EN 14683 - Test 1

Test Report No.: 721653175-1 Report Date: 9 April 2020



SUBJECT Physical Test

TEST LOCATION TÜV SÜD China

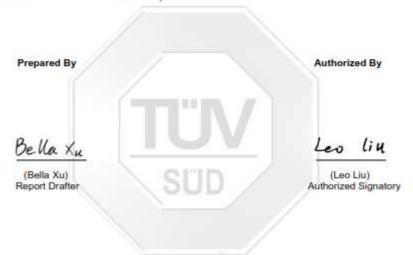
TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District

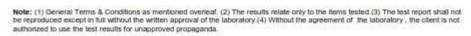
Shanghai 201108, P.R. China

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





Chemical Microbiology Laboratory: TUV SUD Products Testing (Shanghal) Co., Ltd. B-3H, No. 1599 Du Hul Road, Minhang District

B-3/4, No. 1599 Du Hui Road, Minhang Distric Shanghal 201 108 P.R. China Phone: +86 (21) 6037 6375 Fax: +66 (21) 6037 6345 Email: fool.chem@tuv.sud.cn Webpage: www.tuv.sud.cn Regional Head Office: TUV SID Certification and Testing (China) Co., Ltd. No. 151 Heng Tong Road Shanghal 200,070 P.R.China

Page 1 of 3

Test Report No.: 721653175-1 Report Date: 9 April 2020



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 cm²) and clamped into place so as to minimize air leaks and that the tested area of the specimen will be in line and across
- 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 AP as follows:

$$\Delta P = \frac{(X_{mi} - X_{mil})}{4.9}$$

X_{m1}: is pressure in Pa, manometer M1, mean of 5 test areas, low pressure side of the material; X_{n2}: is pressure in Pa, manometer M2, mean of 5 test areas, high pressure side of the material; 4.9 is the cm2 area of the test material;

ΔP is the different pressure per cm2 of the test material expressed in Pa.

Chemical/Microbiology Laboratory: TUV SUD Products Testing (Shanghal) Co., Ltd. B-3/4, No. 1999 Du Hui Road, Mintang District Shanghal P.R. China

Phone: +86 (21) 6037 6375 Fax: +86 (21) 6037 6345 Email: food.chem@tuy-sud.cn Webpage: www.tuv-sud.cn

Regional Head Office: TUV SUD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghal.
200 070 P.R.China

Page 2 of 3

Test Report No.: 721653175-1 Report Date: 9 April 2020



8.Test results

Test Items*		Test Results	Test Methods
Different Pressure Test (Pa/cm²)	1	27.4	EN 14683:2019 Annex C
(rusin)	2	16.7	,
	3	17.9	
	4	15.1	
	5	17.0	4 (1

Note

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







Chemical Microbiology Laboratory: TÜV SÜD Products Testing (Shanghal) Co., LM. B-3/4, No. 1999 Du Hul Road, Minhang District Shanghal 201105 P.R. China

Phone: +86 (21) 6037 6375 Fax: +86 (21) 6037 6345 Email: food.chem@tuy-sud.cn Webpage: www.tuy-sud.cn Regional Head Office: TUV 90D Certification and Testing (China) Co., Ltd. No. 151 Heng Tong Road Shanghal 200 070 P.R.China

Page 3 of 3

EN 14683 - Test 2

Test Report No.: 721653175-6 Report Date: 9 April 2020



SUBJECT Physical Test

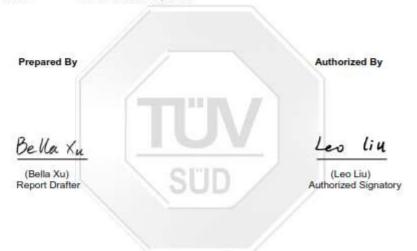
TEST LOCATION TÜV SÜD China

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





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 SUD Products Testing (Shanghal) Co., Ltd.

B-3/4, No. 1999 Du Hui Road, Minhang District Shanghai 201100. P.R. Chins

Phone: +86 (21) 6037 6375 Fax: +86 (21) 6037 6345 Email: food chem@tuv-sud.cn Webpage: www.tuv-sud.cn Regional Head Office: TUV SUD Certification and Testing (China) Co., Ltd. No.151 Heag Tong Road Shanghai 200 070 P.R.China

Page 1 of 3

Test Report No.: 721653175-6 Report Date: 9 April 2020



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° 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: TUV SUD Products Testing (Shanghal) Co., B-3/4, No. 1999 Du Hui Road, Minhang District Shanghal 201108 P.R. China

Phone: +86 (21) 6937 6375 Fax: +86 (21) 6937 6345 Email: food.chem@tuv-sud.cn Webpage: www.tay-sud.co

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

Page 2 of 3





Test Report No.: 721653175-6 Report Date: 9 April 2020



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(%)=
$$\frac{c-T}{c}$$
 X 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	

- 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.
- 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 (Shanghal) Co., Ltd. B.314, No.1999 Du Hul Road, Minhang District Shanghal 2011/00 P.R. China Phone: +86 (21) 6037 6375 Fax: +86 (21) 6037 6345 Email: food.chem@tuv-sud.cn Wetpage: www.tav-sud.cn Regional Head Office: TUV SUD Certification and Testing (China) Co., Ltd. No. 151 Heng Tong Road Stranghal 200 070 P.R.China

Page 3 of 3

EN 14683 - Test 3

Test Report No.: 72163175-8 Report Date: 9 April 2020



SUBJECT **Physical Test**

TOV SOD China TEST LOCATION

> 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 (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: Phone: +05 (21) 6037 6375
TÜV SÜD Products Testing (Shanghal) Co., Fax: +06 (21) 6037 6345
Ltd. Emait: hood chemi@thir-suit on Webpage: www.tur-aud.cn B-34, No.1995 Du Hai Road, Minhang District Shanghai 201100 P.R. China

Regional Head Office: TUV SUD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R. China Page 1 of 3

Test Report No.: 721653175-8 Report Date: 9 April 2020



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
- 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: TUV SUD Products Testing (Shanghal) Co., B-3/4, No. 1999 Du Hui Road, Minnang District Shanchai 201106 P.R. China

Phone: +86 (21) 6037 6375 Fax: +86 (21) 6037 6345 Email: food chem@tuv-sud.on Webpage: www.tuv-sud.cn

Regional Head Office: TUV SUD Certification and Testing (China) Co., Ltd. No. 151 Heng Tong Road Shanghai 700 070 P.R.China

Page 2 of 3



Test Report No.: 721653175-8 Report Date: 9 April 2020



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	0
	3	<2.0	ĺ
	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

-END OF THE TEST REPORT-





Chemical Microbiology Laboratory: TUV SUD Products Testing (Shanghai) Co., Ltd. B-34, No. 1999 Du Hui Road, Minhang District Shanghai 201106 P.R. China

Phone: +66 (21) 6037 6375 Fax: +66 (21) 6037 6345 Email: food chem@tuv-sud.cn Webpage: www.tuv-sud.cn

Regional Head Office: TUV SUD Certification and Testing (China) Co., Ltd.
No. 131 Heng Tong Road Shanghai
200 070 P.R. China

Page 3 of 3