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TEST REPORT

中国认可
国际互认
检测
TESTING
CNAS L0220

Number: GZHT02349342

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

Company Name: **Address:**	SHANDONG INTCO MEDICAL PRODUCTS CO.,LTD NO.9888,QIWANG ROAD, NAOSHAN INDUSTRIAL PARK. QINGZHOU SHANDONG, CHINA
Contact Name:	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:

Sr. Manager Assistant Supervisor

INTERTEK TESTING SERVICES SHENZHEN LTD. GUANGZHOU BRANCH 检验检测专用章 (10)

QIN / pennytao

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
深圳天祥质量技术服务有限公司广州分公司

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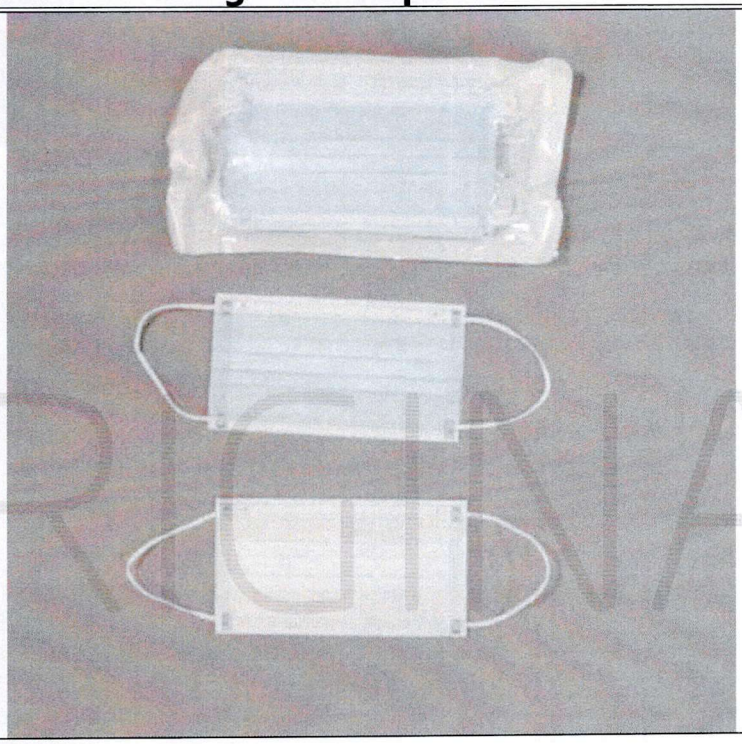
Original Sample Photo



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.

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^2.

Tested Sample	Result (Pa/cm^2)*					Performance Requirement for Medical Face Mask (Pa/cm^2)
	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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Tests Conducted (As Requested By The Applicant)

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^2
4. Flow rate: 28.3 L/min
5. The average plate count results of the positive controls: 2.4×10^3 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

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