

# Test Report

(Electronic version)

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No: **20R000583**

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Applicant: HUNAN ZHENHEYIKANG MEDICAL INSTRUMENT CO.,LTD  
 Address: NO.6 BUILDING JINGXIANG ENERGY,NO.55 XIAGUANG EAST ROAD,GAOXIN DISTRICT, XIANGTAN,HUNAN

Information confirmed by applicant:

Medical protective mask  
 Quantity: seventy pieces  
 Size: three-dimensional type  
 Classification: Type II R

Standard Adopted:

EN 14683:2019+AC:2019 <Medical face masks-Requirements and test methods>

Date Received/Date Test Started: 2020-04-13

Conclusion:

Bacterial filtration efficiency (BFE)	M
Microbial cleanliness	M
Differential pressure	M
Splash resistance pressure	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:  
ZiShan Gao Senior Engineer

*ZiShan Gao*

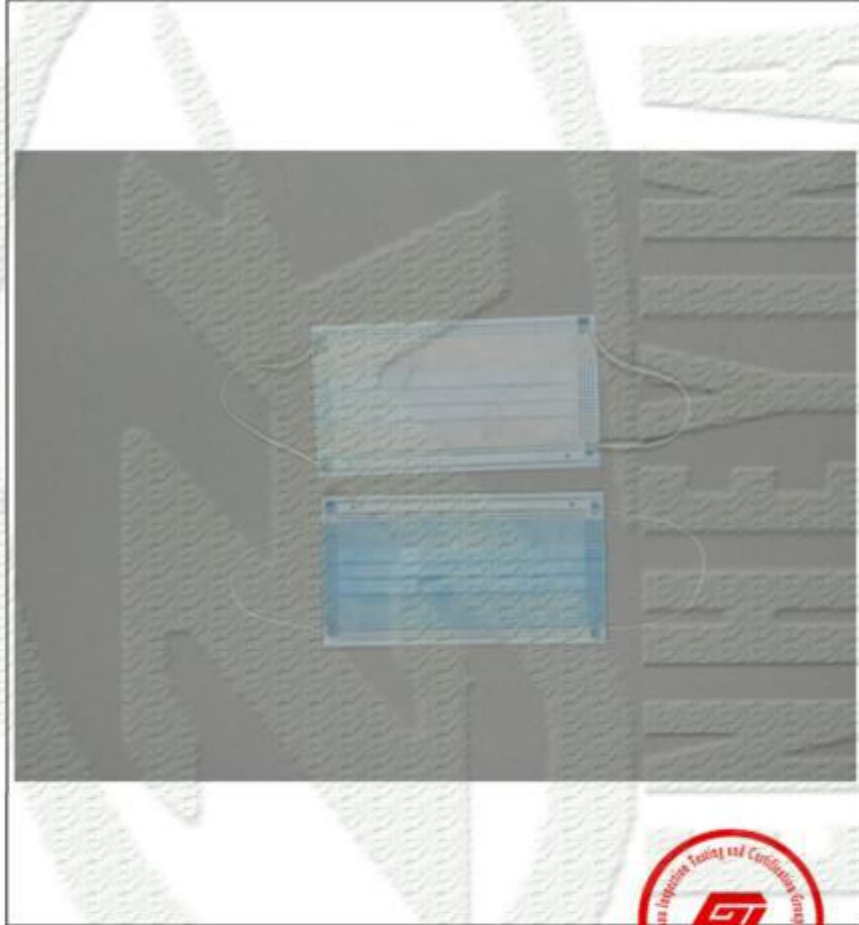


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**Bacterial filtration efficiency (BFE)**

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

**Test principle:**

A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of *Staphylococcus aureus* is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

**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:  $5.0 \times 10^7$  CFU/ml  
Positive control average (C):  $1.9 \times 10^5$  CFU  
Negative monitor count: <1 CFU  
Test area: 40 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±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



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**Results:**

Sample	T	BFEE (%)	Requirement (%)	Classification	Conclusion
1	28	98.52	≥98 EN 14683:2019+AC:2019	Type II R	Pass
2	19	99.00			
3	14	99.26			
4	21	98.89			
5	20	98.95			

**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 (BFEE), %;

C is positive control average;

T is the total plate count for the test specimen.

