

Test Report

SL52035273662401TX

Date: August 03, 2020

Page 1 of 5

TAIZHOU KANGJIAN MEDICAL EQUIPMENT CO., LTD.  
THE MACHINE ELECTRICITY ZONE, 317600 YUHUAN COUNTY TAIZHOU ZHEJIANG, CHINA

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

Sample Description : (A) Disposable Medical Face Mask(non-sterile)

Style No. : Earloops TJ-Z01

Composition : (A) Melt-blown, spun-bound

Sample Color : (A) one side is blue and the other is white

Manufacturer : TAIZHOU KANGJIAN MEDICAL EQUIPMENT CO., LTD.

Roll/ Lot No. : 20200720

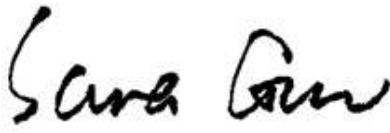
Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Jul 20, 2020

Testing Period : Jul 20, 2020 - Aug 03, 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

**ASTM F2100-2019 Standard Specification for Performance of Materials Used in Medical Face Masks**

**Section 6 Requirement**

**Section 6.1 Bacterial Filtration Efficiency (BFE)**

(ASTM F2101- 2019)

Sample A  
 Test Side : Inside  
 Test Area : Approximately 60 cm<sup>2</sup>  
 Flow Rate : 28.3 L/min (1 ft<sup>3</sup>/min)  
 Pre-Conditioning : Minimum of 4 hours at 21±5°C (70±10°F) and 85±5% R.H.  
 Positive Control Average : 2297.5 CFU  
 Negative Monitor Count : < 1 CFU  
 Mean Particle Size(Pre) : 2.99µm  
 Mean Particle Size(Post) : 2.92µm  
 Test bacteria : Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Plate Count Total for Each Stage	Result
Bacterial Filtration Efficiency (BFE), %	1	< 1 CFU	99.9%
	2	< 1 CFU	99.9%
	3	< 1 CFU	99.9%
	4	< 1 CFU	99.9%
	5	< 1 CFU	99.9%

Remark: Performance Requirement: Level 1 Barrier≥95%, Level 2 Barrier≥98%, Level 3 Barrier≥98%



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**Section 6.1 Differential Pressure**

(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 (70±10°F) 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 (mm H <sub>2</sub> O/cm <sup>2</sup> )	The average value for each test specimen (mm H <sub>2</sub> O/cm <sup>2</sup> )
1	1-1	3.62	3.8
	1-2	3.81	
	1-3	3.98	
	1-4	3.88	
	1-5	3.93	
2	2-1	2.98	3.5
	2-2	2.89	
	2-3	3.83	
	2-4	3.91	
	2-5	3.84	
3	3-1	3.07	3.6
	3-2	3.25	
	3-3	3.97	
	3-4	3.84	
	3-5	3.73	
4	4-1	3.51	3.5
	4-2	3.63	
	4-3	3.17	
	4-4	3.95	
	4-5	3.29	
5	5-1	3.06	3.4
	5-2	3.18	
	5-3	3.87	
	5-4	3.65	
	5-5	3.27	

Remark:

- 1) Performance Requirement: Level 1 Barrier: <5.0mm H<sub>2</sub>O/cm<sup>2</sup>, Level 2 Barrier: <6.0 mm H<sub>2</sub>O/cm<sup>2</sup>, Level 3 Barrier: <6.0 mm H<sub>2</sub>O/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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**Section 6.1 Resistance to Penetration by Synthetic Blood**  
(ASTM F1862/F1862M-2017)

Pressure 80mmHg

<b>Penetration on inside surface</b>							
1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Pass	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	Pass	Pass	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Number of Pass:			32				
Overall result:			Acceptable				

Remark:

- 1) Performance Requirement Level 1 Barrier: 80mmHg, Level 2 Barrier: 120mmHg, Level 3 Barrier: 160mmHg
- 2) Distance of the medical face mask target area surface to the tip of cannula is 30.5cm.
- 3) Condition and Test temperature (21±5)° C, relative humidity (85±5)%
- 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

**Section 6.2 Flammability**  
(16 CFR Part 1610 - 2008)

Sample : A  
Fabric Surface : Smooth  
Test Specimen Direction : Length

<b>As Received</b>	
<b>Burn Code</b>	
(1)	IBE
(2)	IBE
(3)	IBE
(4)	IBE
(5)	IBE

Flammability Classification: Class 1

Requirement: Class 1 for Level 1/ Level 2/ Level 3

**Conclusion: Pass**

**Remarks**

Class 1 Normal Flammability  
Class 1 textiles exhibit normal flammability and are acceptable for use in clothing.

**Burn Code Description:**

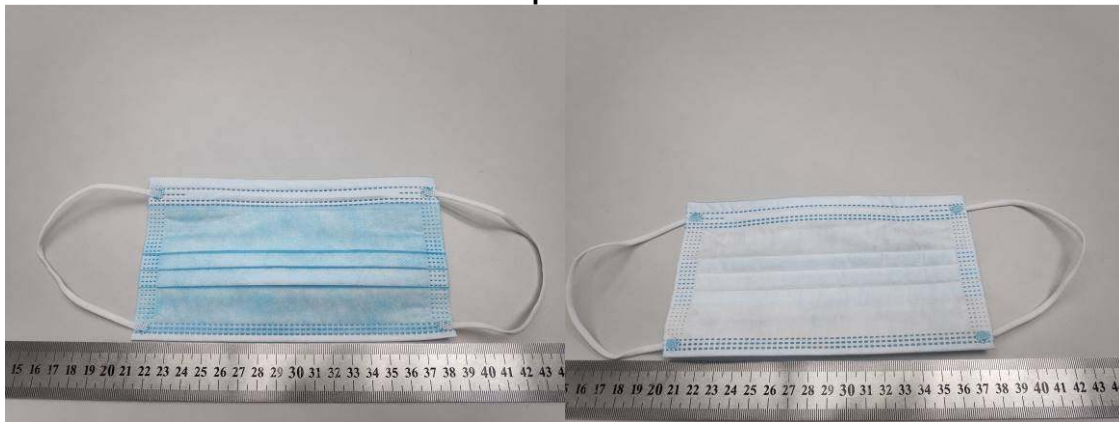
IBE = Ignited, but extinguished



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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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