Kimberly-Clark PROFESSIONAL*

# KIMTECH PURE* M3 Sterile Pouch Face Mask

## The Science of Comfortable Protection

DATA PACK

KIMTECH PURE* BRAND


Printed in the USA. K02031 K4489-10-01 7/10

Kimberly-Clark PROFESSIONAL*

# The Science of Contamination Control

## KIMTECH PURE* M3 Sterile Pouch Face Mask

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, the KIMTECH PURE* M3 Sterile Pouch Face Mask is backed up with technical resources, field support and customer satisfaction guaranteed.

The pouch style design delivers the following product benefits:

- **Pouch design for easier breathing**
- **Consistent seal to reduce fogging**
- **Secure fit to reduce the risk of escaping particles**

A protective, comfortable face mask means better performance. And better performance means better protection.

You can count on 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.

**Target Segment:**

**Pharmaceutical**
- **Injectables**
- **Inhalants**
- **Solid Dose**
- **Human Health**
- **Animal Health**
- **Tissue Processing**
- **Compounding (USP 797)**

KIMTECH PURE* BRAND

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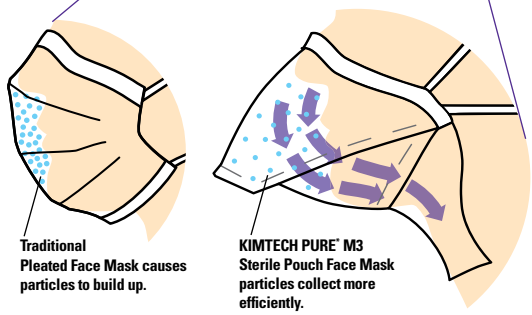
## Turn to the KIMTECH PURE* M3 Sterile Pouch Face Mask for these quality features:

- Recommended for ISO Class 3 or higher cleanroom environments
- No latex material is used in the production
- Triple-bagged for extra protection
- Tight seal around the bridge of the nose to minimize fog potential
- Mask design and headband hold mask in place during use


*The KIMTECH PURE* M3 Sterile Pouch Face Mask features 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.*

### 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.

### Physical Properties

| | |
|---|---|
| Particle Filtration Efficiency @ 0.1 micron, % | 97.2 |
| Bacteria Filtration Efficiency @ 3.0 micron, % | 96.0 |
| Differential Pressure, mm $H_2O/cm^2$ | 1.83 |

**KIMTECH PURE* M3 Pouch Face Mask**

| Code | Description | Color | Style | Units/Bag | Bags/Case | Total/Case |
|---|---|---|---|---|---|---|
| 62483 | **KIMTECH PURE* M3 Sterile Face Mask** | White | Individually packaged, pouch-style mask with apertured polyethylene film and two knitted headbands | 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 $10^{-6}$.

## For more information on KIMTECH* Brand Products, visit our website at www.kimtech.com

**Our Guarantee**

Your total satisfaction means everything to us. If, for any reason, our products do not meet your expectations, Kimberly-Clark will reimburse you‡ for your initial purchase, via FREE product, for up to $1,000. For more information on KIMBERLY-CLARK PROFESSIONAL*, visit us online at **www.kcprofessional.com**, contact your Kimberly-Clark Sales Representative, or call us at 1-888-346-GOKC (4652).

‡ Guarantee extended to consuming end-user accounts only.

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/us**

Reduce Today Respect Tomorrow*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Effective July 2010

## 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<br>M3 STERILE MASK CODE 62483 | AC021101A<br>NA |
| 102.00 | 40 | CA | 62483-02<br>M3 STERILE MASK CODE 62483 | AC020808A<br>NA |
| 103.00 | 40 | CA | 62483-02<br>M3 STERILE MASK CODE 62483 | AC021502A<br>NA |
| 104.00 | 80 | CA | 62483-02<br>M3 STERILE MASK CODE 62483 | AC022302A<br>NA |
| 105.00 | 40 | CA | 62483-02<br>M3 STERILE MASK CODE 62483 | AC021102A<br>NA |
| 106.00 | 40 | CA | 62483-02<br>M3 STERILE MASK CODE 62483 | AC021103A<br>NA |
| 107.00 | 59 | CA | 62483-02<br>M3 STERILE MASK CODE 62483 | AC019601A<br>NA |
| 108.00 | 80 | CA | 62483-02<br>M3 STERILE MASK CODE 62483 | AC019403A<br>NA |
| 109.00 | 80 | CA | 62483-02<br>M3 STERILE MASK CODE 62483 | AC019303A<br>NA |
| 110.00 | 27 | CA | 62483-02<br>M3 STERILE MASK CODE 62483 | AC014701A<br>NA |
| 111.00 | 26 | CA | 62483-02<br>M3 STERILE MASK CODE 62483 | AC018101A<br>NA |
| 112.00 | 27 | CA | 62483-02<br>M3 STERILE MASK CODE 62483 | AC018203A<br>NA |
| 113.00 | 48 | CA | 62483-02<br>M3 STERILE MASK CODE 62483 | AC022401A<br>NA |
| 114.00 | 35 | CA | 62483-02<br>M3 STERILE MASK CODE 62483 | AC021701A<br>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<br>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<br>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