

DOSSIER DE CONFORMITÉ

MASQUE CHIRURGICAL
TYPE IIR

CATÉGORIE DU PRODUIT :

MEDICAL DEVICE CLASS 1

RÉFÉRENCE DU PRODUIT :

LM2504 / LM2504-XS

DESCRIPTION :

MASQUE CHIRURGICAL TYPE IIR



JSE SOURCING

by JSE INVEST



NOM DU PRODUIT : MASQUE CHIRURGICAL TYPE IIR

REFERENCE DU PRODUIT : LM2504

HS CODE : 6307900000

PRÉSENTATION DU PRODUIT

Masques chirurgicaux à usage unique, non stériles (Type IIR).

Masque destiné à empêcher les germes présents dans les voies respiratoires de sortir et de contaminer l'entourage. Permet de limiter la transmission des virus aéroportés par les personnes infectées. Le masque LM2504 est résistant à la projection pour réduire l'exposition potentielle du porteur au sang et aux liquides corporels

CONFORMITÉ DU PRODUIT

Masques conformes aux dispositions réglementaires :

- conformes à la norme harmonisée EN 14683 : 2019 (Type IIR) qui évalue l'efficacité du matériau filtrant dans le sens de l'expiration.
- conformes à la Directive européenne 93/42/CEE du Conseil, du 14 juin 1993 relative aux dispositifs médicaux.
- Marquage CE.

CARACTÉRISTIQUES TECHNIQUES

MASQUES NON STÉRILES A USAGE UNIQUE

EFFICACITÉ DE FILTRATION BACTÉRIENNE : BFE \geq 98 %

RESPIRABILITÉ : $<$ 60 PA/CM²

BIOBURBEN : $<$ 30 CFU/G

DIMENSIONS : 9.5 X 17.5CM

ÉPAISSEUR : 65G /M²

COUCHES : 3

DURÉE DE VIE : 24 MOIS

UTILISATION UNIQUE : EFFICACE 4H

COMPOSITION DU MASQUE

- **PREMIÈRE COUCHE** : PP NON WOVEN SPUNBOND 20 GR/M2
 - **DEUXIÈME COUCHE** : MELT BLOWN FABRIC 25 GR/M2
 - **TROISIÈME COUCHE** : PP NON WOVEN SPUNBOND 20 GR/M2
-
- Un nez intégré pour une meilleure étanchéité.
 - Une couche interne et externe ultra déperlante.
 - Avec élastiques.
 - Sans latex.

INSTRUCTIONS D'UTILISATION



- 1 Tirez et déployez le masque à deux mains pour vous assurer que le pince-nez est vers le haut.



- 2 Tenez le masque sur le visage et tirez la bande élastique jusqu'aux oreilles.



- 3 Appuyez sur le clip du nez pour épouser la forme du nez.



- 4 Durée de vie : 4h. Ne pas réutiliser.

PRÉCAUTIONS D'EMPLOIS

LIMITES D'UTILISATION : Dispositif à usage unique. Utiliser 2 à 3 masques par jour par personne.

STOCKAGE : Les masques ont une durée de conservation limitée et doivent être stockés dans un endroit à l'abri de la lumière et de l'humidité entre 10 et 25°C.

AVERTISSEMENT : Il est essentiel que le masque soit enlevé en dernier, après tout autre matériel de protection (gants, surblouse, lunettes de protection) afin de limiter au maximum tout risque de contamination. Les mains doivent impérativement être désinfectées après le retrait du masque.

RENSEIGNEMENTS FABRICANT

NOM DU FABRICANT : JSE SOURCING

ADRESSE DU SIÈGE SOCIAL : 29 avenue Anatole France, 94220 Charenton le Pont FRANCE

SIREN: 881 880 660

TVA intracom: FR69881880660

EORI : FR88188066000017

BOÎTE

QUANTITÉ
50 pièces / boîte

DIMENSIONS BOITE
18 x 10 x 7,7 cm

TRADUIT EN 6 LANGUES :

Anglais,
Français,
Allemand,
Espagnol,
Portugais,
Italien.

CARTON

QUANTITÉ
40 boîtes/ carton
2 000 pcs/ carton

DIMENSIONS DU CARTON
52 x 38 x 30

POIDS
7,8 KG/ carton

- 1 MASQUES CHIRURGICAUX, 3 PLYS
• Un nez intégré pour une meilleure étanchéité
• Efficiéncia de filtraçáo bacteriana (BFE > 98%) e baixa resistência respiratória
- 2 MASQUES MEDICALS, 3 PLYS
• Alto eficiencia de filtración bacteriana (BFE > 98%) e baixa resistencia à respiração
• Um pedaço de nariz integrado para melhor vedação
- 3 MASCARILLAS MEDICAS, 3 DOBRAS
• Alta eficiencia de filtración bacteriana (BFE > 98%) y baja resistencia respiratoria
• Una pieza de nariz integrada para un mejor sellado
- 4 MEDIZINISCHE GESICHTSMASKEN, 3 FALTEN
• Hohe Bakterien Filtrationseffizienz (BFE > 98%) und geringen Atemwiderstand
• Innen- und Außenschicht ultra wasserabweisend
- 5 MEDICAL FACE MASKS, 3 PLY
• High Bacterial Filtration Efficiency (BFE > 98%) and low breathing resistance
• One integrated nose-piece for better sealing
- 6 MASCHERE MEDICHE, 3 PIEGHE
• Efficiéncia de filtraçáo bacteriana elevada (BFE > 98%) et una faible resistência respiratória
• Un nez intégré et externe ultra déperlante

MASQUE CHIRURGICAL TYPE 2R

DISPOSITIF MEDICAL

BFE > 98%

RÉSISTANT AUX ÉCLABOUSSURES

EN ACCORD AVEC
CONFORMANCE WITH
DE ACORDO COM
IN ÜBEREINSTIMMUNG MIT
ACCORDO CON

CE EN 14683:2019 IIR
93/42/CEE

INSTRUCTIONS D'UTILISATION - INSTRUCCIONES DE USO - INSTRUZIONI PER L'USO - GEBRAUCHSANWEISUNG - INSTRUÇÕES DE USO - INSTRUÇÕES DE USO

- Tirez et déployez le masque à deux mains pour vous assurer que le pince-nez est vers le haut.**
Pull and extend the mask with two hands to be sure the nose clip is upward.
Ziehen und ziehen Sie die Maske mit zwei Händen heraus, um sicherzustellen, dass der Nasenclip nach oben zeigt.
Tire y extiéndalo la máscara con los dos manos para asegurarse de que el clip nasal está hacia arriba.
Puxe e estenda a máscara com as duas mãos para garantir que o clipe nasal esteja voltado para cima.
Tirare ed estendere la mascherina con due mani per assicurarsi che il clip nasale sia verso l'alto.
- Tenez le masque sur le visage et tirez la bande élastique jusqu'aux oreilles.**
Hold the mask on the face and pull the elastic band to the ears.
Halten Sie die Maske auf das Gesicht und ziehen Sie das Gummiband an die Ohren.
Sostenga la máscara en la cara y tire de la banda elástica hacia los oídos.
Segure o máscara no rosto e puxe o elástico para os ouvidos.
Tieni la mascherina sul viso e tira l'elastico sulle orecchie.
- Appuyez sur le clip du nez pour épouser la forme du nez.**
Press the nose clip against the bridge of the nose.
Drücken Sie das Nasenclip gegen die Form der Nase anzuweisen.
Presione el clip nasal para que se ajuste a la forma de la nariz.
Pressione o clipe para ajustar o formato do nariz.
Premi il clip per adattarlo alla forma del naso.
- Durée de vie : 4h. Ne pas réutiliser. Jeter le masque dans une poubelle fermée après usage.**
Do not reuse. Lifetime: 4h. Discard the mask in a closed bin after use.
Lebensdauer: 4h. Nicht wiederverwenden. Entsorgen Sie die Maske nach Gebrauch in einem geschlossenen Behälter.
Vida útil: 4h. No reutilizar. Descarte la máscara en un contenedor cerrado después de usar.
Tempo de vida: 4h. Não reutilize. Descarte a máscara em uma lixeira fechada após o uso.
Durata della vita: 4h. Non riutilizzare. Scaricare la mascherina in un contenitore chiuso dopo l'uso.

MASQUES CHIRURGICAUX TYPE 2R

MASQUES A USAGE UNIQUE, A STOCKER DANS UN ENDROIT PROPRE, SEC ET A L'ABRI DE LA LUMIERE.

- 1 SURGICAL MASKS 3 PLY TYPE IIR
SINGLE USE MASKS, STORE IN A CLEAN, DRY PLACE PROTECTED FROM LIGHT.
- 2 MEDIZINISCHE GESICHTSMASKEN 3 FALTEN TYPE IIR
EINZELNUTZENDE MASKEN AN EINEM SAUBEREN, TROCKENEN UND LICHTGESCHÜTZTEN ORT AUFBEWAHREN.
- 3 MASCARILLAS MEDICAS 3 DOBRAS TYPE IIR
MÁSCARAS DE USO INDIVIDUAL, ALMACENAR EN UN LUGAR LIMPIO, SECO Y PROTEGIDO DE LA LUZ.
- 4 MASCARAS MEDICAS 3 PLEGUES TYPE IIR
MÁSCARAS DE USO ÚNICO, GUARDE EM LOCAL LIMPO E SECO, PROTEGIDO DA LUZ.
- 5 MASCHERE MEDICHE 3 PIEGHE TYPE IIR
MASCHERE USO SINGOLO, CONSERVARE IN LUOGO PULITO, ASCIUTTO E AL RIPARO DALLA LUCE.

JSE Medical

50 PIÈCES

50 PIECES

JSE Medical

- RÉSISTANT AUX ÉCLABOUSSURES**
SPLASH PROOF
SPRITZFEST
A PRUEBA DE SALPICADURAS
PROVA DE AGUA
A PROVA DI SPRUZZI
- FACILE À PORTER**
EASY WEAR
EINFACHE TRAGUNG
FÁCIL DE USAR
DESGASTE FÁCIL
FACILE DA INDOSSARE
- FILTRAGE EFFICACE**
EFFICIENT FILTERING
EFFIZIENTE FILTERUNG
FILTRADO EFICIENTE
FILTRO EFICIENTE
FILTRAZIONE EFFICIENTE
- RESPIRATION SAINNE**
FRESH BREATH
FRISCHER ATEM
ALIENTO FRESCO
HÁLITO FRESCO
ALITO FRESCO

PRODUIT: Masque chirurgical à usage unique
REFERENCE: LM2504
LOT: lot L.TLM250429082020
Norme: CE EN 14683: 2019 IIR 93/42/CEE
DATE D'EXPIRATION: 09/2022
FABRICANT / IMPORTATEUR / DISTRIBUTEUR : JSE SOURCING au capital de 1 200 000€
ADRESSE: 29 avenue Anatole France, 94220 Charenton le Pont FRANCE
info@jsesourcing.com / www.jsesourcing.com / 0180915383
Made in China

7 141261 459251

BOÎTE

QUANTITÉ
50 pièces / boîte

DIMENSIONS BOITE
16 x 10 x 7,7 cm

TRADUIT EN 6 LANGUES :
Anglais,
Français,
Allemand,
Espagnol,
Portugais,
Italien.

MASQUE CHIRURGICAL PÉDIATRIQUE TYPE 2R
MASQUES A USAGE UNIQUE, À STOCKER DANS UN ENDROIT PROPRE, SEC ET À L'ABRI DE LA LUMIÈRE.

1 PEDIATRIC SURGICAL MASK 3 PLY TYPE IIR
SINGLE USE MASKS, STORE IN A CLEAN, DRY PLACE PROTECTED FROM LIGHT

2 KINDERCHIRURGISCHE MASKE 3 FALTEN TYPE IIR
EINZELNUTZENDE MASKEN AN EINEM SAUBEREN, TROCKENEN UND LICHTGESCHÜTZTEN ORT AUFBEWAHREN.

3 MASCARILLA QUIRÚRGICA PEDIÁTRICA 3 DOBRAS TYPE IIR
MASCARAS DE USO INDIVIDUAL, ALMACENAR EN UN LUGAR LIMPIO, SECO Y PROTEGIDO DE LA LUZ.

4 MASCARA CIRÚRGICA PEDIÁTRICA 3 PLEIEGUES TYPE IIR
MASCARAS DE USO ÚNICO, GUARDE EM LOCAL LIMPO, SECO, PROTEGIDO DA LUZ.

5 MASCHERA CHIRURGICA PEDIATRICA 3 PIEGHE TYPE IIR
MASCHERE USO SINGOLO, CONSERVARE IN LUOGO PULITO, ASCIUTTO E AL RIPARO DALLA LUCE.

XS
50 PIÈCES
50 STÜCK
50 PIEZAS
50 PEZZI



1 MASQUES CHIRURGICAUX, 3 PLYS
• Efficacité de filtration bactérienne élevée (BFE >= 98%) et une faible résistance respiratoire
• Un nez intégré pour une meilleure étanchéité
• Couche interne et externe ultra-déperlante

2 MEDICAL FACE MASKS, 3 PLY
• High bacterial filtration efficiency (BFE >= 98%) and low breathing resistance
• one integrated nose-piece for better sealing
• internal and external layer ultra water repellent

3 MEDIZINISCHE GESICHTSMASKEN, 3 FALTEN
• Hohe Bakterienfiltrationseffizienz (BFE >= 98%) und geringen Atemwiderstand
• Ein integriertes Nasenstück für eine bessere Abdichtung
• Innen- und Außenschicht ultra wasserabweisend

4 MASCARILLAS MÉDICAS, 3 DOBRAS
• Alta eficiencia de filtración bacteriana (BFE >= 98%) y baja resistencia a respiratoria
• Una pieza de nariz integrada para un mejor sellado
• Capa interna y externa ultra repelente al agua

5 MÁSCARAS MÉDICAS, 3 PLEIEGUES
• Alta eficiencia de filtración bacteriana (BFE >= 98%) e baixa resistência à respiração
• Uma peça de nariz integrada para melhor vedação
• Camada interna e externa ultra repelente à água

6 MASCHERE MEDICHE, 3 PIEGHE
• Efficacia di filtrazione batterica (BFE >= 98%) e bassa resistenza respiratoria
• Un nosello integrato per una migliore tenuta
• Strato interno ed esterno ultra idrorepellente

MASQUE CHIRURGICAL PÉDIATRIQUE TYPE 2R
DISPOSITIF MEDICAL
CE EN 14683:2019 IIR
93/42/CEE

XS 8-15ANS
BFE > 98%
RÉSISTANT AUX ÉCLABOUSSURES

EN ACCORD AVEC
COMPLIANCE WITH
DE ACUERDO CON
DE ACORDO CON
IN ÜBEREINSTIMMUNG MIT
IN ACCORDO CON



50 PIÈCES



- RÉSISTANT AUX ÉCLABOUSSURES**
SPLASH PROOF
SPRITZFEST
A PRUEBA DE SALPICADURAS
PROVA DE AGUA
A PROVA DI SPRUZZI
- FACILE À PORTER**
EASY WEAR
EINFACHE TRAGUNG
FÁCIL DE USAR
DESGASTE FÁCIL
FACILE DA INDOSSARE
- FILTRAGE EFFICACE**
EFFICIENT FILTERING
EFFIZIENTE FILTERUNG
FILTRADO EFICIENTE
FILTRO EFICIENTE
FILTRAZIONE EFFICIENTE
- RESPIRATION SAINE**
FRESH BREATH
FRISCHER ATEM
ALIENTO FRESCO
HALITO FRESCO
ALITO FRESCO

PRODUIT: Masque chirurgical pédiatrique à usage unique
REFERENCE: LM2504-XS
LOT: lot LTLM2504XS29082020
Norme: CE EN 14683:2019 IIR 93/42/CEE
DATE D'EXPIRATION: 09/2022
FABRICANT / IMPORTATEUR / DISTRIBUTEUR : JSE SOURCING au capital de 1 200 000€
ADDRESS: 29 avenue Anatole France, 94220 Charenton le Pont FRANCE
info@jsesourcing.com / www.jsesourcing.com / 0180915383
Made in China



CARTON

QUANTITÉ
40 boîtes/ carton
2 000 pcs/ carton

DIMENSIONS DU CARTON
52 x 33 x 34 cm

POIDS
7,5 KG/ carton

INSTRUCTIONS D'UTILISATION / **USAGE INSTRUCTIONS** / **GERÄUCHANWEISUNG** / **INSTRUCCIONES DE USO** / **INSTRUÇÕES DE USO** / **ISTRUZIONI PER L'USO**

- Tirez et déployez le masque à deux mains pour vous assurer que le pince-nez est vers le haut.**
Pull out and extend the mask with two hands to be sure the nose clip is upward.
Ziehen und ziehen Sie die Maske mit zwei Händen heraus, um sicherzustellen, dass der Nasenclip nach oben zeigt.
Tire y extendiendo la máscara con los dos manos para asegurarse de que el clip nasal esté hacia arriba.
Puxe e estendendo a máscara com os dois mãos para garantir que o clipe do nariz esteja voltado para cima.
Tirare ed estendere la mascherina con due mani per assicurarsi che il clip nasale sia verso l'alto.
- Tenez le masque sur le visage et tirez la bande élastique jusqu'aux oreilles.**
Hold the mask on the face and pull the elastic band to the ears.
Halten Sie die Maske auf das Gesicht und ziehen Sie das Gummiband an die Ohren.
Sostenga la máscara en la cara y tire de la banda elástica hacia los oídos.
Segure o máscara no rosto e puxe o elástico para os ouvidos.
Tieni la mascherina sul viso e tira l'elastico sulle orecchie.
- Appuyez sur le clip du nez pour épouser la forme du nez.**
Press the nose clip to fit the shape of the nose.
Drücken Sie den Nasenclip auf die Nase an.
Presione el clip nasal para que se ajuste a la forma de la nariz.
Premi la clip per adattarla alla forma del naso.
- Durée de vie : 4h. Ne pas réutiliser. Jeter le masque dans une poubelle fermée après usage.**
Do not reuse. Lifetime: 4h. Discard the mask in a closed bin after use.
Lebensdauer: 4h. Nicht wiederverwenden. Entsorgen Sie die Maske nach Gebrauch in einem geschlossenen Behälter.
Vida útil: 4h. No reutilizar. Descarte la máscara en un contenedor cerrado después de usar.
Tempo de vida: 4h. Não reutilizar. Descarte a máscara em um recipiente fechado após o uso.
Durata della vita: 4h. Non riutilizzare. Scaricare la mascherina in un contenitore chiuso dopo l'uso.



ANNEXES

- DÉCLARATION DE CONFORMITÉ CE
- RAPPORT DE TEST - NORME DIRECTIVE EN14683:2019 (TYPE IIR)



DÉCLARATION DE CONFORMITÉ

Le fabricant, importateur, distributeur, soussigné :

JSE SOURCING 29 AVENUE ANATOLE FRANCE,
94220 CHARENTON LE PONT (FRANCE)

déclare que le produit :

Denomination du produit : MASQUE CHIRURGICAL TYPE IIR

Référence du produit : LM2504 / LM2504-XS

est conforme aux dispositions réglementaires définies par les Directives Européennes et normes harmonisées. Conformément à l'Annexe VII de la Directive 93/42/CEE, JSE Invest déclare avoir à sa disposition l'ensemble de la documentation technique incluant la déclaration CE de conformité et les rapports de test, et les tiens à disposition des autorités nationales pour une durée d'au moins cinq ans.

Les rapports de test n°SL52035285180501TX, effectués par le Laboratoire de Test SGS, ont permis de certifier la conformité du produit LM-2504 / LM2504-XS avec la **norme CE EN 14683:2019 de type IIR de la Directive** relative aux Masques à usage médical - Exigences et méthodes d'essai.

Catégorie : Dispositif médical

Directive : 93/42/CEE

Normes : CE EN 14683:2019

Classification du produit : classe 1 DM

Fait à Paris,

Le 27 Aout 2020 par

Nom et qualité du signataire :

Simon MECHALY
Président

Signature :



JSE SOURCING
Adresse postale :
29 Avenue Anatole France,
94220 Charenton-le-Pont
Tel : +33 (0)1 80 91 53 83
Mail : info@jsesourcing.com





中国认可
国际互认
检测
TESTING
CNAS L0599

Test Report

SL52035285180501TX

Date: August 27, 2020

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JSE SOURCING
29 AVENUE ANATOLE FRANCE 94220 CHARENTON LE PONT FRANCE

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A)Surgical mask EN14683:2019 IIR

Buyer : JSE SOURCING
Brand : JSE MEDICAL
Composition : (A)nonwoven fabric+Melt-blown fabric+nonwoven fabric
Sample Color : (A)Blue
Style No. : LM2504 / LM2504-XS
Lot No. : LTLM250410082020

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Aug 06, 2020
Testing Period : Aug 06, 2020 - Aug 27, 2020
Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)



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Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com
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中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64968763 e sgs.china@sgs.com

Member of the SGS Group (SGS SA)

Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial Filtration Efficiency (BFE)

(EN 14683:2019+AC:2019 Annex B)

Sample: A
 Test Side : Inside
 Test Area : Approximately 60 cm²
 Flow Rate : 28.3 L/min
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Dimensions of test specimen : ~176mm x 155mm
 Positive Control Average : 1969.5 CFU
 Negative Monitor Count : < 1 CFU
 Mean Particle Size : 3.0 ±0.3µm
 Test bacteria : Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
Bacterial Filtration Efficiency (BFE)	1	99.9%
	2	99.9%
	3	99.9%
	4	99.9%
	5	99.9%

Remark:

1) Performance Requirement: Type I ≥95%, Type II ≥98%, Type IIR ≥98%

The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL (Acceptable Quality Level) of 4%.



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 Attention: To check the authenticity of testing / inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com
 3rd Building, No. 889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgs.com.cn
 中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

Test Report

SL52035285180501TX

Date: August 27, 2020

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Clause 5.2.3 Breathability

(EN 14683 :2019+AC:2019 Annex C)

Sample: A

Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks

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

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm ²)	The average value for each test specimen (Pa/cm ²)
1	1-1	56.9	56
	1-2	53.0	
	1-3	54.2	
	1-4	58.5	
	1-5	57.6	
2	2-1	56.9	57
	2-2	55.2	
	2-3	58.1	
	2-4	56.8	
	2-5	59.7	
3	3-1	51.9	55
	3-2	53.3	
	3-3	55.7	
	3-4	59.6	
	3-5	56.3	
4	4-1	58.9	57
	4-2	59.6	
	4-3	52.6	
	4-4	59.3	
	4-5	56.8	
5	5-1	59.2	58
	5-2	54.4	
	5-3	59.8	
	5-4	59.2	
	5-5	57.6	

Remark:

- 1) Performance Requirement: Type I < 40 Pa/cm², Type II < 40 Pa/cm², Type IIR < 60 Pa/cm²
- 2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL (Acceptable Quality Level) of 4%.



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Clause 5.2.4 Splash Resistance

(ISO 22609 :2004)

Sample: A

Test Blood Pressure

: 16.0kPa

Pre-Conditioning

: Minimum of 4 hours at 21±5°C and 85±5% R.H.

Distance of the mask to the tip of cannula

: 300±10mm

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:			32		
Overall result:			Acceptable		

Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
- 2) Test was conducted within 60s after removal from conditioning chamber.
- 3) 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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Test Report

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Date: August 27, 2020

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Clause 5.2.5 Microbial Cleanliness

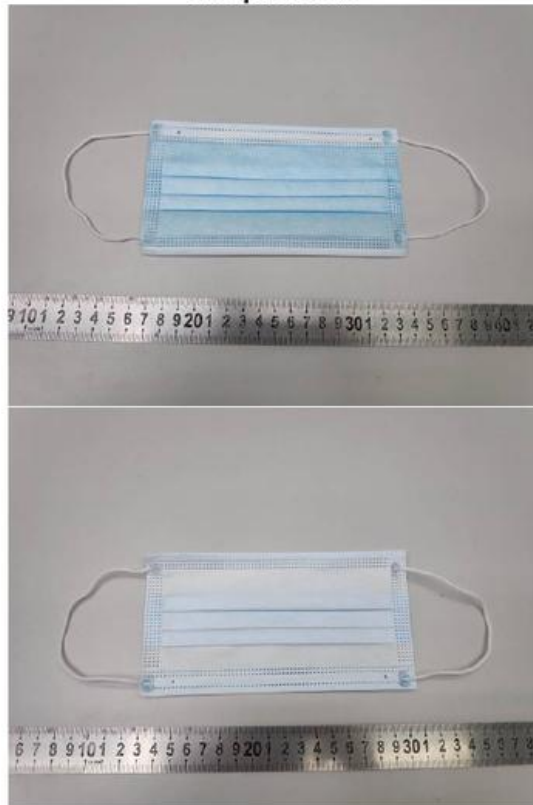
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	2.76	78	28.26
2#	2.74	66	24.09
3#	2.76	36	13.04
4#	2.77	63	22.74
5#	2.79	12	4.30

Remark: Performance Requirement: Type I ≤ 30 CFU/g, Type II ≤ 30 CFU/g, Type IIR ≤ 30 CFU/g

Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report



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