

Test Report

(Electronic version)

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No: 20R004612

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Information confirmed by applicant:

Disposable facial mask

Quantity: 100 pieces

Type:HC-0A

Standard Adopted:

ASTM F 2100-2019 <Standard Specification for Performance of Materials Used in Medical Face Masks>

Date Received/Date Test Started: 2020-07-17

Conclusion:

Bacterial filtration efficiency (BFE)	M
Differential pressure	M
Flammability	M

Note: "M"-Meet the standard's requirement "F"-Fail to meet the standard's requirement "---"-No comment

Remark:

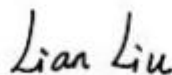
All the tested items are tested under the standard condition (except for indication).

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.

Approved By:

Lian Liu Engineer

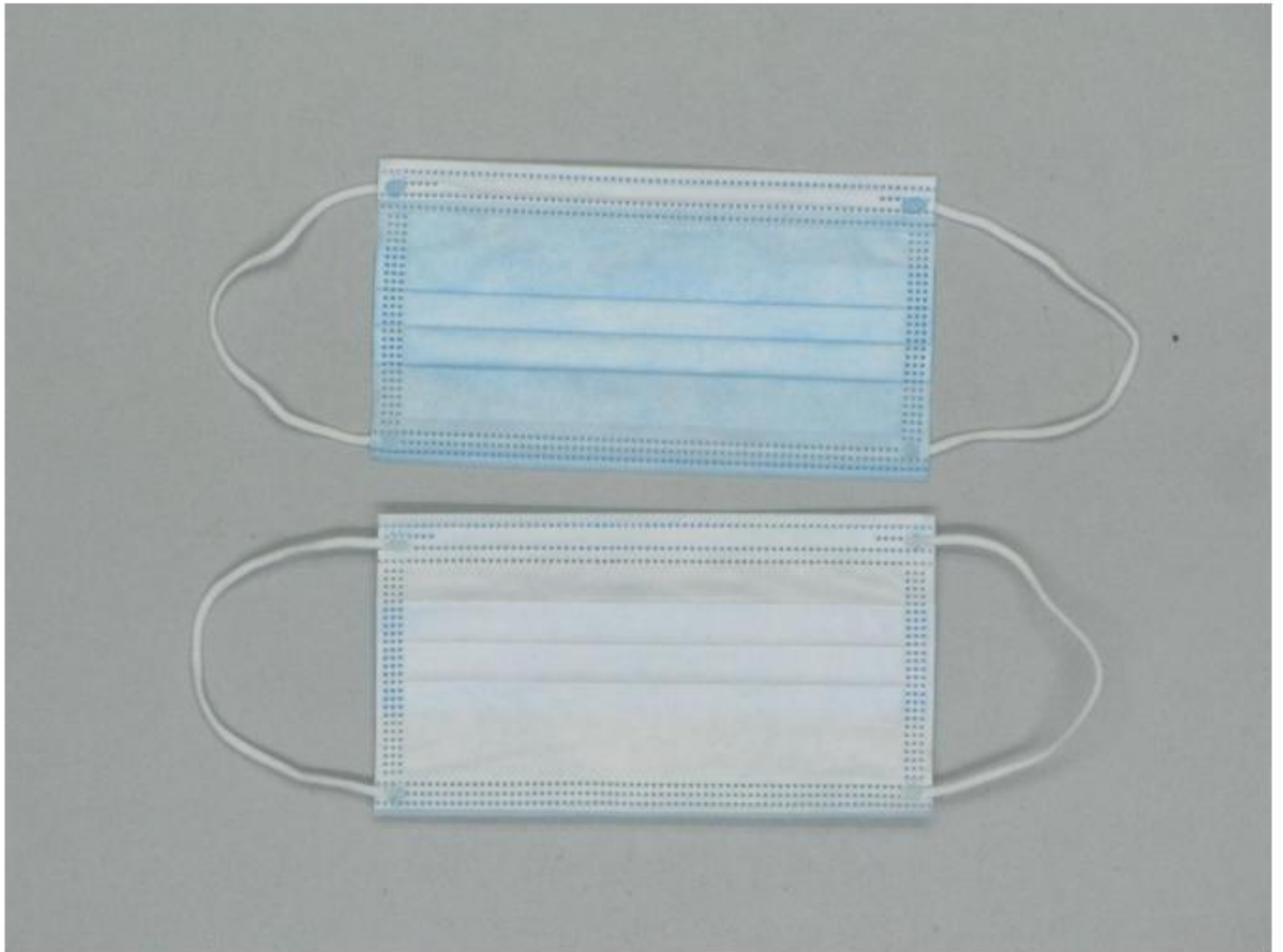


Page 1 of 8

Test Report

(Electronic version)

No: 20R004612



Test Report

(Electronic version)

No: 20R004612

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 calculated 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: 5.0×10^5 CFU/ml
Positive control average (C): 1.9×10^3 CFU
Negative monitor count: <1 CFU
Test area: 49 cm²
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±5) °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



Test Report

(Electronic version)

No: 20R004612

Results:

Sample	T	BFE (%)	Requirement (%)	Performance Level	Conclusion
1	9	99.53	≥98 ASTM F 2100-2019	Level 2	Pass
2	14	99.26			
3	14	99.26			
4	19	99.00			
5	14	99.26			

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.



Test Report

(Electronic version)

No: 20R004612

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: 4.9cm²

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±5)%

Test location: Top left, Bottom left, Middle, Top right and Bottom right



Test Report

(Electronic version)

No: 20R004612

Results:

Sample		1	2	3	4	5	Requirement (mmH ₂ O/cm ²)	Performance Level	Conclusion
Measured value (Pa)	Top left	444	414	457	411	428	<6.0 ASTM F 2100-2019	Level 2	Pass
	Bottom left	327	356	330	363	301			
	Middle	369	452	429	407	374			
	Top right	389	465	405	469	437			
	Bottom right	267	414	345	381	324			
	Average	359	420	393	406	373			
Differential pressure (mmH ₂ O/cm ²)		5.48	5.74	5.18	5.46	5.77			



Test Report

(Electronic version)

No: 20R004612

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 °C

Type of gas: tetrane



Test Report

(Electronic version)

No: 20R004612

Results:

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

Remarks:

IBE---Ignited, but extinguished.



—End of Report—