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Disposable Medical Face Mask Inherent USA FDA Standard

Brand: Inherent

Type No.: YX001, YX011, YX121

Performance standard: FDA ASTM Level 1/2/3, tested by Intertek

Production standards: ISO 10933-10:2010 & ISO 10993-

5:2009, tested by CCIC

Classifications: Level 1 & Level 2 (Non-Sterile), Level 3 (Sterile),

No latex ingredients

Material: Two-layer PP Nonwoven fabric and One-layer BFE95 or BFE99 Meltblown fabric (3 layers)

Mask specifications: Universal, 17,50 x 9,50 cm

Earloop design: Breathable and comfortable for prolonged wearing

Date of manufacture: From July 2020

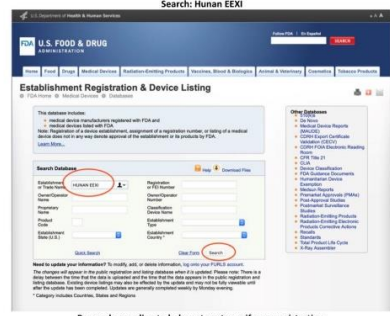
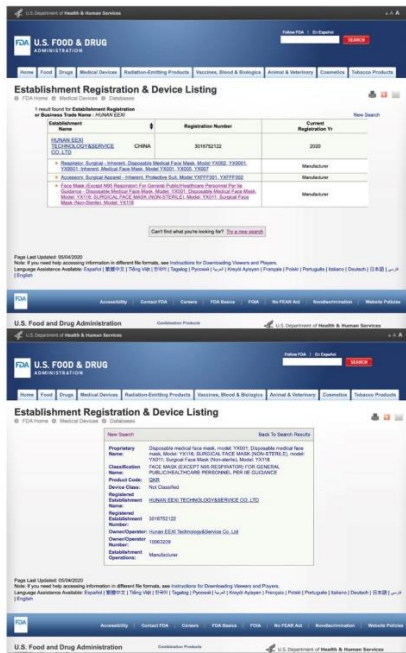
Expiration date: 2 years

Packing specifications: 50 pcs./box, 40 boxes 2000 pcs./carton

Carton measurements: 51.5 x 39 x 35.5 cm, G.W. 9.1 KGS.

P2





Proceed according to below steps to verify our registration.

Report Ref:	GZHT02310773	
Date Received:	Jul 03, 2020	Date Issued: Jul 10, 2020
Company Name:	HUNAN EXXI TECHNOLOGY & SERVICE CO., LTD	
Address:	NO.8, NORTH OF FINGTONG ROAD, LIUYANG HI-TECH INDUSTRIAL DEVELOPMENT ZONE, HUNAN CHINA	
Contact Name:	Luke Lin	

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:	
End Uses:	Medical Face Mask
Ratings:	Level 2
Sample Name:	Disposable Medical Face Mask
Size:	17.5*9.5cm
Colour:	Blue&White
Standard:	ASTM F2100-19 ¹
Date received/ Test Started:	Jul 03, 2020
Ref:	YX001

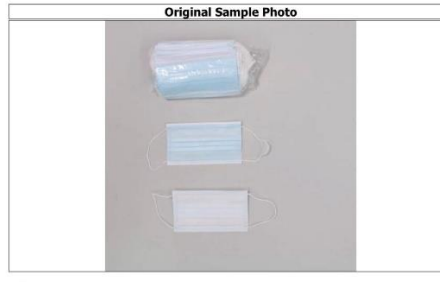
Test was conducted on specific items, at our client's request.

Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch


Lin Lin
General Manager

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Summary of testing:
With reference to following standard:
<ul style="list-style-type: none"> ASTM F2100-19¹ Standard Specification for Performance of Materials Used in Medical Face Masks Level 2 ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of <i>Staphylococcus aureus</i> EN 14683:2019/AC:2019 Medical face masks - Requirements and test methods ASTM F2299/F2299M-17 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres ASTM F1982/F1982M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood 16 CFR Part 1610 Wearing Apparel Flammability
Materials Used in the Submitted Samples Were Found To Comply With the Requirements Of Above Standards As Specified in ASTM F2100-19 ¹ 9.1-9.5.

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Tests Conducted (As Requested By The Applicant)

1. Differential Pressure (ASTM F2100-19¹, Section 9.2, Testing Refer to EN 14683:2019/AC:2019 Annex C):
Air flow: 8 L/min, Test Area Diameter 25 mm, Test Area: 4.9 cm².

Tested Sample	Result (mm H ₂ O/cm ²) ^a					Performance Requirement (for Medical Face Mask (mm H ₂ O/cm ²))
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5	
Location 1	3.2	3.1	3.5	2.9	3.1	Level 2: <6.0
Location 2	3.2	3.3	3.5	3.2	3.3	
Location 3	2.8	3.2	3.4	3.4	3.1	
Location 4	3.2	3.3	3.1	3.4	3.2	
Location 5	3.4	3.1	3.7	2.9	3.5	
Average	3.2	3.2	3.4	3.2	3.2	

^a = All the locations were evenly taken from the main mask body.

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Tests Conducted (As Requested By The Applicant)

5 Sub-Micron Particulate Filtration (ASTM F2100-19¹, Section 9.3, Testing Refer to ASTM F2299/F2299M-17):
Particle size in aerosol: 0.1 µm, Aerosol: Polystyrene Latex Spheres (PSL), Test area: 100 cm², Airflow: 5.33 cm³/s, Sampling time: 1 min.

Tested Sample/Component	Result (%)	Performance Requirement for Medical Face Mask (%)
Specimen (1)	99.4	Level 2: ≥ 98
Specimen (2)	99.1	
Specimen (3)	99.2	
Specimen (4)	99.4	
Specimen (5)	99.3	
Minimum value	99.1	

Remark: The test was performed by an approved third party subcontractor laboratory.

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 acted to conduct the business 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 willful misconduct. No copy of this report (except for full test copy) shall be made without the written approval by Intertek.

Report Ref: GZHT02310751
Date Received: Jul 03, 2020
Date Issued: Jul 10, 2020

Company Name: HUNAN EXKI TECHNOLOGY & SERVICE CO., LTD
Address: NO.6, NORTH OF FINGTONG ROAD, LIUYANG HI-TECH INDUSTRIAL DEVELOPMENT ZONE, HUNAN CHINA
Contact Name: Luke Lin

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:	
End Uses	: Medical Face Mask
Ratings	: Level 3
Sample Name	: Surgical Face Mask
Size	: 17.5*9.5cm
Colour	: Blue&White
Standard	: ASTM F2100-19 ¹
Date received / Test Started	: Jul 03, 2020
Ref	: YX011

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

Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch


Lin Lin
General Manager

doris / pennytao



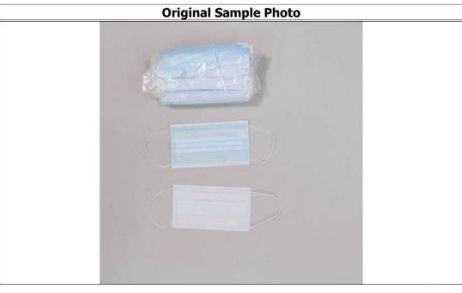
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Summary of testing:

- With reference to following standard:
- ASTM F2100-19¹ Standard Specification for Performance of Materials Used in Medical Face Mask Level 3
 - ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
 - EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods
 - ASTM F2299/F2299M-17 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
 - ASTM F1962/F1962M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood
 - 16 CFR Part 1610 Wearing Apparel Flammability

Materials Used in The Submitted Samples Were Found To Comply With The Requirements of Above Standards As Specified in ASTM F2100-19¹ 9.1-9.5.

Prepared And Checked By:
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Tests Conducted (As Requested By The Applicant)

1. Differential Pressure (ASTM F2100-19⁹, Section 9.2, Testing Refer to EN 14683:2019+AC:2019 Annex C):
Air Flow: 8 L/min, Test Area Diameter 25 mm, Test Area: 4.9 cm²:

Tested Sample	Result (mm H ₂ O/cm ²) ¹					Performance Requirement for Medical Face Mask (mm H ₂ O/cm ²)
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5	
Location 1	3.0	2.9	3.1	3.4	3.3	Level 3: <6.0
Location 2	3.1	3.0	2.8	3.2	3.5	
Location 3	3.2	3.2	3.1	3.0	3.4	
Location 4	3.2	3.1	2.8	3.1	3.3	
Location 5	3.0	3.1	2.8	3.2	3.3	
Average	3.1	3.1	2.9	3.2	3.4	

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

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Tests Conducted (As Requested By The Applicant)

Specimen (22)	No penetration
Specimen (23)	No penetration
Specimen (24)	No penetration
Specimen (25)	No penetration
Specimen (26)	No penetration
Specimen (27)	No penetration
Specimen (28)	No penetration
Specimen (29)	No penetration
Specimen (30)	No penetration
Specimen (31)	No penetration
Specimen (32)	No penetration

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Tests Conducted (As Requested By The Applicant)

2. Resistance to Penetration by Synthetic Blood (ASTM F2100-19⁹, Section 9.4, Testing Refer to ASTM F1862/F1862M-17):
Synthetic Blood Surface Tension: 0.042 N/m, Distance Between Blow Head Front End and Target Area: 300 mm, Artificial Blood Volume: 2 mL, Test Pressure: 160 mmHg, Velocity: 635 cm/s, Use a Fixed Target.

Tested Sample/Component	Result	Performance Requirement for Medical Face Mask Pass Pressure at Level 3: 160 mm Hg
Specimen (1)	No penetration	
Specimen (2)	No penetration	
Specimen (3)	No penetration	
Specimen (4)	No penetration	
Specimen (5)	No penetration	
Specimen (6)	No penetration	
Specimen (7)	No penetration	
Specimen (8)	No penetration	
Specimen (9)	No penetration	
Specimen (10)	No penetration	
Specimen (11)	No penetration	
Specimen (12)	No penetration	
Specimen (13)	No penetration	
Specimen (14)	No penetration	
Specimen (15)	No penetration	
Specimen (16)	No penetration	
Specimen (17)	No penetration	
Specimen (18)	No penetration	
Specimen (19)	No penetration	
Specimen (20)	No penetration	
Specimen (21)	No penetration	

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Tests Conducted (As Requested By The Applicant)

3. Flammability Test (ASTM F2100-19⁹, Section 9.5, Testing Refer to 16 CFR Part 1610 -2008):

X	Plain Surface	Raised Surface	Requirement Class 1
Burn Direction:	<input checked="checked" type="checkbox"/> Length <input type="checkbox"/> Width		
Prelim Plain Surface:			
Length:	IBE		
Width:	Original* (seconds)		
1.	IBE		
2.	IBE		
3.	IBE		
4.	DNI		
5.	DNI		
6.	-		
7.	-		
8.	-		
9.	-		
10.	-		
Average:	-		
Classification:	<input checked="checked" type="checkbox"/> Class 1, Normal Flammability <input type="checkbox"/> Class 2, Intermediate Flammability, Raised Surface <input type="checkbox"/> Class 3, Rapid And Intense Burning		
Explanation Of Flammability Results:			
DNI	Did not ignite.		
IBE	Ignited but extinguished.		

* The disposable fabrics and garments need not to be refurbished in accordance with 16 CFR Part 1610.35 (d)(2).

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Tests Conducted (As Requested By The Applicant)

4 Bacterial Filtration Efficiency (BFE)
As per ASTM F2100-19¹ Standard Specification for Performance of Materials Used in Medical Face Masks
Section 6.1 and ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Material, Using a Biological Aerosol of Staphylococcus aureus.

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	Level 3: ≥ 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: 2.2x10⁷ CFU
6. The average plate count results of the negative controls: < 1 CFU
7. CFU = Colony Forming Unit.

Tests Conducted (As Requested By The Applicant)

5 Sub-Micron Particulate Filtration (ASTM F2100-19¹, Section 9.3, Testing Refer to ASTM F2299/F2299M-17);
Particle size in aerosol: 0.1 µm, Aerosol: Polystyrene Latex Spheres (PSL), Test area: 100 cm², Airflow: 5.33 cm/s, Sampling time: 1 min.

Tested Sample/Component	Result (%)	Performance Requirement for Medical Face Mask (%)
Specimen (1)	99.3	Level 3: ≥ 98
Specimen (2)	99.3	
Specimen (3)	99.8	
Specimen (4)	99.6	
Specimen (5)	99.4	
Minimum value	99.3	

Remark: The test was performed by an approved third party subcontractor laboratory.

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 under 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 these terms and conditions. We have agreed to conduct the Review and certify based 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 willful misconduct. No copy of this report except for full test copy shall be made without the written approval by Intertek.

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Report Ref:	GZHT02310742	Date Issued:	Jul 10, 2020
Date Received:	Jul 03, 2020		
Company Name:	HUNAN EXEIT TECHNOLOGY & SERVICE CO., LTD		
Address:	NO.6, NORTH OF PINGTONG ROAD, LIUYANG HI-TECH INDUSTRIAL DEVELOPMENT ZONE, HUNAN CHINA		
Contact Name:	Luke Lin		

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:	
End Uses	: Medical Face Mask
Rating	: Level 3
Sample Name	: Surgical Face Mask
Size	: 17.5*9.5cm
Colour	: Blue&White
Standard	: ASTM F2100-19 ¹
Date received/ Test Started	: Jul 03, 2020
Ref	: YX121

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



Prepared And Checked By:
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Page 1 Of 9

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For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

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General Manager



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Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
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Number: GZHT02310742

Summary of testing:

With reference to following standard:

- ASTM F2100-19¹ Standard Specification for Performance of Materials Used in Medical Face Masks Level 3
- ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials Using a Biological Aerosol of *Staphylococcus aureus*
- EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods
- ASTM F2399/F2399M-17 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood
- 16 CFR Part 1610 Warning Apparel Flammability

Materials Used in The Submitted Samples Were Found To Comply With The Requirements Of Above Standards As Specified in ASTM F2100-19¹ 9.1.9.5.

Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

Lin Lin
General Manager

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Intertek Testing Services (Shenzhen) Ltd. Guangzhou Branch
深圳天祥质量检测有限公司广州分公司

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Number: GZHT02310742

Tests Conducted (As Requested By The Applicant)

1 Differential Pressure (ASTM F2100-19¹, Section 9.2, Testing Refer to EN 14683:2019+AC:2019 Annex C):
Air flow: 8 L/min, Test Area Diameter 25 mm, Test Area: 4.9 cm².

Tested Sample	Result (mm H ₂ O/cm ²) [±]					Performance Requirement for Medical Face Mask (mm H ₂ O/cm ²)
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5	
Location 1	3.5	3.3	3.0	3.3	3.6	Level 3: < 6.0
Location 2	3.3	3.4	3.5	3.2	3.1	
Location 3	3.3	3.3	3.5	3.3	3.1	
Location 4	3.1	3.4	3.3	3.5	3.9	
Location 5	3.2	3.2	3.4	3.3	3.0	
Average	3.3	3.3	3.3	3.3	3.2	

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

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2 Resistance to Penetration by Synthetic Blood (ASTM F2100-19¹, Section 9.4, Testing Refer to ASTM F1862/F1862M-17):
Synthetic Blood Surface Tension: 0.042 N/m, Distance Between Slow Head Front End and Target Area: 300 mm,
Artificial Blood Volume: 2 mL, Test Pressure: 160 mmHg, Velocity: 635 cm/s, Use a Fixed Target.

Tested Sample/Component	Result	Performance Requirement for Medical Face Mask Puls Pressure at Level 3: 160 mm Hg
Specimen (1)	No Penetration	
Specimen (2)	No Penetration	
Specimen (3)	No Penetration	
Specimen (4)	No Penetration	
Specimen (5)	No Penetration	
Specimen (6)	No Penetration	
Specimen (7)	No Penetration	
Specimen (8)	No Penetration	
Specimen (9)	No Penetration	
Specimen (10)	No Penetration	
Specimen (11)	No Penetration	
Specimen (12)	No Penetration	
Specimen (13)	No Penetration	
Specimen (14)	No Penetration	
Specimen (15)	No Penetration	
Specimen (16)	No Penetration	
Specimen (17)	No Penetration	
Specimen (18)	No Penetration	
Specimen (19)	No Penetration	
Specimen (20)	No Penetration	
Specimen (21)	No Penetration	
Specimen (22)	No Penetration	

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Tests Conducted (As Requested By The Applicant)

Specimen (23)	No Penetration
Specimen (24)	No Penetration
Specimen (25)	No Penetration
Specimen (26)	No Penetration
Specimen (27)	No Penetration
Specimen (28)	No Penetration
Specimen (29)	No Penetration
Specimen (30)	No Penetration
Specimen (31)	No Penetration
Specimen (32)	No Penetration

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Tests Conducted (As Requested By The Applicant)

Number: GZHT02310742

3 Flammability Test (ASTM F2100-19¹, Section 9.5, Testing Refer to 16 CFR Part 1610 -2008):

Table with columns for Plain Surface and Raised Surface, including burn direction, length, width, and classification results.

* The disposable fabrics and garments need not to be refurbished in accordance with 16 CFR Part 1610.35 (a)(2).

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Tests Conducted (As Requested By The Applicant)

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4 Bacterial Filtration Efficiency (BFE) As per ASTM F2100-19¹ Standard Specification for Performance of Materials Used in Medical Face Masks...

Table showing Bacterial Filtration Efficiency (BFE) results for five specimens, all exceeding 99.9%.

- 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: 2.1x10³ CFU. 6. The average plate count results of the negative controls: < 1 CFU. 7. CFU = Colony Forming Unit.

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Tests Conducted (As Requested By The Applicant)

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5 Sub-Micron Particulate Filtration (ASTM F2100-19¹, Section 9.3, Testing Refer to ASTM F2299/F2299M-17):

Table showing Sub-Micron Particulate Filtration results for five specimens, all at 99.5% efficiency.

Remark: The test was performed by an approved third party subcontractor laboratory. End of Report

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