

No:20R002628



## **Test Report**

(Electronic version)

## Verification Website: www.gttc.net.cn Verification Code: UJCM-1737-04

Issue Date: 2020-06-04

Applicant:XIANTAO HONGWEI NON-WOVEN FABRIC PRODUCTS CO.,LTDAddress:TAIZIHU INDUSTRIAL PARK, XIANTAO CITY, HUBEI, CHINA

Information confirmed by applicant: Disposable medical face mask Quantity: 60 pieces Type:Face mask with elastic for adult: 17.5\*9.5cm Standard Adopted: ASTM F 2100-2019 <Standard Specification for Performance of Materials Used in Medical Face Masks> Date Received/Date Test Started: 2020-05-20 Conclusion: Bacterial filtration efficiency (BFE) Μ Differential pressure Μ Resistance to penetration by synthetic blood М Flammability Μ Note: "M"-Meet the standard's requirement "F"-Fail to meet the standard's requirement "---"-No comment Remark:

All the tested items are tested under the standard condition (except for indication).

Copies of the report are valid only re-stamped.

The experiment was carried out at No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.



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Approved By: <u>Yuan Liu</u> Engineer Yuan Lin





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**Bacterial filtration efficiency (BFE) Test Method:** ASTM F 2101-2019

#### **Test principle:**

The medical face mask material is clamped between a six-stage cascade impactor and an aerosol chamber. The bacterial aerosol is introduced into the aerosol chamber using a nebulizer and a culture suspension of Staphylococcus aureus. The aerosol is drawn through the medical face mask material using a vacuum attached to the cascade impactor. The six-stage cascade impactor uses six agar plates to collect aerosol droplets which penetrate the medical face mask material. Control samples are collected with no test specimen clamped in the test apparatus to determine the upstream aerosol counts. The agar plates from the cascade impactor are incubated for 48 h and counted to determine the number of viable particles collected. The ratio of the upstream counts to the downstream counts collected for the test specimen are calcu lated and reported as a percent bacterial filtration efficiency.

### **Test equipment:**

Incubator Electronic balance Autoclave Experimental system for bacterial filtration efficiency (BFE) of mask

#### The environmental conditions of the laboratory and test condition:

Total bacteria: 0 CFU/plate Total fungi: 0 CFU/plate Blank experiment: Aseptic growth Test environment temperature: 24.5 °C, Relative humidity: 56.0% Culture Medium: TSA agar medium Culture temperature: 37°C, Culture time: 48h Test bacteria : staphylococcus aureus ATCC 6538 Concentration of bacterium: 5.0×10<sup>5</sup> CFU/ml Positive control average (C):  $1.9 \times 10^3$  CFU Negative monitor count: <1 CFU Test area: 49 cm<sup>2</sup> Dimensions of the test specimens: 15cm×15cm Flow rate: 28.3 l/min Pretreatment: Condition each specimen for 4 h by exposure to a temperature of  $(21\pm5)^{\circ}$  C and a relative humidity of (85±5)% Mean particle size: 3.0 µm The medical face mask in contact with the bacterial challenge: inside







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### **Results:**

Sample	Т	BFE (%)	Requirement (%)	Performance Level	Conclusion
1	23	98.78			
2	21	98.89			
3	15	99.21	≥95	Level 1	Pass
4	21	98.89	ASTM F 2100-2019		
5	22	98.84			

### **Remarks:**

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:  $B = (C - T) / C \times 100$ 

where

B is bacterial filtration efficiency (BFE), %;

C is positive control average;

T is the total plate count for the test specimen.









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### **Differential pressure**

Test method: EN 14683:2019+AC:2019 Annex C

#### **Test principle:**

This procedure was performed to evaluate the differential pressure of the medical face mask material by measuring the air exchange pressure through a measured surface area at a constant air flow rate.

#### **Test equipment:**

GTTC-YLC-1 Apparatus for measuring differential pressure

#### The environmental conditions of the laboratory and test condition:

Air flow: 8 l/min Test area: 4.9cm<sup>2</sup> Pretreatment: Condition each specimen for a minimum of 4 h by exposure to a temperature of (21±5)°C and a relative humidity of  $(85\pm5)\%$ 

General location of the areas of the mask the differential measurements:specimen center







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Results:			•	
Sample	Differential pressure (mmH <sub>2</sub> O/cm <sup>2</sup> )	Requirement (mmH <sub>2</sub> O/cm <sup>2</sup> )	Performance Level	Conclusion
1	3.74			
2	3.81	<5.0		
3	3.88	ASTM F 2100-2019	Level 1	Pass
4	3.52			
5	4.42			









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## Resistance to penetration by synthetic blood

Test method: ASTM F1862/F1862M-2017

## **Test principle:**

A volume of synthetic blood is disbursed at a specimen mask by a pneumatically controlled valve from a set distance to simulate the impact (splatter) of blood or other body fluid onto the specimen. The velocity and volume of fluid are set to simulate a given healthcare scenario. Any evidence of synthetic blood penetration on the inner facing of the medical face mask (side contacting the wearer's face) constitutes a failure. Results are reported as pass/fail. Specimen medical face masks are evaluated at velocities of 450, 500, and 635 cm/s. These correspond to the velocityexiting a small arterial puncture at human blood pressures of 10.7, 16.0, and 21.3 kPa (80, 120, and 160 mmHg). Test results are reported at each velocity or corresponding pressure, and the medical face mask is rated at the highest corresponding blood pressure for which medical face mask specimens demonstrate an acceptable quality limit of 4.0.

### **Test equipment:**

Test apparatus for synthetic blood penetration LFY-227 Air compressor Graduated cylinder Electronic balance Targeting plate

#### The environmental conditions of the laboratory and test condition:

Condition each specimen for a minimum of 4 h by exposure to a temperature of  $(21\pm5)^{\circ}$ C and a relative humidity of  $(85\pm5)$ %

Surface tension of synthetic blood: 0.042 N/m







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	Measured value	Doguinomont	Dorformonce	
Sample	Pressure	Requirement	Performance	Conclusion
	80 mmHg	(mmHg)	Level	
1	pass			
2	pass			
3	pass			
4	pass			
5	pass			
6	pass			
7	pass			
8	pass			
9	pass			
10	pass			
11	pass			
12	pass			
13	pass			
14	pass			
15	pass			
16	pass			
17	pass	$\geq 80$	Level 1	Pass
18	pass	ASTM F 2100-2019		
19	pass			
20	pass			
21	pass			
22	pass			
23	pass			
24	pass			
25	pass			
26	pass			
27	pass			
28	pass			
29	pass			
30	pass			
31	pass			
32	pass			
Final result	pass 4.0 % is met for a single sampli		Testing	and Certification





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Flammability Test method: 16 CFR Part 1610

#### **Test principle**

Each specimen cut from the textile shall be inserted in a frame, brushed if it has a raised-fiber surface, and held in a special apparatus at an angle of 45 °. A standardized flame shall be applied to the surface near the lower end of the specimen for 1 second, and the time required for the flame to proceed up the fabric a distance of 127 mm (5 in) shall be recorded. A notation shall be made as to whether the base of a raised-surface textile fabric ignites or fuses.

### **Test equipment:**

Flammability apparatus Drying oven Brushing device

## The environmental conditions of the laboratory and test condition:

Pretreatment: the specimens shall be dried in the oven for 1 h at  $105 \,^{\circ}\text{C}$ Type of gas: tetrane







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Results:						
Sample	Burning time before washing		Flowmohilit		Def	
	Length (Face)	Width (Face)	Flammability class	Requirement	Performance Level	Conclusion
1	IBE	IBE	Class 1, Normal	Class 1, Normal Flammability	Level 1	Pass
2	IBE	IBE				
3	IBE	IBE				
4	IBE	IBE				
5	IBE	IBE				
Average	IBE	IBE				
Final result	IBE		Flammability	ASTM F 2100-2019		
Flammability characteristic	Melt					

**Remarks:** 

IBE----Ignited, but extinguished.



—End of Report——