

Number: GZHT02311781-S1

Report Ref:	GZHT02311781-S1	THIS IS TO SUPERSEDE REPORT NO. GZHT02311781 DATED Jul 20, 2020
Date received:	Jul 06, 2020	Date Issued: Jul 22, 2020
Company Name: Address:		5.1.2e
Contact Name:		

The Following Sample Was Subn	itted And Identified By/On Behalf Of The Applicant As:
End Uses	: Sterile Medical Face Mask
Ratings	: Type IIR
Sample Name	: Disposable Medical Mask(TYPE IIR)
Size	: 175X95mm
Colour	: White& Blue
Standard	: EN 14683:2019+AC:2019
Manufacture	: SHENGGUANG MEDICAL INSTRUMENT CO., LTD
Date received/ Test Started	: Jul 06, 2020
Ref	: Lot No.: 7 Lot
	Date code: 20200623

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

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Intertek Testing Services Shenzhen Ltd. Guangzhou Branch Intertek Testing Service Stienzhen Ltd. Guangzhou Branch 深圳天祥质量技术服务有限公司广州分公司 5.1.2e E101/E201/E301/E401/E501/E601/2707/E001, No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, Prina 中国广州经济技术开发区科学域彩频路 7号之二第 1-8 层 02 房 00 年 101. E201 E301 E401 E501 E601 E701 E801 e: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730 E201、E301、E401、E501、E601、E701、E801 Tel: +86 20 8213 9001 Fax: +86 20 8208 9909 Postcode: 510663 (10



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Original Sample Photo

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Summary of testing:

With reference to following standard:

• EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods Type IIR

Materials Used in The Submitted Sample Were Found To Comply With The Type IIR Requirements of EN 14683:2019+AC:2019 with respect to Splash Resistance Pressure and Bacterial Filtration Efficiency tests.

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Tests Conducted (As Requested By The Applicant)

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Splash Resistance Pressure (ISO 22609:2004): 1

Synthetic Blood Surface Tension: 0.042N/m, Distance Between Blow Head Front End And Target Area: 305 mm, Artificial Blood Volumes: 2 mL, Blood Pressure: 16.0 kPa, Velocity: 550 cm/s, Without Targeting-plate Used

Condition test specimens for a minimum of 4 hours in an environment of temperature (21±5) °C and relative humidity $(85\pm5)\%$ and conduct the test within 1 minute of removal from conditioning chamber.

Tested Sample	Sample Observation		Performance Requirement for Medical Face Mask	
Specimen (1)	No Penetration	Pass	Type IIR: No Penetration at 16.0 kPa	
Specimen (2)	No Penetration	Pass		
Specimen (3)	No Penetration	Pass		
Specimen (4)	No Penetration	Pass	_	
Specimen (5)	No Penetration	Pass		
Specimen (6)	No Penetration	Pass		
Specimen (7)	No Penetration	Pass		
Specimen (8)	No Penetration	Pass		
Specimen (9)	No Penetration	Pass		
Specimen (10)	No Penetration	Pass		
Specimen (11)	No Penetration	Pass		
Specimen (12)	No Penetration	Pass		
Specimen (13)	No Penetration	Pass		
Specimen (14)	No Penetration	Pass		
Specimen (15)	No Penetration	Pass		
Specimen (16)	No Penetration	Pass	-	
Specimen (17)	No Penetration	Pass		
Specimen (18)	No Penetration	Pass		
Specimen (19)	No Penetration	Pass		
Specimen (20)	No Penetration	Pass		
Specimen (21)	No Penetration	Pass		
Specimen (22)	No Penetration	Pass		

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Specimen (23)	No Penetration	Pass	
Specimen (24)	No Penetration	Pass	
Specimen (25)	No Penetration	Pass	
Specimen (26)	No Penetration	Pass	
Specimen (27)	No Penetration	Pass	
Specimen (28)	No Penetration	Pass	
Specimen (29)	No Penetration	Pass	
Specimen (30)	No Penetration	Pass	
Specimen (31)	No Penetration	Pass	
Specimen (32)	No Penetration	Pass	
Conclusion*:		Accepted	
* = An acceptable qualit specimens show "page	ty limit of 4.0% is met for a single ass" results.	e sampling plan when 2	29 or more of the 32 tested

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Tests Conducted (As Requested By The Applicant)

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Bacterial Filtration Efficiency (BFE) 2

As Per EN 14683:2019+AC:2019 Medical face masks - Requirements And Test Methods Annex B.

Test Item	Results (%)				Performance <u>Requirement for</u> <u>Medical Face</u> <u>Mask (%)</u>	
	Specimen (1)	Specimen (2)	Specimen (3)	Specimen (4)	Specimen (5)	
Bacterial Filtration Efficiency (BFE)	99.9	99.8	99.8	99.9	99.9	Type IIR: ≥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 cm²
- 4. Flow rate: 28.3 L/min

5. The average plate count results of the positive controls: 2.2x10³ CFU

- 6. The average plate count results of the negative controls: < 1 CFU
- 7. CFU = Colony Forming Unit

Remark: The test was performed In Caipin Road, Guangzhou Science City, GETDD, Guangzhou, Guangdong.

End of Report

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To : Attention :		Date :	Jul 22, 2020

Re : Report Revision Notification

Labtest Report Number GZHT02311781 date JUL 20, 2020

Please be informed that all the content recorded in the above captioned report will be void. This captioned report is now superseded by a revised Labtest Report, Number GZHT02311781-S1, issued on Jul 22, 2020.

Thank you for your attention

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