

Test Report

(Electronic version)

Verification Website: www.gtgc.net.cn

Verification Code: RYED-1217-14

No: **20R000583**

Issue Date: 2020-04-23

Applicant: HUNAN ZHENHEYIKANG MEDICAL INSTRUMENT CO.,LTD
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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

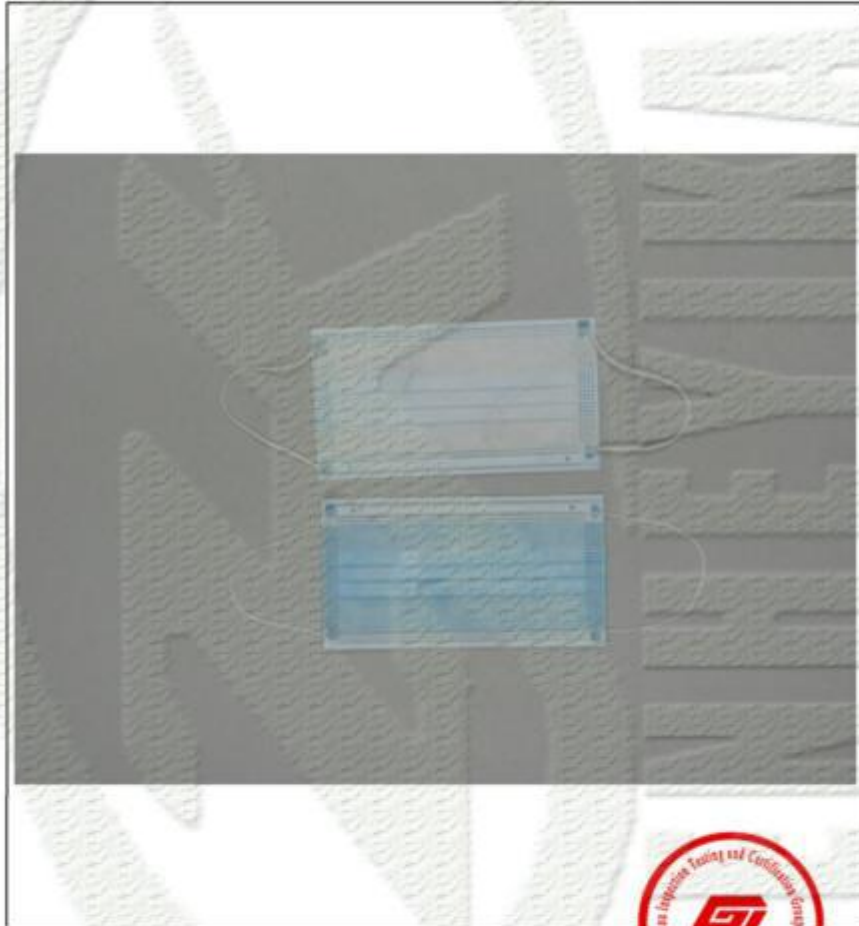


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Bacterial filtration efficiency (BFE)

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



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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.

