

# Test Report

(Electronic version)

Verification Code: OKCM-2928-04  
Verification Website: www.gttc.net.cn

No: 20R005460MO

Issue Date: 2020-08-31

Applicant: GUANGXI ZHIXUN MEDICAL EQUIPMENT CO., LTD  
Address: 5/F, UNIT 2, BUILDING A1, NANNING ECOLOGICAL INDUSTRIAL PARK, NO.110,  
ZHENXING ROAD, NANNING

Information confirmed by applicant:

Medical surgical mask (non sterile)

Quantity: 100 pieces

Type: NA-01R

Classification: Type II R

Standard Adopted:

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

Date Received/Date Test Started: 2020-08-13

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:

Modified content: modified client confirmed information.

This report replaces test report 20R005460 which has become invalid automatically.

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 Guo

ZiShan Guo Senior Engineer



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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:  $5.0 \times 10^5$  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 ±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	BFE (%)	Requirement (%)	Classification	Conclusion
1	28	98.53	≥98 EN 14683:2019+AC:2019	Type II R	Pass
2	31	98.37			
3	24	98.74			
4	31	98.37			
5	26	98.63			

**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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## Microbial cleanliness

**Test method:** EN ISO 11737-1:2018, Membrane filtration

## Test principle:

Take the required samples from the original packaging. Weigh a certain amount of sample and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl and 2 g/l Tween 20). The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0.45  $\mu$ m filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) for fungi enumeration. The plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively. The total bioburden is expressed by addition of the TSA and SDA counts.

## Test equipment:

Constant temperature incubator

Electronic balance

Pressure steam sterilizer

Biosafety cabinet

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

Test environment temperature: 24.5°C, Relative humidity: 56.0%

Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth



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**Results:**

Sample	Weight (g)	Bacteria (CFU per mask)	Fungi (CFU per mask)	Microbial cleanliness (CFU per mask)	Microbial cleanliness (CFU/g)	Requirement (CFU/g)	Classification	Conclusion
1	3.1	21	9	30	10	≤30 EN 14683:2019+AC:2019	Type II R	Pass
2	3.1	20	10	30	10			
3	3.0	24	8	32	11			
4	3.1	21	7	28	9			
5	3.1	21	7	28	9			



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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±5)%

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



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**Results:**

Sample		1	2	3	4	5	Requirement (Pa/cm <sup>2</sup> )	Classification	Conclusion
Measured value (Pa)	Top left	162	160	152	162	166	<60 EN 14683:2019+AC:2019	Type II R	Pass
	Bottom left	159	155	157	152	152			
	Middle	157	158	159	132	147			
	Top right	150	162	157	154	152			
	Bottom right	150	161	166	149	164			
	Average	156	159	158	150	156			
Differential pressure (Pa/cm <sup>2</sup> )		31.8	32.4	32.2	30.6	31.8			





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## Splash resistance pressure

Test method: ISO 22609:2004

## Test principle:

A specimen medical face mask is supported on an apparatus. A volume of synthetic blood is sprayed horizontally at the specimen mask to simulate the scenario of a mask being splashed by a punctured blood vessel. The volume of fluid, distance to impact, orifice size and fluid velocity are defined in this method and intended to be consistent with this health care scenario. Any evidence of synthetic blood penetration on the side of the medical face mask contacting the wearer's face constitutes failure. Results are reported as "pass/fail". Specimen medical face masks are evaluated at a total of three different velocities corresponding to human blood pressures of 10.6 kPa, 16.0 kPa, and 21.3 kPa. Test results are reported at each velocity 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  $(21 \pm 5)^\circ\text{C}$  and a relative humidity of  $(85 \pm 5)\%$

Pressure: 16.0 kPa

Velocity: 550 cm/s



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**Results:**

Sample	Measured value	Requirement (kPa)	Classification	Conclusion
	Pressure			
	16.0 kPa			
1	pass	≥16.0 EN 14683:2019+AC:2019	Type II R	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			
18	pass			
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			
<b>Final result</b>	pass			

**Remarks:**

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.



—End of Report—