

# TEST REPORT



中国认可  
国际互认  
检测  
TESTING  
CNAS L0220

Number: GZHT02349342

<b>Report Ref:</b>	GZHT02349342
<b>Date received/ Test Started:</b>	Sep 24, 2020/Oct 14, 2020
<b>Date Issued:</b>	Oct 23, 2020

<b>Company Name:</b>	SHANDONG INTCO MEDICAL PRODUCTS CO.,LTD
<b>Address:</b>	NO.9888,QIWANG ROAD, NAOSHAN INDUSTRIAL PARK. QINGZHOU SHANDONG, CHINA
<b>Contact Name:</b>	黄聪敏

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:	
End Uses	: Non-Sterile Medical Face Mask
Ratings	: Type IIR
Sample Name	: Medical Face Mask
No. Of Sample	: One (100 pieces)
Size	: 17.5X9.5cm
Colour	: Blue
Standard	: EN 14683:2019+AC:2019
Date received/ Test Started	: Sep 24, 2020/Oct 14, 2020
Ref	: Type No.: FM301

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

Approved by:

*Jana*

*Erica Yu*

Sr. Manager

Assistant Supervisor



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## Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

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**Original Sample Photo**



Approved by:

Sr. Manager

Assistant Supervisor



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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 Microbial Cleanliness, Bacterial Filtration Efficiency, Differential Pressure and Splash Resistance Pressure tests.

ORIGINAL

Approved by:

Sr. Manager

Assistant Supervisor



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Tests Conducted (As Requested By The Applicant)

- 1 Differential Pressure (EN 14683:2019+AC:2019 Annex C):  
Air flow: 8 L/min, Test area diameter 25 mm, Test area: 4.9 cm<sup>2</sup>.

Tested Sample	Result (Pa/cm <sup>2</sup> )*					Performance Requirement for Medical Face Mask (Pa/cm <sup>2</sup> )
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5	
Location 1	34.9	32.1	30.0	35.1	38.1	Type IIR: < 60
Location 2	31.2	31.2	34.4	40.8	35.5	
Location 3	36.3	38.7	37.9	35.4	38.9	
Location 4	37.6	34.4	36.3	38.4	40.4	
Location 5	36.5	36.6	34.8	37.6	39.4	
Average	35.3	34.6	34.7	37.5	38.5	

\* = All the locations were evenly taken from the main mask body.

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- 2 Splash Resistance Pressure (ISO 22609:2004):  
Synthetic Blood Surface Tension: 0.042 N/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±5)% and conduct the test within 1 minute of removal from conditioning chamber.  
Test Environment Condition: Temperature 24.0°C, Relative Humidity 87.0%

Tested Sample	Observation	Pass/Fail	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	

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Tests Conducted (As Requested By The Applicant)

Specimen (21)	No Penetration	Pass
Specimen (22)	No Penetration	Pass
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 quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show "pass" results.

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Tests Conducted (As Requested By The Applicant)

## 3 Bacterial Filtration Efficiency (BFE)

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

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	Type IIR: ≥98

### Remarks:

1. Biological Aerosol: Staphylococcus aureus (ATCC 6538).
2. Testing side: Inside of the test specimen was facing towards the challenge aerosol.
3. Test area: 78 cm<sup>2</sup>
4. Flow rate: 28.3 L/min
5. The average plate count results of the positive controls:  $2.4 \times 10^3$  CFU
6. The average plate count results of the negative controls: < 1 CFU
7. CFU = Colony Forming Unit

Remark: This test item was conducted in Caipin Road, Guangzhou Science City, GETDD, Guangzhou, Guangdong.

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Tests Conducted (As Requested By The Applicant)

4 Microbial Cleanliness

As Per EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods Annex D.

Test Item	Result ( cfu/g )					Limit (cfu/g)
	Specimen (1)	Specimen (2)	Specimen (3)	Specimen (4)	Specimen (5)	
Microbial Cleanliness	<1#	<1#	<1#	<1#	<1#	Type IIR: ≤30

Remark:

cfu = colony forming unit

≤ = Not more than

# = No colony was detected at the extraction liquid of the samples.

Remark: This test item was conducted in Caipin Road, Guangzhou Science City, GETDD, Guangzhou, Guangdong.

End of Report

*This report is made solely on the basis of your instructions and/or information and materials supplied by you. It is not intended to be a recommendation for any particular course of action. Intertek does not accept a duty of care or any other responsibility to any person other than the Client in respect of this report and only accepts liability to the Client insofar as is expressly contained in the terms and conditions governing Intertek's provision of services to you. Intertek makes no warranties or representations either express or implied with respect to this report save as provided for in those terms and conditions. We have aimed to conduct the Review on a diligent and careful basis and we do not accept any liability to you for any loss arising out of or in connection with this report, in contract, tort, by statute or otherwise, except in the event of our gross negligence or wilful misconduct. No copy of the test report(except for full text copy) shall be made without the written approval by Intertek.*

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