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Test Report

Number: GZHT02307014

Report Ref:	GZHT02307014		
Date Received:	Jun 23, 2020	**Date Issued:**	Jun 30, 2020

Company Name: **Address:**	3A MEDICAL PRODUCTS CO.,LTD YU AN INDUSTRIAL PARK，230001 LIU AN PEOPLE'S REPUBLIC OF CHINA
Contact Name:	邓颖

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:		
End Uses	:	Medical Face Mask
Ratings	:	Level 3
Sample Name	:	Disposable Medical Mask With Ties
Size	:	17.5x9.5cm
Colour	:	Navy
Standard	:	ASTM F2100-19$^{\varepsilon 1}$
Manufacturer	:	3A MEDICAL PRODUCTS
Brand	:	3A MEDICAL
Buyer	:	Newline
Date received/ Test Started	:	Jun 23, 2020
Ref	:	3A1002L3 皖械 20202140040 anhui food and drugadministstion of firearms production xu 20202140040 shanghai international holding crop.Gmbh(europe)

Test was conducted on specific items, at our client's request.

Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

Lin Lin
General Manager

Ula / abbyqzeng

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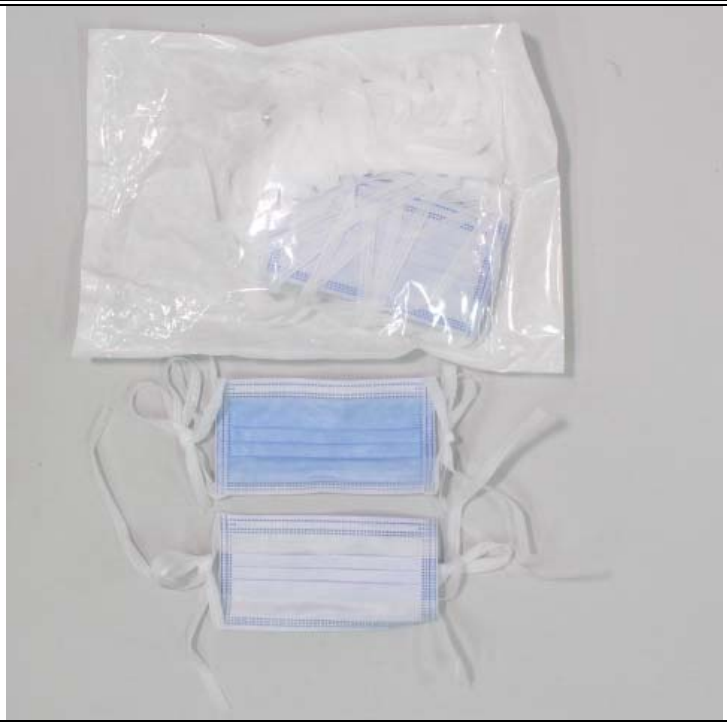
Original Sample Photo



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Summary of testing:

With reference to following standard:
• ASTM F2100-19$^{\varepsilon 1}$ Standard Specification for Performance of Materials Used in Medical Face Masks Level 3 • ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus • EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods • ASTM F2299/F2299M-17 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres • ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood • 16 CFR Part 1610 Wearing Apparel Flammability

Materials Used in The Submitted Samples Were Found To Comply With The Requirements Of Above Standards As Specified in ASTM F2100-19$^{\varepsilon 1}$ 9.1-9.5.

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Tests Conducted (As Requested By The Applicant)

1 Flammability Test (ASTM F2100-19$^{\varepsilon 1}$, Section 9.5, Testing Refer to 16 CFR Part 1610 -2008):

As Received			
X	Plain Surface		Raised Surface

Burn Direction :	☒ Length ☐ Width	
Prelim Plain Surface :		
Length: IBE		
Width:		
	Original* (seconds)	Requirement Class 1
1.	IBE	
2.	IBE	
3.	IBE	
4.	DNI	
5.	DNI	
6.	-	
7.	-	
8.	-	
9.	-	
10.	-	
Average :	-	

Classification :	☒	Class 1, Normal Flammability
	☐	Class 2, Intermediate Flammability, Raised Surface
	☐	Class 3, Rapid And Intense Burning

Explanation Of Flammability Results:	
DNI	Did not ignite.
IBE	Ignited but extinguished.

* The disposable fabrics and garments need not to be refurbished in accordance with 16 CFR Part 1610.35 (a)(2).

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Tests Conducted (As Requested By The Applicant)

2 Bacterial Filtration Efficiency (BFE)

As Per ASTM F2100-19$^{\varepsilon 1}$ Standard Specification for Performance of Materials Used in Medical Face Masks Clause 9.1 and ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus.

Test Item	Results (%)					Performance Requirement for Medical Face Mask (%)
	Specimen (1)	Specimen (2)	Specimen (3)	Specimen (4)	Specimen (5)	
Bacterial Filtration Efficiency (BFE)	>99.9	>99.9	99.9	>99.9	>99.9	Level 3: ≥98

Remarks:
1. Biological Aerosol: Staphylococcus aureus (ATCC 6538).
2. Testing side: Outside of the test specimen was facing towards the challenge aerosol.
3. Test area: 78 cm^2
4. Flow rate: 28.3 L/min
5. The average plate count results of the positive controls: 2400 CFU
6. The average plate count results of the negative controls: < 1 CFU
7. CFU = Colony Forming Unit

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3 Differential Pressure (ASTM F2100-19$^{\varepsilon 1}$, Section 9.2, Testing Refer to EN 14683:2019+AC:2019 Annex C): Air flow: 8L/min, Test Area Diameter 25 mm, Test Area: 4.9 cm^2.

Tested Sample	Result (mm H_2O/cm^2)*					Performance Requirement for Medical Face Mask (mm H_2O/cm^2)
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5	
Location 1	4.3	4.6	3.9	4.1	4.0	Level 3: < 6.0
Location 2	4.5	3.8	4.2	4.0	4.5	
Location 3	4.0	4.0	3.9	4.1	4.8	
Location 4	3.9	4.3	4.4	4.2	4.5	
Location 5	4.1	4.3	4.3	4.3	4.1	
Average	4.2	4.2	4.1	4.1	4.4	
* = All the locations were evenly taken from the main mask body.						

4 Sub-Micron Particulate Filtration (ASTM F2100-19$^{\varepsilon 1}$, Section 9.3, Testing Refer to ASTM F2299/F2299M-17): Particle size in aerosol: 0.1 μm, Aerosol: PSL, Test area: 100 cm^2, Airflow: 5.33cm/s, Sampling time: 1 min.

Tested Sample/Component	Result (%)	Performance Requirement for Medical Face Mask (%)
Specimen (1)	98.4	Level 3: ≥ 98
Specimen (2)	98.0	
Specimen (3)	98.1	
Specimen (4)	98.3	
Specimen (5)	98.3	

Remark: Test was conducted by external provider

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5 Resistance to Penetration by Synthetic Blood (ASTM F2100-19$^{\varepsilon 1}$, Section 9.4, Testing Refer to ASTM F1862/F1862M-17):
Synthetic blood surface tension: 0.040 N/m, Distance between blow head front end and target area: 300 mm, Artificial blood volumes: 2 mL, Test Pressure: 160mmHg, Velocity: 635 cm/s, Use a fixed target.

Tested Sample/Component	Result	Performance Requirement for Medical Face Mask Pass Pressure at Level 3: 160 mm Hg
Specimen (1)	None seen	
Specimen (2)	None seen	
Specimen (3)	None seen	
Specimen (4)	None seen	
Specimen (5)	None seen	
Specimen (6)	None seen	
Specimen (7)	None seen	
Specimen (8)	None seen	
Specimen (9)	None seen	
Specimen (10)	None seen	
Specimen (11)	None seen	
Specimen (12)	None seen	
Specimen (13)	None seen	
Specimen (14)	None seen	
Specimen (15)	None seen	
Specimen (16)	None seen	
Specimen (17)	None seen	
Specimen (18)	None seen	
Specimen (19)	None seen	
Specimen (20)	None seen	

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Tests Conducted (As Requested By The Applicant)

Specimen (21)	None seen
Specimen (22)	None seen
Specimen (23)	None seen
Specimen (24)	None seen
Specimen (25)	None seen
Specimen (26)	None seen
Specimen (27)	None seen
Specimen (28)	None seen
Specimen (29)	None seen
Specimen (30)	None seen
Specimen (31)	None seen
Specimen (32)	None seen

Remark: Test was conducted by external provider

End of Report

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