SCHEDA TECNICA
HTN0309

Nome commerciale:	MASCHERA CHIRURGICA
Destinazione d'uso:	PROTEZIONE
Codice:	HTN0309
Classe di appartenenza:	I
Nr. Repertorio:	1957586/R
CND:	T020601
Fabbricante:	ZHEJIANG LONGTERM MEDICAL TECHNOLOGY CO.,LTD. Huancheng North Road 493, Mo gan Mountian National Hightech district, 313200Deqing, Zhejiang,P R China
Rappresentante europeo:	Lotus B.V. Koningin Julianaplein 10,le Verd, 2595AA,The Hague, Netherlands
Distributore esclusivo Italia:	MeHoS s.r.l. Viale delle Industrie, 5 20020 Arese – MI

Immagini del prodotto

Indicazioni per l'uso

Per tutti i chirurghi ed il personale di sala operatoria che desiderano una protezione ideale durante gli interventi che hanno come soggetti pazienti potenziali portatori di infezioni.

Caratteristiche

Maschera chirurgica di Tipo IIR costituita da tre strati laminati a “sandwich”: tessuto non tessuto – Meltblown (filtrazione batterica) - tessuto non tessuto. Questi 3 strati sono strutturati per la specifica funzione cui sono destinati: resistente agli spruzzi di liquidi, protettiva, filtrante, antimacerante.

CARATTERISTICHE	VALORI
Dimensioni	mm 95 x 175 (± 1)
Peso	g. 4,0 (variabile tra - 5% e il + 10%)
1° strato esterno colorato	Cellulosa – poliestere
2° strato filtrante	Melt blown di fibrille di polipropilene
3° strato interno antimacerante	Polipropilene - polietilene
Bordi	Polipropilene bianco anallergico
Stringi naso	Filo metallico diametroricoperto da polipropilene bianco, atraumatico, conformabile
Fissaggio	Sistema con elastico auricolare
Saldatura	Ad ultrasuoni
Maschera:	Tipo IIR
Efficienza filtrante (B.F.E.)	> 99% secondo la norma UNI EN 14683:2019
Resistenza al flusso respiratorio	< 40 Pa/cm2 secondo la norma UNI EN 14683:2019
Resistenza agli spruzzi di liquidi	Resistente alla pressione di 16 kPa, secondo il metodo di prova ISO 22609, secondo la norma UNI EN 14683:2019
Carica Microbica	≤ 30 UFC/g secondo la Norma UNI EN 14683:2019
Prodotto monouso o pluriuso	Monouso
Sterilità	Non Sterile
Normative di riferimento	Direttiva CEE 93/42, Classe I Norma UNI EN 14683:2019 Norma UNI EN ISO 10993, parte 5 e parte 10 Norma UNI EN ISO 13485:2016
Modalità di conservazione	Proteggere dalla luce solare diretta e conservare in un luogo fresco e asciutto, in ambienti privi di odori e lontano da fonti di calore.
Vita utile del prodotto	3 anni
Confezione	50pz
Altre caratteristiche	Tessuti non tessuti estremamente morbidi Buona drappeggiabilità Adatta a pelli sensibili Monouso Inodore Anti-fog

Contenuto della confezione

Maschera Chirurgica

Presenza di lattice, ftalati (DEHP), farmaci, sostanze, tessuti biologici

Descrizione	SI	NO
Lattice		X
DEHP		X
BPA		X
Farmaci		X
Sostanze		X
Tessuti Biologici		X

Smaltimento

Il dispositivo, dopo l'utilizzo, deve essere trattato e smaltito in base alle vigenti disposizione di legge.

Declaration of Conformity

Manufacturer: Zhejiang Longterm Medical Technology Co., Ltd.

Address: Huancheng North Road 493, Mo Gan Mountain National High-tech district, Deqing, Zhejiang, People's Republic of China

European Representative: Lotus NL B.V.

Address: Koningin Julianaplein 10,1e Verd,2595AA The Hague,THE NETHERLANDS

Product: Surgical Face Mask

Model Code: Flat,Folding

Classification: I Rule: Rule 1 of MDD

UMDN Code: 12447

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

Zhejiang Longterm Medical Technology Co. Ltd is exclusively responsible for the Declaration of Conformity.

CE

DIRECTIVES

General Applicable Directive:

COUNCIL DIRECTIVE 93/42/EEC

Applicable standard

EN14683-2019 Medical face masks - Requirements and test methods

Expire date: 2023-04-08

Place, Date: Deqing, Zhejiang, China /Apr.08th, 2020

Signature: Kangping Wu

Name: Kangping Wu

Position : General Manager

Test Report No.: 721653344-1
Report Date: 17 April 2020

SUBJECT	**Physical 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	**Zhejiang Longterm Medical Technology Co., Ltd.**
CLIENT ADDRESS	Huancheng North Road 493, Mo gan mountain National High-tech district, 313200 Deqing, Zhejiang, People's Republic of China
TEST PERIOD	17-Mar-2020~08-Apr-2020

Prepared By

Anny Zhang

(Anny Zhang)
Report Drafter

Authorized By

Leo Liu

(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.

Chemical/Microbiology Laboratory:
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Differential pressure of a medical face mask

1.Purpose

The purpose of the test was to measure the differential pressure of a medical face mask.

2.Sample description was given by the client

Surgical Mask
17.5cm*9.5cm
Lot:202002296801
Manufacture: Zhejiang Longterm Medical Technology Co., Ltd

3.References

EN 14683:2019 Annex C

4.Apparatus

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 Each test specimen shall be conditioned at (21±5)°C and (85±5) % relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.

6. Procedure

6.1 The test specimen is placed across the 2.5 cm diameter orifice(total area 4.9 cm^2) and clamped into place so as to minimize air leaks and that the tested area of the specimen will be in line and across the flow of air.
6.2 The pump is started and the that tested area of the specimen will be in line and across the flow of air.
6.3 The manometers M1 and M2 are read and recorded.
6.4 The procedure described in steps 6.1~6.3 is carried out on 5 different areas of the mask and readings averaged.

7. Calculation

For each test specimen calculate the different pressure ΔP as follows:

$$\Delta P = \frac{(X_{m1}-X_{m2})}{4.9}$$

X_{m1}: is pressure in Pa, manometer M1, mean of 5 test areas, low pressure side of the material;
X_{m2}: is pressure in Pa, manometer M2, mean of 5 test areas, high pressure side of the material;
4.9 is the cm^2 area of the test material;
ΔP is the different pressure per cm^2 of the test material expressed in Pa.

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8.Test results

Test Items*		Test Results	Test Methods
Different Pressure Test (Pa/cm^2)	1	51.2	EN 14683:2019 Annex C
	2	50.2	
	3	50.3	
	4	52.2	
	5	48.9	

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-

Chemical/Microbiology Laboratory:
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SUBJECT	**Physical 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	**Zhejiang Longterm Medical Technology Co., Ltd.**
CLIENT ADDRESS	Huancheng North Road 493, Mo gan mountain National High-tech district, 313200 Deqing, Zhejiang, People's Republic of China
TEST PERIOD	17-Mar-2020~08-Apr-2020

Prepared By

Anny Zhang

(Anny Zhang)
Report Drafter

Authorized By

TÜV SÜD PRODUCTS TESTING (SHANGHAI) CO., LTD. 德商德商品检测(上海)有限公司

Leo Liu

(Leo Liu)
Authorized Signatory

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Synthetic Blood Penetration Test for Masks

1.Purpose

For evaluating the resistance of medical face masks to penetration by a fixed volume of synthetic blood at a high velocity.

2.Sample description was given by the client

Surgical Mask
17.5cm*9.5cm
Lot:202002296801
Manufacture: Zhejiang Longterm Medical Technology Co., Ltd

3.References

EN 14683:2019
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 13 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).

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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 1.005, Table 1 gives the target difference in weight plus lower and upper limits for a velocity range within 2% of the target.

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

Table 1 Target weight differences

Fluid Pressure (mmHg)	Weight difference for 1 s difference in spurt duration (g)		
	Min.	Target	Max.
80	2.456	2.506	2.556
120	3.002	3.063	3.124
160	3.466	3.537	3.607

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:
(ρ is the density of the test fluid.) $t = 0.5 + (2 \times \rho - g \text{ at } 0.5 \text{ s}) / (g \text{ at } 1.5 \text{ s} - g \text{ at } 0.5 \text{ s})$.

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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7.Test results

Test Items*		Test Results	Test Methods
Penetration of Synthetic Blood Pressure: 120 mmHg (16.0 kPa)	1	None Seen	EN 14683:2019 ISO 22609:2004
	2	None Seen	
	3	None Seen	
	4	None Seen	
	5	None Seen	
	6	None Seen	
	7	None Seen	
	8	None Seen	
	9	None Seen	
	10	None Seen	
	11	None Seen	
	12	None Seen	
	13	None Seen	

Note:

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

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

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No.151 Heng Tong Road Shanghai
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Test Report No.: 721653344-3
Report Date: 17 April 2020

SUBJECT	**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	**Zhejiang Longterm Medical Technology Co., Ltd.**
CLIENT ADDRESS	Huancheng North Road 493, Mo gan mountain National High-tech district, 313200 Deqing, Zhejiang, People's Republic of China
TEST PERIOD	17-Mar-2020~08-Apr-2020

Prepared By

(Anny Zhang)
Report Drafter

Authorized By

(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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Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the Bacterial Filtration Efficiency (BFE) of medical face mask material.

2. Sample description was given by the client

Surgical Mask

17.5cm*9.5cm

Lot:202002296801

Manufacture: Zhejiang Longterm Medical Technology Co., Ltd

3. References

EN 14683:2019 Annex B

4. Apparatus and materials

4.1 *Staphylococcus aureus* ATCC 6538
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 throuth 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 in contact with the challenge.
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control afer 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 (35±2)°C for (48±4) h.
6.10 Count each of the six-stage plates of the Anderson sampler.

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7. Calculation

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

$$BFE(\%)=\frac{C-T}{C} \times 100$$

Where:

C= average plate count total for positive controls

T= plate count total for sample

8. Test results

Test Items*		Test Results	Test Methods
Bacterial Filtration Efficiency(BFE)(%) *Staphylococcus aureus* ATCC 6538	1	99.8	EN 14683:2019 Annex B
	2	99.7	
	3	99.7	
	4	99.8	
	5	99.7	

Note:

1.Control average: 1766 CFU.

2.Mean particle size:3.1 μm.

3.Testing side: outside of specimen

4.Testing area: 39.5cm².

5.The test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

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

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-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
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Test Report No.: 721653344-4
Report Date: 17 April 2020

SUBJECT	**Physical 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	**Zhejiang Longterm Medical Technology Co., Ltd.**
CLIENT ADDRESS	Huancheng North Road 493, Mo gan mountain National High-tech district, 313200 Deqing, Zhejiang, People's Republic of China
TEST PERIOD	17-Mar-2020~14-Apr-2020

Prepared By

(Anny Zhang)
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Cleanliness of Microbial (Bioburden) Test for Masks

1. Purpose

For determination of a population of microorganisms.

2. Sample description was given by the client

Surgical mask

17.5cm*9.5cm

Lot: 202002296801

Manufacture: Zhejiang Longterm Medical Technology Co., Ltd

3. References

EN 14683:2019

EN ISO 11737-1:2006

4. Apparatus and materials

4.1 Orbital shaker
4.2 Sterile 500 mL bottle
4.3 Extraction liquid (1 g/L Peptone, 5 g/L NaCl and 2 g/L Tween 20)
4.4 Tryptone soya agar (TSA)
4.5 Sabouraud dextrose agar (SDA) with chloramphenicol
4.6 Filtration equipment
4.7 Sterilized membrane (0.45μm)

5. Test specimen

5.1 As requested by client, take a total of 5 masks.

6. Procedure

6.1 Weight each mask prior testing
6.2 The full mask is aseptically removed from the packaging and placed in a stomacher bag.
6.3 Pour into 100 mL extraction liquid and process 5 min in a stomacher individually by highest speed.
6.4 After this extraction step, 100 mL of the extraction liquid is filtered through a 0.45μm 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 with chloramphenicol for fungi enumeration. Additionally, plate 10 mL, 1 mL and 0.1 mL of the extraction liquid both for TSA and SDA with chloramphenicol.
6.5 The plates are incubated for 3 d at 30℃ and 7 d at 25℃ for TSA and SDA plates respectively.
6.6 The colonies formed on incubation are counted.

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7. Calculation

The total bioburden is expressed by addition of the TSA and SDA counts. Microbial cleanliness is based on the mask weigh, which is the total bioburden per gram tested.

8. Test results

Test Items		Test results	Test Methods
Microbial cleanliness (CFU/g)	1	2.0	EN 14683:2019 EN ISO 11737-1:2006
	2	2.0	
	3	<2.1	
	4	2.1	
	5	8.2	

Note:

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-END OF THE TEST REPORT-

20x10.5x8.5cm

MeHoS

PROTECTION

50 PCS

DISPLOSABLE FACE MASK

DISPLOSABLE FACE Type IIR

MeHoS

1. NONWOVEN
2. MELT-BLOWN NONWOVEN
3. SKIN-FRIENDLY NONWOVEN

PROTECTION

50 PCS

Instruction

Distributed in EMEA:
MehoS srl
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e-mail: info@mehos.eu

DISPLOSABLE FACE MASK

EN - Disposable surgical face mask with elastic band
Free from latex and Nickel
Three-Layer: non-fiber glass filter medium
EN14683 Type IIR
Perfect Fit
Great comfort during prolonged wear
Optimal for sensitive skin

IT - Mascherina chirurgica con elastic auricolare
Senza latex e senza nichel
Filtro a tre strati privi di vetro
EN14683 Type IIR
Forma perfetta
Massimo confort dopo uso prolungato
Non irritante

FR - Masque chirurgical usage unique à élastiques
Sans latex et sans nickel
Un filtre à triple épaisseur sans fibre de verre
EN14683 Type IIR
Forme ergonomique
Grand confort pendant usage prolongé
Matériaux non irritants

DE - Einmal OP-Mundschutz mit Elastikband
Latexfrei und nickelfrei
3-lagiges glasfaserfreies Filtermedium
EN14683 Type IIR
Optimal Passform
Hoher Komfort bei längerer Tragedauer
Hautfreundliche Materialien

PROTECTION

50 PCS

DISPLOSABLE FACE MASK

REF: HTN0309
SIZE: 17.5x9.5cm
QTY: 50 PCS
LOT 20200601
2020-06
2023-05

EC Authorized Representative :
Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd,
2595AA, The Hague, Netherlands.

MANUFACTURER:
Zhejaing Longterm Medical Technology Co.,Ltd
Huancheng North Road 493, Mo Gan Mountain National
High-Tech District, 313200 Deqing, Zhejiang, China

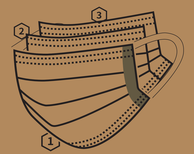
MADE IN CHINA

44x42x44.5cm　　实际数量：50

MeHoS®　REF: HTN0309

DISPLOSABLE FACE MASK

1. NONWOVEN
2. MELT-BLOWN NONWOVEN
3. SKIN-FRIENDLY NONWOVEN



SIZE: 17.5x9.5cm

CE　PROTECTION

50PCS/BOXES 40BOXES/CTN

LOT .: 20200601
MFG.: 2020-06
EXP.: 2023-05
G.W.: KGS
N.W.: KGS
MEAS: 44 x 42 x 44.5 CM

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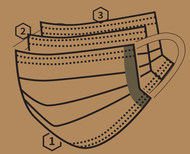

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