
Medizinische Einweg-Gesichtsmaske (Nicht Steril)
Disposable Medical Face Mask (Non-Sterile)
EUROPAPA
10 × 5 Päckchen
50 PCS
Außenschicht: Bleifreier Vliesstoff
Mittelschicht: Schmelzgeblasenen Filtrationsschicht
Innenschicht: Weiche feuchtigkeitsbeständige Schutzschicht
BFE Bacterial Filtration Efficiency ≥98%
3 Lagig
LATEX
Latexfrei
Einweg

Medizinische Einweg-Gesichtsmaske (Nicht Steril)
Disposable Medical Face Mask (Non-Sterile)

EUROPAPA

10 x 5 Päckchen 50 PCS

BFE ≥ 98 %

10 x 5 Päckchen 50 PCS

1.

DE Legen Sie die weiße Seite der Maske in Richtung Gesicht.

EN Place the white side of the mask toward face.

2.

Legen Sie einen Ohrriemen um jedes Ohr und stellen Sie sicher, dass die Maske Nase und Mund vollständig bedeckt.

Loop one ear strap around each ear and make sure the mask covers the nose and mouth completely.

3.

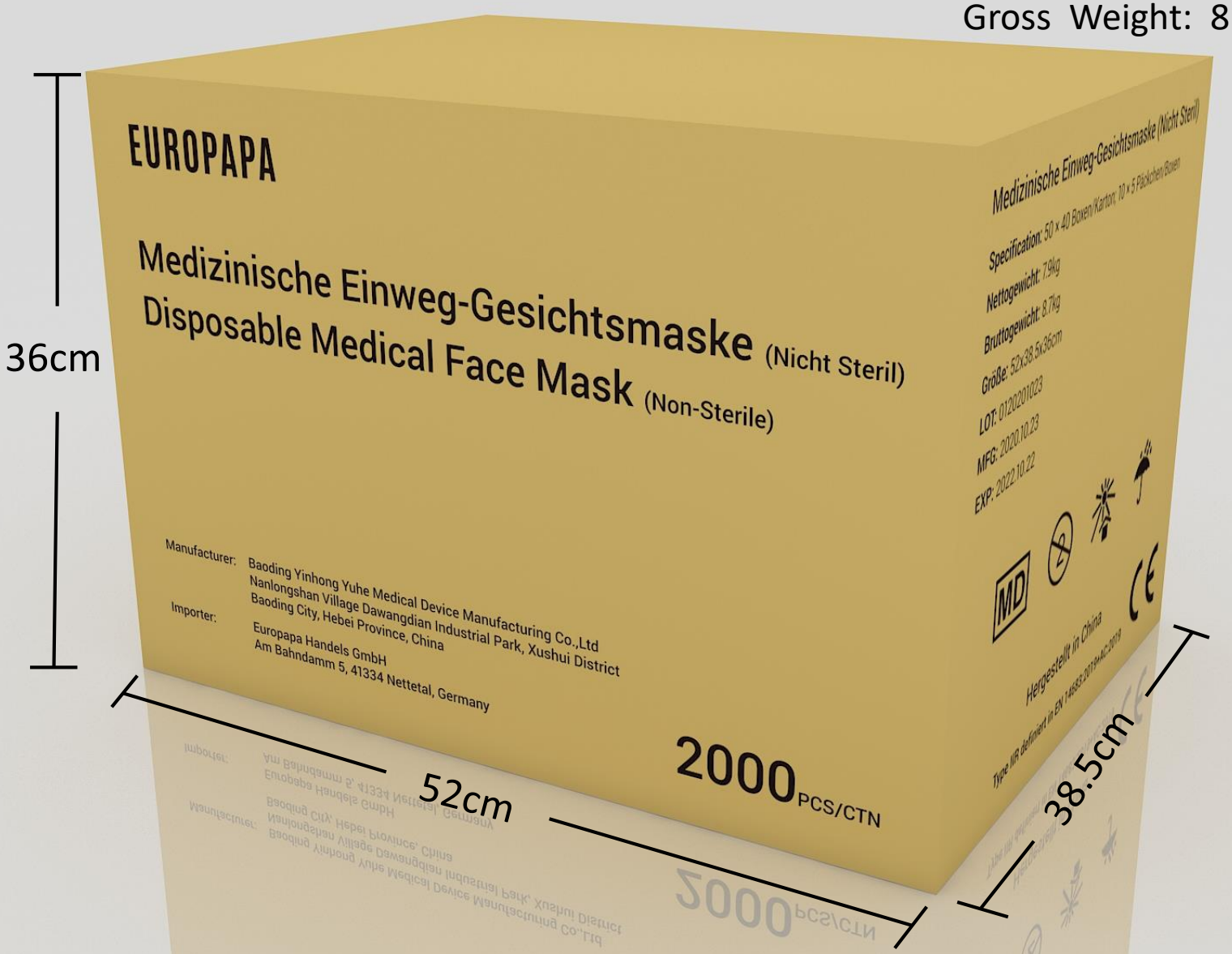
Stellen Sie den Nasenrücken so ein, dass die Maske genau an Nase und Wangen anliegt.

Adjust the bridge of the nose so that the mask fits snugly against the nose and cheeks.


Medizinische Einweg-Gesichtsmaske (Nicht Steril)
Disposable Medical Face Mask (Non-Sterile)
EUROPAPA
Outer hydrophobic non-woven layer
Inter melt-blown filter layer
Inner soft absorbent layer
BFE Bacterial Filtration Efficiency ≥98%
3-Layer
Latex Free
Do Not Reuse
10 × 5 Packs
50 PCS

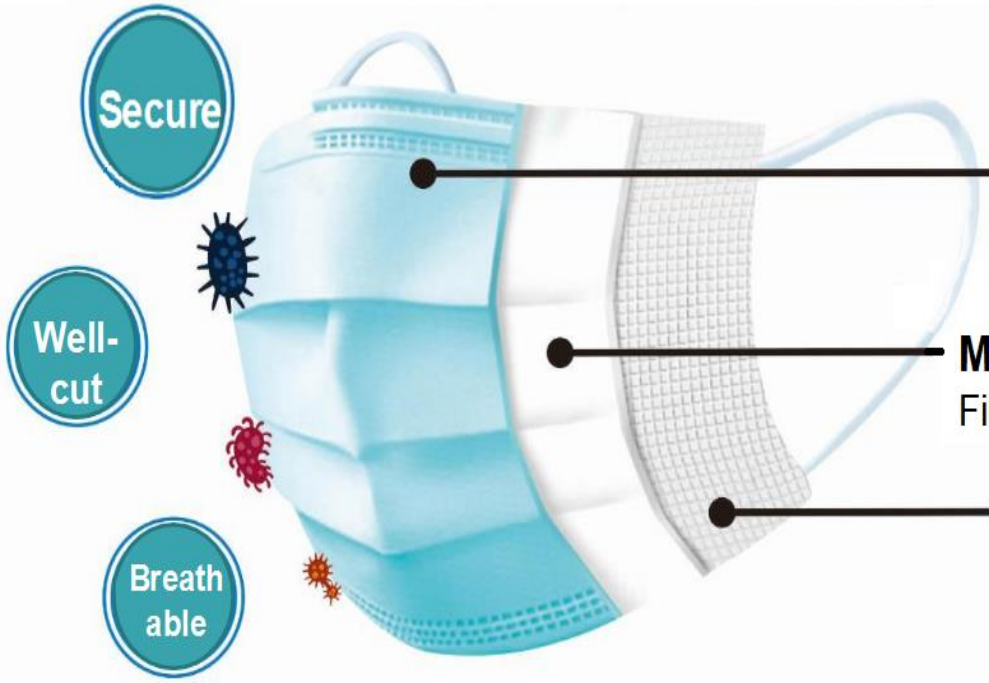

EUROPAPA
Medizinische Einweg-Gesichtsmaske (Nicht Steril)
Disposable Medical Face Mask (Non-Sterile)
BFE ≥ 98%
10 x 5 Packs
50 PCS
Hersteller:
(Manufacturer)
Baoding Yinhong Yuhe Medical Device Manufacturing Co., Ltd
Nanlongshan Village, Dawangdian Industrial Park, Xushui District
Baoding City, Hebei Province, China
Importeur:
(Importer)
Europapa Handels GmbH
Am Bahndamm 5
41334 Nettetal, Germany
DE
Executive Standard:
Größe:
Type IIR definiert in EN 14683:2019+AC:2019
17.5cm x 9.5cm
EN
Executive Standard:
Size:
Type IIR defined in EN 14683:2019+AC:2019
17.5cm x 9.5cm
4 270001 904737
EN14683 Type IIR
CE

Bruttogewicht: 8.7kg
Gross Weight: 8.7kg



Construction

3-Layer Construction



SS Non-woven cloth
Block relatively large particulate

Medical Standard Melt-blown Fabric（BFE99）
Filter both oily and non-oily substance while breath freely

SS Non-woven cloth
Comfortable, skin-friendly

Materials

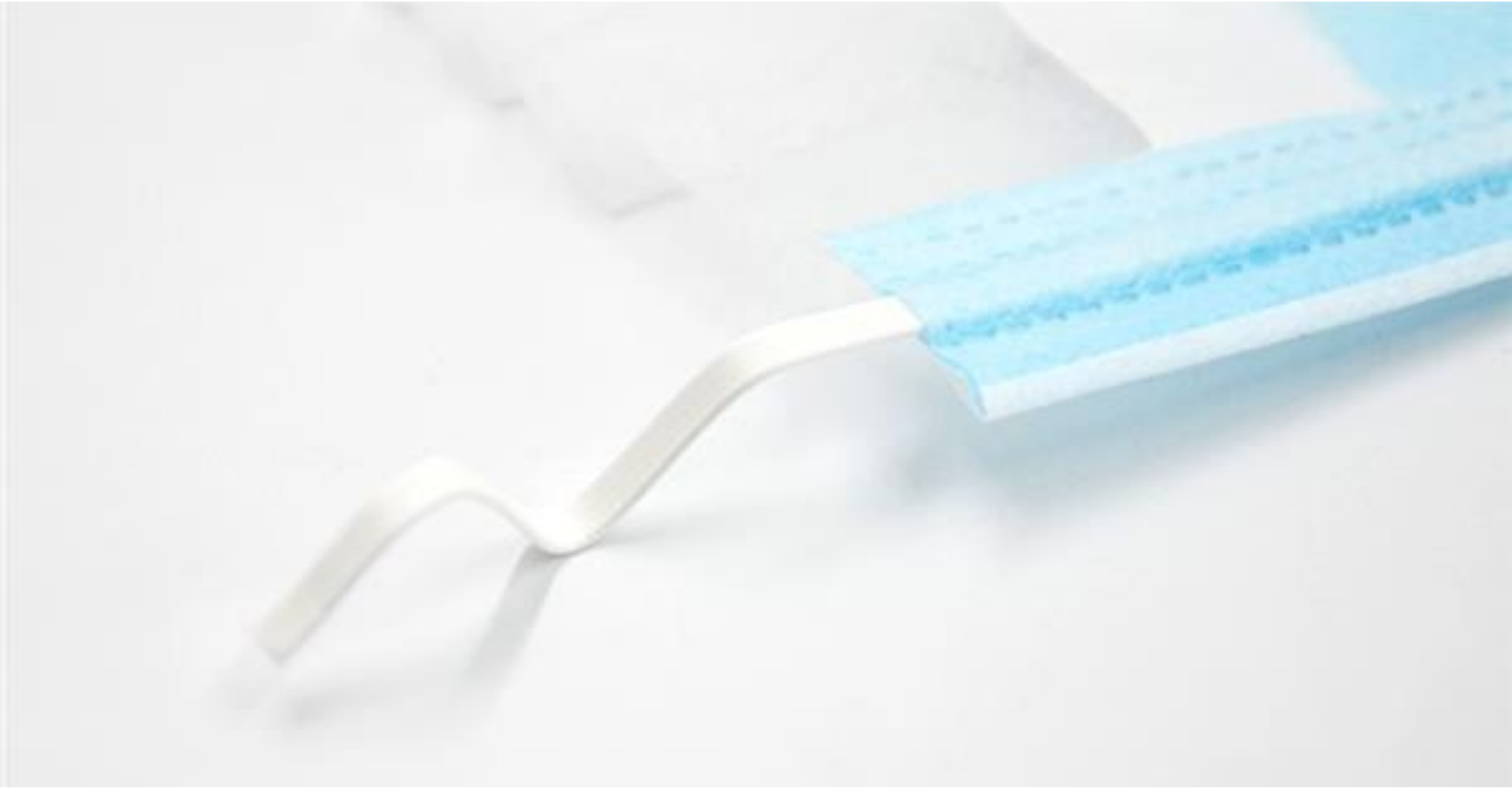
Skin-Friendly

Stop Bacteria

High-elastic earloop

Materials

Nose Bridge—High plasticity



Elaborate Packaging

5*10 PKGS/BOX

In the Name List of Medical Devices and Supplies Companies

中国医药保健品进出口商会
服务产业链 | 助力国际化

首页 关于商会 新闻中心 行业服务 权威发布 商会会刊 企

新闻中心 > 通知公告

动态更新：取得国外标准认证或注册的医疗物资生产企业清单

2020年06月03日 中国医药保健品进出口商会 分享

6月3日，取得国外标准认证或注册的医疗物资生产企业清单继续更新，其中，医用口罩清单新增60家企业，医用防护服清单新增8家企业，呼吸机清单新增1家企业，红外体温计清单新增2家企业，新型冠状病毒检测试剂清单新增17家企业。

取得国外标准认证或注册的医疗物资生产企业清单

Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries

动态更新：2020年6月3日 下载

序号	生产企业	统一社会信用代码	国外注册认证情况
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
793	保定银虹裕赫医疗器械制造有限公司 Bao Ding Yin Hong Yu He Medical Device Manufacturing Co. Ltd.	91130609MA0EK4UC9G	欧盟CE
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]

EC Declaration of Conformity

Manufacturer:

Baoding Yinhong Yuhe medical device manufacturing Co., Ltd

Nanlongshan village, Dawangdian Industrial Park, Xushui District, Baoding City, Hebei Province, China

whose single Authorized EU-Representative:

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
DIMID: DE/0000047791
Lin Sun
Tel: 0049- 1715605732
E-mail: info.m@luxuslw.de

We, the manufacturer, herewith declare that the products

Disposable Medical Mask

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of

Baoding Yinhong Yuhe medical device manufacturing Co., Ltd

Nanlongshan village, Dawangdian Industrial Park, Xushui District, Baoding City, Hebei Province, China

保定裕赫医疗器械制造有限公司 1306098815515

保定, 2020年3月31日
Place, date

徐晓明, 总经理
Legally binding signature, Function

Test Report No.: 721653909
Report Date: 29 April 2020

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	**Bao Ding Yin Hong Yu He Medical device Manufacturing Co. Ltd.**
CLIENT ADDRESS	Long Shan Village ,Da Wang Dian Industrial Park ,Xu Shui Dist. Bao Ding,China
TEST PERIOD	10-Apr-2020~19-Apr-2020

Prepared By	**Authorized By**
Bella Xu	Leo Liu
(Bella Xu)	(Leo Liu)
Report Drafter	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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Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

TEST REPORT

Sample Description	:	Disposable Medical Mask
Sample Quantity	:	50 pieces
Lot Number/Batch Code	:	20200401
Specification	:	Flat/ Ear Hanging
Size	:	17.5cm * 9.5 cm
Type of Mask	:	Type IIR
Brand Name	:	/

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Standard	Judgement
1	Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	Pass
2	Differential Pressure Test	EN 14683:2019+AC:2019(E) Annex C	Pass
3	Synthetic Blood Penetration Test	ISO 22609:2004	Pass
4	Microbial Cleanliness Test	EN 14683:2019+AC:2019(E) Annex D	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	56.6 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~13#: None seen
4	Microbial Cleanliness Test	Specimen 1#: 3 CFU/g Specimen 2#: 2 CFU/g Specimen 3#: 7 CFU/g Specimen 4#: 3 CFU/g Specimen 5#: 4 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

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

2. Sample description was given by client

Sample description : Disposable Medical Mask
Specification : Flat/ Ear Hanging
Lot Number : 20200401
Sample Receiving Date : 2020-04-10

3. Test Method

EN 14683:2019+AC:2019(E) 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 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	21	45	0	0	0	0	0	0
2	99	83	0	0	0	0	0	0
3	146	198	0	0	0	0	0	0
4	190	236	0	0	0	0	0	0
5	1288	1438	0	0	0	0	0	0
6	559	551	0	0	0	0	0	0
Total (*T*), CFU	2303	2551	<1	<1	<1	<1	<1	<1
Average (C), CFU	$2.4x10^3 = (P_A+P_B) / 2$							
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.							

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 Medical Mask
Specification : Flat/ Ear Hanging
Lot Number : 20200401
Sample Receiving Date : 2020-04-10

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) 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#	59.7	56.6	< 60	Pass
2#	57.6			
3#	54.7			
4#	54.5			
5#	56.7			

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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 Medical Mask
Specification	:	Flat/ Ear Hanging
Lot Number	:	20200401
Sample Receiving Date	:	2020-04-10

3.Test Method

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).

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 1 s 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.

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
11#	None Seen		Pass
12#	None Seen		Pass
13#	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 Medical Mask
Specification : Flat/ Ear Hanging
Lot Number : 20200401
Sample Receiving Date : 2020-04-10

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 counting the total colonies of the TSA and SDA plates.

Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	2	1	3	According to EN ISO 11737-1:2018 the microbial cleanliness of the mask shall be ≤30 CFU/g tested.	Pass
2#	2	0	2		
3#	6	1	7		
4#	3	0	3		
5#	3	1	4		

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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