EN 14683 - Test 1

Test Report No.: 721653175-1
Report Date: 9 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	**Topgene & Osmunda Medical Device Co., Ltd.**
CLIENT ADDRESS	Floor 3, No. 64 Lianglong Road, Huashan Zhen, Huadu District, Guangzhou
TEST PERIOD	18-Mar-2020~07-Apr-2020

Prepared By	**Authorized By**
Bella Xu	Leo liu
(Bella Xu) Report Drafter	(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:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
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

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 face mask
Lot: 200302W
Manufacture: Topgene & Osmunda Medical Device 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.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1989 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
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

8.Test results

Test Items*		Test Results	Test Methods
Different Pressure Test (Pa/cm^2)	1	27.4	EN 14683:2019 Annex C
	2	16.7	
	3	17.9	
	4	15.1	
	5	17.0	

Note:
1.The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.
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.

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1989 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
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

EN 14683 - Test 2

Test Report No.: 721653175-6
Report Date: 9 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	**Topgene & Osmunda Medical Device Co., Ltd.**
CLIENT ADDRESS	Floor 3, No. 64 Lianglong Road, Huashan Zhen, Huadu District, Guangzhou
TEST PERIOD	18-Mar-2020~07-Apr-2020

Prepared By	**Authorized By**
Bella Xu	Leo liu
(Bella Xu) Report Drafter	(Leo Liu) Authorized Signatory

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
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

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 face mask
Lot: 200302W
Manufacture: Topgene & Osmunda Medical Device 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 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.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1988 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
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

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 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	99.5	EN 14683:2019 Annex B
	2	99.0	
	3	99.6	
	4	99.1	
	5	99.3	

Note:

1.Control average: 2673 CFU.

2.Mean particle size:2.8 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.

7.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:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1988 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
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

EN 14683 - Test 3

Test Report No.: 72163175-8
Report Date: 9 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	**Topgene & Osmunda Medical Device Co., Ltd.**
CLIENT ADDRESS	Floor 3, No. 64 Lianglong Road, Huashan Zhen, Huadu District, Guangzhou
TEST PERIOD	18-Mar-2020~07-Apr-2020

Prepared By	**Authorized By**
Bella Xu	Leo liu
(Bella Xu) Report Drafter	(Leo Liu) Authorized Signatory

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
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

Cleanliness of Microbial (Bioburded) Test for Masks

1. Purpose

For determination of a population of microorganisms.

2. Sample description was given by the client

Surgical face mask
Lot: 200302W
Manufacture: Topgene & Osmunda Medical Device Co., Ltd.

3. References

EN 14683:2019
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℃ and 7 d at 25℃ 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.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
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

8. Test results

Test Items*		Test results	Test Methods
Microbial cleanliness (CFU/g)	1	<2.0	EN 14683:2019 EN ISO 11737-1:2018
	2	<2.0	
	3	<2.0	
	4	<2.0	
	5	<2.0	

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:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
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