

Mascarilla Polipropileno Quirúrgica Con Gomas.

CARACTERÍSTICAS DEL PRODUCTO

- Mascarilla de Polipropileno Rectangular de 3 capas, con 3 pliegues que provocan un mejor acople anatómico. Con tira moldeable en la parte superior para una mejor sujeción nasal y con elástico de ajuste para un mejor acople en ambos pabellones auditivos.
- Producto de un solo uso, NO REUTILIZAR
- Tiempo máximo de uso 4 horas.
- Mascarilla Quirúrgicas Tipo IIR



PROPIEDADES FÍSICAS

- Materia prima
Primera Capa: Polipropileno (PP) con una densidad de 25 grs/m³.
Segunda Capa: MeltBlown con una densidad de 25 grs/m³.
Tercera Capa: Polipropileno (PP) con una densidad de 25 grs/m³.
- Medidas: 17,5 x 9,5 cm
- Elástico de ajuste suaves para un ajuste confortable en ambos pabellones auditivos.

COLORES DISPONIBLES

Referencia	Color	Código EAN Caja	Código EAN Envase
64702	Azul ●	8 436045 02743 6	8 436045 02744 3



Mascarilla Polipropileno Quirúrgica Con Gomas.

ALMACENAJE Y LOGÍSTICA:

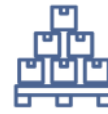
- Almacenar siempre en el embalaje original, en un lugar seco y a temperaturas oscilantes entre -2° y $+50^{\circ}$ (se aconseja siempre entre $+5^{\circ}$ y $+30^{\circ}$). No exponer directamente a la luz solar.
- Caja exterior con descripción completa, pictogramas informativos y código de barras
- Presentación: 40 envases de 50 unidades. Caja de 2000 mascarillas
- Medidas Caja: 52x38x30 cm



Envase:
50 unidades.



Caja:
40 envases



Palet:
36 cajas.

NORMATIVAS

- **Reglamento (EU) 2017/745** Relativa a Productos sanitarios (MDR).
Producto Sanitario Clase I
- **EN-14683:2019+AC:2019** Norma mascarillas Quirúrgica de
Eficacia de Filtración Bacteriana $\geq 98\%$
Respirabilidad/Presión Diferencial: $< 60\%$
Presión de Resistencia a las Salpicaduras: ≥ 16
Limpieza Microbiana/Carga Biológica ≤ 30 UFC/g
Certificado SGS: SL52115296627601TX
Laboratorio Acreditado por CNAS N^o: L0599
- **Producto 100 % Libre de Látex**





DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2016
EN ISO 20417: 2021
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 14683:2019+AC:2019 Type IIR

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-FM-10.
All the supporting documentation is retained at the premises of the manufacturer.
The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.
On behalf of SUNGO Europe office, we confirmed we are EU REP of the company who issue this document.



[Handwritten Signature]

Authorized Signature (S)

Manufacturer

Name: FEIXI HONGWEI MEDICAL DEVICES CO., LTD

Address: 2nd Floor, Building 6, Junction of Chuangxin Ave and Changgu Rd, Economic Development Zone, Feixi County, Hefei City, Anhui, China

Product Information

Name: DISPOSABLE MEDICAL FACE MASK
Model: 12.5*7CM; 14.5*9.5CM; 17.5*9.5CM; 20*7CM
OR OTHER SIZE; WITH EAR-LOOP ELASTIC; WITH HEAD-LOOP ELASTIC; TIES-ON

GMDN: 35177

Basic UDI-DI: 697491661FM007J2

Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: *[Handwritten Signature]*

Date: 2021.8.23

Position: GM

Place: Anhui/China



FEIXI HONGWEI MEDICAL DEVICES CO., LTD
2ND FLOOR, BUILDING 6, ANHUI ANHENG PAPER AND PLASTIC PRODUCTS CO., LTD., JUNCTION OF
CHUANGXIN AVENUE AND CHANGGU ROAD, ECONOMIC DEVELOPMENT ZONE, FEIXI COUNTY, HEFEI
CITY, ANHUI PROVINCE

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

Sample Description : (A) Disposable Medical Face Mask
Sample Color : (A) blue
Claimed Type : TYPE IIR
Lot No. : HW202108002
Test Performed : Selected test(s) as requested by applicant
Sample Receiving Date : Aug 18, 2021
Testing Period : Aug 24, 2021 - Sep 07, 2021
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).

Comment:

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods	(A)
Clause 5.2 Performance Requirement	
Clause 5.2.2 Bacterial filtration efficiency (BFE)	M
Clause 5.2.3 Breathability	M
Clause 5.2.4 Splash Resistance	M
Clause 5.2.5 Microbial Cleanliness	M
Clause 5.2.6 Biocompatibility	EXCLUDED

Remark: M=Meet EN 14683:2019+AC:2019 Performance Requirement (Type IIR)
F=Below EN 14683:2019+AC:2019 Performance Requirement (Type IIR)

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)

SGS does not verify authenticity of any Brand/Trademark of products. Buyers must check if the product is genuine with the Brand/Trademark owner directly.



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.
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
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd. 3rd Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
Testing Center: 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 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 158mm
 Positive Control Average : 2473 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	99.8%
	3	99.9%
	4	99.8%
	5	99.9%

Remark:

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



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.
 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
 SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd. 3rd Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgs.com.cn
 Testing Center for Standards Technical Services (Shanghai) Co., Ltd. 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

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	48.4	46
	1-2	49.5	
	1-3	43.6	
	1-4	43.3	
	1-5	43.6	
2	2-1	45.9	45
	2-2	43.4	
	2-3	42.3	
	2-4	46.7	
	2-5	44.8	
3	3-1	46.7	47
	3-2	42.6	
	3-3	43.1	
	3-4	51.9	
	3-5	48.8	
4	4-1	55.1	49
	4-2	45.3	
	4-3	41.0	
	4-4	54.7	
	4-5	46.8	
5	5-1	46.9	46
	5-2	48.1	
	5-3	41.9	
	5-4	43.5	
	5-5	47.8	

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%.



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

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

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd. 3rd Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.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

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.



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.
 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
 SGS-CTE (Shanghai) Technical Services Co., Ltd. 3rd Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.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

Clause 5.2.5 Microbial Cleanliness

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

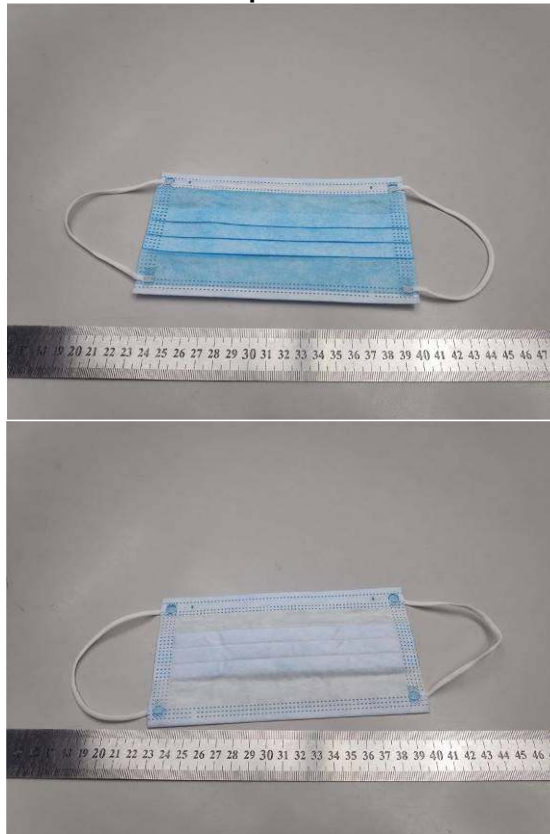
Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1	2.91	18.60	6.39
2	2.88	22.32	7.75
3	2.92	29.76	10.19
4	3.00	22.32	7.44
5	2.98	26.04	8.74

Recovery Efficiency : 80.4 %
Correction Factor : 1.2

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



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.
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
SGS Standards Technical Services (Shanghai) Co., Ltd. 3rd Building, No. 889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgs.com.cn
Testing Center: 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