

Test Report

SL52035273071601TX

Date: July 22, 2020

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FUJIAN MEO MEDICAL TECHNOLOGY LTD.
FLOOR 4TH, NO.1 PRODUCTION BUILDING, NO.36, GUOBAO ROAD, DONGQIAO BUSINESS
DEVELOPMENT ZONE, NINGDE CITY, FUJIAN, CHINA

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

Sample Description : (A) Disposable face mask (Claimed Type I)

Sample Color : (A) blue

Manufacturer : FUJIAN MEO MEDICAL TECHNOLOGY LTD.

Batch Number : 20200706

Sample Receiving Date : Jul 13, 2020

Testing Period : Jul 14, 2020 - Jul 22, 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).

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

Comment:

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods	(A)
Clause 5.2 Performance Requirement	
Clause 5.2.2 Bacterial filtration efficiency (BFE)	M
Clause 5.2.3 Breathability	M
Clause 5.2.4 Splash Resistance	EXCLUDED
Clause 5.2.5 Microbial Cleanliness	EXCLUDED
Clause 5.2.6 Biocompatibility	EXCLUDED

Remark: M=Meet EN 14683:2019+AC:2019 Performance Requirement (Type I)
F=Below EN 14683:2019+AC:2019 Performance Requirement (Type I)

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

Sara Guo (Account Executive)

Helen 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 : ~173mm x 171mm
 Positive Control Average : 2496.5 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	99.9%
	2	99.9%
	3	99.9%
	4	99.9%
	5	99.9%

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%.



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	39.5	37
	1-2	36.1	
	1-3	34.3	
	1-4	35.9	
	1-5	38.9	
2	2-1	37.9	39
	2-2	39.2	
	2-3	37.7	
	2-4	38.5	
	2-5	39.6	
3	3-1	35.9	38
	3-2	38.7	
	3-3	39.3	
	3-4	38.6	
	3-5	37.3	
4	4-1	36.7	38
	4-2	39.3	
	4-3	38.7	
	4-4	38.2	
	4-5	38.9	
5	5-1	36.1	36
	5-2	36.0	
	5-3	35.9	
	5-4	37.6	
	5-5	32.4	

Remark:

- 1) Performance Requirement: Type I < 40 Pa/cm², Type II < 40 Pa/cm², Type IIR < 60 Pa/cm²
- 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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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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