

## Sartocheck® 5 Plus Filter Tester

Keeps Your Risk Factors  
Under Complete Control

New Software Release Q2 2022 –  
Version 2.1.0



### Product Information

The Sartocheck® 5 Plus represents the ideal intersection point of today's most relevant industry requirements for filter integrity testing within demanding GMP environments. A combination of a unique approach to Quality Risk Management (QRM) as well as optimal data integrity, intuitive usability, and minimized risk factors for Health, Safety, and Environment (HSE) set a new standard for filter integrity test devices.

### Surpass the Requirements of QRM

The regulatory focus on QRM (cf. ICHQ9 and the new Annex 1 written by EMA in cooperation with the US-FDA, WHO, and PICs) also applies to filter integrity testing, as a fundamental element of sterility assurance.

The Sartocheck® 5 Plus Filter Tester uses program-specific parameters allowing the automatic identification of testing anomalies before or during the test. This prevents time-consuming, costly variations, potential drug recalls, and 483 warning letters.

### Experience the Comfort of Intuitive Usability

An optimal user experience speeds up process workflows due to intuitive guidance and ease of use. The high-quality touchscreen of the Sartocheck® 5 Plus Filter Tester provides a unique viewing angle, an intuitive user interface, a logical menu structure, and simple data entry options. This allows straightforward programming of tests and QRM enhancement features, as well as error-free operation in GMP production environments.

### Reach the Ultimate Level of Data Integrity

Filter integrity test values are part of the batch protocol and are used to justify the drug release. Long-term reliable data is crucial to avoid quality deviations and potential 483 warning letters.

The integrity and security of filter integrity test data must not be seen only as an IT problem, but also as a potential global business risk. Low standards of data integrity and security may not only jeopardize the activities of the drug manufacturing company, but more critically, endanger the health of patients.

### Discover the Simplicity of HSE

Integrity testing often involves the use of chemicals and hazardous materials, e.g., alcohol. The Sartocheck® 5 Plus is certified for use in explosion-hazardous areas (ATEX) and is compatible with all current cleaning agents and VHP. This ensures maximum safety for operators and manufacturing facilities.



## Quality Risk Management

- Automatic detection of incorrect test setups
  - Program-specific min. and max. values for volume determination
  - Program-specific min. diffusion | intrusion values
  - Program-specific min. flow at pressure end during a bubble point test
- Automatic detection of abnormal test conditions
  - Detection of abnormal pressure increase
  - Detection of environmental temperature outside prerequisite conditions and temperature changes (roadmap – requires sensor)
  - Detection of unstable test values (roadmap – pat. pending)
- Self-test at booting and before each test
- Comprehensive Failure Mode Effects Analysis (FMEA), including instructions for setting program-specific QRM values to avoid false passed and false failed test results
- Calculation tool for the impact of unlikely calibration offsets

## Usability

- Intuitive iF-design-rewarded Human Machine Interface (HMI)
- 12.1" bright touchscreen with a  $\pm 88^\circ$  viewing angle
- Large digital keypad - no need for a pen – compatible with glove use
- 10 system languages
- LDAP: log on with network user credentials
- Automatic test time for faster testing
- Data transfer
- Automation by OPC UA or Modbus TCP
- Additional keyboards (Korean and Cyrillic)
- LDAP group-based role management
- Filtering of displayed audit trail events
- Audit trail export in a digitally signed write-protected PDF
- Remote administration via OPC UA
- Memory management (21CFR Part 11)
- Printing via printer server
- DNS name support
- Scheduled export of the audit trail in PDF format
- Improved program parameters for large crossflow system (TFF) systems

## Data Integrity

- Custom Linux-based OS with SSB custom architecture
- Audit trail with time zone-synchronized (NTP) events
- Write-protected and constantly monitored root file system
- Encrypted double data backup | redundant data storage
- 4 eyes principle | electronic signatures
- Comprehensive and flexible role management
- Locking out user after X number of unsuccessful login attempts
- Serial number of the device in every audit trail entry
- Easy to read audit trail on the screen
- Harmonized time representations
- A major update of the root file system of the SC5 in the Q2 2022 release will further strengthen the data security aspects of the software
- Mandatory "Why" comment when modifying program parameters (Q2 2022)
- Blocking of abusive test attempts (Q2 2022)

Request the Data Integrity statement for more details.

## Health, Safety, and Environment (HSE)

- Splash-proof (IP64)
- Ex-proof (ATEX IECEx & FM certified)
- Safe testing and re-testing of alcohol-wetted filters
- Continuous and clear visualization of pressure status
- Resistant to all current cleaning agents
- H<sub>2</sub>O<sub>2</sub>-vapor-resistant (VHP)
- PFA tubings (FDA 21 CFR 177 and USP Class VI compliant)
- Optional kit for automated cleaning of the pneumatics with up to 0.5M NaOH at 50 °C, available in Q3 2022 (requires at least software version 2.0.0). See the Contamination Control Strategy documentation for additional information
- Optional accessory kit for backflow protection (26787---AK---EV)

# Technical Data

Test Methods	
Diffusion	
Bubble point (detection by over proportionality)	
Combined diffusion and bubble point	
Water intrusion test	
Pressure drop   leak test	
Measuring Ranges	
Diffusion and intrusion test pressure	50 – 6,600 mbar   0.73 – 95.7 psi
Programmable max. diffusion flow	0.01 – 4,800 ml/min.
Programmable max. intrusion water flow	0.005 ml/min. – 60.000 ml/min.
Max measurable   displayable diffusion flow	24,000 ml/min. (5 times the max. programmable value)
Max. measurable   displayable intrusion water flow	300 ml/min. (5 times the max. programmable value)
Programmable min. bubble point	250 – 6,550 mbar   3.63 – 95.0 psi
Programmable pressure drop (not higher than the test pressure)	0.5 – 6,600 mbar   0.01 – 95.7 psi
Sample net volume with volume measurement	
▪ with int. reference vessel	14 L
▪ with ext. reference vessel	150 L
Max. sample net volume for pressure drop test	1,000 L
Power Supply	
Power requirements	100 – 240 V AC at 50   60 Hz
Max. power input	74 W
Average power usage	66 W
Power consumption in standby mode	14.8 W

A country-specific cable is delivered with each device.

## Internal battery

The Sartocheck 5 is equipped with an internal battery. This battery (CR2032) contains less than 0.3 g lithium.

Pneumatics	
Max. inlet pressure	8,000 mbar   116 psi
Overpressure protection	Max. inlet pressure + 4,000 mbar
Min. inlet pressure	4,000 mbar   58 psi
Internal reference volume	1,023 ml conforming to Pressure Equipment Directive 2014/68/EU max. Pressure = 12 bar pressure certificate
Measuring Accuracies	
Measured pressure	± 0.1% full scale (± 7.2 mbar   ± 0.104 psi)
Measured pressure drop	0.2% of the measured value before rounding
Volume determination	± 4%
Diffusion	± 5% or 0.05 mL/min, whichever is higher
Intrusion	± 5% or 0.05 mL/min, whichever is higher
Bubble point	± 50 mbar   0.73 psi, can be improved to ± 25 mbar   0.36 psi (configurable pressure steps)
Accelerated bubble point	± 50 mbar   ± 0.73 psi from the starting pressure to one pressure step above the min. bubble point
Dimensions, Weight, and Noise	
Dimensions (W × D × H)	348 × 379 × 286 mm
Weight	16.8 kg
Weight of the packaging	2.2 kg
Cargo   gross weight	20.6 kg
Cargo volume	95,304 cm <sup>3</sup>
Cargo dimensions	570 × 440 × 380 mm
Max. noise at 1 m during depressurization with venting tubings	68 dB(A) at 6,600 mbar (95.7 psi) 51 dB(A) at 3,000 mbar (47.9 psi)

## Manufacturing Site

Designed, developed, and manufactured in Germany  
Otto-Brenner Strasse 20  
Goettingen, Germany

## End-user Training

The Sartocheck® comes with end-user training.

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## Materials of Construction and Roughness

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All materials used for the external surfaces and the fluid paths are animal free.

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## External Surfaces

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- Ra 1.6 µm or better
  - Stainless steel 304L
  - Heat strengthened glass (see "Screen and Protective Glass")
  - Plastic polymer (Edistir® polystyrene PBBE free) painted with chemical resistant Alexit-lacquer 5300
  - Aluminum painted with chemical resistant Alexit-lacquer 5300
  - Rubber feet: Taber H-18 abrasion resistant (ASTM-501C)
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## Pneumatic Fluid Path of the Sartocheck® 5 Plus

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- Ra 1.6 µm or better
  - Aluminum (inlet valve block, no potential product contact)
  - Stainless steel 304L (process valve block)
  - Stainless steel 316L (connectors)
  - EPDM (connector gaskets), FDA 21 CFR 177 and USP Class VI (A)
  - PFA tubings, FDA 21 CFR 177 and USP Class VI (A)
  - PTFE (valve block membrane FDA 21 CFR 177 and USP Class VI (A))
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## Pneumatic Fluid Path of the Accessory Kit for External Venting

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- Ra 1.6 µm or better
  - Stainless steel 304L (valves)
  - Stainless steel 316L (connectors)
  - EPDM (connector gaskets) FDA 21 CFR 177 and USP Class VI (A)
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## External Tubings (Inlet and Test Tubing)

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- PFA tubings, FDA 21 CFR 177 and USP Class VI (A)
  - Stainless steel 316L (connectors)
  - EPDM (connector gaskets) FDA 21 CFR 177 and USP Class VI (A)
  - Sintered Polyethylene (inlet filter)
  - Polypropylene (inlet filter housing)
  - Stainless steel 316L Parker nipple
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## Screen and Protective Glass

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Size	12.1" (Format 16:10; 262.6 × 164.7 mm   10.34 × 6.48 inch)
Type	TFT LED-Backlit color
Resolution	1,280 × 800 pixels
Luminosity	400 CD/m <sup>2</sup>
Viewing angle vertical and horizontal	± 88° (total 176°)
Shock resistance	Thermally toughened glass DIN EN 12150-1; IEC 60068-2-75
Antiglare	LS Touch Gloss 85 ± 10   60° on front side

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## Connectors and Ports

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All connectors on the device are specifically defined in order to avoid mix up between different connections. E.g., the test tubing can only be connected to the outlet of the device.

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## Pneumatic Connectors

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Inlet tubing towards pressurized line	Parker nipple (Parker reference 26SFAW13MXN)
Inlet tubing towards device	Staubli RBE03 female
Test tubing towards sample to be tested	Staubli RBE03 female

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## Pneumatic Tubings

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All pneumatic tubings have been leak-tested at the end of manufacturing.

Use only original test tubings of original length with original connectors to avoid any mix-up.

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## Communication Ports

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- Industrial automation for OPC UA and Modbus TCP
  - Ethernet RJ45 for networking and data transfer
  - USB (4 ports) for software upgrades, barcode reader, and USB printer
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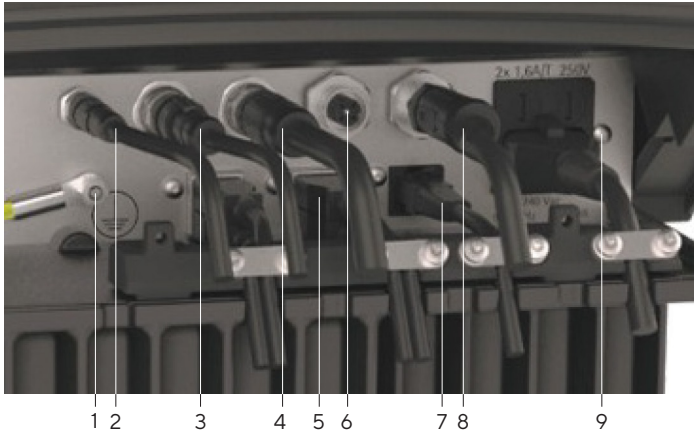
## Operating Conditions

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Environmental temperature and humidity according to IEC 61010-1	0 °C to 40 °C (32 - 104°F) From 0 °C to 31 °C 80% RH From 31 °C to 40 °C linearly decreasing to 50% RH
Altitude	100 m below sea level to 3000 m above sea level
Ingress protection rating of the device as per EN 60529   IEC 60529	IP64 under normal conditions IP4X for use in potentially explosive atmospheres
Ingress protection of the Accessory Kit for External Venting as per EN 60529   IEC 60529	IP65
Explosion-prone areas (device only)	Zone 2, Groupe II-B (IECEx, ATEX)   Class 1 Zone 2 Group II-B (USA)
Explosion-prone areas (Accessory Kit for Venting)	Zone 1 Group II-B (IECEx, ATEX)   Class 1, Div. 1, Zone 1 Group II-B (USA)

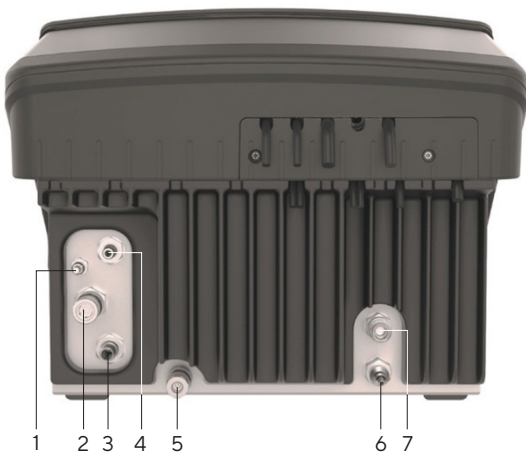
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## Connectors on the backside



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|--|--------------------------|
| 1 Earth                                    | 5 4 × USB (e.g. printer) |
| 2 Future environmental, temperature sensor | 6 Future extender box    |
| 3 External pressure sensor                 | 7 RJ45                   |
| 4 External valves                          | 8 Industrial automation  |
|  | 9 Power                  |

## Back cover closed



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|------------------------|-----------------------------------|
| 1 Device cleaning      | 5 Ext. reference tank             |
| 2 Outlet   test tubing | 6 Inlet pressure, max. 8 barg,    |
| 3 Sample vent          | 7 External valves pressure supply |
| 4 Device vent          |                                   |

## Fixation of cables



## Operating System and Memory

- Custom Linux Distribution made by Sartorius
- Flash memory 4 GB
- RAM 2 GB
- Internal inaccessible SD card 8 GB
- CPU MSC NanoRISC i.MX6 D 800 MHz

## Memory Capacity

The memory can hold approximately 21,900 test results. At a rate of 10 tests per day, 365 days per year, the memory will be full after approximately 6 years.

## Test Result Calculation, Evaluation, and Rounding

The test evaluation is done before the rounding, meaning that, e.g., a measured diffusion value with 16 decimals of 4.4000000000000001 ml/min. will give a failed test if the max. diffusion value is set to 4.40 ml/min. The test result rounding is done according to the tie-breaking rule called "round half to even". This is the default rounding mode used in IEEE 754 computing functions and operators.

## Storage and Transportation Conditions

From -10 °C to +60 °C (14 - 140°F) at 90% RH noncondensing humidity. The original cardboard box is single-use shipping only. For subsequent shipping, please use the solid transportation box 26787---ST (see accessories).

## Language Options

- English
- German
- French
- Spanish
- Italian
- Mandarin (simplified)
- Portuguese (Brazilian)
- Japanese
- Korean
- Russian

### Cleaning and Chemical Compatibility of External Surfaces (Based on Alexit Lacquer Compatibility)

Do not use any abrasive cloth.  
Only smooth cloths or towels are allowed.

- Spor-Klenz® Ready-To-Use Cold Sterilant
- 3% Hydrogen Peroxide WFI Sterile Solution
- Septihol® Sterile Alcohol Solution 70% IPA
- Water for injection
- Sodium hydroxide (NaOH) 10%
- Hydrochloric acid (HCL) 20%
- Sulfuric acid (H2SO4) 20%
- Acetic acid 10%
- Ammoniac 10%
- Quaternary ammonium compounds 0.2%
- Cleansinald (Quaternary ammoniums blended with alkyl amines)
- Bacterianos (Glutaraldehyde 0.5 mg/g and didecyldimethylammonium chloride 1.2 mg/g; pH 3 – 5, contact time > 15 min.)
- Aniospray (Ethanol 226 mg/g, Chlorure de didécyldiméthylammonium 0.53 mg/g, chlorhydrate de polyhexaméthylène biguanide 0.64 mg/g contact time > 15 min.)
- Amphospray (Ethanol 327.4 mg/g, N-(3-aminopropyl)-Ndodé-cylpropane- 1,3-diamine 0.33 mg/g), chlorure de didécyldiméthylammonium 1.09 mg/g), chlorhydrate de polyhexaméthylène biguanide 0.96 mg/g)
- Formaldehyde 37%
- Sodium hypochlorite 6%
- Ethanol (60%, 70%, and pure)
- Acetone (pure)
- Ethyl acetate (pure)
- Minncare Cold Sterilant
- Vaporized Hydrogen Peroxide (VHP) at 1400 ppm

### Cleaning of Internal Pneumatics

Use only the original Accessory Kit for Cleaning (available Q3 2022)

#### Warning!

Inflammable or explosion-prone liquids must not be used for internal cleaning because the Accessory Kit for Cleaning is not compliant to hazardous areas or liquids.

Use the following cleaning agents:

- Sodium hydroxide up to 0.5 M at 25 °C (77°F)
- Citric acid 10% at 25 °C (77°F)
- Sodium hypochlorite 10% at 25 °C (77°F)
- 3% Hydrogen Peroxide at 25 °C (77°F)

## Sartocheck® 5 and 5 Plus Filter Tester Comparison

Feature	Sartocheck® 5	Sartocheck® 5 Plus
QRM-related program parameters	No	Yes
Automation (OPC UA and Modbus TCP)	No	Yes
Data integrity	Identical	Identical
HSE – ATEX   IECEx   FM	Identical	Identical
Usability	Identical	Identical
Accuracy	Identical	Identical
Cleanability	Identical	Identical
Accessory kits (External Venting Kit and Cleaning Kit)	Compatible (cleaning kit available in Q3 2022)	Compatible (cleaning kit available in Q3 2022)
Included software upgrades	Selected upgrades are included until the software release end of 2023	Yes – All upgrades until the software release end of 2023

# Ordering Information

## Sartocheck® Filter Tester

Description	Article No.
Sartocheck® 5 Filter Tester	26787---FT

### Equipment included in 26787---FT

Sartocheck® 5 Filter Tester
Inlet tubing for compressed gas 2m (26787---IT)
Test tubing 2 m (26787---TT---02)
Test certificate
Calibration certificate
Installation and operating instructions
Power cord (region-specific)
Screw driver (T20 × 100) for fixation of cables
Networking cable (RJ45)
Printer cable (USB)

## Sartocheck® Plus Filter Tester

Description	Article No.
Sartocheck® 5 Plus Filter Tester	26787---FT---P

### Equipment included in 26787---FT---P

Sartocheck® 5 Plus Filter Tester
Inlet tubing for compressed gas 2 m (26787---IT)
Test tubing 2 m (26787---TT---02)
Test certificate
Calibration certificate
Installation and operating instructions
Risk assessment for integrity testing   FMEA (PDF)
Power cord (region-specific)
Screw driver (T20 × 100) for fixation of cables
Networking cable (RJ45)
Printer cable (USB)



## Accessories and Spare Parts

Description	Article No.
USB printer (without paper)	YDP30
Archivable paper 90 m and ink ribbon	69Y03285
Archivable self-adhesive paper 90 m and ink ribbon	69Y03286
Thermal paper 5 rolls of 24 m	69Y03287
Self-adhesive thermal paper 5 rolls of 13 m	69Y03288
Inlet tubing for compressed gas 2 m	26787---IT
Test tubing 2 m	26787---TT---02
Test tubing 5 m	26787---TT---05
Test tubing 15 m	26787---TT---15
Test tubing for external venting	26787---TT-AKEV
Complete tubing-cable wrap for AKEV 2 m	26787---02-AKEV
Complete tubing-cable wrap for AKEV 5 m	26787---05-AKEV
Accessory Kit for External Venting	26787---AK---EV (max. 10 accessory kits per device due to calibration data)
Tubing for "device vent"	26787---VT---DE
Tubing for "sample vent"	26787---VT---SA
Accessory kit for cleaning of the pneumatics (available Q3 2022)*	
Germany (German manual)	26787---AKDE-CL
UK, India & US   Canada (English manual)	26787---AKEN-CL
France (French manual)	26787---AKFR-CL
Italy (Italian manual)	26787---AKIT-CL
Spain & Argentina (Spanish manual)	26787---AKES-CL
Portugal & Brazil (Portuguese manual)	26787---AKPT-CL
China (Chinese manual)	26787---AKCN-CL
Japan (Japanese manual)	26787---AKJP-CL
Korea (Korean manual)	26787---AKKR-CL
Russia (Russian manual)	26787---AKRU-CL
Switzerland, Belgium & Canada (English, German, French & Italian manuals)	26787---AKVA-CL
South Africa, Australia   New Zealand, Israel and Denmark (English manual)	26787---AKVB-CL

Description	Article No.
10 L pressure vessel including safety valve and manometer, certified for EU	26787---AKPV-EU
Additional waste vessel for the accessory kit for cleaning (available Q3 2021)	26787---AKWV-CL
Barcode Scanner (None ATEX)	26787---BS
External reference volume	26787---ER
Additional tubing for the external reference volume	26787---TE-RV
Solid transportation box for the Sartocheck® 5   5 Plus	26787---ST
Midisart® Test Manifold for parallel bubble point	1Z-LB-0002
Triclamp 25 mm - Staubli nipple RBE03 open	7ZML--0009
Triclamp 25 mm - Staubli nipple RBE03 closed	7ZML--0015
Triclamp 50.5 mm with autom. RBE03 nipple	7ZML--0055
Triclamp 50.5 mm with autom. closure coupling	7ZML--0056
Luer lock male - Staubli nipple RBE03 open	7ZV--0115

## Services

Description	Article No.
Validation package for Sartocheck® 5   5 Plus	26787---V3---FT
Sartocheck® 5   5 Plus installation	S872QINST
Sartocheck® 5   5 Plus installation pack (incl. travel exp.)	S872QINSTP
Valve Kit installation	S873IINST
Valve Kit installation pack (incl. travel exp.)	S873IINSTP
Sartocheck® 5   5 Plus IQ   OQ	S872QIQOQ
Sartocheck® 5   5 Plus IQ   OQ service pack (incl. travel exp.)	S872QIQOQP
Valve Kit IQ   OQ	S873IIQOQ
Valve Kit IQ   OQ service pack (incl. travel exp.)	S873IIQOQP
Service level agreement Advanced	S872QSLAA
Service level agreement Comprehensive	S872QSLAC
Service level agreement Essential	S872QSLAE


\* For more details, please refer to the Contamination Control Strategy (CCS) datasheet.

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