifications**

Pump output	7.000 l/h @ 4 bar   60 psi
Filter area	0.4 to 7 m <sup>2</sup>
Max. Inlet pressure	4 bar   60 psi
Min. working volume	< 5.000 ml (depending on the accessories)
Weight	300 kg
Dimensions (L×W×H)	1.500×800×1.500 mm (depending on the accessories)

#### Ordering informations and accessories

Sartoflow Beta Basic System With Sartocon 2Plus holding device, three pressure indicators over pressure and dry running protection	400 V 50 Hz: 179SFG-0340 110 V 60 Hz: 179SFG-0311
Sartoflow Beta DL, Sartocon 2Plus holding device Three pressure transducers, two magnetic flow meters 21CFR Part 11 compliant digital data recorder	400 V 50 Hz: 179SFG-04-00-40 110 V 60 Hz: 179SFG-04-00-11
Sartoflow Beta sps, Sartoflow10 holding device Three pressure transducers, two magnetic flow meters Conductivity probe 21CFR Part11 compliant digital data recorder Feed and Retentate pressure control, predefined process steps	179sfg-08-02 400 V 50 Hz: 179SFG-08-02-40 110 V 60 Hz: 179SFG-08-02-11
Sartoflow Beta sps tank skid for automatic diafiltration with Sartoflow Beta sps Jacketed 40 I tank on movable skid, Level probe, Spray ball, Peristaltic pump	179SFZT-05

Complete  $IQ \mid QQ$  package and additional options on request

Available Sartocon® cassettes are described in Chapter "Crossflow Consumables" on page 127.







## Membrane Chromatography

Sartobind® re-usable	160
Sartobind® SingleSep	162

#### Sartobind® re-usable **Process Scale Membrane Adsorbers Ion Exchange**

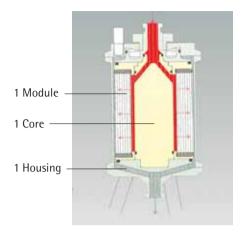




Sartobind re-usable is a membrane chromatography system for the purification of biomolecules in the pharmaceutical and biotech industry. The technology combines the advantages of conventional chromatography columns in terms of separation power and capacity with membrane technology regarding mass transfer, high throughput and robustness. Sartorius Membrane Adsorbers are used e.g. for the purification of therapeutic proteins, antibodies and viruses and for the removal of contaminants such as DNA. endotoxins, host cell proteins and viruses.

- Simple set up
- High chemical stability (regeneration in 1 N NaOH, storage 0.1 N NaOH)
- Robust: no trouble with air entrapment, channeling or bed cracking
- Membrane pore size of >3 μm allows separation of large biomolecules and
- Low set up and down times
- 20-100 times faster than conventional columns without sacrificing capacity
- Low cycle times = less product loss
- Reusable
- Validation and Extractables Guides available
- Scalable

#### For a complete re-usable system you need:



#### Related products for production

Sartobind SingleSep capsules Sartobind Epoxy re-usable Sartobind IDA re-usable Sartobind rProtein A re-usable Sartobind Aldehyde re-usable Sartobind re-usable plastic containers Sartobind MA units laboratory scale

Special catalogue for laboratory products available on request: Publication number: . S--0300-е

#### Technical data

Order No. modules	Order No. cores	Order No. housings*	Flow rate [I/min × 100 kPa]	protein	vol- ume
91-X-01K-15-03	90-CR-P015-03	90-HS-P003	0.4-0.6	0.7-1	35
91-X-02K-15-06	90-CR-P015-06	90-HS-P006	0.8-1.3	1.5-2	70
91-X-05K-15-12	90-CR-P015-12	90-HS-P012	1.7-2.6	3-4	140
91-X-10K-15-25	90-CR-P015-25	90-HS-P025	3.4-5.1	6-8	280
91-X-20K-15-50	90-CR-P015-50	90-HS-PO50	6.8-10	12-16	560
91-X-02K-30-03	90-CR-P030-03	90-HS-P003	0.2-0.3	1.5-2	72
91-X-05K-30-06	90-CR-P030-06	90-HS-P006	0.4-0.6	3-4	144
91-X-10K-30-12	90-CR-P030-12	90-HS-P012	0.8-1.1	6-8	288
91-X-20K-30-25	90-CR-P030-25	90-HS-P025	1.5-2.2	12-16	575
91-X-40K-30-50	90-CR-P030-50	90-HS-P050	3.0-4.5	24-32	1150
91-X-05K-60-03	90-CR-P060-03	90-HS-P003	0.08-0.12	3-4	133
91-X-10K-60-06	90-CR-P060-06	90-HS-P006	0.16-0.24	6-8	266
91-X-20K-60-12	90-CR-P060-12	90-HS-P012	0.3-0.5	12-16	533
91-X-40K-60-25	90-CR-P060-25	90-HS-P025	0.6-0.9	24-32	1065
91-X-80K-60-50	90-CR-P060-50  - Height of module	90-HS-PO50 in cm of layers 15 (4 mm)	1.3-1.9	48-64	2130
	60 (16 mm bed he	eight) on area in cm² × 10		11	

Minimum static binding capacity was measured with bovine serum albumin and lysozyme:  $0.6 \text{ mg/cm}^2$  for D = Diethylamine, C = Carboxylic acid, and  $0.8 \text{ mg/cm}^2$  for Q = Quaternary ammonium, S = Sulfonic acid and hen egg. For downscale trials use Sartobind MA 75.

<sup>\*</sup> Instead of PO (Polyoxymethylene) use SD when ordering stainless steel housings.

#### Sartobind® SingleSep



Sartobind SingleSep ion exchange capsules are designed to remove contaminants at accelerated flow rates. This is a direct result of negligible mass transfer effects and is made possible by the  $>3 \mu m$  microporous membrane. The design allows for robust chromatographic separations and drastically reduced validation costs. SingleSep capsules are used for DNA removal from therapeutic proteins, host cell protein removal and viral clearance.

- Ready-to-use format
- Simple and fast set up
- No trouble with air entrapment, channeling or bed cracking
- Membrane pore size of  $> 3 \mu m$  allows purification of large biomolecules and viruses
- Low unspecific adsorption = less product loss
- Reduced validation costs
- Autoclaving at 121°C for 30 min, one cycle

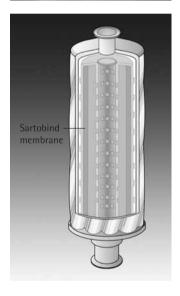


Sartobind SingleSep capsules are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. They have passed Plastic Class VI, particles and extractables test according to current United States Pharmacopoeia (USP) and are tested for protein binding capacity prior to release. Each package contains a certificate of quality.

#### **Related products**

Sartobind re-usable Sartobind MA units laboratory scale

Special catalogue for laboratory products available on request: Publication number S--0300-e



#### Membrane

Base material	Stabilized reinforced cellulose
Membrane thickness	275 μm
Membranes	– strong cation exchanger S (sulfonic acid) – strong anion exchanger $\Omega$ (quaternary ammonium)

#### Capsule

Design	cylindric, nominal number of layer: 15
Bed height	4 mm
Material Capsule	Polypropylene

#### Operation

Depyrogenation	1 N NaOH
Max. pressure	0.4 MPa (4 bar   58 psi)

#### Technical data

Order No. capsules	Description	Connector	Nominal protein binding capacity [g]	Bed volume [ml]	Quan- tity
92IEXQ42D4-00A	Sartobind Q SingleSep mini capsule	hose barb	0.2	7	4
92IEXS42D4-00A	Sartobind S SingleSep mini capsule	hose barb	0.2	7	4
92IEXQ42D4-SSA	Sartobind Q SingleSep mini capsule	sanitary	0.2	7	4
92IEXS42D4-SSA	Sartobind S SingleSep mini capsules	sanitary	0.2	7	4
92IEXQ42D9-00A	Sartobind Q SingleSep 5" capsules	hose barb	2	70	4
92IEXS42D9-00A	Sartobind S SingleSep 5" capsules	hose barb	2	70	4
92IEXQ42D9-SSA	Sartobind Q SingleSep 5" capsule	sanitary	2	70	4
92IEXS42D9-SSA	Sartobind S SingleSep 5" capsules	sanitary	2	70	4
92IEXQ42D1-SS	Sartobind Q SingleSep 10" capsule	sanitary	5.28	180	1
92IEXS42D1-SS	Sartobind S SingleSep 10" capsule	sanitary	5.28	180	1

Minimum static binding capacity was measured with bovine serum albumin and hen egg lysozyme: 0.8  $\rm mg/cm^2$  for Q and S membranes.



## Virus Filter

Virosart® CPV Capsules

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## Virosart® CPV Capsules The Parvo Virus Retentive PESU Filter Capsule for Biopharmaceutical Applications

#### Introduction

Virus filtration with Virosart® CPV is an integral part of the 3 step viral clearance technology platform of Sartorius featuring virus filtration, virus inactivation and virus adsorption. Virosart® CPV has been especially developed for the removal of relevant, as well as adventitious viruses from the biopharmaceutical feed stream.

#### **Applications**

Virosart® CPV is being used for effective virus retention in biopharmaceutical processes as follows:

- Upstream- & downstream processing of biotechnological feed streams
- Downstream processing of human and animal plasma derived feed streams

#### **Product benefits**

Virosart® CPV provides highest viral safety to your manufacturing process. Virosart® CPV retains more than 4 log of Parvoviruses and 6 log of Retroviruses. The PESU membrane of Virosart® CPV offers exceptional high flow rates and a maximum in capacity to speed up your virus filtration process and meet your economical expectations.

#### Filter area | Batch filtration

Virosart® CPV capsules height 9 feature 2.000 cm² effective filter area and thus offer massive flow rates to filter small batches from 10 liter to 100 liter in the shortest time possible. Smaller batch volumes from 1 liter to 10 liter are being filtered using Virosart CPV 180 cm² capsules.

#### Scalability

Consistent and predictable bench scale studies and spiking studies can reliably be performed using Virosart® CPV Minisart capsules (5 cm² filter area). Virosart® CPV 180 cm² capsules are being used for upscaling trial work and small scale manufacturing.

## Integrity testing & Bacteriophage retention

Virosart® CPV filters have been validated for 4 log removal of bacteriophage PP7. Correlation of IT test data & bacteriophage retention is demonstrated in the validation guide.

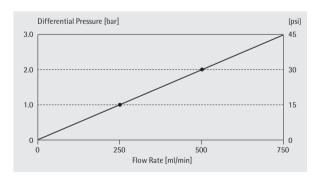
#### Quality control

Each individual element is tested for integrity by diffusion test prior to release assuring absolute reliability.

#### **Documentation**

Virosart® CPV filter elements are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for Virosart® CPV Standard Filter Cartridges & MaxiCaps®



Pore size

CPV (20 nm nominal)

Available sizes | Filtration area

Capsules

Size 9 0.2 m<sup>2</sup> | 2 ft<sup>2</sup>

Available connectors for Virosart® CPV capsule height 9

00 single stepped hose barb

inlet & outlet

FF 3/4" Tri-Clamp (Sanitary)

inlet & outlet

#### Extractables

Virosart® CPV filters meet or exceed the requirements for WFI quality standards set by the USP 26

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test Non-fiber releasing according to 21 CFR

#### Sterilization

#### Autoclaving

121°C @ 1 bar | 14.5 psi for 30 min No in-line steam sterilization of capsules!

#### **Technical references**

Validation Guide

- SPK5754-e05021 | 85030-522-02

#### Brochure

- SPK1509-e05021 | 85030-521-89

Virus Information Guide

- SPK5752-e05021 | 85030-521-91

#### Materials

Membrane	Double layer Polyethersulfone, symmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule housing	Polypropylene

#### **Operating parameters**

Max. allowable differential pressure	5 bar   58 psi at 20°C 2 bar   29 psi at 80°C
Max. allowable back pressure	2 bar   29 psi at 20°C

#### **Order information**

	Pore size	Pack size	Test pressure	Max. diffusion
5455328V9FFV	CPV (20 nm nom.)	2 capsules/ box	4.5 bar   65.2psi	10 ml/min/ capsule
5455328V900V	CPV (20 nm nom.)	2 capsules/ box	4.5 bar   65.2psi	10 ml/min/ capsule

#### Virosart® CPV The Parvo Virus Retentive PESU Filter for Biopharmaceutical Applications





Virus filtration with Virosart® CPV is an integral part of the 3 step viral clearance technology platform of Sartorius featuring virus filtration, virus inactivation and virus adsorption. Virosart® CPV has been especially developed for the removal of relevant, as well as adventitious viruses from the biopharmaceutical feed stream.

#### **Applications**

Virosart® CPV is being used for virus retention in biopharmaceutical processes as follows:

- Upstream- & downstream processing of biotechnological feed streams
- Downstream processing of human and animal plasma derived products

#### **Product benefits**

Virosart® CPV provides highest viral safety to your manufacturing process. Virosart® CPV retains more than 4 log of Parvo Viruses and 6 log of Retroviruses. The PESU membrane of Virosart® CPV features highest flow rates and maximum capacity to speed up your virus filtration process.

#### Scalability

Consistent and predictable bench scale- &t spiking studies can reliably be performed with Virosart® CPV Minisart (5 cm²) capsules. They feature the identical type of membrane as the process elements.

## Integrity testing & Bacteriophage retention

Virosart® CPV filters have been validated for 4 log removal of bacteriophage PP7. Correlation of IT test data & bacteriophage retention is demonstrated in the validation quide.

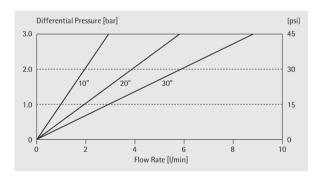
#### **Quality control**

Each individual element is tested for integrity by diffusion test prior to release assuring absolute reliability.

#### **Documentation**

Virosart® CPV filter elements are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for Virosart® CPV Standard Filter Cartridges & MaxiCaps®



#### Pore size

CPV (20 nm nominal)

#### Available sizes | Filtration area

#### Standard filter cartridges

Size 1	0.7 m <sup>2</sup> 7 ft <sup>2</sup>	
Size 2	1.4 m <sup>2</sup>   14 ft	
Size 3	2.1 m <sup>2</sup> 21 ft	2

#### **MaxiCaps**

Size 1	0.7 m <sup>2</sup>	7 ft <sup>2</sup>
Size 2	1.4 m <sup>2</sup>	14 ft <sup>2</sup>
Size 3	2.1 m <sup>2</sup>	21 ft <sup>2</sup>

#### **Available connectors**

Sanitary for MaxiCaps® & code 7 for cartridges

#### **Extractables**

Virosart® CPV filters meet, or exceed the requirements for WFI quality standards set by the USP 26

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

#### Sterilization

#### Steaming | Autoclaving

121°C @ 1 bar | 14.5 psi for 30 min

No in-line steam sterilization of MaxiCaps®

#### **Technical references**

Validation Guide

- SPK5754-e05021 | 85030-522-02

#### Brochure

- SPK1509-e05021 | 85030-521-89

#### Virus Information Guide

- SPK5752-e05021 | 85030-521-91

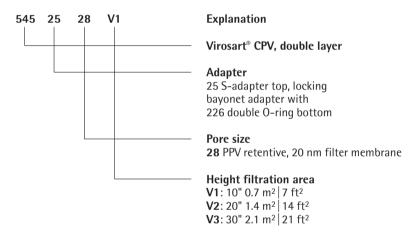
#### Materials

Membrane	Double layer Polyethersulfone, symmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule housing	Polypropylene

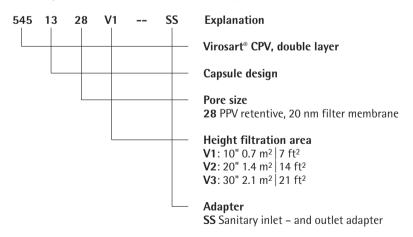
#### **Operating parameters**

Max. allowable differential pressure	5 bar   58 psi at 20°C 2 bar   29 psi at 80°C 1 bar   14.5 psi at 121°C
Max. allowable back pressure	2 bar   29 psi at 20°C 1 bar   14.5 psi at 100°C 0.5 bar   7 psi at 121°C

#### Ordering information Virosart® CPV standard filter cartridges



#### Ordering information Virosart® CPV MaxiCaps®





## Disposable Liquid Handling Systems

Biopharmaceutical Fluid Handling	172
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#### Integrated Solutions for Biopharmaceutical Fluid Handlingsm









Biopharmaceutical companies are confronted with ever changing and ever more complex challenges in the manufacturing of new drug products. Faced with growing demands on time to market, validation, security, capacity and under pressure to reduce capital spending, biopharmaceutical manufacturers can benefit greatly by using disposable manufacturing systems in many areas of the manufacturing process.

Disposable manufacturing in the biopharmaceutical industry requires innovative, integrated solutions for fluid handling and it is for this reason that Sartorius and TC-Tech have formalized a cooperation to create solutions based on these requirements and operating environments.

The combination of TC-Techs flexible biopharmaceutical bag container systems and the filtration expertise and validation services of Sartorius will help biopharmaceutical companies to address the key challenges in biopharmaceutical manufacturing: Time to Market, Production Efficiency, Cost of Goods, Process Security, Validation Complexity.

The integrated, fully scalable process solutions provided by Sartorius & TC Tech are designed for processing of a broad range of biopharmaceutical process fluids such as cell culture media (serum and non serum containing), buffers, intermediate and final products, cell harvest fluids, reagents and sanitizing agents. Biopharmaceutical companies will experience significant improvements in manufacturing performance by integration of single-use, disposable bag-container/filter assemblies.

Discover our value adding fluid processing solutions!

Feature	Benefits
Available from stock	Rapid delivery
Standard products	No lead time for custom design
Pre-assembled and pre-sterilized	Ready to use; eliminates risk of on-site connections
Wide variety of filter and bag sizes	Easy adaption to your process
Available from a single source	Reduction of lead times and procurement activities

#### Standard Disposable Systems for Biopharmaceutical Fluid Handling

The Sartorius | TC Tech alliance now enhances these benefits of the disposable Technology providing standard, pre-sterilized disposable systems to the biopharmaceutical industry. Standard filter and bag assemblies have been developed to help customers implement disposable technology faster and more economically.

Sartorius | TC Tech has developed two product lines of standard disposable filter and bag systems: Gammasart BioSystem™ SA and Gammasart BioSystem™ DF

Gammasart BioSystem™ SA and DF are standard items available from stock, eliminating lead times associated with the design and fabrication of custom designs. Furthermore, Gammasart BioSystem™ SA and DF are integrated systems that minimize installation time and operator errors. The wide variety of filter and bag sizes allows easy adaption to your process.

Gammasart BioSystem™ offers another important advantage for your entire process development: TC Tech Sterile Fluid Handling Bags and Sartorius Sartopore® 2 Gamma capsules ensure easy scale-up of your process from lab scale to production scale.

- TC Tech Sterile Fluid Handling Bags are characterized by a consistent LDPE fluid contact layer throughout the entire product range
- Sartopore® 2 Gamma capsules feature the same materials and type of construction from the smallest up to the largest filter element

#### Gammasart BioSystem SA™ Preassembled, Sterile Filter and Bag Assemblies



#### Description

The Gammasart BioSystem SA line of ready to use, preassembled sterile filter and bag assemblies is designed for sterilizing grade filtration, storage and transport of biopharmaceutical solutions. Each assembly incorporates a Sartopore 2 sterilizing grade filter capsule with broad chemical and pH compatibility, scaled to handle a wide range of biopharmaceutical products.

#### **Applications**

Typical applications include sterile filtration, storage and transport of:

- Cell Culture Media
- Buffers
- Bulk Harvest
- Intermediates
- WFI

#### Easy to use

Gammasart BioSystem SA's are delivered preassembled and sterile, ready for immediate use. There is no need for assembling individual components on site. Gammasart BioSystem SA's are integrated systems that minimize installation time and operator errors.

#### **Flexibility**

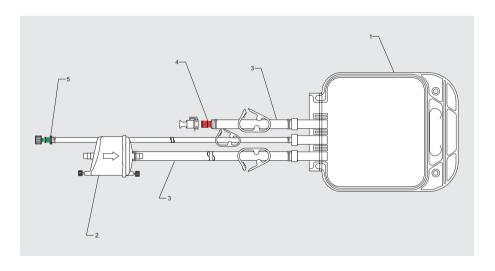
Gammasart BioSystem SA's are available in a variety of filter and bag sizes allowing easy adaption to process volume and media. Two different outlet connections are provided for flexible incorporation into your process. The quick disconnect can be attached directly or adapted to a variety of connections. The female luer fitting may be used for direct connection or sampling. A 36" length of heat weldable tubing is provided for use with a Sterile Connection Device (SCD).

#### Cost and risk reduction

Disposable bag assemblies incorporating filter capsules reduce the risk of cross contamination from batch-to-batch and product-to-product dramatically. Cost and time consuming CIP&tSIP operations are eliminated. This results in significant cost savings throughout the entire manufacturing process. Additionally, Gammsart BioSystem SA presterilized, preassembled single use Filter and Bag Assemblies eliminate the risk of on site aseptic connections.

#### Available from stock

Gammasart BioSystem SA's are standard products available from stock, avoiding lead times associated with the design and fabrication of custom designs.



Components	
Filter Capsule	Sartopore 2, 0.2 µm Sterilizing Grade Gamma Capsule
Bag Chamber	LDPE Fluid Contact Surface EVOH Gas Barrier Layer Nylon strength Layer
Tubing	C-Flex 082 Heat Sealable   Weldable
Outlet Fittings	Quick Disconnect Female Luer

Available sizes   Filter size			
1 Liter	Size 4, 150 cm <sup>2</sup>   .15 ft <sup>2</sup>		
2 Liter	Size 4, 150 cm <sup>2</sup>   .15 ft <sup>2</sup>		
5 Liter	Size 5, 300 cm <sup>2</sup>   .3 ft <sup>2</sup>		
10 Liter	Size 5, 300 cm <sup>2</sup>   .3 ft <sup>2</sup>		
20 Liter	Size 5, 300 cm <sup>2</sup>   .3 ft <sup>2</sup>		
50 Liter	Size 7, 500 cm <sup>2</sup>   1/2 ft <sup>2</sup>		
100 Liter	Size 8, 1000 cm <sup>2</sup>   1 ft <sup>2</sup>		
200 Liter	Size 8, 1000 cm <sup>2</sup>   1 ft <sup>2</sup>		

#### Extractables

Sartopore 2 γ Capsules meet or exceed the requirements for WFI quality standards set by the current USP.

## Sterilization

Presterilized by Gamma Irradiation

Regulatory compliance Filters Capsules: 100% Integrity Tested

Filter integrity test correlated to HIMA/ASTM F838-83 bacterial Challenge Test.

All materials Non-Pyrogenic according to USP Bacterial Endotoxins

All materials pass USP Class VI Test

Filter is non-fiber releasing according to 21 CFR

Assembly P/N	Description	Item 1 Bag chamber	Item 2 Bag port - Filter (Tubing length)	Item 3 Tubing	Item 4 Bag port 2 (Tubing length)	Item 5 Bag port 3	Case Oty
TC-145001	Gammasart BioSystem SA1	1 liter	5441307H4G-00, Sartopore 2 0.2 μm, 150 cm², Gamma Capsule (18")	C-Flex <sup>®</sup> Clear 082 1/4"×7/16"	QDC Insert with Cap (6")	36" SCD® Tubing w/ Female Luer & Plug	5
TC-145002	Gammasart BioSystem SA2	2 liter with Handle	5441307H4G-00, Sartopore 2 0.2 μm, 150 cm², Gamma Capsule (18")	C-Flex <sup>®</sup> Clear 082 3/8"×5/8"	QDC Insert with Cap (6")	36" SCD® Tubing w/ Female Luer & Plug	5
TC-145005	Gammasart BioSystem SA5	5 liter with Handle	5441307H5G-00, Sartopore 2 0.2 μm, 300 cm², Gamma Capsule (18")	C-Flex <sup>®</sup> Clear 082 3/8"×5/8"	QDC Insert with Cap (6")	36" SCD® Tubing w/ Female Luer & Plug	5
TC-145010	Gammasart BioSystem SA10		5441307H5G-00, Sartopore 2 0.2 μm, 300 cm², Gamma Capsule (18")	C-Flex <sup>®</sup> Clear 082 3/8" × 5/8"	QDC Insert with Cap (6")	36" SCD® Tubing w/ Female Luer & Plug	5
TC-145020	Gammasart BioSystem SA20		5441307H5G-00, Sartopore 2 0.2 μm, 300 cm², Gamma Capsule (18")	C-Flex <sup>®</sup> Clear 082 3/8"×5/8"	QDC Insert with Cap (6")	36" SCD® Tubing w/ Female Luer & Plug	5
TC-145050	Gammasart BioSystem SA50	50 liter	5441307H7G-SO, Sartopore 2 0.2 μm, 1/2 ft <sup>2</sup> Gamma Capsule (36")	C-Flex <sup>®</sup> Clear 082 1/2"×3/4"	QDC Insert with Cap (6")	36" SCD® Tubing w/ Female Luer & Plug	3
TC-145100	Gammasart BioSystem SA100	100 liter 0	5441307H8G-SO, Sartopore 2 0.2 μm, 1 ft <sup>2</sup> Gamma Capsule (36")	C-Flex <sup>®</sup> Clear 082 1/2"×3/4"	QDC Insert with Cap (6")	36" SCD® Tubing w/ Female Luer & Plug	3
TC-145200	Gammasart BioSystem SA200	200 liter O	5441307H8G-SO, Sartopore 2 0.2 µm, 1 ft <sup>2</sup> Gamma Capsule (36")	C-Flex® Clear 082 1/2" × 3/4"	QDC Insert with Cap (6")	36" SCD® Tubing w/ Female Luer & Plug	2

## Gammasart BioSystem™ DF – Preassembled Bag and Filter-Bag Systems for Concentration, Diafiltration and Aseptic Handling



#### Description

The Gammasart BioSystem™ DF line of ready-to-use, preassembled bag and filter-bag systems are designed for cycles in downstream processes. They are ideally suited to be connected to Sartorius Sartoflow Alpha and Sartoflow Beta crossflow systems. Two different sets have been developed to meet your needs:

#### 1. Aseptic handling set

Incorporate sterile fluid handling bags equipped with Sartopore® 2 sterilizing-grade filter capsules and a steam-through connection. The medium can be sterile filtered into the pre-sterilized bag and can be connected to existing aseptic recirculation tanks via a steam-through connection.

2. Concentration and diafiltration set Incorporate sterile fluid handling bags especially designed for Concentration and Diafiltration cycles in purification steps in biopharmaceutical processes. Also non-aspetic buffer preparation cycles can be ideally performed using Gammasart BioSystem™ DF. This provides the flexibility

#### **Applications**

The broad chemical and pH compatibility of Gammasart BioSystem™ DFs assure the handling of a wide range of biopharmaceutical fluids such as:

needed in advanced processes.

- Buffers
- Bulk harvest
- Intermediates

#### Easy to use

Gammasart BioSystem™ DFs for aseptic handling are delivered pre-assembled and sterile, and are ready-to-use. No assembly of individual components is needed. Gammasart BioSystem™ DFs are integrated systems that minimize installation time and operator errors.

#### **Flexibility**

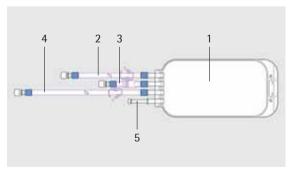
Gammasart BioSystem™ DFs incorporate a variety of bag and filter sizes. This allows easy adaptation to process volume and media. Tri-clamp connections (Concentration and Diafiltration set) and additionally a steam-through connection (Aseptic Handling Set) ensure convenient integration into existing processes.

#### Cost and risk reduction

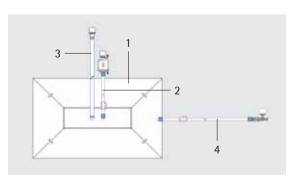
Disposable bag technology used in biopharmaceutical manufacturing, e.g. for recirculation and buffer preparation steps, reduces the risk of cross contamination from batch to batch and product to product dramatically. Costand time-consuming CIP & SIP operations are eliminated. This results in significant cost savings within the entire manufacturing process.

#### Validation

Sartorius | TC Tech has conducted extensive biological, chemical, and physical testing on its complete line of sterile fluid handling bags and filters. Sartorius | TC Tech makes this data available to customers in the form of Validation Guides. Availability of this data facilitates validation of filter and bag assemblies and reduces validation costs to pharmaceutical manufacturers.



Concentration and Diafiltration Set TC-143950



Aseptic Handling Set TC-143967

Components		Available bag sizes   filter sizes		Accessories	
Bag Chamber	Multiple Film Construc- tion, LDPE Fluid Contact Surface on All Bag Sizes	Concentration and Diafiltration Set 10-liter 20-liter 50-liter		Tanks TC-670015-H2.25 (50 L)	
Filter Capsule (Aseptic Handling Set)	Sartopore® 2, 0.2 µm Sterilizing-Grade Gamma Capsule	100-liter 200-liter 500-liter		TC-670030-H2.25 (100 L) TC-670055-H2.25 (200 L) TC-120000-H (Dolly w/Cutout)	
Tubing	C-Flex <sup>®</sup> Clear 082	Aseptic Handling Set  Volume Bag Filtration Area Filter Capsule  10-liter Size 7, 500 cm²   ½ ft²  20-liter Size 7, 500 cm²   ½ ft²		PolyTote	
Outlet Fittings	3/4" (11/2") Sanitary Fitting Steam-through Connector (Aseptic Handling Set)			TC-120500 (500 L PolyTote) TC-120501 (500 L SS Dolly)	
Aseptic Handling Set: Sterilization Concentration and Diafiltration Set:	Pre-sterilized by Gamma Irradiation non-sterile	50-liter 100-liter 200-liter 500-liter	Size 7, 500 cm <sup>2</sup>   ½ ft <sup>2</sup> Size 8, 1,000 cm <sup>2</sup>   1 ft <sup>2</sup> Size 8, 1,000 cm <sup>2</sup>   1 ft <sup>2</sup> Size 9, 2,000 cm <sup>2</sup>   2 ft <sup>2</sup>	TC-011033	

#### Concentration and Diafiltration Set

Assembly P/N	Item 1 Bag chamber	Item 2 Bag port 1 – Feed	Item 3 Bag port 2 – Diafiltration	Item 4 Bag port 3 – Retentate	Item 5 Bag port 4 – Septum
TC-143950 TC-143951 TC-143952	20-liter	1/2" × 3/4" C-Flex® Clear 082 Tubing, 50 cm Length, 3/4" Sanitary Fitting	1/2" × 3/4" C-Flex® Clear 082 Tubing, 15 cm Length, 3/4" Sanitary Fitting	1/2" × 3/4" C-Flex® Clear 082 Tubing, 100 cm Length, 3/4" Sanitary Fitting	Septum
TC-143960 TC-143961 TC-143962	200-liter	1"×13/8" C-Flex® Clear 082 Tubing, 50 cm Length, 11/2" Sanitary Fitting	1"×13/8" C-Flex® Clear 082 Tubing, 400 cm Length, 11/2" Sanitary Fitting	1"×1 <sup>3</sup> / <sub>8</sub> " C-Flex <sup>®</sup> Clear 082 Tubing, 200 cm Length, 1 <sup>1</sup> / <sub>2</sub> " Sanitary Fitting	

#### Asentic Handling Set

Aseptic Handling Set					
Assembly P/N	Item 1 Bag chamber	Item 2 Bag port 1 – Feed	Item 3 Bag port 2 – Retentate	Item 4 Bag port 3 – Optional	Item 5 Bag port 4 - Septum
TC-143955 TC-143956 TC-143957	20-liter	1/2" × 3/4" C-Flex® Clear 082 Tubing, 15 cm Length, Sartopore® 2 Gamma Filter Capsule 5441307H7G-S0	1/2" × 3/4" C-Flex® Clear 082 Tubing, 150 cm Length, SIP Connector 3/4" × 11/2" Sanitary Fitting	½" × ¾" C-Flex <sup>®</sup> Clear 082 Tubing, 15 cm Length	Septum
Assembly P/N	Item 1 Bag chamber	Item 2 Bag port 1 – Feed	Item 3 Bag port 2 – Retentate	Item 4 Bag port 3 – Aseptic connection to recirculation tank	
TC-143965 TC-143966 TC-143967	200-liter	1/2" × 3/4" C-Flex® Clear 082 Tubing, 50 cm Length, Sartopore® 2 Gamma Filter Capsule 5441307H8G-S0 Filter Capsule 5441307H9G-S0 (TC-143967)	1" × 13/8" C-Flex® Clear 082 Tubing, 200 cm Length, 11/2" Sanitary Fitting	1/2" × 3/4" C-Flex® Clear 082 Tubing, 400 cm Length, SIP Connector 11/2" Sanitary Fitting	

#### Sterile Fluid Handling Bags Standard Product Range 60 ml, 300 ml, 1 Liter, 2 Liter



- 1 liter standard
- 1 Port cover
- 2 QDC coupling insert
- 3 Septum injection port
- 4 Hanger port



- 2 liter SCD®
- 1 Tube ratchet clamp
- 2 Tubing for sterile welder

Our 60 ml – 2 liter sterile fluid handling bags are ideal for small volume bench-top work. Typical applications include specialty media dispensing and final product storage. Well suited for QC sampling in a manifold system. Hanger port facilitates complete drainage. May be frozen to –80°C. Consult TC Tech | Sartorius for recommendations on handling frozen bags.

#### **Specifications**

## Specifications for sterile fluid handling bags

#### 1 liter, 2 liter standard LDPE fluid contact surface Septum injection port 2 lines C-Flex® formulation 082 – 152.4 mm (6") length – 6.35 mm (1/4") ID 2 QDC coupling inserts

2 tube ratchet clamps

2 port covers

Provided sterile via 25 kGy – 40 kGy gamma Individually packaged

#### 1 liter, 2 liter SCD®

LDPE fluid contact surface
Septum injection port
1 line C-Flex® formulation 082 –
91.44 cm (3') length – 3.175 mm (1/8") ID
1 line C-Flex® formulation 082 –
152.4 mm (6") length – 6.35 mm (1/4") ID
1 QDC coupling insert
2 tube ratchet clamps
1 male luer with female luer plug
1 tube port cover
Provided sterile via 25 kGy – 40 kGy gamma
Individually packaged

#### **Options**

#### Fittings

QDC sealing cap QDC coupling body | sealing plug Sanitary fitting Male | female luer with plug Hose barb Female luer for syringe connection

#### **Tubing**

Platinum cured silicone Peroxide cured silicone PharMed® PVC C-Flex® formulation 001, 050, 072

#### Other

Sterilizing filter Manifold system

#### Order numbers for sterile fluid handling bags

Order number	Description	Quantity
TC-110050-AF	Storage bag, 60 ml standard*	50 per case
TC-110550-AF	Storage bag, 100 ml standard*	50 per case
TC-110650-AF	Storage bag, 250 ml standard*	50 per case
TC-110150-AF	Storage bag, 300 ml standard*	50 per case
TC-110125-AF	Storage bag, 1 liter standard*	25 per case
TC-111225-AF	Storage bag, 1 liter SCD	25 per case
TC-110225-AF	Storage bag, 2 liter standard	25 per case
TC-110425-AF	Storage bag, 2 liter SCD	25 per case

<sup>\*</sup> equipped with Male | Female Luer with plug

Call for custom design consultation.

#### Sterile Fluid Handling Bags Standard Product Range 5 Liter, 10 Liter, 20 Liter



10 liter Standard

- 1 QDC coupling insert
- 2 Port cover
- 3 Septum injection port



20 liter SCD®

- 1 Tubing for sterile welder
- 2 Tube ratchet clamp
- 3 Hanger port

The 5 liter, 10 liter, 20 liter sterile fluid handling bags accommodate fluid volumes commonly associated with bench-top and pilot plant work. Typical applications include buffer storage and harvest collection. Hanger ports facilitate complete drainage.

May be frozen to -80°C. Consult TC Tech | Sartorius for recommendations on handling frozen bags.

#### **Specifications**

## Specifications for sterile fluid handling bags

#### Standard

LDPE fluid contact surface
Septum injection port
1 line C-Flex® formulation 082 –
152.4 mm (6") Length – 6.35 mm (1/4") ID
1 line C-Flex® formulation 082 –
152.4 mm (6") Length – 9.525 mm (3/8") ID
2 QDC coupling inserts
2 tube ratchet clamps
2 port covers
Provided sterile via 25 kGy – 40 kGy Gamma: Individually packaged

#### SCD<sup>®</sup>

LDPE fluid contact surface
Septum injection port
1 line C-Flex® formulation 082 –
91.44 cm (3') Length – 3.175 mm (1/8") ID
1 line C-Flex® formulation 082 –
152.4 mm (6") Length – 9.525 mm (3/8") ID
1 QDC coupling insert
1 male Luer with female Luer plug
2 tube ratchet clamps
1 port cover
Provided sterile via 25 kGy – 40 kGy Gamma: Individually packaged

#### **Options**

#### **Fittings**

QDC sealing cap QDC coupling body | sealing plug Sanitary fitting Male | female Luer with plug Hose barb Female luer for syringe connection

#### **Tubing**

Platinum cured silicone Peroxide cured silicone PharMed® PVC C-Flex® formulation 001, 050, 072

#### Other

Sterilizing filter Manifold system Steam-in-Place bag connector

#### Order numbers for sterile fluid handling bags

Order number	Description	Quantity
TC-111320-AF	Storage bag, 5 liter standard	20 per case
TC-111420-AF	Storage bag, 5 liter SCD	20 per case
TC-112320-AF	Storage bag, 10 liter standard	20 per case
TC-112420-AF	Storage bag, 10 liter SCD	20 per case
TC-113315-AF	Storage bag, 20 liter standard	15 per case
TC-113415-AF	Storage bag, 20 liter SCD	15 per case

Call for custom design consultation.

#### Sterile Fluid Handling Bags 50 Liter, 100 Liter, 200 Liter, 300 Liter



200 liter standard

- 1 Port cover
- 2 QDC coupling insert
- 3 Tube ratchet clamp



200 liter standard in cylindrical tankDesigned to fit cylindrical tanks

Our 50 liter, 100 liter, 200 liter, 300 liter sterile fluid handling bags accommodate fluid volumes associated with pilot plant work and full scale production. Typical applications include media storage, buffer storage and purified water storage.

Standard bags are designed to fit in cylindrical tanks such as NALGENE® tanks. Custom configurations available to fit your existing container.

#### **Specifications**

## Specifications for sterile fluid handling bags

#### Standard

LDPE fluid contact surface
1 line C-Flex® formulation 082 –
91.44 cm (3') Length – 6.35 mm (1/4") ID
1 line C-Flex® formulation 082 –
91.44 cm (3') Length – 9.525 mm (3/8") ID
2 QDC coupling inserts
2 tube ratchet clamps
2 Port covers
Provided sterile via 25 kGy – 40 kGy Gamma
Individually packaged

#### SCD® (50 liter & 100 liter only)

LDPE fluid contact surface

1 line C-Flex® formulation 082 –
91.44 cm (3') Length – 3.175 mm (1/8") ID
1 line C-Flex® formulation 082 –
76.2 cm (2.5') Length – 6.35 mm (1/4") ID
1 QDC coupling insert
1 tube ratchet clamp
1 port cover
1 plug
Provided sterile via 25 kGy – 40 kGy Gamma
Individually packaged

#### **Options**

#### Fittings

QDC sealing cap
QDC coupling body | sealing plug
Sanitary fitting
Male | female Luer with plug
Hose barb
Female luer for syringe connection

#### Tubing

Platinum cured silicone Peroxide cured silicone PharMed® PVC C-Flex® formulation 001, 050, 072

#### Other

Sterilizing filter
Manifold system
Steam-in-place bag connector

#### Order numbers for sterile fluid handling bags

Order number	Description	Quantity
TC-114205-AF	Storage bag, 50 liter standard	5 per case
TC-114505-AF	Storage bag, 50 liter SCD	5 per case
TC-115205-AF	Storage bag, 100 liter standard	5 per case
TC-115505-AF	Storage bag, 100 liter SCD	5 per case
TC-116205-AF	Storage bag, 200 liter standard	5 per case

#### Call for custom design consultation.

NALGENE is a trademark of Nalge Nunc International

#### Sterile Fluid Handling Bags 500 Liter, 1000 Liter



500 liter standard in PolyTote

1 QDC coupling insert and coupling body allows for recirculation loop

2 Bottom drain line

The 500 liter and 1000 liter sterile fluid handling bags are designed to meet the demands of industrial volume filling, transport and storage. The unique design allows for easy placement in a PolyTote® container and filling with minimal bag adjustment. Bottom drain line facilitates complete fluid evacuation. Suitable for shipping via ground or sea.

#### **Specifications**

## Specifications for sterile fluid handling bags

# 500 liter & 1000 liter Standard 3 lines 12.7 mm (1/2") × 19.05 mm (3/4") platinum cured silicone Top lines 121.92 cm (4') in length Bottom line 243.84 cm (8') in length 1 QDC 12.7 mm (1/2") coupling body 1 QDC 12.7 mm (1/2") sealing plug 2 QDC 12.7 mm (1/2") coupling inserts 2 QDC 12.7 mm (1/2") sealing caps 3 tube ratchet clamps

Provided sterile via 25 kGy - 40 kGy Gamma

#### **Options**

#### Fittings 19.05 mm (3/4") mini sanitary fitting 25.4 mm (1") sanitary fitting Hose barb

# **Tubing**Peroxide cured silicone PharMed® PVC C-Flex® formulation 082 001, 050, 072 19.05 mm (3/4") ID fill line 19.05 mm (3/4") ID drain line

#### Other Sterilizing filter Steam-in-place bag connector

#### Order numbers for sterile fluid handling bags

Order number	Description	Quantity
TC-120555-AF	Storage bag, 500 liter standard	2 per case
TC-120565-AF	Storage bag, 1000 liter standard	Sold individually

Call for custom design consultation.

### **Tank Liners & Cylindrical Tanks**



100 liter tank with bottom drain bag



200 liter tank with liner

Tank Liners are designed to fit cylindrical tanks by Nalge Nunc International and others. The utilization of tank liners avoids costs associated with tank cleaning & cleaning validation. Additionally risks associated with cross-contamination are reduced and tank turnaround time is accelerated.

The tank liners are constructed of the same film materials used in sterile fluid handling bags thereby reducing validation costs. Cylindrical tanks offered are constructed of HDPE and include graduation markings in liters and gallons.

## **Specifications**

## Specifications for tank liners & cylindrical tanks 50 liter – 100 liter

#### **Tanks**

HDPE construction Gallon & liter calibrations HDPE cover

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50 liter	Dimensions	$33 \times 69 \text{ cm}$
100 liter	Dimensions	$46 \times 76 \text{ cm}$
200 liter	Dimensions	$56 \times 91$ cm
300 liter	Dimensions	$61 \times 122$ cm
400 liter	Dimensions	$71 \times 112$ cm
550 liter	Dimensions	$79 \times 124$ cm
750 liter	Dimensions	$91 \times 130$ cm

#### Liners

LDPE fluid contact surface Provided sterile via 25 kGy – 40 kGy Gamma Individually packaged

#### Options

PVDF tank construction PP tank construction Bottom drain port Standard dolly SS dolly

#### Order numbers for sterile fluid handling bags

Order number	Description	Quantity
TC-650510-AF	Tank liner, 50 liter	10 per case
TC-651010-AF	Tank liner, 100 liter	10 per case
TC-652005-AF	Tank liner, 200 liter	5 per case
TC-653005-AF	Tank liner, 300 liter	5 per case
TC-654005-AF	Tank liner, 400 liter	5 per case
TC-655005-AF	Tank liner, 500 liter	5 per case
TC-657575-AF	Tank liner, 750 liter	5 per case
TC-670015	Cylindrical tank, 50 liter, HDPE, with cover	Sold individually
TC-670030	Cylindrical tank, 100 liter, HDPE, with cover	Sold individually
TC-670055	Cylindrical tank, 200 liter, HDPE, with cover	Sold individually
TC-670080	Cylindrical tank, 300 liter, HDPE, with cover	Sold individually
TC-670100	Cylindrical tank, 400 liter, HDPE, with cover	Sold individually
TC-670150	Cylindrical tank, 500 liter, HDPE, with cover	Sold individually
TC-670200	Cylindrical tank, 750 liter, HDPE, with cover	Sold individually
TC-670015-H	Cylindrical tank with bottom drain port, 50 liter, HDPE, with cover	Sold individually
TC-670030-H	Cylindrical tank with bottom drain port, 100 liter, HDPE, with cover	Sold individually
TC-670055-H	Cylindrical tank with bottom drain port, 200 liter, HDPE, with cover	Sold individually
TC-670080-H	Cylindrical tank with bottom drain port, 300 liter, HDPE, with cover	Sold individually
TC-670100-H	Cylindrical tank with bottom drain port, 400 liter, HDPE, with cover	Sold individually

# PolyTote® Container System for 500 Liter, 1000 Liter Standard Bags



- 1 Folding side panels removable end panels for easy storage
- 2 Easy access for fill preparation
- 3 Designed for partial fill with one panel removed



- 1 Complete fill with minimal bag adjustment
- 2 Secure tubing storage
- 3 Shipping stacking cover in place

Our 500 liter and 1000 liter PolyTote containers are designed to meet the demands of industrial filling, transport and storage. Used in conjunction with the fluid handling bags these containers optimize handling of biopharmaceutical processing fluids. With features such as a sloped floor for efficient drainage, removable end panels for easy fill preparation, and a secure tube storage area to protect bottom drain assembly, the PolyTote container provides for hassle-free operation.

The PolyTote container also maximizes utilization of valuable floor space as it is stackable 3 units high full and 5 units high empty. Suitable for shipping via ground or sea. Collapsible upon return.

### **Specifications**

## Specifications for 500 liter & 1000 liter PolyTote

#### 500 liter & 1000 liter PolyTote

HDPE construction
Stackable 3 high full
Stackable 5 high empty
Bottom drain
Sloped floor
Tube & fitting storage area w/ security cover
Collapsing side panels
Removable end panels
Shipping cover
Autoclavable

#### 500 liter

91.44 cm (36")×126.37 cm (49 3/4")× 83.82 cm (33") [W×L×H] 103 kg (227 lb) tare weight 579 kg (1276 lb) capacity

#### 1000 liter

91.44 cm (36")×126.37 cm (49 3/4")× 134.62 cm (53") [W×L×H] 165 kg (364 lb) tare weight 1197 kg (2640 lb) capacity

#### Dolly

304 L stainless steel Electro polished 25 kg (55 lb) weight 1197 kg (2640 lb) capacity Clean room wheels

#### Order numbers

Order number	Description	Quantity
TC-120500	500 liter PolyTote container	Sold individually
TC-121000	1000 liter PolyTote container	Sold individually
TC-120501	500 liter PolyTote Dolly	Sold individually
TC-121001	1000 liter PolyTote Dolly	Sold individually

# LevTech Disposable Mixing System



Replace stainless steel mixing tanks LevTech mixing system



1 Magnetic levitation & coupling2 HDPE impeller (pictured outside bag)



LevTech core technology (exploded view)

- 1 Single-use bag
- 2 Bag interface plate with alignment post
- 3 Thermal separation
- 4 Superconductor

#### Description

The LevTech system is a unique, innovative disposable mixing system using patented LevTech mixing technology. For the first time the efficiency and speed of traditional mixing can be achieved in single-use bags avoiding extensive cleaning validation.

#### Operation principle

The LevTech Mixing System utilizes patended superconductor technology to levitate and drive a single-use impeller inside sterile disposable fluid handling bags. When aligned with the specially designed impeller, the drive unit causes the impeller to levitate and lock in position. A variable speed controller allows the impeller to be run at the desired speed.

#### **Applications**

The LevTech drive delivers strong torque for efficient mixing of most biopharmaceutical solutions. Typical applications include:

- Liquid Liquid Mixing
- Powder Liquid Mixing
- Buffer & Media Preparation
- Product Formulation | Reformulation
- Viral Inactivation
- Bulk Intermediate Resuspension
- Final Bulk Storage, Shipping and Mixing

#### **Flexibility**

The LevTech drive unit operates independently of the tank, dolly and bag so that a single drive unit can serve multiple tanks of different sizes. Jacketed tanks are available in order to control the temperature inside the bag. Standardized tanks and bags are available in sizes between 50 L and 500 L. Mixing bags may be readily customized to optimise the integration into specific processes. Expert design service is available on-site through Sartorius | TC Tech experts on a worldwide basis.

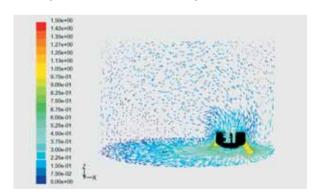
#### **CE** compliance

The LevTech Mixing System has been extensively tested according to the ISO/IEC Guide 22. The unit is in effective conformance to the respective guidelines. A certificate is available upon request.

#### **Impeller**



#### Velocity Vectors in Gammasart BioSystem MX



Velocity vectors in the in LevTech DB-200E disposable mixing bag with levitating impeller running at 170 RPM. Vectors are colored by magnitude (m/s.)

### **Drive unit specifications**

Power	Single Phase 230 V, 3 A, 50/60 Hz
Input Wattage	<350 Watts
Footprint	37 inches×16 inches (94 cm×41 cm)
Height (Handle)	31 inches (79 cm)
Weight	103 lb (47 kg)
Ambient temperature	4° to 30°C
Ambient Humidity	Less than 75%
Mobility	Mounted on Stainless Steel Cart with Four Clean Room Wheels and Push Handles
IP Rating	IP23
Impeller Speed	0-180 RPM
Initial Set-up Time	45 Minutes
Vessel Changeover Time	<7 Minutes
CE Mark	Compliant
Material for External Surfaces	Stainless Steel #316

## **Dolly specifications**

Material	Stainless Steel #316
Finish	Bead Blasting
Wheels	Clean Room Wheels
Dimensions	34 inches (86 cm) W× 40 inches (101 cm) L× 36 inches (94.5 cm) H
Load Capacity	1,250 lb (570 kg)
Weight	80 lb (36.5 kg)

## Ordering information

Part number Hardware	Description
LT-DBMC010	Superconducting drive machine with European certification on cart. Control panel (220V) and lifting mechanism on handle and welded body. Includes tool kit with accessories
LT-DBMC022	Superconducting drive machine with European certification and UK plug on cart. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories
LT-DBMC015	Upgraded elevated stainless steel 316 dolly on clean room wheels, with push handle and guide rail for drive positioning and lifting.
LT-DBMC021	Upgraded elevated stainless steel 316 dolly on clean room wheels, with push handle and guide rail for drive positioning and lifting – polished to 180 grit.
LT-DBMC030	30 liter rotationally molded retaining MDPE plastic tank
LT-DBMC050	50 liter rotationally molded retaining MDPE plastic tank
LT-DBMC100	100 liter rotationally molded retaining MDPE plastic tank
LT-DBMC200	200 liter rotationally molded retaining MDPE plastic tank
LT-DBMC250	250 liter rotationally molded retaining MDPE plastic tank
LT-DBMC300	300 liter rotationally molded retaining MDPE plastic tank
LT-DBMC350	350 liter rotationally molded retaining MDPE plastic tank
LT-DBMC500 two-part constru	500 liter rotationally molded retaining MDPE plastic tank with action
LT-DBCl001	Magnetic charger with bearing
LT-DBAK004	Testing Impeller

## LevTech disposable bags Standard configuration

TC-159513-AF	50 L Gammasart BioSystem™ MX, STD, 3 Ports, w/Drain
TC-159514-AF	100 L Gammasart BioSystem™ MX, STD, 3 Ports, w/Drain
TC-159515-AF	200 L Gammasart BioSystem™ MX, STD, 3 Ports, w/Drain
TC-159517-AF	300 L Gammasart BioSystem™ MX, STD, 3 Ports, w/Drain
TC-159518-AF	350 L Gammasart BioSystem™ MX, STD, 3 Ports, w/Drain
TC-159519-AF	500 L Gammasart BioSystem™ MX, STD, 3 Ports, w/Drain

# IFS4 Stainless Steel Weighing Platforms for LevTech Sanitary Mixing System







#### Description

The IF series represents a new generation of industry weighing technology, from 5 g to 3,000 kg, from basic weighing to convenient, application-oriented weighing systems. IF S4 Flat Bed Scales from Sartorius are ideally suited to be used in conjunction with the LevTech Sanitary Mixing System.

#### **Applications**

IF S4 Flat Bed Scales are used for level control and level management in typical mixing applications in the biopharmaceutical industry:

Liquid - Liquid Mixing:

- Final Formulation
- Intermediate pH Adjustment
- Bulk Intermediate Suspension | Resuspension
- Ultrafiltration | Diafiltration Retentate
- Viral Inactivation

Powder - Liquid Mixing

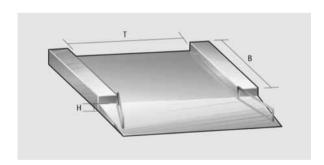
- Excipient Preparation
- Buffer Preparation
- Media Preparation

#### **Accuracy**

The IF weighbridges are designed as flat-bed scales using strain-gauge technology, with capacities of 600 kg, 1,500 kg, 3,000 kg and a resolution of 30,000 digits for non-legal-for-trade applications and 1×3,000 digits (single-range) or 2×3,000 e (multiple-range) for Accuracy Class III applications.

#### Easy to clean

On IF scales, the surface roughness of parts that have contact with the product, such as the load plate, is well below EHEDG recommendations. The surface is completely smooth, making it easy to clean. Because there are no moving parts on the IF scale, it can be used in cleanrooms rated to class 10,000 in accordance with US Federal Standard 209 D (equivalent to Class C in accordance with EEC-GMP).



Stainless steel
(304/316)
Bead blasting   eletro-polishing
using metal sheets with pressed edges; i.e., no welded seams
sinfect
300 kg, 600 kg, 1,000 kg 1,500 kg
3,000 d, 15,000 d
800×800 mm
$1,040 \times 800$ mm without ramp; $1,040 \times 1,150$ mm with ramp
1,000×1,000 mm
$1,240 \times 1,000$ mm without ramp; $1,240 \times 1,350$ mm with ramp
35 mm/Optional 25 mm
includes in delivery package
secure access to platform
Stop bar
Lifting device by gas springs (Pharmaline version)
6 m

## Ordering information

## 1. Part: Selection of the platform

Order number	Weighing capacity			,	9	Platform dimensions B×T in mm	Material load plate and frame	•
IFS4-300II	300 kg	20	10	100	50/100	800×800	St. steel	6 m
IFS4-300LL	300 kg	20	10	100	50/100	1,000×1,000	St. steel	6 m
IFS4-600II	600 kg	50	20	200	100/200	800×800	St. steel	6 m
IFS4-600LL	600 kg	50	20	200	100/200	1,000×1,000	St. steel	6 m
IFS4-1000II	1,000 kg	100	50	500	200/500	800×800	St. steel	6 m
IFS4-1000LL	1,000 kg	100	50	500	200/500	1,000×1,000	St. steel	6 m
IFS4-1500II	1,500 kg	100	50	500	200/500	800×800	St. steel	6 m
IFS4-1500LL	. 1,500 kg	100	50	500	200/500	1,000×1,000	St. steel	6 m

## 2nd Part: Selection of the readability

-NCE	Readability 2×3,000 e
-LCE	Readability 3,000 e
-1	Readability 30,000 d
-L	Readability 15,000 d

## 3rd Part: Options: IFS4 stainless steel platforms

	Option	Platform dimensi	ions B×T in mm
		II	LL
		$800\!\times\!800$	1,000×1,000
Optional height 25 mm (st	andard =	35 mm) for weigh	ing capacities
300 kg	V1	•	•
600 kg	V1	•	•
1,000 kg	V1	•	•
1,500 kg	V1	•	
Optional height 35 mm (st	andard =	45 mm) for weigh	ing 4 capacities
300 kg	V2		
600 kg	V2		
	1.70		
1,000 kg	V2		
1,500 kg  AISI 304, 2B cold-rolled st	V2 eel & gla	ss bead-blasted	•
1,500 kg  AISI 304, 2B cold-rolled st For all weighing capacities:  AISI 316 Ti, 2B cold-rolled	V2 reel & gla R6 steel	ss bead-blasted	•
1,000 kg 1,500 kg  AISI 304, 2B cold-rolled st For all weighing capacities:  AISI 316 Ti, 2B cold-rolled For all weighing capacities:	V2 reel & gla R6 steel	ss bead-blasted •	•
1,500 kg  AISI 304, 2B cold-rolled st For all weighing capacities:  AISI 316 Ti, 2B cold-rolled For all weighing capacities:  Others	V2 teel & gla R6 steel R2	ss bead-blasted	•
1,500 kg  AISI 304, 2B cold-rolled st For all weighing capacities:  AISI 316 Ti, 2B cold-rolled For all weighing capacities:  Others Stop bar	V2 reel & gla R6 steel	ss bead-blasted  •	•
1,500 kg  AISI 304, 2B cold-rolled st For all weighing capacities:  AISI 316 Ti, 2B cold-rolled For all weighing capacities:  Others Stop bar Operation in zone 2	V2 teel & gla R6 steel R2	ss bead-blasted  •	•
1,500 kg  AISI 304, 2B cold-rolled st For all weighing capacities:  AISI 316 Ti, 2B cold-rolled For all weighing capacities:  Others Stop bar Operation in zone 2 and 22 hazardous areas	V2 teel & gla R6 steel R2	ss bead-blasted  •	•
1,500 kg  AISI 304, 2B cold-rolled st For all weighing capacities:  AISI 316 Ti, 2B cold-rolled For all weighing capacities:  Others Stop bar Operation in zone 2 and 22 hazardous areas (ATEX marking:	V2 reel & gla R6 steel R2	ss bead-blasted	•
1,500 kg  AISI 304, 2B cold-rolled st For all weighing capacities:  AISI 316 Ti, 2B cold-rolled For all weighing capacities:  Others Stop bar Operation in zone 2 and 22 hazardous areas (ATEX marking: II 3 GD Eex nR II T6 T80°C)	V2 teel & gla R6 steel R2	ss bead-blasted  •	•
1,500 kg  AISI 304, 2B cold-rolled st For all weighing capacities:  AISI 316 Ti, 2B cold-rolled For all weighing capacities:  Others Stop bar Operation in zone 2 and 22 hazardous areas (ATEX marking:	V2 reel & gla R6 steel R2	ss bead-blasted  •  •	•

### **Connectors & Accessories**

## Quick disconnect Sanitary Luer Accessories Accessories QDC coupling insert BarbLock™ ultra-secure Tygopure<sup>™</sup> sanitary fitting Male luer Tube ratchet clamp tubing retainer QDC sealing cap 19.05 mm (3/4") Female luer plug Port cover Filter mini sanitary fitting QDC coupling body 38.1 mm (1.5") sanitary fitting Female luer Magnetic stir bar T Connector QDC sealing plug 25.4 mm (1") Reducer Male luer plug Y Connector C-Flex molded sanitary end QDC 19.05 mm (3/4") 19.05 mm (3/4") Injection port Bio clamp silicone molded sanitary end coupling body The following Connectors & Accessories are pictured to assist with bag design and are not generally offered for stand-alone sale: – All luer fittings - All tubing with molded sanitary ends - Tube ratchet clamps



QDC 19.05 mm (3/4") coupling insert



25.4 mm (1") silicone molded sanitary end

- Port covers
- Magnetic stir bars
- T Connectors
- Injection ports

Contact TC Tech | Sartorius for BarbLock ordering information.

## **Specifications & Order Information**

## Quick disconnect fittings

## QDC coupling insert

Order number	Description	Quantity
TC-214200-G	QDC, 6.35 mm (1/4") coupling insert, polycarboriate	25 per case
TC-214300-G	QDC, 9.525 mm (3/8") coupling insert, polycarbonate	25 per case
TC-214400-G	QDC, 12.7 mm (1/2") coupling insert, polycarbonate	25 per case
TC-214500-G	QDC, 9.525 mm (3/8") coupling flow insert, polycarbonate	25 per case
TC-215200-G	QDC, 6.35 mm (1/4") coupling insert, polysulfone	25 per case
TC-215300-G	QDC, 9.525 mm (3/8") coupling insert, polysulfone	25 per case
TC-215400-G	QDC, 9.525 mm (3/8") flow coupling insert, polysulfone	25 per case
TC-216500-G	QDC, 12.7 mm (1/2") coupling insert, polysulfone	25 per case

## QDC sealing caps

Order number	Description	Quantity
TC-216200-G	QDC, 6.35 mm (1/4") & 9.525 mm (3/8") sealing cap w/ lock, Polycarb	25 per case
TC-216300-G	QDC, 6.35 mm (1/4") & 9.525 mm (3/8") sealing cap, polycarbonate	25 per case
TC-216400-G	QDC, 12.7 mm (1/2") sealing cap, polycarbonate	25 per case
TC-216600-G	QDC, 12.7 mm (1/2") sealing cap, polycarbonate	25 per case
TC-216700-G	QDC, 6.35 mm (1/4") & 9.525 mm (3/8") sealing cap, polysulfone	25 per case
TC-216800-G	QDC, 12.7 mm (1/2") sealing cap, polysulfone	25 per case

## QDC coupling body

Order number	Description	Quantity
TC-211200-G	QDC, 6.35 mm (1/4") coupling body, polycarbonate	25 per case
TC-211300-G	QDC, 9.525 mm (3/8") coupling body, polycarbonate	25 per case
TC-211400-G	QDC, 12.7 mm (1/2") coupling body, polycarbonate	25 per case
TC-211500-G	QDC, 12.7 mm (1/2") coupling body, w/ lock, Polycarb	25 per case
TC-212200-G	QDC, 6.35 mm (1/4") coupling body, polysulfone	25 per case
TC-212300-G	QDC, 9.525 mm (3/8") coupling body, polysulfone	25 per case
TC-212400-G	QDC, 9.525 mm (3/8") coupling body, w/ lock, polysulfone	25 per case
TC-212500-G	QDC, 12.7 mm (1/2") coupling body, polysulfone	25 per case
TC-212600-G	QDC, 6.35 mm (1/4") coupling body, w/ lock, polysulfone	25 per case

## QDC sealing plug

Order number	Description	Quantity
TC-217300-G	QDC, 6.35 mm (1/4") & 9.525 mm (3/8") sealing plug, polycarbonate	25 per case
TC-217400-G	QDC, 12.7 mm (1/2") sealing plug, polycarbonate	25 per case
TC-217600-G	QDC, 6.35 mm (1/4") & 9.525 mm (3/8") sealing plug, polysulfone	25 per case
TC-217700-G	QDC, 12.7 mm (1/2") sealing plug, polysulfone	25 per case

## QDC 3/4" components

Order number	Description	Quantity
TC-219100-D	QDC, 19.05 mm (3/4") coupling body, polysulfone	10 per case
TC-219200-D	QDC, 19.05 mm (3/4") coupling insert, polysulfone	10 per case
TC-219300-D	QDC, 19.05 mm (3/4") sealing plug, polysulfone	10 per case
TC-219400-D	QDC, 19.05 mm (3/4") sealing cap, polysulfone	10 per case

### Bio clamp

Order number	Description	Quantity
TC-540075-D	19.05 mm (3/4") sanitary clamp, nylon   fiberglass	10 per case
TC-540150-D	38.1 mm (1.5") sanitary clamp, nylon   fiberglass	10 per case

## Sanitary fittings

## Tygopure® 3/4" mini sanitary fitting

Order number	Description	Quantity
TC-4925PP-D	Tygopure, 6.35 mm (1/4") barb, polypropylene	10 per case
TC-4925PS-D	Tygopure, 6.35 mm (1/4") barb, polysulfone	10 per case
TC-4937PP-D	Tygopure, 9.525 mm (3/8") barb, polypropylene	10 per case
TC-4937P5-D	Tygopure, 9.525 mm (3/8") barb, polysulfone	10 per case
TC-4950PP-D	Tygopure, 12.7 mm (1/2") barb, polypropylene	10 per case
TC-4950PS-D	Tygopure, 12.7 mm (1/2") barb, polysulfone	10 per case
TC-49005G-D	Tygopure silicone gasket	10 per case

## 3/4", 1", 1.5" polypropylene sanitary fitting

Order number	Description	Quantity
TC-540101-D	mini sanitary, 3.175 mm (1/8") HB	10 per case
TC-540301-D	mini sanitary, 6.35 mm (1/4") HB	10 per case
TC-540401-D	mini sanitary, 9.525 mm (3/8") HB	10 per case
TC-540501-D	mini sanitary, 12.7 mm (1/2") HB	10 per case
TC-540601-D	mini sanitary, 15.875 (5/8") mm HB	10 per case
TC-540701-D	mini sanitary, 19.05 mm (3/4") HB	10 per case
TC-540102-D	1" sanitary, 3.175 mm (1/8") HB	10 per case
TC-540302-D	1" sanitary, 6.35 mm (1/4") HB	10 per case
TC-540402-D	1" sanitary, 9.525 mm (3/8") HB	10 per case
TC-540502-D	1" sanitary, 12.7 mm (1/2") HB	10 per case
TC-540702-D	1" sanitary, 19.05 mm (3/4") HB	10 per case
TC-540802-D	1" sanitary, 25.4 mm (1") HB	10 per case
TC-540103-D	1.5" sanitary, 3.175 mm (1/8") HB	10 per case
TC-540303-D	1.5" sanitary, 6.35 mm (1/4") HB	10 per case
TC-540403-D	1.5" sanitary, 9.525 mm (3/8") HB	10 per case
TC-540503-D	1.5" sanitary, 12.7 mm (1/2") HB	10 per case
TC-540703-D	1.5" sanitary, 19.05 mm (3/4") HB	10 per case
TC-540803-D	1.5" sanitary, 25.4 mm (1") HB	10 per case

## Polycarbonate reducers, connectors, Y connectors

Order number	Description	Quantity
TC-230300-G	Connector, 4.763 mm (3/16") × 6.35 mm (1/4")	25 per case
TC-230400-G	Connector, 6.35 mm (1/4") × 6.35 mm (1/4")	25 per case
TC-230500-G	Connector, 6.35 mm (1/4") × 9.525 mm (3/8")	25 per case
TC-230600-G	Connector, 6.35 mm (1/4") × 12.7 mm (1/2")	25 per case
TC-230700-G	Connector, 9.525 mm (3/8") × 9.525 mm (3/8")	25 per case
TC-230800-G	Connector, 12.7 mm (1/2") × 9.525 mm (3/8")	25 per case
TC-230900-G	Connector, 9.525 mm (3/8") × 15.875 mm (5/8")	25 per case
TC-231000-G	Connector, 12.7 mm (1/2") × 12.7 mm (1/2")	25 per case
TC-231100-G	Connector, 4.763 mm (3/16") × 4.763 mm (3/16") w/ luer	25 per case
TC-231200-G	Connector, 4.763 mm (3/16") × 6.35 mm (1/4") w/ luer	25 per case
TC-231300-G	Connector, 6.35 mm (1/4") $\times$ 6.35 mm (1/4") w/ luer	25 per case
TC-231400-G	Connector, 6.35 mm (1/4") × 9.525 mm (3/8") w/ luer	25 per case
TC-231500-G	Connector, 9.525 mm (3/8") × 9.525 mm (3/8") w/ luer	25 per case
TC-231600-G	Connector, 12.7 mm (1/2") × 12.7 mm (1/2") w/ luer	25 per case
TC-231700-G	Y connector, 4.763 mm (3/16") all	25 per case
TC-231800-G	Y connector, 6.35 mm (1/4") all	25 per case
TC-231900-G	Y connector, 9.525 mm (3/8") $\times$ 6.35 mm (1/4") $\times$ 6.35 mm (1/4")	25 per case
TC-232000-G	Y connector, 9.525 mm (3/8") × 9.525 mm (3/8") × 6.35 mm (1/4")	25 per case
TC-232100-G	Y connector, 9.525 mm (3/8") all	25 per case
TC-232200-G	Y connector, 12.7 mm (1/2") × 9.525 mm (3/8") × 9.525 mm (3/8")	25 per case
TC-232300-G	Y connector, 12.7 mm (1/2") all	25 per case
TC-232400-G	Y connector, 4.763 mm (3/16") all w/ luer	25 per case
TC-232500-G	Y connector, 6.35 mm (1/4") all w/ luer	25 per case
TC-232600-G	Y connector, 9.525 mm (3/8") all w/ luer	25 per case

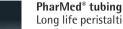
### **Pharmaceutical Grade Tubing**



Tygon® silicone tubing, formulation 3350

Tygon® silicone tubing, formulation 3350 Platinum cured silicone tubing with ultrasmooth inner bore to reduce potential for particle entrapment. Fully characterized in accordance with USP 24 and ISO 10993

guidelines. Extensive lot-to-lot biological and chemical testing ensures purity for critical applications. Shore A, 50.



Long life peristaltic pump tubing with low particulate generation. Can be repeatedly autoclaved. Opaque to visible and UV light for sensitive fluid protection. Fully characterized

in accordance with USP and ISO 10993 guidelines. Shore A, 64.





C-Flex® tubing, clear formulation 082, 050

**C-Flex**® **tubing, clear formulation 082, 050** Clear thermoplastic elastomer tubing that is

heat sealable and bondable. Low protein binding minimizes potential for active ingredient loss. Low gas permeability helps

maintain pH. Fully characterized in accordance with USP 24 guidelines. Formulation 082, Shore A, 60. Formulation 050, Shore A, 50.



C-Flex® tubing, clear formulation 072, 001

C-Flex® tubing, clear formulation 072, 001

Opaque thermoplastic elastomer tubing that is heat sealable and bondable with long peristaltic pump life. Low protein binding minimizes potential for active ingredient loss.

Fully characterized in accordance with USP 24 guidelines. Formulation 072, Shore A, 60. Formulation 001, Shore A, 50.



Platinum cured silicone tubing

Platinum cured silicone tubing

Platinum cured silicone tubing for use throughout the biopharmaceutical

manufacturing process. Meets USP <88> Class 6 criteria. Shore A, 50.



Peroxide cured silicone tubing

Peroxide cured silicone tubing

Peroxide cured silicone tubing with ultrasmooth inner bore. Exceptional resiliency and durability. Meets USP <88> Class 6 criteria. Shore A, 50.



Tygon® silicone tubing, formulation 3370

**Tygon® silicone tubing, formulation 3370** Platinum cured silicone tubing with braid

Platinum cured silicone tubing with braid reinforcement for increased pressure resistance. Withstands repeated CIP and

SIP sterilization cycles. Excellent bend radius. Shore A, 70.



"Y" Elements for peristaltic pumps

### "Y" Elements for peristaltic pumps

TC Tech | Sartorius "Y" elements are designed for use in Watson Marlow® 505 L & 605 L peristaltic pump heads. "Y" elements are constructed of platinum cured silicone tubing and polypropylene fittings. Individually packaged. May be sterilized by steam or gamma radiation.



Tubing on spools

Tubing on spools

TC Tech | Sartorius offers a variety of tubing products on spools. Spools allow for easy dispensing and reduced scrap. Contact

TC Tech | Sartorius for additional products or sizes on spools.

## Order information for tubing

Tygon® silicone tubing, formulation 3350

Order number	Description   ID   OD	Quantity per roll
TC-490150	Tubing, silicone 3350, 0.794 mm (1/32") × 2.381 mm (3/32")	15.24 m (50 ft)
TC-490250	Tubing, silicone 3350, 1.588 mm (1/16") × 3.175 mm (1/8")	15.24 m (50 ft)
TC-490350	Tubing, silicone 3350, 1.588 mm (1/16") × 4.763 mm (3/16")	15.24 m (50 ft)
TC-490450	Tubing, silicone 3350, 2.381 mm (3/32") × 3.969 mm (5/32")	15.24 m (50 ft)
TC-490550	Tubing, silicone 3350, 2.381 mm (3/32") × 5.556 mm (7/32")	15.24 m (50 ft)
TC-490650	Tubing, silicone 3350, 3.175 mm (1/8") × 4.763 mm (3/16")	15.24 m (50 ft)
TC-490750	Tubing, silicone 3350, 3.175 mm (1/8") × 6.35 mm (1/4")	15.24 m (50 ft)
TC-490950	Tubing, silicone 3350, 3.969 mm (5/32") × 5.556 mm (7/32")	15.24 m (50 ft)
TC-491150	Tubing, silicone 3350, 4.763 mm (3/16") × 6.35 mm (1/4")	15.24 m (50 ft)
TC-491250	Tubing, silicone 3350, 4.763 mm (3/16") × 7.938 mm (5/16")	15.24 m (50 ft)
TC-491350	Tubing, silicone 3350, 4.763 mm (3/16") × 9.525 mm (3/8")	15.24 m (50 ft)
TC-491450	Tubing, silicone 3350, 4.763 mm (3/16") × 11.113 mm (7/16")	15.24 m (50 ft)
TC-491650	Tubing, silicone 3350, 6.35 mm (1/4") × 7.938 mm (5/16")	15.24 m (50 ft)
TC-491750	Tubing, silicone 3350, 6.35 mm (1/4") × 9.525 mm (3/8")	15.24 m (50 ft)
TC-491850	Tubing, silicone 3350, 6.35 mm (1/4") × 11.113 mm (7/16")	15.24 m (50 ft)
TC-491950	Tubing, silicone 3350, 6.35 mm (1/4") × 12.7 mm (1/2")	15.24 m (50 ft)
TC-492250	Tubing, silicone 3350, 7.938 mm (5/16") × 11.113 mm (7/16")	15.24 m (50 ft)
TC-492350	Tubing, silicone 3350, 7.938 mm (5/16") × 12.7 mm (1/2")	15.24 m (50 ft)
TC-492750	Tubing, silicone 3350, 9.525 mm (3/8") × 12.7 mm (1/2")	15.24 m (50 ft)
TC-492850	Tubing, silicone 3350, 9.525 mm (3/8") × 14.288 mm (9/16")	15.24 m (50 ft)
TC-492950	Tubing, silicone 3350, 9.525 mm (3/8") × 15.875 mm (5/8")	15.24 m (50 ft)
TC-493250	Tubing, silicone 3350, 11.113 mm (7/16") × 14.288 mm (9/16")	15.24 m (50 ft)
TC-493350	Tubing, silicone 3350, 11.113 mm (7/16") × 15.875 mm (5/8")	15.24 m (50 ft)
TC-493650	Tubing, silicone 3350, 12.7 mm (1/2") × 15.875 mm (5/8")	15.24 m (50 ft)
TC-493750	Tubing, silicone 3350, 12.7 mm (1/2") × 17.463 mm (11/16")	15.24 m (50 ft)
TC-493850	Tubing, silicone 3350, 12.7 mm (1/2") × 19.05 mm (3/4")	15.24 m (50 ft)
TC-494550	Tubing, silicone 3350, 15.875 mm (5/8") × 20.638 mm (13/16")	15.24 m (50 ft)
TC-494650	Tubing, silicone 3350, 15.875 mm (5/8") × 22.225 mm (7/8")	15.24 m (50 ft)
TC-495350	Tubing, silicone 3350, 19.05 mm (3/4") × 25.4 mm (1.0")	15.24 m (50 ft)
TC-496250	Tubing, silicone 3350, 25.4 mm (1.0") × 31.75 mm (1 1/4")	15.24 m (50 ft)
TC-496950	Tubing, silicone 3350, 31.75 mm (1 1/4") × 38.1 mm (1 1/2")	15.24 m (50 ft)
TC-497450	Tubing, silicone 3350, 38.1 mm (1 1/2") × 50.8 mm (2.0")	15.24 m (50 ft)

## Pharmed® tubing

Order number	Description   ID   OD	Quantity per roll
TC-486525	Tubing, PharMed, .020" × .145"	7.62 m (25 ft)
TC-486625	Tubing, PharMed, 0.794 mm (1/32") $\times$ 3.969 mm (5/32")	7.62 m (25 ft)
TC-480225	Tubing, PharMed, 1.588 mm (1/16") $\times$ 3.175 mm (1/8")	7.62 m (25 ft)
TC-480325	Tubing, PharMed, 1.588 mm (1/16") × 4.763 mm (3/16")	7.62 m (25 ft)
TC-480525	Tubing, PharMed, 2.381 mm (3/32") × 5.556 mm (7/32")	7.62 m (25 ft)
TC-480625	Tubing, PharMed, 3.175 mm (1/8") × 4.763 mm (3/16")	7.62 m (25 ft)
TC-480725	Tubing, PharMed, 3.175 mm (1/8") × 6.35 mm (1/4")	7.62 m (25 ft)
TC-481225	Tubing, PharMed, 4.763 mm (3/16") × 7.938 mm (5/16")	7.62 m (25 ft)
TC-481325	Tubing, PharMed, 4.763 mm (3/16") × 9.525 mm (3/8")	7.62 m (25 ft)
TC-481725	Tubing, PharMed, 6.35 mm (1/4") × 9.525 mm (3/8")	7.62 m (25 ft)
TC-481825	Tubing, PharMed, 6.35 mm (1/4") × 11.113 mm (7/16")	7.62 m (25 ft)
TC-481925	Tubing, PharMed, 6.35 mm (1/4") × 12.7 mm (1/2")	7.62 m (25 ft)
TC-482225	Tubing, PharMed, 7.938 mm (5/16") × 11.113 mm (7/16")	7.62 m (25 ft)
TC-482725	Tubing, PharMed, 9.525 mm (3/8") × 12.7 mm (1/2")	7.62 m (25 ft)
TC-482925	Tubing, PharMed, 9.525 mm (3/8") × 15.875 mm (5/8")	7.62 m (25 ft)
TC-483825	Tubing, PharMed, 12.7 mm (1/2") × 19.05 mm (3/4")	7.62 m (25 ft)
TC-484625	Tubing, PharMed, 15.875 mm (5/8") × 22.225 mm (7/8")	7.62 m (25 ft)
TC-485325	Tubing, PharMed, 19.05 mm (3/4") × 25.4 mm (1.0")	7.62 m (25 ft)

## C-Flex® tubing, formulation 082

Order number	Description   ID   OD	Quantity per roll
TC-410150	Tubing, C-Flex clear 082, 0.794 mm (1/32") × 2.381 mm (3/32")	15.24 m (50 ft)
TC-411250	Tubing, C-Flex clear 082, 1.588 mm $(1/16") \times 3.175$ mm $(1/8")$	15.24 m (50 ft)
TC-411350	Tubing, C-Flex clear 082, 1.588 mm (1/16") × 4.763 mm (3/16")	15.24 m (50 ft)
TC-412250	Tubing, C-Flex clear 082, 3.175 mm (1/8") $\times$ 6.35 mm (1/4")	15.24 m (50 ft)
TC-413250	Tubing, C-Flex clear 082, 4.763 mm (3/16") × 7.938 mm (5/16")	15.24 m (50 ft)
TC-413350	Tubing, C-Flex clear 082, 4.763 mm (3/16") × 9.525 mm (3/8")	15.24 m (50 ft)
TC-414150	Tubing, C-Flex clear 082, 6.35 mm (1/4") × 9.525 mm (3/8")	15.24 m (50 ft)
TC-414250	Tubing, C-Flex clear 082, 6.35 mm (1/4") × 11.113 mm (7/16")	15.24 m (50 ft)
TC-414350	Tubing, C-Flex clear 082, 6.35 mm (1/4") × 12.7 mm (1/2")	15.24 m (50 ft)
TC-415250	Tubing, C-Flex clear 082, 7.938 mm (5/16") × 12.7 mm (1/2")	15.24 m (50 ft)
TC-416150	Tubing, C-Flex clear 082, 9.525 mm (3/8") × 12.7 mm (1/2")	15.24 m (50 ft)
TC-416250	Tubing, C-Flex clear 082, 9.525 mm (3/8") × 15.875 mm (5/8")	15.24 m (50 ft)
TC-416350	Tubing, C-Flex clear 082, 9.525 mm (3/8") × 14.288 mm (9/16")	15.24 m (50 ft)
TC-418150	Tubing, C-Flex clear 082, 12.7 mm (1/2") × 17.463 mm (11/16")	15.24 m (50 ft)
TC-418250	Tubing, C-Flex clear 082, 12.7 mm (1/2") × 19.05 mm (3/4")	15.24 m (50 ft)
TC-419150	Tubing, C-Flex clear 082, 15.875 mm (5/8") × 22.225 mm (7/8")	15.24 m (50 ft)
TC-410115	Tubing, C-Flex clear 082, 19.05 mm (3/4") × 25.4 mm (1.0")	4.57 m (15 ft)
TC-410215	Tubing, C-Flex clear 082, 19.05 mm (3/4") $\times$ 28,575 mm (1 1/8")	4.57 m (15 ft)
TC-410315	Tubing, C-Flex clear 082, 19.05 mm (3/4") × 31.75 mm (1 1/4")	4.57 m (15 ft)
TC-410615	Tubing, C-Flex clear 082, 25.4 mm (1.0") × 34.925 mm (1 3/8")	4.57 m (15 ft)
TC-410815	Tubing, C-Flex clear 082, 25.4 mm (1.0") × 38.1 mm (1 1/2")	4.57 m (15 ft)

## C-Flex® tubing, formulation 072

Order number	Description   ID   OD	Quantity per roll
TC-420150	Tubing, C-Flex opaque 072, 0.794 mm (1/32") × 2.381 mm (3/32")	15.24 m (50 ft)
TC-421250	Tubing, C-Flex opaque 072, 1.588 mm (1/16") × 3.175 mm (1/8")	15.24 m (50 ft)
TC-421350	Tubing, C-Flex opaque 072, 1.588 mm (1/16") × 4.763 mm (3/16")	15.24 m (50 ft)
TC-422250	Tubing, C-Flex opaque 072, 3.175 mm (1/8") × 6.35 mm (1/4")	15.24 m (50 ft)
TC-423250	Tubing, C-Flex opaque 072, 4.763 mm (3/16") × 7.938 mm (5/16")	15.24 m (50 ft)
TC-423350	Tubing, C-Flex opaque 072, 4.763 mm (3/16") × 9.525 mm (3/8")	15.24 m (50 ft)
TC-424150	Tubing, C-Flex opaque 072, 6.35 mm (1/4") × 9.525 mm (3/8")	15.24 m (50 ft)
TC-424250	Tubing, C-Flex opaque 072, 6.35 mm (1/4") × 11.113 mm (7/16")	15.24 m (50 ft)
TC-424350	Tubing, C-Flex opaque 072, 6.35 mm (1/4") × 12.7 mm (1/2")	15.24 m (50 ft)
TC-425250	Tubing, C-Flex opaque 072, 7.938 mm (5/16") × 12.7 mm (1/2")	15.24 m (50 ft)
TC-426150	Tubing, C-Flex opaque 072, 9.525 mm (3/8") × 12.7 mm (1/2")	15.24 m (50 ft)
TC-426250	Tubing, C-Flex opaque 072, 9.525 mm (3/8") × 15.875 mm (5/8")	15.24 m (50 ft)
TC-426350	Tubing, C-Flex opaque 072, 9.525 mm (3/8") × 14.288 mm (9/16")	15.24 m (50 ft)
TC-428150	Tubing, C-Flex opaque 072, 12.7 mm (1/2") × 17.463 mm (11/16")	15.24 m (50 ft)
TC-428250	Tubing, C-Flex opaque 072, 12.7 mm (1/2") × 19.05 mm (3/4")	15.24 m (50 ft)
TC-429150	Tubing, C-Flex opaque 072, 15.875 mm (5/8") × 22.225 mm (7/8")	15.24 m (50 ft)
TC-420115	Tubing, C-Flex opaque 072, 19.05 mm (3/4") × 25.4 mm (1.0")	4.57 m (15 ft)
TC-420215	Tubing, C-Flex opaque 072, 19.05 mm (3/4") × 28,575 mm (1 1/8")	4.57 m (15 ft)
TC-420315	Tubing, C-Flex opaque 072, 19.05 mm (3/4") × 31.75 mm (1 1/4")	4.57 m (15 ft)
TC-420615	Tubing, C-Flex opaque 072, 25.4 mm (1.0") × 34.925 mm (1 3/8")	4.57 m (15 ft)
TC-420815	Tubing, C-Flex opaque 072, 25.4 mm (1.0") × 38.1 mm (1 1/2")	4.57 m (15 ft)

## Platinum cured silicone tubing

Order number	Description   ID   OD	Quantity per roll
TC-500750	Tubing, silicone platinum, 3.175 mm (1/8") $\times$ 6.35 mm (1/4")	15.24 m (50 ft)
TC-501850	Tubing, silicone platinum, 6.35 mm (1/4") $\times$ 11.113 mm (7/16")	15.24 m (50 ft)
TC-501250	Tubing, silicone platinum, 4.763 mm (3/16") × 7.938 mm (5/16")	15.24 m (50 ft)
TC-501350	Tubing, silicone platinum, 4.763 mm (3/16") $\times$ 9.525 mm (3/8")	15.24 m (50 ft)
TC-502950	Tubing, silicone platinum, 9.525 mm (3/8") $\times$ 15.875 mm (5/8")	15.24 m (50 ft)
TC-503850	Tubing, silicone platinum, 12.7 mm (1/2") $\times$ 19.05 mm (3/4")	15.24 m (50 ft)

## Peroxide cured silicone tubing

Order number	Description   ID   OD	Quantity per roll
TC-460750	Tubing, silicone peroxide, 3.175 mm (1/8") $\times$ 6.35 mm (1/4")	15.24 m (50 ft)
TC-461350	Tubing, silicone peroxide, 4.763 mm (3/16") × 9.525 mm (3/8")	15.24 m (50 ft)
TC-461750	Tubing, silicone peroxide, 6.35 mm (1/4") $\times$ 9.525 mm (3/8")	15.24 m (50 ft)
TC-461850	Tubing, silicone peroxide, 6.35 mm (1/4") × 11.113 mm (7/16")	15.24 m (50 ft)
TC-461950	Tubing, silicone peroxide, 6.35 mm (1/4") $\times$ 12.7 mm (1/2")	15.24 m (50 ft)
TC-462250	Tubing, silicone peroxide, 7.938 mm (5/16") × 11.113 mm (7/16")	15.24 m (50 ft)
TC-462350	Tubing, silicone peroxide, 7.938 mm (5/16") × 12.7 mm (1/2")	15.24 m (50 ft)
TC-462750	Tubing, silicone peroxide, 9.525 mm (3/8") × 12.7 mm (1/2")	15.24 m (50 ft)
TC-462850	Tubing, silicone peroxide, 9.525 mm (3/8") × 14.288 mm (9/16")	15.24 m (50 ft)
TC-462950	Tubing, silicone peroxide, 9.525 mm (3/8") × 15.875 mm (5/8")	15.24 m (50 ft)
TC-463780	Tubing, silicone peroxide, 12.7 mm (1/2") × 17.463 mm (11/16")	15.24 m (50 ft)
TC-463850	Tubing, silicone peroxide, 12.7 mm (1/2") × 19.05 mm (3/4")	15.24 m (50 ft)
TC-464650	Tubing, silicone peroxide, 15.875 mm (5/8") × 22.225 mm (7/8")	15.24 m (50 ft)
TC-465350	Tubing, silicone peroxide, 19.05 mm (3/4") × 25.4 mm (1.0")	15.24 m (50 ft)
TC-465450	Tubing, silicone peroxide, 19.05 mm (3/4") × 28,575 mm (1 1/8")	30.48 m (100 ft)

## "Y" Elements for peristaltic pumps

## 505 L series pump head

Order number	Description   ID   OD	Quantity
TC-151840-D	"Y" segment, silicone, #15, 4.763 mm (3/16") × 9.525 mm (3/8")	10 per case
TC-151842-D	"Y" segment, silicone, # 119, 1.588 mm (1/16") × 6.35 mm (1/4")	10 per case
TC-151843-D	"Y" segment, silicone, #120, 3.175 mm (1/8") × 7.938 mm (5/16")	10 per case
TC-151844-D	"Y" segment, silicone, #24, 6.35 mm (1/4") × 11.113 mm (7/16")	10 per case
TC-151845-D	"Y" segment, silicone, #121, 7.938 mm (5/16") × 12.7 mm (1/2")	10 per case
TC-151846-D	"Y" segment, silicone, #122, 9.525 mm (3/8") × 14.288 mm (9/16")	10 per case

## 605 L series pump head

Order Description   ID   OD number		Quantity
TC-151841-D	"Y" segment, silicone, #185, 8 mm × 16 mm	10 per case
TC-151847-D	"Y" segment, silicone, #186, 12 mm × 20 mm	10 per case

## Tubing on spools

Order number	Description   ID   OD	Quantity per spool
TC-412201	Tubing, C-Flex clear 082, 3.175 mm $(1/8") \times 6.35$ mm $(1/4")$	152.40 m (500 ft)
TC-414101	Tubing, C-Flex clear 082, 6.35 mm (1/4") $\times$ 9.525 mm (3/8")	76.20 m (250 ft)
TC-414201	Tubing, C-Flex clear 082, 6.35 mm (1/4") $\times$ 11.113 mm (7/16")	91.44 m (300 ft)
TC-416201	Tubing, C-Flex clear 082, 9.525 mm $(3/8") \times 15.875$ mm $(5/8")$	45.72 m (150 ft)
TC-416301	Tubing, C-Flex clear 082, 9.525 mm (3/8") × 14.288 mm (9/16")	60.96 m (200 ft)
TC-418201	Tubing, C-Flex clear 082, 12.7 mm (1/2") × 19.05 mm (3/4")	27.43 m (90 ft)
TC-422201	Tubing, C-Flex opaque 072, 3.175 mm (1/8") $\times$ 6.35 mm (1/4")	152.40 m (500 ft)
TC-424201	Tubing, C-Flex opaque 072, 6.35 mm (1/4") × 11.113 mm (7/16")	76.20 m (250 ft)
TC-426201	Tubing, C-Flex opaque 072, 9.525 mm (3/8") × 15.875 mm (5/8")	60.96 m (200 ft)
TC-428201	Tubing, C-Flex opaque 072, 12.7 mm (1/2") × 19.05 mm (3/4")	27.43 m (90 ft)
TC-462601	Tubing, silicone peroxide, 8 mm × 12 mm	76.20 m (250 ft)
TC-491201	Tubing, silicone 3350, 4.763 mm (3/16") × 7.938 mm (5/16")	152.40 m (500 ft)
TC-491301	Tubing, silicone 3350, 4.763 mm (3/16") × 9.525 mm (3/8")	152.40 m (500 ft)
TC-492901	Tubing, silicone 3350, 9.525 mm (3/8") × 15.875 mm (5/8")	76.20 m (250 ft)
TC-493801	Tubing, silicone 3350, 12.7 mm (1/2") × 19.05 mm (3/4")	76.20 m (250 ft)
TC-503701	Tubing, silicone platinum, 12.7 mm (1/2") × 17.463 mm (11/16")	76.20 m (250 ft)
TC-521201	Tubing, silicone platinum, 4.763 mm (3/16") × 7.938 mm (5/16")	76.20 m (250 ft)
TC-521801	Tubing, silicone platinum, 6.35 mm (1/4") × 11.113 mm (7/16")	76.20 m (250 ft)
TC-522901	Tubing, silicone platinum, 9.525 mm (3/8") × 15.875 mm (5/8")	76.20 m (250 ft)
TC-523701	Tubing, silicone platinum, 12.7 mm (1/2") × 17.463 mm (11/16")	76.20 m (250 ft)
TC-523801	Tubing, silicone platinum, 12.7 mm (1/2") $\times$ 19.05 mm (3/4")	76.20 m (250 ft)

## **Pharmaceutical Grade Tubing**



Available gamma irradiated. Available as custom tube assembly. Call TC Tech | Sartorius for details.



### Order information for tubing

## $Tygon^{\text{$\emptyset$}}\ braided\ silicone\ tubing,\ formulation\ 3370$

Order number	Description   ID   OD	Quantity per roll
TC-471850	Tubing, silicone 3370 lB, 4.763 mm (3/16") × 0.443"	15.24 m (50 ft)
TC-471950	Tubing, silicone 3370 IB, 6.35 mm (1/4") × 0.515"	15.24 m (50 ft)
TC-472050	Tubing, silicone 3370 IB, 9.525 mm (3/8") × 0.687"	15.24 m (50 ft)
TC-472150	Tubing, silicone 3370 IB, 12.7 mm (1/2") × 0.847"	15.24 m (50 ft)
TC-472250	Tubing, silicone 3370 IB, 15.875 mm (5/8") × 0.980"	15.24 m (50 ft)
TC-477150	Tubing, silicone 3370 IB, 19.05 mm (3/4") × 1.150"	15.24 m (50 ft)
TC-472450	Tubing, silicone 3370 IB, 25.4 mm (1.0") × 1.390"	15.24 m (50 ft)
TC-472525	Tubing, silicone 3370 lB, 31.75 mm (1 $1/4$ ") $\times$ 1.636"	7.62 m (25 ft)
TC-472625	Tubing, silicone 3370 IB, 38.1 mm (1 1/2") × 1.900"	7.62 m (25 ft)



### C-Flex® tubing, formulation 050

Order number	Description   ID   OD	Quantity per roll
TC-430150	Tubing, C-Flex clear 050, 0.794 mm (1/32") × 2.381 mm (3/32")	15.24 m (50 ft)
TC-431250	Tubing, C-Flex clear 050, 1.588 mm (1/16") × 3.175 mm (1/8")	15.24 m (50 ft)
TC-431350	Tubing, C-Flex clear 050, 1.588 mm (1/16") × 4.763 mm (3/16")	15.24 m (50 ft)
TC-432250	Tubing, C-Flex clear 050, 3.175 mm $(1/8") \times 6.35$ mm $(1/4")$	15.24 m (50 ft)
TC-433250	Tubing, C-Flex clear 050, 4.763 mm (3/16") × 7.938 mm (5/16")	15.24 m (50 ft)
TC-433350	Tubing, C-Flex clear 050, 4.763 mm (3/16") × 9.525 mm (3/8")	15.24 m (50 ft)
TC-434350	Tubing, C-Flex clear 050, 6.35 mm (1/4") × 9.525 mm (3/8")	15.24 m (50 ft)
TC-434250	Tubing, C-Flex clear 050, 6.35 mm (1/4") × 11.113 mm (7/16")	15.24 m (50 ft)
TC-434350	Tubing, C-Flex clear 050, 6.35 mm (1/4") × 12.7 mm (1/2")	15.24 m (50 ft)
TC-435250	Tubing, C-Flex clear 050, 7.938 mm (5/16") × 12.7 mm (1/2")	15.24 m (50 ft)
TC-436150	Tubing, C-Flex clear 050, 9.525 mm (3/8") × 12.7 mm (1/2")	15.24 m (50 ft)
TC-436250	Tubing, C-Flex clear 050, 9.525 mm $(3/8") \times 15.875$ mm $(5/8")$	15.24 m (50 ft)
TC-436350	Tubing, C-Flex clear 050, 9.525 mm $(3/8") \times 14.288$ mm $(9/16")$	15.24 m (50 ft)
TC-438150	Tubing, C-Flex clear 050, 12.7 mm $(1/2") \times 17.463$ mm $(11/16")$	15.24 m (50 ft)
TC-438250	Tubing, C-Flex clear 050, 12.7 mm (1/2") $\times$ 19.05 mm (3/4")	15.24 m (50 ft)
TC-439150	Tubing, C-Flex clear 050, 15.875 mm (5/8") × 22.225 mm (7/8")	15.24 m (50 ft)
TC-430115	Tubing, C-Flex clear 050, 19.05 mm (3/4") × 25.4 mm (1.0")	4.57 m (15 ft)
TC-430215	Tubing, C-Flex clear 050, 19.05 mm (3/4") × 28,575 mm (1 1/8")	4.57 m (15 ft)
TC-430315	Tubing, C-Flex clear 050, 19.05 mm (3/4") × 31.75 mm (1 1/4")	4.57 m (15 ft)
TC-430615	Tubing, C-Flex clear 050, 25.4 mm (1.0") × 34.925 mm (1 3/8")	4.57 m (15 ft)
TC-430815	Tubing, C-Flex clear 050, 25.4 mm (1.0") × 38.1 mm (1 1/2")	4.57 m (15 ft)

## C-Flex® tubing, formulation 001

Order number	Description   ID   OD	Quantity per roll
TC-440150	Tubing, C-Flex opaque 001, 0.794 mm (1/32") $\times$ 2.381 mm (3/32")	15.24 m (50 ft)
TC-441250	Tubing, C-Flex opaque 001, 1.588 mm (1/16") × 3.175 mm (1/8")	15.24 m (50 ft)
TC-441350	Tubing, C-Flex opaque 001, 1.588 mm (1/16") $\times$ 4.763 mm (3/16")	15.24 m (50 ft)
TC-442250	Tubing, C-Flex opaque 001, 3.175 mm (1/8") $\times$ 6.35 mm (1/4")	15.24 m (50 ft)
TC-443250	Tubing, C-Flex opaque 001, 4.763 mm (3/16") $\times$ 7.938 mm (5/16")	15.24 m (50 ft)
TC-443350	Tubing, C-Flex opaque 001, 4.763 mm (3/16") × 9.525 mm (3/8")	15.24 m (50 ft)
TC-444150	Tubing, C-Flex opaque 001, 6.35 mm (1/4") $\times$ 9.525 mm (3/8")	15.24 m (50 ft)
TC-444450	Tubing, C-Flex opaque 001, 6.35 mm (1/4") $\times$ 11.113 mm (7/16")	15.24 m (50 ft)
TC-444350	Tubing, C-Flex opaque 001, 6.35 mm (1/4") $\times$ 12.7 mm (1/2")	15.24 m (50 ft)
TC-445250	Tubing, C-Flex opaque 001, 7.938 mm (5/16") $\times$ 12.7 mm (1/2")	15.24 m (50 ft)
TC-446150	Tubing, C-Flex opaque 001, 9.525 mm (3/8") $\times$ 12.7 mm (1/2")	15.24 m (50 ft)
TC-446250	Tubing, C-Flex opaque 001, 9.525 mm (3/8") $\times$ 15.875 mm (5/8")	15.24 m (50 ft)
TC-446350	Tubing, C-Flex opaque 001, 9.525 mm (3/8") $\times$ 14.288 mm (9/16")	15.24 m (50 ft)
TC-448150	Tubing, C-Flex opaque 001, 12.7 mm (1/2") $\times$ 17.463 mm (11/16")	15.24 m (50 ft)
TC-448250	Tubing, C-Flex opaque 001, 12.7 mm (1/2") $\times$ 19.05 mm (3/4")	15.24 m (50 ft)
TC-449150	Tubing, C-Flex opaque 001, 15.875 mm (5/8") $\times$ 22.225 mm (7/8")	15.24 m (50 ft)
TC-440115	Tubing, C-Flex opaque 001, 19.05 mm (3/4") $\times$ 25.4 mm (1.0")	4.57 m (15 ft)
TC-440215	Tubing, C-Flex opaque 001, 19.05 mm (3/4") x 28.575 (1 1/8")	4.57 m (15 ft)
TC-440315	Tubing, C-Flex opaque 001, 19.05 mm (3/4") $\times$ 31.75 mm (1 1/4")	4.57 m (15 ft)
TC-440615	Tubing, C-Flex opaque 001, 25.4 mm (1.0") × 34.925 mm (1 3/8")	4.57 m (15 ft)
TC-440815	Tubing, C-Flex opaque 001, 25.4 mm (1.0") × 38.1 mm (1 1/2")	4.57 m (15 ft)

Filter Cartridge Housings





# Filter Cartridge Housings

Multi-Rounds Filter Housings	20
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### **Multi-Rounds Filter Housings**



#### Introduction

Quality gas or liquid filtration systems require both quality housings and quality filter cartridges. To meed this need, Sartorius has been producing a sanitary line of housings with quality as the primary objective. Sartorius multi-round housings have been designed to meet the scale-up requirements of pharmaceutical and biotechnology processing. These housings are designed specifically for sterile filtration with special attention taken with the choice of materials, durability, cleanability, ease of use and quality control.

#### Quality of materials

Only 316L Stainless steel is used for all wetted surfaces to provide maximum durability. Supplied O-rings and gaskets are compounded only from FDA approved materials that meet the requirements for direct contact with food and pharmaceutical products.

#### Quality surface finishes

All Sartorius Sanitary housings come standard with internal finishes of at least 0.5 micron Ra and are electropolished. Electropolishing removes surface impurities in stainless steel left over from the machining and the finishing processes. Such impurities are sites for future initiation of corrosion and possible sources of contaminates leaching into the product. Electropolishing also smoothes the microscratches left by mechanical polishing, thus reducing the total surface area the product will contact, and making it harder for bacteria or contaminates to lodge on leaves a highly corrosion resistant, passive film on the surface of the steel (passivation). Thus electropolishing is the recommended finish for all applications where cleanliness and corrosion resistance are critical.

#### Ease in cleaning

Sartorius utilizes a unique filter cup design that is conductive for allowing a thorough cleaning. The raised filter cup design eliminates small grooves and tight spaces that might be difficult to verify or validate the cleaning while still permitting free complete drainage of the filter housing. The entire housing is cleaned, even under the receiver plate. CIP caps are also available.

#### **Quality control and documentation**

An important feature of pharmaceutical process validation is documentation. All our housings are given stringent inspections during and after manufacturing including dimensional checks, weld inspections, surface measurements and hydrostatic testing. Each housing is labled by laser with a matching serial number on the bell and base. This serial number provides complete tractability for the Quality Control Certificate, Material Test Reports, and Weld Logs.

#### Ease of installation

Sartorius housings are sold ready to install with all gaskets, o-rings and clamps. All that is required are the components needed to connect to your existing hardware.

#### PED 97/23/EC Standard

Sartorius Stainless Steel Housings are designed and manufactured according the Pressure Equipment Directive PED 97/23/EC. Our manufacturing process follows the highest quality standards and is monitored by an internal quality control system as well as by independent notified bodies on a regular basis.

Available heights 3-Round 5, & 7 Round 10", 20", 30", 40" 10", 20", 30", 40"

Surface finishes

Ra < 0.5 μm EP Ra < 1.6 μm EP Interior Exterior

**Housing ratings**Pressure -1 + 10 bar Temperature -10 + 150°C

### Materials

All wetted surfaces	316L
Clamps	304
Seals	Silicone (Viton or EPDM optional)

### Mini & 1 Element Filter Housings



#### Introduction

There has been, and is, an increasing demand for quality filter cartridge systems for sterilizing and polishing filtration processes. A large emphasis has been placed on the integrity of construction of the filter cartridges. However, the filter cartridge housing is just as an important part of any filtration system. Without a proper housing the cartridge is useless. Even the best cartridge cannot do the job if enclosed in a housing that allows fluid to bypass the filter, has external leaks, are not chemically or mechanically compatible with the application. Quality gas or liquid filtration systems require both quality housings and quality filter cartridges. To meed this need, Sartorius has been producing a sanitary line of housings with quality as the primary objective.

#### Quality of materials

Only 316L Stainless steel is used for all wetted surfaces to provide maximum durability. Supplied O-rings and gaskets are compounded only from FDA approved materials that meet the requirements for direct contact with food and pharmaceutical products.

#### Quality surface finishes

All Sartorius Sanitary housings come standard with internal finishes of at least 0.5 micron Ra and are electropolished. Electropolishing removes surface impurities in stainless steel left over from the machining and the finishing processes. Such impurities are sites for future initiation of corrosion and possible sources of contaminates leaching into the product. Electropolishing also smoothes the microscratches left by mechanical polishing, thus reducing the total surface area the product will contact, and making it harder for bacteria or contaminates to lodge on the housing surface.

Finally, electropolishing leaves a highly corrosion resistant, passive film on the surface of the steel (passivation). Thus electropolishing is the recommended finish for all applications where cleanliness and corrosion resistance are critical.

#### Ease in cleaning

Sartorius utilizes a unique filter cup design that is conductive for allowing a thorough cleaning. The raised filter cup design eliminates small grooves and tight spaces that might be difficult to verify or validate the cleaning while still permitting free complete drainage of the filter housing.

#### **Flexibility**

Sartorius offers the widest range of housing sizes and design options to exactly match your flow rate and pressure differential requirements. Connections are available in many styles and sizes. Custom designs and unique configurations are available upon request.

#### **Quality control and documentation**

An important feature of pharmaceutical process validation is documentation. All our housings are given stringent inspections during and after manufacturing including dimensional checks, weld inspections, surface measurements and hydrostatic testing. Each housing is labled by laser with a matching serial number on the bell and base. This serial number provides complete tractability for the Quality Control Certificate, Material Test Reports, and Weld Logs.

#### Ease of installation

Sartorius housings are sold ready to install with all gaskets, o-rings and clamps. All that is required are the components needed to connect to your existing hardware.

#### PED 97/23/EC Standard

Sartorius Stainless Steel Housings are designed and manufactured according the Pressure Equipment Directive PED 97/23/EC. Our manufacturing process follows the highest quality standards and is monitored by an internal quality control system as well as by independent notified bodies on a regular basis.

**Available heights** Mini

5" 5", 10", 20", 30", 40" Single Round

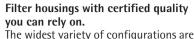
Surface finishes Interior Ra < 0.5 μm EP Ra < 1.6 μm EP Exterior

**Housing ratings**Pressure -1 + 10 bar -10 + 150°C Temperature

Materials

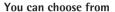
All wetted surfaces	316L
Clamps	304
Seals	Silicone (Viton or EPDM optional)

## Filter Cartridge Housings for the Pharmaceutical Industry Modular System for Stainless Steel Filter Housings



neet the needs of the pharmaceutical industry.

That is why we have broken down the housing into its individual components. This enables you to select the components you need and configure your housing on your own using our special software. Then we will manufacture your custom-designed housing in compliance with certified quality standards.



- different vent valves or units
- pipes according to DIN, ISO or BSOD
- connectors and clamps such as Tri-clamps, flanges, and threaded fittings according to all conventional standards.

#### The standard we offer you

	,
Material	AISI 316 L
Surfaces	Inner: Ra < 0.5 μm; Outer: Ra < 1.6 μm
Temperature range	-10+150°C
Pressure range	-1+10 bar
Adapters	Mini: 15; standard 10" cartridge: 25
Housing clamp lock	Sanitary clamp
Clamp gasket	Silicone (FDA)

## We manufacture your housing in compliance with certified quality standards.

We stock a sufficient number of all the individual components for the modular system. This guarantees that delivery will be prompt and that high quality standards are maintained.

Our standard documentation includes material certificates in compliance with EN 10204 3.1 and FDA certificates of compliance for gasket materials.

#### PED 97/23/EC Standard

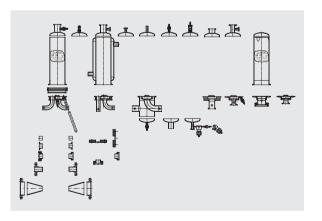
Sartorius Stainless Steel Housings are designed and manufactured according the Pressure Equipment Directive PED 97/23/EC. Our manufacturing process follows the highest quality standards, and is monitored by an internal quality control system as well as by an independent notified on a regular basis.

Besides supplying you with all the modular system components you need, we will be happy to provide any other variations to customize your housing design.

# Modularly Designed System (M.D.S). The Sartorius software for drafting a complete modular housing.

Using our M.D.S. software, the final drawing of a modular, custom-configured housing can be produced within minutes. This drawing will also be used to prepare the cost estimate. After you have checked and approved the draft, the drawing will be sent on to our production department.





#### Your added benefits

- Fast configuration of your housing according to your needs
- Ability to review your housing on-site in the proper scale
- Quick order processing
- Prompt delivery
- Our software speaks your language: choose from English, French, German, Italian and Spanish

#### Our service is better

- Competent advice on-site
- Professional drawing based on your on-site specifications
- Better prices

## You can choose from the following modular programs

Mini 1-round housing Standard 1-round housing Standard 3-round housing Standard 5-round housing

#### This is how you configure your housing.

We'll show you the variety of individual components that our modular system provides for you to combine and configure.

Just use the code numbers to select the elements you want.

Thanks to our modularly designed system software (M.D.S), you can review your housing selection right away and make changes, if necessary.

## Your filter housing will be composed of the following basic components

- Top part of the housing with vent
- Housing bell (of the appropriate height)
- Gaskets (made of various materials)
- Clamp for filter housing lock (Tri-clamp)
- Housing base:
- a) without condensate run-off valves b) with condensate run-off valves (connecting pipes available in types compliant with DIN, ISO, BSOD).
- Fittings
- Extra valve options
- Documentations

All filter housings are available in a choice of the following designs:
T type, in-line type or L type.

#### **Brief example**

Drawing	Modular design code	Technical description
	BA001	Fittings, general: Clamp 50.5 mm Pipe: 38.1 mm x 1.65 mm Side fittings: New pharma valve (PTFE tip, silicone O-ring)
		Pipe: 101.6 mm x 2.0 mm TC 119.0 mm
	Bell height BBOH0 BBOH1 BBOH2 BBOH3 BBOH4	Housing bell for: 5" filter cartridges 10" filter cartridges 20" filter cartridges 30" filter cartridges 40" filter cartridges
	BC0K2	2-piece joint clamp with 2 hexagon nuts, 119.0 mm, (4") Temp.: -10+150°C Pressure: +10 bar (limited by housing)
		Base plate adapter 25  – with removable legs  – without vent valve
	BE004 BE005 BE006	Pipe dimensions: BSOD 1": 25.4 mm × 1.65 mm DIN DN 25: 29.0 mm × 1.5 mm ISO DN 25: 33.7 mm × 2.0 mm



# Filter Integrity Testing Systems

Sartocheck® Junior BP-Plus	210
Sartocheck 3	212
Sartocheck 3 EPS	214
Sartocheck® 4	216
Sartocheck 4 MultiUnit	218
Sartorius Trolley System	220

# Sartocheck® Junior BP-Plus For Diffusion & Bubble Point Integrity Testing of Membrane Filter Systems



Sartocheck Junior BP-Plus is an automatic, microprocessor-controlled tester designed to check the integrity of membrane filter systems and provide a hard copy of the test data and results. It measures the following upstream integrity values:

- The diffusion rate
- The bubble point

A special, built-in program is available for determining the net upstream volume of your filtration systems. A comprehensive test report is printed out to meet cGMP requirements.

To increase the clarity of the test and to ensure 100% traceability of the results, complete test parameters and conditions of the test are also printed on hard copy, including:

- Net upstream volume
- Test pressure (actual value)
- Pressure drop
- Test time and date

To program a test, simply enter the maximum allowable air diffusion rate and the minimum required bubble point specified by the filter manufacturer. You can use the Sartocheck Junior BP-Plus to determine the bubble point of disc filter systems, from syringe filter holders to 293 mm filter holders, and complete integrity tests (diffusion and bubble point) on capsules, mini filter cartridges and single standard filter cartridges up to 30" high.

#### Sartocheck Junior BP-Plus features:

#### Test programs and data backup

Up to 3 test programs can be stored in the non-volatile memory of the Sartocheck unit; the program parameters are entered on the keypad. Data is backed up by the non-volatile memory.

#### Total test time

The Sartocheck Junior BP-Plus can complete a routine test in 8 minutes or less (includes both the diffusion and the bubble point) depending on the type of filtration system.

#### **Continuous test updates**

Continuous display updates of the momentary diffusion rate or the momentary pressure drop during a test cycle enable you to make a quick estimate of the integrity of your system during the first few minutes of the test. You can interrupt the test cycle at any time and automatically obtain a printout of the test results available up to this point.

#### Flushing the unit

You can flush the internal pneumatic unit any time using the built-in flushing program.

#### Languages

The Sartocheck Junior BP-Plus has built-in multi-language capabilities in English, German, French, Spanish and Italian. You can have the same test record printed out in several languages and obtain any number of copies.

#### Quality assurance

The high performance standards of Sartocheck Junior BP-Plus is assured over long periods:

- Easy calibration using the keypad
- Annual service maintenance contracts are available through our wide service network

#### **User-friendly features**

The unit is battery-operable, splash-proof and easy to handle. Its backlit display makes it easy to read the test results even in dark rooms. An acoustic signal indicates the end of the test, so operator attendance is not required. Red and green indicator lights can be seen at a distance for convenient pass or fail evaluation.

#### **Validation**

We will be glad to help you in getting your Sartocheck Junior BP-Plus validated. We can provide validation literature or validation services.

#### Data processing

Data processing: The interface diskette allows you to transfer the test data to an IBM-compatible PC.

#### Available Options:

- Computer interface cable
- Interface disk for IBM-compatible PC

#### **Equipment supplied**

- Sartocheck Junior BP-Plus Tester
- Tubing for compressed gas, inlet and outlet, with compressed air filter
- 1 liter external pressure tank, complete with pressure connections
- Battery charger
- Ink ribbon cassette and paper roll
- Installation and operating instructions, test and calibration certification

## **Technical specifications**

Power requirements (mains) for battery charger	220/240 V, 50 Hz 110/120 V, 60 Hz
Power supply	7.2 V, 1.8 Ah
Maximum inlet pressure	8 bar (120 psi)
Minimum inlet pressure	1 bar over test pressure (14.5 psi)

### Measuring ranges

Test pressure	100–6000 mbar (1.5–87 psi)
Net housing volume	0.05-5 liters
Diffusion	0-999 ml/min
Pressure drop rate	0-200 mbar/min (0-2.9 psi/min)
Bubble point	0.5-6 bar (7.3-87 psi)

### Measuring accuracy

<del>-</del> .	( C.)
Test pressure	± 0.5% (of the max. value)
Pressure regulation	± 0.4% (at 2.5 bar   36 psi)
Volume measurement	± 5%
Diffusion measurement	± 6%*
Bubble point	± 0.1 bar (1.5 psi)

## **Operating conditions**

Constant ambient temperature	+15° to +35°C
Storage temperature	0° to +40° C
Relative humidity	10-80%

### Order information

Order number	16296
Order number	10290

<sup>\*</sup> at 1000 mbar (14.5 psi) atmospheric pressure and with a pressure drop « test pressure

## Sartocheck 3 Microprocessor-controlled Integrity Tester



Sartocheck 3 is a fully automatic, microprocessor-controlled integrity tester to check the integrity of membrane filter systems. They measure the following upstream integrity values:

- Diffusion test
- Bubble Point test
- Diffusion and Bubble Point test
- Water Intrusion test | Water Flow test
- Pressure Drop test
- Multipoint Diffusion test

All the test relevant data and parameter are printed on the hard copy, including:

- Product, product lot, used filter cartridge(s)
- Wetting agent
- Test parameter (test pressure, time, limit values, ...)
- Results, including actual test pressure, net volume, pressure drop, actual test value, evaluation)
- Date and time

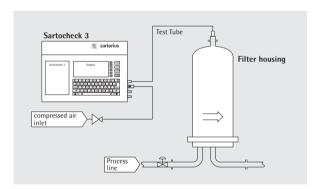
## The benefits of integrity testing with Sartocheck 3

- Easy to use
- Designed for use in bio-, pharmaceutical production environments
- Reliable and accurate measuring procedure
- Individual selectable password protected programming
- Comprehensive validation guide including
  - IQ and OQ check lists
  - Installation and operating instruction

#### PC remote control

- Validatable data transfer via PMS interface;
  - operational functions can be driven and monitored on the PC via PMS interface (Process Management System)
  - installation of the WINCHECK software

Test set-up of integrity testing for membrane filters for liquids



Power requirements	85 – 240 V AC, 47 – 440 Hz
Maximum power input	60 watts
Maximum operating pressure	9999 mbar
Internal limit pressure	7000 mbar
Dimensions (W $\times$ D $\times$ H1 $\times$ H2)	460×360×65×126 mm
Weight	11.2 kg
Measuring ranges Test pressure Pressure drop System inlet volume (with external ref. Vessel)	100 – 6000 mbar 0 – 999 mbar max. 50,000 ml
Measuring accuracy Internal relative pressure Internal test pressure Pressure drop Volume determination Bubble Point	± 12 mbar ± 0.2 % full scale ± 1 mbar ± 4 % ≤ ± 50 mbar
Operating conditions Ambient temperature Rel. humidity	+15°C to + 35°C 10 – 80 %

## **Equipment supplied**

-danbinent amblanen	
Sartocheck 3	16286
Memory Card	83058-000-00
Tubing for compressed gas inlet	18104
Tubing for compressed gas outlet	18103
Ribbon cassette	6982141
Rolls of printer paper	6982142
Test certificate	
Calibration certificate	
Brief instruction	
Installation and operating instructions	
Mains lead (country-specific)	

## Accessories

WINCHECK software package	17011010
WINCHECK interface cable (D-Sub 25/9)	6982148
Memory Card	6982128
Tubing for compressed gas inlet	18104
Tubing for compressed gas outlet	18103
Validation package	16280

## Sartocheck 3 EPS Filter Integrity Testing Without Limits



Sartocheck 3 EPS is a fully automatic, microprocessor-controlled integrity tester including the External Pressure Sensor Technology. Sartocheck 3 EPS is especially designed for performing the Water Intrusion Test (WIT) with highest process reliability:

#### Accuracy

- Avoids interfering influences on the test results of the WIT based on height differences between filter housing and integrity tester. E.g.: WIT on Water for Injection storage tanks.
- No temperature influences on the connection between Sartocheck 3 EPS and filter housing due to data transfer by an electronic cable.

#### **Flexibility**

- No limitations on the distance between filter housing and Sartocheck 3 EPS up to 200 m with the delivered standard cable.
- Ideal for Clean room and EX proof areas.
- Control function via PLC interface, suitable for installation and communication between PLC (autoclaves, freeze dryer, filling machines, ...) and Sartocheck 3 EPS.

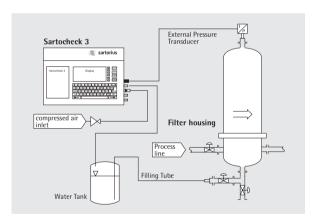
#### Sanitary design

 The external pressure transducer can remain on top of the filter housing during in-line steaming of the filter system.

#### **Validation**

- Individual selectable password protected programming.
- Validatable data transfer via PMS interface (Process Management System).
- Comprehensive validation package is available including IQ and OQ Check lists.
- On-site Validation support by Sartorius validation experts.

Test set-up of integrity testing for membrane filter for gas | air



Power requirements	85–240 V AC, 47–440 Hz
Maximum power input	60 watts
Maximum operating pressure	9999 mbar
Internal limit pressure	7000 mbar
Dimensions (W $\times$ D $\times$ H1 $\times$ H2)	460×360×65×126 mm
Weight	11,2 kg
Measuring ranges Test pressure Pressure drop System inlet volume (with external ref. Vessel)	100 – 6000 mbar 0 – 999 mbar max. 50000 ml
Measuring accuracy Internal relative pressure Internal test pressure External relative pressure External test pressure Pressure drop Volume determination Bubble Point	± 12 mbar ± 0.2 % full scale ± 6 mbar ± 0.1 % full scale ± 1 mbar ± 4 % ≤ ± 50 mbar
Operating conditions Ambient temperature Rel. humidity	+ 15°C to + 35°C 10 – 80 %

## **Equipment supplied**

Sartocheck 3 EPS	16286EPS
External Pressure Transducer	17011003
Memory Card	83058-000-00
Tubing for compressed gas inlet	18104
Tubing for compressed gas outlet	18103
Ribbon cassette	6982141
Rolls of printer paper	6982142
Test certificate	
Calibration certificate	
Brief instruction	
Installation and operating instructions	
Mains lead (country-specific)	

## Accessories

WIT-Kit, valve switch box to control 3 external valves	17005Z0003
External Pressure Transducer	17011003
Memory Card	6982128
Validation package	16281

## Sartocheck® 4 Fully Automatic Integrity Testing Device



#### Description

Sartocheck 4 is the consequent further development of the most successful filter integrity tester of its class, the Sartocheck 3. Based on the straightforward operator concept that distinguished its predecessor, Sartocheck 4's user-friendliness has been improved even more thanks to the following features:

- Touch screen
   Rapid and direct program selection and data entry on the display
- Large, color TFT display
   Clear and easy-to-read display data
- Standard PC keyboard design Familiar keyboard design
- Online assistance Immediate and direct help available in the display
- Straightforward menu guidance Quick and reliable handling
- External Pressure transducer and external valves
   Flexible operation
- Easy to clean
   Cleaning and drying of the internal valve block and internal reference vessel

Sartocheck 4 performs the following tests:

- Bubble Point
- Diffusion
- Bubble Point and Diffusion (combination test)
- Pressure Drop Test
- Water Intrusion Test (WIT)
- Water Flow Test (WFT)
- Multipoint Diffusion Test

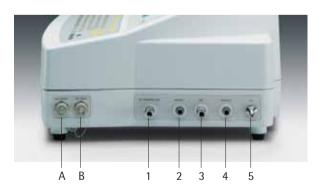
#### In compliance with 21 CFR part 11

The electronic archiving of processing data is currently one of the most critical subjects. Doing full justice to this topical issue, Sartocheck 4 complies with 21 CFR Part 11 in all relevant points:

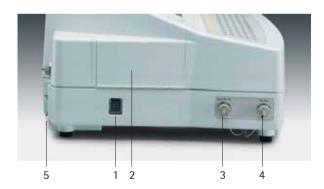
- User management: The system administrator allocates individual access rights to every user. As soon as the user has logged in, all his actions are coded with his name and recorded in the audit trail. After a configurable time, the user will be automatically logged-off.
- Data security: Sartocheck 4 manages up to 250 test programs and 500 test results in an internal database. The user is requested to archive the results database onto a disk. This ensures that no data are overwritten or get lost. In addition to the internal data storage the Sartocheck 4 is able to communicate with a network. Via standard RJ45 connection, all data can be easiely up-load on a FTP Server. For more information call our technical support.
- Audit trail: The audit trail documents all GMP-relevant user actions. All warnings and errors are stored on the audit trail with a real-time stamp.

#### Qualification

Sartocheck 4 qualification ensures that integrity tests to be conducted are carried out with high precision and accurate reproducibility. Our comprehensive Sartocheck 4 validation documentation provides the necessary support for the user. Our Technical Support Specialists are additionally available to help on-site.



- 1: external reference tank
- 2: Venting 1
- 3: Out
- 4: Venting 2
- 5: In
- A: external Sensor
- B: external Valve



- 1: main switch
- 2: 3,5" floppy drive
- 3: Serial Port TU
- 4: PLC Port
- 5: RJ45 Network

T	
Technical	specification

Power requirements	100 – 240 V AC, 50/60 Hz
Maximum power input	74 watts
Maximum operating pressure	9999 mbar   145 psi
Minimum inlet pressure	4000 mbar   58 psi
Dimensions (W $\times$ D $\times$ H1 $\times$ H2)	460 × 390 × 140 × 245
Measuring ranges	100 × 000 × 110 × 210
Test pressure	100-8000 mbar   1,5-116 psi
Pressure drop	1-2000 mbar   0,01-29 psi
System inlet volume	
- with internal ref. Vessel	9000 ml
- with external ref. Vessel	max. 100 l
Measuring accuracy Pressure	0.10/ full cools
riessure	± 0,1 % full scale ± 9,5 mbar
Pressure drop	± 1 mbar
Volume determination	± 4 %
Diffusion	± 5 %
Water-Intrusion	± 5 %
Bubble Point	± 50 mbar   ± 0,7 psi
Operating conditions	+15°C to +35°C
Ambient temperature Rel. humidity	10 - 80 %
Touch screen	10 00 /0
Size	10.4" TFT
Features	256 colors
Comunication ports	
Serial Port TU	RS232
Serial Port MU	RS485
PLC Port	binary signals 12 pins
Network	RJ45
Language option	English, German, French, Spanish, Italian
Language option  Equipment supplied	English, German, French, Spanish, Italian
	English, German, French, Spanish, Italian  16288
Equipment supplied Sartocheck 4	
Equipment supplied Sartocheck 4 Tubing for compressed gas inlet	16288
Equipment supplied Sartocheck 4	16288 18104 18103
Equipment supplied Sartocheck 4 Tubing for compressed gas inlet Tubing for compressed gas outlet Ribbon cassette	16288 18104 18103 6982141
Equipment supplied Sartocheck 4 Tubing for compressed gas inlet Tubing for compressed gas outlet Ribbon cassette Rolls of printer paper	16288 18104 18103
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Equipment supplied Sartocheck 4 Tubing for compressed gas inlet Tubing for compressed gas outlet Ribbon cassette Rolls of printer paper Sartocontrol CD Test certificate Calibration certificate Installation and operating instruction	16288 18104 18103 6982141 6982142
Equipment supplied Sartocheck 4 Tubing for compressed gas inlet Tubing for compressed gas outlet Ribbon cassette Rolls of printer paper Sartocontrol CD Test certificate Calibration certificate Installation and operating instruction Validation package	16288 18104 18103 6982141 6982142
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Equipment supplied Sartocheck 4 Tubing for compressed gas inlet Tubing for compressed gas outlet Ribbon cassette Rolls of printer paper Sartocontrol CD Test certificate Calibration certificate Installation and operating instruction Validation package	16288 18104 18103 6982141 6982142
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Equipment supplied Sartocheck 4 Tubing for compressed gas inlet Tubing for compressed gas outlet Ribbon cassette Rolls of printer paper Sartocontrol CD Test certificate Calibration certificate Installation and operating instruction Validation package Mains lead (country specific)  Accessories External pressure transducer	16288 18104 18103 6982141 6982142 ons 16288VP
Equipment supplied Sartocheck 4 Tubing for compressed gas inlet Tubing for compressed gas outlet Ribbon cassette Rolls of printer paper Sartocontrol CD Test certificate Calibration certificate Installation and operating instruction Validation package Mains lead (country specific)  Accessories External pressure transducer Valve set for external venting	16288 18104 18103 6982141 6982142 ons 16288VP
Equipment supplied Sartocheck 4 Tubing for compressed gas inlet Tubing for compressed gas outlet Ribbon cassette Rolls of printer paper Sartocontrol CD Test certificate Calibration certificate Installation and operating instruction Validation package Mains lead (country specific)  Accessories External pressure transducer Valve set for external venting Valve set for external filling (WIT)	16288 18104 18103 6982141 6982142 ons 16288VP
Equipment supplied Sartocheck 4 Tubing for compressed gas inlet Tubing for compressed gas outlet Ribbon cassette Rolls of printer paper Sartocontrol CD Test certificate Calibration certificate Installation and operating instruction Validation package Mains lead (country specific)  Accessories External pressure transducer Valve set for external venting Valve set for external filling (WIT) Serial Port Interface*	16288 18104 18103 6982141 6982142 ons 16288VP
Equipment supplied Sartocheck 4 Tubing for compressed gas inlet Tubing for compressed gas outlet Ribbon cassette Rolls of printer paper Sartocontrol CD Test certificate Calibration certificate Installation and operating instruction Validation package Mains lead (country specific)  Accessories External pressure transducer Valve set for external venting Valve set for external filling (WIT)	16288 18104 18103 6982141 6982142 ons 16288VP
Equipment supplied Sartocheck 4 Tubing for compressed gas inlet Tubing for compressed gas outlet Ribbon cassette Rolls of printer paper Sartocontrol CD Test certificate Calibration certificate Installation and operating instruction Validation package Mains lead (country specific)  Accessories External pressure transducer Valve set for external venting Valve set for external filling (WIT) Serial Port Interface* cable TU/TU:	16288 18104 18103 6982141 6982142  DONS 16288VP  1ZE0018 1ZE0025 1ZE0026
Equipment supplied Sartocheck 4 Tubing for compressed gas inlet Tubing for compressed gas outlet Ribbon cassette Rolls of printer paper Sartocontrol CD Test certificate Calibration certificate Installation and operating instruction Validation package Mains lead (country specific)  Accessories External pressure transducer Valve set for external venting Valve set for external filling (WIT) Serial Port Interface* cable TU/TU: 0.5 m	16288 18104 18103 6982141 6982142  DONS 16288VP  1ZE0018 1ZE0025 1ZE0026
Equipment supplied Sartocheck 4 Tubing for compressed gas inlet Tubing for compressed gas outlet Ribbon cassette Rolls of printer paper Sartocontrol CD Test certificate Calibration certificate Installation and operating instruction Validation package Mains lead (country specific)  Accessories External pressure transducer Valve set for external venting Valve set for external filling (WIT) Serial Port Interface* cable TU/TU: 0.5 m 2 m	16288 18104 18103 6982141 6982142  DONS 16288VP  1ZE0018 1ZE0025 1ZE0026
Equipment supplied Sartocheck 4 Tubing for compressed gas inlet Tubing for compressed gas outlet Ribbon cassette Rolls of printer paper Sartocontrol CD Test certificate Calibration certificate Installation and operating instruction Validation package Mains lead (country specific)  Accessories External pressure transducer Valve set for external venting Valve set for external filling (WIT) Serial Port Interface* cable TU/TU: 0.5 m 2 m 5 m	16288  18104  18103  6982141  6982142   DONS  16288VP   1ZE0018  1ZE0025  1ZE0026  1ZE0008  1ZE0009  1ZE0010
Equipment supplied Sartocheck 4 Tubing for compressed gas inlet Tubing for compressed gas outlet Ribbon cassette Rolls of printer paper Sartocontrol CD Test certificate Calibration certificate Installation and operating instruction Validation package Mains lead (country specific)  Accessories External pressure transducer Valve set for external venting Valve set for external filling (WIT) Serial Port Interface* cable TU/TU: 0.5 m 2 m 5 m Validation Package	16288  18104  18103  6982141  6982142   DISS  16288VP   1ZE0018  1ZE0025  1ZE0026  1ZE0008  1ZE0010  16288VP

<sup>\*</sup> Available 04/05

#### Sartocheck 4 MultiUnit Next Generation of Filter Integrity Testing





#### Description

The Sartocheck 4 MultiUnit has been developed to enable parallel integrity testing of multiple filters in the biopharmaceutical industry. The MultiUnit is a identical copy of the Sartocheck 4, without the user interface and the data management system. Each MultiUnit connected to a Sartocheck 4 is operated and controlled by this Sartocheck 4 via a RS485 connection.

#### Efficiency

Up to 4 MultiUnits can be connected to one Sartocheck 4 allowing to integrity test up to 5 different filter systems in parallel including the testing capabilities of the Sartocheck 4 itself. Testing up to 5 filters in parallel allows to reduce the time required for filter integrity testing in bio-pharmaceutical production significantly and increases the efficiency of your production process.

#### **Flexibility**

There is no distance limitation between the Sartocheck 4 and the connected MultiUnits. The MulitUnits can be placed all over your production facility and are centrally controlled and operated by the Sartocheck 4. A printout of the test results of the MultiUnit is made by the printer of the Sartocheck 4 and the test data can be transferred to a network for review and achiving.

#### Data transfer security

The Sartocheck 4 MultiUnit is an independent test unit with its' own power supply, electronics and pneumatics. It will maintain the test results even if switched off or if the connection is lost until the handshake communication with the Sartocheck 4 confirms

that the test results have been transferred successfully. If the MultiUnit is switched off during the test it will transfer a corresponding error message as soon as the communication has been automatically reestablished.

#### **Traceability**

The Sartocheck 4 test result printout contains the serial number of the MultiUnit, the user name (log on identity), a unique file name and all the information that has been entered in the batch protocol. The included software, Sartocontrol, can be used to print the test results on an external printer in A4 format.

#### Patent pending thermal insulation

The Sartocheck 4 and its' Multiunit feature a unique, patent pending separation of the electronic components and the temperature sensitive pneumatics in addition to the efficient vent fan. This superior solution avoids any thermal influence on the integrity test measurement from the unit itself.

#### Clean room venting adapter

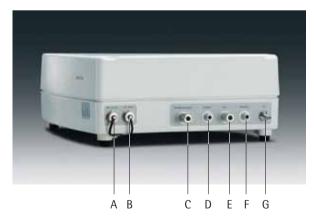
The Sartocheck 4 and its' MultiUnit can be equipped with an optional venting fan adapter that allows to contain the out coming air in order to avoid any dispersion of particles in a clean room.

#### Sartorius Validation Package

The MultiUnit is delivered with a comprehensive validation package including an IQ & OQ protocol that can be accomplished by qualified Sartorius personnel. Assistance for PQ can also be provided from the Sartorius Technical Support team.



- 1. MultiUnit RS485 in out
- 2. MultiUnit RS485 in out
- 3. MultiUnit PLC in out
- 4. Sartocheck 4 PLC in out
- 5. Sartocheck 4 RS485 in out



- A. Ext. sensor
- B. Ext. valve
- C. Ext. reference tank
- D. Venting 1
- E. Outlet (test gas)
- F. Venting 2
- G. Inlet comp. gas

### **Specifications**

#### **Technical specifications**

Power requirements	100-240 V AC 50/60 Hz
Maximum operating pressure	9999 mbar   145 psi
Minimum inlet pressure	4000 mbar   58 psi
Measuring ranges	
Test pressure	100 – 8000 mbar   1.5 – 116 psi
Pressure drop	1 – 2000 mbar   0.01 – 29 psi
System net volume	
- with internal ref. vessel	9000 ml
- with external ref. vessel	100 l
Measuring accuracy	
Pressure	± 0.1% full scale
	± 9.5 mbar
Pressure drop	± 1 mbar
Volume determination	± 4%
Diffusion	± 5%
Water intrusion	± 5%
Bubble point	± 50 mbar   0.7 psi
Operating conditions	
Ambient temperature	+15 to + 35°C
Relative humidity	10-80%
Max distance between SC4	
and multiunit (RS485)	100 m

#### **Equipment supplied**

MultiUnit 16288TU  Tubing for compressed gas inlet 18104  Tubing for test gas 18103  Test certificate  Calibration certificate  Installation and operating instructions  Validation package		
Tubing for test gas 18103  Test certificate  Calibration certificate  Installation and operating instructions	MultiUnit	16288TU
Test certificate Calibration certificate Installation and operating instructions	Tubing for compressed gas inlet	18104
Calibration certificate  Installation and operating instructions	Tubing for test gas	18103
Installation and operating instructions	Test certificate	
operating instructions	Calibration certificate	
Validation nackage	motanacion ana	
variation package	Validation package	
Mains lead (country specific)	Mains lead (country specific)	

#### Accessories

External pressure Transducer	1ZE0018
Valve kit for ext. venting (1 valve)	1ZE0025
Valve kit for WIT and or external pressure sensor (3 valves)	1ZE0026
Cleaning kit	16288CK
Clean room venting adapter	1ZE0021

### Sartorius Trolley System Gain Flexibility and Mobility – Increase Process Reliability



The system consists of the integrity tester, Sartocheck 3 EPS, on top of a trolley. The Trolley System includes the equipment needed for automatic Water Intrusion Testing, e.g., pressure tank for the test water, pneumatically controlled valves, PLC.

#### Mobile easy-to-use system

It is easy to move the system right to where the filters to be tested are located. Only the tubing for filling as well as the external pressure transducer need to be connected to the filter housing.

#### High process reliability

The entire filter test procedure is performed completely automatically by the Trolley System as follows:

- The filter housing is filled with test water
- The test is carried out according to the Water Intrusion Test Method
- The tested housing is drained
- Once the test has been completed and passed, the tubing and the external pressure transducer can be disconnected from the filter system.
- The tested filter system is now ready to use in production.

#### **Flexibility**

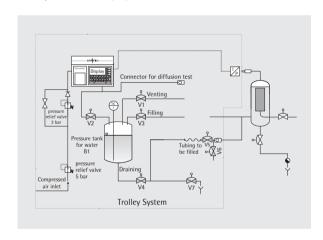
Besides automatic WIT, the system can also be used for standard integrity testing of hydrophilic filters by the Diffusion and Bubble Point Tests.

#### Sanitary design

Ideal for bio-, pharmaceutical production, the internal pressure vessel and the piping for water are steam-sterilisable

Thanks to Sartorius' external pressure transducer technology, there are no longer any limitations concerning the distance between the filter housing and the integrity test system. The Sartocheck 3 EPS features an external pressure transducer that is conveniently located directly on top of the housing. It uses this transducer to control the initial pressure accurately according to the value entered.

#### Set-up of the Trolley System



### **Specifications**

#### **Technical specifications**

#### Electrical

Power requirements	110   230 V AC, 50   60 Hz
Power input	500 VA
Fuse protection	max. 10 A

#### Pneumatic

Inlet compressed air	min. 5 bar max. 10 bar	
Connection	Stäubli RBE03/male	

#### Steam | test water

Steam inlet temperature	max. 134°C
Steam inlet pressure	max. 2 bar
Test water inlet temperature	max. 30°C
Test water inlet pressure	max. 4 bar
Connection	Sanitary DN ISO 8   Ø 50.5 mm
External valve connection	Stäubli RBE06   OD male
External pressure transducer	Stäubli RBE03   OD female
Dimensions	650×450×800 mm
Material pressure vessel and piping	ANSI 316L

#### **Ambient operating conditions**

Temperature	+15°C to +30°C
Rel. humidity	15 to 95% (indoors) no condensation

#### **Equipment supplied**

Integrity Test "Trolley System" (without Sartocheck 3 EPS)	17005AL4708
External valve box (valve for draining and filling) including connectors and tubing	
PLC, SIMATIC	
Temperature sensor	
Level sensor	
Diaphragm valves	
Pressure tank, 20 l	
Documentation	





# FACTS® Services

# Added Value for Your Business

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# Do You Need a Fresh Approach? DISCOVER® – Surveys and Audits





The pharma | biotech industry is highly regulated and confronted with everchanging compliance parameters. In addition to complying with these regulations, companies must increase capacity and lower costs to remain competitive. The first step of any improvement is a precise analysis of the current situation.

Our customers deserve to get expert advice exactly when and where they need it. A dedicated team of professionals will visit your facility to conduct a full plant survey in which the review of equipment, operating procedures and documentation is carried out in complete confidentiality. Our recommendations for improvements can help make your facility compliant with cGMP and regulatory guidelines and, in addition, optimize product recovery.

We understand industry regulatory requirements and can take the headache out of inspections and auditing.

#### We specialize in:

- Steam-In-Place (SIP) procedures
- Clean-In-Place (CIP) procedures
- Filter handling for optimum results
- Integrity test methods
- Hardware design options
- Validation documentation
- Process designs and qualification
- Technical studies
- Regulatory compliance

We then will use the plant survey report as the basis for process optimization and appropriate, organized and efficient project management. This provides the Sartorius-Client team with a guide for working together with you effectively, on a project-by-project basis.

#### DISCOVER® - Case study

A well-known pharmaceutical company was producing a vaccine that had to be pre-filtered. There were 60 production campaigns a year, each of 3000 L. At the time, the company was using 24×40 inch filters for coarse filtration and 24×40 inch filters for fine filtration. The processing time was 2 hours.

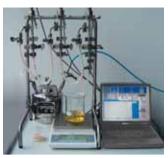
Sartorius provided the company with 11×40 inch special prefilters and 11×40 inch fine filters. The processing time was cut to one hour and there was no product loss.

Total annual savings were \$263,000.

#### For direct inquiries

DISCOVER® – Surveys and Audits discover.info@sartorius.com

# Are You Getting What You Really Need? INCREASE® – Process Optimization







Our goal is to find the optimal process solution for your specific application. We understand that reducing cost per liter, improving yield and implementing efficient process times while increasing product and process reliability are the major success factors that our customers require. Our attention to all detailed aspects of your filtration process can help you achieve an optimal process and maximum value.

#### Filter selection

The first step is selecting the right filters. We primarily base this selection on published and calculated data. We review the filter membranes with emphasis on chemical and physical compatibility in contact with pharmaceutical products and cleaning agents, particle and bacteria retention, adsorption properties, required flow rate and total throughput.

#### Filterability studies

In order to help our customers select a filter or a compatible combination of filters, our specialists perform filterability trials using filter discs or small pleated devices with your product under actual process conditions. To maximize your process for zero tolerance with inefficiencies and to optimize flow pressure ratios, Sartorius has designed a filterability kit called the Zero-T. It is run by a highly refined software program that generates a permanent report featuring throughput and scale-up analysis.

#### Scale-up

We believe that our flexibility is a critical aspect of excellent customer service. Whether you need laboratory or process scale filter units, we've got just what you need for manufacturing sterile products in the pharma | biotech industry. By offering a wide selection of 150 cm² to 18,000 cm² of filtration area we enable our customers to accurately make the necessary adjustments for full process scale-up using the same geometry, construction and pleated filter materials in all unit sizes.

Sartorius products can be tailored to optimize your complete downstream processing. We can even meet the most exacting process requirements; for example, our Sartobind membrane adsorbers are extending the possibilities in chromatography. We offer ready to use, disposable units that perform extremely well in the purification of high-value products. The units can be used for ion-exchange applications.

#### INCREASE® - Case study

A pharmaceutical company produces a high viscosity eye drop solution. The batch size is 5000 L and 100 batches are produced annually at 7 production sites. The company was using  $5\times30$  inch cartridge filters with a processing time of 18 hours because of numerous integrity test failures and early blockage of the filter.

Sartorius resolved the problem by using  $5 \times 20$  inch Sartopore 2 filters. Processing time was cut to 10 hours and there were no filter blockages.

Total annual savings were \$190,000.

#### For direct inquiries

INCREASE® – Process Optimization increase.info@sartorius.com

### Is Time an Issue for You? CONFIDENCE® – Validation Services







Every Sartorius sterilizing grade filter is manufactured with complete traceability of materials. Our validation guides provide extensive information on technical specifications, testing and quality assurance.

Make the choice that helps bring your products to market rapidly – on time, every time. Sartorius offers the most comprehensive, documented validation studies in just 30 days.

Extractables Guides complete this information by summarizing data evaluated during worst case qualitative studies developed by Sartorius in cooperation with a well recognized research institute for elastomer technology.

Within the scope of process validation, the biopharmaceutical industry needs to prove that process components, such as filters, do not affect the pharmaceutical product by removal of ingredients from it or by release of substances into it. In addition, for sterilizing grade filtration the microbial retentivity of the filter has to be validated.

#### **Process validation**

The Sartorius CONFIDENCE® program supplies scientific evidence for validation studies by using your product formulation under simulated process conditions. We will evaluate your process with you to define relevant testing conditions on the basis of current regulatory requirements of the relevant national health authorities and industry standards, such as those established by the Parenteral Drug Administration (PDA) Technical Report No. 26 "Sterilizing Filtration of Liquids." CONFIDENCE® reflects the assurance you'll enjoy knowing that we focus on all aspects of actual worst case scenarios.

To us, full service means testing all your suppliers' products – from filters and bags to tubing, stoppers and containers – whether they are manufactured by us or by one of your other suppliers.

#### **Flexibility**

We respect our customers' individualism. You'll experience total peace of mind with the Sartorius validation services program. Our customized methodology and documentation ensures regulatory compliance for the critical steps in your manufacturing process.

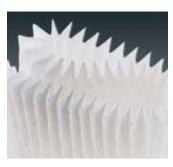
Thanks to our scale-up | scale-down philosophy, we guarantee full process relevance. Depending on volume, we use pleated filter elements with the smallest filtration area (starting at 150 cm²) made of the identical filter materials as those used in your actual manufacturing process.

#### Quality

Our state-of-the-art validation laboratories work with qualified test equipment. Specifically for microbiological retention studies, Sartorius has designed different automatic systems that ensure process relevance by considering the influencing parameters for filter performance, like temperature, time, pressure | flow rate and sterilization methods.

The pharma|biotech market is increasingly focusing on targeted cancer therapy. Cytotoxic products require specific handling. In consideration of the relevant safety issues, Sartorius has installed procedures and a laboratory environment to meet the challenges of product specific validation testing for cytotoxic drug products.

Talking about our customers' processes is all about confidentiality and trust. This is one of Sartorius' strengths as theoretical evaluation or a database approach has never been part of our validation service portfolio. Our validation test scope ensures product and process specific significance. We define the choice of test methods together with our customers by following the principle of minimum test effort while ensuring maximum process reliability. A complete filter validation program typically includes:





#### Bacteria challenge

Regulatory agencies define a sterilizing grade filter as one that will produce a sterile effluent after a microbial challenge of ≥1×107 CFU/cm² of Effective Filtration Area. Sartorius will first conduct viability studies with industry standard test organisms or the customer's indigenous bioburden to determine the most appropriate test methodology. Sartorius then simulates customers "worst case" process conditions in the laboratory using scaled down process filter devices.

#### Extractables Leachables

Extractables may be a concern with regard to filters in contact with pharmaceutical products. Regulatory agencies are asking manufacturers of such products to demonstrate that the product does not contain objectionable levels of extractables. Extracts from worst case extractions using water or ethanol at elevated temperatures are analyzed to qualitatively identify potential extractables. Although the information from this type of study may be valuable for evaluations on potential extractables release. it does not predict all interactions between the filter and the formulation. Sartorius also offers testing of extracts from actual formulations.

An array of analytical techniques is used to detect and identify extractables, even in the most complex formulations. These techniques include, but are not limited to, RP-HPLC, GC-MS and FTIR. As there is a growing number of materials to be tested for extractables, Sartorius has extended its tests to include filters, tubing, bags, bottles, vials, stoppers and packaging materials.

#### Chemical compatibilty

First, each component of the product formulation is reviewed for potential chemical interaction with the filter material. For chemical compatibility testing, the filter membrane is exposed to the product formulation under the customer's worst case process conditions and tested by comparison of specific parameters prior to and after exposure to the product.

#### Product wet integrity test

Integrity testing is a non-destructive method of determining the presence of defects in the filter. The use of drug formulation or other process fluids as wetting media may require integrity test limit values that are different from water. Testing by Sartorius provides correct and reproducible product specific integrity test limit values.

#### **Adsorption studies**

The binding of product components to filter material may affect product efficacy and stability. Several factors influence the process of binding; these include temperature and pH. Sartorius offers adsorption studies using appropriately sensitive analytical test methods for protein and preservative determination.

#### Particle release testing

In general, particle release from filters should be minimized. For instance, injectable solutions should be essentially free from particles that can be observed on visual inspection. For the determination of particle size and amount after product contact, Sartorius uses a laser scattering sensor of a suitably high precision. Testing is performed in accordance with the relevant pharmacopoeia.

#### CONFIDENCE® - Case study

A biotechnology company was about to introduce a new antiviral drug for HIV treatment. The sales potential was \$450 million annually, translating to daily sales of over 1 million dollars. Delays in the NDA and other application costs were mounting. Other vendors offered to complete filter validations over a period of 2–3 months. Sartorius offered CONFIDENCE® Validation Services and committed to a 30-day delivery time. We kept our promise.

The difference in sales was over 40 million dollars.

#### For direct inquiries

CONFIDENCE® – Validation Services confidence.info@sartorius.com

# Where Do You Want to Grow Tomorrow? EXPAND® – Training and Seminars





"The only person who is educated is the one who has learned how to learn ... and change." (Carl Rogers)

At Sartorius, we realize that proper training and ongoing education are challenging tasks. We will help you expand your mind with our comprehensive course program specifically designed to address up-to-date regulatory needs and technical training in the biopharmaceutical industry.

Our independent scientific technical training courses cover both theoretical and practical aspects with a strong emphasis on hands-on, practical exercises. Completion of these training courses is documented in a certificate, which is a GMP requirement.

Our team of qualified seminar speakers and technical trainers will meet you at your place or ours.

In 2001, Sartorius unveiled a new state-of-the-art-facility in Goettingen, Germany. Plant 2001 is home to the prestigious Sartorius College, where not only seminars and technical training courses, but also conferences and conventions are held on a regular basis. Sartorius College also hosts a multitude of seminars every year, covering a variety of topics, including communications, management, economics and science. All these practical, professional, and motivating seminars are held at facilities equipped to meet the standards of contemporary learning.

Training courses are conducted at Sartorius College or on site and may be customized for the needs of your company. Our comprehensive list of seminars and courses include:

- Filtration Basics Principles and Practice
- Regulatory Requirements for the Pharmaceutical and Biotechnology Industries
- Integrity Test Methods
- Crossflow Filtration
- Steam Sterilization
- Cleaning Validation
- Filter Validation
- Fermentation and Downstream Processing
- Membrane Adsorber Technology
- Microbiological Quality Control

Visit our website at www.sartorius.com for a current list of courses and seminars.

#### For direct inquiries EXPAND® – Training and Seminars expand.info@sartorius.com

#### **Mechatronics services**

Our Mechatronics Division is a combination of mechanical and electrical engineering expertise providing quality weighing instrumentation from micrograms in laboratory research to tons in industry, in addition to checkweighers and metal detectors. The diversity of products provides users with the most advanced weighing technology. Our Mechatronics Calibration laboratories are recognized throughout the world for their expertise and accuracy. Software validation and systems qualification are the core competencies of our service group.

Support of the Mechatronics Services also covers calibration of our MD8 Air Samplers as well as calibration and qualification of the Sartocheck filter integrity testing systems.



### BioPharm-Alliance, answers for your critical success factors

#### Time-to-Market

#### Design review and technology transfer:

We review process designs and scale-up to achieve optimal output and regulatory approval for you.

#### Time-to-Approval:

Our regulatory guidance, inspection readiness and submittal services accelerate validation and compliance procedures.

#### Validation organization:

This service evaluates your user requirements and leads to a design of the validation master plan. We organize the plan for systemic efficiency in your manufacturing process.

#### Cost of goods

#### Yield enhancement:

Process plant surveys evaluate individual process steps to eliminate or reduce yield losses during downstream processing.

#### Process and down-time reduction:

We investigate and analyze processes to mitigate bottlenecks and lag time within the process.

#### Capacity utilization:

We implement new technologies in downstream processing and processing controls to enhance process flow utilization.

#### Labor efficiency:

Appropriate training of your personnel supports process improvement initiatives and proper adherence to protocols.

#### **Production capacity**

#### Yield improvement:

We'll show you how to maximize yield improvement with your existing process that will result in increased capacity.

#### Process times flow enhancement:

Achieve efficiencies in your process with state-of-the-art equipment and upstream improvement process surveys.

#### **Process controls:**

Appropriate process controls avoid prolonged quarantines, reprocessing or production stoppage of your product.

#### Regulatory compliance

#### FDA | EMEA | ISO compliance:

We'll design and write validation and operating procedures as well as submittal documentation to regulatory authorities.

#### Quality systems audit:

Together, we'll review new or existing quality systems to improve process controls while meeting regulatory requirements.

#### Regulatory guidance:

We'll help you implement regulatory requirements or changes and train personnel accordingly.

#### **Documentation submittal support:**

Lern from us about protocols and filings for inspection by regulators to minimize delays in the approval process.





# Microbiological Control

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#### MD8 airscan® Air Sampler for Critical Applications





The system consists of the MD8 airscan air sampler and disposable gelatine filter units. The system is routinely used for the quantitative detection of air-borne organisms, mainly in sterile areas of class A and B (classification according to "EU-Guide for GMP"), isolators, or blow-fill-seal machines.

The very high air flow rate of 8 m<sup>3</sup>/h enables isokinetic sample removal at flow speed usual in laminar flow as well as for the filtration of 1 m<sup>3</sup> air very quickly (less than 8 minutes). The filter unit can be placed remote from the air sampler.

The MD8 airscan air sampler allows to adjust selectively and easily air flow rate and sample removal speed. By means of a specially developed calibration unit (see accessories) the user can calibrate the MD8 airscan locally, e.g. within the scope of validation steps.

After removing the sample, the gelatine filter can be placed directly on the agar culture medium for incubation and colony growth.

#### **Specifications**

#### Specifications for the MD8 airscan air sampler

Air flow rate	2.0 m <sup>3</sup> /h – 8 m <sup>3</sup> /h adjustable in 100 liter steps
Timer	1–99 minutes, adjustable in 1 minute steps
Max. deviation	±5% in a temperature range of 15°–35°C
Noise level	For gelatine membrane filters, max. 62 dB (A)
Weight	Approx. 6.5 kg
Dimensions (L×W×H)	375×242×228 mm
Correction of the air flow rate setting	When the entered air flow rate cannot be attained, the display shows the max. attainable flow rate for a corresponding new setting below this value.

#### Ordering information for the MD8 airscan air sampler

16746	MD8 airscan air sampler, 230 V, 50 Hz
16747	MD8 airscan air sampler, 115 V, 60 Hz
16748	MD8 airscan air sampler, 100 V, 50-60 Hz

Each version can be switched from 50 to 60 Hz and back.

#### Accessories for the MD8 airscan air sampler

17801 Holder for disposable gelatine filter units	

#### Ordering information for consumables

Disposable gelatine units, sterile, pack of 10

1752880ACD	Individually packed in 1 Polyethylene bag each
1752880BZD	Individually packed in 3 Polyethylene bags each
1752880VPD	Individually packed in 3 Polyethylene bags each, but label on innermost bag

Special brochures available on request. Order no. SLF3001-e SM-3011-e

#### **AirPort MD8 Battery-Power, Portable Air Sampler**





AirPort MD8 is the new air sampler for the pharmaceutical industry, the biotechnology, the food and beverage industry, for hospitals environmental care and for works safety.

#### AirPort MD8 offers the following benefits

- Battery-powered and portable for universal use.
- Battery power level clearly indicated so constant performance during sampling is guaranteed.
- Ergonomic design and easy to clean.

- Flexible adjustment possibilities of the volume flow and the sample volume.
- User friendly prompting with the option of five languages; English, French, German, Italian and Spanish.
- Parameters last used stored even after automatic shut-off.
- The device can be calibrated locally.

AirPort MD8 uses the gelatine membrane filter method guaranteeing reliable and exact measurement results.



#### Specifications for AirPort MD8

-	
Volume flow regulation	By an integrated impeller wheel.
Volume flow adjustable in three steps	30 l/min., 40 l/min and 50 l/min.
Fixed given sample volumes	25, 50, 100, 250, 500, 750 and 1000 liters. In addition, the sample volume can be chosen manually in 5-liter steps.
Operational life with one battery charge	Approx. 4.5 hours
Noise level	For gelatine membrane filters 48 dB (A)
Weight	Approx. 2.5 kg
Dimensions (L×W×H)	300×135×165 mm

#### Power supply

Battery	NiMH 16.8 Volt/3800 mAh
Battery charger input	100-240 V/47-63 Hz/600 mA
Battery charger output	24 V/1000 mA
Charging time	Approx. 4.5 hours for empty battery

#### Ordering information for the AirPort MD8

16757	AirPort MD8, complete with holder (17801) for gelatine
	disposable units and battery charger (69898525).

#### **Accessories for the AirPort MD8**

17801	Adapter for disposable gelatine filter units.
69898525	Battery charger

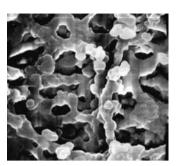
#### Ordering information for consumables

Disposable gelatine units, sterile, pack of 10

1752880ACD	Individually packed in 1 Polyethylene bag each
1752880BZD	Individually packed in 3 Polyethylene bags each
1752880VPD	Individually packed in 3 Polyethylene bags each, but label on innermost bag

Special brochure available on request. Order no. SM-1502-e

#### **Gelatine Membrane Filters**



Gelatine filters in conjunction with the MD8 air samplers (gelatine filter method) are used for collection of airborne microbes and viruses. Gelatine filter disposables are individually packed, presterilized and ready-to-connect units, each consisting of a gelatine membrane filter and a holder. Gelatin membrane filters are still available as filter discs, suitable for the filter holder 17655 (80 mm diameter) supplied with the MD8 airscan air samplers as well as in smaller diameters.

Gelatine filters in conjunction with the MD8 air samplers offer the following features and benefits:

- "Absolute" retention rate (99.9995% for Bac. sub. niger spores, 99.94% for T3 phages).
- The filter maintains the viability of collected microorganisms for a relevant and meaningful sampling time.
- Gelatine filters are completely watersoluble. Therefor microbes in one sample can be cultivated in on different nutrient media or low and high bacteria counts can be measured. The sample is not affected by inhibitors.
- The solubility of the gelatine filter is a prerequisite for virus sampling.

### **Specifications**

#### Specifications of gelatine filters

Gelatine filters	water soluble, pore size 3 μm, thickness approx. 250 μm
Thermal resistance	Max. 60°C
Residual dampness content	46-49%
Air flow rate	Approx. 2.7 I/min./cm <sup>2</sup> at $\Delta P = 0.05$ bar
Retention rates	1. Bac. subtilis niger spores 99.9995% at 0.25 m/s inlet velocity. 2. Coli-Phages: phage T1, 99.9% at 0.3 m/s inlet velocity and 50% rel. air humitity. Phage T3, 99.94% at 0.3 m/s inlet velocity and 80% rel. humitity.
Filtration area	38.5 cm <sup>2</sup>
Conditions for use	Room temperature, max. 30°C, max. air humity 85%
Sterilization	Supplied presterilized by gamma irradiation

#### Disposable gelatine units, sterile, pack of 10

#### Order number

1752880ACD	Individually packed in 1 Polyethylene bag each
1752880BZD	Individually packed in 3 Polyethylene bags each
1752880VPD	Individually packed in 3 Polyethylene bags each, but label on innermost bag

#### Gelatine disc filter, sterile, sealed in units of five each in a polyethylene bag

Order number	Diameter	Package size
1260280ALK	80 mm	50
1260250ALN	50 mm	100
1260250ALK	50 mm	50
1260247ALN	47 mm	100
1260247ALK	47 mm	50
1260237ALK	37 mm	50

Special brochure available on request. Order no. SLF3001-e | SM-3011-e

# Accessories for the MD8 Air Samplers



#### New calibration unit

The user himself can calibrate the MD 8 airscan and AirPort MD8 directly on the job by means of the calibration unit\*.

This is absolutely necessary above all within the scope of validation steps, for which it is important, that the shown air flow rate (desired value at the MD8) corresponds to the actual air amount (actual value at the calibration device). The calibration unit is supplied complete with battery charger | power supply unit (specific for the country in which it is used), filter holder, connectors set and connection tube (PVC, 2 m).

\* Alternatively, a maintenance agreement can be signed. Within the scope of the contractual services, Sartorius technicians will carry out a calibration of the MD8 at regular intervals

#### Specifications for calibration unit

•	
Dimensions	Length, 300 mm (without filter holder), Width, 390 mm with handles Height, 182 mm min., 200 mm max. (adjustable feet)
Connectors	Quick locks (bayonet principle)
Operational life with full battery	Approx. 4 hours
Weight	Approx. 11 kg
Charge time for empty battery	Approx. 10 hours
Measuring range	1–16 m³/h
Max. fault	1 to 16 m <sup>3</sup> /h, ±2%
Type of protection	IP 40
Allowable ambient temperature	Min. 0°C, max. 40°C

#### **Tubing and connectors set**

If the disposable gelatine filter unit is not placed directly at the MD8 airscan, but in a distance from it, a flexible plastic hose (2 m or 5 m), a connectors set and, if not available, a holder (tripod 16970, double socket 16976, clamp 17037) are necessary for the connection between filter and MD8 airscan. The autoclavable silicone hose is used instead of the flexible plastic hose, if the MD8 airscan has to be used in sterile rooms, operating rooms, isolators, blow-fill-seal machines, etc. With this hose attached to the air outlet connector (exhaust), the waste air can be led off into an other room.

#### Case

A stable case for the transport and the storage of a MD 8 airscan incl. accessories.

#### Aluminium stack

It consists of a middle part, 10 numbered filter holders and 2 end caps. The stack is first sterilized (by 180°C dry heat, 2 h), and then equipped with the filters under sterile conditions (LF-cleanbench). The prepared filter holders are put on a side of the middle part. After removing the sample, the inserted filter holders are put on the other side of the middle part, so that used and not-used filter holders are separated from each other.

#### Accessories for isolator application

For the monitoring of isolators with MD8 airscan we recommend to use stainless steel accessories such as adapters 17016 (DN25) or 17030 (DN30), clamps 17033 for sanitary flanges, connector 17659---001 or 17659---003 (for tri clamp) and the filter holder for gelatine filter disposables 17801---001 as well as a Sartofluor capsule with PTFE membrane and sanitary flange inlet and outlet, for sterile air filtration inserted between the MD8 airscan and isolator. This construction makes it possible that the MD8 air sampler remains outside the critical work area (the barrier function between different clean room classes is maintained).

#### Accessories for remote control function

Users of the MD8 airscan now have the possibility of operating this air sampler from a distance using either of two remote control configurations:

a) Via a PC (with Microsoft 95/98 or higher) with MD8 airscan dialog system and cable connection to the MD8 airscan (1ZE---0004). b) Via a PLC interface unit (1ZE---0003).

### Gelatine membrane filter, 80 mm, sterile, pack of 50 for use with stack

Gelatine membrane filters are still available as 80 mm filter discs, suitable for the filter holder supplied with the MD8 airscan. The filters are sterile supplied, but the filter holders have to be sterilized by dry heat (180°C, 2h) and then equipped with the filters under sterile conditions. For performing routine check-ups, a stack is recommended in this case.

#### Further consumables for air monitoring

If gelatine filters cannot be used (high humidity, high temperature), it is recommended to use cellulose nitrate filters.

#### Accessories for the MD8 air samplers

#### Order numbers

16756	Calibration unit for the MD8 air samplers
17208	Case for MD8 airscan
17656	Aluminium stack for MD8 air samplers

#### Replacement parts for the stack

#### Order numbers

17655	Individual filter holders for gelatine filter type 1260280ALK
17660	Middle part
17661	End cap

#### **Tubing and connectors set**

#### Order numbers

17085	Flexible PVC hose with reinforced ends (2 m)
17088	Flexible PVC hose with reinforced ends (5 m)
17662	Silicone tubing, sterilizable (1 m, state length required)
17657	Set of connectors (consisting of 17658 and 17659), aluminium
17658	Connector (air sampler inlet to flexible hose), aluminium
17659	Connector (flexible hose to filter holder   adapter), aluminium

#### Accessories for isolator application

#### Order numbers

0.46	
17016	Adapter (DN 25 hose barb to 1"-1 1/2" sanitary flange) to connect MD8 airscan to an isolator via silicone tubing and a filter capsule, stainless steel
17030	Adapter (DN 30 hose barb to 1"-1 1/2" sanitary flange) to connect MD8 airscan to an isolator via flexible PVC hose and filter capsule, stainless steel
17033	Clamp for 1" – 1 1/2" sanitary flanges, stainless, stainless steel
17659001	Connector (flexible hose to filter holder adapter), hose nipple, stainless steel
17659003	Connector (flexible hose to filter holder adapter), tri clamp, stainless steel
17801001	Adapter for gelatin filter disposables, stainless steel
5181307T9SS	Sartofluor Capsule with PTFE membrane and sanitary flange inlet and outlet, for sterile air filtration inserted between the MD8 airscan and isolator

#### Accessories for remote control function

#### Order numbers

1ZE0003	Remote control (Interface) for MD8 airscan designed for PLC units
1ZE0004	Remote control for MD8 airscan for use with PC (dialog system software)

#### Consumables used with stack

Gelatine disc filters, 3 µm pore size, 80 mm, 50 pieces/pack

#### Order numbers

12602-080 ALK	Gelatine disc filter, sterile, sealed in units of five each in a
	polyethylene bag

#### Further consumables for air monitoring

Cellulose nitrate membrane filters, 80 mm diameter, 100 pieces/pack

#### Order numbers

Oraci namocis		
1140480ALN	Cellulose nitrate membrane filters, 0.8 µm, white with black grid, presterilized in bags of 5	
1300480ALN	Cellulose nitrate membrane filters, 0.8 $\mu$ m, gray with white grid, presterilized in bags of 5	
1130180ALN	Cellulose nitrate membrane filters, 8 µm, white no grid, presterilized in bags of 5	

### Gridded Membrane Filters from Cellulose Nitrate (Cellulose Ester) acc. to ISO Standards, Sterile and Individually Packaged, for Colony Counts



Sterile, individually packed filters have long become standard for routine microbiological quality control because of the user benefits they offer.

They are pre-sterilized and ready-to-use and save preparatory time. As they are individually packed, they avoid the possibility of contamination of remaining filters in opened packs and conform with GLP, having filter identification and lot number printed on each individual envelope.

The increasing demand on these filters required the construction of a new packaging machine with ultra-modern stamping. Each membrane is checked to ensure it is not damaged in any way, is positioned correctly with no slippage under the edge seal, has perfect grid printing and is free of particles. Each envelope is checked for readable lettering. Quality control par excellence!

These membrane filters are in accordance with the following norms: ISO 7704. ISO 7899-2. ISO 8199. ISO 9308-1 and EN 12780. In addition to this they have been manufactured for use especially at the same time with Sartorius Nutrient Pads in accordance with the AFNOR (French Standards), the American Petroleum Institute, the American Society for Microbiology, the APHA Standard Methods, the Association of Official Analytical Chemists, the British drinking water guideline, the British Standards, the DGHM (German Association of Hygiene and Microbiology), the DIN Guidelines (German Standards), the European Brewery Community, the European drinking water guideline 98/83, the European Pharmacopoeia, the German Pharmacopoeia. the International Commission for Uniform Methods of Sugar Analysis, the International Dairy Federation, the International Fruit Juice Producers, the ISO Guidelines, the LMBG (German food law), the method described by Lanaridris & Lafon-Lafourcade, the method described in the journal of Food Protection, the method described in the journal of the Institute of Brewing, the methods of the Central European brewery commission, the MNO (Mineral Table Water Guideline), the National Canners Association, the testing procedures for packaging stuff, the U.S. Environmental Protection Agency, the United States Pharmacopoeia, the US Department of Agriculture, the VLB (German Institute of brewery), the Zentralblatt für Hygiene (Journal of Hygiene), the US Federal Drug Administration and Internal Standard Operation Procedures.

#### **Specifications**

#### The membrane filters

All membranes are made of cellulose nitrate, a material which assures effective retention with high flow rates and optimum colony growth. The printed grid with a size of 3.1×3.1 mm makes the counting easier, especially for higher bacteria counts and for microcolonies, but does not influence the growth. The various filter colors allow the best contrast to the colonies and particles.

#### High flow membranes

The standard membrane filter for microbiological analysis is an 0.45  $\mu m$  filter. One special variant is the High Flow membrane. It provides 30% higher flow rates in comparison to traditional 0.45  $\mu m$  membranes. The special pore structure of the new 0.45  $\mu m$  HighFlow membrane filters allows shorter filtration times due to higher flow rates and throughputs. As every Sartorius 0.45  $\mu m$  membrane filter lot these membranes are also tested and released according to ISO 7704.

#### Additional membrane filters

Cellulose nitrate (cellulose ester) membrane filters, gridded, non-sterile packaged (page 244).

Cellulose nitrate (cellulose ester) and cellulose acetate membrane filters, white, individually, sterile packaged (page 246).
Hydrophobic edge membranes are used

Hydrophobic edge membranes are used mainly in the sterility testing of solutions containing antibiotics (page 248).

#### Microsart<sup>™</sup> e.motion





#### Microsart™ e.motion Dispenser

Fully automated membrane filter dispenser for individually sterile cellulose nitrate filter discs.

The membrane filters are fully automatically removed from their sterile package – either in a touch-free mode via an optical sensor or at the touch of a button. A pedal switch can be optionally connected to the dispenser. Thanks to their new motorized traction roller, each filter is quickly and reliably dispensed. Membranes that accidentally slide out of their packaging or that even get damaged in the process are now problems of the past.

The controller specially developed for the Microsart™ e.motion prevents unwanted dispensing of several membrane filters at a time – it's simple, "fail-safe," and fast.

The clear, compact design of the dispenser allows quick and easy cleaning. The Microsart™ e.motion has an interface port available so that other sensor systems can be connected to control the dispenser. The dispenser's low weight makes it easy to transport. Both its functions and design are ideal, giving you the versatility and flexibility you need in your lab.

#### **Applications**

Membrane Filters for Colony Count, Particle Testing and Microscopy

Just a small sampling of the advantages you will benefit from when using the Microsart™ e.motion Dispenser:

- Fully automated membrane filter dispenser
- Works hands-free by an optical sensor
- Works by touch button
- Compact design
- Rapid and reliable transport due to sprocket feed roll technology
- Easy insertion of the filter band
- Easy-to-clean

#### Specifications of the Microsart™ e.motion dispenser

Dimensions (L×H×W) in mm	204×213×165
Weight	2.9 kg
Operating voltage	110 V/230 V optional
Frequency	50-60 Hz
Max. power	Consumption 10 W
Dispensing speed	0.5 sec
Dispenser delay	5 sec
Certificates	CE mark and EMC directive, European Standards EN 50081-1 and -2, EN 50082-1 and -2, EN 61010

#### Order number for Microsart™ e.motion dispenser

16712	Microsart™ e.motion dispenser, fully automated membrane filter dispenser
1ZE0028	Pedal switch for Microsart™ e.motion Dispenser

#### Microsart™ e.motion Membrane Filters

The membrane filter band specially designed for the Microsart™ e.motion can be conveniently inserted, and changed easily and rapidly as needed, even without having to completely use up a complete package quantity. Each box contains 100 membrane filters individually sealed on a special pleated band, and is designed so that it is easy to open and seal for storage. Microsart™ e.motion – reliable help in your lab.

Just a small sampling of the advantages you will benefit from when using the Microsart™ e.motion Membrane Filters:

- Outstanding recovery rates for microorganisms
- 0.45 μm are acc. to ISO 7704
- Multi-fit: Fits into various dispensers
- Protective paper-free
- Packaged on a special pleated band
- Product data are printed on
- High Flow membranes available
- Gamma irradiated, 25kGray

#### **Specifications**

Please refer to the membrane type: Cellulose nitrate (cellulose ester), gridded, individually, sterile packaged

#### Order numbers for Microsart™ e.motion Membrane Filters Diameter 47 mm or 50 mm, in pack of 3×100 membranes, individually, sterile packaged, without protective paper

	- h h - h	
white   black	11407Z-47SCM	0.2 μm
white   black	11407Z-50SCM	0.2 μm
white   black	114H6Z-47SCM	0.45 μm High Flow
white   black	114H6Z-50SCM	0.45 μm High Flow
white   green	139H6Z-47SCM	0.45 μm High Flow
white   black	11406Z-47SCM	0.45 μm
white   black	11406Z-50SCM	0.45 μm
gray   white	13006Z-47SCM	0.45 μm
gray   white	13006Z-50SCM	0.45 μm
green dark green	13806Z-47SCM	0.45 μm
green dark green	13806Z-50SCM	0.45 μm
white   green	13906Z-47SCM	0.45 μm
white   green	13906Z-50SCM	0.45 μm
gray   white	13005Z-47SCM	0.65 μm
gray   white	13005Z-50SCM	0.65 μm
gray   white	13004Z-47SCM	0.8 μm
gray   white	13004Z-50SCM	0.8 μm

# Cellulose Nitrate (Cellulose Ester) Membrane Filters, Gridded, Individually, Sterile Packaged

#### **Applications**

Membrane Filters for Colony Count, Particle Testing and Microscopy

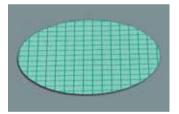
Just a small sampling of the advantages you will benefit from when using this type of membrane filter:

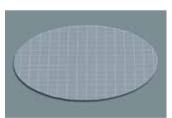
- Outstanding recovery rates for microorganisms
- 0.45 μm are acc. to ISO 7704
- High Flow membranes available
- Three different colors available Certified Quality
- Gamma irradiated, 25kGray

#### **Specifications**

•	
Design	47 or 50 mm in diameter, white, grey or green and gridded
Growth Promotion Test acc. to ISO 7704	<ul> <li>No enhancement or inhibition by the grid lines</li> <li>No enhancement or inhibition due to chemical extractables</li> <li>No enhancement or inhibition by the sterilization process</li> </ul>
Sterility Test	Sterile
Thermal resistance	130°C max.
Thickness acc. to DIN 53105	115–145 μm
Chemical Compatibility	Aqueous solutions (pH 4-8), hydrocarbons and several other organic solvents.







#### Typical performance rates for various pore sizes

Pore size		0.2 μm*	0.45 μm**	0.45 μm High Flov	0.65 μm v**
Flow rate for water per cm <sup>2</sup> at 1 bar acc. to DIN 58355	in ml/min	20	70	100	130
Coliform retention	in %	100	100	100	n.a.
Recovery rate lot-released acc. to ISO 7704	in %	≥ 90	≥ 90	≥ 90	≥ 90

- \*) Pore size determined by quantitative retention of Brevundimonas diminuta in accordance with the ASTM Document F 838-83 (1993) Standard test method for determining bacterial retention of membrane filters utilized for liquid filtration.
- \*) Pore size determined by quantitative retention of Serratia marcescens in accordance with the Standard Methods of Water and Waste Water

White membrane with black grid, for detection of bacteria with dyed media, particle count & microscopy, type 114, individually, sterile packaged

Pore size	Order No.	Diameter	Pack size
0.2 μm	1140747ACN	47 mm	100
	1140747ACR	47 mm	1,000
	1140750ACN	50 mm	100
	1140750ACR	50 mm	1,000
0.45 μm	1140647ACN	47 mm	100
	1140647ACR	47 mm	1,000
	1140650ACN	50 mm	100
	1140650ACR	50 mm	1,000
0.45 μm High Flow*	114H647ACN	47 mm	100
	114H647ACR	47 mm	1,000
	114H650ACN	50 mm	100
	114H650ACR	50 mm	1,000
0.65 μm	1140547ACN	47 mm	100
	1140550ACN	50 mm	100
0.8 μm	1140447ACN	47 mm	100
	1140447ACR	47 mm	1,000
	1140450ACN	50 mm	100
1.2 μm	1140347ACN	47 mm	100
	1140347ACR	47 mm	1,000
	1140350ACN	50 mm	100
	1140350ACR	50 mm	1,000

White membrane with green grid, for detection of bacteria with dyed media, particle count and microscopy, type 139, individually, sterile packaged

P		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
0.45 μm	1390647ACN	47 mm	100
	1390647ACR	47 mm	1,000
	1390650ACN	50 mm	100
	1390650ACR	50 mm	1,000
0.45 μm High Flow*	139H647ACN	47 mm	100
	139H647ACR	47 mm	1,000
	139H650ACN	50 mm	100
0.65 μm	1390547ACN	47 mm	100
1.2 μm	1390347ACN	47 mm	100

Green membrane with dark green grid, providing optimal contrast to light-colored or transparent bacteria colonies, type 138, individually, sterile packaged

0.45 μm	1380647ACN	47 mm	100
	1380647ACR	47 mm	1,000
	1380650ACN	50 mm	100
	1380650ACR	50 mm	1 000

Gray membrane (after wetting black) with white grid, for detection of yeasts and molds, particle count and microscopy, type 130, individually, sterile packaged

sterne packag	cu		
0.45 μm	1300647ACN	47 mm	100
	1300647ACR	47 mm	1,000
	1300650ACN	50 mm	100
	1300650ACR	50 mm	1,000
0.65 μm	1300547ACN	47 mm	100
	1300550ACN	50 mm	100
	1300550ACR	50 mm	1,000
0.8 μm	1300447ACN	47 mm	100
	1300447ACR	47 mm	1,000
	1300450ACN	50 mm	100

#### Cellulose Nitrate (Cellulose Ester) Membrane Filters, Gridded, Non-Sterile Packaged



Membrane Filters for Colony Count, Particle **Testing and Microscopy** 

Just a small sampling of the advantages you will benefit from when using this type of membrane filter:

- Outstanding recovery rates for microorganisms
- 0.45 μm are acc. to ISO 7704
- Three different colors available

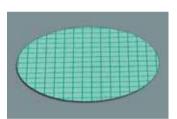
#### **Specifications**

Design25, 47 or 50 mm in diameter, white, grey or green and griddedGrowth Promotion Test acc. to ISO 7704- No enhancement or inhibition by the grid lines - No enhancement or inhibition due to chemical extractablesThermal resistance130°C max.Thickness acc. to DIN 53105115–145 μmChemical CompatibilityAqueous solutions (pH 4-8), hydrocarbons and several other organic solvents.		
acc. to ISO 7704- No enhancement or inhibition due to chemical extractablesThermal resistance130°C max.Thickness acc. to DIN 53105115–145 μmChemical CompatibilityAqueous solutions (pH 4–8), hydrocarbons and	Design	·
Thickness acc. to DIN 53105 115–145 μm  Chemical Compatibility Aqueous solutions (pH 4–8), hydrocarbons and		- No enhancement or inhibition due to chemical
Chemical Compatibility Aqueous solutions (pH 4-8), hydrocarbons and	Thermal resistance	130°C max.
	Thickness acc. to DIN 53105	115–145 μm
	Chemical Compatibility	

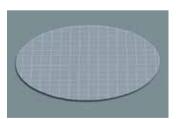


#### Typical performance rates for various pore sizes

Pore size		0.2 μm*	0.45 μm**	0.65 μm
Flow rate for water per cm <sup>2</sup> at 1 bar acc. to DIN 58355	in ml/min	20	70	130
Coliform retention	in %	100	100	n. a.
Recovery rate lot-released acc. to ISO 7704	in %	≥ 90	≥ 90	≥ 90



- Pore size determined by quantitative retention of Brevundimonas diminuta in accordance with the ASTM Document F 838-83 (1993) Standard test method for determining bacterial retention of membrane filters utilized for liquid filtration.
- Pore size determined by quantitative retention of Serratia marcescens in accordance with the Standard Methods of Water and Waste Water



White membrane with black grid, for detection of bacteria with dyed media, particle count & microscopy, type 114, non-sterile

Pore size	Order No.	Diameter	Pack size
0.2 μm	1140725N	25 mm	100
	1140747N	47 mm	100
	1140747R	47 mm	1,000
	1140750N	50 mm	100
0.45 μm	1140625N	25 mm	100
	1140647N	47 mm	100
	1140647R	47 mm	1,000
	1140650N	50 mm	100
	1140650R	50 mm	1,000
0.65 μm	1140547N	47 mm	100
0.8 μm	1140425N	25 mm	100
	1140447N	47 mm	100
	1140450N	50 mm	100
1.2 μm	1140325N	25 mm	100
	1140347N	47 mm	100
	1140350N	50 mm	100

White membrane with green grid, for detection of bacteria with dyed media, particle count and microscopy, type 139, non-sterile

0.45 μm	1390647N	47 mm	100
	1390647R	47 mm	1,000
	1390650N	50 mm	100
	1390650R	50 mm	1,000

Green membrane with dark green grid, providing optimal contrast to light-colored or transparent bacteria colonies, type 138, non-sterile

0.45 μm	1380647N	47 mm	100
	1380647R	47 mm	1,000
	1380650N	50 mm	100
	1380650R	50 mm	1.000

Gray membrane (after wetting black) with white grid, for detection of yeasts and molds, particle count and microscopy, type 130, non-sterile

		, ., ,	
0.45 μm	1300625N	25 mm	100
•	1300647N	47 mm	100
	1300647R	47 mm	1,000
	1300650N	50 mm	100
0.65 μm	1300547N	47 mm	100
•	1300550N	50 mm	100
0.8 μm	1300447N	47 mm	100
	1300450N	50 mm	100

# Cellulose Nitrate (Cellulose Ester) and Cellulose Acetate Membrane Filters, White, Individually, Sterile Packaged



Sterile, individually packed filters have long become standard for routine microbiological quality control because of the user benefits they offer. They are pre-sterilized and ready-to-use and save preparatory time. As they are individually packed, they avoid the possibility of contamination of remaining filters in opened packs and conform with GLP, having filter identification and lot number printed on each individual envelope.

#### Materials

The membranes are made of even cellulose nitrate (cellulose ester), a material which assures effective retention with high flow rates and optimum colony growth or cellulose acetate, a material which combines high flow rates and thermal stability with very low adsorption characteristics.

#### **Additional applications**

11301, a white CN membrane filter with a pore size of 8  $\mu$ m is used as a prefilter in a special prefilter attachment (16807) for bacteriological analyses. It retains the coarse suspended particles, whereas it allows microorganisms to pass through. These microbes are trapped on the surface of the underlying bacteria–retentive membrane filter (e. g. 0.45  $\mu$ m).

11107, a white CA membrane filter with a pore size of  $0.2~\mu m$  is the filter of choice for sterile filtration, such as nutrient media, buffer and sera. This membrane is validated by the Bacteria Challenge Test.

#### **Applications**

Membrane Filters for Colony Count, Sterility Testing, Particle Testing and Microscopy

Just a small sampling of the advantages you will benefit from when using this type of membrane filter:

- Outstanding recovery rates for microorganisms
- Defined particle retention
- 0.45 μm are acc. to ISO 7704
- 0.2 μm are validated by BCT
- Certified Quality
- Gamma irradiated, 25kGray

### **Specifications**

Design	47 or 50 mm in diameter, white
Growth Promotion Test acc. to ISO 7704	<ul><li>No enhancement or inhibition by the sterilization process</li><li>No enhancement or inhibition due to chemical extractables</li></ul>
Sterility Test	Sterile
Thermal resistance	130°C max.   CA: 180°C
Thickness acc. to DIN 53105	CN: 115–145 μm   CA: 120 μm (average value)
Chemical Compatibility	Aqueous solutions (pH 4–8), hydrocarbons and several other organic solvents.

Cellulose nitrate membrane filters, white, for colony count, sterility testing, particle count & microscopy, type 113, individually, sterile packaged

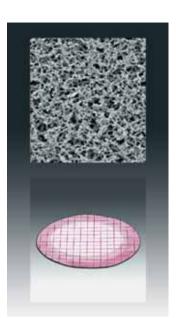
Pore size	Order No.	Diameter	Pack size	
0.45 μm	1130647ACN 1130650ACN	47 mm 50 mm	100 100	
0.65 μm	1130547ACN 1130550ACN	47 mm 50 mm	100 100	
0.8 μm	1130447ACN 1130450ACN	47 mm 50 mm	100 100	
1.2 μm	1130347ACN 1130350ACN	47 mm 50 mm	100 100	
3 μm	1130247ACN 1130250ACN	47 mm 50 mm	100 100	
8 μm	1130147ACN 1130150ACN	47 mm 50 mm	100 100	

Cellulose acetate membrane filters, white, for colony count, sterility testing, particle count & microscopy\*, type 111, individually, sterile packaged

0.2 μm	1110747ACN 1110750ACN	47 mm 50 mm	100 100	
0.45 μm	1110647ACN	47 mm	100	
	1110650ACN	50 mm	100	

<sup>\*</sup> If cellulose nitrate is not compatible

# Hydrophobic Edged Cellulose Nitrate (Cellulose Ester) and Cellulose Acetate Membrane Filters, Individually, Sterile Packaged & Non-Sterile



Hydrophobic edge membranes are used mainly for colony count and sterility testing of solutions containing substances with antibiotic characteristics. The hydrophobic edge avoids the penetration of any growth-inhibitory substance into the membrane clamp zone wherefrom it could not be rinsed out and the substance could inhibit microbial growth during incubation.

The membranes are made of even cellulose nitrate (cellulose ester), a material which assures effective retention with high flow rates and optimum colony growth or cellulose acetate, a material which combines high flow rates and thermal stability with very low adsorption characteristics.

#### **Applications**

Membrane Filters for Colony Count and Sterility Testing

Just a small sampling of the advantages you will benefit from when using this type of membrane filter:

- Outstanding retention rates for microorganisms
- 0.45 μm are acc. to ISO 7704
- 0.2  $\mu m$  are validated by BCT
- Certified Quality

#### Specifications

- P		
Design	25, 47 or 50 mm in diameter, white or white with black grid	
Growth Promotion Test acc. to ISO 7704	<ul> <li>No enhancement or inhibition by the grid lines</li> <li>No enhancement or inhibition due to chemical extractables</li> <li>No enhancement or inhibition by the sterilization process</li> </ul>	
Sterility Test	Sterile	
Thermal resistance	130°C max.   CA: 180°C	
Thickness acc. to DIN 53105	CN: 115–145 µm   CA: 120 µm (average value)	
Chemical Compatibility	Aqueous solutions (pH 4–8), hydrocarbons and several other organic solvents	

Cellulose nitrate membrane filters, white with black grid, 3 mm hydrophobic edge, for colony count & sterility testing, type 131, individually, sterile packaged

Pore size	Order No.	Diameter	Pack size
0.2 μm	1310747ACN	47 mm	100
	1310750ACN	50 mm	100
0.45 μm	1310647ACN	47 mm	100
	1310650ACN	50 mm	100

Cellulose nitrate membrane filters, white with black grid, 6 mm hydrophobic edge, for colony count & sterility testing, type 131, individually, sterile packaged

0.45 μm 13106--47----HEN 47 mm 100

Cellulose nitrate membrane filters, white with black grid, 3 mm hydrophobic edge, for colony count & sterility testing, type 131, non-sterile

0.2 μm	1310725N	25 mm	100
	1310747N	47 mm	100
	1310750N	50 mm	100
0.45 μm	1310625N	25 mm	100
	1310647N	47 mm	100
	1310650N	50 mm	100
8 μm	1310147N	47 mm	100
	1310150N	50 mm	100

Cellulose nitrate membrane filters, white, 3 mm hydrophobic edge, for colony count & sterility testing, type 131, non-sterile

8 μm 13101--50----AHN 50 mm 100

Cellulose nitrate membrane filters, white with black grid, 6 mm hydrophobic edge, for colony count & sterility testing, type 131, non-sterile

0.2 μm	1310747HCN	47 mm	100
0.45 μm	1310647HCN	47 mm	100

Cellulose acetate membrane filters, white with black grid, 3 mm hydrophobic edge, for colony count & sterility testing\*, type 135, individually, sterile packaged

0.2 μm	1350747ACN	47 mm	100
0.45 μm	1350647ACN	47 mm	100
	1350650ACN	50 mm	100

Cellulose acetate membrane filters, white with black grid, 3 mm hydrophobic edge, for colony count & sterility testing\*, type 135, sterile, packaged of 10 discs per sleeve

0.45 μm 13506--47----ALS 47 mm 100

Cellulose acetate membrane filters, white with black grid, 3 mm hydrophobic edge, for colony count & sterility testing\*, type 135, non-sterile

0.2 μm	1350747N	47 mm	100
0.45 μm	1350647N	47 mm	100

Cellulose acetate membrane filters, white with black grid, 6 mm hydrophobic edge, for colony count & sterility testing\*, type 135, non-sterile

0.45 um	1350647HCN	47 mm	100

<sup>\*</sup> If cellulose nitrate is not compatible

# Nutrient Pad Sets – Dehydrated Media Pads in Petri Dishes, with Matching Membrane Filters for Economical, Time-saving Microbiological Quality Control

Sartorius Nutrient Pad Sets have been used successfully in the membrane filter method for 20 years. Practical and easy to handle, they reduce labor and simplify many microbiological testing procedures.

Nutrient pads are sterile, dehydrated culture media. Once they are moistened with 3.0–3.5 ml of sterile and demineralized (or distilled) water they are ready to use immediately.

#### Ready-to-use up to 24 month

The standard NPS box contains 100 sterile nutrient pads, each of which is individually inserted in a petri dish and sterilized. Ten each of these petri dishes are sealed in an aluminum bag. This special packaging in bags protects the sensitive formula constituents of the nutrient pads during transport and storage from fluctuations in humidity and temperature. As a result, it quarantees the high quality of our NPS throughout their entire shelf life ranging from 18 to 24 months. This make the Sartorius Nutrient Pads Sets unique: No other ready-to-use Nutrient media around the globe assures consistent high quality and reproducible results up to 24 month.

Currently, Sartorius offers more than 30 different Nutrient Pad Set types to meet the diverse objectives of microbiological analysis. Beyond the European drinking water directive, they comply with other international regulations and recommendations: international pharmacopoeias, DIN and ISO standards, the American Standards for Water and Foods, mineral water regulations, brewery guidelines, such as MEBAC or EBC, and recommendations of the food industry, such as LMBG, NCA and ICUMSA, etc.

All Nutrient Pad Set types are supplied with the appropriate membrane filters, which are also presterilized and individually packaged. The membrane filters tailored to meet the special requirements of microbial detection are available with 47 mm or 50 mm diameters.



#### **Economy**

No time-consuming and labour-intensive preparation of the nutrient media (sterilization, cleaning, etc.).

#### Easy handling

Nutrient pad sets can also be used in laboratories without comprehensive micro-biological equipment.

#### Consistent quality

During the production, each nutrient pad set batch is compared with the corresponding agar medium, in order to guarantee consistent quality and reproducible results.

#### Trouble-free storage

Nutrient pad sets can be stored at room temperature in a warehouse, between 18 and 24 months depending on the type.









#### Order numbers for nutrient pad sets in petri dishes

**Nutrient Pad Sets for total colony count,** individually, sterile packaged in petri dishes, 100 per box, with 100 individually, sterile packaged 47 mm membrane filters

<b>Determination of</b>	NPS type*	Order No.**
Total count	Caso (1)	1406347N
Total count	R2A (1)	1408447N
Total count	Standard TTC (1)	1405547N
Total count	Standard TTC I mod. (1)	1408547N
Total count	Standard (1)	1406447N
Total count	TGE (1)	1407647N
Total count	Yeast extract (1)	1409047N

**Nutrient Pad Sets for E. coli, coliforms and enterobacteria,** individually, sterile packaged in petri dishes, 100 per box, with 100 individually, sterile packaged 47 mm membrane filters

E. E. coli and coliforms	Chromocult (7)	1408747N
E. coli	ECD (2)	1408247N
E. coli and coliforms	Endo (2)	1405347N
Enterobacteria, E. coli	MacConkey (2)	1409747N
E. coli and coliforms	m FC (2)	1406847N
E. coli and coliforms	Teepol (Lauryl Sulphate) (2)	1406747N
E. coli and coliforms	Tergitol TTC (2)	1405647N

**Nutrient Pad Sets for other faecal bacteria,** individually, sterile packaged in petri dishes, 100 per box, with 100 individually, sterile packaged 47 mm membrane filters

Enterococci	Azide (1)	1405147N
Salmonellae	Bismuth Sulfite (1)	1405747N

**Nutrient Pad Sets for non-faecal, pathogenic bacteria,** individually, sterile packaged in petri dishes, 100 per box, with 100 individually, sterile packaged 47 mm membrane filters

Pseudomonas aeruginosa	Cetrimide (2)	1407547N
Staphylococci, Staph, aureus	Chapman (2)	1407447N

### **Nutrient Pad Sets for yeasts and molds, individually,** sterile packaged in petri dishes, 100 per box, with 100 individually, sterile packaged 47 mm membrane filters

Determination of	NPS type*	Order No.**
Wild yeasts	Lysine (3)	1406147N
Yeasts and molds	Malt extract (8)	1408647CCN
Yeasts and molds	Malt extract (6)	1408647N
Yeasts and molds	Sabouraud (3)	1406947N
Yeasts and molds	Schaufus Pottinger (m Green yeast and mold) (4)	1407047N
Yeasts and molds	Schaufus Pottinger (m Green yeast and mold) (5)	1407247N
Yeasts and molds	Schaufus Pottinger (m Green yeast and mold) (6)	1408047N
Yeasts and molds	Schaufus Pottinger (m Green yeast and mold) (3)	1408347N
Yeasts and molds and bacteria	Wallerstein (WL Nutrient) (2)	1408947N
Yeasts and molds	Wort (3)	1405847N

### **Nutrient Pad Sets for product-spoiling microorganisms,** individually, sterile packaged in petri dishes, 100 per box, with 100 individually, sterile packaged 47 mm membrane filters

	, , ,	
Thermophilic spore formers and mesophilic bacteria	Glucose Tryptone (2)	1406647N
Leuconostoc oenos and other wine spoiling organ.	Jus de Tomate (Tomato Juice) (1)	1407947N
Acid-tolerant microorganisms	Orange Serum   pH 5.5 (1)	1406247N
Acid-tolerant microorganisms	Orange Serum   pH 3.2 (1)	1409647N
Lactobacilli and Pediococci and other beer spoiling organisms	VLB-S7-S (2)	1405947N
Mesophilic slime-forming bacteria esp. Leu. mesenteroides	Weman (1)	1406547N

### **Nutrient Pad Sets starter kit,** individually, sterile packaged in petri dishes, 100 per box, with 100 individually, sterile packaged 47 mm membrane filters

E. coli and coliforms, total count,	Mixed Types: Endo, Standard,	1409547N
veasts and molds	Wort (1, 2, 3)	

#### Order numbers for nutrient pad sets in PE bags

**Nutrient Pads and 47 mm membrane filters,** sterile packaged in polyethylene bags, 50 per box

<b>Determination of</b>	NPS type*	Order No.**
E. coli and coliforms	Endo (2)	1400347K
Total count	Standard TTC (1)	1400547K
E. coli and coliforms and other bio-indicators of faecal contamination	Tergitol TTC (2)	1400647K
Yeasts and molds	Wort (3)***	1400850K

Sterile water in ampoules, for moistening NPS, 3.5 ml each, 100 per box

100 ampoules with sterile water 1ZZ—K0001

Special brochure available on request f.o.c. Order no. SM-4017-e.

- \* The membrane filters are selected for optimum growth together with the corresponding nutrient media. The supplied membrane filter type is listed within brackets:
  - (1) = green with dark green grid, 0.45 μm pore size
  - (2) = white with green grid, 0.45  $\mu$ m pore size
  - (3) = gray (after wetting black) with white grid, 0.65 μm pore size
  - (4) = white with green grid, 0.65  $\mu$ m pore size
  - (5) = white with green grid, 1.2  $\mu$ m pore size
  - (6) = gray (after wetting black) with white grid, 0.8 μm pore size
  - (7) = white with black grid, 0.45  $\mu$ m pore size
  - (8) = gray (after wetting black) with white grid, 0.45 μm pore size
- \*\* Diameter of the membrane filter, 47 mm. Order number for nutrient pad set with 50 mm membrane filter as above, but --47-----N replaced by --50-----N.
- \*\*\* This NPS type is only available with 50 mm membranes.



#### **Nutrient Pad Set poster**

The photo shows a poster, original size 70 cm×50 cm, with growth patterns and typical applications for the nutrient pad sets, described on the previous page. On request, you can obtain this poster free of charge. Order no. SM-0001-e.

#### **Culture Media in Bottles and Tubes Absorbent Pads and Petri Dishes**



#### Agar Media

The traditional culture media for microorganisms is agar media. This can be used for the membrane filtration method or for direct incubation. There are two different forms available: Agar media in tubes are for pouring agar plates. The content of one tube is sufficient for two 90 mm or three 60 mm petri dishes. Agar media in bottles are the cost-effective alternative for casting plates.



#### Liquid Broth Media

Liquid culture media broth for direct incubation or for wetting an absorbent pad before a membrane filter is placed on it. They available in tubes and in bottles.

#### **Absorbent pads**

Sartorius 1.4 mm thick absorbent pads are wetted with the appropriate liquid culture medium before a membrane filter is placed on them. They come presterilized in plastic magazines, which fit onto the Sartorius manual dispensing device. The absorbent pads are available in two diameters: 47 mm with approx. 3 ml absorption capacity and 50 mm with approx. 3.5 ml absorption capacity.



#### Agar Media in 250 ml bottles, 4 bottles per box

Determination of	Agar type	Order No.
Total count	Nutrient	14144A
E. coli and coliforms	Endo	14156A
Yeasts and molds	Sabouraud	14166A
Yeasts and molds	Wort	14157A
Wild yeasts	Lysine	14143A
Lactobacilli and Pediococci and other beer spoiling organisms	VLB-S7-S	14148A



#### Agar Media in 20 ml tubes, 50 tubes per box

<b>Determination of</b>	Agar type	Order No.
Total count	Nutrient	14137K
Total count	Standard	14131K
E. coli and coliforms	Endo	14158K
Yeasts and molds	Malt extract	14135K
Yeasts and molds	Wort	14138K
Acid-tolerant microorganisms	Orange Serum	14130K
Leuconostoc oenos and other wine spoiling organ.	Jus de Tomate (Tomato Juice)	14140K

#### Broth Media in 250 ml bottles, 50 bottles per box

Determination of	Broth type	Order No.
Total count	Caso (0.45 µm)	14162K

#### Lactose Broth Media, concentrated in bottles, for drinking water analysis

Concentration factor	Packaging	Order No.
Two times concentrated	4 bottles à 100 ml	14155A
Three times concentrated	1 bottles à 1,000 ml	14160

#### Broth Media in 20 ml tubes, 50 tubes per box

Determination of	Broth type	Order No.
Total count	Nutrient	14132K
Lactobacilli and Pediococci and other beer spoiling organisms	VLB-S7-S	14127K

#### Absorbent Pads, 47 mm, sterile packaged in 10 magazines, each with 100 pads

Description	Packaging	Order No.
Absorbent Pads, 10×100 pads	1,000 per box, incl. one dispenser	1541047ALR
Absorbent Pad Set, 10×100 pads plus 1,000 membrane filters (0.45 μm, white   green)	1,000 per box, incl. two dispensers	1390647APR

#### Absorbent Pads, 50 mm, sterile packaged in 10 magazines, each with 100 pads

Description	Packaging	Order No.
Absorbent Pads, 10×100 pads	1,000 per box,	1541050ALR
	incl. one dispenser	

#### Absorbent Pads, 50 mm, sterile packaged in petri dishes

Description	Packaging	Order No.
Absorbent Pad Set, 100 pads in petri dishes, sterile packaged	100 per box	1540050N
Absorbent Pad Set, 100 pads in petri dishes plus 100 membrane filters (0.45 µm, green   dark green)	100 per box	1540050FRN

#### Disposable Petri Dishes, auto-sterile, 100 per box

Diameter	Order No.
60 mm	1431160N
90 mm	1431190N

#### Biosart® 100 Monitors



The membrane filtration method is the suitable technique for microbiological analysis of pharmaceuticals, water, cosmetics, foods and beverages. The use of ready-to-use disposable units is optimal for these applications.

#### Biosart® 100 Monitors

Biosart® 100 Monitors have been specifically designed for microbiological testing of pharmaceuticals, cosmetics, food, beverages, water and other liquids. These sterile disposables with an incorporated membrane filter and cellulose pad are ready to use. After filtration, just remove the 100 ml funnel to convert the Monitor into a petri dish. Culture media for wetting the pad are available in individually sterilized, convenient plastic ampoules. Biosart® 100 Monitors are ready to use filter units designed to be placed onto the bases of a vacuum manifold.

#### **High Flow membranes**

Biosart® 100 Monitors are also available with the new incorporated 0.45  $\mu m$  High Flow membranes. The special pore structures allows shorter filtration times due to 30% higher flow rates.

#### **Applications**

Colony Count, Particle Testing and Microscopy

Just a small sampling of the advantages you will benefit from when using Biosart® 100 Monitors:

#### - Safe & reliable:

Sterile, individually, sterile packaged available, validated, certified Membrane filters: Meet ISO 7704; available in various colors; can be used for documentation; without any hydrophobic adhesive areas

#### - Saves time:

Ready to connect; easy to use and practical handling features

#### - Economy:

High flow rate, large filtration area, high total throughput

#### - Saves money:

Only needs a minimal amount of equipment

#### - Reduces waste:

Reduced volume after autoclaving means easy disposal

#### **Specifications**

- 1	
Housing	Polystyrene
Membrane filter	Cellulose nitrate (cellulose ester); choice of white, green or grey, with grid; can be used as documentation
Plug and adapter	Polyethylene
Pad	Cellulose
Capacity	100 ml, 10 ml graduations
Pore size	0.2 μm, 0.45 μm or 0.65 μm
Filter diameter	47 mm or 56 mm
Filtration area	14.5 cm <sup>2</sup> or 21.2 cm <sup>2</sup>
Max. operating pressure	Vacuum only
Sterilization	Gamma irradiation
Outlet	6.5×1.5 mm
Lot certificates	Recovery rate, sterility and specifications

Biosart® 100 Monitors, 100 ml, 47 mm, individually, sterile packaged, 48 units

Pore size	Membrane filter* Color   Grid color	Order No.
0.2 μm	CN white   black	16401-47-07ACK
0.45 μm	CN white   black	16401-47-06ACK
0.45 μm	CN green   dark green	16402-47-06ACK
0.45 μm	CN gray white	16403-47-06ACK

#### Biosart® 100 Monitors, 100 ml, 47 mm, sterile packaged, 48 units

0.45 μm High Flow	CN white   black	16401-47-H6K
0.45 μm	CN white   black	16401-47-06K
0.45 μm	CN green   dark green	16402-47-06K
0.45 μm	CN gray   white	16403-47-06K
0.8 μm	CN gray   white	16403-47-04K
0.45 μm	RC white	16404-47-06K

<sup>\*</sup> CN = Cellulose nitrate (Cellulose ester)

RC = Regenerate Cellulose

#### **Biosart® 100 Monitor Adapters**

Description	Adaptation	Order No.
Biosart® 100 Adapter, silicone	Biosart® 100 Monitor onto Sartorius stainless steel frits e. g. 16840 (Combisart® base support) or onto 16841 (individual base)	16414
Biosart® 100 Adapter, polypropylene	Biosart® 100 Monitor onto 50 mm supports	16415
Biosart® 100 Adapter, polypropylene	Biosart® 100 Monitor onto 56 mm supports and vacuum pumps	16416

### Biosart® 100 Nutrient Media



**Applications** Colony Count

Just a small sampling of the advantages you will benefit from when using Biosart® 100 Media:

- In compliance with international standards

- Certificate of quality for every batch

- Ready-to-use - pre-sterilized media

- Long shelf life

#### Biosart® 100 Nutrient Media, 2.5 ml, individually, sterile packaged in ampoules, 50 units

Determination of	Media type	Order No.*
Total count	Caso (acc. USP)	16400-02CA-K
Total count	R2A (acc. EP)	16400-02RA-K
Total count	TGE Total Count	16400-02TC-K
Total count	Total count TTC	16400-02TZ-K
E. coli and coliforms	m Endo	16400-02EN-K
E. coli and coliforms	m FC	16400-02MF-K
E. coli and coliforms	Laury Sulfate   Teepol	16400-02LS-K
E. coli and coliforms	Tergitol TTC	16400-02TT-K
Enterococci	KF Strep   Azide	16400-02KF-K
Pseudomonas aeruginosa	Cetrimide	16400-02CE-K
Yeasts and molds	Sabouraud (acc. USP)	16400-02SB-K
Yeasts and molds	m Green yeast and mold   Schaufus Pottinger	16400-02MG-K
Yeasts and molds	m Green yeast and mold selective	16400-02GS-K
Yeasts and molds and bacteria	WL Media   Wallerstein	16400-02WN-K
Bacteria in fermentation processes	WL Differential   Wallerstein	16400-02WL-K
Acid-tolerant microorganisms	Orange Serum	16400-02OS-K

#### Biosart® 250 Funnels



#### Biosart® 250 Funnel

The Biosart® 250 Funnel has been specially designed for microbiological and analytical quality assurance in industry. The sterile 250 ml plastic funnel guarantees fast filtration and high sample throughputs during routine testing. Its large inner diameter allows high flow rates, and the tapered inner walls permit thorough flushing of the funnel, after filtration. Biosart® 250 Funnels are also individually, sterile packaged available.

#### **Applications**

Colony Count, Particle Testing and Microscopy

Just a small sampling of the advantages you will benefit from when using Biosart® 250 Funnels:

#### - Safe & reliable:

Sterile, individually, sterile packaged available, certified, membrane filter can be used as documentation, use a new, sterile funnel for each test in order to avoid cross contamination!

#### - Simpler handling:

No more holding of hot funnels! And the complete filtration is visible, particularly useful when using manifolds in routine testing.

#### - Saves time:

Ready to use; practical design that is easy to use; ensures high flow rates, high throughputs; no preparation time necessary, just change the funnel, rather than spending time sanitizing it!

#### - Saves money:

No additional equipment needed, can be autoclaved to a limited extent.

#### **Specifications**

•	
Material	Polypropylene
Capacity	250 ml, 50 ml graduations
Filter diameter	47 mm (or 50 mm), prefilter 40 mm
Filtration area	12.5 cm <sup>2</sup>
Max. operating pressure	Vacuum only
Sterilization	Ethylene oxide
Lot certificates	Sterility and Performance Tests

#### Biosart® 250 Funnels, ready to use filter funnels, 250 ml, 50 units

Description	Order No.
Biosart <sup>®</sup> 250 Funnel, 50 units, individually, sterile packaged	1640725ACK
Biosart® 250 Funnel, 50 units, sterile packaged	1640725ALK

Further information available on request f.o.c. Order no. SL-3017-e

#### Combisart®, Individually and Multi-Branch Systems









The Sartorius Combisart®, system enables you to select the optimal hardware and consumables for your needs in microbiological analysis or particle count in quality assurance. Combisart® features a modular design and field-proven standard accessories to make your choice easier.

#### **Flexibility**

At the heart of the Combisart® system is a stainless steel manifold designed to accommodate all types of filter holders and funnels such as:
Ready-to-use units like Biosart® 100 Monitors and Biosart® 250 Funnels
Flammable units such as stainless steel funnels for colony counting
Autoclavable re-usable funnels made of glass or polycarbonate

#### Sterile venting

A special feature of the Combisart® manifold are the stainless steel three-way valves (taps). They allow the vacuum for each filter holder to be individually controlled and each filter station to be sterilely vented. This rules out secondary contamination of the underside of the filter. Since the most reliable sterilization method is autoclaving, the Combisart® design offers a unique advantage for this method. After inserting the membrane filters in the filter holders, you can simply unscrew them as an entire unit from each workstation and autoclave them. You can even pour out a non-filterable sample from each unit. And Combisart® makes filtration equally easy for left- or right-handed users in your laboratory, because funnels can be positioned to suit the individual user.

#### The right equipment for your application

The 3- or 6-branch manifolds allow time-saving when mass examinations. In connection with the single base 16840 they are flexible to adapt disposable Biosart 250 of stainless steel funnels. The stainless steel filter support of the single base 16840 allows a homogenous distribution of the residues on the membrane filter surface. 3 or 6 polycarbonate holders of the type 16511 can be screwed onto the manifold directly. Glass units (16306 or 16307) can be fitted by using corresponding adapterstopper-combinations. The Biosart<sup>®</sup> 100 adapter 16414 ensure that the Monitors are positioned perfectly level minimizing the risk of contamination during filtration. For low number of samples to test, we recommend the use of the 1-branch manifold or one of our individual systems on the top of a suction flask.

Just a small sampling of the advantages you will benefit from when using the Combisart® 250 System:

#### - Safe & reliable:

Sterile venting of each membrane after filtration, sterilization acc. to ISO 8199, special polished stainless steel surfaces allow easy cleaning & rinsing

#### - Saves time:

Filtration of 3 or 6 samples in parallel, easy pouring out of non-filterable samples, equally easy for right- and left-handed users

#### - Economy:

Maximum Flexibility due to different set-ups, space-saving in the autoclave, low height is advantageous for working on a clean bench, Stainless steel 304 – long lifecycle

### **Specifications**

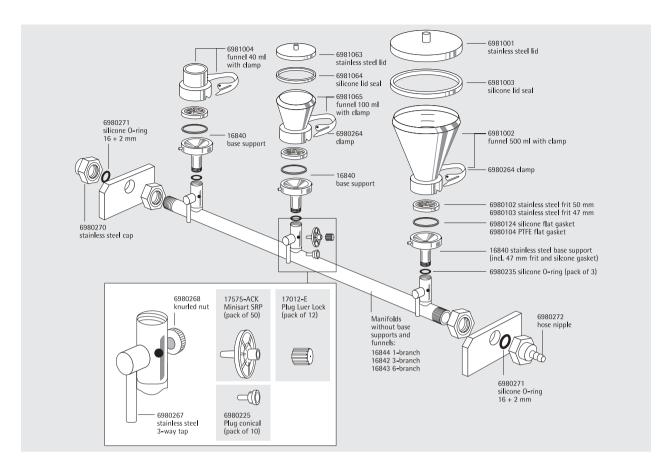
Stainless steel quality	High-grade stainless steel: B.S. 304S31   AISI 304
Dimensions in mm (L H D)	3-branch manifold: 435   103   120 6-branch manifold: 910   103   120
Max. operating pressure	Vacuum only
Sterilization	by autoclaving (max. 134°C), by dry heat (max. 180°C), by flaming, by other methods acc. to ISO 8199
Parts and materials	Lid, funnel, base part, - filter support, clamp and tap made of stainless steel. Silicone flat gasket. Silicone lid seal
Flow rate per filter station for water at 90% vacuum	200 ml/min with 0.2 μm membrane filter 600 ml/min with 0.45 μm membrane filter
Filtration area	12.5 cm <sup>2</sup>
Suitable membrane filter diameter	50 mm (47 mm, if using a 47 mm frit filter support 6980103)
Outlet spouts (individual system)	10 mm outside diameter
Inlets (branches only)	Female threads, TR 20×2
Outlet (branches only)	Hose nipple, DN 10

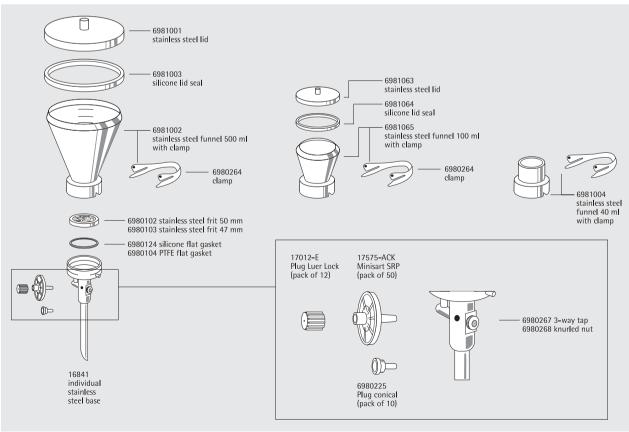
### Combisart® individual system and multi-branch manifolds, made of high-grade stainless steel, pre-assembled with stainless steel funnels and lids

Description	Capacity	Order No.
Combisart® individual filter holder, stainless steel, 100 ml	1×100 ml	16219-CS
Combisart® individual filter holder, stainless steel, 500 ml	1×500 ml	16201-CS
Combisart® 3-branch stainless steel manifold 100 ml	3×100 ml	16824-CS
Combisart® 3-branch stainless steel manifold 500 ml	3×500 ml	16828-CS
Combisart® 6-branch stainless steel manifold 100 ml	6×100 ml	16832-CS
Combisart® 6-branch stainless steel manifold 500 ml	6×500 ml	16831-CS

## Combisart® individual and multi-branch bases, made of high-grade stainless steel, without funnels and lids, to accommodate various funnel types

Description	Order No.
Combisart <sup>®</sup> individual base, stainless steel, with frit, to accommodate stainless steel funnels and Biosart <sup>®</sup> 100/250	16841
Combisart® 1-branch stainless steel manifold, without frit	16844
Combisart® 3-branch stainless steel manifold, without frits	16842
Combisart® 6-branch stainless steel manifold, without frits	16843
Combisart® base support with frit, stainless steel, accommodate stainless steel funnels and Biosart® 100/250	16840





#### Accessories and replacement parts for the Combisart® System

Description	Quantity	Order No.
Minisart SRP25, sterile filter for venting, 0.2 μm, individually sterile packaged, could be autoclaved 5 times.	50	17575ACK
Plug Luer Lock, to close the Minisart inlet, if sterile venting is not required	12	17012E
Plug, conical, to close the venting hole beside the 3-way-valve, if sterile venting is not required	10	6980225
Silicone O-ring for base support 16840 male thread	3	6980274
Silicone O-ring for manifold female threads	3	6980235
Silicone flat gasket underneath the frit	1	6980124
PTFE flat gasket underneath the frit	1	6980104
Stainless steel frit, 50 mm diameter	1	6980102
Stainless steel frit, 47 mm diameter	1	6980103

#### Funnels, lids, seals and filter holders to connect on the Combisart® system

Description	Capacity	Membrane filter diameter	Order No.
Stainless steel funnel with closure clamp	100 ml	47   50 mm	6981065
Lid, stainless steel	for 100 ml funnel		6981063
Lid seal, silicone	for 100 ml funnel		6981064
Stainless steel funnel with closure clamp	500 ml	47   50 mm	6981002
Lid, stainless steel	for 500 ml funnel		6981001
Lid seal, silicone	for 500 ml funnel		6981003
Stainless steel funnel with closure clamp	40 ml	47   50 mm	6981004
Polycarbonate filter holder, complete with filter support and funnel	250 ml	47 mm	16511
Glass filter holder, complete with filter support, funnel and metal clamp	30 ml	25 mm	16306
Glass filter holder, complete with filter support, funnel and metal clamp	250 ml	47   50 mm	16307

#### Combisart® Adapter, to accommodate various funnel types

Description	Adaptation	Order No.
Biosart® 100 Adapter, silicone	Biosart® 100 Monitors onto 16840 (Combisart® base support) or onto 16841 (individual base)	16414
Biosart® 100 Adapter, stainless steel with silicone stopper	Biosart® 100 Monitors onto Combisart® manifolds 16842 and 16843	16835
Glass funnel Adapter, stainless steel with silicone stopper	16306/15 (glass funnel, 30 ml) onto Combisart® manifolds 16842 and 16843	16836
Glass funnel Adapter, stainless steel with silicone stopper	16307 (glass funnel, 250 ml) onto Combisart® manifolds 16842 and 16843	16837

### Traditional Multi-Branch Manifolds and Individual Filter Holders made of Stainless Steel, Glass and Polycarbonate

#### **Individual filter holders**

The three stainless steel holder types differ only in the funnel capacity (either 40 ml, 100 ml or 500 ml). They have been designed specifically for applications in which the particles or microorganisms retained on the membrane filter surface are of interest. The stainless steel frit filter support ensures a uniform distribution of the residues. Simple handling is very important regarding routine examinations. Stainless steel taps in the base allow the vacuum to be turned on and off. The special closure clamps simplify the addition or removal of the funnels adding to the ease of use.



The manifold systems are available with 100 ml or 500 ml capacity funnels. The three or six separate filter holders save time when mass examinations of 100 ml volume samples have to be carried out. Due to the stainless steel taps on the manifold ports the vacuum for each holder can be turned on and off individually. The stainless steel frit a homogenous distribution of the residues on the membrane filter surface. Funnel and filter support can be disinfected by flaming.

#### Glass filter holders

These filter holders are available for the filtration of small volumes with a 30 ml top part and for larger volumes with a 250 ml top part. They can be sterilized by autoclaving (max. 134°C) or by dry heat (max. 180°C). The glass frit ensures uniform distribution of retained residue.

#### Polycarbonate filter holders

Type 16510 is complete with receiver flask, and can be operated with vacuum as well as with slight overpressure (0.5 bar is recommended for highest standing times). Type 16511 is like 16510, but without receiver flask. It is used on a suction flask or a vacuum manifold e. g. Combisart® systems. Both devices can be sterilized by autoclaving (max. 121°C).





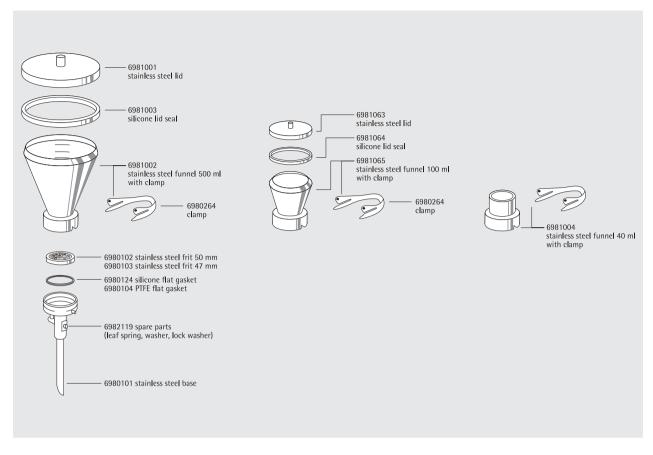


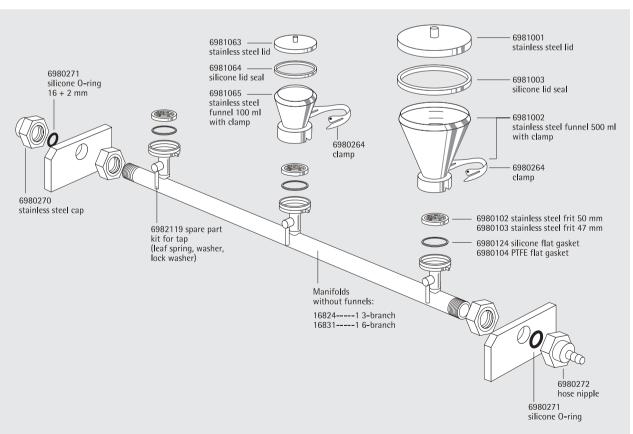




# Specifications Multi-Branch Manifolds and Individual Filter Holders

Stainless steel quality	High-grade stainless steel: B.S. 304S31   AISI 304
Dimensions in mm (W H D)	3-branch manifold: 3×100 ml: 432   184   120 3×500 ml: 442   262   132 6-branch manifold: 6×100 ml: 906   268   120 6×500 ml: 916   329   132
Max. operating pressure	Vacuum or max. 2 bar pressure (29 psi)
Sterilization	by autoclaving (max. 134°C), by dry heat (max. 180°C), by flaming, by other methods acc. to ISO 8199
Parts and materials	Lid, funnel, base part, - filter support, clamp and tap made of stainless steel. Silicone flat gasket. Silicone lid seal
Flow rate per filter station for water at 90% vacuum	200 ml/min with 0.2 μm membrane filter 600 ml/min with 0.45 μm membrane filter
Filtration area	12.5 cm <sup>2</sup>
Suitable membrane filter diameter	50 mm (47 mm, if using a 47 mm frit filter support 6980103)
Outlet spouts (individual system)	10 mm outside diameter
Outlet (branches only)	Hose nipple, DN 10





## Individual stainless steel filter holders, pre-assembled with stainless steel funnels and lids

Description	Capacity	Order No.
Individual stainless steel filter holder, 100 ml	1×100 ml	16219
Individual stainless steel filter holder, 500 ml	1×500 ml	16201
Individual stainless steel filter holder without lid, 40 ml	1×40 ml	16220

#### Multi-branch manifolds, stainless steel, with stainless steel funnels and lids

Description	Capacity	Order No.
3-branch stainless steel manifold, 100 ml	3×100 ml	16824
3-branch stainless steel manifold, 500 ml	3×500 ml	16828
6-branch stainless steel manifold, 100 ml	6×100 ml	16832
6-branch stainless steel manifold, 500 ml	6×500 ml	16831

#### Glass filter holders

Description	Capacity	Membrane filter diameter	Order No.
Glass filter holder, complete with filter support, funnel and metal clamp	30 ml	25 mm	16306
Glass filter holder, complete with filter support, funnel and metal clamp	250 ml	47   50 mm	16307

#### Polycarbonate filter holder

Description	Capacity	Membrane filter diameter	Order No.
Polycarbonate filter holder, with 250 ml top part and receiver flask, for vacuum or pressure filtration	250 ml	47 mm	16510
Polycarbonate filter holder, with 250 ml top part, for vacuum filtration only	250 ml	47 mm	16511

### Accessories for Vacuum Filter Holders and Manifold Systems

#### Suction flasks and stoppers



#### Suction flask, 2 liter capacity

Vacuum-resistant flask made of Duran 50 glass with plastic safety hose nipple according to the – German Industrial Standard no. 12476. Outer diameter of the hose nipple, 9 mm. Inner dia– meter of the opening, 60 mm. Stoppers are not enclosed.

A 1 liter capacity flask is available for countries which do not have safety restrictions on glass hose nipples.

#### Order numbers Suction flask, 2 liter capacity

166721	Suction flask, 5 liters acc. to DIN 12476, incl. stopper and glass tube
16672	Suction flask, 2 liters acc. to DIN 12476, without stopper
17204	Tube connector for connecting a Combisart® stainless steel manifold to a suction flask 2 or 1 liter
16606	Suction flask, 1 liter (not available in countries which have safety restrictions on glass hose nipples)

#### Order numbers for bored stoppers for suction flask 2 liters 16672

Description	Adaptation	Order No.	
Silicone stopper	Combisart <sup>®</sup> individual base 16841 or other individual stainless steel filter holders (16201, 16219, 16220) onto the suction flask 16672	17173	
Silicone stopper	16307 (glass funnel, 250 ml) onto the suction flask 16672	17174	
Silicone stopper	16306/15 (glass funnels, 30 ml) onto the suction flask 16672	17175	

#### Order numbers for bored stoppers for suction flask 1 liter 16606

Description	Adaptation	Order No.
Silicone stopper	Combisart <sup>®</sup> individual base 16841 or other individual stainless steel filter holders (16201, 16219, 16220) onto the suction flask 16606	17004
Silicone stopper	16307/16 (glass funnel, 250 ml) onto the suction flask 16606	17005
Silicone stopper	16306/15 (glass funnels, 30 ml) onto the suction flask 16606	17006

#### Water traps

Used between suction flask and vacuum source, in order to prevent overflow of filtrate into an electric vacuum pump



#### Vacusart®

Vacusart® is a ready-to-connect filtration unit, consisting of a polypropylene housing and a hydrophobic, but air permeable PTFE membrane with a pore size of 0.45 µm. Vacusart® is perfectly suitable for the protection of vacuum pumps.

#### Order number Vacusart®

#### Order No.

17804-----M Pack of 3



#### Woulff's bottle, 500 ml

Used between suction flask and vacuum source. Allows simple control of the vacuum with glass units without a separate tap and prevents furthermore the filtrate from overflowing from the – suction flask.

#### Order number Woulff's bottle, 500 ml

#### Order No.

16610



#### Rubber vacuum hose (1 meter)

Thick walled rubber hose for connecting the system components, e. g. suction flasks, vacuum pumps, etc. When ordering, please state length required in meters.

#### Order number Rubber vacuum hose (1 meter)

#### Order No.

16623





Electric vacuum pumps Neoprene membrane pumps with low noise level, oil- and maintenance-free; reliable sources of vacuum

#### Specifications of electric vacuum pumps

	16694-2-50-22 16694-1-40-22	16694-2-50-06 16694-1-60-06
Final vacuum	100 mbar, (76 torr), 90% vacuum	100 mbar (76 torr), 90% vacuum
Max. flow rate	22 l/min	6 l/min
Wattage	130 W	65 W
Weight	7.1 kg	1.9 kg
Dimensions (W×H×D)	261×204×110 mm	164×141×90 mm
Max. ambient temperature	40°C	40°C
Recommended application	Multiple filtration runs with multi- branch manifold	Individual filtration run with one filter holder

#### Order numbers electric vacuum pumps

Description	Order No.
Multiple filtration runs: 100 mbar final vacuum, 22 l/min max., 230 V, 50 Hz	16694-2-50-22
Multiple filtration runs: 100 mbar final vacuum, 22 l/min max., 115 V, 60 Hz	16694-1-60-22
Individual filtration run: 100 mbar final vacuum, 6 l/min max., 230 V, 50 Hz	16694-2-50-06
Individual filtration run: 100 mbar final vacuum, 6 l/min max., 115 V, 60 Hz	16694-1-60-06
Replacement parts	Order No.
Replacement kit for 16694-2-50-06 and -1-60-06, set of one membrane, two valve springs and two head seals	1ED0054
Replacement kit for 16694-2-50-22 and -1-60-22, set of one membrane, two valve springs and two head seals	1ED0055

#### Order numbers traditional pumps

Description	Order No.
Multiple filtration runs: 13 mbar final vacuum, 26 l/min max., 220 V, 50 Hz	16612
Multiple filtration runs: 13 mbar final vacuum, 26 l/min max., 110 V, 60 Hz	16615
Individual filtration run: 100 mbar final vacuum, 20 l/min max., 220 V, 50 Hz	16692
Individual filtration run: 100 mbar final vacuum, 20 l/min max., 110V, 60 Hz	16695
Replacement parts	Order No.
Set of two neoprene membranes, four valve springs and two neoprene head seals for 16612/16615	6986017
Set of one neoprene membrane, two valve springs and one neoprene head seal for 16692/16695	6986105



#### Water jet pump

Simple vacuum source. For connection to a water tap with G3/4 male thread.

#### Order number Water jet pump

Description	Order No.
Water jet pump, with G 3/4 male thread	16611



#### Hand operated vacuum pump

Practical vacuum source, also outside of a laboratory. Up to 80% vacuum can be obtained. The body is of PVC. Supplied completely with gauge, vacuum release lever and a 60 cm length of clear plastic tubing.

#### Order number Hand operated vacuum pump

Description	Order No.
Hand operated vacuum pump with gauge	16673



#### Dosing Syringe

The most convenient way to moist the NPS with water is to use a dosing syringe with an adapted Minisart syringe filter. Simultaneous sterilization and dosing of demineralized water in 3.5 ml steps is easy done by dropping the sinker at the end of the suction tubing into the water, and the dosing syringe filled and dosed by operating the twigger automatically.

#### **Order numbers Dosing Syringe**

Description	Order No.
Dosing Syringe, 0.5–5 ml	16685-2
Minisart, 0.2 μm, individually, sterile packaged	17597K



#### Colony counter

Compact, handy battery operated colony counter, is as simple to use as a ball-point pen, and has a 4-digit LCD-display. The counter is supplied with an additional marker refill.

#### **Order numbers Colony counter**

Description	Order No.
Colony counter	17649
Replacement part: Black marker refill	6981540



#### Incubator

Compact, space saving incubator for the incubation of membrane filters on nutrient pads or other nutrient media. The incubator has a capacity of 15 liters and is designed to hold the following numbers and sizes of petri dishes: 200×47 mm or 160×56 mm | 60 mm or 72×90 mm.

The swing-up cover and removable insertion plate simplify loading and unloading. The cover is opaque avoiding light penetration into the chamber.

#### **Specifications**

#### Incubator

	18113
Voltage	230 V
Frequency	50/60 Hz
Rated power	0.2 kW
Weight	5.5 kg (12 lbs)
Max. load for insertion plate	5 kg (12 lbs)
Dimensions (W $\times$ H $\times$ D)	Inner 270×205×288 mm Outer 340×270×431 mm
Temperature range	20°C (or 5°C above room temperature) to 50°C
Temperature deviation	over less than ±0.2°C (at 37°C and RT 20°C)
Spacial temperature deviation	less than ±0.8°C

Description	Order No.
Incubator	18113



#### Stainless steel tweezers

Membrane filters should only be handled with suitable tweezers in order to avoid contamination which can result from hand contact. Sartorius stainless steel tweezers can be flamed and they are autoclavable. They have blunt-edged tips for a careful, firm hold of the membrane filter.

#### **Order number Stainless steel tweezers**

Description	Order No.
Tweezers	16625



#### Stainless steel prefilter attachment

The stainless steel prefilter holder allows the removal of coarse, solid particles from samples for microbiological analysis before and during the actual bacteria retentive filtration. The device is clipped between funnel and base of the stainless steel vacuum filter holders, it can be autoclaved and flamed. 11301, a white cellulose nitrate membrane filter with a pore size of 8 µm is used as the prefilter and it retains the coarse suspended particles from the sample, whereas it allows microorganisms to pass through. These microbes are trapped on the surface of the underlying bacteria-retentive membrane filter (e. g. 0.45 µm). After filtration is complete, the test filter is incubated, and the colonies can grow on the filter surface without disturbance from, or being hidden by, an excess of particles.

#### Order numbers Stainless steel prefilter attachment

Description	Order No.
Prefilter attachment	16807
Cellulose nitrate membranes with 50 mm diameter and 8 µm pore size for the prefilter holder, pack of 100,	11201 FO ACN
sterile, individually packaged	1130150ACN
Replacement part: Support plate, autoclavable, flamable	6981139



#### Container for anaerobic incubation

Stainless steel container with 11.8 cm inner diameter, 10.7 cm depth and a with metal insert for convenient insertion and removal of petri dishes. Transparent plastic lid holds two taps for the vacuum exhaust and for cleaning with inert gas, with 6 mm hose nipples (for 16623), vacuum gauge and sealing ring. For up to fourteen 60 mm, or up to six 90 mm petri dishes.

#### Order numbers

Description	Order No.
Anaerobic Container	16671

## Sterility Test Systems Sterisart® NF





International pharmacopeias require the complete sterility of pharmaceutical products that are injected into the blood stream or that otherwise enter the body below the skin surface. As a manufacturer of such products, you are required to supply proof of sterility of the final product batch.

Sterisart® NF is a completely closed system for the sterility testing of pharmaceutical products. It is based on the membrane filter method, however it eliminates the procedure of manipulating the filters. By this the main risk of a secondary contamination and false positive results is eliminated. A peristaltic pump transfers the sample into the filtration units, and after rinsing, the filtration units are filled with media and used for incubation of the filters without any contact to the environment.

Special brochures available on request. Order no. SLD1002-e, SLD1001-e, SL-2019-e, SLD2006-e, SLD2005-e, SLD2007-e

### Sterisart® NF offers the following features and benefits

- Reliable, Sartochem membrane:
- High retention of microbes
- Low adsorption
- High mechanical stability
- Easy to use:
  - Pre-installed color-coded tube clamps
  - Easy-to-read graduated marks
  - User-friendly, several practical adapters available
- Product- lot number identification
- Secure:
  - Gas-impermeable packaging for protection against sterilants

#### **Specifications**

#### Technical specifications for Sterisart® NF

-	
Pore size of the Sartochem membrane filter	0.45 μm, tested with Serratia marcescens
Filter area	15.7 cm <sup>2</sup> in each Sterisart container
Flow rate (for water)	500 ml/min at 1 bar (approx. 15 psi)
Pore size of the air filters	0.2 μm PTFE, validated acc. to HIMA for the retention of B. diminuta
Sample container capacity	120 ml (graduation marks at 50, 75 and 100 ml)
Max. operating pressure	3 bar (approx. 44 psi) at 20°C
Max. operating temperature	50°C
Sterilization	ETO (ethylene oxid gas) or gamma irradiation

#### Technical specifications for Sterisart universal pump

10–700 ml/min (dependent on the tubing)
< 45 dB (A)
90–230 VAC (a.c. voltage)
-15/+10%
47-63 Hz
100 W
T 1.6 A
+10°C - +40°C
IP 20
Self-convection and fan
420×220×120 (W×H×D)
approx. 11 kg

Order no. for universal pump	Description
16413	Sterisart universal pump
16412V	Pump adapters for use of Sterisart systems in available Millipore pumps

Additional accessories are available on request, such as a pump cover for Millipore sterility test units, order number 1ZG---0004.

#### Recommended disposable sterility test units for use with pump

Order no. for Sterisart® NF	Description
16466ACD	Sterisart® NF alpha, dual-needle metal spike for closed containers (box of 10, individually sterilized with ETO; single-packed).
16467ACD	Sterisart® NF alpha, 6 cm metal needle for open containers (box of 10, individually sterilized with ETO; single-packed).
16468ACD	Sterisart® NF alpha, system for medical devices with luer or luer lock connectors (box of 10, individually sterilized with ETO; single-packed).
16466GBD	Sterisart® NF gamma, dual-needle metal spike for closed containers (box of 10, individually gamma sterilized, double-packed, optimal for use in isolators).
16467GBD	Sterisart® NF gamma, 6 cm metal needle for open containers (box of 10, individually gamma sterilized, double-packed, optimal for use in isolators).
16468GBD	Sterisart® NF gamma, system for medical devices with luer or luer lock connectors (box of 10, individually gamma sterilized, double-packed, optimal for use in isolators).
16469GBD	Sterisart® NF gamma, system with adapter for prefilled syringes (box of 10, individually gamma sterilized, double-packed, optimal for use in isolators).
16470GBD	Sterisart® NF gamma, system for difficult-to- dissolve powders in unvented vials (box of 10, individually gamma sterilized, single-packed, optimal for use in isolators).
16475GBD	Sterisart® NF gamma, system for lyophilized or soluble powders in unvented vials (box of 10, individually gamma sterilized, double-packed, optimal for use in isolators).
16476GBD	Sterisart® NF gamma, system with short dual-needle metal spike for closed containers (box of 10, individually gamma sterilized, double-packed, optimal for use in isolators).
16596HNK	Venting Needle for Ampoules, collapsible bags and vials, gamma sterilized (box of 50).
Further units on request	16464ACD, 16464GBD

### **Re-usable Sterility Test System**



Re-usable sterility test system for the sterility testing of injection and infusion solutions. The filter holders are easy to clean, dishwatersafe and autoclavable. The system can be designed according to the needs of the user, and the membrane filter can be chosen according to requirements.

### **Specifications**

#### Specifications of the filter holders

•	
Material	Glass cylinder; polypropylene base and sealing plug; anodized aluminum closing cap.
Sealing	Silicone gasket, 36/47 mm (6980573) Silicone O-ring, 40.5x 3.5 mm (6980574)
Filter diameter	47 mm
Filtration area	12.5 cm <sup>2</sup>
Capacity	16523: 130 ml (56 ml up to the mark for aerobic incubation at a level of 60 mm, 110 ml up to the mark at the 115-mm level).
Operating pressure	Vacuum only
Sterilization	Autoclaving at 121°C

#### General accessories for the re-usable sterility test system

Order numbers	Description
16523	Filter holder with 130 ml capacity
16826	Stainless steel manifold
17756	Stainless-steel adapter
16966	T-distributor for 2 filter holders
16967	Filling cap with filling needle
16968	Silicone adapter
16696	Peristaltic pump
16699	Silicone tubing, 4x1.5 mm
16974	Holding rod for inlet tube/needle
16975	Incubation rack
16978	Tube clamps (tubing clips)
17574K	Venting filters, 50 pieces

### Additional accessories for re-usable sterility test system (for ampoule testing)

Order numbers	Description	
16963	Inlet tube	
16973	Holding tongs	
16969	Ampoule breaker	
16976	Clamp holder	
16970	Support stand	

## Additional accessories for re-usable sterility testing system (for testing infusion solutions in bottles)

Order numbers	Description
16964	Inlet needle (long)
169645	Inlet holder (short)

## Consumables (membrane filters, 47 mm, 100 pieces/pack) for the re-usable sterility test system

Order numbers	Pore size	Description	Application
1130647N	0.45 μm	Cellulose nitrate membrane filter	pH 4-8, most hydrocarbons
1310647HCN	0.45 μm	Cellulose nitrate membrane filter with hydrophobic edge	pH 4-8, most hydrocarbons
1110647N	0.45 μm	Cellulose acetate membrane filter	pH 4-8, most alcohols, hydrocarbons and oils
1350647HCN	0.45 μm	Cellulose acetate membrane filter with hydrophobic edge	pH 4-8, most alcohols, hydrocarbons and oils
1840647N	0.45 μm	Regenerated cellulose membrane filter	pH 3-12, solvent-resistant
1140747N	0.45 μm	Cellulose nitrate membrane filter	pH 4-8, most hydrocarbons
1310747HCN	0.45 μm	Cellulose nitrate membrane filter with hydrophobic edge	pH 4-8, most hydrocarbons
1110747N	0.45 μm	Cellulose acetate membrane filter	pH 4-8, most alcohols, hydrocarbons and oils
1350747HCN	0.45 μm	Cellulose acetate membrane filter with hydrophobic edge	pH 4-8, most alcohols, hydrocarbons and oils
1840747N	0.45 μm	Regenerated cellulose membrane filter	pH 3-12, solvent-resistant



#### Peristaltic pump

#### Specification

- I	
Maximum rotor speeds	50 rpm and 400 rpm
Operating voltages and frequencies	110-240 V 50/60 Hz
Speed control ratio	20:1
Power rating	100 VA
Operating temperature	5°C to 40°C
Storage temperature range	-40°C to 70°C
Weight	5.35 kg, 12 lb
Noise	<70 dBA at 1 m
Standards	IEC 335-1, EN 60529 (IP31)
Machinery Directive	98/37/EC EN 60204-1
Low Voltage Directive	73/23/EEC EN 61010-1
EMC Directive	89/336/EEC EN 50081-1/EN 50082-1

#### Order number

16696





# Weigh | Detect | Control

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#### **Complete Scales**







#### **CB Counting Scales**

... are ideal even for inexperienced operators. With the new rotary selector, reference quantities can be intuitively and reliably selected.

- 3 displays for piece count, avg. piece weight and wt. readout
- Max. accuracy: 1,000 on the pan = 1,000 on the display
- Sturdy plastic housing rugged in every respect
- Lightweight chassis for portable use
- Battery-operable around the clock and beyond!

#### **Economy Series**

... are high quality scales with standard application programs for low budgets. They are easy to operate and ideal for simple weighing tasks.

- Weighing capacities: 3 kg to 150 kg
- Total ease of operationBuilt-in application programs (e.g. counting)
- SPEED UP technology for weight readouts within approx. 0.5 s
- Backlit LCD

#### **Quality Series**

... are high-resolution, rugged and universal scales with an extensive choice of accessories and a wide variety of application programs.

- Weighing capacities: 7 kg to 300 kg
- 25 product memories
  Numeric keypad, e.g. for entering the ref. quantity
- Built-in, combinable application programs
- Backlit LCD; analogue bar graph
- Can also be operated in Zone 2

#### **Complete Scales**







#### **Combics Series**

... cover a range of rugged industrial scales combinable with your choice of indicators and peripheral equipment. Flexible configuration capabilities. With programs for counting, checkweighing, totalizing, ...

- Weighing capacities: 3 kg to 3 t
- 13 platform sizes
- 4 indicators with various application levels
- Painted and stainless steel versions
- Special options (interfaces, materials, ...)
- Stainless steel models can be optionally used in Zones 2 and 22

#### **Stainless Excellence Complete Scales**

... hygienic-washdown design to meet special requirements for easy, thorough cleaning and rugged daily use in the food industry.

- From 0.1 q to 15 kg optionally factory-verified accuracy class III
- HACCP EHEDG compliance
- IP68 IP66 protection
- High-alloy stainless steel grades
  Accurate and fast +|- checking

#### **Factory Series Precision Scales**

... are high-resolution industrial scales that are ideal for use within quality systems.

- Monolithic weigh cell with built-in calibration weight
- From 0.01 to 300 kg, also verifiable for legal metrology, accuracy class I
- Fast and reliable, high-resolution weighing results
- Certified IP protection, UL approvals
- Also suitable for control of measuring and test equipment
- Can be integrated into networks

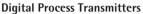
#### **Process Transmitters** | Analogue-Digital Converters



#### **Analogue Process Transmitters**

... designed for tank and hopper scales. Models with an intrinsically safe load cell interface can also be used for applications in hazardous areas.

- 0.1% accuracy
- IP65 field housing or 19" Euroformat
- Process control via 2 outputs, analogue output 4..20mA
- Theoretical calibration via DIP switches



... modern field instrumentation for tank and hopper scales. Models with an intrinsically safe load cell interface can be used for applications in hazardous areas.

- High accuracy, 3,000e, class I
- ModBus, Jbus, Dust protocol, DDE driver serial
- IP65 field housing or 19" Euroformat
- 3 inputs, 3 outputs, analogue output
   4..20mA
- Smart Calibration



- ... are used to integrate scales into process control and automated systems, and have an optional fieldbus interface.
- High accuracy, 3,000e, class I
- Profibus DP, Interbus S, DeviceNet
- IP65 field housing, aluminium stainless steel
- 3 inputs, 3 outputs, analogue output 4..20mA
- Smart Calibration

#### **Process Transmitters**

- ... for especially easy connection to PLCs via Profibus. A DIN rail simplifies mounting in control panels.
- Highly accurate digital signal processing
- Accuracy 6,000e, class I
- Configurable using PALM PDA or Windows®-PC
- IP20 protection, DIN rail mounting
- Smart Calibration







#### **Indicators**









#### **Display and Control Units**

- ... optimised for counting and
- + checkweighing.
- With numerous application programs
- IDs, 25 product memories
- Connect up to four 360-ohm load cellsRS-232C serial port
- Protection rating: IP65 | NEMA 4

#### **Stainless Excellence Indicators**

- ... hygienic-washdown design to meet special requirements for easy, thorough cleaning and rugged design. They can be connected to platforms or load cells for the widest variety of applications.
- HACCP EHEDG compliance
- IP68 IP66 protection, high-alloy stainless steel
- EC type-approval certificate, with suitable load cells, verifiable for legal metrology
- Fast and accurate + | checking
- Connects to many platforms and load cells

#### **Combics Indicators**

- ... high operating reliability; practical application programs; customizable printouts; additional, optionally retrofittable interfaces.
- Up to 9 application programs (e.g. counting, +|- checkweighing, ...)

  - Standard RS-232C interface port
- EC type-approval certificate; with suitable load cells, verifiable for legal metrology
- Analogue bar graph, colour-coded LEDs
- Stainless steel models can be optionally used in Zone 2 and 22

#### isi Terminals

- ... with custom-tailored, practical application programs that can be combined with one another and with an extensive range of accessories and interfaces.
- Application programs (e.g. counting, filling, ...)
- Up to 10 function keys for operator quidance
- Alphanumeric keypad
- Can also be operated in Zone 2 hazardous areas



#### **Indicators**



#### **Digital Weighing Indicators**

... required for evaluating weighing signals. The display and keys provide easy operator guidance. On-site installation possible.

- 16-bit resolution
- 3 digital control inputs | outputs For panel installation; 85 to 250 V power supply
- IP65 protection (front)
- Numerous interfaces



#### **Compact Weighing Indicators**

... are ideal for platform, tank and hopper scales as well as weighbridges. Operation either by front panel or via remote terminal.

- Communication with higher-level systems
- Easy connection to PLCs
- Various options and protocols available
- EC type-approval certificate, 3,000e, class III
- ModBus, JBus, Dust protocol, Profibus-DP, DDE driver



#### **System Controllers**

... are ideal for high accuracy platform scales, weighbridges, fill workstations, batching applications & charge and discharge processes.

- EC type-approval certificate, 5,000e, class III
- PLC function integrated
- Communication via fieldbus and Ethernet
- Housing for various mounting options, stainless steel, IP65
- Interface for external PC keyboard

#### **Load Cells**











#### **Single Point Load Cells**

- ... very low profile. They are used in bench and counting scales as well as checkweighers.
- For legal metrology acc. to OIML R60
- For various platform sizes
- Accuracy classes N, C3, C3MR, C3MR+
- Capacity range from 1 kg to 500 kg
- IP65 68 69K protection

#### **Tension Load Cells**

- ... manufactured from high-strength special or stainless steel. They are used in hybrid scales and for suspended vessels.
- Highly corrosion-resistant
- Hermetically welded, IP67 | 68
- For legal metrology acc. to OIML R60
- Accuracy classes N, C3, C6
- Capacity range from 60 kg to 5 t

#### **Compression Load Cells**

- ... feature absolute accuracy in tank and hopper scales. They are made of highly corrosion-resistant stainless steel and are impervious to vibration.
- Accuracy classes L, D1, C3, C6
- Capacity range from 30 kg to 300 t
- Operating temperature range-30°C to +95°C
- IP68 | NEMA 6 protection
- Especially rugged and reliable

#### **Bending Beam Load Cells**

- ... entirely made of stainless steel and designed for use in platform, tank, hopper and hybrid scales.
- Hermetically welded, IP67
- For legal metrology acc. to OIML R60
- Accuracy classes N, C3, C3MR, C3MR+
- Capacity range from 5 kg to 500 kg

#### **Shear Beam Load Cells**

- ... made of high-strength special or stainless steel and used in platform and tank hopper scales.
- Highly corrosion-resistant
- Hermetically welded, IP67
- For legal metrology acc. to OIML R60
- Accuracy classes N, C3, C3MR, C3MR+
- Capacity range from 91kg to 5 t

#### **Load Cells**







#### PanCake® Level Cell

- ... the ideal solution for all level control requirements using level-by-weight measurements of liquids and solids. Thanks to its ultra-low profile, it needs only a height of 25 35 mm to install.
- Entirely made of stainless steel
- Hermetically welded, IP68 | NEMA 6
- Accuracy class L
- Analogue output 4..20mA (option)
- Capacity range from 500 kg to 16 t

#### **Truck Scale Load Cells**

- ... specially designed to meet the requirements of truck scales. They are highly resistant to surge voltage, ensuring maximum reliability.
- Proven rocker pin design
- Hermetically welded, IP68, IP69K
- Accuracy classes C3, C4
- Capacity range from 20 to 75 t
- Maintenance-free, rugged and reliable

#### **Mounting Kits**

- ... particularly designed for use in tank and hopper weighing. They are matched to the specific load cells, and can be easily installed.
- Made of mild steel or stainless steel Capacity range from 201
- Capacity range from 30 kg to 300 t
- Rugged construction resistant to high lateral loads
- Maintenance-free constrainers and swivel eyes

#### Accessories

- ... and cable junction boxes for industrial applications in hazardous areas and in legal metrology; (extension) cables for load cells, printers and interface cards.
- Additional interface cards for controllers
- Ex equipment, e.g. remote displays
- Cables for installing load cells at large distances
- Cable junction boxes with IP65 | 68 | 69K NEMA 4x /6
- Installation cables for load cells

#### **System Controllers**











#### X4 Process Controllers, "X-Family"

... the right choice for weighing applications in all industrial processes. Versatile for control and communication.

- EC type-approval certificate; 6,000e, class
- Integrated PLC function
- Communication through fieldbuses and Ethernet
- Weight and 2-line text display
- Front dimensions 192×96 mm

#### X5 System Controllers, "X-Family"

... with a maximum of functionality set new standards for control and weighing electronics in the industrial area. The right choice for a variety of applications.

- Easy menu-guided operation
- Integrated PLC function
- Option cards already installed
- Pre-programmed applications
- Easily adaptable with PR1750
- Approved for ATEX Zone 2+22 and FM class I, Div. 2

#### X6 System Controllers, "X-Family"

... offer the complete functionality of X5 system controllers with an additionally integrated keypad in the classic 19" housing.

- Easy menu-quided operation
- Integrated PLC function
- Option cards already installed
- Pre-programmed applications
- Easily adaptable with PR1750

#### **PowerTools**

... are PC programs to facilitate getting the most out of your system controllers. These tools are supplied on CD and can be used with all "X-Family" controllers.

- DisplayIt: remote control by any Windows® PC
- RecoverIt: backs up all data incl. EAROM
- Translatelt: translates all operating texts
- AccessIt: uploads all databases to a PC for editing
- FlashIt: easily loads software updates

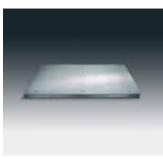
#### PR 1750 Program Development Tool

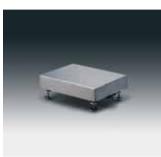
... for flexibility in programming system controllers. It enables you to meet customer-specific requirements precisely by extending standard software capabilities.

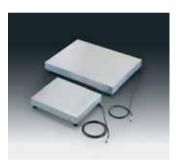
- Easy operation thanks to structured menus
- Programming conforms to IEC 61131
- Library functions specially designed for weighing applications
- Powerful debugging tool
- Tools for convenient project documentation



#### **Platforms**







#### **Combics Weighing Platforms**

... from 0.1 q to 3,000 kg, these are a whole new generation of rugged and flexible industrial scales.

- Accuracy 3,000e, 2 × 3,000e, class ∰; 15,000d, 30,000 d
- 13 different sizes
- IP65 IP68 protection
- Finish: epoxy coated or various stainless steel grades
- Accessories include drive-on ramps, pit frames
- Stainless steel models can optionally be operated in Zones 2 and 22

#### **Stainless Excellence Platforms**

... feature a hygienic-washdown design to meet special requirements for thorough cleaning and rugged daily use. The SEP platform is a safe investment in all quality assurance applications.

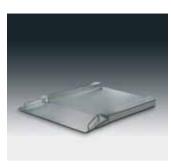
- 0.1 g to 15 kg
- HACCP|EHEDG complianceIP68|IP66 protection
- High-alloy stainless steel in various grades
- For use in legal metrology with type-approved indicators (class III)

#### **IS Weighing Platforms**

... from 0.001 g to 300 kg can be used in automated processes. Verifiable in class I and class .

- Fast weighing; high resolution
- With built-in motorised calibration weight
  RS-485 or RS-232C interface
- Rugged, industry-compatible design
- High IP protection rating
- Some models can be operated in Zones 2 and 22

#### **Platforms**



#### IF Flat-bed Scales

... from 5 q to 3,000 kg are especially easy to load.

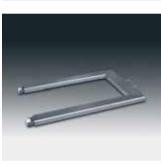
- $-1 \times 3,000e \mid 2 \times 3,000e$ (for legal metrology); class (III)
- High resolution can be set
  Ultra-low profile design; IP68 protection
- Painted or stainless steel finish (also electropolished)
- Can be used in Zone 1, 2, 22



#### IF Flat-bed Scales "PharmaLine"

... from 10 g to 3,000 kg are especially easy to load.

- $-1 \times 3,000e \mid 2 \times 3,000e$ (for legal metrology); class III
- High resolution can be set
- Ultra-low profile design; IP68 protection
- Painted or stainless steel finish (also electropolished)
- Can be used in Zone 1, 2, 22
- Very easy to clean with lifting device



#### **IU Pallet Scales**

... from 10 g to 3,000 kg allow exceptionally flexible use.

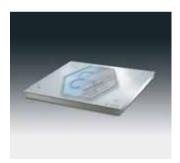
- $-1 \times 3,000e \mid 2 \times 3,000e$ (for legal metrology); class I
- Higher resolution can be set
- High protection rating: IP68
  Hot-galvanised or stainless steel version
  Can be used Zone 1, 2, 22

#### **Explosion-protected Weighing Products**









#### **Explosion-protected Complete Scales**

... are adapted to meet different requirements for resolution and application levels.

- Intrinsically safe scales from 0.001 g to 300 kg
- Conform to ATEX, with international approval certificates for Zone 1
- Monolithic system with internal built-in calibration weight
- Network-compatible (Factory series)
- Configurable backlit display (Factory series)
- Variety of power supply options (also battery)

#### **Explosion-protected Indicators**

... are used with load cells and analogue and digital platforms. Variety of power supply options (also battery).

- Intrinsically safe and with ATEX and international Ex approvals for Zone 1, 21, 20, 2 and 22
- Integrated, powerful analogue digital converter and graphical display
- Can be used as legal measuring instruments
- Verification documents for intrinsic safety included
- With filling application

#### **Explosion-protected Terminal**

... are operating terminals for all "X-Family" controllers. They are specially designed for hazardous areas and feature a rugged stainless steel housing.

- "Plug and play" function
- Easy to integrate via serial interface
- Can be used in Zone 1
- High-contrast LCD

#### **Explosion-protected Platforms**

... are analogue stainless steel scales that can be used as floor, flat-bed and pallet scales and, with a monolithic weigh cell, as high-resolution platforms.

- ATEX-compliant; many with int'l. approvals; for Zone 1, 21, 20, 2, 22 depending on model
- Model dependent type-approved monolithic system, built-in calibration weight
- High-resolution platforms with data interface
- Many can be used in hazardous dust atmospheres

#### **Explosion-protected Weighing Products**







#### **Intrinsically Safe Interfaces**

... isolate circuits for the safe area from those of the hazardous areas. They have intrinsically safe data interfaces or intrinsically safe load cell supply circuits, thus permitting safe connection.

- Safe separation of Ex equipment for data communication
- Highly accurate load cell supply
- Also for applications in legal metrology
- Especially easy to install and use

#### **Explosion-protected Process Transmitters**

... are the classical instrumentation for process, platform and tank scales. The transmitters have an integrated intrinsically safe load cell power supply.

- Accuracy up to 3000e, class Ⅲ
- IP65 field housing or 19" Euroformat
- Calibration|adjustment possible without weights
- Analogue output 4..20mA or serial interface
- Digital inputs and outputs

#### **Explosion-protected Load Cells**

... have been specially designed and optimised for use in the typical process weighing applications in hazardous areas.

- Wide capacity range: up to 300 t
- Ex-certified for Zone 0, 1, 2, 20, 21 and 22, ATEX compliant
- Entirely hermetic IP68 encapsulation
- Complete with blue connecting cable

#### **Dynamic Weighing Products**





#### Weighing Modules

... for static + | - checkweighing with automatic sorting via motorised, bidirectional conveyor belt.

- Weighing capacity: 7 kg
- Classification accuracy: + | 0.4 q
- Max. 30 weighings per minute
- + | checkweighing with 25 product memories
- Interfaces: RS-232C, relay



#### Modules for Weighing in Motion

... constitute a flexible range of inexpensive dynamic checkweighers for bag filling and sealing machines, in-line completeness checks, determination of shipping data, and many more applications.

- Weighing capacities from 6 kg to 120 kg
- Dynamic accuracies of + |-1| q to + |-20| q
- For products up to 1,800  $\times$  900 mm (L  $\times$  W)
- + checkweighing with product memories
- Options: interfaces, st. steel finish. volumetric measurement



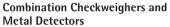
... offer all the advantages of in-line checkweighing whenever project budgets do not allow the use of a fully-equipped checkweigher. Can be connected to QC systems.

- Weighing capacities: 3,000 g to 6,000 g
- Zone of indecision: from + | 1 g up, optionally for use in legal metrology
- Throughput: up to 170 products /min.
- Stainless steel, IP65
- Adjustable transport height and belt speed

#### **Premium Checkweighers**

... provide a wide range of weighing systems from 600 g to 100 kg. Special versions and complete integratability into the QA system SPCfWin cover all requirements.

- Zone of indecision: from + | 20 mg up; for legal metrology according to OIML R51
- Throughput: up to 600 products/min.
- IP65, stainless steel: compliant to HACCP
- Sophisticated conveyor and sorting technology
- Clean design for complete hygiene



... a combined product solution for double safety.

- Optimal availability due to independent electronics
- Sorting separate for weights and metal particles
- IP65 stainless steel; HACCP compliance
- Compact version







# Average Weight Control | Quality Assurance

#### Average Weight Control | Quality Assurance









#### **SPCfWin Terminal Scales**

... combine compact dimensions and unique user-friendly features in a high-quality system. Premium weighing technology with isoTEST for integration into quality management systems.

- Average weight control | Attribute testing
- Weighing ranges: 620 g to 34 kg; protection ratings up to IP65
- Verif. scale intervals ≥ 10 mg (one solution for every product)
- Graphical display with soft keys; sophisticated evaluation
- Off-line mode ensures optimal availability

#### **SPCfWin Standard Terminals**

... with a generous offer of interfaces and platforms allow use of product solutions directly at the production line for short control intervals.

- Average weight control | Attribute testing
- IP65 protection; optional stainless steel version
- Alphanumeric input
- Function keys for fast and error-free
- Off-line mode ensures optimal availability

#### **Premium Terminal**

... especially compact industrial terminal with extensive offer of interfaces; perfect for quality control and control applications.

- Closed, painted steel housing; IP65
- Tiltable display and control unit
- Backlit VGA display; 7.7"; full keypad; function keys
- Motherboard with 486-based processor
- Interfaces: 4 × serial, parallel, Ethernet; 4 relays

#### **Combics3 AWC Terminal**

... featuring the user-friendly design and industry-compatibleruggedness of the Combics system, is now available for average weight control of prepackages and attribute testing in networks.

- Compact solution for networking using Ethernet TCP/IP
- All stainless steel and IP67 protected
- For average weight control and attribute
- For the most diverse weighing capabilities and resolutions
- Completely integrated in the extensive Combics system

#### Average Weight Control | Quality Assurance







# Compact Stand-Alone SartoPac Basic System

... combines compact dimensions and unique user-friendly features in a high-quality system. Premium weighing technology with isoCAL | isoTEST for integration into quality systems.

- Average weight control | SPC |
   Pharmacopoeia
- Weighing ranges: 230 g to 34 kg, protection up to IP65
- Verif. scale intervals ≥1 mg (one solution for every product)
- Graphical display with soft keys; sophisticated evaluation
- 100 product memories (500 memories optional)

#### Industrial PC - IPC

... particularly rugged, industry-compatible, compact version; allows the most sophisticated applications to be used directly in the processing area.

- Closed stainless steel housing
- Protection ratings up to IP65; compliant to HACCP
- INTEL or AMD processors, 128 MB RAM
- Colour TFT touch screen with XGA or SVGA resolution
- Windows® 2000 operating system

#### Sartorius ProControl for Windows®

... modular scale-up system for recording, monitoring, evaluating and archiving all quantitative and qualitative product, process and environmental parameters.

- Average weight control | SPC | Attribute testing | HACCP
- Ranges from stand-alone to network systems
- Solutions for every requirement
- Optimal central computer and workstation ergonomics
- The most advanced software platform quarantees a future-proof investment

# Metal Detectors

#### **Metal Detectors**





#### **Metal Detectors**

... detect metal particles and sort out contaminated products. An extensive offer of detector coils and conveyors enable us to provide the ideal customised product solutions.

- Product quality assurance acc. to ISO 9001
- Safeguard against machine damage and downtimes
- Optimal compliance with legal requirements, such as HACCP
- The most advanced multi-frequency technology
- Interface for printer and QA system SPCfWin

#### **OBSERVER Metal Detector**

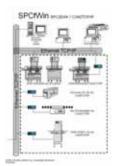
... detects magnetized iron and even stainless steel contaminants in aluminumpackaged products.

- Exclusively designed sensors based
- on magnetic field measuring technology

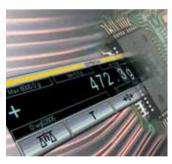
   Position-specific rejection by light-barrier synchronization - Rejection monitoring optional - Interactive prompts:
- Interactive prompts via four-line, backlit LCD

#### **Software Solutions**









#### Recipe | Formula Management Systems

... allow data management of raw materials, recipes or formulas and materials, and serve as central operating workstations for batching applications in automated processes.

- Easy-to-operate with Windows® user interface
- Control of up to 16 parallel formulation processes
- Several formulation processes can be performed in parallel
- Production and consumption data are generated and archived
- Open S88 interfaces for "X-Family" and PLC
- Choice of user languages

#### **Universal Networking of Serial Terminals**

... to the Sartorius Com2TCP | IP; nearly all terminals and instruments with a serial port can be connected via Ethernet TCP | IP to the quality assurance system Sartorius ProControl for Windows® or to individual data systems.

- Connects all terminals and instruments with a serial port
- Moisture analyzers (e.g. Sartorius MA | MMA).
- Electronic thermometers (important for HACCP)
- Checkweighers, metal detectors

#### **Customised Applications**

... allow the use of weighing equipment with a PC. Under Microsoft Access®, a number of different applications have been created:

- Density determination using a balance
- Differential weighing using a balance
- Sieve analysis using a scale
- Recording of machine downtimes and error sources

#### **Communication Tools**

... hardware and software for connecting and networking balances, scales, gauges and sensors.

- Verifiable scale driver with Alibi memory
- Data transfer to PC applications with control functions
- Fill level monitoring of tanks, hoppers, and fermenters with central display on a PC

# Chemical Compatibility 1. Filter Materials and Mini Cartridges

	Cellulose acetate	Cellulose nitrate	Reg. Cellulose	PTFE	Poly- amide	Glass fiber	Polycar- bonate	Poly- ether- sulfone	Sartobran P cartridge	Sartofluor cartridge
Solvents	111	113	184	118	250	134	230	154		
Acetone	-	-	•	•	-	•	0	-	-	E
Acetonitrile	?	?	•	•	-	?	?	•	?	?
Gasoline	•	•	•	•	•	•	•	•	V	_
Benzene	•	•	•	•	•	•	?	•	-	_
Benzyl alcohol	0	0	•	•	•	•	?	-	0	•
n-Butyl acetate	0	-	•	•	•	•	•	•	E	?
n-Butanol	•	•	•	•	•	•	•	•	•	•
Cellosolve	•	-	•	•	?	•	-	•	-	_
Chloroform	-	•	•	•	•	•	-	-	-	_
Cyclohexane	0	0	•	•	?	•	•	-	0	V
Cyclohexanone	-	-	•	•	•	•	?	?	-	_
Diethylacetamide	-	-	•	•	•	•	?	?	-	?
Diethyl ether	•	-	•	•	•	•	•	?	-	_
Dimethyl formamide	-	-	0	•	0	•	-	?	-	•
Dimethylsulfoxide	-	-	•	•	•	•	-	-	_	•
Dioxane	-	-	•	•	•	•	-	•	-	•
Ethanol, 98%	•	0	•	•	•	•	•	•	•	•
Ethyl acetate	_	-	•	•	•	•	?	-	_	_
Ethylene glycol	•	0	•	•	?	•	•	•	•	•
Formamide	?	?	?	•	?	•	=	?	=	•
Glycerin	•	•	•	•	•	•	•	•	•	•
n-Heptane	•	•	•	•	?	•	?	?	•	V
n-Hexane	•	•	•	•	•	•	•	?	V	_
Isobutanol	0	0	•	•	•	•	•	?	-	•
Isopropanol	•	0	•	•	•	•	•	•	•	•
Isopropyl acetate	0	-	•	•	?	•	?	•	=	•
Methanol, 98%	•	-	•	•	?	•	•	•	•	•
Methyl acetate	-	-	•	•	•	•	?	-	_	•
Methylene chloride	-	0	•	•	•	•	-	-	-	_
Methyl ethyl ketone	_	-	•	•	•	•	?	-	_	•
Methyl isobutyl ketone	•	_	•	•	•	•	?	?	-	_
Monochlorobenzene	•	•	•	•	•	•	-	?	V	V
Nitrobenzene	•	0	•	•	•	•	-	?	_	_
n-Pentane	•	•	•	•	•	•	•	?	V	V
Perchloroethylene	•	•	•	•	•	•	•	?	V	V
Pyridine	-	-	•	•	•	•	-	_	_	_
Carbon tetrachloride	0	•	•	•	•	•	?	•	_	?
Tetrahydrofuran	_	_	•	•	•	•	_	_	_	_
Toluene	•	•	•	•	•	•	?	•	-	_

Key to symbols see next page.

	Cellulose acetate	Cellulose nitrate	Reg. Cellulose	PTFE	Poly- amide	Glass fiber	Polycar- bonate	Poly- ether- sulfone	Sartobran P cartridge	Sartofluor cartridge
Solvents	111	113	184	118	250	134	230	154		
Trichloroethane	0	•	•	•	?	•	?	?	-	?
Trichloroethylene	•	•	•	•	•	•	-	•	-	?
Xylene	•	•	•	•	•	•	•	•	-	-
Acids										
Acetic acid, 25%	•	•	•	•	0	?	0	•	•	?
Acetic acid, 96%	-	-	•	•	-	?	?	•	-	•
Hydrofluoric acid, 25%	•	0	0	•	-	?	•	?	-	-
Hydrofluoric acid, 50%	•	0	-	•	-	?	•	?	-	_
Perchloric acid, 25%	-	0	0	•	-	?	?	?	-	•
Phosphoric acid, 25%	•	0	0	•	-	?	?	?	•	•
Phosphoric acid, 85%	0	0	0	•	-	?	-	?	-	V/E
Nitric acid, 25%	-	0	-	•	-	?	•	•	-	V
Nitric acid, 65%	-	-	-	•	-	?	•	•	-	-
Hydrochloric acid, 25%	-	0	-	•	-	?	•	•	-	V/E
Hydrochloric acid, 37%	-	-	-	•	-	?	•	•	-	V/E
Sulfuric acid, 25%	-	0	0	•	-	•	?	•	-	•
Sulfuric acid, 98%	-	_	-	•	-	?	-	?	-	_
Trichloroacetic acid, 25%	_	0	•	•	-	?	?	?	-	•
Bases										
Ammonium, 1N	•	•	0	•	•	•	-	•	E	•
Ammonium hydroxide,25%	-	0	-	0	•	0	-	•	-	•
Potassium hydroxide,32%	_	-	0	•	0	0	_	•	-	•
Sodium hydroxide, 32%	-	-	0	•	0	0	-	•	-	•
Sodium, 1N	0	-	0	•	•	•	-	•	-	•
Aqueous solutions										
Formalin, 30%	0	•	0	•	0	•	•	•	-	•
Sodium hypochlorite, 5%	•	0	•	•	0	•	?	?	-	•
Hydrogen peroxide, 35%	•	•	0	•	0	?	?	?	•	•

#### Key to symbols

 = compatible = not compatible ○ = limited compatibility

? = not tested

E = compatible after replacing silicone O-ring with an EPDM O-ring

V = compatible after replacing the silicone O-ring with a Viton O-ring

#### Contact time: 24 hours at 20°C

Chemical compatibilities can be influenced by various factors.

Therefore, we recommend that you confirm compatibility with the liquid you wish to filter by performing a trial filtration run before you begin with actual filtration.

## 2. Filter Holder, Cartridge Housing and O-ring Materials

	Glass	Poly- carbonate	Poly- propylene	PTFE	Stainless steel	EPDM O-ring	PTFE O-ring	Silicone O-ring	Viton O-ring
Solvents									
Acetone	•	0	•	•	•	•	•	_	_
Acetonitrile	•	?	•	•	•	0	•	_	•
Gasoline	•	0	•	•	•	-	•	_	•
Benzene	•	_	-	•	•	-	•	_	•
Benzyl alcohol	•	_	•	•	•	0	•	•	•
n-Butyl acetate	•	_	0	•	•	•	•	-	-
n-Butanol	•	•	•	•	•	•	•	•	•
Cellosolve	•	_	-	•	•	0	•	_	_
Chloroform	•	_	-	•	•	-	•	_	•
Cyclohexane	•	0	•	•	•	-	•	-	•
Cyclohexanone	•	_	•	•	•	-	•	-	_
Diethylacetamide	•	-	?	•	•	?	•	•	-
Diethyl ether	•	-	0	•	•	_	•	-	-
Dimethyl formamide	•	_	•	•	•	•	•	0	-
Dimethylsulfoxide	•	?	?	•	•	?	•	0	-
Dioxane	•	-	0	•	•	•	•	-	_
Ethanol, 98%	•	•	•	•	•	•	•	•	•
Ethyl acetate	•	_	•	•	•	•	•	_	-
Ethylene glycol	•	•	•	•	•	•	•	•	•
Formamide	•	_	•	•	•	•	•	-	0
Glycerin	•	0	•	•	•	•	•	•	•
n-Heptane	•	•	•	•	•	-	•	•	•
n-Hexane	•	•	•	•	•	-	•	-	•
Isobutanol	•	•	•	•	•	•	•	•	•
Isopropanol	•	0	•	•	•	•	•	•	•
Isopropyl acetate	•	•	•	•	•	•	•	_	-
Methanol, 98%	•	_	•	•	•	•	•	•	•
Methyl acetate	•	?	•	•	•	•	•	_	-
Methylene chloride	•	_	-	•	•	-	•	-	0
Methyl ethyl ketone	•	-	•	•	•	•	•	-	-
Methyl isobutyl ketone	•	-	?	•	•	-	•	-	-
Monochlorobenzene	•	_	•	•	•	_	•	_	•
Nitrobenzene	•	-	0	•	•	-	•	-	-
n-Pentane	•	•	•	•	•	_	•	-	•
Perchloroethylene	•	_	0	•	•	_	•	_	•
Pyridine	•	-	0	•	•	_	•	-	_
Carbon tetrachloride	•	-	0	•	•	_	•	_	•
Tetrahydrofuran	•	_	0	•	•	_	•	_	_
Toluene	•	_	•	•	•	-	•	-	0

Key to symbols see next page.

	Glass	Poly- carbonate	Poly- propylene	PTFE	Stainless steel	EPDM O-ring	PTFE O-ring	Silicone O-ring	Viton O-ring
Solvents									
Trichloroethane	•	-	?	•	•	-	•	-	•
Trichloroethylene	•	-	-	•	•	-	•	-	•
Xylene	•	-	0	•	•	-	•	-	0
Acids									
Acetic acid, 25%	•	•	•	•	•	•	•	•	-
Acetic acid, 96%	•	-	•	•	•	•	•	?	-
Hydrofluoric acid, 25%	-	-	•	•	-	0	•	-	0
Hydrofluoric acid, 50%	-	-	•	•	-	0	•	-	0
Perchloric acid, 25%	•	0	•	•	-	•	•	-	•
Phosphoric acid, 25%	•	0	•	•	0	•	•	-	•
Phosphoric acid, 85%	•	0	•	•	0	•	•	-	•
Nitric acid, 25%	•	-	•	•	-	0	•	-	•
Nitric acid, 65%	•	-	-	•	-	-	•	-	•
Hydrochloric acid, 25%	•	0	•	•	-	0	•	-	•
Hydrochloric acid, 37%	•	-	•	•	-	•	•	-	•
Sulfuric acid, 25%	•	•	•	•	0	•	•	-	•
Sulfuric acid, 98%	•	-	-	•	-	-	•	-	•
Trichloroacetic acid, 25%	•	0	•	•	-	•	•	_	-
Bases Ammonium, 1N	•	_	•	•	•	•	•	_	_
Ammonium hydroxide, 25%	•	-	•	•	•	•	•	•	-
Potassium hydroxide, 32%	•	-	•	•	•	•	•	0	0
Sodium hydroxide, 32%	•	-	•	•	•	•	•	0	•
Sodium, 1N	•	-	•	•	•	•	•	•	•
Aqueous solutions Formalin, 30%	•	•	•	•	•	•	•	0	•
Sodium hypochlorite, 5%	•	•	•	•	•	•	•	•	•
Hydrogen peroxide, 35%	•	•	•	•	•	•	•	•	•

#### Key to symbols

= compatible- = not compatible ○ = limited compatibility

? = not tested

Contact time: 24 hours at 20°C Chemical compatibilities can be influenced by various factors. Therefore, we recommend that you confirm compatibility with the liquid you wish to filter by performing a trial filtration run before you begin with actual filtration.

### 3. Ready-to-Connect Filtration Units

	Midisart 2000	Minisart	Minisart HY	Minisart RC	Minisart SRP	Sartobran 300	Sartobran P Capsule	Sartofluor Capsule	Sartolab P20
Solvents									
Acetone	•	-	-	•	_	-	-	•	-
Acetonitrile	•	-	?	•	•	?	?	?	?
Gasoline	•	•	•	•	•	•	•	•	0
Benzene	•	-	-	?	•	-	-	0	-
Benzyl alcohol	•	?	?	?	•	0	0	•	-
n-Butyl acetate	•	-	-	?	•	•	•	•	-
n-Butanol	•	0	0	•	•	•	•	•	•
Cellosolve	0	-	-	•	0	_	-	0	_
Chloroform	•	-	-	•	•	-	-	•	_
Cyclohexane	•	-	-	?	•	0	0	•	0
Cyclohexanone	•	-	-	?	•	-	_	•	_
Diethylacetamide	•	_	_	•	•	_	_	•	-
Diethyl ether	•	?	?	?	•	0	0	•	-
Dimethyl formamide	•	_	_	?	•	_	_	•	-
Dimethylsulfoxide	•	-	-	•	•	-	-	•	-
Dioxane	•	_	_	•	•	_	_	0	-
Ethanol, 98%	•	-	-	•	•	•	•	•	•
Ethyl acetate	•	0	0	•	•	-	-	0	-
Ethylene glycol	•	?	?	•	•	•	•	•	•
Formamide	•	?	?	?	•	?	?	•	-
Glycerin	•	•	•	?	•	•	•	•	0
n-Heptane	•	•	•	?	•	•	•	•	•
n-Hexane	•	•	•	•	•	•	•	•	•
Isobutanol	•	0	0	•	•	0	0	•	0
Isopropanol	•	0	0	-	•	•	•	•	0
Isopropyl acetate	•	0	0	?	•	0	0	•	0
Methanol, 98%	•	-	-	•	•	•	•	•	-
Methyl acetate	•	_	_	?	•	_	_	•	-
Methylene chloride	•	-	_	•	•	_	-	0	-
Methyl ethyl ketone	•	_	_	•	•	_	_	•	-
Methyl isobutyl ketone	•	?	?	?	•	?	?	•	-
Monochlorobenzene	•	?	?	?	•	•	•	•	-
Nitrobenzene	•	?	?	?	•	0	0	•	-
n-Pentane	•	•	•	•	•	•	•	•	•
Perchloroethylene	•	0	0	?	•	0	0	•	-
Pyridine	•	-	-	?	•	-	_	•	-
Carbon tetrachloride	•	0	0	?	•	0	0	•	-
Tetrahydrofuran	•	_	_	•	•	_	_	0	-
Toluene	•	-	-	•	•	•	•	•	-

Key to symbols see next page.

	Midisart 2000	Minisart	Minisart HY	Minisart RC	Minisart SRP	Sarto- bran 300	Sartobran P Capsule	Sartofluor Capsule	Sartolab P20
Solvents									
Trichloroethane	•	0	0	•	•	?	?	•	-
Trichloroethylene	0	?	?	?	0	-	-	-	-
Xylene	•	-	-	•	•	0	0	•	-
Acids Acetic acid, 25%	•	0	0	?	?	•	•	•	•
Acetic acid, 96%	•	-	-	?	•	_	-	•	-
Hydrofluoric acid, 25%	•	0	0	?	•	•	•	•	_
Hydrofluoric acid, 50%	•	0	0	?	•	-	-	•	-
Perchloric acid, 25%	•	?	?	?	•	_	_	•	-
Phosphoric acid, 25%	•	•	•	?	•	•	•	•	•
Phosphoric acid, 85%	-	?	?	?	-	0	0	-	0
Nitric acid, 25%	•	-	-	?	•	-	-	•	-
Nitric acid, 65%	•	-	-	?	•	-	-	0	-
Hydrochloric acid, 25%	•	-	-	?	•	-	-	•	-
Hydrochloric acid, 37%	•	-	-	?	•	-	-	•	-
Sulfuric acid, 25%	•	-	-	?	•	-	-	•	-
Sulfuric acid, 98%	•	-	-	?	•	-	-	•	-
Trichloroacetic acid, 25%	•	-	-	•	•	-	-	•	-
Bases Ammonium, 1N	•	•	•	?	•	•	•	•	-
Ammonium hydroxide, 25%	•	0	0	?	•	0	0	•	-
Potassium hydroxide, 32%	•	_	_	?	•	-	-	•	-
Sodium hydroxide, 32%	•	_	_	?	•	-	-	•	-
Sodium, 1N	•	0	0	?	•	0	0	•	-
Aqueous solutions Formalin, 30%	•	_	_	?	•	0	0	•	0
Sodium hypochlorite, 5%	•	•	•	?	•	-	-	•	•
Hydrogen peroxide, 35%	•	•	•	?	•	•	•	•	•

#### Key to symbols

= compatible- = not compatible

• = limited compatibility

= not compatible ? = not tested

Contact time: 24 hours at 20°C

Chemical compatibilities can be influenced by various factors.

Therefore, we recommend that you confirm compatibility with the liquid you wish to filter by performing a trial filtration run before you begin with actual filtration.

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