



中国认可
国际互认
检测
TESTING
CNAS L0599
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Test Report

SL52045311631601TX

Date: November 16, 2020

QINGDAO ORPHILA MEDICAL TECHNOLOGY CO., LIMITED
RM0501, FUTAI SQUARE NO18 HONGKONG MIDDLE ROAD, QINGDAO SHANDONG, CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A) Children Mask

Composition : (A) 60% Nonwoven, 40% Melt-Blown Fabric

Sample Color : (A) White

Style No. : OM-M145-W

Lot No. : 2020102703

Manufacturer : Qingdao Orphila Medical Technology Co., Limited. West Coast Branch

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Nov 02, 2020

Testing Period : Nov 03, 2020 - Nov 16, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)



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Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods**Clause 5.2 Performance Requirement****Clause 5.2.2 Bacterial Filtration Efficiency (BFE)**

(EN 14683:2019+AC:2019 Annex B)

Sample: A

Test Side : Inside
Test Area : Approximately 60 cm²
Flow Rate : 28.3 L/min
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen : ~140mm x 155mm
Positive Control Average : 2167 CFU
Negative Monitor Count : < 1 CFU
Mean Particle Size : 3.0 ±0.3µm
Test bacteria : Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
Bacterial Filtration Efficiency (BFE)	1	99.2%
	2	99.4%
	3	99.2%
	4	99.7%
	5	99.4%

Remark:

- 1) Performance Requirement: Type I ≥ 95%, Type II ≥ 98%, Type IIR ≥ 98%
- 2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL (Acceptable Quality Level) of 4%.



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Clause 5.2.3 Breathability

(EN 14683 :2019+AC:2019 Annex C)

Sample: A

Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks

Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.

Test Area : 4.9 cm²

Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm ²)	The average value for each test specimen (Pa/cm ²)
1	1-1	34.9	36
	1-2	33.1	
	1-3	35.3	
	1-4	36.1	
	1-5	38.2	
2	2-1	33.5	35
	2-2	32.8	
	2-3	34.2	
	2-4	38.7	
	2-5	33.4	
3	3-1	33.7	38
	3-2	36.4	
	3-3	38.1	
	3-4	39.7	
	3-5	39.9	
4	4-1	34.5	36
	4-2	34.6	
	4-3	30.6	
	4-4	39.5	
	4-5	39.0	
5	5-1	32.9	36
	5-2	35.5	
	5-3	33.4	
	5-4	39.2	
	5-5	39.7	

Remark:

- Performance Requirement: Type I<40 Pa/cm², Type II<40 Pa/cm², Type IIR<60 Pa/cm²
- The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.



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Clause 5.2.5 Microbial Cleanliness

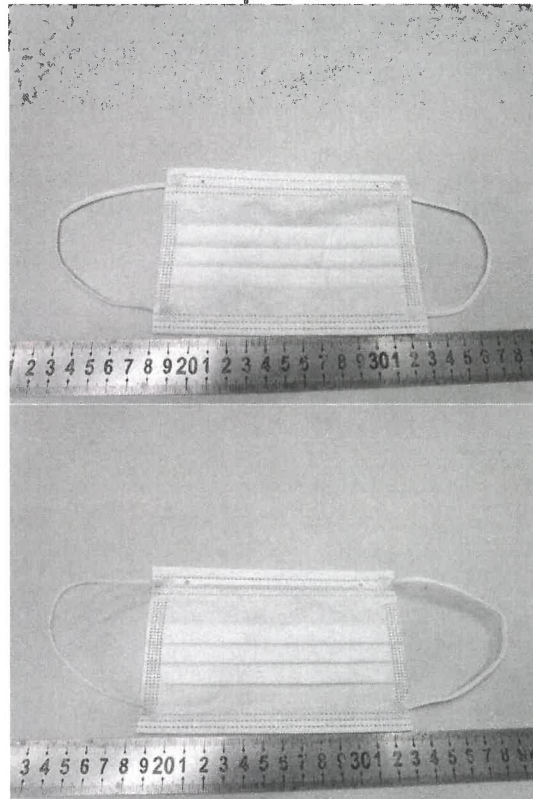
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	2.76	<3	<1.09
2#	2.75	<3	<1.09
3#	2.68	6	2.24
4#	2.71	6	2.21
5#	2.73	6	2.20

Remark: Performance Requirement: Type I ≤ 30 CFU/g, Type II ≤ 30 CFU/g, Type IIR ≤ 30 CFU/g

Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report



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