



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

Bella Xu
(Bella Xu)
Report Drafter

Authorized By



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.



Cleanliness of Microbial (Bioburden) Test for Masks

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 Weigh 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.





拓普奥达 (广州) 医疗用品有限公司 (仅供展示)
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-

