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

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(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 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.

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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.

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