Kimberly-Clark PROFESSIONAL*

DATA PACK

KIMTECH PURE* M3 Sterile Pouch Face Mask

The Science of Contamination Control

KIMTECH PURE* BRAND

Kimberly-Clark PROFESSIONAL*

The Science of Contamination Control

KIMTECH PURE* M3 Sterile Pouch Face Masks

Your employees deserve the best in Comfort, Protection and Performance. Your process requires constant monitoring to prevent contamination. Like all KIMBERLY-CLARK PROFESSIONAL* facial protection, KIMTECH PURE* M3 Sterile Pouch Face Masks are backed up with field support and technical resources in order to guarantee customer satisfaction.

Better performance means better protection.

The pouch style design delivers the following:

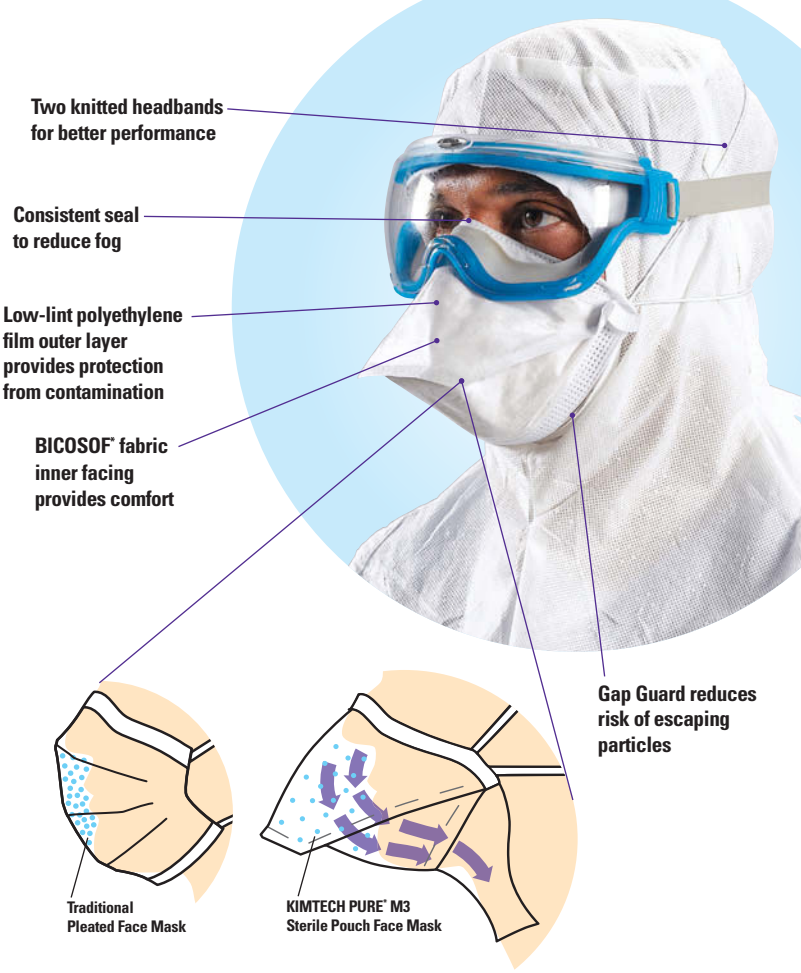
- **Pouch design means easier breathing and greater comfort**
- **Consistent seal to reduce fogging and maintain clear vision**
- **Secure fit and gap guard to reduce the risk of contamination**

You can count on the KIMTECH PURE* Brand from KIMBERLY-CLARK PROFESSIONAL* for world-class contamination control in sterile environments. Our masks are designed for maximum bacterial and particle filtration. That's why KIMBERLY-CLARK PROFESSIONAL* is one of the world's leading providers of face masks.

- **Recommended for ISO Class 3 or higher cleanroom environments**
- **Excellent bacterial filtration**
- **Low lint polyethylene film outer layer**

KIMTECH PURE* BRAND

KIMTECH PURE* M3 Sterile Pouch Face Masks



Product Specifications

- Recommended for ISO Class 3 or higher cleanroom environments
- No latex material is used in the production
- Individually and triple-bagged for extra protection
- Tight seal around the bridge of the nose to minimize fog potential
- Mask design and two knitted headbands hold mask in place during use
- Low lint polyethylene film outer layer

Quality Standards

- Gamma irradiated with Sterility Assurance Level of 10^{-6}
- Certificates of Irradiation are available online at www.kimtech.com/certificates
- Manufactured in ISO 9001:2000 registered facilities

KIMTECH PURE M3 Sterile Pouch Face Masks feature a large breathing chamber that provides superior breathability, comfort and airflow over pleated masks. The mask filtration is spread out over a larger area, therefore reducing the chance for particle buildup.*

PHYSICAL PROPERTIES (Target values)

Particle Filtration Efficiency @ 0.1 microns,	97.2%
Bacterial Filtration Efficiency @ 3.0 micron	96.0%
Differential Pressure, mm H_2O/cm^2	1.88

KIMTECH PURE* M3 Pouch Face Mask

Product Code	Colour	Units/Bag	Bags/Case	Total/Case
62483	White	20	10	200

Each batch of product is sterilized following ANSI/AAMI/ISO 11137, "Sterilization of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilization" and AAMI TIR33, "Sterilization of Health Care Products – Radiation – Substantiation of a Selected Sterilization Dose – Method VDmax".
These products are gamma sterilized to Sterility Assurance Level of 10^{-6}.

KIMTECH* masks are designed, tested and recommended to be used for the protection of the components of the process and materials used. They are not intended to provide respiratory protection to the wearer, therefore they can't be considered personal protective equipment and can't carry a CE mark as such.

Data presented on this customer data sheet was generated from samples which were taken to be typical of standard product. The data and other information contained herein are the property of Kimberly-Clark.

Kimberly-Clark professional products are only manufactured to authorised specifications. It is our policy to design, manufacture and deliver products which meet our specifications for quality, performance and safety. The products listed above are manufactured and audited according to ISO EN 9001 Quality Management System guidelines. In common with the ISO 9001 philosophy, we also conduct internal quality and good manufacturing practices audits at all manufacturing facilities to ensure the systems work as designed and products provided are safe to use. Internal quality system assessments are carried out by independent quality personnel based in Europe and the U.S.A. Additional information can be provided upon request.

Reduce Today, Respect Tomorrow* is the KIMBERLY-CLARK PROFESSIONAL* approach to sustainability. It begins with the understanding that the way we use resources today shapes the world of tomorrow. And it has led us to focus on reducing consumption at every stage of the product lifecycle – from design and manufacture to distribution and disposal. Reduction is the key to lowering the environmental impact of our activities as well as those of customers. To learn more, visit **www.kcpreducetoday.com/uk**

Reduce Today Respect Tomorrow*

INFORMATION SERVICE
For technical enquiries please email infofax@kcc.com
For sales enquiries please email kimtech.support@kcc.com

www.contaminomics.com

Contaminomics

Kimberly-Clark PROFESSIONAL*

KIMTECH PURE* M3 Sterile Pouch Face Mask Donning Procedure

The Science of Comfortable Protection.

Pre Hood Donning Procedure

Step 1

Carefully open the protective packaging.

Step 2

While holding the mask through the protective packaging, reach in and separate the head band straps.

Step 3

Pull bands over the head and secure while holding the gap guard to keep mask in place.

Step 4

Pinch nose wire into place.

Step 5

Inhale and exhale to check for secure fit.

Step 6

Put hood on over the mask

KIMTECH PURE* BRAND

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KIMTECH PURE* M3 Sterile Pouch Face Mask Donning Procedure

The Science of Comfortable Protection.

Post Hood Donning Procedure

Step 1

Carefully open the protective packaging.

Step 2

While holding the mask through the protective packaging, reach in and separate the head band straps.

Step 3

Pull bands over the head and secure while holding the protective packaging to avoid contaminating the mask.

Step 4

Reach under the hood and pull the gap guard to the inside of the hood.

Step 5

Pinch nose wire into place.

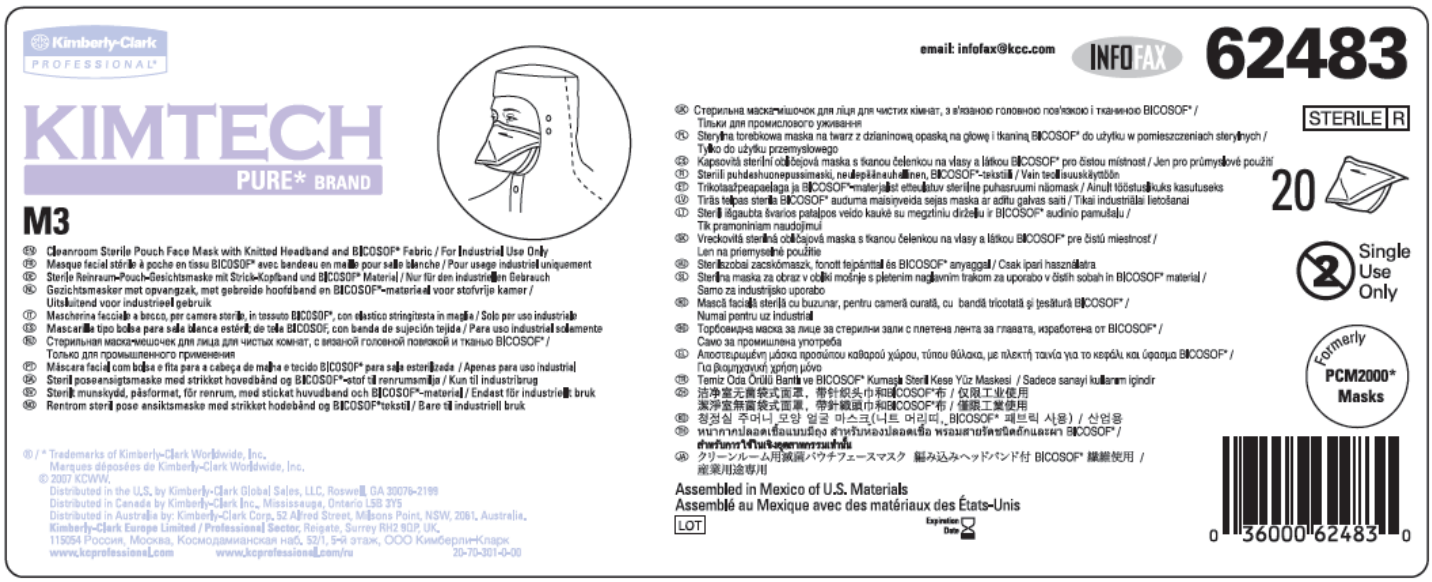
Step 6

Inhale and exhale to check for secure fit.

KIMTECH PURE* BRAND

Case label

Bag label



1. Executive Summary

SteriPro Labs commenced validation testing on the Kimtech Pure* M3 Sterile Facemask, part number 62483 on May 18, 2010 per SteriPro protocol number 797100373-P Rev. 0. The study was conducted to substantiate a 25-kGy dose and validates the effectiveness of Gamma Radiation for sterilization of the Kimtech Pure* M3 Sterile Facemask. The validation was based on the practices recommended by ANSI/AAMI/ISO 11137-2: *Sterilization of Health Care Products – Radiation – Establishing the sterilization dose – Method VD-Max25*. A protocol for substantiation of 25-kGy was utilized to verify that a minimum sterilization dose of 25-kGy will provide a Sterility Assurance Level (SAL) of 10^{-6} or no more than one nonsterile unit for each one million units sterilized. The pre-sterilization bioburden level was determined for three independent lots in this study (see respective test reports included in the validation binder). A bioburden recovery factor was determined for the product; the factor was used to adjust each bioburden result. The verification dose was determined utilizing Table 9 in the ANSI/AAMI/ISO 11137-2. This study supports the release of products for which exposure to the minimum dose of 25-kGy is demonstrated by the use of calibrated dosimeters. In accordance with ANSI/AAMI/ISO 11137-2: Method VD-Max25, statistical verification was successfully completed since not more than one positive sterility test culture was observed after irradiation at the calculated verification dose. The average bioburden was less than 1,000 organisms, statistical verification of the bioburden resistance was accepted, and therefore the sterilization dose of 25 kGy is the 10^{-6} SAL dose for the Kimtech Pure* M3 Sterile Facemask.

2. Method

Finished routine production units of the Kimtech Pure* M3 Sterile Facemask in standard final packaging were sampled before sterilization. The Sample Item Proportion (SIP) used for all testing was one (1.0). An inoculated bioburden recovery validation was performed, and was utilized for this study. Bioburden testing was performed on the three independent lots for determination of the verification dose. An additional thirteen nonsterile, final packaged samples were exposed to the verification dose. These samples were subjected to Sterility and Bacteriostasis/ Fungistasis tests. All testing methods and procedures were in accordance with AAMI Standards. The method utilized for this study was ANSI/AAMI/ISO 11137-2: *Sterilization of Health Care Products – Radiation – Establishing the sterilization dose – Method VD-Max25.* The verification dose for this product was calculated as described in the Results Section of this report.

3. Results

3.1 Efficiency of Recovery Factor (Bioburden Recovery Validation)

The bioburden recovery validation was performed on five devices using the inoculated recovery method (See Test Report Number 440018-MIC-004-I). The efficiency of recovery factor (ERF) of 0.63 was determined and utilized for the bioburden results, and the determination of the verification dose.

3.2 Bioburden Testing

The methodology used to obtain the bioburden count for calculating the verification dose for each lot was the same. The procedure is noted on each bioburden test report provided by the testing lab. Table 1 summarizes the results of the three lots and is reported as colony forming units (cfu) per device:

Table 1 – Bioburden Results		
Test Report Number	**Lot Number**	**Total Theoretical Bioburden**
440013-MIC-004-I	C01423	28.6 cfu/device
440016-MIC-004-I	C01433	22.2 cfu/device
440017-MIC-004-I	C01451	45.2 cfu/device
Overall Average		32.0 cfu/device

The total bioburden for each lot was determined by summing the aerobic and yeast/mold averages, which have the ERF, applied to them. Any numbers that were less than an amount were treated as whole numbers for all calculations.

3.3 Verification Dose

The appropriate verification dose for this validation was determined using the bioburden information provided on the bioburden test reports for each lot. A dose calculation report for the product is provided in the data section of this report. The overall average of 32.0 cfu per device was utilized since no single lot average was more than twice the overall average. Using 32.0 cfu per device, the verification dose was determined from Table 9 in the ANSI/AAMI/ISO 11137-2 guidelines. The verification dose for this validation and future dose audits is 8.4 kGy.

3.4 Dosimetry Readings

The delivered dose for the verification samples is shown in the Certificate of Processing (See Work Order Number 451327) provided in this report. The verification dose delivered for the samples had a minimum dose of 8.0 kGy and a maximum dose of 8.8 kGy, which did not vary from the calculated verification dose by more than $\pm$ 10 percent, the acceptable range.

3.5 Bacteriostasis/ Fungistasis

Bacteriostatic or fungistatic characteristics were not shown to be associated with the sterility cultures of the test article when challenged with *Bacillus subtilis*, ATCC 6633, *Candida albicans*, ATCC 10231, and *Aspergillus niger*, ATCC 16404 (See Test Report Number 455748-MIC-027-I).

3.6 Test of Sterility

After the verification dose was applied to the verification samples, they were placed on test of sterility. The results of the sterility test are summarized in Table 2:

Table 2 – Test of Sterility of Verification Samples

Test Report Number	Product Name	Number Tested	Number Positive
455747-MIC-036-I	Kimtech Pure* M3 Sterile Facemask	10	0

There were no positive samples on the test of sterility. This was within the acceptance criteria of no more than one positive sample per ten verification dose samples.

**Note* Results and conclusions apply only to the test article tested. SteriPro Consulting makes no further evaluation of these results. Any extrapolation of these data to other samples is the responsibility of the sponsor.*

4. Analysis

In accordance with ANSI/AAMI/ISO 11137-2: Method VD-Max25, statistical verification was successfully completed since not more than one positive sterility test culture was observed after irradiation at the determined verification dose for the lot tested. The average bioburden was less than 1,000 organisms and statistical verification of the bioburden resistance was accepted and therefore the sterilization dose of 25 kGy will be accepted as the 10^{-6} SAL dose for the Kimtech Pure* M3 Sterile Facemask.

Routine sterilization of subsequent manufacturing lots will require demonstration, through dosimetry, that this 10^{-6} sterility assurance dose has been achieved at the point of minimum absorbed dose in each irradiation carrier load.

In addition, dose mapping of routine production loads, to determine reproducible points of minimum absorbance, and calibration of physico-chemical dosimeters, to be located at those points, will be required to demonstrate the degree of process control required for dosimetric release of sterilized products. These procedures will be the responsibility of the sponsor and Sterigenics.

To substantiate the continued validity of 25-kGy dose as a 10^{-6} SAL dose, verification dose audits must be performed according to an established schedule, as specified in ANSI/AAMI/ISO 11137-1.

5. Record Storage

All raw data pertaining to this study are retained in the designated SteriPro Labs archive.

6. References

6.1 ANSI/AAMI/ISO 11137-1-2006, Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

6.2 ANSI/AAMI/ISO 11137-2-2006, Sterilization of health care products – Radiation – Part 2: Establishing the Radiation Dose

6.3 ANSI/AAMI/ISO 11737-1-2006, Sterilization of medical devices – Microbiological methods – Part 1: Estimation of population of microorganisms on products

6.4 ANSI/AAMI/ISO 11737-2-2009, Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

6.5 USP/NF, U.S. Pharmacopoeia (current version)

Certificate of Processing

STERIGENICS 3125 Wichita Ct. Fort Worth TX 76140
TEL 817 293-0999 FAX 817 293-2933 www.sterigenics.com

R55480102
RIS0001

08/31/10 14:32:48 GMT

Customer Name: Kimberly-Clark - Accounts Payable
P.O.# 12485731

Processing Facility: Fort Worth

Work Order # 493856
Sales Order # 435107

25-45 kGy KCC25, GAMMA TREATMENT

Irradiation Date/Time: 08/30/10 17:10:00 GMT
Irradiation Cell: CELL C

SO Line #	Qty	UOM	Customer Item Number / Customer Item Description	Customer Lot Number / Customer Load Number
101.00	80	CA	62483-02 M3 STERILE MASK CODE 62483	AC021101A NA
102.00	40	CA	62483-02 M3 STERILE MASK CODE 62483	AC020808A NA
103.00	40	CA	62483-02 M3 STERILE MASK CODE 62483	AC021502A NA
104.00	80	CA	62483-02 M3 STERILE MASK CODE 62483	AC022302A NA
105.00	40	CA	62483-02 M3 STERILE MASK CODE 62483	AC021102A NA
106.00	40	CA	62483-02 M3 STERILE MASK CODE 62483	AC021103A NA
107.00	59	CA	62483-02 M3 STERILE MASK CODE 62483	AC019601A NA
108.00	80	CA	62483-02 M3 STERILE MASK CODE 62483	AC019403A NA
109.00	80	CA	62483-02 M3 STERILE MASK CODE 62483	AC019303A NA
110.00	27	CA	62483-02 M3 STERILE MASK CODE 62483	AC014701A NA
111.00	26	CA	62483-02 M3 STERILE MASK CODE 62483	AC018101A NA
112.00	27	CA	62483-02 M3 STERILE MASK CODE 62483	AC018203A NA
113.00	48	CA	62483-02 M3 STERILE MASK CODE 62483	AC022401A NA
114.00	35	CA	62483-02 M3 STERILE MASK CODE 62483	AC021701A NA
	702	CA	Total	

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	-------Signed By------- User	Date / Time
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.4 kGy	Pass	JWORDEN JACK WORDEN	08/31/10 13:36:43 GMT
				Reason Code Test			
450.00	Maximum Dose	25.0 kGy	45.0 kGy	35.2 kGy	Pass	JWORDEN JACK WORDEN	08/31/10 13:36:43 GMT
				Reason Code Test			

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: Terry O'Connor
Work Order Completions

Date: 08/31/10 14:32:25 GMT