

Présentation de l'offre SUNSMED



GLOBAL

Masque Chirurgical Type II R

Enfant 14,5 x 9,5 cm **CE**



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Introduction 2S Global

La société 2S Global spécialisée dans l'import export propose de guider ses clients dans leurs processus d'approvisionnements avec un accompagnement et des conseils tout au long de la procédure d'achat : de la commande à la livraison finale.

- **Notre objectif** : simplifier l'acquisition d'équipement de protection individuelle pour protéger le plus rapidement possible vos concitoyens ou les collaborateurs de vos entreprises.
- **Un service client réactif** : Notre équipe a plus de 10 ans d'expérience dans l'Import Export entre l'Asie du Sud-Est et l'Europe. Notre obsession : vous accompagner durant chaque étape de votre commande.



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Co-Fondateur

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Co-Fondateur

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Rodolphe@2s-global.com

Nos offres

Nous vous proposons plusieurs types d'équipement de protection individuelle afin de protéger efficacement vos collaborateurs. Nous sommes notamment spécialisés dans les masques de protection individuelle et masques médicaux.



CONTACT 10H/24 - 6J/7

Nous sommes à votre disposition par téléphone ou par messagerie instantanée.



+ DE 300 CLIENTS

Plus de 300 collectivités locales et entreprises nous font confiance afin de protéger efficacement leurs concitoyens et leurs salariés.



EQUIPES À VOTRE SERVICE

Nos équipes sont à votre disposition et sont basées en France et en Chine



LIVRAISON SÉCURISÉE

Nos livraisons sont express, gratuites et sécurisées

Fiche technique

Masque Chirurgical – Type II R



Caractéristiques

- Masque chirurgical Type II R
- Modèle médical – 14,5 x 9,5 cm
- Lanières élastique aux oreilles
- Masque Bleu avec barrette nasale
- Masque avec marquage **CE**

Normes

Standard: EN 14683:2019 Type II R
Classification: Class I
ISO: ISO 13485

Conditions de stockages: espace propre, ventilé, sec
Date limite d'utilisation: 3 ans sous conditions de stockage
Pays de fabrication: Chine

Description



1/ Polypropylène non tissé
Doux, agréable pour la peau,
filtration grosses particules



2/ Filtre en Melt-blown
Couche filtrante, absorption
des micro-germes



3/ Polypropylène non tissé
Doux, agréable pour la peau,
filtration grosses particules

Protection 3 plis

- Antibactérien
- Anti-pollen
- EFB > 98%
- Anti-postillon
- Anti-poussière
- Anti-cheveux

Packing



50 Masques



X1
50 masques par boîte
(50 masques)



X40
40 boîtes par carton
(2000 masques)

Caractéristiques logistiques

Poids brute carton: 7,3 kg
Poids volumétrique: 0,06 CBM

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2S Global ©

Conditionnement & Stockage

1. Conditionnement



Boîtes de 50 masques



50 Masques par sachet plastique



X1
1 sachet de 50
masques par boîte
(50 masques)



X40
40 boîtes par carton
(2000 masques)

Caractéristiques logistiques

Poids brute carton : 7,3 kg

Poids volumétrique : 0,059 CBM

Poids taxable : 10,8 kg

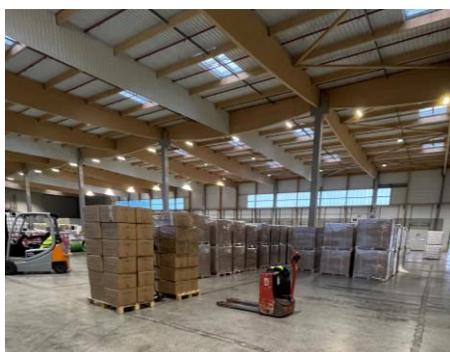
Données palettes

Dimensions : 80 x 120 x 200 cm
Poids : 200 kg

Nombre carton : 24

Masques par palette : 48 000

2. Conditions de stockage



Conditions de stockages :
Espace propre, ventilé, sec
Maintenir à l'abri du soleil

Durée de conservation :
3 ans
sous conditions de stockage

Date limite de conservation :
octobre 2024

Photos du stock disponible à l'entrepôt de Lyon

Copie du pack - BAT

Le BAT de la boîte est donné à titre indicatif. Il pourra faire l'objet de modification selon vos remarques et besoins. Le design est également susceptible d'évoluer pour rester en ligne avec la législation douanière en vigueur en Europe et en Chine.

165X100X80MM



Copie du pack - Photos



Copie de la notice

CONSIGNES D'UTILISATION

AVERTISSEMENT

Pour protéger votre santé et celle des autres, il est très important de respecter ces consignes d'utilisation.

- Portez ce masque quand vous êtes **en contact avec d'autres personnes que celles avec lesquelles vous vivez.**
- Vérifiez toujours que le masque est **bien ajusté et couvre votre bouche et votre nez.**
- **Ce masque ne remplace pas les gestes barrières** (lavage régulier des mains, distanciation physique, réduction des contacts avec d'autres personnes). **Il ajoute une barrière physique, à utiliser notamment lorsque vous êtes en contact étroit avec d'autres personnes**

Comment mettre mon masque chirurgical ?



Avant de le mettre :

01. Avant de toucher le masque, lavez-vous les mains avec de l'eau et du savon ou une solution hydro-alcoolique.
02. Inspectez le masque et assurez-vous qu'il n'y a pas de trous, déchirures ou dégradations.
03. Il est recommandé de porter le masque sur une peau nue, en évitant le contact avec les cheveux.
04. Ne modifiez jamais le masque de quelque façon que ce soit.

Pour le mettre :

01. Tournez le masque dans la bonne direction (bord rigide en haut, face blanche vers vous).
02. Posez-le sur votre visage.
03. Faites passer les boucles autour de vos oreilles (masques à boucles aux oreilles), ou attachez la partie supérieure (masques à lanières élastiques ou à attaches à nouer en haut et en bas).
04. Ajustez la bande pour le nez
05. Attachez la partie inférieure si nécessaire (masques à lanières élastiques ou à attaches à nouer en haut et en bas).
06. Ajustez le masque de façon à recouvrir le nez, la bouche et que le bord inférieur recouvre votre menton.

Lorsque vous le portez :

01. Évitez de le toucher et de le déplacer.
02. Ne le mettez jamais en position d'attente sur le front ou sur le menton.

Il faut changer le masque :

01. Quand vous avez porté le masque 4h.
02. Quand vous souhaitez boire ou manger.
03. Quand il devient difficile de respirer.
04. Si le masque s'humidifie.
05. Si le masque est endommagé.
06. Si le masque est déformé et ne tient plus correctement contre votre visage.

Pour l'enlever :

01. Lavez-vous les mains avec de l'eau et du savon ou de la solution hydro-alcoolique.
02. Décrochez les lanières pour décoller le masque de votre visage ou dénouez les nœuds, puis enlevez le masque en le maintenant par les attaches du haut.
03. Vous ne devez l'enlever qu'en touchant les bords, les attaches ou les boucles. Ne touchez pas la partie qui couvre votre bouche et votre nez.
04. Jetez-le tout de suite dans une poubelle qui se ferme.
05. Pour terminer : lavez-vous à nouveau les mains avec de l'eau et du savon ou de la solution hydro-alcoolique

Photos du produit



Photo 1 masque à plat:

- Face extérieure
- Face intérieure



Photo 2 masque ouvert:

- Face extérieure
- Face intérieure

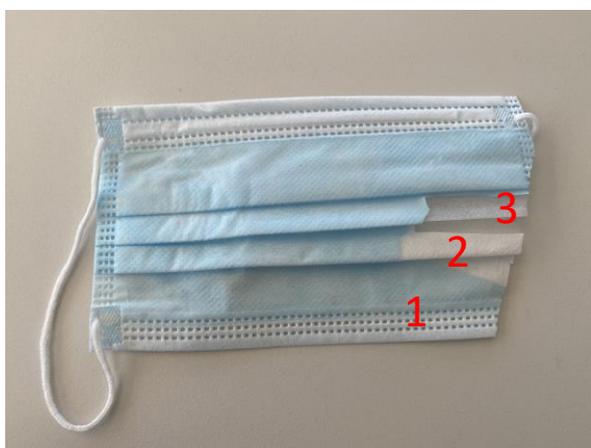


Photo 3 masque 3 plis:

- Couche 1: polypropylène non tissé
- Couche 2: Meltblown
- Couche 3: polypropylène non tissé

Déclaration CE

EC Certificate



**Production Quality Assurance
MDD Annex V**

Registration No.: DD 2180495-1

Manufacturer: Sunsmmed Protective Products Ltd.
No. 18, Industrial Park, Maozui Town
Xiantao City,
433000 Hubei
P.R. China

Products: Aspects of manufacture concerned with securing and maintaining sterile conditions:
Sterile Surgical Caps, Sterile Surgical Face Masks, Sterile Surgical Gowns,
Sterile Bed Protections, Sterile Surgical Drapes, Sterile Surgical Packs

Replaces Approval, Registration No.: DD 60111758 0001

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 15095978 009

Effective date: 2020-12-24

Expiry date: 2024-05-26

Issue date: 2020-12-24



Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

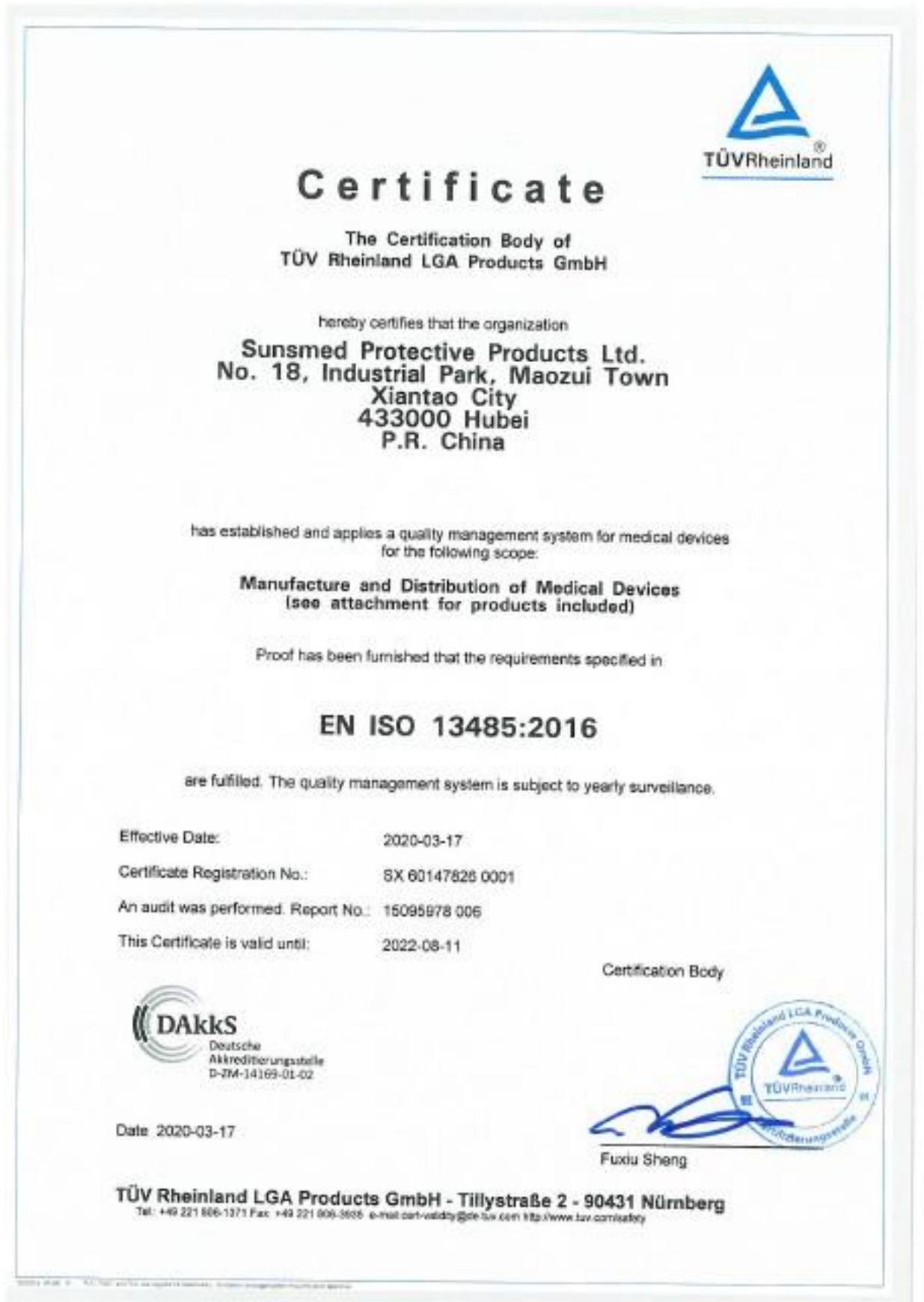
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Déclaration de conformité du fabricant

CE		DECLARATION OF CONFORMITY		CE	
Regarding Medical Device Regulation (EU) 2017/745					
Manufacturer:	Sunsmed Protective Products Ltd.				
Address:	No.18,Industrial Park, Maozui Town, XiantaoCity, 433000, Hubei Province, China				
EC Representative:	SUNGO Europe B.V.				
Address:	Olympisch Stadion 24, 1076DE Amsterdam, Netherlands				
Product Name:	Disposable Medical Face Mask				
Model:	S-203IIR				
SRN:	/		Basic UDI-DI:	(01)06973296770015	
Classification:	Class I				
Rule:	Rule 1, Annex VIII, Regulation (EU) 2017/745				
Conformity Assessment Procedure:	Annex II+III of Regulation (EU) 2017/745				
We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards.					
EN ISO 14971: 2012					EN ISO 15223-1: 2016
EN 1041:2008+A1:2013					ISO 10993-1: 2018
EN ISO 10993-5: 2009					EN ISO 10993-10: 2013
EN 14683:2019+AC:2019					
<i>For and on behalf of</i> SUNSMED PROTECTIVE PRODUCTS LIMITED					
Signature:	仙桃盛美工贸有限公司				
Name / Position:	孙娜 Sun Na General Manager				
<i>Authorized Signature(s)</i>					
Date of Issue :	2020/11/13				
Expiry date:	2024/5/24				
Place:	Xian tao / China				

ISO13485 de l'usine 1/2



ISO13485 de l'usine 2/2

		
TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg		Doc.: 1/1, Rev.: 0
Attachment to Certificate		
Registration No.:	SX 60147826 0001	
Report No.:	15095978 006	
Organization:	Sunsméd Protective Products Ltd. No. 18, Industrial Park, Maozui Town Xiantao City 433000 Hubei P.R. China	
Scope:	Products: <ul style="list-style-type: none">- Surgical Caps- Non Woven Face Masks- Surgical Gowns- Isolation Gowns- Coveralls- Sleeve Protectors- Shoe Covers- Bed Protections- PE Plastic Aprons- Surgical Drapes- Surgical Packs	
		Certification Body
		 
Date: 2020-03-17		Fuxiu Sheng

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SUNSMED PROTECTIVE PRODUCTS LTD.
INDUSTRIAL PARK, MAOZUI TOWN, XIANTAO CITY, HUBEI PROVINCE, 433000, CHINA

The following samples were submitted and identified on behalf of the client as:

MEDICAL FACE MASK

SGS Case No. : CA320202730679
Lot No. / Batch Code : NOT PROVIDED
Sample Description : BLUE MASK
Quantity Submitted : 100 PCS
Manufacturer : SUNSMED PROTECTIVE PRODUCTS LTD.
Country of Origin : CHINA
Sample Receiving Date : JUL 22, 2020
Test Performing Date : JUL 22, 2020 TO AUG 18, 2020

Test Requested : Please refer to the result summary.

Test Method & Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks	PASS (Level 3)

Signed for and on behalf of
SGS Hong Kong Ltd.

Au Kam Chi, Gigi
Technical Manager

Signed for and on behalf of
SGS Hong Kong Ltd.

Tsang Chuk Hai
Senior Microbiologist

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ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks

Scope : This specification covers testing and requirements for materials used in the construction of medical face masks that are used in providing healthcare services such as surgery and patient care. This specification provides for the classification of medical face mask material performance.

Number of Specimen : 100 pcs of complete product

Clause	Test Items/requirement	Test Result Summary
5	Classification	See Table 1
6	Requirements	
6.1	The properties of the medical face mask material shall conform to the specifications requirements in Table 1, as tested in accordance with Section 9. ^Bacterial filtration efficiency (ASTM F2101) ^Differential pressure (EN 14683:2019 Annex C) ^Sub-Micron Particulate Filtration (ASTM F2299)	> 98% < 6.0 mm H ₂ O/cm ² > 98%
6.2	Resistance to penetration by synthetic blood (ASTM F1862) ^Flammability 16 CFR Part 1610	Penetration not seen at 160 mm Hg Class 1

Note:

- ^A Results of compliance for tests requested is justified according to decision rule based on the non-binary statement with guard band (is equal to the expanded measurement uncertainty with a 95% coverage probability, $w = U_{95}$) as stated in ILAC-G8:09/2019 Clause 4.2.3.
"Pass - The measured values were observed in tolerance at the points tested. The specific false accept risk is up to 2.5%."
"Fail - One or more measured values were observed out of tolerance at the points tested". The specific false reject risk is up to 2.5%.

Table 1 Medical Face Mask Material Requirements by Performance Level

Characteristics	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier
Bacterial filtration efficiency, %	≥ 95	≥ 98	≥ 98
Differential pressure, mm H ₂ O/cm ²	< 5.0	< 6.0	< 6.0
Sub-micron particulate filtration efficiency at 0.1 micron, %	≥ 95	≥ 98	≥ 98
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result [#]	80	120	160
Flame spread	Class 1	Class 1	Class 1

[#] - An acceptable quality limit of 4.0 % is met for a single sampling plan when 29 or more of the 32 tested specimens show "pass" results.

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Result 1 Bacterial filtration efficiency ASTM F2101-19

Test Side : White colour (Inside)
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Dimensions of test specimen : 145 mm x 94 mm
 BFE Test Area : 49 cm²
 BFE Flow Rate : 28.3 l/min
 Test bacteria : Staphylococcus aureus ATCC 6538
 Mean Particle Size : 2.8 µm
 Positive Control Average : 1.9 x 10³ CFU
 Negative Monitor Count : < 1 CFU

Test Specimen	Percent BFE (%)
1	99.9
2	99.9
3	99.9
4	99.9
5	99.9

Note: Plate count total for each stage can be provided upon request.

Result 2 Differential pressure EN14683:2019+AC:2019 Appendix C

Test Side : White colour (Inside)
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Test Area : 4.9 cm²
 Flow Rate : 8 l/min

Test Location	ΔP (mm H ₂ O/cm ²)				
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5
Top Centre	3.8	4.4	4.1	4.4	4.2
Centre	4.2	4.5	4.8	4.2	4.2
Bottom Centre	4.2	4.2	4.1	3.9	4.4
Centre Left	4.5	4.1	4.1	3.8	3.9
Centre Right	3.9	4.5	4.2	4.0	4.7
Average	4.1	4.3	4.2	4.1	4.3

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Result 3 Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres (ASTM F2299/F2299M-03 (Reapproved 2017))

Test Side : Blue colour (Outside)
 Pre-Conditioning : Minimum of 4 hours at 21±3°C and 30-50±5% R.H.
 Test Condition : 21±3°C and 50±5% R.H.
 Test Area : 41.81 cm²
 Flow Rate : 38.4 L/min
 Face Velocity : 15.4 cm/s
 Particle Size : 0.1 µm
 Average Filtration Efficiency : 98.80%
 Standard Deviation : 0.001

Test Specimen	Pressure Drop (inH ₂ O)	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	0.473	8474	418597	98.45
2	0.473	5769	393439	98.53
3	0.473	5353	405309	98.68
4	0.473	4927	401526	98.77
5	0.473	5966	419375	98.58

Note: The procedure incorporated a non-neutralized challenge. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks.

Result 4 Resistance to penetration by synthetic blood ASTM F1862/F1862M-17

Test Side : Blue colour (Outside)
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Test Condition : 21±5°C and 85±10% R.H.
 Test Pressure : 180 mmHg
 No of Test Specimen Tested : 32
 No of Test Specimen Passed : 31

Test Specimen #	Synthetic Blood Penetration
1, 3-32	None Seen
2	Yes

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Result 5 Flammability Test of Clothing Textiles (16 CFR Part 1610 - October 20, 2008 Edition)

Sample : Fabric cut from submitted sample
Fabric Surface : Plain (Face)
Test Specimen Direction : Length

As Received		
	Flame Spread (sec.)	Burn Code
(1)	--	IBE
(2)	--	IBE
(3)	--	IBE
(4)	--	IBE
(5)	--	IBE
Flammability Classification:		Class 1
Requirement:		Class 1

Remarks:

- Class 1 – Normal Flammability**
 Class 1 textiles exhibit normal flammability and are acceptable for use in clothing.
 Test Criteria for plain surface textile fabric:
 (A) There are no burn times; or
 (B) There is only one burn time and it is equal to or greater than 3.5 seconds; or
 (C) The average burn time of two or more specimens is equal to or greater than 3.5 seconds.
- Disposable fabrics and garments shall not apply to be refurbished before testing.

Burn Code Description:

IBE = Ignited, but extinguished

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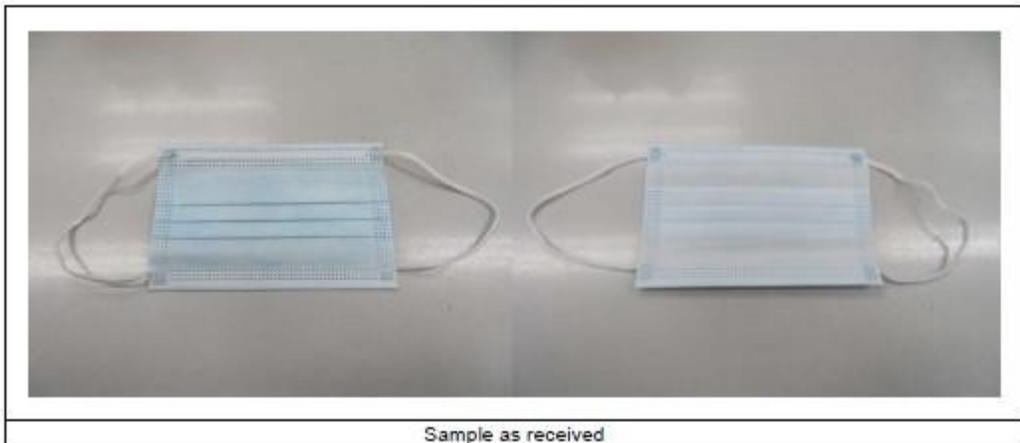
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Photo Appendix



*** End of Report ***

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