广检集团 GTTC

CMA 170000113982 ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L10314

Test Report

(Electronic version)

Verification Website: www.gttc.net.cn

Verification Code: WAIJ-5464-44

No:20R003360MO Issue Date: 2020-07-15

Applicant: ADM PROMOTIONS (SHANGHAI) CO., LTD.
Address: ROOM 25A, NO. 238 EAST NANDAN ROAD, XU HUI DISTRICT, SHANGHAI

Information confirmed by applicant:

Disposable medical （Type ⅡR）

Quantity: 50 pieces

Type: 175×95mm

Date code: 20200623

Manufacture's name: SHENGGUANG MEDICAL INSTRUMENT CO.,LTD

Standard Adopted:

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

Date Received/Date Test Started: 2020-07-03

Conclusion:

Bacterial filtration efficiency (BFE)	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 20R003360 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: 5.1.2e

5.1.2e

Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

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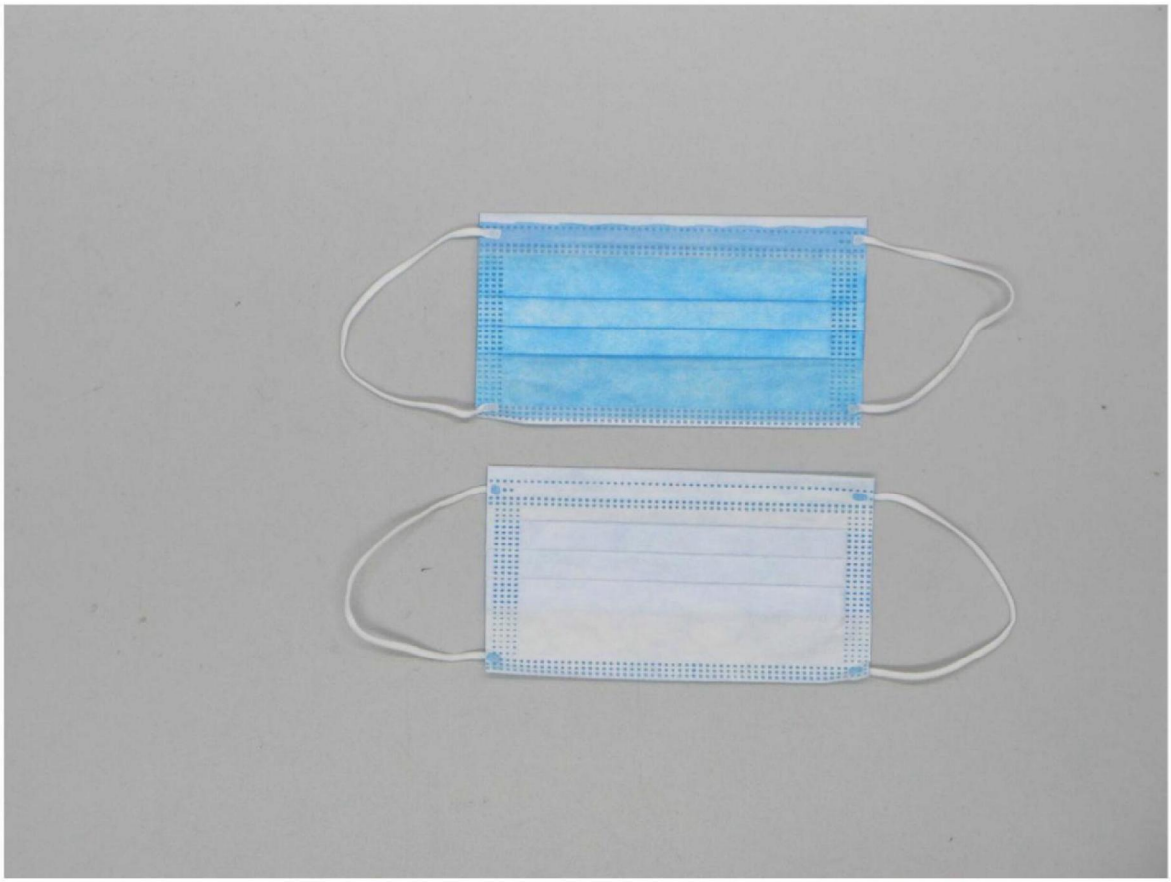

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Bacterial filtration efficiency (BFE)
Test method: EN 14683: 2019+AC: 2019 Annex B

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: 49 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	8	99.58	≥98 EN 14683:2019+AC:2019	Type ⅡR	Pass
2	13	99.32			
3	13	99.32			
4	12	99.37			
5	8	99.58			

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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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±5)℃ and a relative humidity of (85±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 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 2[illegible] show "pass" results.

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———End of Report———

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