





Date: August 28,2020

中国认可 国际互认 检测 TESTING **CNAS L0599** 

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SL52025269146401TX-1 Test Report

XIANTAO ZHUOBO INDUSTRIAL CO., LTD

BUILDING ONE. HUANCHENGXI ROAD, PENGCHANG TOWN, XIANTAO

THIS REPORT CANCELS AND SUPERSEDES THE TEST REPORT NO. SL52025269146401TX

**DATE: Jun 20, 2020 ISSUED BY SGS (SHANGHAI)** 

**UPDATED TEST INFORMATION** 

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

(A)Disposable medical mask(Non-sterile) Sample Description

SGS Internal Ref No. SHHL2005519723MD

Style No. XTBZ-1 Sample Color (A)blue

Lot No./Batch No. 20200525001

Selected test(s) as requested by applicant Test Performed

Sample Receiving Date Jun 01, 2020

Testing Period Jun 01, 2020 - Jun 20, 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)

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 cm<sup>2</sup>

28.3 L/min Flow Rate

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

Dimensions of test specimen  $\sim 173 \text{ mm x } 155 \text{ mm}$ 

Positive Control Average 1809 CFU **Negative Monitor Count** : < 1 CFU Mean Particle Size  $3.0 \pm 0.3 \mu m$ 

Test bacteria Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result	
Bacterial Filtration Efficiency (BFE)	1	99.7%	
	2	99.7%	
	3	99.8%	
	4	99.9%	
	5	99.9%	

#### Remark:

- Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%
- 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

Randomly test in different location (1 around and 4 away from the centric Test Side

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> 8 l/min Flow Rate

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm²)	The average value for each test specimen (Pa/cm²)	
	1-1	35.6		
	1-2	34.9		
1	1-3	35.5	34	
	1-4	33.0		
	1-5	30.4		
	2-1	30.1		
	2-2	34.4		
2	2-3	30.6	32	
	2-4	31.2		
	2-5	34.6		
3	3-1	32.5		
	3-2	34.4		
	3-3	32.9	32	
	3-4	27.9		
	3-5	33.4		
4	4-1	35.2		
	4-2	32.9		
	4-3	36.1	34	
	4-4	35.7		
	4-5	29.6		
5	5-1	33.8		
	5-2	31.5		
	5-3	33.6	34	
	5-4	32.9		
	5-5	37.5		

## Remark:

- 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>
- 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

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

Distance of the mask to the tip of cannula 300±10mm

Test	Penetration on	Conclusion	Test	Penetration on	Conclusion
Specimen#	inside surface		Specimen#	inside surface	
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	Seen	Fail	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	Seen	Fail	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	Seen	Fail
16	None Seen	Pass	32	None Seen	Pass
Numbe	r of Pass:	29			
Overa	erall result:				

### Remark:

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

Toot Coooling on #	Maala Maiabta	Total Bioburden,	Total Bioburden,	
Test Specimen#	Mask Weight(g)	(CFU/mask)	(CFU/g)	
1#	2.86	33	12.00	
2#	2.88	45	16.00	
3#	2.71	42	16.00	
4#	2.88	27	9.00	
5#	2.85	45	16.00	

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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