

Test Report SL52025269709001TX
XIANTAO FORTUNE MEDICAL SUPPLIES CO., LTD.
NO.182 NEW STREET, HECHANG, HUBEI, CHINA

Date: June 29, 2020

Page 1 of 4

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

Sample Description : (A) Disposable face mask

Composition : (A) Non-woven fabric

Sample Color : (A) Blue

Manufacturer : XIANTAO FORTUNE MEDICAL SUPPLIES CO., LTD.

Lot No./Batch No. : Not provided

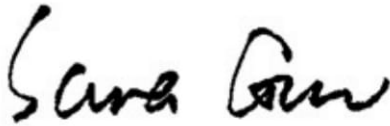
Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Jun 03, 2020

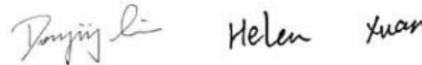
Testing Period : Jun 05, 2020 - Jun 29, 2020

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

Conditioning Parameters : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Dimensions of test specimen : 174 mm x 151 mm
 Test Area : ~60 cm²
 Test Side : Inside
 Flow Rate : 28.3 l/min
 Positive Control Average : 2713 CFU
 Negative Monitor Count : < 1 CFU

	1#	2#	3#	4#	5#
(BFE), %	99.9	99.9	99.9	99.9	99.9

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

Clause 5.2.3 Breathability

(EN 14683 :2019+AC:2019 Annex C)

Sample: A

Test number and location : 5 random areas for each specimen (face mask)
 Conditioning Parameters : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Test Area : 4.9 cm²
 Flow Rate : 8 l/min

	1#	2#	3#	4#	5#
Differential pressure ΔP (Pa/cm ²)	36	36	38	37	37

Remark: Performance Requirement: Type I < 40 Pa/cm², Type II < 40 Pa/cm², Type IIR < 60 Pa/cm²



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Clause 5.2.4 Splash Resistance

(ISO 22609 :2004, Pressure 16.0 kPa)

Sample: A

Penetration on inside surface							
1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Fail	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Fail	Pass	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Fail	Pass
Number of Pass:			29				
Overall result:			Acceptable				

Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥ 16.0 kPa
- 2) Distance of the medical face mask target area surface to the tip of cannula is 300 ± 10 mm.
- 3) Condition and Test temperature $(21 \pm 5)^{\circ}\text{C}$, relative humidity $(85 \pm 10)\%$
- 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

Clause 5.2.5 Microbial Cleanliness

(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Sample Number	Mask Weight(g)	Total Bioburden, (cfu/mask)	Total Bioburden, (cfu/g)
1#	2.58	3	1.16
2#	2.66	3	1.13
3#	2.62	<3	<1.15
4#	2.64	6	2.27
5#	2.63	6	2.28

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



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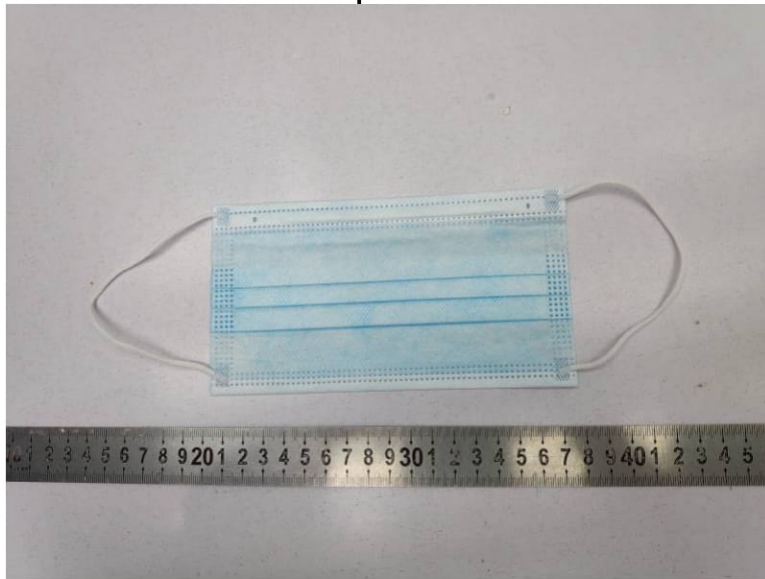
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Sample Photo



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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