

Number: GZHT02306272

Report Ref:	GZHT02306272		
Date Received:	Jun 18, 2020	Date Issued:	Jun 30, 2020

Company Name: Address:		
Control November	5.1.2e	
Contact Name:		

1	
The Following Sample Was Subm	itted And Identified By/On Behalf Of The Applicant As:
End Uses :	Sterile Medical Face Mask
Ratings :	Type IIR
Sample Name :	Disposable Medical Mask
Size :	175X95mm
Colour :	White/Blue
Standard :	EN 14683:2019+AC:2019
Manufacturer :	Shengguang Medical Instrument Co., Ltd
Date received/ Test Started :	Jun 18, 2020
Ref :	Lot No.: 6Lot

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

Prepared And Checked By:

For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

AL / hilaryxu



Page 1 Of 6

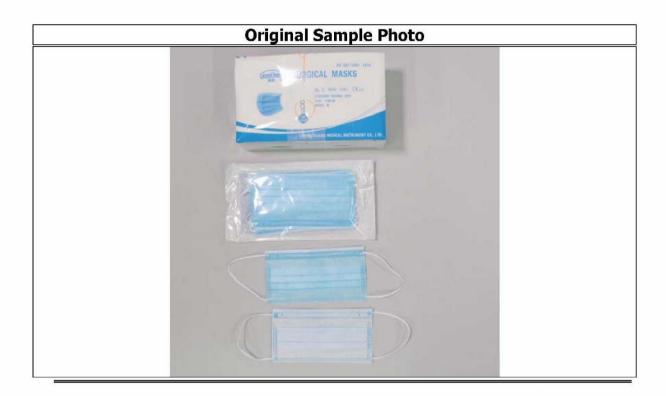
Intertek Testing Services Strenzhen Ltd. Guangzhou Branch

E201、E301、E401、E501、E601、E701、E801 Tel: +86 20 8213 9001 Fax: +86 20 8208 9909 Postcode: 510663

1: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730



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AL / hilaryxu



Page 2 Of 6

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深圳天祥质量技术服务点版公司广州分公司 5.1.2e E101/E201/E301/E401/E501/E601/E701/E901, Hengyun Building No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, Thina Frommic & Technolog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,创

Hengyun Building, 235 Kaifa Ave., Guangzhou pomic & Technological Development District, Guangzhou, China 文字 广州经济技开发区开发大道 235 号恒运大厦 3楼

1: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730

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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 Bacterial Filtration Efficiency and Splash Resistance Pressure tests.

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AL / hilaryxu



Page 3 Of 6

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omic & Technological Development District, Guangzhou, China 中国广州经济技开发区开发大道 235 号恒运大厦 3楼

te: +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



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Tests Conducted (As Requested By The Applicant)

Bacterial Filtration Efficiency (BFE) As Per EN 14683:2019+AC:2019 Medical face masks - Requirements And Test Methods Annex B.

Test Item	Results (%)			<u>Performance</u>		
	Specimen (1)	Specimen (2)	Specimen (3)	Specimen (4)	Specimen (5)	Requirement for Medical Face Mask (%)
Bacterial Filtration Efficiency (BFE)	99.9	99.5	99.7	99.9	99.7	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: 2400 CFU
- 6. The average plate count results of the negative controls: < 1 CFU
- 7. CFU = Colony Forming Unit

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Page 4 Of 6

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5.1.2e E101/E201/E301/E401/E501/E601/E701/E701/E701.

No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, Snina

田屬

Hengyun Building, 235 Kaifa Ave., Guangzhou omic & Technological Development District, Guangzhou, China

: +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

中国广州经济技术开发区科学城彩频路7号之二第1-8层02房、



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Tests Conducted (As Requested By The Applicant)

2 Splash Resistance Pressure (ISO 22609:2004):

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: 16.0 kPa, Velocity: 550 cm/s, Use A Fixed Target.

Tested Sample	<u>Result</u>	Performance Requirement for Medical Face Mask Type IIR: No penetration at 16.0 kPa
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	
Specimen (21)	None seen	
Specimen (22)	None seen	
Specimen (23)	None seen	
Specimen (24)	None seen	

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Page 5 Of 6

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深圳天祥质量技术服务有限公司广州分公司

Hengyun Building, 235 Kaifa Ave., Guangzhou comic & Technological Development District, Guangzhou, China 中文广州经济技开发区开发大道 235 号恒运大厦 3 楼

d: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730



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Tests Conducted (As Requested By The Applicant)

Tested Sample Result Performance Requirement for Medical Face Mask

Type IIR: No penetration at 16.0 kPa

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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Page 6 Of 6

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E101/E201/E301/E401/E501/E601/

No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, China 中国广州经济技术开发区科学城彩频路7号之二第1-8层02房、 EN ES

中国广州经济技开发区开发大道 235 号恒运大厦 3 楼 +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730

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