

Test Report

SL52035261738501TX

Date: July 13, 2020

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ZHEJIANG HONGYU MEDICAL COMMODITY CO., LTD
NO.668 CHANHUA ROAD FOTANG TOWN INDUSTRIAL FUNCTIONAL AREA 322002 YIWU CITY,
ZHEJIANG PROVINCE PEOPLE'S REPUBLIC OF CHINA

Sample Description : (A) Disposable medical face mask

SGS Internal Ref No. : 14S20011961&14S20011961-01

Product specifications : 17.5cm x9.5cm

Manufacture date : 2020/3/22

Sample Color : (A) Blue

Period of validity : 2022/3/21

Manufacturer : ZHEJIANG HONGYU MEDICAL COMMODITY CO., LTD

Roll/ Lot No. : 20200303

Batch No. : 20062401

Proposed Care Instruction : -

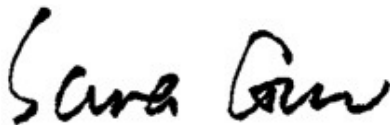
Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Jun 29, 2020

Testing Period : Jun 29, 2020 - Jul 13, 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 : 175 mm x 150 mm
 Positive Control Average : 2079 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)

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	34.3	37
	1-2	39.5	
	1-3	40.1	
	1-4	37.4	
	1-5	35.3	
2	2-1	39.1	39
	2-2	38.7	
	2-3	35.3	
	2-4	40.6	
	2-5	39.5	
3	3-1	41.5	38
	3-2	34.9	
	3-3	34.8	
	3-4	40.2	
	3-5	37.2	
4	4-1	39.5	39
	4-2	38.7	
	4-3	38.2	
	4-4	38.0	
	4-5	40.1	
5	5-1	38.7	38
	5-2	41.8	
	5-3	35.9	
	5-4	39.4	
	5-5	35.9	

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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Clause 5.2.4 Splash Resistance

(ISO 22609 :2004)

Sample: A

Test Blood Pressure : 16.0kPa
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Distance of the mask to the tip of cannula : 300±10mm
 Target plate method used : No

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:			32		
Overall result:			Acceptable		

Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
- 2) Test was conducted within 60s after removal from conditioning chamber.
- 3) 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.



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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#	3.74	9	2.41
2#	3.78	6	1.59
3#	3.75	<3	<0.8
4#	3.77	12	3.18
5#	3.70	27	7.30

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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