Kimberly-Clark PROFESSIONAL*

KIMTECH™

DATA PACK

Kimtech™ M3 Certified Sterile Face Mask – Pouch Style

62483

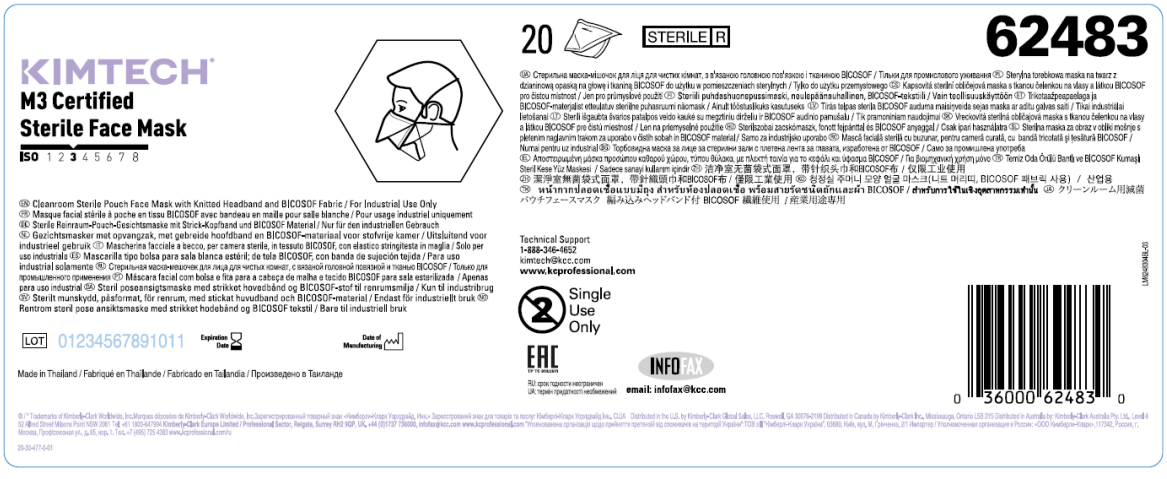
Publication code:
5290.01 EN 09.1

Table of Content

Label Design

Case Label:

Bag Label:



KIMTECH™

Face Mask Donning Procedure

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 gaps 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™

Face Mask Donning Procedure

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™

1400 Holcomb Bridge Road
Roswell, GA 30076

November 25, 2019

Re: **Certificate of Conformance**
KIMTECH* M3 Certified Sterile Face Mask
Product Code: 6248304
Lot Number: TH92768830
Date of Manufacture: October 2019
Expiration: 3 years from date of manufacture (see case label for date)
Location of Manufacture: Samut Prakan, Thailand

Dear Valued Customer:

This is to certify that the above referenced product conforms to Kimberly-Clark Corporation's internal specifications and advertised claims for this product. We use a system of in process product testing and audit inspections to assure that only product which meets specifications is released for shipment to customers.

We would also like to inform you that the above referenced product is manufactured in facilities that meet the quality system requirements of ISO 9001:2015.

Each batch of product is sterilized following the universally recognized standard: ANSI/AAMI/ISO 11137, "American National Standard, Sterilization of Healthcare Products—Requirements for Validation and Routine Control—Radiation Sterilization." This International Standard specifies requirements for validation, process control and routine monitoring in the irradiation sterilization of health care products. These products are sterilized to substantiate a Sterility Assurance Level of 10^{-6}.

Thank you for your interest in our product. Should you require additional information, please contact our Customer Service Team at 800-255-6401.

Sincerely,

Emily Adams
Technical Support Specialist, Quality & Regulatory Team
Kimberly-Clark Professional

STERIS

http://www.steris-ast.com

Certificate of Irradiation

This is to certify that, under the irradiation batch number

T2019 2298

for the account of ***THP 311***

Synergy Health (Thailand) Ltd. treated by gamma radiation from cobalt-60 products that the customer said to be:-

Product name ***KIMTECH M3 Certified Sterile Face Mask***

Total quantity ***80 cartons***

Purchase order no. ***PS620650***

Product description

Product	*Lot no.*	*Quantity (cartons)*
6248304	*TH92768830*	*80*

The process was applied according to specification: ***T-B311192514***

The first tote was irradiated on: ***12 October 2019***

The applied doses were checked with calibrated dosimeters traceable to a national laboratory of metrology.

The dose specification is ***25.0*** kilograys minimum and ***45.0*** kilograys maximum

The calculated dose received is ***32.0*** kilograys minimum and ***39.0*** kilograys maximum

Approved by/date: Paradee T. 15 Oct. 19

Paradee Thammajanya, QA Manager

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Microbiological Validation according to EN ISO 11137-2:2015, Method VD_{MAX}^{25} (Substantiation of 25kGy As a Sterilization Dose) Initial Validation

62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC

Product Lot No.: TH73410000 (MFG 7341, MFG 7342 MFG 7343)

Lab Report No. : 18020036

Applicant : [redacted]
45/2, 45/3 Moo 2 Sukhaprachasan 2 Road,
Bangpud, Pakkred
Nonthaburi 11120
Thailand.

Performed by: Synergy Sterilisation (M) Sdn Bhd
Laboratory
Plot 203, Kuala Ketil Industrial Estate
09300 Kuala Ketil, Kedah.
Malaysia.

Synergy Sterilisation (M) Sdn Bhd
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APPROVAL PAGE

SYNERGY STERILISATION (M) SDN BHD

Responsible for the work performed at the microbiology laboratory of Synergy Sterilisation (M) Sdn Bhd being executed according to internal procedures, and for the writing of this report.

Report made by:	Signature:	Date:
Mali a/p Sieng Lab Technician		01/02/2018

Approved by:

Noorani Binti Abd Samad Microbiologist	*NOORANI ABD SAMAD* Microbiologist Synergy Sterilisation (M) Sdn. Bhd.	05/02/2018

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Synergy Sterilisation (M) Sdn Bhd
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1.0 SUMMARY

This study was undertaken in accordance with Method VD max ^{25} of "Sterilization of healthcare products – Radiation Part 2 – Establishing the sterilization dose EN ISO 11137-2:2015.
The study was to substantiate a Sterilization dose of 25kGy.

3 batches of 62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC were assayed for bioburden levels. The overall average for the batch tested was 16.0 CFU /unit sample. No single batch was shown to be more than twice this overall average and therefore this overall average was used to determine the sub process verification dose.

With reference to table 9 of the EN ISO 11137 – 2:2015 documents, the nearest value listed equal to or greater than the bio burden level is 16.0 CFU. Therefore the sub- process dose required for the sterility assurance level of 10^{-1} is 7.6 kGy +/- 10% (6.9 kGy – 8.3 kGy).

Therefore 10 units were irradiated at this dose and subsequently individually tested for sterility. After the full incubation period all tests gave a negative result, therefore statistical verification for the sub process dose is accepted.

In conclusion, a dose of 25kGy will provide a sterility assurance level of 10^{-6}.

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2 MATERIALS & METHODS

2.1 Product

62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BOCOSOF FABRIC

Bioburden validation:

- TH73410000 (MFG 7341)

Bioburden Estimation:

- TH73410000 (MFG 7341)
- TH73410000 (MFG 7342)
- TH73410000 (MFG 7343)

Verification dose experiment and subsequent sterility test:

- TH73410000 (MFG 7341)

Bacteriostasis/Fungistasis test.

- TH73410000 (MFG 7341)

Sample Item Portion (SIP): 1.0

2.2 Micro-organisms

• *Staphylococcus aureus*	ATCC 6538
• *Bacillus spizizenii*	ATCC 6633
• *Pseudomonas aeruginosa*	ATCC 9027
• *Candida albicans*	ATCC 10231
• *Aspergillus brasiliensis*	ATCC 16404
• *Bacillus atrophaeus*	NRRL#B4418

2.3 Media

• Tryptone Soya Agar	TSA
• Tryptone Soya Broth	TSB
• Phosphate Buffer	PB

Test	**Media Batch No.**
Bioburden Validation	7598 PB 11/01/2018 & 7623 TSA 21/01/2018
Bioburden Assessment	7598 PB 11/01/2018 & 7634 TSA 27/01/2018
Bacteriostasis & Fungstasis	7622 TSB 21/01/2018 & 7623 TSA 21/01/2018
Product Sterility	7660 TSB 09/02/2018 & 7664 TSA 10/02/2018

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2.4 Test Method

2.4.1 Bioburden Validation

The Bioburden validation was carried out using the inoculation method.

- 5 products were irradiated with a dose of 25 kGy minimum.
- Each of the 5 samples was inoculated with 1 ml of the 10^2 *Bacillus atrophaeus* NRRL#B4418 inoculum suspension with 100cfu/ml. For items with a low Bioburden, a micro-organism concentration of less than 100 cfu on the product should be appropriate.
- The inoculated product was allowed to dry overnight (under Biosafety Cabinet, class 5).
- The inoculated product was added with 300 ml PB aseptically (under Biosafety Cabinet, class 5).
- The product and PB were stomached for 5 minutes.
- The whole of the solution was filtered through a 0.45 micron cellulose nitrate membrane filter.
- The membrane filter was then placed onto a sterile Tryptone Soy Agar plates.
- 1 ml of the *Bacillus atrophaeus* inoculum suspension was put on sterile TSA plates directly (in duplicate).
- All plates were incubated for 5 days at 30-35°C.
- The number of colonies on the plates was counted.
- The number of micro-organisms removed from the inoculated products was expressed as a fraction of the number of micro-organisms inoculated on to the product.
- The mean recovery efficiency and correction factor were calculated.

2.4.2 Bioburden Estimation

The average Bioburden per product unit of the three batches was determined, according to the internal procedures.

- Each product was added with 300 ml PB aseptically (under Biosafety Cabinet, class 5).
- The sterile bag containing product and the PB were stomached for 5 minutes.
- The eluent was filtered through a 0.45 micron cellulose nitrate membrane filter in two equal parts:
    - 150ml of the eluent on TSA for aerobic micro-organisms
    - 150ml of the eluent on TSA for yeasts and moulds.
- This will result in a dilution factor of 2.
- Incubation conditions:
    - TSA: 5 days at 30-35°C (aerobic micro-organisms)
    - TSA: 5 days at 20-25°C (yeasts and moulds)

The result was calculated by multiplying the counted colonies on the plate with the dilution factor and the correction factor. When 0 colonies are counted on the plate, the result is reported as "< 1 x (dilution factor) / (correction factor)". The Total Bioburden is the sum of Aerobic micro-organisms and Yeast /Moulds.

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2.4.3 Application of the verification dose

The 10 product were irradiated at Synergy Sterilisation (M) Sdn Bhd with the determined verification dose. After receiving back the samples from production, sterility testing was executed on the samples.

2.4.4 Test of Sterility

The sterility test was performed according to the internal procedures.

- The sterility test was carried out in the cleanroom.
- The 10 samples were tested with the direct immersion method using a sterile bottle of 300 ml sterile TSB as the growth medium.
- Incubation conditions: 28°C – 32°C for 14 days.
- A negative control was tested under the same test conditions.
- During the preparation of the sterility test the environment of the cleanroom was monitored for the presence of micro-organisms.
- The number of positive results was observed by determining visual growth.

2.4.5 Bacteriostasis and Fungistasis test.

Before the test of sterility, 5 negative samples were each inoculated with 0.1 ml (not more than 100 cfu) of *Staphylococcus aureus*, *Bacillus spizizenii*, *Pseudomonas aeruginosa*, *Candida albicans* and *Aspergillus brasiliensis*. The samples were incubated at 28°C - 32°C. Samples inoculated were checked for visual growth after 5 days.

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3 RESULTS

3.1 Bioburden Validation

The product was inoculated after which the recovery of the micro-organism was determined. Recovery was found to be 50.94897%. This has resulted in a correction factor of 0.5064. This value will be used in all future Bioburden estimations.

Detailed results are listed in Appendix II (Certificate of Analysis bioburden validation).

3.2 Bioburden Estimation

The average overall Bioburden is: 16.0 cfu/unit.
The average Bioburden of the individual batches is:

- Lot no. TH73410000 (MFG 7341): 17.7 cfu/unit
- Lot no. TH73410000 (MFG 7342): 17.8 cfu/unit
- Lot no. TH73410000 (MFG 7343): 12.6 cfu/unit

These are the results of the number of micro-organisms removed from the product multiplied with the dilution factor (= 2) and divided with the correction factor (= 0.5064).

The detailed results of the Bioburden estimation are shown in Appendix III (Certificate of Analysis bioburden test).

3.3 Application of the verification dose

The overall average for the batch tested was 16.0 CFU /unit sample has been used for determining the verification dose.

Using the Verification Dose Table 9 in EN ISO 11137-2 , it was determined that with average Bioburden of 16.0 cfu/unit, the nearest value listed equal to or greater than the bioburden level is 16.0 cfu/unit. Therefore, a Verification Dose of 7.6 kGy should be used.

The application of the verification dose was performed at the Synergy Sterilisation (M) Sdn Bhd facility in Kuala Ketil. The actual dose delivered was min. 7.0 kGy and max. 7.2 kGy. This complies with the limit of 7.6 kGy +/- 10% as described in section 4.4. The Certificate of Gamma irradiation and Dose Verification Report is shown in Appendix V.

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3.4 Sterility test

The samples were tested on sterility after application of the verification dose. No positive results have been observed in the test of sterility (thus all samples were sterile). Furthermore, the monitoring of the clean room during the preparation of the sterility test and the positive and negative controls complied with the limits.

Detailed results of the sterility test are listed in Appendix VI (Certificate of Analysis sterility test).

3.5 Bacteriostasis and Fungistasis test

Before the test of sterility, 5 negative samples were inoculated each with a different micro-organism, as described in section 5.4.5. The product did not demonstrate any inhibitory effect on the micro-organisms examined, because growth was confirmed visually for all of the 5 micro-organisms. It can therefore be concluded that the product either does not have antimicrobial activity or that this is sufficiently neutralized in a media volume of 300 ml sterile TSB.

The result of the Bacteriostasis/Fungistasis test is also mentioned in Appendix V (Certificate of Analysis sterility test).

Positive controls are performed on all 5 organisms.

4 CONCLUSION

The microbiological validation has been successful and the Sterilization Dose of 25 kGy for S.A.L. 10^{-6} has been validated for the 62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC.

5 REFERENCES

EN ISO 11137-2:2015	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
ISO 11737-1:2006	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of micro-organisms on products
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

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APPENDIX I

SUMMARY OF TEST RESULTS.

[redacted]
45/2, 45/3 Moo 2 Sukhaprachasan 2 Road,
Bangpud, Pakkred
Nonthaburi 11120
Thailand.

Test	**Microbiological Validation according to EN ISO 11137-2: 2015**
Lab Report No.	**18020036 Method VDMAX^{25} (INITIAL)**
Date Received	18/12/2017
Product description	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC
Synergy Sample Log No.	6113
Lot number	• Lot no. TH73410000 (MFG 7341) • Lot no. TH73410000 (MFG 7342) • Lot no. TH73410000 (MFG 7343)

Test Description	*COA No.*	*Lot number*	*Test results*	
Bioburden validation	515	TH73410000 (MFG 7341)	Correction factor	0.5064
Bioburden assay (cfu/unit)	6879	TH73410000 (MFG 7341)	Average bioburden	17.7
	6880	TH73410000 (MFG 7342)	Average bioburden	17.8
	6881	TH73410000 (MFG 7343)	Average bioburden	12.6
			Average bioburden for Verification	16.0
			Dose Determination	7.6 kGy
Verification dose (kGy)	S12042531-1-1 (7.6)	TH73410000 (MFG 7341)	Applied dose Min.7.0; Max. 7.2	
Bacteriostasis & Fungistasis	527	TH73410000 (MFG 7341)	All positive (Pass)	
Sterility test	3715	TH73410000 (MFG 7341)	All negative (Pass)	

Conclusion

The microbiological validation has been successful and the Sterilization Dose of 25 kGy for S.A.L. 10^{-6} has been validated for the 62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC.

Remarks :
See Certificates of Analysis for detailed results.

Examined by Synergy Sterilization (M) Sdn. Bhd.
01/02/2018
Noorani Abd Samad
Microbiologist

Synergy Sterilisation (M) Sdn Bhd
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APPENDIX II

BIOBURDEN VALIDATION TEST RESULTS.

[redacted]
45/2, 45/3 Moo 2 Sukhaprachasan 2 Road,
Bangpud, Pakkred
Nonthaburi 11120
Thailand.

Test	**Inoculation method**		
COA No.	515	Date received	29/12/2017
Synergy Sample Log No.			
Sample description	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC		
Analysis according	IS0 11737-1		

Microbiology

Product No.	*Lot No.*	*Result*	*Unit*
Sample 1	TH73410000 (MFG 7341)	70	cfu/unit
Sample 2	TH73410000 (MFG 7341)	71	cfu/unit
Sample 3	TH73410000 (MFG 7341)	69	cfu/unit
Sample 4	TH73410000 (MFG 7341)	69	cfu/unit
Sample 5	TH73410000 (MFG 7341)	70	cfu/unit

Bacillus atrophaeus NRRL#B4418, sample 1	126	cfu/unit	added
Bacillus atrophaeus NRRL#B4418, sample 2	148	cfu/unit	added
	137	cfu/unit	added (mean value)

Average percent Recovery	50.9489	%
Recovery efficiency factor	1.9628	
Standard deviation for above percent recovery	±0.6107	%
Recovery factor :	1.9628 x 0.6107% =0.0120 + 1.9628 = 1.9748	
Recovery correction factor	**0.5064** (1/1.9748)	

**** Recovery Correction factor =1/[(recovery efficiency factor x standard deviation recovery) + recovery efficiency factor]***

Remarks :
See Certificates of Analysis for detailed results.

Examined by Synergy Sterilization (M) Sdn. Bhd.
01/02/2018
Noorani Abd Samad
Microbiologist

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APPENDIX III

BIOBURDEN ASSESSMENT TEST RESULTS.

[redacted]
45/2, 45/3 Moo 2 Sukhaprachasan 2 Road,
Bangpud, Pakkred
Nonthaburi 11120
Thailand.

Test	**Bioburden Test**		
COA No.	6879,6880,6881		
Synergy Sample Log No.	6113	Date Received	18/12/2017
Sample according	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	Dilution Factor	2X
Analysis according	ISO 11737-1	Correction Factor	0.5064

Microbiology

No.	Identification sample Product No.	Lot No.	Yeast & Moulds cfu/150ml	Aerobic bacteria cfu/150ml	Total bioburden cfu/unit	Mean value per batch cfu/unit
No.1	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7341)	1	<1	3.9	
No.2	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7341)	7	10	67.1	
No.3	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7341)	<1	1	3.9	
No.4	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7341)	<1	1	3.9	
No.5	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7341)	<1	<1	<1	
No.6	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7341)	1	1	7.9	
No.7	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7341)	3	<1	11.8	
No.8	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7341)	3	4	27.6	
No.9	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7341)	3	6	35.5	
No.10	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7342)	<1	4	15.8	17.7
No.11	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7342)	<1	1	3.9	
No. 12	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7342)	3	3	23.7	
No. 13	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7342)	5	2	27.6	
No. 14	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7342)	<1	<1	<1	

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No. 15	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7342)	1	1	7.9	
No. 16	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7342)	4	7	43.4	
No. 17	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7342)	7	1	31.6	
No. 18	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7342)	1	5	23.7	
No. 19	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7342)	<1	3	11.8	
No. 20	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7342)	<1	1	3.9	17.8
No. 21	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7343)	9	3	47.4	
No. 22	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7343)	<1	1	3.9	
No. 23	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7343)	<1	2	7.9	
No. 24	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7343)	<1	4	15.8	
No. 25	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7343)	<1	2	7.9	
No. 26	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7343)	<1	2	7.9	
No. 27	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7343)	<1	<1	<0.0	
No. 28	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7343)	3	3	23.7	
No. 29	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7343)	<1	<1	<1	
No. 30	62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC	TH73410000 (MFG 7343)	1	2	11.8	12.6

Total bioburden = Aerobe bacteria + Yeast & Moulds
Bioburden for verification 16.0

Remarks :
See Certificates of Analysis for detailed result

Examined by Synergy Sterilization (M) Sdn. Bhd.
01/02/2018
Noorani Abd Samad
Microbiologist

Synergy Sterilisation (M) Sdn Bhd
- Laboratory - Plot 203, Kuala Ketil Industrial Estate, 09300 Kuala Ketil, Kedah. - Tel. +60 (0)4 4152111 - Fax +60 (0)4 4152121
E-mail: malaysia_ast@steris.com Website: www.steris-ast.com ISO 9001/13485 certified

synergyhealth

APPENDIX IV

PRODUCT STERILITY AND BACTEROSTASIS & FUNGISTASIS TEST RESULTS.

[redacted]
45/2, 45/3 Moo 2 Sukhaprachasan 2 Road,
Bangpud, Pakkred
Nonthaburi 11120
Thailand.

Test	Sterility Test	Bacteriostasis & Fungistasis Test		
COA No.	3715	527	Date Received:	18/12/2017
Synergy Sample Log No.	6113			
Sample according	62483 KIMTECH PURE STERILE M3 POUCH MASKWITH KNITTED HEADBAND AND BICOSOF FABRIC		Lot No.:	TH73410000 (MFG 7341)
Analysis according	ISO 11737-1			

Microbiology		Result	Remarks
Number of samples tested		10	
Number of samples negative on sterility test		10	Days of testing : 14
Number of samples positive on sterility test		0	Days of testing : 14
Bacteriostasis/fungistasis test on negative sample (to determine inhibitory substances)		Complies	
Internal control sample (negative control)		Complies	
Environmental research (airborne and surface contamination)		Complies	
Sterility test carried out in:	Cleanroom		
Positive Control:	1) *Staphylococcus aureus*	Growth	
	2) *Bacillus spizizenii*	Growth	
	3) *Pseudomonas aeruginosa*	Growth	
	4) *Candida albicans*	Growth	
	5) *Aspergillus brasiliensis*	Growth	

Remarks :
See Certificates of Analysis for detailed results.

Examined by Synergy Sterilization (M) Sdn. Bhd.
01/02/2018
Noorani Abd Samad
Microbiologist

Synergy Sterilisation (M) Sdn Bhd
- Laboratory - Plot 203, Kuala Ketil Industrial Estate, 09300 Kuala Ketil, Kedah. - Tel. +60 (0)4 4152111 - Fax +60 (0)4 4152121
E-mail: malaysia_ast@steris.com Website: www.steris-ast.com ISO 9001/13485 certified

APPENDIX V

STERIS

http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 29-Jan-2018

MY03S12042531-1-1

This is to certify that Synergy Sterilisation (M) Sdn. Bhd., a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 9001 Quality Management System
EN ISO 13485 Quality System - Medical Devices

[redacted]
57/169, 57/6 MOO 1
BANGMUANGMAI, MUANG-SAMUTPRAKARN
10270
SAMUTPRAKARN
THAILAND

Order Information

Account Number:	101223
Synergy Health Sales Part Reference:	1057428
Customer Reference Number:	PODS600483
Product Description:	SAMPLE IRRADIATION 0.1 - 15 kGy
Quantity Received:	1
Customer Unit Lot/Batch Number:	SEE BELOW
Other Process Details:	DESCRIPTION: 62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC LOT NUMBER: TH73410000 PART NO: MFG7341 IRRADIATION DATE: 16/01/2018 DOSE REQUIRED: 7.6 kGy +/-10% (6.9 - 8.3 kGy) ACTUAL DOSE RECEIVED: MIN:7.0 kGy MAX:7.2 kGy

STERIS

http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 29-Jan-2018

MY03S12042531-1-1

This is to certify that Synergy Sterilisation (M) Sdn. Bhd., a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 9001 Quality Management System
EN ISO 13485 Quality System - Medical Devices

[redacted]
57/169, 57/6 MOO 1
BANGMUANGMAI, MUANG-SAMUTPRAKARN
10270
SAMUTPRAKARN
THAILAND

Irradiation Data

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

APPLICATION OF VERIFICATION DOSES

Reported by : 31/01/2018
Anis Fahimah
QA Officer

Approved by : 31/01/2018
Noraiza Zakaria
QA Manager

Report Number	:	18-044-VD
Sample Batch Number	:	S12042531-1-1
Customer Name	:	[redacted]
A/C Number	:	101223
Sample Description	:	62483 Kimtech Pure Sterile M3 Pouch Mask with Knitted Headband and Bicosof fabric Lot No: TH 73410000 Part No: MFG7341

Microbiological dose setting methods described in EN ISO11137-2 : 2015 require the irradiation of samples at a given dose within a range of +/- 10 %.

This exercise is to confirm that the doses applied to all samples throughout the package are within the specified range of 7.6 kGy +/- 10% (6.9 kGy – 8.3 kGy).

Dose values are obtained by reading calibrated ***Amber Perspex*** dosimeters placed among the samples as described in Attachment 1. Dosimeters are distributed throughout the package to ensure that the positions of maximum and minimum doses are identified and that the absorbed doses in these positions can be recorded.

Samples are processed with key parameters of both the product and the total exposure time being recorded. After irradiation, dosimeters are recovered and the absorbed doses from each position from the samples are calculated and recorded. Detail results are recorded in Attachment 2.

SUMMARY

The one carton sample were irradiated within the required dose range of 6.9 kGy – 8.3 kGy and actual dose received were 7.0 kGy to 7.2 kGy.

LOAD DESCRIPTION

Type of carton	:	Corrugated inner box
Carton dimension (mm) L X W X H	:	220 X 85 X 125
Weight of 1 carton (kg)	:	245.8 g
Density	:	0.11

PROCESSING INFORMATION

Average dose rate	:	1.98 kGy / h
Verification dose requested	:	6.9 kGy – 8.3 kGy
Minimum dose less 10% tolerance (rounded off to the upper 0.1 kGy)	:	6.9 kGy
Minimum exposure time (hh:mm)	:	3 Hours 29 Minutes
Maximum dose plus 10% tolerance (rounded off to the lower 0.1 kGy)	:	8.3 kGy
Maximum exposure time	:	4 Hours 11 Minutes
Exposure started on / at	:	16 / 01 / 2018 at 20:17
Exposure was interrupted for	:	0 Minutes
Exposure finished on / at	:	16 / 01 / 2018 at 23:52
Actual exposure time	:	3 Hours 35 Minutes

DOSIMETRY RESULTS SUMMARY

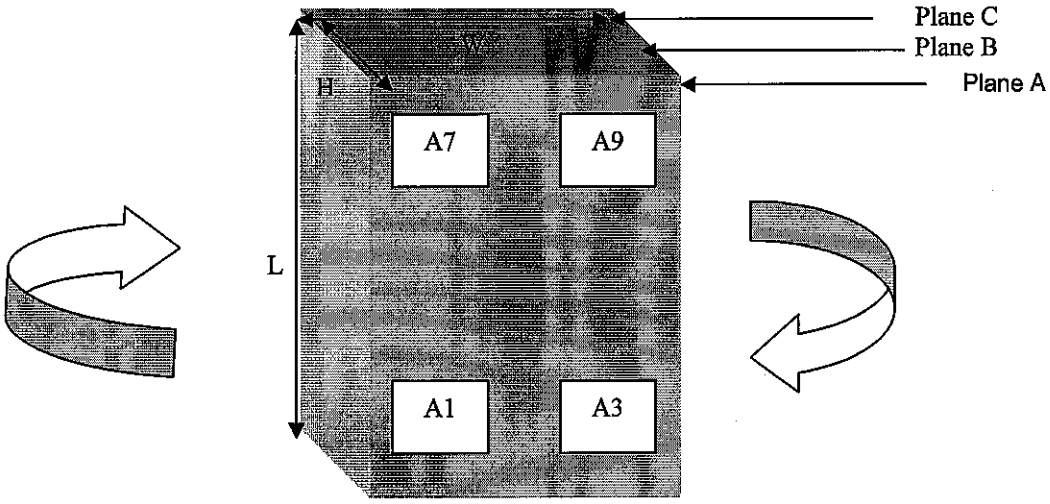
	Minimum dose	Maximum dose
Dose requested (kGy)	6.9	8.3
Actual dose received (kGy)	7.0	7.2

Reference : Attach detailed dosimetry report.

EXPOSURE TO RADIATION

For irradiation, a carton is placed on a hanging cage. The rotation of the carton aims at obtaining doses within the narrowest possible range. The exposure time is calculated from the times when the cage start touching at the end unit of the TEKSI.

CARTON LOADING DIAGRAM ON TEKSI



Represents dosimeter location at each plane

Performance Qualification

Job Reference	S12042531-1-1
Product ID	PO: DS600483
Customer	[redacted]

Position	Optical Density1	Optical Density2	Thickness	Dose	Notes
A1	485.2000	0.0000	2.9000	7.2000	
A3	538.9000	0.0000	3.2100	7.2000	
A7	508.6000	0.0000	3.0500	7.1000	
A9	540.4000	0.0000	3.2200	7.2000	
B1	455.2000	0.0000	2.7300	7.1000	
B3	525.0000	0.0000	3.1800	7.0000	
B7	510.1000	0.0000	3.0600	7.1000	
B9	524.8000	0.0000	3.1800	7.0000	

APPENDIX VI

SYNERGY STERILISATION (M) SDN BHD (512058-V)

(formerly known as Isotron (Malaysia) Sdn Bhd)

Customer: [redacted]
45/2,45/3 Moo 2 Sukhaprachasan 2 Road,
Bangpud,Pakkered,
Nonthaburi 11120
Thailand.

STANDARDS MALAYSIA ACCREDITED LABORATORY
MS ISO/IEC 17025
TESTING
SAMM NO : 309

bsi. UKAS MANAGEMENT SYSTEMS 003
ISO 13485:2003
CERT NO: MD 75461

bsi. ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY
ISO 9001:2008
CERT NO: FS60510

BIOBURDEN METHODOLOGY VALIDATION – INOCULATION METHOD
CERTIFICATE OF ANALYSIS

Certificate No.: 515

Purchase Order No.: DS600483

Synergy sample Log No.: 6113

Product Name: 62483 Kimtech Pure Sterile M3 Pouch Mask With Knitted Headband And Bicosof Fabric

Product Lot No.: TH73410000 (MFG 7341)

No. of Samples: 5 pcs

Date Samples Received: 18/12/2017

Date Tested: 29/12/2017

Date Incubation Completed: 03/01/2018

Results:

Item Description	Test Results	Reference Standard
	CFU /Unit	ISO 11737- 1
Sample 1	70	
Sample 2	71	
Sample 3	69	
Sample 4	69	
Sample 5	70	
Positive Control : (Count Verification)	137	

Comments: Recovery Correction Factor : 0.5064
Method:
All work was carried out under the protection of laminar air flow using aseptic technique. Each unit was treated individually .The sample was transferred into sterile bag. A suspension of *B.atrophaeus* was prepared in sterile water and dilution series performed.1 ml of the 10^2, suspension was aseptically transferred onto each sample. The inoculum was then allowed to air dry overnight and added 300 ml of sterile Maximum Recovery Diluent (MRD). The sample was stomached for 5 minutes. The eluent was filtered through a 0.45 micron cellulose nitrate membrane filter. The membrane filter was then placed onto a sterile Tryptone Soy Agar plates. The plates were incubated at 30°C - 35°C for 5 days before enumeration of the resulting Colony Forming Units (CFU).
Media Batch No: 7598 PB 11/01/2018 & 7623 TSA 21/01/2018.

Certified By: _____
NOORANI ABD SAMAD
Microbiologist
Synergy Sterilisation (M) Sdn. Bhd.

Date: 03/01/2018

SYNERGY STERILISATION (M) SDN BHD (512058-V)

(formerly known as Isotron (Malaysia) Sdn Bhd)

MS ISO/IEC 17025
TESTING
SAMM NO : 309

ISO 13485:2003
CERT NO: MD 75461

ISO 9001:2008
CERT NO: FS60510

Customer: [redacted]
45/2,45/3 Moo 2 Sukhaprachasan 2 Road,
Bangpud,Pakkered,
Nonthaburi 11120,
Thailand.

BIOBURDEN TEST
CERTIFICATE OF ANALYSIS

Certificate No.: 6879
Purchase Order No.: DS 600483
Synergy sample Log No.: 6113
Product Name: 62483 Kimtech Pure Sterile M3 Pouch Mask With Knitted Headband And Bicosof Fabric
Product Lot No.: TH 73410000 (MFG 7341)
Date Samples Received: 18/12/2017
No. of Samples: 10 pcs
Correction Factor: 0.5064
Date Tested: 05/01/2018
Date Incubation Completed: 10/01/2018

Results:

Item Description	Test Results	Reference Standard
	CFU/Unit	ISO 11737-1
Sample 1	3.9	
Sample 2	67.1	
Sample 3	3.9	
Sample 4	3.9	
Sample 5	<1	
Sample 6	7.9	
Sample 7	11.8	
Sample 8	27.6	
Sample 9	35.5	
Sample 10	15.8	
Average	17.7	

Comments: Media Batch No: 7598 PB 11/01/2018 & 7634 TSA 27/01/2018
NOTE: <1 = No colonies are present/below limit of detection.

Certified By: _____ **Date:** 11/01/2018
NOORANI ABD SAMAD
Microbiologist
Synergy Sterilisation (M) Sdn. Bhd.

SYNERGY STERILISATION (M) SDN BHD (512058-V)

(formerly known as Isotron (Malaysia) Sdn Bhd)

STANDARDS MALAYSIA ACCREDITED LABORATORY

MS ISO/IEC 17025
TESTING
SAMM NO : 309

Customer: [redacted]
45/2,45/3 Moo 2 Sukhaprachasan 2 Road,
Bangpud,Pakkered,
Nonthaburi 11120,
Thailand.

bsi. UKAS MANAGEMENT SYSTEMS 003

ISO 13485:2003
CERT NO: MD 75461

bsi. ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

ISO 9001:2008
CERT NO: FS60510

BIOBURDEN TEST
CERTIFICATE OF ANALYSIS

Certificate No.: 6880
Purchase Order No.: DS 600483
Synergy sample Log No.: 6113
Product Name: 62483 Kimtech Pure Sterile M3 Pouch Mask With Knitted Headband And Bicosof Fabric
Product Lot No.: TH 73410000 (MFG 7342)
Date Samples Received: 18/12/2017
No. of Samples: 10 pcs
Correction Factor: 0.5064
Date Tested: 05/01/2018
Date Incubation Completed: 10/01/2018

Results:

Item Description	Test Results	Reference Standard
	CFU/Unit	ISO 11737-1
Sample 1	3.9	
Sample 2	23.7	
Sample 3	27.6	
Sample 4	<1	
Sample 5	7.9	
Sample 6	43.4	
Sample 7	31.6	
Sample 8	23.7	
Sample 9	11.8	
Sample 10	3.9	
Average	17.8	

Comments: Media Batch No: 7598 PB 11/01/2018 & 7634 TSA 27/01/2018
NOTE: <1 = No colonies are present/below limit of detection.

Certified By: _____ **Date:** 11/01/2018
NOORANI ABD SAMAD
Microbiologist
Synergy Sterilisation (M) Sdn. Bhd.

SYNERGY STERILISATION (M) SDN BHD (512058-V)

(formerly known as Isotron (Malaysia) Sdn Bhd)

STANDARDS MALAYSIA ACCREDITED LABORATORY

MS ISO/IEC 17025
TESTING
SAMM NO : 309

bsi. UKAS MANAGEMENT SYSTEMS 003

ISO 13485:2003
CERT NO: MD 75461

bsi. ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

ISO 9001:2008
CERT NO: FS60510

Customer: [redacted]
45/2,45/3 Moo 2 Sukhaprachasan 2 Road,
Bangpud,Pakkered,
Nonthaburi 11120,
Thailand.

BIOBURDEN TEST
CERTIFICATE OF ANALYSIS

Certificate No.: 6881
Purchase Order No.: DS 600483
Synergy sample Log No.: 6113
Product Name: 62483 Kimtech Pure Sterile M3 Pouch Mask With Knitted Headband And Bicosof Fabric
Product Lot No.: TH 73410000 (MFG 7343)
Date Samples Received: 18/12/2017
No. of Samples: 10 pcs
Correction Factor: 0.5064
Date Tested: 05/01/2018
Date Incubation Completed: 10/01/2018

Results:

Item Description	Test Results	Reference Standard
	CFU/Unit	ISO 11737-1
Sample 1	47.4	
Sample 2	3.9	
Sample 3	7.9	
Sample 4	15.8	
Sample 5	7.9	
Sample 6	7.9	
Sample 7	<1	
Sample 8	23.7	
Sample 9	<1	
Sample 10	11.8	
Average	12.6	

Comments: Media Batch No: 7598 PB 11/01/2018 & 7634 TSA 27/01/2018
NOTE: <1 = No colonies are present/below limit of detection.

Certified By: _____ **Date:** 11/01/2018

NOORANI ABD SAMAD
Microbiologist
Synergy Sterilisation (M) Sdn. Bhd.

SYNERGY STERILISATION (M) SDN BHD (512058-V)

(formerly known as Isotron (Malaysia) Sdn Bhd)

Customer: [redacted]
45/2, 45/3 Moo 2 Sukhaprachasan 2 Road,
Bangpud,Pakkered,
Nonthaburi 11120,
Thailand.

MS ISO/IEC 17025
TESTING
SAMM NO : 309

ISO 13485:2003
CERT NO: MD 75461

ISO 9001:2008
CERT NO: FS60510

BACTERIOSTASIS & FUNGISTASIS TEST CERTIFICATE OF ANALYSIS

Certificate No.: 527
Purchase Order No.: DS600483
Synergy sample Log No.: 6113
Product Name: 62483 Kimtech Pure Sterile M3 Pouch Mask With Knitted Headband And Bicosof Fabric
Product Lot No.: TH73410000 (MFG 7341)
Date Samples Received: 18/12/2017
Date Tested: 29/12/2017
Date Incubation Completed: 03/01/2018

Results: Pass

Item Description	Test Results	Reference Standard
B.spizizenii in TSB (ATCC 6633)	Positive	ISO 11737-2
P.aeruginosa in TSB (ATCC 9027)	Positive	
C.albicans in TSB (ATCC 10231)	Positive	
A.brasiliensis in TSB (ATCC 16404)	Positive	
S.aureus in TSB(ATCC 6538)	Positive	
Negative control in TSB	Negative	
Positive control for 5 organisms	All Positive	

Comments: Volume of Media used :300 ml
Incubation Temperature : TSB at 28-32 deg C .
Media Batch No: 7622 TSB 21/01/2018 & 7623 TSA 21/01/2018.

Certified By: _____ **Date:** 03/01/2018
NOORANI ABD SAMAD
Microbiologist
Synergy Sterilisation (M) Sdn. Bhd.

SYNERGY STERILISATION (M) SDN BHD (512058-V)

(formerly known as Isotron (Malaysia) Sdn Bhd)

STANDARDS MALAYSIA ACCREDITED LABORATORY

MS ISO/IEC 17025
TESTING
SAMM NO : 309

Customer: [redacted]
45/2, 45/3 Moo 2 Sukhaprachasan 2 Road,
Bangpud, Pakkred
Nonthaburi 11120
Thailand.

bsi. UKAS MANAGEMENT SYSTEMS 003

ISO 13485:2003
CERT NO: MD 75461

bsi. ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

ISO 9001:2008
CERT NO: FS60510

PRODUCT STERILITY TEST CERTIFICATE OF ANALYSIS

Certificate No.: 3715
Purchase Order No.: DS600483
Synergy sample Log No.: 6113
Synergy Batch No.: S12042531-1-1
Date Processed: 16/01/2018
Product Name: 62483 KIMTECH PURE STERILE M3 POUCH MASK WITH KNITTED HEADBAND AND BICOSOF FABRIC
Product Lot No.: TH73410000 (MFG 7341)
No. of Samples: 10 pcs
Date Samples Received: 18/12/2017
Date Tested: 18/01/2018
Date Incubation Completed: 01/02/2018

Results: PASS

Item Description	Test Results	Reference Standard
Product Sterility Test in Tryptone Soya Broth	All Negative	ISO 11737-2

Incubation condition: 30 ± 2°C

Comments:
Volume of media used :300ml
(Direct Immersion Method)
Media Batch No: 7660 TSB 09/02/2018 & 7664 TSA 10/02/2018.

Certified By: _____
NOORANI ABD SAMAD
Microbiologist
Synergy Sterilisation (M) Sdn. Bhd.

Date: 05/02/2018

LABORATORY TESTING

DOSE MAPPING REPORT - TOTE

Report number : **T2018 0489**
After source load number T17

1. PREAMBLE

Customer	:	[redacted]
Procedure reference	:	QWI-55 Performance Qualification for Medical Device, Rev.7
Irradiation batch number	:	T2018 0489
Product	:	**Kimtech Pure M3 Sterile Mask (code no. 6248304)**
Date of irradiation	:	03 March 2018

2. OBJECTIVE

- The exercise is carried out for the Performance Qualification (PQ) with the Gamma Tote Irradiator located at Synergy Health (Thailand) Ltd.
- The purpose of this triplicate dose mapping is to study the dose distribution pattern within the load volume, 42 boxes/tote (6 layers of 7 boxes), 0.682 m3 (80.2% of tote filling), determine the appropriate processing time, determine the variability of the absorbed dose between representative totes, select the positions where routine dosimeter should be placed and establish the correlation factors for products at density 0.14 g/cm3.
- Routine Dosimeter Instruction Sheet (RDIS) will be prepared and furnished once the product is agreed for routine treatment.

Top view of 1st layer

3. ACCEPTANCE CRITERIA

Minimum dose	:	25.0 kGy
Maximum dose	:	45.0 kGy

4. LOAD CHARACTERISTICS

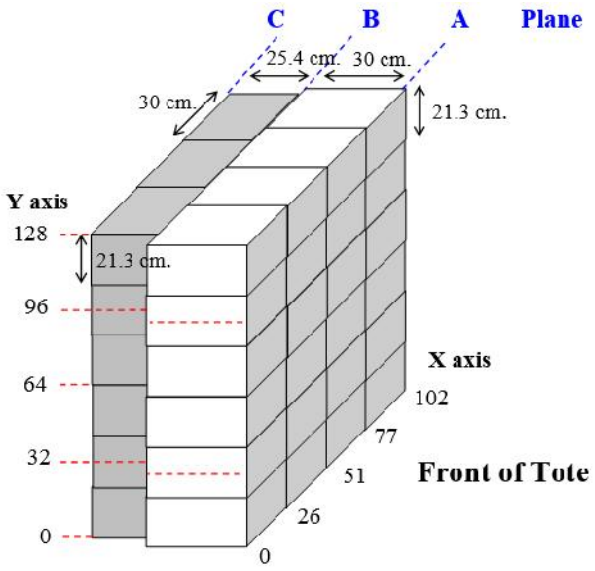
Tote container dimension	105 x 60 x (h) 135 cm, weigh 36.5 kg Maximum loaded 250 kg/tote
Dimension of box	(w) 25.4 x (l) 30.0 x (h) 21.3 cm, weight 2.3 kg
Product loaded dimension	102.2 x 55.7 x (h) 128 cm, weight 97.5 kg
Arrangement of box	6 layers of 7 boxes
Number of box	42 boxes/tote
Number of tote	3 totes
Number of dosimeter	225 dosimeters in total (75 dosimeter/tote)
Overall density of products stacked	0.13 g/cm3
Density of box	**0.14 g/cm3**
Specification number	T-T000000001
1st tote dose map	Carrier no. 8 Pincode no. 3182
2nd tote dose map	Carrier no. 205 Pincode no. 3734
3rd tote dose map	Carrier no. 288 Pincode no. 8773

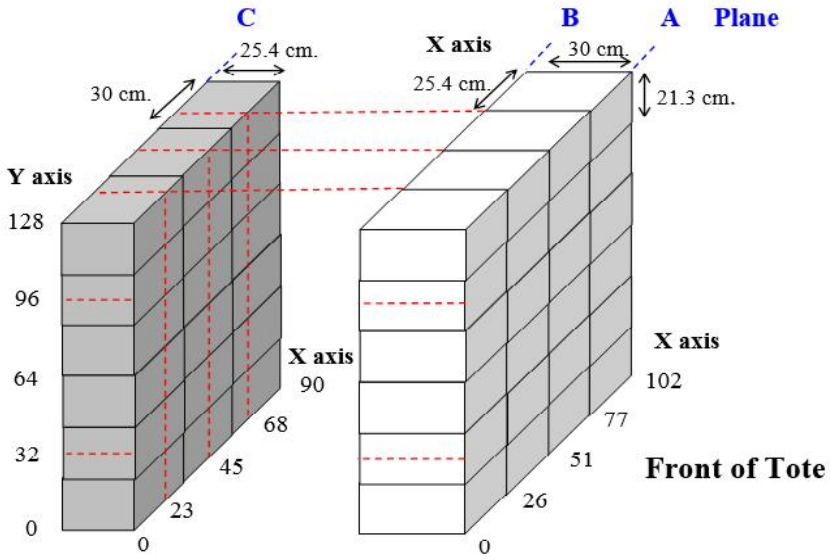
5. PROCESS PARAMETERS

	1st run	**2nd run**	**3rd run**
Date of Irradiation	03 March 2018		
Total Raised Source Panels Activity (Ci)	4,206,169		
Source Configuration	1+2 (6 PASSES)		
Value of X at Date of Irradiation (second)	22.86		
Exposure Time (minute)	257		
Exposure Parameters (X)	8.89 X		
Number of Laps	1 cycle (2 laps)		

6. SCHEMATIC VIEWS

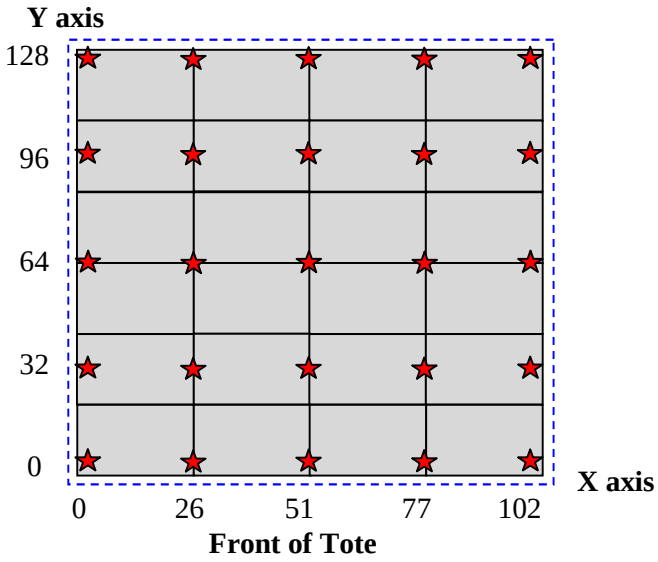
Dosimeter coding: ★ represents a dosimeter that will be taped onto a case at horizontal plane which is characterized and ordered by **Plane, X axis and Y axis.**
For example (A,0,0) (A,0,64) (B,51,128)



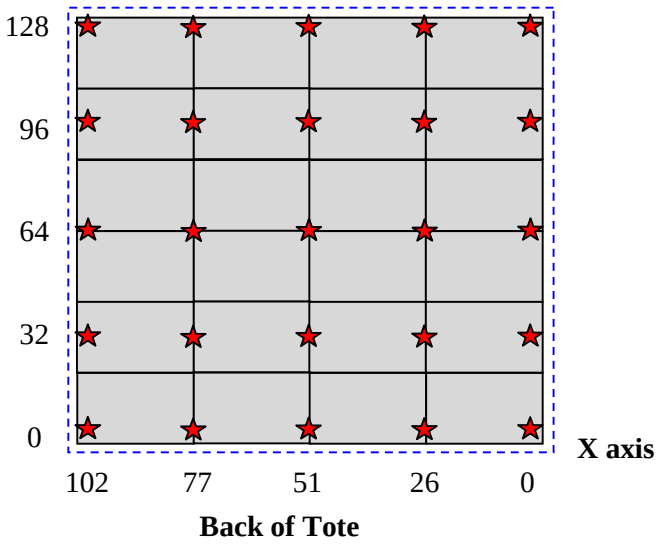


Note : At the location (A,51,0) a routine dosimeter location is so called 'FA0'.

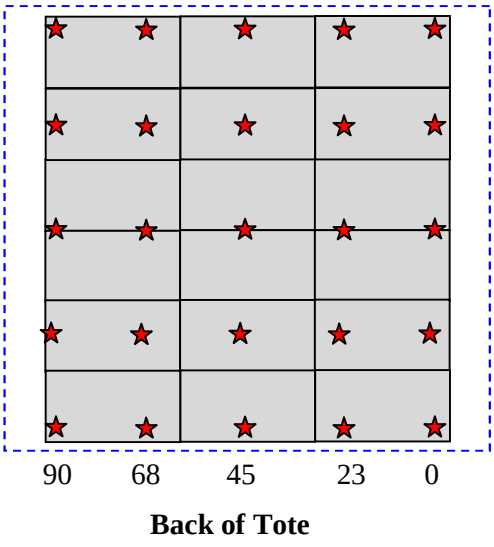
Front View of Plane A



Back View of Plane B



Back View of Plane C



Dosimeter codes and locations of Plane A which is characterized and ordered by Plane A, X axis and Y axis.

Front View of Plane A

	A,0,128	A,26,128	A,51,128	A,77,128	A,102,128
	A,0,96	A,26,96	A,51,96	A,77,96	A,102,96
Left	A,0,64	A,26,64	A,51,64	A,77,64	A,102,64 Right
	A,0,32	A,26,32	A,51,32	A,77,32	A,102,32
	A,0,0	A,26,0	A,51,0	A,77,0	A,102,0

Dosimeter codes and locations of Plane B which is characterized and ordered by Plane B, X axis and Y axis.

Back View of Plane B

	B,102,128	B,77,128	B,51,128	B,26,128	B,0,128
	B,102,96	B,77,96	B,51,96	B,26,96	B,0,96
Left	B,102,64	B,77,64	B,51,64	B,26,64	B,0,64 Right
	B,102,32	B,77,32	B,51,32	B,26,32	B,0,32
	B,102,0	B,77,0	B,51,0	B,26,0	B,0,0

Dosimeter codes and locations of Plane C which is characterized and ordered by Plane C, X axis and Y axis.

Back View of Plane C

Left

C,90,128	C,68,128	C,45,128	C,23,128	C,0,128
C,90,96	C,68,96	C,45,96	C,23,96	C,0,96
~~C,90,64~~	~~C,68,64~~	~~C,45,64~~	~~C,23,64~~	~~C,0,64~~
C,90,32	C,68,32	C,45,32	C,23,32	C,0,32
C,90,0	C,68,0	C,45,0	C,23,0	C,0,0

Right

7. DOSIMETER READINGS

	Location	Run 1	Run 2	Run 3	Mean	Stdev	CV	Sum of Squared Differences
	A,0,0	32.8	33.8	31.9	32.9	0.95	2.90	1.81
	A,26,0	35.0	36.0	35.4	35.5	0.52	1.47	0.55
Dref, Dmax	**A,51,0**	35.4	36.9	35.7	**36.0**	0.78	2.17	1.22
	A,77,0	35.3	36.3	35.6	35.7	0.49	1.38	0.49
	A,102,0	33.4	34.5	33.5	33.8	0.59	1.74	0.69
	A,0,32	31.4	32.7	31.9	32.0	0.67	2.09	0.90
	A,26,32	33.1	34.6	33.9	33.9	0.74	2.19	1.10
	A,51,32	33.8	35.1	34.1	34.3	0.66	1.92	0.87
	A,77,32	34.1	35.2	34.1	34.5	0.62	1.80	0.77
	A,102,32	31.9	32.9	32.8	32.5	0.52	1.61	0.55
	A,0,64	31.6	32.0	31.7	31.8	0.19	0.61	0.08
	A,26,64	33.5	34.0	33.6	33.7	0.25	0.76	0.13
	A,51,61	34.0	34.5	34.4	34.3	0.23	0.68	0.11
	A,77,64	33.6	34.4	36.2	34.7	1.33	3.84	3.56
	A,102,64	31.9	32.2	32.4	32.2	0.28	0.87	0.16
	A,0,96	32.8	32.9	33.0	32.9	0.11	0.34	0.02
	A,26,96	35.0	34.7	34.9	34.9	0.13	0.38	0.04
	A,51,96	35.2	35.1	35.4	35.2	0.12	0.35	0.03
	A,77,96	35.3	34.8	35.1	35.1	0.25	0.73	0.13
	A,102,96	33.2	33.0	33.7	33.3	0.37	1.12	0.28
	A,0,128	33.8	33.1	32.9	33.3	0.47	1.42	0.44
	A,26,128	35.2	35.5	35.5	35.4	0.18	0.50	0.06
	A,51,128	35.7	35.4	35.7	35.6	0.15	0.42	0.04
	A,77,128	35.2	35.0	35.6	35.3	0.34	0.96	0.23
	A,102,128	33.7	33.3	33.9	33.6	0.34	1.01	0.23
Dmin	**B,102,0**	30.3	30.8	30.2	**30.4**	0.32	1.06	0.21

Location	Run 1	Run 2	Run 3	Mean	Stdev	CV	Sum of Squared Differences
B,77,0	31.4	31.8	31.4	31.6	0.20	0.62	0.08
B,51,0	32.0	32.0	31.6	31.9	0.22	0.68	0.09
B,26,0	31.3	32.2	31.8	31.8	0.41	1.28	0.33
B,0,0	30.5	31.7	30.8	31.0	0.62	2.00	0.77
B,102,32	30.3	31.7	30.5	30.9	0.74	2.40	1.09
B,77,32	31.6	32.1	31.6	31.8	0.29	0.92	0.17
B,51,32	31.3	31.3	31.4	31.3	0.05	0.16	0.01
B,26,32	31.6	32.2	31.6	31.8	0.33	1.05	0.22
B,0,32	30.6	32.1	30.9	31.2	0.75	2.41	1.13
B,102,64	31.1	32.1	30.6	31.3	0.72	2.30	1.04
B,77,64	31.7	31.8	31.5	31.7	0.14	0.44	0.04
B,51,64	31.8	30.9	31.5	31.4	0.46	1.47	0.43
B,26,64	31.6	31.2	31.3	31.4	0.23	0.74	0.11
B,0,64	30.7	32.8	31.3	31.6	1.04	3.30	2.17
B,102,96	31.1	32.0	30.5	31.2	0.75	2.40	1.12
B,77,96	31.5	31.6	31.3	31.5	0.13	0.41	0.03
B,51,96	31.8	31.0	31.6	31.5	0.45	1.44	0.41
B,26,96	31.6	31.6	31.5	31.6	0.08	0.26	0.01
B,0,96	31.0	32.1	31.2	31.4	0.61	1.94	0.74
B,102,128	31.8	31.5	30.5	31.2	0.69	2.20	0.94
B,77,128	31.8	31.7	31.8	31.8	0.04	0.12	0.00
B,26,128	32.0	31.3	31.5	31.6	0.38	1.20	0.29
B,0,128	31.2	32.2	31.6	31.7	0.50	1.59	0.51
C,90,0	32.6	32.6	31.5	32.2	0.67	2.09	0.90
C,68,0	33.9	34.3	33.6	33.9	0.32	0.94	0.20
C,45,0	34.2	35.1	34.0	34.4	0.60	1.74	0.72
C,23,0	33.8	33.3	34.1	33.7	0.40	1.19	0.32
C,0,0	32.9	33.4	32.5	32.9	0.47	1.43	0.44
C,90,32	31.6	32.3	31.8	31.9	0.37	1.17	0.28
C,68,32	32.9	33.8	32.6	33.1	0.62	1.89	0.78
C,45,32	33.4	34.0	33.3	33.6	0.39	1.17	0.31
C,23,32	33.2	33.8	33.1	33.4	0.37	1.12	0.28
C,0,32	32.2	32.8	32.0	32.4	0.43	1.32	0.36
C,90,64	32.4	31.9	30.8	31.7	0.81	2.56	1.32
C,68,64	32.9	33.3	32.3	32.8	0.48	1.47	0.47
C,45,64	33.4	34.0	33.0	33.5	0.50	1.50	0.50
C,23,64	32.9	33.3	32.9	33.0	0.19	0.59	0.08
C,0,64	31.6	32.5	32.3	32.1	0.46	1.43	0.42
C,90,96	33.5	33.3	31.7	32.9	0.97	2.95	1.88
C,68,96	34.5	34.4	33.8	34.2	0.40	1.16	0.31
C,45,96	34.9	34.8	34.5	34.7	0.17	0.50	0.06
C,23,96	34.9	34.4	34.4	34.6	0.29	0.83	0.17
C,0,96	33.1	33.7	33.3	33.4	0.30	0.90	0.18
C,90,128	34.5	33.3	31.9	33.2	1.32	3.97	3.48
C,68,128	35.0	34.9	34.1	34.7	0.50	1.44	0.50
C,45,128	34.9	35.6	35.0	35.2	0.38	1.08	0.29
C,23,128	35.3	35.0	35.2	35.2	0.17	0.48	0.06
C,0,128	33.2	34.7	34.6	34.1	0.84	2.46	1.41

Doses were read out using the following calibrated instruments :

- Red Perspex dosimeter : Harwell, Type 4034, Batch PF
- Spectrophotometer : Spectronic 401, Serial no. 381B273004
- Digital micrometer : Sony digital indicator U12A, Serial no. 000623

Summary

Mean Minimum Dose Value (kGy)	Mean Minimum Dose Location	Mean Maximum Dose Value (kGy)	Mean Maximum Dose Location	Dose Uniformity Ratio
30.4	**(B,102,0)**	**36.0**	**(A,51,0)**	**1.18**

7.1 Using an exposure time of 257 minutes (8.89X), the delivered doses in the presentation described are between 30.4 kGy and 36.0 kGy. The dose uniformity is 1.18.

7.2 The highest dose (A,51,0) is in the front of tote at the lowest layer and is a routine monitoring location so called (FA0), which allows facilitated placement. The lowest dose (B,102,0) is in the center in the bottom right side of the tote. The minimum location is not accessible from the outside of the loaded product.

8. METHODOLOGY & CONCLUSIONS

Methods for analyzing the dose mapping data and the uncertainty calculation are taken from American Society for Testing and Materials no. ASTM E2303.

8.1 Definition

D_{ref}	=	Reference Dose
D_{min}	=	Minimum Dose
D_{max}	=	Maximum Dose
R_{min}	=	Reference Minimum
R_{max}	=	Reference Maximum
CF_{min}	=	Correlation Factor for Dmin
CF_{max}	=	Correlation Factor for Dmax
Stdev	=	Standard Deviation
CV	=	Coefficient of Variance
X	=	A time value used by Synergy in order to keep the expression of the processing times constant in the form of nX. The value of X is inversely proportional to the Cobalt-60 activity.

Pooled variance is calculated as follows; Sum of sum of squared differences/2 x population size

This is calculated to determine variance and ultimately the uncertainty in the population. The dose map run all 3 replicates under the same conditions, however natural variation does exist in the process and this needs to be accounted for.

Minimum detectable difference is calculated by using a t-test on the sum of sum of squared differences figures.

This is a test of significance – which supports the statistical variability between the 3 runs. This calculation confirms that the real statistical variability in the process has been captured.

Expected value of R_{min} and R_{max} The uncertainty is applied by using the pooled variance (assumption is made that all data is normally distributed). The formula is as follows

R_{min} = (Mean D_{ref} / Mean D_{min}) + (Mean D_{ref} / Mean D_{min} ^3) x Pooled Variance

R_{max} = (Mean D_{ref} / Mean D_{max}) - (Mean D_{ref} / Mean D_{max} ^3) x Pooled Variance

8.2 Analysis Results

Pooled variance ($s^2_{overall}$)	0.28	
Minimum detectable difference (δ)	0.72	
Mean Minimum dose (D_{min})	30.4	kGy
Mean Maximum dose (D_{max})	36.0	kGy
Mean Reference dose (D_{ref}) at location	36.0	kGy
Expected value of Reference Minimum (R_{min})	1.185	
Expected value of Reference maximum (R_{max})	1.000	

Ratio	
1/Rmin	**0.844**
1/Rmax	**1.000**

These corrected values for the correlation factors are used to calculate minimum and maximum doses for routine processing.

8.3 Setting Process Parameters for Routine Processing

Actual processing time (Xtreated) of the dose map = 8.89 X
For the dose specification = 25.0 kGy minimum, 45.0 kGy maximum

For the $(CF_{min})corr$ = 0.844 , the minimum D_{ref} can be (D_{min} spec/ CF_{min}) = 29.6 kGy
For the $(CF_{max})corr$ = 1.000 , the maximum D_{ref} can be (D_{max} spec/ CF_{max}) = 45.0 kGy

Using the safety factor of 5%, the X processing time is calculated as;
Min X = [1.05 * (D_{ref} min / D_{ref} mean) * X treated from dose mapping] = **7.68** X
Max X = [0.95 * (D_{ref} max / D_{ref} mean) * X treated from dose napping] = **10.56** X

This dose mapping result can be applied to the product density in the range +/-10% of the product density dose mapped. The irradiation processing parameters are as follow:

	Dose specification (kGy)	**Applicable product density**	**X timer Set**	**Correlation factor at routine location (A,51,0)**
Minimum	**25.0**	**0.13 g/cm^3**	**7.68 X**	**0.844 $D_{A,51,0}$**
Maximum	**45.0**	**0.15 g/cm^3**	**10.56 X**	**1.000 $D_{A,51,0}$**

Note: *At location **(A,51,0)** a routine dosimeter location is so called **'FA0'***

8.4 Deviation Between Triplicate Totes at Extreme Locations

		1st run	2nd run	3rd run	Worst deviation between 3 totes
Minimum	Dose (kGy)	30.3	30.8	30.2	2.0%
	Location	B,102,0 B,102,32	B,102,0	B,102,0	-
Maximum	Dose (kGy)	35.7	36.9	36.2	3.4%
	Location	A,51,128	A,51,0	A,77,64	-
Dose Uniformity Ratio (DUR)		1.18	1.20	1.20	1.7%
Routine location, A,51,0 (kGy)		35.4	36.9	35.7	4.2%

Note:

- *It is the responsibility of the customer to routinely provide the product in the presentation and orientation outlined in the report.*
- *The customer undertakes to notify Synergy Health in writing whenever the size, weight or composition of the products or their packaging is varied from that which has previously been supplied and validated.*

	Name/ Position	Signature	Date
Report issued by:	Rungtiwa Supina QA Officer	Rungtiwa S.	6 Mar. 2018
Report reviewed by:	Paradee Thammajanya QA Manager	Paradee T.	6 Mar. 18