Products Name……:	Surgical Mask
Manufacturer……:	Guangdong Taibao Medical Science And Technology Co., Ltd.
Address……:	Yingge Mountain Avenue North, Yingge Mountain Industrial Park, Puning City, Guangdong Province, P.R. China.
Test Information:	
Test Location……:	TÜV SÜD Products Testing (Shanghai) Co., Ltd.
Test Address……:	B-3/4, No. 1999 Du Hui Road, Minhang District Shanghai 201108, P. R. China.
Standard……:	EN 14683:2019 Surgical masks-Requirements and test methods
Test procedure……:	CE-MDD

The classification of medical face masks according to the EN 14683:2019

Table 1—Performance requirements for medical face masks

Test	Type Ⅰ	Type Ⅱ	Type ⅡR
Bacterial filtration efficiency(BFE), %	≥95	≥98	≥98
Differential pressure(Pa/cm²)	<40	<40	<60
Splash resistance pressure(kpa)	Not required	Not required	≥16,0
Microbial cleanliness(cfu/g)	≤30	≤30	≤30

[a] Type Ⅰ medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type Ⅰ masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

Classification…… :	☐ Type Ⅰ
	☐ Type Ⅱ
	☑ Type ⅡR

After testing, the surgical masks meet the requirements of **Type ⅡR** in EN 14683:2019 standard. See the following specific report for detailed.

Performance	Test report No.
Bacterial Filtration Efficiency (BFE)	721653065-6
Differential pressure	721653065-1
Synthetic Blood Penetration	721653065-4
Cleanliness of Microbial	721653065-5

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	**Guangdong Taibao Medical Science And Technology CO.,LTD.**
CLIENT ADDRESS	Yingge Mountain Avenue North, Yingge Mountain Industrial Park, Puning City, Guangdong Province.
TEST PERIOD	13-Mar-2020~31-Mar-2020

Prepared By

Bella Xu

(Bella Xu)
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
Size: 17.5*9.5cm
Model: non-sterile
Lot/Batch#: 20200202

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 form 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 (20~52) 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 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	>99.9	EN 14683:2019 Annex B
	2	>99.9	
	3	>99.9	
	4	>99.9	
	5	>99.9	

Note:

1.Control average: 2007 CFU.

2.Mean particle size:2.8 μm.

3.Testing side: outside of specimen

4.Testing area: 39.5cm^2.

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.

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

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Test Report No.: 721653065-1
Report Date: 2 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	**Guangdong Taibao Medical Science And Technology CO.,LTD.**
CLIENT ADDRESS	Yingge Mountain Avenue North, Yingge Mountain Industrial Park, Puning City, Guangdong Province.
TEST PERIOD	13-Mar-2020~31-Mar-2020

Prepared By

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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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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
Size: 17.5*9.5cm
Model: non-sterile
Lot/Batch#: 20200202

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
Differentiae Pressure Test (Pa/cm^2)	1	30.1	EN 14683:2019 Annex C
	2	33.6	
	3	29.5	
	4	29.6	
	5	30.8	

Note:
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Test Report No.: 721653065-4
Report Date: 2 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	**Guangdong Taibao Medical Science And Technology CO.,LTD.**
CLIENT ADDRESS	Yingge Mountain Avenue North, Yingge Mountain Industrial Park, Puning City, Guangdong Province.
TEST PERIOD	13-Mar-2020~31-Mar-2020

Prepared By

Bella Xu

(Bella Xu)
Report Drafter

Authorized By

(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
Size: 17.5*9.5cm
Model: non-sterile
Lot/Batch#: 20200202

3.References

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 1.003, 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 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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7.Test results

Test Items*		Test Results	Test Methods
Penetration of Synthetic Blood Pressure: 120 mmHg (16.0 kPa)	1	None Seen	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	

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Test Report No.: 721653065-5
Report Date: 2 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	**Guangdong Taibao Medical Science And Technology CO.,LTD.**
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TEST PERIOD	13-Mar-2020~31-Mar-2020

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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
Size: 17.5*9.5cm
Model: non-sterile
Lot/Batch#: 20200202

3. References

EN ISO 11737-1:2018

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°C and 7 d at 25°C for TSA and SDA plates respectively.
6.6 The colonies formed on incubation are counted.

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.

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8. Test results

Test Items*		Test Results	Test Methods
Microbial cleanliness (CFU/g)	1	<1.7	EN ISO 11737-1:2018
	2	<1.6	
	3	<1.6	
	4	<1.7	
	5	<1.7	

Note:

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