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TEST REPORT

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检测
TESTING
CNAS L0220

Number: GZHT02367675

Report Ref:	GZHT02367675		
Date received:	Nov 24, 2020/Dec 02, 2020	**Date Issued:**	Dec 11, 2020

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

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	:	Nov 24, 2020/Dec 02, 2020
Ref	:	Type No.: FM301T

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

Approved by:

Sr. Manager Senior Chemist

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 检验检测专用章 (10)

QIN / hilaryxu

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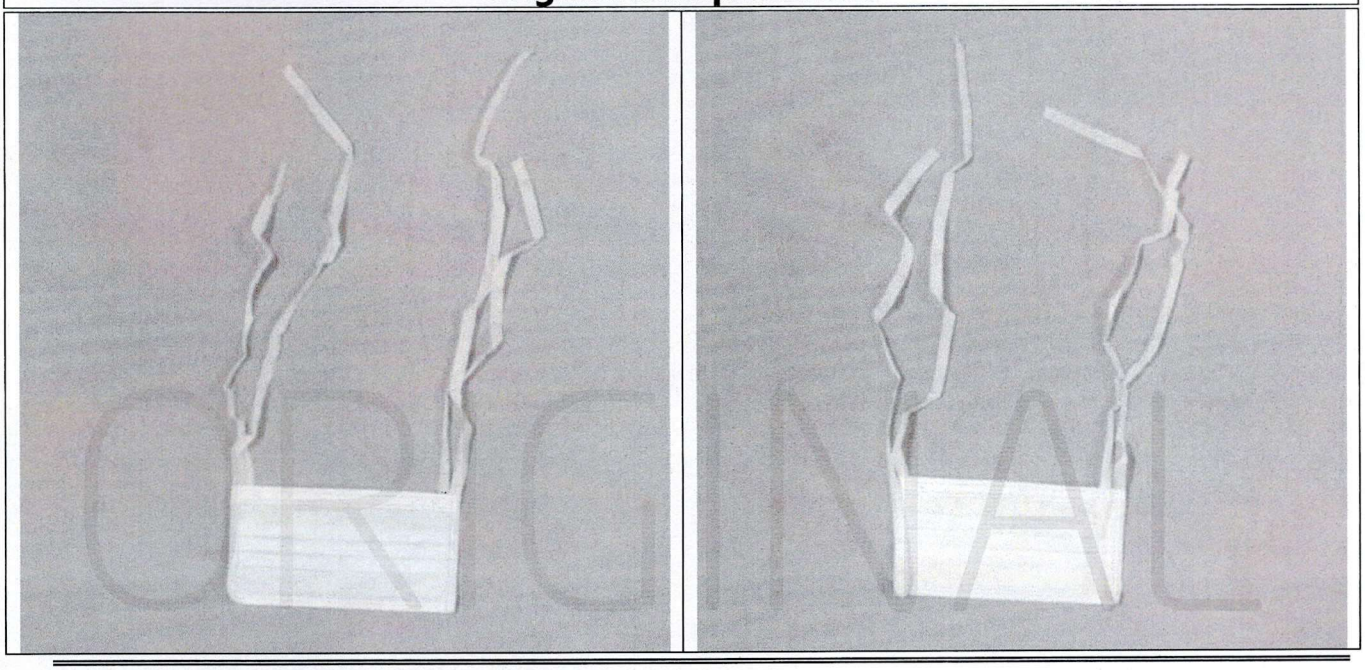
Original Sample Photo



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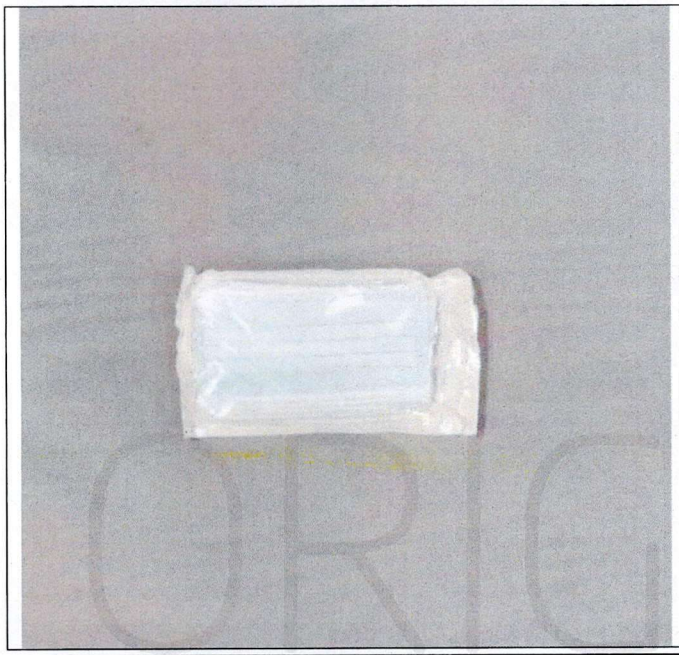

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Summary of testing:

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 Senior Chemist

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TEST REPORT

Number: GZHT02367675

Tests Conducted (As Requested By The Applicant)

1 Splash Resistance Pressure (*ISO 22609:2004*):
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±5)% and conduct the test within 1 minute of removal from conditioning chamber.
Test Environment Condition: Temperature 22.0°C, Relative Humidity 81.0%

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	
Specimen (21)	No Penetration	Pass	
Specimen (22)	No Penetration	Pass	
Specimen (23)	No Penetration	Pass	

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Tests Conducted (As Requested By The Applicant)

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.		

2 Differential Pressure (EN 14683:2019+AC:2019 Annex C):
Air flow: 8L/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	22.4	24.2	24.0	18.4	22.9	Type IIR: < 60
Location 2	23.5	25.5	26.1	21.1	22.0	
Location 3	31.3	30.0	29.3	26.8	27.9	
Location 4	37.3	43.0	41.6	31.7	35.1	
Location 5	34.1	38.0	36.0	32.7	33.9	
Average	29.7	32.1	31.4	26.1	28.4	
* = All the locations were evenly taken from the main mask body.						

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Tests Conducted (As Requested By The Applicant)

3 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.

4 Bacterial Filtration Efficiency (BFE)

Test Method: EN 14683: 2019+AC: 2019 Annex B

Summary of Test Method:
A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. The bacterial aerosol is introduced into the aerosol chamber using a nebulizer and a culture suspension of Staphylococcus aureus. The aerosol is drawn through the medical face mask material using a vacuum attached to the cascade impactor. The six-stage cascade impactor uses six agar plates to collect aerosol droplets which penetrate the medical face mask material. Control samples are collected with no test specimen clamped in the test apparatus to determine the upstream aerosol counts. The agar plates from the cascade impactor are incubated for (20 to 52) h and counted to determine the number of viable particles collected.
The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Conditioning of the Specimens: 4 h at (21 ± 5) ℃ and (85 ± 5) % relative humidity

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Tests Conducted (As Requested By The Applicant)

Test Condition:

Biological Aerosol: *Staphylococcus aureus* (ATCC 6538)
Testing side: Inside of the test specimen was facing towards the challenge aerosol
Test area: 78 cm^2
Flow rate: 28.3 L/min
The average plate count results of the positive controls: 2.2×10^3 CFU
The average plate count results of the negative controls: < 1 CFU
Mean particle size (MPS): 2.7 μm
Incubation condition: (37 ± 2) ℃ for (20 to 52) h
Number of test specimens: 5

Test Procedure:

1. Preparation of the bacterial challenge: Dilute the culture in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
2. Deliver the challenge to the nebulizer using a peristaltic or syringe pump. Connect tubing to nebulizer and peristaltic pump and into the challenge suspension; purge tubing and nebulizer of air bubbles.
3. Perform a positive control run without a test specimen clamped into the test system to determine the number of viable aerosol particles being generated.
4. Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer.
5. Immediately begin sampling the aerosol using the cascade impactor. Adjust the flow rate through the cascade impactor to 28.3 L/m.
6. Time the challenge suspension to be delivered to the nebulizer for 1 min.
7. Time the air pressure and cascade impactor to run for 2 min.
8. At the conclusion of the positive control run, remove plates from the cascade impactor.
9. Place new agar plates into the cascade impactor and clamp the test specimen into the top of the cascade impactor, with the inside oriented toward the challenge as intended.
10. Repeat the challenge procedure for each test specimen and positive control sample.
11. Perform a negative control sample by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control sample.
12. Incubate agar plates at (37 ± 2) °C for (20 to 52) h.
13. Count each of the six-stage plates of the cascade impactor.
14. Total the counts from each of the six plates for the test specimens and positive controls. Calculate the filtration efficiency percentages.

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Tests Conducted (As Requested By The Applicant)

Calculation:

The Bacterial Filtration Efficiency (BFE), was calculated as a percentage using the following equation:

% BFE= (C-T)/C × 100

where,
C = Average plate counts total for test controls;
T = Plate count total for the test specimen.

Test Result:

Tested Specimen	Result		Performance Requirement in EN 14683: 2019+AC: 2019 (% BFE)
	The Total Plate Count (T) (CFU)	Bacterial Filtration Efficiency (BFE) (%)	
Specimen (1)	0	>99.9	Type IIR: ≥ 98
Specimen (2)	0	>99.9	
Specimen (3)	0	>99.9	
Specimen (4)	0	>99.9	
Specimen (5)	0	>99.9	

Remarks:

CFU = Colony Forming Unit

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

End of Report

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