

Test Report

SL52215338513301TX

Date: November 25, 2022

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ZHEJIANG TAISILK FASHION CO.,LTD.
NO. 588, EAST SECTION OF TIYUCHANG ROAD, TAIZHOU CITY, ZHEJIANG PROVINCE

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

Sample Description : (A) Disposable medical mask
Sample Color : (A) blue
Claimed Type/Level : EN 14683 Type IIR
Style No. : FH003
Lot No. : C20220530
Factory : Zhejiang TAISILK Fashion Co.,LTD.

Proposed Care Instruction : -

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

Sample Receiving Date : Nov 11, 2022
Testing Period : Nov 14, 2022 - Nov 25, 2022

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).

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	M
Clause 5.2.5 Microbial Cleanliness	M
Clause 5.2.6 Biocompatibility	EXCLUDED

Remark: M=Meet EN 14683:2019+AC:2019 Performance Requirement (Type IIR)

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

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 : ~175mm x 150mm
 Positive Control Average : 2027 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%.



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Clause 5.2.3 Breathability

(EN 14683:2019+AC:2019, Annex C; Test number and location: Test in different location on each of the 5 masks;
 Pre-Conditioning: Minimum of 4 hours at 21±5°C(70±10°F) and 85±5% R.H.;
 Test Area: 4.9 cm²;
 Flow Rate: 8 l/min.)

A

As Received	No. 1	No. 2	No. 3	No. 4	No. 5
Differential Pressure					
Top Centre(Pa/cm ²)	40.0	46.9	50.1	53.1	54.4
Centre Left(Pa/cm ²)	42.7	46.3	52.1	52.7	57.3
Centre(Pa/cm ²)	43.3	54.8	57.3	50.6	57.4
Centre Right(Pa/cm ²)	41.3	54.3	49.2	55.2	50.8
Bottom Centre(Pa/cm ²)	44.2	47.6	51.1	55.5	49.9
Average Differential Pressure(Pa/cm ²)	42	50	52	53	54

Remark:

- 1) Performance Requirement for EN 14683 :2019+AC:2019 Annex C: 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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Clause 5.2.4 Splash Resistance

(ISO 22609:2004)

A							
<u>Type IIR- 16.0kPa</u>	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6	No. 7
Resistance to Penetration by Synthetic Blood(Grade)	Pass	Pass	Pass	Pass	Pass	Pass	Pass
<u>Type IIR- 16.0kPa</u>	No. 8	No. 9	No. 10	No. 11	No. 12	No. 13	No. 14
Resistance to Penetration by Synthetic Blood(Grade)	Pass	Pass	Pass	Pass	Pass	Pass	Pass
<u>Type IIR- 16.0kPa</u>	No. 15	No. 16	No. 17	No. 18	No. 19	No. 20	No. 21
Resistance to Penetration by Synthetic Blood(Grade)	Pass	Pass	Pass	Pass	Pass	Pass	Pass
<u>Type IIR- 16.0kPa</u>	No. 22	No. 23	No. 24	No. 25	No. 26	No. 27	No. 28
Resistance to Penetration by Synthetic Blood(Grade)	Pass	Pass	Pass	Pass	Pass	Pass	Pass
<u>Type IIR- 16.0kPa</u>	No. 29	No. 30	No. 31	No. 32			
Resistance to Penetration by Synthetic Blood(Grade)	Pass	Pass	Pass	Pass			

Number of Test Specimen Passed:32

Conclusion: Pass

Remark:

1. Pre-Conditioning: Minimum of 4 hours at 21±5°C and 85±5% R.H.
2. Distance of the mask to the tip of cannula: 300±10mm.
3. Test was conducted within 60s after removal from conditioning chamber.
4. An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results.
5. Pass: No Penetration on inside surface
Fail: Penetration on inside surface

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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	3.21	26.46	8.24
2	3.07	15.12	4.93
3	3.09	18.90	6.12
4	3.09	15.12	4.89
5	3.11	7.56	2.43

Recovery Efficiency : 79.1%
Correction Factor : 1.3

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

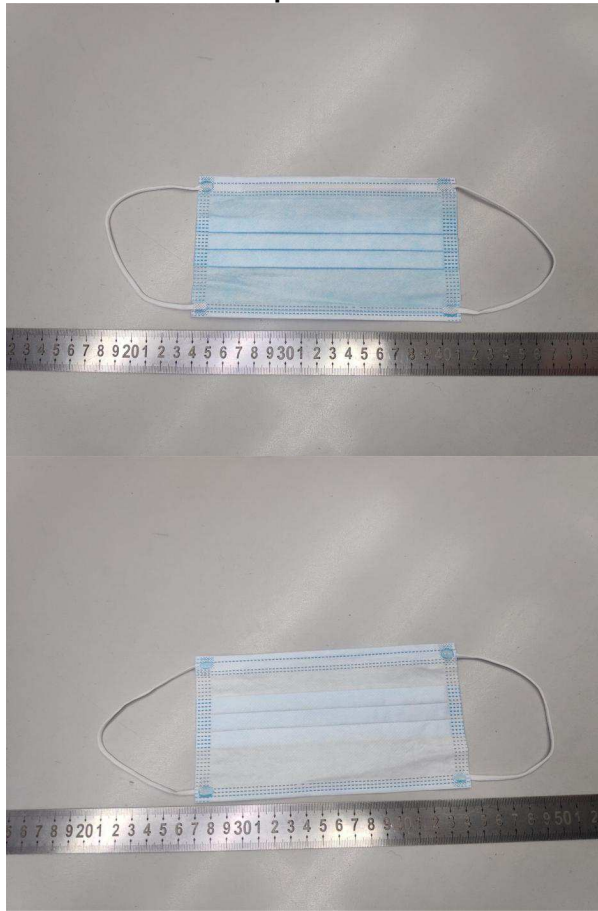


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Sample Photo



Product information is provided by applicant without verification or authentication of the brand.

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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