



SL52045311658401TX

QUZHOU GLORY SAFETY CLOTHING CO.,LTD NO15,10TH ROAD, HUIBU TOWN, CHANGSHAN COUNTY, QUZHOU CITY, ZHEJIANG, CHINA

The following sample(s) was/were submitted and identified on behalf of the client as: Sample Description : (A)Single-use medical face mask(non-sterile) Sample Color (A)Blue : Style No. **GFM-M001** : Lot No. : 201015 Test Performed Selected test(s) as requested by applicant : Sample Receiving Date Nov 02, 2020 : **Testing Period** : Nov 03, 2020 - Nov 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)

Donying li Helen Xuan

Dongjing Liu / Hailian Xuan (Authorized Signatory)



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 e sgs.china@sgs.com



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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 Test Area Flow Rate Pre-Conditioning Dimensions of test specimen Positive Control Average Negative Monitor Count Mean Particle Size		Inside Approximately 60 cm <sup>2</sup> 28.3 L/min Minimum of 4 hours at $21\pm5^{\circ}$ C and $85\pm5^{\circ}$ R.H. ~173mm x 157mm 1907 CFU < 1 CFU 3.0 $\pm$ 0.3µm
Mean Particle Size	:	•
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 cm <sup>2</sup>
Flow Rate	8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm <sup>2</sup> )	The average value for each test specimen (Pa/cm <sup>2</sup> )
	1-1	36.1	
	1-2	37.8	
1	1-3	39.1	38
	1-4	39.9	
	1-5	39.4	
	2-1	38.4	
	2-2	37.9	
2	2-3	39.1	39
	2-4	38.5	
	2-5	39.4	
	3-1	38.3	
	3-2	39.4	
3 4 5	3-3	39.2	39
	3-4	37.5	
	3-5	38.4	
	4-1	37.4	
	4-2	38.4	
	4-3	38.9	39
	4-4	39.4	
	4-5	38.6	7
	5-1	39.5	
	5-2	36.4	
	5-3	38.6	38
	5-4	38.4	
	5-5	37.5	7

Remark:

- 1) Performance Requirement: Type I<40 Pa/cm<sup>2</sup>, Type II<40 Pa/cm<sup>2</sup>, Type IIR<60 Pa/cm<sup>2</sup>
- 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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t (86-21) 61402666

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f (86-21) 64958763 e sgs.china@sgs.com



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## Clause 5.2.4 Splash Resistance

(ISO 22609 :2004)

Sample: A **Test Blood Pressure** Pre-Conditioning Distance of the mask to the tip of cannula

16.0kPa

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

300±10mm

:

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
- Test was conducted within 60s after removal from conditioning chamber. 2)
- An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested 3) 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)

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Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	3.31	6	1.81
2#	3.32	<3	<0.9
3#	3.31	<3	<0.91
4#	3.32	<3	<0.9
5#	3.31	12	3.63

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



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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