

Test Report

Number: GZHT02297110

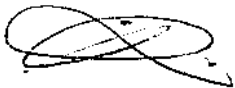
Report Ref:	GZHT02297110		
Date received:	May 29, 2020	Date Issued:	Jun 08, 2020

Company Name:	GUANGZHOU DAYUN MEDICALTECHNOLOGY CO., LTD.		
Address:	BUILDING B2,NO. 632,XINTANG AVENUE, XINTANG,ZENGCHENG DISTRICT, GUANGZHOU,GUANGDONG		
Contact Name:	LIU PAN		

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:	
End Uses	: Medical Face Mask
Ratings	: Level 1
Sample Name	: Disposable Medical Mask
Size	: 17.5*9.5CM
Colour	: Blue
Standard	: ASTM F2100-19 ^{e1}
Brand	: KUNKKA
Manufacturer	: GUANGZHOU DAYUN MEDICAL TECHNOLOGY CO., LTD.
Date received/ Test Started	: May 29, 2020
Ref	: DY-01

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



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Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

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Original Sample Photo



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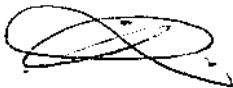
Summary of testing:

With reference to following standard:

- ASTM F2100-19^{e1} Standard Specification for Performance of Materials Used in Medical Face Masks Level 1
- 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^{e1} 9.1-9.5.

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Tests Conducted (As Requested By The Applicant)

1 Wearing Apparel Flammability:
16 CFR Part 1610 (As Amendment In 2008)

X	Plain Surface		Raised Surface
Burn Direction :		<input checked="" type="checkbox"/> Length	<u>Requirement</u> Class 1
		<input type="checkbox"/> Width	
Prelim Plain Surface :			
Length: IBE			
Width: -			
		Original* (seconds)	
1.	IBE		
2.	IBE		
3.	DNI		
4.	DNI		
5.	DNI		
6.	-		
7.	-		
8.	-		
9.	-		
10.	-		
Average :		-	

Classification :	<input checked="" type="checkbox"/>	Class 1,	Normal Flammability
	<input type="checkbox"/>	Class 2,	Intermediate Flammability, Raised Surface
	<input type="checkbox"/>	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^{E1} 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 1: ≥95

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 cm²
4. Flow rate: 28.3 L/min
5. The average plate count results of the positive controls: 2300 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^{e1}, 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 cm².

<u>Tested Sample/Component</u>	<u>Result (mm H₂O/cm²)</u>	<u>Performance Requirement for Medical Face Mask (mm H₂O/cm²)</u> Level 1: < 5.0
Specimen (1)	4.7	
Specimen (2)	4.7	
Specimen (3)	4.3	
Specimen (4)	4.3	
Specimen (5)	4.6	
Average	4.5	

Remark : Test was conducted by external provider.

- 4 Resistance to Penetration by Synthetic Blood (ASTM F2100-19^{e1}, Section 9.4, Testing Refer to ASTM F1862/F1862M-17):
Synthetic blood surface tension: 0.041N/m, Distance between blow head front end and target area: 300 mm, Artificial blood volumes: 2 mL, Test Pressure: 80mmHg, Velocity: 450cm/s, Use a fixed target.

<u>Tested Sample/Component</u>	<u>Result</u>	<u>Performance Requirement for Medical Face Mask</u> Pass Pressure at Level 1: 80 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	

Remark: Test was conducted by external provider

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Tests Conducted (As Requested By The Applicant)

- 5 Sub-Micron Particulate Filtration (ASTM F2100-19^{e1}, 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: 5.33 cm/s , Sampling time: 1 min.

<u>Tested Sample/Component</u>	<u>Result (%)</u>	<u>Performance Requirement for Medical Face Mask (%)</u>
Specimen (1)	98.0	Level 1: ≥ 95
Specimen (2)	98.1	
Specimen (3)	97.4	
Specimen (4)	95.1	
Specimen (5)	95.7	

Remark: Test was conducted by external provider

End of Report

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