Test Report

(Electronic version)

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Verification Code: HWFY-0538-24

No:20R000125 Issue Date: 2020-04-15

Applicant: GUANGDONG ZHIER MEDICAL INSTRUMENTS CO., LTD.
Address: NO.1-5 CHONGYONG ROAD, ZHONGCHONG VILLAGE COMMITTEE, LELIU TOWN, SHUNDE DISTRICT, FOSHAN, GUANGDONG, CHINA

Information confirmed by applicant:

Medical face mask(non-sterile)

Quantity: eighty pieces

Lot number: 2020040001

Model: ZE-01

Size: 17.5cm×9.5cm

Classification: Type ⅡR

Standard Adopted:

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

Date Received/Date Test Started: 2020-03-31

Conclusion:

Bacterial filtration efficiency (BFE)	M
Microbial cleanliness	M
Differential pressure	M
Splash resistance pressure	M
Materials and construction	M
Design	M
General	M

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

Remark:
The authorization of bacterial filtration efficiency (BFE), differential pressure, splash resistance pressure, materials and construction, design, general is not received from CNAS.
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: Nan Ma

Nan Ma 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℃, Relative humidity: 56.0%
Culture medium: TSA agar medium
Culture temperature: 37℃， 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: 40 cm^2
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)℃ 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	17	99.11	≥98 EN 14683:2019+AC:2019	Type ⅡR	Pass
2	23	98.79			
3	24	98.74			
4	19	99.00			
5	25	98.68			

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 µm 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℃ and 7 days at (20 to 25)℃ 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℃, 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:

Microbial	Measured value (CFU/g)	Microbial cleanliness (CFU/g)	Requirement (CFU/g)	Classification	Conclusion
Bacteria	6	16	≤30 EN 14683:2019+AC:2019	**Type ⅡR**	**Pass**
Fungi	10				

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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^2

Pretreatment: Condition each specimen for a minimum of 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%

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

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Results:

Sample	Measured value (Pa)	Differential pressure (Pa/cm²)	Requirement (Pa/cm²)	Classification	Conclusion
1	162	37.6	＜60 EN 14683:2019+AC:2019	**Type ⅡR**	**Pass**
2	201				
3	173				
4	184				
5	202				
Average	184				

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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:
Pretreatment: Condition each specimen for 24 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
Surface tension of synthetic blood: 0.042 N/m
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 ⅡR	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			
Final result	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.

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Materials and construction

Test Method: EN 14683:2019+AC:2019 5.1.1

Results:

Requirement	Conclusion
The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	**Pass**
The medical face mask shall not disintegrate, split or tear during intended use.	**Pass**
In the selection of the filter and layer materials, attention shall be paid to cleanliness.	**Pass**

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Design

Test Method: EN 14683:2019+AC:2019 5.1.2

Results:

Requirement	Conclusion
The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.	**Pass**
Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).	**Pass**

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General

Test Method: EN 14683:2019+AC:2019 5.2.1

Results:

Requirement	Conclusion
All tests shall be carried out on finished products or samples cut from finished products.	**Pass**

———End of Report———

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