



KIMTECH™

Kimtech™ M3 Certified Sterile Face Mask – Pleated Style

62467 / 62470 / 62494

DATA PACK



Table of Content

1. Label Design (page 3-5)
2. Certificate of Conformance (page 6-8)
3. Certificate of Irradiation (page 9-10)
4. Sterile Dose Validation Study (page 11-32)

Label Design

Case Label:

62467**02**

KIMTECH^{*}
M3 Certified
Sterile Face Mask
ISO 1 2 3 4 5 6 7 8

① Cleanroom Sterile Face Mask with Soft Ties 18 cm and BICOSOF[®] Fabric / For Industrial Use Only

② Masque facial stérile en tissu BICOSOF[®] avec attaches souples de 18 cm pour salle blanche / Pour usage industriel uniquement

③ Steriel Reinraum-Gesichtsmaske mit weichen Bändern, 18 cm, und BICOSOF[®] Material / Nur für den industriellen Gebrauch

④ Steriel gezichtsmasker met zachte banden 18 cm en BICOSOF[®] materiaal voor stofvrije kamer / Uitsluitend voor industrieel gebruik

⑤ Mascherina facciale sterile, per camera bianca, in tessuto BICOSOF[®] con lacci morbidi da 18 cm / Solo per uso industriale

⑥ Mascarella estéril para sala blanca de tela BICOSOF[®] con cintas maleables de 18 cm / Para uso industrial solamente

⑦ Маска для лица для чистых помещений, стерильная, с мягкими тесемками – 18 см, и тканью BICOSOF[®] / Только для промышленного применения

⑧ Máscara facial estéril com atilhos macios de 18 cm e tecido BICOSOF[®] para sala esterilizada / Apenas para uso industrial

⑨ Steril rennsumsigtmasker med bløde stropper, 18 cm, og BICOSOF[®] stof / Kun til industribrug

⑩ Sterilt munnskydd for renrum, med mjuka band 18 cm och BICOSOF[®]-material / Endast för industriellt bruk

⑪ Steril rentömsansiktmasker med myke snøreband 18 cm og BICOSOF[®]-stoff / Bare til industriell bruk

⑫ Стерильна маска для чистих кімнат, з 18-см м'якими зав'язками і тканиною BICOSOF[®] / Тільки для промислового уживання

⑬ Jawla maska na twarz z 18 cm, miękkimi wiązadłami i tkaniną BICOSOF[®], do użytku w pomieszczeniach sterylnych / Tylko do użytku profesjonalnego

⑭ Obličejová sterilní maska s 18cm měkkými mašlemi a látkou BICOSOF[®] pro čistou místnost / Jen pro průmyslové použití

⑮ Steriili BICOSOF[®]-tekstiilikasvosmaski puhdasuonekäyttöä varten, 18 cm pehmeät nauhat / Vain teollisuuskäyttöön

10 x 20 = 200

STERILE R

Single Use Only

© / * Trademarks of Kimberly-Clark Worldwide, Inc.
Marques déposées de Kimberly-Clark Worldwide, Inc.
Зарегістрований торговельний знак «Кімберлі-Кларк Ворлдвайд, Інк.»
Зарегістрований знак для товарів та послуг Кімберлі-Кларк Ворлдвайд, Інк., США

© KCWW

Made in Thailand / Fabriqué en Thaïlande / Fabricado en Tailandia /
Произведено в Таиланде
Distributed in the U.S. by Kimberly-Clark Global Sales, LLC, Roswell, GA 30076-2199
kimtech@kcc.com

Distributed in Canada by Kimberly-Clark Inc., Mississauga, Ontario L5B 3Y5
Distributed in Australia by Kimberly-Clark Australia Pty Limited Level 4, 52 Alfred St
Milsons Point NSW 2061 Tel: +61 1800 647 994

Kimberly-Clark Europe Limited / Professional Sector, Reigate, Surrey RH2 9QP, UK.
+44 (0)1737 736000, infofax@kcc.com
www.kcprofessional.com

* Уповноважена організація щодо прийняття претензій від споживачів на території України:
ТОВ «П "Кімберлі-Кларк Україна", 03680, Київ, вул. М. Гринченка, 2/1
Імпортер / Уповноважена організація в Росії: «ООО Кімберлі-Кларк»,
117342, Росія, г. Москва, Профсоюзная ул., д. 65, корп. 1, Тел: +7 (495) 725 4383
www.kcprofessional.com/ru

LOT


Expiry Date

1 00 36000 62467 7

20-70-280-0-06

Bag Label:

KIMTECH^{*}
M3 Certified
Sterile Face Mask
ISO 1 2 3 4 5 6 7 8



email: infofax@kcc.com

INFOFAX
62467
STERILE R

① Mascarella estéril para sala blanca de tela BICOSOF[®] con cintas maleables de 18 cm / Para uso industrial solamente

② Masque facial stérile en tissu BICOSOF[®] avec attaches souples de 18 cm pour salle blanche / Pour usage industriel uniquement

③ Steriel Reinraum-Gesichtsmaske mit weichen Bändern, 18 cm, und BICOSOF[®] Material / Nur für den industriellen Gebrauch

④ Steriel gezichtsmasker met zachte banden 18 cm en BICOSOF[®] materiaal voor stofvrije kamers / Uitsluitend voor industrieel gebruik

⑤ Mascherina facciale sterile, per camera bianca, in tessuto BICOSOF[®] con lacci morbidi da 18 cm / Solo per uso industriale

⑥ Mascarella estéril para sala blanca de tela BICOSOF[®] con cintas maleables de 18 cm / Para uso industrial solamente

⑦ Маска для лица для чистых помещений, стерильная, с мягкими тесемками – 18 см, и тканью BICOSOF[®] / Только для промышленного применения

⑧ Máscara facial estéril com atilhos macios de 18 cm e tecido BICOSOF[®] para sala esterilizada / Apenas para uso industrial

⑨ Steril rennsumsigtmasker med bløde stropper, 18 cm, og BICOSOF[®] stof / Kun til industribrug

⑩ Sterilt munnskydd for renrum, med mjuka band 18 cm och BICOSOF[®]-material / Endast för industriellt bruk

⑪ Steril rentömsansiktmasker med myke snøreband 18 cm og BICOSOF[®]-stoff / Bare til industriell bruk

⑫ Стерильна маска для чистих кімнат, з 18-см м'якими зав'язками і тканиною BICOSOF[®] / Тільки для промислового уживання

⑬ Jawla maska na twarz z 18 cm, miękkimi wiązadłami i tkaniną BICOSOF[®], do użytku w pomieszczeniach sterylnych / Tylko do użytku profesjonalnego

⑭ Obličejová sterilní maska s 18cm měkkými mašlemi a látkou BICOSOF[®] pro čistou místnost / Jen pro průmyslové použití

⑮ Steriili BICOSOF[®]-tekstiilikasvosmaski puhdasuonekäyttöä varten, 18 cm pehmeät nauhat / Vain teollisuuskäyttöön

20

Single Use Only

Formerly CR Classic[®] Masks

LOT

Expiry Date

0 36000 62467 0

20-70-299-0-04

Label Design

Case Label:

6247002

KIMTECH[®]

M3 Certified

Sterile Face Mask

ISO 1 2 3 4 5 6 7 8

① Cleanroom Sterile Face Mask with Earloops 18 cm and BICOSOF[®] Fabric / For Industrial Use Only

② 18-cm körvessződe és BICOSOF[®] anyagból puhaszűrűnű nőkészlet / Ainult tööstuslikuks kasutuseks

③ Tírás telpas sterila sejas maska ar ausu olcópán (18 cm) un BICOSOF[®] audumu / Tikai industriālai lietošanai

④ Steriln sanitārisēs zonas veido kaukē su 18 cm auselēmis ir BICOSOF[®] audino pamušālu / Tik pramonijam naudojimai

⑤ Obličajová sterilní maska s 18cm ušnými pútkami a látkou BICOSOF[®] pre čistú miestnosť / Len na priemyselné použitie

⑥ Sterilizsoba steril maszk, fülakasztóval és BICOSOF[®] anyaggal, 18 cm-es / Csak ipari használatra

⑦ Sterilna maska za obraz s trakovi za ušesa za uporabo v čistih sobah, 18 cm in BICOSOF[®] material / Samo za industrijsko uporabo

⑧ Mască facială sterilă pentru cameră sterilă cu elastic auricular 18 cm, din material BICOSOF[®] / Numai pentru uz industrial

⑨ Маска за лице за стерилни зали с примки за ушите 18 см, и плат от типа BICOSOF[®] / Само за промишлена употреба

⑩ Αποστειρωμένη μάσκα προσώπου Cleanroom με θηλέες για τα αυτιά 18 cm και ύφασμα BICOSOF[®] / Για βιομηχανική χρήση μόνο

⑪ Temiz Oda 18 cm Kulak Halkalı ve BICOSOF[®] Kumaşı Steril Yüz Maskesi / Sadece sıral kullanim içindir

⑫ 清潔室用清毒口罩・附18釐米耳帶・BICOSOF[®] 布 / 仅限工業使用

⑬ 청정실 무균 얼굴 마스크 (18cm 귀걸이, BICOSOF[®] 패브릭 사용) / 산업용

⑭ 清室用清毒口罩・附18釐米耳帶・BICOSOF[®] 布 / 仅限工業使用

⑮ クリーンルーム用滅菌フェースマスク 18cm耳かケループ付 BICOSOF[®] 繊維使用 / 産業用途専用

10 x 20 = 200

STERILE R

Single Use Only

LOT

Expiry Date

20-70-296-0-05

1 00 36000 62470 7

© / * Trademarks of Kimberly-Clark Worldwide, Inc.

Marques déposées de Kimberly-Clark Worldwide, Inc.

Зарегистрированный товарный знак «Кимберли-Кларк Уорлдвайд Инк.»

Зарегистрований знак для товарів та послуг «Кимберлі-Кларк Уорлдвайд Інк., США

© KCCWW

Made in Thailand / Fabriqué en Thaïlande / Fabricado en Tailandia /

Произведено в Таиланде

Distributed in the U.S. by Kimberly-Clark Global Sales, LLC, Roswell, GA 30076-2199

kimtech@kcc.com

Distributed in Canada by Kimberly-Clark Inc., Mississauga, Ontario L5B 3Y5

Distributed in Australia by Kimberly-Clark Australia Pty Limited Level 4, 52 Alfred St

Milsons Point NSW 2061 Tel: +61 1800 647 994

KimberlyClark Europe Limited / Professional Sector, Reigate, Surrey RH2 9QP, UK,

+44 (0)1737 736000, infofax@kcc.com

www.kcprofessional.com

*Уповноважена організація щодо прийняття претензій від споживачів на території України:

ТОВ «Імбіл-Кларк Україна», 03680, Київ, вул. М. Гринченка, 2/1

Импортер: Уповноваженная организация в России: «ООО Имбиль-Кларк»,

117342, Россия, г. Москва, Профсоюзная ул., д. 65, корп. 1. Тел.: +7 (495) 725 4383

www.kcprofessional.com/ru

Bag Label:

62470

KIMTECH[®]

M3 Certified

Sterile Face Mask

ISO 1 2 3 4 5 6 7 8

① Mascherilla sterile per sala bianca da tela BICOSOF[®] con auricolares de 18 cm / Para uso industrial solamente

② 18-cm körvessződe és BICOSOF[®] anyagból puhaszűrűnű nőkészlet / Ainult tööstuslikuks kasutuseks

③ Tírás telpas sterila sejas maska ar ausu olcópán (18 cm) un BICOSOF[®] audumu / Tikai industriālai lietošanai

④ Steriln sanitārisēs zonas veido kaukē su 18 cm auselēmis ir BICOSOF[®] audino pamušālu / Tikai pramonijam naudojimai

⑤ Obličajová sterilní maska s 18cm ušnými pútkami a látkou BICOSOF[®] pre čistú miestnosť / Len na priemyselné použitie

⑥ Sterilizsoba steril maszk, fülakasztóval és BICOSOF[®] anyaggal, 18 cm-es / Csak ipari használatra

⑦ Sterilna maska za obraz s trakovi za ušesa za uporabo v čistih sobah, 18 cm in BICOSOF[®] material / Samo za industrijsko uporabo

⑧ Mască facială sterilă pentru cameră sterilă cu elastic auricular 18 cm, din material BICOSOF[®] / Numai pentru uz industrial

⑨ Маска за лице за стерилни зали с примки за ушите 18 см, и плат от типа BICOSOF[®] / Само за промишлена употреба

⑩ Αποστειρωμένη μάσκα προσώπου Cleanroom με θηλέες για τα αυτιά 18 cm και ύφασμα BICOSOF[®] / Για βιομηχανική χρήση μόνο

⑪ Temiz Oda 18 cm Kulak Halkalı ve BICOSOF[®] Kumaşı Steril Yüz Maskesi / Sadece sıral kullanim içindir

⑫ 清潔室用清毒口罩・附18釐米耳帶・BICOSOF[®] 布 / 仅限工業使用

⑬ 청정실 무균 얼굴 마스크 (18cm 귀걸이, BICOSOF[®] 패브릭 사용) / 산업용

⑭ 清室用清毒口罩・附18釐米耳帶・BICOSOF[®] 布 / 仅限工業使用

⑮ クリーンルーム用滅菌フェースマスク 18cm耳かケループ付 BICOSOF[®] 繊維使用 / 産業用途専用

20

STERILE R

Single Use Only

LOT

Expiry Date

20-70-297-0-04

0 36000 62470 0

© / * Trademarks of Kimberly-Clark Worldwide, Inc.

Marques déposées de Kimberly-Clark Worldwide, Inc.

Зарегистрированный товарный знак «Кимберли-Кларк Уорлдвайд Инк.»

Зарегистрований знак для товарів та послуг «Кимберлі-Кларк Уорлдвайд Інк., США

© KCCWW

Made in Thailand / Fabriqué en Thaïlande / Fabricado en Tailandia /

Произведено в Таиланде

Distributed in the U.S. by Kimberly-Clark Global Sales, LLC, Roswell, GA 30076-2199

kimtech@kcc.com

Distributed in Canada by Kimberly-Clark Inc., Mississauga, Ontario L5B 3Y5

Distributed in Australia by Kimberly-Clark Australia Pty Limited Level 4, 52 Alfred St

Milsons Point NSW 2061 Tel: +61 1800 647 994

KimberlyClark Europe Limited / Professional Sector, Reigate, Surrey RH2 9QP, UK,

+44 (0)1737 736000, infofax@kcc.com

www.kcprofessional.com

*Уповноважена організація щодо прийняття претензій від споживачів на території України:

ТОВ «Імбіл-Кларк Україна», 03680, Київ, вул. М. Гринченка, 2/1

Импортер: Уповноваженная организация в России: «ООО Имбиль-Кларк»,

117342, Россия, г. Москва, Профсоюзная ул., д. 65, корп. 1. Тел.: +7 (495) 725 4383

www.kcprofessional.com/ru

Label Design

Case Label:

62494 02

KIMTECH[®]

M3 Certified
Sterile Face Mask

ISO 1 2 3 4 5 6 7 8

④ Cleanroom Sterile Face Mask with Soft Ties 23 cm and BICOSOF[®] Fabric / For Industrial Use Only

④ 23 cm pehmete paelte ja BICOSOF[®] materjaliga puhasturumi steriilne näokaitse / Ainult tööstuslikuks kasutuseks

④ Sterilās telpas sejas maska ar mīkstām saistēm (23 cm) un no BICOSOF[®] auduma / Tikai industriālai lietošanai

④ Steril švarīgū patalpoj veido kauke su 23 cm mīkstās raistēlais ir BICOSOF[®] audiniu / Tik pramoniniam naudojimui

④ Sterilná obličejová maska do čistej miestnosti s mäkkými 23cm stuhami a látkou BICOSOF[®] / Len na priemyselne použitie

④ Tisztaszobai steril arcvédő maszk 23 cm-es puha megkötőkkel BICOSOF[®] szövetből / Csak ipari használatra

④ Sterilna maska za obraz z mehkim trakovi za uporabo v čistih sobah, 23 cm in BICOSOF[®] material / Samo za industrijsko uporabo

④ Mască sterilă pentru camera sterilă, cu legături moi, de 23 cm și material BICOSOF[®] / Numai pentru uz industrial

④ Sterilna maska za obraz z mehkim trakovi za uporabo v čistih sobah, 23 cm in BICOSOF[®] material / Samo za industrijsko uporabo

④ Маска стерильная для чистой комнаты, с мягкими ушками — 23 см и, ткань BICOSOF[®] / Только для промышленного применения

④ Αποστειρωμένη μάσκα προσώπου καθαρού χώρου με μαλακά λουράκια διαστάσεως 23 cm και ύφασμα BICOSOF[®] / Για βιομηχανική χρήση μόνο

④ Temiz Oda 23 cm Yumuşak Bağlı ve BICOSOF[®] Kumaşlı Steril Yüz Maskesi / Sadece sınai kullanim içindir

④ 带有 23 cm 软带和 BICOSOF[®] 纤维结构的洁净室无菌面罩 / 仅限工业使用

④ 帶有 23 cm 軟帶和 BICOSOF[®] 纖維結構的潔淨室無菌面罩 / 僅限工業使用

④ 청정실 얼굴 얼굴 마스크(23 cm의 부드러운 끈이 있으며 BICOSOF[®] 직물 성분) / 산업용

④ 無菌室用医療滅菌マスク(23 cmのソフトな紐、BICOSOF[®] 布使用) / 産業用途専用

10 x 20 = 200

STERILE

Single
Use
Only

© / * Trademarks of Kimberly-Clark Worldwide, Inc.
 Marques déposées de Kimberly-Clark Worldwide, Inc.
 Зарегистрированные товарные знаки «Kimberly-Clark Уорлдвайд, Инк.»
 Зарегистрований знаки для товарів та послуг «Kimberly-Clark Уорлдвайд, Інк.» OSHA

© KCCWW

Made in Thailand / Fabriqué en Thaïlande / Fabricado en Tailandia /
 Произведено в Таиланде
 Distributed in the U.S. by Kimberly-Clark Global Sales, LLC, Rosewell, GA 30076-2199
 kimtech@kcc.com
 Distributed in Canada by Kimberly-Clark Inc., Mississauga, Ontario L5B 3Y5
 Distributed in Australia by: Kimberly-Clark Australia Pty Limited Level 4, 52 Alfred St
 Milsons Point NSW 2061 Tel: +61 1600 647 994
 Kimberly-Clark Europe Limited / Professional Sector, Reigate, Surrey RH2 9QP, UK
 +44 (0)1737 736000, infofax@kcc.com
 www.kcprofessional.com

*Уповноважена організація щодо прийняття притенцій від споживачів на території України:
 ТОВ «ІІ "Кімберлі-Кларк Україна"», 05080, Київ, вул. М. Гринченка, 2/1
 Інтернет / Уповноважена організація в Росії: «ООО "Кімберлі-Кларк"»,
 117342, Росія, м. Москва, Гродомская ул., д. 65, корп. 1, Тел. +7 (495) 725 4383
 www.kcprofessional.com/ru

LOT

Expiry Date

1 00 36000 62494 3

Bag Label:

KIMTECH[®] M3 Certified Sterile Face Mask ISO 1 2 3 4 5 6 7 8



- ④ Cleanroom Sterile Face Mask with Soft Ties 23 cm and BICOSOF[®] Fabric / For Industrial Use Only
- ④ Masque facial stérile en tissu BICOSOF[®] avec attaches souples 23 cm pour salle blanche / Pour usage industriel uniquement
- ④ Steril Reinraum-Gesichtsmaske mit weichen Bändern, 23 cm, und BICOSOF[®] Material / Nur für den industriellen Gebrauch
- ④ Steril gezichtsmasker met zachte banden 23 cm en BICOSOF[®] materiaal voor stofvrije kamers / Uitsluitend voor industrieel gebruik
- ④ Mascherina facciale sterile, per camera sterile, in tessuto BICOSOF[®] con lacci morbidi da 23 cm / Solo per uso industriale
- ④ Mascara facial estéril para sala blanca de tela BICOSOF[®] con cintas maleables de 23 cm / Para uso industrial solamente
- ④ Маска для лица для чистых помещений, стерильная, с мягкими тесемками — 23 см, и тканью BICOSOF[®] / Только для промышленного применения
- ④ Mascara facial estéril com elástico macios de 23 cm e tecido BICOSOF[®] para sala esterilizada / Apenas para uso industrial
- ④ Steril rennsumsniagsmaske med bløde stropper, 23 cm, og BICOSOF[®] stof / Kun til industrielt bruk
- ④ Steril munskydd för renrum, med mjuka band 23 cm och BICOSOF[®] material / Endast för industriellt bruk
- ④ Steril ansiktssmaske for rentrom med myke snørebånd 23 cm og BICOSOF[®] stoff / Bare til industriell bruk

© / * Trademarks of Kimberly-Clark Worldwide, Inc. Marques déposées de Kimberly-Clark Worldwide, Inc. Зарегистрированные товарные знаки «Kimberly-Clark Уорлдвайд, Инк.» Зарегистрований знаки для товарів та послуг «Kimberly-Clark Уорлдвайд, Інк.» OSHA

© KCCWW

Made in Thailand / Fabriqué en Thaïlande / Fabricado en Tailandia / Произведено в Таиланде

Distributed in the U.S. by Kimberly-Clark Global Sales, LLC, Rosewell, GA 30076-2199 kimtech@kcc.com

Distributed in Canada by Kimberly-Clark Inc., Mississauga, Ontario L5B 3Y5

Distributed in Australia by: Kimberly-Clark Australia Pty Limited Level 4, 52 Alfred St Milsons Point NSW 2061 Tel: +61 1600 647 994

Kimberly-Clark Europe Limited / Professional Sector, Reigate, Surrey RH2 9QP, UK +44 (0)1737 736000, infofax@kcc.com

*Уповноважена організація щодо прийняття притенцій від споживачів на території України: ТОВ «ІІ "Кімберлі-Кларк Україна"», 05080, Київ, вул. М. Гринченка, 2/1

Интернет / Уповноважена організація в Росії: «ООО "Кімберлі-Кларк"», 117342, Росія, м. Москва, Гродомская ул., д. 65, корп. 1, Тел. +7 (495) 725 4383 www.kcprofessional.com/ru

20-70-283-0-05

LOT

Expiry Date

email: infofax@kcc.com

INFO FAX

62494

STERILE

- ④ Стерильная маска для чистых комнат, с 23-см мягкими завязками и тканью BICOSOF[®] /
 Тільки для промислового застосування
- ④ Maske na twarz do użytku w sterylizowanych pomieszczeniach z 23 cm miękkimi wiązadkami i tkaniną BICOSOF[®] /
 Tyko do użytku przemysłowego
- ④ Obličejová sterilní maska s 23cm měkkými mašlemi a látkou BICOSOF[®] pro čistou místnost / Jen pro průmyslové použití
- ④ Steril BICOSOF[®]-sektistmaski puhastuonokäyttöä varten, 23 cmn pehmeät nauhat / Vain teollisuuskäyttöön
- ④ 23cm pehmete paelte ja BICOSOF[®] materjaliga steriilne puhasturumi näokaitse / Ainult tööstuslikuks kasutuseks
- ④ Trilās telpas sejas maska ar mīkstām saistēm (23 cm) un BICOSOF[®] audumu / Tikai industriālai lietošanai
- ④ Steril švarīgū veido kauke su 23 cm mīkstās raistēlais ir BICOSOF[®] audinu / Tik pramoniniam naudojimui
- ④ Tisztaszobai steril arcvédő maszk s 23cm mēkkmými mašlemi a látkou BICOSOF[®] pre čistú miestnosť /
 Len na priemyselne použitie
- ④ Sterilna maska za obraz z mehkim trakovi za uporabo v čistih sobah, 23 cm in BICOSOF[®] material / Samo za industrijsko uporabo
- ④ Mască facială sterilă pentru camera sterilă cu șiret moale 23 cm, din material BICOSOF[®] / Numai pentru uz industrial
- ④ Маска за лице за стерилни зали с меки връзки 23 cm, и плат от типа BICOSOF[®] /
 Само за промишлен употреба
- ④ Αποστειρωμένη μάσκα προσώπου Cleanroom με μαλακά λουράκια διαστάσεως 23 cm και ύφασμα BICOSOF[®] /
 Για βιομηχανική χρήση μόνο
- ④ Temiz Oda 23 cm Yumuşak Bağlı ve BICOSOF[®] Kumaşlı Steril Yüz Maskesi / Sadece sınai kullanim içindir
- ④ 清潔室用消毒口罩・附23釐米軟帶・BICOSOF[®]布 / 僅限工業使用
- ④ 청정실 얼굴 마스크(23cm 연한 끈, BICOSOF[®] 패브릭 사용) / 산업용
- ④ 無菌室用 Cleanroom フェースマスク 23 cm ソフトタイ付 BICOSOF[®] 繊維使用 / 産業用途専用

20

Single Use Only

Formerly CR Classic[®] Masks

0 36000 62494 6

KIMTECH[™]



1400 Holcomb Bridge Road
Roswell, GA 30076

December 11, 2019

Re: Certificate of Conformance

KIMTECH* M3 Certified Sterile Face Mask

Product Code: 6246702

Lot Number: TH93094609

Date of Manufacture: November 2019

Expiration: 5 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,

A handwritten signature in cursive script, appearing to read "Emily Adams".

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



1400 Holcomb Bridge Road
Roswell, GA 30076

December 11, 2019

Re: Certificate of Conformance

KIMTECH* M3 Certified Sterile Face Mask

Product Code: 6247002

Lot Number: TH92904609

Date of Manufacture: October 2019

Expiration: 5 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,

A handwritten signature in cursive script, appearing to read "Emily Adams".

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



1400 Holcomb Bridge Road
Roswell, GA 30076

December 11, 2019

Re: Certificate of Conformance

KIMTECH* M3 Certified Sterile Face Mask

Product Code: 6249402

Lot Number: TH92884609

Date of Manufacture: October 2019

Expiration: 5 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,

A handwritten signature in cursive script, appearing to read "Emily Adams".

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



<http://www.steris-ast.com>

Certificate of Irradiation

This is to certify that, under the irradiation batch number

T2019 2560

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 **120 cartons**

Purchase order no. **PS620717**

Product description

| <i>Product</i> | <i>Lot no.</i> | <i>Quantity (cartons)</i> |
|----------------|----------------|---------------------------|
| 6246702 | TH93094609 | 120 |

The process was applied according to specification: **T-B311192513**

The first tote was irradiated on: **16 November 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 **50.0** kilograys maximum

The calculated dose received is **26.2** kilograys minimum and **32.6** kilograys maximum

Approved by/date:

Paradee 7. 18 Nov. 19

Paradee Thammajanya, QA Manager

Processing Site: Same as below

Registered Office: 700/465 Amata Nakorn Industrial, Moo 7, Tambon Donhuaroh, Amphur Muang Chonburi, CHONBURI 20000 THAILAND

VAT Number: 0115541003872



<http://www.steris-ast.com>

Certificate of Irradiation

This is to certify that, under the irradiation batch number

T2019 2507

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 **1,272 cartons**

Purchase order no. **PS620699**

Product description

| <i>Product</i> | <i>Lot no.</i> | <i>Quantity (cartons)</i> |
|----------------|----------------|---------------------------|
| 6247002 | TH92904609 | 120 |
| 6249402 | TH92884609 | 1,152 |

The process was applied according to specification: **T-B311192513**

The first tote was irradiated on: **9 November 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 **50.0** kilograys maximum

The calculated dose received is **29.9** kilograys minimum and **39.8** kilograys maximum

Approved by/date:

Paradee 7. 11 Nov. 19

Paradee Thammajanya, QA Manager

Processing Site: Same as below

Registered Office: 700/465 Amata Nakorn Industrial, Moo 7, Tambon Donhuaroh, Amphur Muang Chonburi, CHONBURI 20000 THAILAND
VAT Number: 0115541003872

**DOSE AUDIT VDM_{ax} STUDY ACCORDING TO
EN ISO 11137**

**STERILIZATION OF HEALTHCARE PRODUCTS - RADIATION
ESTABLISHING THE STERILIZATION DOSE
PART 2: 2015**

“SUBSTANTIATION OF 25kGy AS A STERILIZATION DOSE”

Face mask 9” tie Kimtech pure M3 sterile mask 62494-02

REPORT NO. 18110329

OCTOBER-NOVEMBER 2018

Report Prepared By: *09/11/2018* Lab Technician

Report Approved By: *09/11/2018* Microbiologist

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

PAGE OF CONTENTS

| | Page |
|---|--------|
| Page of Contents | 2 |
| Summary | 3 |
| Introduction | 4 |
| Estimation of Bioburden | 5 – 7 |
| Determination of Sub-Process Verification Dose | 7 |
| Sterility Testing | 8 – 11 |
| Test Media Formula | 11 |
| Environmental Monitoring Data Sheet | 12 |
| Appendix I (Certificate of Irradiation & Application of Verification Doses) | |
| Appendix II (Certificates of Analysis) | |

SUMMARY

This study was undertaken in accordance with VD_{Max}²⁵ of “Sterilization of Healthcare Products – Radiation Part 2- EN ISO 11137-Part 2:2015 –Substantiation of 25kGy as a Sterilization Dose”.

1 batch of 10 samples of Face mask 9” tie Kimtech pure M3 sterile mask 62494-02 was assayed for bioburden levels. The overall average for the batch tested was 281.1 CFU/unit. The sub-process verification dose required for the sterility assurance level of 10^{-1} was 8.6 kGy $\pm 10\%$ (7.8 kGy – 9.4 kGy), which was determined during the dose substantiation of 25kGy. 10 units of the sample were irradiated at this dose and subsequently individually tested for sterility. After completion of the incubation period, all tests gave a negative result, therefore statistical verification for the sub-process dose was accepted. Actual dose delivered was 7.8 kGy minimum and 8.1 kGy maximum.

INTRODUCTION

Sterility is an absolute term, but the assurance that any given item is sterile is a probability function. The sterility assurance level (SAL) is defined as the probability of any given unit being non-sterile after exposure to a validated sterilization process.

The VD Max exercise depends upon experimental verification that the product microbial flora is equally or more sensitive to irradiation than a given standard reference distribution.

The method requires determination of the average bioburden of the product and an experiment to verify that the bioburden reference at a 10^{-1} SAL is not more resistant than the bioburden population. The verification experiment is performed by irradiating 10 samples at a sub-process dose. The parameters for identifying the sub-process dose are the average bioburden of the product determined during the VD_{Max}²⁵ Study. The delivered dose for the experiment is allowed to differ from the determined sub-process dose by no more than $\pm 10\%$. Statistical verification is accepted if there are no more than one positive sterility tests from the 10 samples tested. If there are 2 positives, a confirmatory verification dose experiment shall be conducted.

ESTIMATION OF BIOBURDEN

Introduction

The objective of this test was to estimate the bioburden levels on the Face mask 9” tie Kimtech pure M3 sterile mask 62494-02. This is essential to verify that there is no significant increase in the bioburden counts that passing a sterilization dose audit may be unlikely. In this study, method employed for the removal of microorganisms was by elution technique of stomaching. Testing involved membrane filtration of the eluent, followed by incubation of the filter in an appropriate growth medium to give visible colonies. For enumeration purpose, both total aerobic and yeast and mould counts were considered as the total bioburden estimate.

Method

All work was carried out under the protection of biosafety cabinet using aseptic technique. Each unit was treated individually. The sample was transferred into a sterile bag and 300ml of sterile Maximum Recovery Diluent (MRD-Peptone Water) was added and stomached for 3 minutes. 150ml of the eluate was filtered through a 0.45 µm cellulose nitrate membrane filter. The membrane filter was then transferred onto the TSA plates and the plates were incubated at 30° C - 35° C for 5 days. Another 150ml of the eluent was filtered in the same manner, transferred onto the TSA plates and incubated at 20° C - 25° C for 5 days, after which the number of the colony forming units (CFU) were enumerated.

The recovery correction factor of 0.5777 and a dilution factor of 2 were used to calculate the total bioburden of a product.

Results

| | | |
|--|---|--|
| Customer Name | : | 45/2, 45/3 Moo 2 Sukhprachasan 2 Road, Bangpud, Pakkred, Nonthaburi 11120, Thailand. |
| Test Number | : | 7782 |
| Test Product | : | Face mask 9" tie Kimtech pure M3 sterile mask 62494-02 |
| Product Lot No. | : | TH 82768776 |
| Product Part No. | : | 62494-02 |
| Date Samples Received | : | 05/10/2018 |
| Date Tested | : | 11/10/2018 |
| Date Completed | : | 16/10/2018 |
| Number of Sample | : | 10pcs |
| Signature | : | <i>[Signature]</i> 09/11/2018 |
| Peptone & NaCl Mfr. Batch No. | : | VM 851914 & K 47011104 |
| Peptone Water Batch No. | : | 8414 PW 01/11/2018 |
| TSA Mfr. Batch No. | : | VM 828458 |
| TSA Batch No. | : | 8425 TSA 04/11/2018 |
| Negative Control | : | All Negative |
| Incubation | : | 20° - 25°C & 30° - 35°C for 5 days |

| CERT NO: 7782 | | | |
|---|------------------------------------|-------------------------------|--|
| LOT NO: TH 82768776 (Part No: 62494-02) | | | |
| SAMPLE | YEAST AND MOLD COUNT 20-25°C | BACTERIAL COUNT 30-35°C | TOTAL CFU * DILUTION FACTOR/ RECOVERY FACTOR |
| 1 | 33 | 25 | 200.8 |
| 2 | 19 | 49 | 235.4 |
| 3 | 21 | 22 | 148.9 |
| 4 | 42 | 51 | 322.0 |
| 5 | 28 | 43 | 245.8 |
| 6 | 46 | 63 | 377.4 |
| 7 | 15 | 12 | 93.5 |
| 8 | 71 | 47 | 408.5 |
| 9 | 54 | 67 | 418.9 |
| 10 | 58 | 46 | 360.0 |
| AVERAGE | | | 281.1 |

Reference

ISO 11737-1:2006 Sterilization of medical devices – Microbiological methods – Part 1:
Determination of a population of microorganisms on products

EN ISO 11137 – 2:2015 Sterilization of healthcare products – Radiation – Part 2:
Establishing the Sterilization Dose

DETERMINATION OF THE SUB – PROCESS VERIFICATION DOSE

The sub-process verification dose determined during the Dose Substantiation of 25kGy for a Sterility Assurance Level (SAL) of 10^{-1} was 8.6 kGy $\pm 10\%$. With reference to the Table 9 of EN ISO 11137 – 2:2015 document, this dose corresponded to the bioburden level of 260.0 CFU. The overall average bioburden estimated during the Dose Substantiation of 25kGy was 247.6 CFU/unit. The average bioburden estimates of the sample determined at Dose Audit was 281.1 CFU/unit. Therefore, the sub-process verification dose applied to the 10 samples for Sterility Test was 8.6 kGy $\pm 10\%$ (7.8 kGy – 9.4 kGy). The actual dose delivered to the 10 samples was 7.8 kGy minimum and 8.1 kGy maximum.

STERILITY TESTING

Introduction

The objective of this test was to determine if viable microorganisms are still present on samples after samples have been irradiated. For Sterility Testing of the Face mask 9" tie Kimtech pure M3 sterile mask 62494-02, only one medium type is utilized, and the test articles are tested as individual sample, rather than looped or combined into a composite sample. Sterility Testing of the Face mask 9" tie Kimtech pure M3 sterile mask 62494-02 was performed using Direct Immersion method. The interpretation was done by turbidimetric analysis: a cloudy medium indicates the proliferation of bacteria. Conversely, a clear medium indicates the absence of growth.

Before a product is tested for sterility, Growth Promotion Test must be performed on new batches of growth medium used for Sterility Testing. The objective of the Growth Promotion Test is to demonstrate the medium used in the Sterility Testing will detect microorganisms.

Method


Sterility testing was carried out under the protection of laminar flow in a cleanroom operated in accordance with LWI 51 (Test of Sterility-Gamma Processing) and monitored in accordance with LWI 20 (Cleaning and Environmental Monitoring of Cleanroom) supplemented with placed by settle plates and contact plates.

Prior to testing, 10 samples of the Face mask 9" tie Kimtech pure M3 sterile mask 62494-02 were irradiated at 7.8 kGy minimum and 8.1 kGy maximum. Each of the sample was then aseptically transferred into a sterile bag containing 300ml of sterile Tryptone Soya Broth to completely immerse the sample. The samples were incubated at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for 14 days and inspected daily for signs of microbial growth.

For Growth Promotion Test, the new batch of Tryptone Soya Broth was inoculated with a small number of *Bacillus spizizenii* ATCC 6633, *Candida albicans* ATCC 10231, *Aspergillus brasiliensis* ATCC 16404, *Pseudomonas aeruginosa* ATCC 9027 and *Staphylococcus aureus* ATCC 6538, respectively. The media were then incubated at 20°-25°C for 5 days for fungi (*Candida albicans* ATCC 10231 & *Aspergillus brasiliensis* ATCC 16404) and at 30°-35°C for 3 days for bacteria (*Bacillus spizizenii* ATCC 6633, *Pseudomonas aeruginosa* ATCC 9027 and *Staphylococcus aureus* ATCC 6538). After the incubation period, growth was shown by a cloudy medium while a clear medium indicated no growth.

Results

(1) Growth Promotion Test

| | | |
|--------------------|---|--|
| Medium | : | Tryptone Soya Broth |
| TSB Mfr. Batch No. | : | VM 822159 |
| TSB Batch No. | : | 8440 TSB 10/11/2018 |
| Incubation | : | 20°C-25°C for 5 days & 30°C-35°C for 3 days |
| Test Organisms | : | <i>Bacillus spizizenii</i> ATCC 6633 |
| | : | <i>Candida albicans</i> ATCC 10231 |
| | : | <i>Aspergillus brasiliensis</i> ATCC 16404 |
| | : | <i>Pseudomonas aeruginosa</i> ATCC 9027 |
| | : | <i>Staphylococcus aureus</i> ATCC 6538 |
| Date Tested | : | 10/10/2018 |
| Date Completed | : | 13/10/2018 (30°C-35°C) & 15/10/2018 (20°C-25°C) |
| Signature | : |  09/11/2018 |

| Tryptone Soy Broth (8440 TSB 10/11/2018) | |
|---|-----------|
| Test Organism | Result |
| <i>Bacillus spizizenii</i> ATCC 6633 | Growth |
| <i>Candida albicans</i> ATCC 10231 | Growth |
| <i>Aspergillus brasiliensis</i> ATCC 16404 | Growth |
| <i>Pseudomonas aeruginosa</i> ATCC 9027 | Growth |
| <i>Staphylococcus aureus</i> ATCC 6538 | Growth |
| Negative Control | No Growth |
| Positive Control | Growth |

(2) Sterility Testing

| | | |
|-----------------------|---|--|
| Customer Name | : | 45/2, 45/3 Moo 2 Sukhprachasan 2 Road, Bangpud, Pakkred, Nonthaburi 11120, Thailand. |
| Test Number | : | 4075 |
| Test Product | : | Face mask 9" tie Kimtech pure M3 sterile mask 62494-02 |
| Product Lot No. | : | TH 82768776 |
| Product Part No. | : | 62494-02 |
| Date Samples Received | : | 05/10/2018 |
| Date Tested | : | 24/10/2018 |
| Date Completed | : | 07/11/2018 |
| TSB Mfr. Batch No. | : | VM 822159 |
| TSB Batch No. | : | 8440 TSB 10/11/2018 |
| Incubation | : | 30°±2°C for 14 days |
| Signature | : | <i>J 09/11/2018</i> |

| Day | Number Negative | Number Positive | Date | Initials |
|-----|--------------------|--------------------|------------|---------------------|
| 1 | 10 | Nil | 25/10/2018 | <i>J 09/11/2018</i> |
| 2 | 10 | Nil | 26/10/2018 | <i>J 09/11/2018</i> |
| 3 | 10 | Nil | 27/10/2018 | <i>J 09/11/2018</i> |
| 4 | 10 | Nil | 28/10/2018 | <i>J 09/11/2018</i> |
| 5 | 10 | Nil | 29/10/2018 | <i>J 09/11/2018</i> |
| 6 | 10 | Nil | 30/10/2018 | <i>J 09/11/2018</i> |
| 7 | 10 | Nil | 31/10/2018 | <i>J 09/11/2018</i> |
| 8 | 10 | Nil | 01/11/2018 | <i>J 09/11/2018</i> |
| 9 | 10 | Nil | 02/11/2018 | <i>J 09/11/2018</i> |
| 10 | 10 | Nil | 03/11/2018 | <i>J 09/11/2018</i> |
| 11 | 10 | Nil | 04/11/2018 | <i>J 09/11/2018</i> |
| 12 | 10 | Nil | 05/11/2018 | <i>J 09/11/2018</i> |
| 13 | 10 | Nil | 06/11/2018 | <i>J 09/11/2018</i> |
| 14 | 10 | Nil | 07/11/2018 | <i>J 09/11/2018</i> |

TEST PASSED ✓ FAILED

Signature: *J 09/11/2018*

Reference

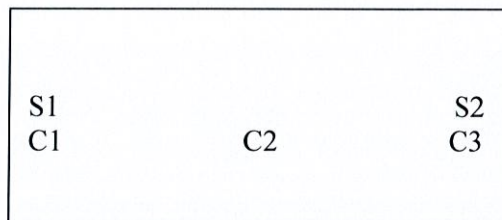
EN ISO 11137 – 2:2015 Sterilization of healthcare products – Radiation – Part 2:
Establishing the Sterilization Dose

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

MEDIA FORMULAE

| | |
|--|-------------------------------|
| Tryptone Soya Agar Tryptone Soya Agar pH 7.3 ±0.2 | gm/L 40.0 |
| Tryptone Soya Broth Tryptone Soya Broth pH 7.3 ±0.2 | gm/L 30.0 |
| Maximum Recovery Diluent Peptone Sodium Chloride pH 7.2 ±0.2 | gm/L 8.5 1.0 |

ENVIRONMENTAL MONITORING DATA SHEET



BIOSAFETY CABINET

Key:

S = settle plates

C = contact plates

Date exposed : 24/10/2018

Date read : 31/10/2018

Total : 0 CFU

| | TOTAL CFU |
|------|------------|
| Date | 31/10/2018 |
| S1 | 0 |
| S2 | 0 |

| | TOTAL CFU |
|------|------------|
| Date | 31/10/2018 |
| C1 | 0 |
| C2 | 0 |
| C3 | 0 |

Media Batch No.: 8458 TSA 17/11/2018

Analyst: *D. 09/11/2018*

APPENDIX I



<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 01-Nov-2018

MY03S12184855-1-1

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

45/2-3 MOD 2 SUKHAPHACHASAN 2 ROAD
BANGPUD
PAKKRED
NONTABURI 11120
THAILAND

Order Information

| | |
|--------------------------------------|---|
| Account Number: | 101223 |
| Synergy Health Sales Part Reference: | 1057428 |
| Customer Reference Number: | PO DS610445 |
| Product Description: | SAMPLE IRRADIATION 0.1 - 15 kGy |
| Quantity Received: | 1 |
| Customer Unit Lot/Batch Number: | SEE BELOW |
| Other Process Details: | DESCRIPTION: FACE MASK 9" TIE KIMTECH PURE M3 STERILE MASK LOT NUMBER: TH 82768776 PART NO: 62494-02 IRRADIATION DATE: 22/10/2018 DOSE REQUIRED: 8.6 kGy +/-10% (7.8 - 9.4 kGy) ACTUAL DOSE RECEIVED: MIN:7.8 kGy MAX:8.1 kGy |

Processing Site: Plot 203, Kuala Ketil Industrial Park, Kuala Ketil, 09300 Phone No: +60(0)44152111

Registered Office: Suite 18.01 18th Floor, MWE Plaza, 8, Lebuhr Farquhar, 10200, Penang, MALAYSIA
VAT Number: 000859889664



<http://www.steris-ast.com>


Certificate of Irradiation

Date Issued: 01-Nov-2018

MY03S12184855-1-1

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


45/2-3 MOD 2 SUKHAPHACHASAN 2 ROAD
BANGPUD
PAKKRED
NONTABURI 11120
THAILAND


Irradiation Data

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


Processing Site: Plot 203, Kuala Ketil Industrial Park, Kuala Ketil, 09300 Phone No: +60(0)44152111

Registered Office: Suite 18.01 18th Floor, MWE Plaza, 8, Lebuhr Farquhar, 10200, Penang, MALAYSIA
VAT Number: 000859889664

APPLICATION OF VERIFICATION DOSES

Reported by :  01/11/18
Anis Fahimah
QA Officer

Approved by :  02/11/2018
Azwin Yusuf
QA Executive

Report Number : 18-480-VD
Sample Batch Number : S12184855-1-1
Customer Name : 
A/C Number : 101223
Sample Description : Face Mask 9" Tie Kimtech Pure M3 Sterile Mask
Lot No: TH 82768776
Part No: 62494-02

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

This exercise is to confirm that the doses applied to all samples throughout the package are within the specified range of 8.6 kGy $\pm 10\%$ (7.8 kGy – 9.4 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 7.8 kGy – 9.4 kGy and actual dose received were 7.8 kGy to 8.1 kGy.

LOAD DESCRIPTION

Type of carton : Corrugated inner box

Carton dimension (mm) L X W X H : 280 X 95 X 155

Weight of 1 carton (g) : 303.85

Density (g/cm³) : 0.07

PROCESSING INFORMATION

Average dose rate : 2.03 kGy / h

Verification dose requested : 7.8 kGy – 9.4 kGy

Minimum dose less 10% tolerance (rounded off to the upper 0.1 kGy) : 7.8 kGy

Minimum exposure time (hh:mm) : 3 Hours 50 Minutes

Maximum dose plus 10% tolerance (rounded off to the lower 0.1 kGy) : 9.4 kGy

Maximum exposure time : 4 Hours 38 Minutes

Exposure started on / at : 22 / 10 / 2018 at 22:10

Exposure was interrupted for : 0 Minutes

Exposure finished on / at : 23 / 10 / 2018 at 02:05

Actual exposure time : 3 Hours 55 Minutes

DOSIMETRY RESULTS SUMMARY

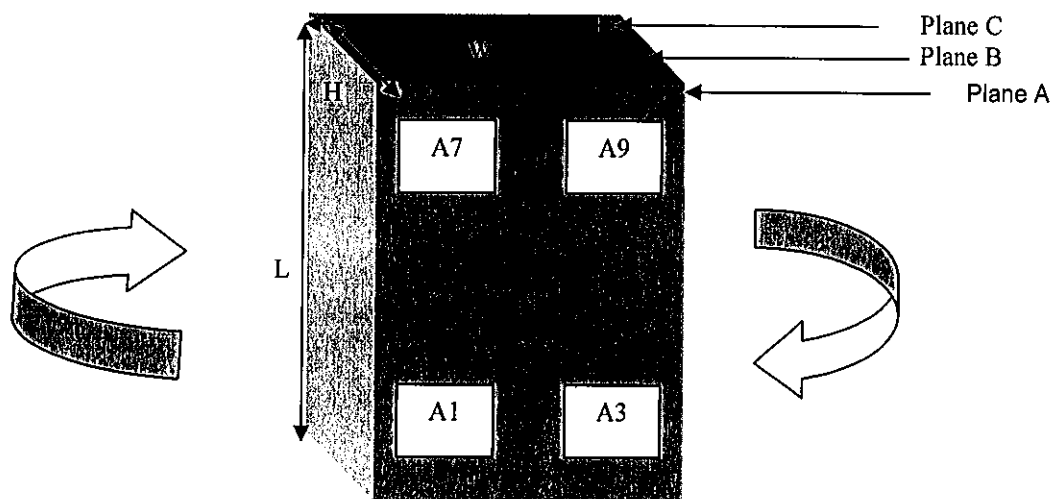
| | Minimum dose | Maximum dose |
|----------------------------|--------------|--------------|
| Dose requested (kGy) | 7.8 | 9.4 |
| Actual dose received (kGy) | 7.8 | 8.1 |

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 S12184855-1-1

Product ID PO: DS 610445

Customer [REDACTED]

| Position | Optical Density1 | Optical Density2 | Thickness | Dose | Notes |
|----------|------------------|------------------|-----------|--------|-------|
| A1 | 624.7000 | 0.0000 | 3.2900 | 8.0000 | |
| A3 | 678.3000 | 0.0000 | 3.4600 | 7.9000 | |
| A7 | 544.5000 | 0.0000 | 2.8600 | 8.1000 | |
| A9 | 612.7000 | 0.0000 | 3.1100 | 8.0000 | |
| B1 | 542.0000 | 0.0000 | 2.8400 | 7.9000 | |
| B3 | 600.4000 | 0.0000 | 3.0600 | 7.8000 | |
| B7 | 543.9000 | 0.0000 | 2.8400 | 8.0000 | |
| B9 | 574.0000 | 0.0000 | 2.9300 | 7.9000 | |

APPENDIX II

Customer:
 45/2,45/3 Moo 2 Sukhprachasan 2 Road,
 Bangpud, Pakkred,
 Nonthaburi 11120,
 Thailand.


**BIOBURDEN TEST
 CERTIFICATE OF ANALYSIS**

Certificate No.: 7782
Purchase Order No.: DS610445
STERIS sample Log No.: 6841
Product Name: Face Mask 9" tie Kimtech pure M3 sterile mask 62494-02
Product Lot No.: TH 8276 8776 (Part No: 62494-02)
Date Samples Received: 05/10/2018
No. of Samples: 10 pcs
Correction Factor: 0.5777
Date Tested: 11/10/2018
Date Incubation Completed: 16/10/2018

Results:

| Item Description | Test Results | | | Reference Standard |
|------------------|------------------------|------------------------|-----------------------|--------------------|
| | CFU/150ml (20-25°C) | CFU/150ml (30-35°C) | CFU/Unit Total No. | ISO 11737-1 |
| Sample 1 | 33 | 25 | 200.8 | |
| Sample 2 | 19 | 49 | 235.4 | |
| Sample 3 | 21 | 22 | 148.9 | |
| Sample 4 | 42 | 51 | 322.0 | |
| Sample 5 | 28 | 43 | 245.8 | |
| Sample 6 | 46 | 63 | 377.4 | |
| Sample 7 | 15 | 12 | 93.5 | |
| Sample 8 | 71 | 47 | 408.5 | |
| Sample 9 | 54 | 67 | 418.9 | |
| Sample 10 | 58 | 46 | 360.0 | |
| Average | | | 281.1 | |

Comments: Method: Each unit was treated individually, the sample was transferred into a sterile stomaching bag and added 300 ml of sterile Peptone Water. The sample was stomached for 3 minutes. 150ml eluent was filtered through a 0.45 µm cellulose nitrate membrane. The filter was then placed onto a sterile Tryptone Soya Agar plate. The plates were incubated at 30°C-35°C for bacterial count and another 150ml the eluent filtered in a similar manner. The plates were incubated at 20°C - 25°C for fungal for 5 days before enumeration of the resulting Colony Forming Units (CFU). (Dilution Factor: 2X).
 Media Batch No: 8414 PW 01/11/2018 & 8425 TSA 04/11/2018

Certified By:

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

16/10/2018

LABORATORY TESTING

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

**PRODUCT STERILITY TEST
CERTIFICATE OF ANALYSIS**


Certificate No.: 4075
Purchase Order No.: DS610445
STERIS Sample Log No.: 6841
STERIS Batch No.: S12184855-1-1
Date Processed: 22/10/2018
Product Name: Face Mask 9" tie Kimtech Pure M3 sterile mask 62494-02
Product Lot No.: TH 8276 8776 (Part No:62494-02)
No. of Samples: 10 pcs
Date Samples Received: 05/10/2018
Date Tested: 24/10/2018
Date Incubation Completed: 07/11/2018

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: 8458 TSA 17/11/2018 & 8440 TSB 10/11/2018.

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

Date: 09/11/2018