MASCARILLA QUIRÚRGICA 3 CAPAS CON GOMAS TIPO IIR

Estas mascarillas cumplen con los requisitos del Reglamento (UE) 2017/745, relativo a los productos sanitarios, en Clase I, y la norma armonizada: EN 14683:2019+AC:2019, relativa a las mascarillas quirúrgicas. Requisitos y métodos de ensayo.

DESCRIPCIÓN Y CARACTERÍSTICAS

Mascarilla desechable de tres capas, fabricada con polipropileno. No estéril. Con clip nasal ajustable y sujeción mediante gomas elásticas. Disponible en color azul y en color verde. Tipo IIR, resistente a las salpicaduras.

La utilización principal prevista de las mascarillas quirúrgicas es proteger al paciente de los agentes infecciosos y, además, en determinadas circunstancias, proteger a quien lleva puesta la mascarilla contra las salpicaduras de líquidos potencialmente contaminados. Las mascarillas quirúrgicas pueden estar previstas también para que los pacientes y otras personas las lleven puestas para reducir el riesgo de propagación de infecciones, particularmente en situaciones epidémicas o pandémicas.

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	TEST ENSAYO	TEST STANDARD TIPO IIR	RESULTADO
EFICACIA DE FILTRACIÓN BACTERIANA (BFE) (%)	EN 14683:2019+AC:2019 (ANEXO B)	≥ 98	PASA
RESPIRABILIDAD O PRESIÓN DIFERENCIAL (Pa/cm^2)	EN 14683:2019+AC:2019 (ANEXO C)	< 60	PASA
Presión de resistencia a las salpicaduras (kPa)	EN 14683:2019+AC:2019 ISO 22609:2004	≥ 16.0	PASA
LIMPIEZA MICROBIANA (UFC/g)	EN 14683:2019+AC:2019 (ANEXO D)	≤ 30	PASA

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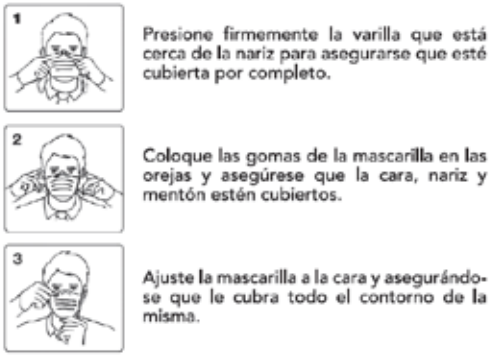
RECOMENDACIONES Y USO

- Se recomienda que se revise y se compruebe el producto antes de su uso, y de forma periódica durante su utilización.
- Para su conservación y almacenaje, deben de estar alejados de fuentes de calor y de focos de luz. Guardar en lugar fresco y seco.
- No exponer a altas temperaturas.



ESPECIFICACIONES TÉCNICAS Y OTROS DATOS DE INTERÉS

TALLA	**ÚNICA**	
DIMENSIONES	17,5 x 9,5 cm	
ESPESOR CAPAS	25*25*30 g/m^2	
REFERENCIA – COLOR AZUL	22355	
REFERENCIA – COLOR VERDE	22013	
EMBALAJE	CAJITA	CAJA
	50 UNIDADES	2.000 UNIDADES

LOGÍSTICA

DIMENSIONES CAJA (cm)			PESO	EUROPALET 1200 X 800				
LARGO	ANCHO	ALTO	CAJA	BASE	CAPAS	ALTURA	CAJAS	CAJITAS
52	38	34	8,7Kg (Aprox.)	4	4	1,52m	16	640

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DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745

Manufacturer:	Hubei Wanli Protective products Co.,Ltd
Address:	Yuanshi,Ganhe,Xiantao,Hubei,China
EC Representative:	SUNGO Europe B.V.
Address:	Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name:	Face Mask
Model:	17.5*9.5cm, 14.5*9cm, 21*7cm
Classification:	Class I
Rule:	Rule 1, Annex VIII, Regulation (EU) 2017/745
Conformity Assessment Procedure:	Annex II+III of Regulation (EU) 2017/745
SRN:	/
Basic UDI-DI:	/

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	

Signature: Yonggang Liu

Name / Position: Yonggang Liu / GM

Date: 2020.9.11

Place: Hubei / China

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

SUBJECT	**Physical & Microbiological Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**HUBEI WANLI PROTECTIVE PRODUCTS CO., LTD**
CLIENT ADDRESS	YUANSHI, GANHE, XIANTAO, HUBEI,433000 CHINA
TEST PERIOD	12-Jun-2020~29-Jun-2020

Prepared By

(Bella Xu)
Report Drafter

Authorized By

TÜV SÜD PRODUCTS TESTING (SHANGHAI) CO., LTD.

(Leo Liu)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

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TEST REPORT

Sample Description	:	Disposable Face Mask
Sample Quantity	:	50 pieces
Lot Number/Batch Code	:	2020060146
Specification	:	WLM2002
Size	:	17.5*9.5cm
Brand Name	:	/

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Method	Test Standard Type ⅡR	Judgement
1	Bacterial Filtration Efficiency Test (BFE), %	EN 14683:2019+AC:2019(E) Annex B	≥ 98	Pass
2	Differential Pressure Test (Pa/cm^2)	EN 14683:2019+AC:2019(E) Annex C	< 60	Pass
3	Synthetic Blood Penetration Test (kPa)	EN 14683:2019+AC:2019(E) ISO 22609:2004	≥ 16.0	Pass
4	Microbial Cleanliness Test (CFU/g)	EN 14683:2019+AC:2019(E) Annex D	≤ 30	Pass

Note: Pass = Meet customer requirements;
Fail = Fail customer requirements;
# = No comment;
N.D. = Not detected.

Photo of Samples

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Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.9% Specimen 2#: 99.9% Specimen 3#: 99.9% Specimen 4#: 99.9% Specimen 5#: 99.9%
2	Differential Pressure Test	50.6 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~32#: None seen
4	Microbial Cleanliness Test	Specimen 1#: <1 CFU/g Specimen 2#: 23 CFU/g Specimen 3#: 20 CFU/g Specimen 4#: 15 CFU/g Specimen 5#: 9 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of masks.

2. Sample description was given by client

Sample description	:	Disposable Face Mask
Specification	:	WLM2002
Lot Number	:	2020060146
Sample Receiving Date	:	2020-06-12

3. Test Method

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

4. Apparatus and materials

4.1 *Staphylococcus aureus* ATCC 6538 (Particle Diameter 3.0±0.3μm).
4.2 Peptone water.
4.3 Tryptic Soy Broth(TSB).
4.4 Tryptic Soy Agar(TSA).
4.5 Bacterial filtration efficiency test apparatus.
4.6 Six-stage viable particle Anderson sampler.
4.7 Flow meters.

5. Test specimen

5.1 As requested by client, take a total of 5 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
6.4 Perform a positive control run without a test specime to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.
  6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediaterly begin sampling the aerosol using the Anderson sampler.
  6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
  6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
  6.4.4 At the conclusion of the positive control ran, remove plates from the Anderson sampler.
6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen facing towards the bacterial challenge (test area: 77cm^2).
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control after completion of the sample set.
6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
6.9 Incubate agar plates at (37±2)°C for (20 to 52) h.
6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacture of Anderson sampler. The filtration efficiency percentages are calculated as follows:

$$BFE=(C-T) / C \times 100$$

T is the total plate count for the test specimen.

C is the mean of the total plate counts for the two positive controls.

8. Test results*

P Value / Stage Number	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	48	94	0	0	0	0	0	0
2	96	147	0	0	0	0	0	0
3	171	256	0	0	0	0	0	0
4	308	308	0	0	0	0	0	0
5	1314	1341	0	3	1	2	1	0
6	588	513	0	0	0	0	0	0
Total (*T*), CFU	2525	2659	<1	3	1	2	1	<1
Average (C), CFU	$2.6 \times 10^3 = (P_A+P_B) / 2$							
BFE ,%				99.9	99.9	99.9	99.9	99.9
Requirements	≥ 98							
Remarks	*P* is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. *T* is the total of *P* value for the test specimen. *C* is the mean of the total of *P* value of the two positive controls.							

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Differential pressure Test

1.Purpose

The purpose of the test was to measure the differential pressure of masks.

2.Sample description was given by client

Sample description	:	Disposable Face Mask
Specification	:	WLM2002
Lot Number	:	2020060146
Sample Receiving Date	:	2020-06-12

3.Test Method

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

4. Apparatus and materials

Differential pressure testing instrument

5.Test specimen

5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5) °C and (85±5)% relative humidity.

6. Procedure

6.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 L/min.
6.2 The pretreated specimen is placed across the orifice (total area 4.9cm^2, test area diameter 25mm, airflow direction from the inside of the mask to the outside of the mask) and clamped into place so as to minimize air leaks.
6.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.
6.4 The differential pressure is read directly.
6.5 The procedure described in steps 6.1-6.4 is carried out on 5 different areas of the mask and readings averaged.

Results:

Specimen	Test Results* (Pa/cm^2)	Average （Pa/cm^2）	Requirements	Judgement
1#	46.6	50.6	< 60	Pass
2#	52.3			
3#	47.1			
4#	53.9			
5#	53.0			

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Synthetic Blood Penetration Test

1.Purpose

For evaluation of resistance of masks to penetration by a fixed volume of synthetic blood at a high velocity.

2.Sample description was given by client

Sample description	:	Disposable Face Mask
Specification	:	WLM2002
Lot Number	:	2020060146
Sample Receiving Date	:	2020-06-12

3.Test Method

EN 14683:2019+AC:2019(E).

ISO 22609:2004.

4.Apparatus and materials

4.1 Synthetic blood.

4.2 Tensiometer.

4.3 Synthetic blood penetration test apparatus;

4.4 Targeting plate.

4.5 Air pressure source.

4.6 Ruler.

4.7 Balance.

4.8 Controlled temperature and humidity chamber.

5.Test specimen

5.1 As requested by client, take a total of 32 test specimens.

5.2 Prior to testing, condition all test specimens for a minimum of 4h at (21±5)°C and (85±5) % relative humidity.

6.Procedure

6.1 Prepare the synthetic blood (40~44 mN/m) for the test.

6.2 Determine the density of the synthetic blood.

6.3 Fill the reservoir with new synthetic blood.

6.4 Position the test specimen 30.5 cm (12 in.) from the exit of the canula.

6.5 Set the reservoir pressure to the approximate pressure.

6.6 Place the targeting plate approximately 1 cm away from the mask.

6.7 Set the valve timer to 0.5 s. Collect and weigh the amount of fluid delivered (before the targeting

hole).

6.8 Set the valve timer to 1.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

6.9 Calculate the difference in weight of the two spurts. For a test fluid with a density of 1.003, Table 1 gives the target difference in weight plus lower and upper limits for a velocity range within 2% of the target.

Table 1 Target weight difference

Fluid Pressure (mmHg)	Weight difference for 1s difference in spurt duration (g)		
	Min.	Target	Max.
120	3.002	3.063	3.124

6.10 Adjust the reservoir pressure and repeat steps 6.7 to 6.9 until the weight difference is within the target range.

6.11 Record the weight difference for the spurts exiting the nozzle.

6.12 Record the pressure in the reservoir.

6.13 Set the valve time to 0.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.14 Set the valve time to 1.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.15 The difference in weight between the 0.5 s and 1.5 s spurts through the targeting plate shall be within +2 % ~ -5 % of the difference in weight from the nozzle.

6.16 If the differential weight is less than 95 % of the weight difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.

6.17 If the differential weight is more than 102 % of the weight difference exiting the nozzle, repeat the weight measurements exiting the nozzle (steps 6.7 to 6.11).

6.18 For standard synthetic blood, the timer duration can be estimated using the formula:
(p is the density of the test fluid.) $t = 0.5 + (2\times p$ - g at 0.5 s) / (g at 1.5 s - g at 0.5 s).

6.19 Record the timer setting to use as the starting point for subsequent testing.

6.20 Mount a test specimen on the specimen holding fixture. If the mask contains pleats, spread the pleats out when mounting the mask onto the fixture to present a single layer of material as the target area.

6.21 Squirt the synthetic blood onto the test specimen for the calculated time. Ensure that the synthetic blood hits the target area of mask.

6.22 Inspect the inside surface for synthetic blood penetration within 10 s of squirting the synthetic blood against the target area.

6.23 Report the results (none / penetration) for each test specimen at the test pressure.

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Results:

Specimen	Test Results*	Requirements	Judgement
1#	None Seen	Pass Pressure at 16.0 kPa (120mmHg)	Pass
2#	None Seen		Pass
3#	None Seen		Pass
4#	None Seen		Pass
5#	None Seen		Pass
6#	None Seen		Pass
7#	None Seen		Pass
8#	None Seen		Pass
9#	None Seen		Pass
10#	None Seen		Pass
12#	None Seen		Pass
13#	None Seen		Pass
14#	None Seen		Pass
15#	None Seen		Pass
16#	None Seen		Pass
17#	None Seen		Pass
18#	None Seen		Pass
19#	None Seen		Pass
20#	None Seen		Pass
22#	None Seen		Pass
23#	None Seen		Pass
24#	None Seen		Pass
25#	None Seen		Pass
26#	None Seen		Pass
27#	None Seen		Pass
28#	None Seen		Pass
29#	None Seen		Pass
30#	None Seen		Pass
31#	None Seen		Pass
32#	None Seen		Pass

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Microbial Cleanliness Test

1. Purpose

The purpose of the test was to measure microbial cleanliness of mask.

2. Sample description was given by client

Sample description	:	Disposable Face Mask
Specification	:	WLM2002
Lot Number	:	2020060146
Sample Receiving Date	:	2020-06-12

3. Test Method

According to EN ISO 11737-1:2018 to determine the microbial cleanliness of mask material, and refer to the procedure as described in EN 14683:2019+AC:2019(E) Annex D

4. Apparatus and materials

4.1 Orbital shaker.
4.2 0.45 um filter.
4.3 Tryptic Soy Agar (TSA).
4.4 Sabouraud Dextrose Ager (SDA) with chloramphenicol.
4.5 Formula of Extraction Liquid: 1g/L peptone, 5g/L NaCl and 2g/L Tween 20.
4.6 Extraction apparatus.

5. Test specimen

5.1 As requested by client, take a total of 5 mask samples.
5.2 Mask samples for testing are provided in the original primary packaging.
5.3 Condition at (18 to 26)℃ and (45 to 65)% relative humidity during testing.

6. Procedure

6.1 Five test specimens are selected from the top, bottom and 3 randomly chosen marks.
6.2 The mask is aseptically removed from the packaging and placed in a sterile 500 mL bottle containing 300 mL of extraction liquid.
6.3 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.
6.4 After extracting, 100mL of the extraction liquid is filtered through a 0.45 um filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 mL aliquot of the same extraction liquid is filtered in the same way and the filter plated on SDA for fungi enumeration.
6.5 The plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively.
6.6 Calculate the colonies of each agar plate.

7. Calculation

For each test specimen calculate the microbial cleanliness as follows by:

$$Ni = 3\, n_i / M$$

$$\text{Microbial Cleanliness} = N_1 + N_2$$

i = 1, 2.

n = Colonies of the TSA plate or the SDA Plate.

M = Weight of the mask.

Results*:

Specimen	1#	2#	3#	4#	5#
Weight of the Mask (M, g)	3.00	3.20	3.19	3.10	3.05
Colonies of the TSA Plate (n_1)	0	15	12	10	7
Colonies of the SDA Plate (n_2)	0	8	8	5	2
Aerobic Microbial Number (N_1, CFU/g)	0	15	12	10	7
Fungi Number (N_2, CFU/g)	0	8	8	5	2
Microbial Cleanliness, (CFU/g)	<1	23	20	15	9
Requirements	≤ 30				

Note:

1.*denotes this test was carried out by external laboratory assessed as competent.

2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

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