MÁSCARA Sky Xtra: Características Principais de Desempenho

Nota: *Este documento é uma tradução cortês da versão original em Inglês disponível em https://www.flashbay.com/images/certificates/Sky_Xtra_Performance.pdf e caso existam diferenças de significado entre esta tradução e o documento original, o documento original deverá manter-se.*

O desempenho da Máscara Sky Xtra relativamente aos requisitos para o desempenho de filtração de partículas e respirabilidade das Máscaras Facias, foi determinada por uma identidade independente, como pode ver em seguida:

	FFP2	CWA 17553:2020 - Nível 90%
Filtração EN 149:2001+A1:2009, Cláusula 8.11 & AFNOR-SPEC-S76-001:2020, Referência a EN13274-7: 2019 Alterado	APRONVADO	APRONVADO
Respirabilidade EN 149:2001+A1:2009, Cláusula 8.9 & EN ISO 9237-1995	APRONVADO	APRONVADO

Teste contra o Desempenho Funcional do modelo FFP2

Adicionalmente, as Máscaras Sky Xtra foram testadas independentemente pelo laboratório NTEK contra o desempenho funcional requerido pelos modelos FPP2 e demonstraram as seguintes características quando novas:

	Requisitos	Resultado*	
Penetração do Material de Filtro **(EN 149:2001+A1:2009, Cláusula 8.11)**	Maxima penetração no teste aerosol: Cloreto de Sódio @ 95 L/m ≤ 6% Óleo de Parafina @ 95 L/m ≤ 6%	Cloreto de Sódio ≤ 2.07% Óleo de Parafina ≤ 4.39%	APRONVADO
Resistência Respiratória **(EN 149:2001+A1:2009, Cláusula 8.9)**	Maxima resistência de penetração (mbar): Inspiração @ 30 L/min ≤ 0.7 Inspiração @ 95 L/min ≤ 2.4 Expiração @ 160 L/min ≤ 3.0	Inspiração @ 30 L/min ≤ 0.4 Inspiração @ 95 L/min ≤ 1.46 Expiração @ 160 L/min ≤ 1.27	APRONVADO
Perda Interna Total **(EN 149:2001+A1:2009 Cláusula 8.5)**	Perda Interna Total ≤ 8%	Perda Interna Total < 8%	APRONVADO

**NTEK resultados dos testes em apêndice*

Teste para conformidade com CWA 17553:2020

Adicionalmente, as Máscaras Sky Xtra foram testadas independentemente pela Intertek contra requisitos comuns para Eficiência de Filtração de Partículas (EFP) em ambas máscaras novas e após 25 lavagens a 60ºC e determinaram ter as seguintes características:

	Requirement	New*	After 25 washes*
Particulates Filtration Efficiency (PFE) (AFNOR-SPEC-S76-001:2020, Reference to EN13274-7: 2019 Modified)	Nível 90%: ≥ 90% Nível 70: ≥ 70%	> 99.5% (Média) APROVADO - Nível 90%	> 90% (Média) APROVADO - Nível 90%

**Os relatórios de teste Intertek estão incluídos em apêndice*

Em adição às medidas NTEK's para Resistência Respiratória de acordo com EN 149:2001 + A1:2009 Intertek mede a Permeabilidade do Ar de acordo com EN ISO 9237-1995 e com um teste de pressão de 100 Pa e um teste de área de 20 cm2 , a máscara Sky determinou ter Permeabilidade ao Ar de 153.0 L/s/m2 quando nova, confortavelmente em excesso dos requisitos CWA 17553:2020 iguais ou superiores a 96 L/s/m2.

Os resultados dos testes para a Máscaras Sky Xtra estão apresentados nas seguintes páginas.

Flashbay
Fevereiro 2021

Test Report

Applicant: Flashbay Electronics
Address: Building 2, Jixun Industial Park, Xinjiao, Dong'ao Village, Shatian Town, Huiyang District, Huizhou City, Guangdong Province, P.R.China

The following sample(s) was/were submitted and identified on behalf of the client as:

Product name:	Face Mask
Model:	Sky Xtra(SKX)
Manufacturer:	Flashbay Electronics
Address:	Building 2, Jixun Industial Park, Xinjiao, Dong'ao Village, Shatian Town, Huiyang District, Huizhou City, Guangdong Province, P.R.China
Classification:	FFP2 NR
Sample quantity:	30 Pcs
Sample Received Date:	Feb. 04, 2021
Testing Period:	Feb. 04, 2021~ Feb. 22, 2021

Test Requirement:

According to the requirement of the client, the test item(s) of the sample is referring to the standard EN 149:2001+A1:2009.

Test Result(s): Please refer to the following page(s)

Test Method: Please refer to the following page(s)

Compiled by: _____ Reviewed by: _____

Approved by: _____ Date: 2021-02-23

Test Result

Clause 7.9.2 Penetration of Filter Material

(EN 149:2001+A1:2009, Clause 8.11)

<table>
<tr><th>Test Requirement</th><th>Results</th></tr>
<tr><td>The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.
<table>
<tr><td rowspan="2">Classification</td><td colspan="2">Maximum penetration of test aerosol(%)</td></tr>
<tr><td>Sodium chloride test 95 L/min</td><td>Paraffin oil test 95 L/min</td></tr>
<tr><td>FFP1</td><td>20</td><td>20</td></tr>
<tr><td>FFP2</td><td>6</td><td>6</td></tr>
<tr><td>FFP3</td><td>1</td><td>1</td></tr>
</table></td><td>Detail refer to Appendix 1</td></tr>
</table>

Appendix 1: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)	
			Average in 30s after 3 min	Max. during exposure
Sodium chloride test	A.R.	1#	2.07	/
		2#	1.64	/
		3#	1.19	/
Paraffin oil test	A.R.	4#	4.38	/
		5#	3.86	/
		6#	4.39	/
Flow rate of test aerosol: 95.0 L/min				

Clause 7.9.1 Total Inward Leakage

(EN 149:2001+A1:2009 Clause 8.5)

Test Requirement	Results
For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1 11% for FFP2 5% for FFP3 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 22% for FFP1 8% for FFP2 2% for FFP3	Detail refer to Appendix 2

Appendix 2: Summarization of Test Data

Subject	Sample	Condition	Normal Breathing (%)	Head Side/Side (%)	Head Up/Down (%)	Speak Loudly (%)	Normal Breathing (%)	Mean (%)
Gu	7#	A.R.	7.2	7.3	7.5	7.6	7.3	7.38
Hu	8#	A.R.	6.8	6.9	7.2	7.4	6.9	7.04
Wang	9#	A.R.	6.5	6.6	6.7	6.8	6.6	6.64
Long	10#	A.R.	7.4	7.6	7.7	7.9	7.5	7.62
Gao	11#	A.R.	6.9	7.1	7.2	7.4	7.1	7.14
Huang	15#	A.R.	6.9	7.1	7.2	7.3	7.1	7.12
Zhou	16#	A.R.	5.2	5.4	5.6	5.7	5.3	5.44
Ma	17#	A.R.	7.2	7.3	7.4	7.6	7.4	7.38
Wu	18#	A.R.	7.5	7.7	7.8	7.9	7.6	7.70
Li	19#	A.R.	6.2	6.3	6.4	6.6	6.4	6.38

Facial Dimension:

Subject	Length of Face (mm)	Width of Face (mm)	Depth of Face (mm)	Width of Mouth (mm)
Gu	114	127	119	52
Hu	128	144	135	53
Wang	112	136	122	50
Long	119	134	128	51
Gao	130	154	144	52
Huang	130	140	125	53
Zhou	100	148	125	55
Ma	120	158	110	50
Wu	110	148	121	44
Li	112	146	112	50

Clause 7.16 Breathing Resistance

EN 149:2001+A1:2009, Clause 8.9)

<table>
<tr><th>Test Requirement</th><th>Results</th></tr>
<tr><td>The breathing resistances apply to valved and valveless filtering half masks and shall meet the requirements as the following table.
<table>
<tr><td rowspan="2">Classification</td><td colspan="3">Maximum permitted resistance (mbar)</td></tr>
<tr><td colspan="2">Inhalation</td><td>Exhalation</td></tr>
<tr><td>30 L/min</td><td>95 L/min</td><td>160 L/min</td></tr>
<tr><td>FFP1</td><td>0.6</td><td>2.1</td><td>3.0</td></tr>
<tr><td>FFP2</td><td>0.7</td><td>2.4</td><td>3.0</td></tr>
<tr><td>FFP3</td><td>1.0</td><td>3.0</td><td>3.0</td></tr>
</table></td><td>Detail refer to Appendix 3</td></tr>
</table>

Appendix 3: Summarization of Test Data

Specimen	Condition	Inhalation(mbar)		Exhalation resistance(mbar)				
		At 30 L/min	At 95 L/min	At 160 L/min				
				A	B	C	D	E
12#	A.R.	0.38	1.43	1.25	1.26	1.24	1.25	1.25
13#		0.39	1.45	1.26	1.25	1.26	1.26	1.25
14#		0.40	1.46	1.26	1.25	1.26	1.27	1.26

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

Remark:

According to the requirement of the client, only the specimen of “A.R.” has been tested.

Sample photo(s):

Fig.1

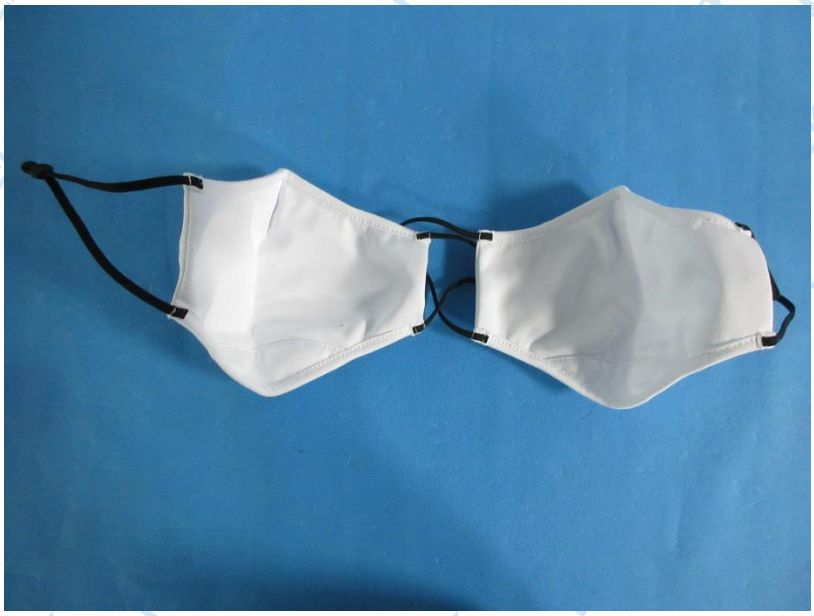


Fig.2

This testing report displaces the original report of No. S21020400101E, and the original one No. S21020400101E was invalid since the date of this testing report released.

****End of Report****

intertek
Total Quality. Assured.

Test Report

Number: GZHT02363627-S1

Report Ref:	GZHT02363627-S1	THIS IS TO SUPERSEDE REPORT NO. GZHT02363627 DATED Dec 01, 2020	
Date received:	Nov 16, 2020	**Date Issued:**	Dec 10, 2020

Company Name: **Address:**	FLASHBAY ELECTRONICS BUILDING 2,JIXUN INDUSTRIAL PARK DONG'AO VILLAGE,SHATIAN TOWN HUIYANG DISTRICT,HUIZHOU CITY GUANGDONG PROVINCE,P.R.CHINA
Contact Name:	Levin

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:		
End Uses	:	Face Mask
Ratings	:	-
Sample Name	:	Knitted Face Mask
No. Of Sample	:	One(53 pieces)
Size	:	-
Colour	:	Black
Standard	:	-
Date received/ Test Started	:	Nov 16, 2020
Ref	:	Sky

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

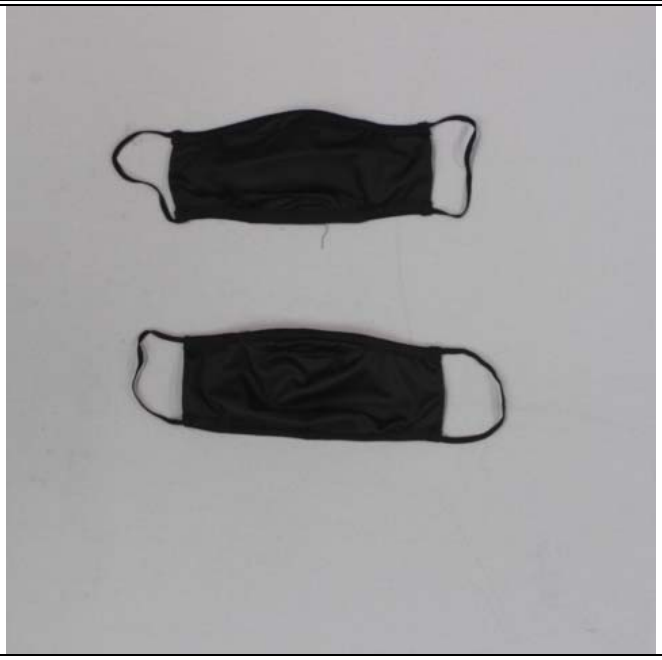
QIN / hilaryxu

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
Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801, 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、01 房、101、E201、E301、E401、E501、E601、E701、E801
Tel: +86 20 8213 9001 Fax: +86 20 8208 9909 Postcode: 510663
3/F., Hengyun Building, 235 Kaifa Ave., Guangzhou Economic & 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
Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730

Test Report

Number: GZHT02363627-S1

Original Sample Photo



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

Lin Lin
General Manager

QIN / hilaryxu

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
Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801, 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、01 房、101、E201、E301、E401、E501、E601、E701、E801
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3/F., Hengyun Building, 235 Kaifa Ave., Guangzhou Economic & 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
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Test Report

Number: GZHT02363627-S1

Tests Conducted (As Requested By The Applicant)

1 Penetration Test As Received (AFNOR-SPEC-S76-001:2020, Reference to EN13274-7: 2019 Modified)

TEST RESULTS:

Efficiency of Filter Material				
Aerosol	Standard terms Methods	**Unit**	**Result**	
Sodium Chloride	Aerosol particles: NaCl Flow rate: 6cm/s Sampling time: 1min Temperature: 22.3℃ Relative humidity: 36%RH Test area: 56.7cm² Particle Diameter: around 3 μm	%	#1	99.96
			#2	99.94
			#3	99.98
			#4	99.94
			#5	97.71
			Average	99.51
Paraffin Oil	Aerosol particles: Paraffin oil Flow rate: 6 cm/s Sampling time: 1min Temperature: 22.3℃ Relative humidity: 36%RH Test area: 56.7cm² Particle Diameter: around 3 μm	%	#1	99.98
			#2	99.93
			#3	99.23
			#4	99.76
			#5	99.91
			Average	99.76

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

QIN / hilaryxu

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
Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801, 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、01 房、101、E201、E301、E401、E501、E601、E701、E801
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中国广州经济技开发区开发大道 235 号恒运大厦 3 楼
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Tests Conducted (As Requested By The Applicant)

2 Bacterial Filtration Efficiency (BFE)

Test Method: With reference to 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

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: $2.5x10^3$ CFU
The average plate count results of the negative controls: < 1 CFU
Mean particle size (MPS): 2.7μm
Incubation condition: (37 ± 2) ℃ for (20 to 52) h
Number of test specimens: 5

QIN / hilaryxu

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
Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801, No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, China
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中国广州经济技开发区开发大道 235 号恒运大厦 3 楼
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Test Report

Number: GZHT02363627-S1

Tests Conducted (As Requested By The Applicant)

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.

QIN / hilaryxu

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
Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801, 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、01 房、101、E201、E301、E401、E501、E601、E701、E801
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Test Report

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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		
	The Total Plate Count (T) (CFU)	Bacterial Filtration Efficiency (BFE) (%)	
Specimen (1)	201	91.9	
Specimen (2)	573	76.8	
Specimen (3)	233	90.6	
Specimen (4)	454	81.6	
Specimen (5)	591	76.1	

Remarks:

CFU = Colony Forming Unit

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

QIN / hilaryxu

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
Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801, No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, China
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中国广州经济技术开发区开发大道 235 号恒运大厦 3 楼
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Test Report

Number: GZHT02363627-S1

Tests Conducted (As Requested By The Applicant)

3 Air Permeability As Received (EN ISO 9237-1995):

153.0 L/s/m²

Remark: Test Pressure = 100 Pa
Test Area = 20 cm²

End of Report

QIN / hilaryxu

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
Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801, No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, China
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Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730

To : FLASHBAY ELECTRONICS
Attention : Levin Date : Dec 10, 2020

Re : Report Revision Notification

Labtest Report Number GZHT02363627 date DEC 01, 2020

Please be informed that all the content recorded in the above captioned report will be void. This captioned report is now superseded by a revised Labtest Report, Number GZHT02363627-S1 , issued on Dec 10, 2020 .

Thank you for your attention

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

Lin Lin
General Manager

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
Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801, 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、01 房、101、E201、E301、E401、E501、E601、E701、E801
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中国广州经济技术开发区开发大道 235 号恒运大厦 3 楼
Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730

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Test Report

Number: GZHT02368390

Report Ref:	GZHT02368390		
Date received/ Test Started:	Nov 26, 2020	**Date Issued:**	Dec 09, 2020

Company Name: **Address:**	FLASHBAY ELECTRONICS BUILDING 2, JIXUN INDUSTRIAL PARK DONG'AO VILLAGE, SHATIAN TOWN HUIYANG DISTRICT, HUIZHOU CITY GUANGDONG PROVINCE, P.R.CHINA
Contact Name:	Levin

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:		
End Uses	:	Face Mask
Ratings	:	-
Sample Name	:	Knitted Face Mask (After 25 times Washed by Client)
No. Of Sample	:	One(46 pieces)
Size	:	-
Colour	:	Black
Standard	:	-
Date received/ Test Started	:	Nov 26, 2020
Ref	:	SKY(After 25 times Washed)

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

AL / hilaryxu

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
Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801, 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、01 房、101、E201、E301、E401、E501、E601、E701、E801
Tel: +86 20 8213 9001 Fax: +86 20 8208 9909 Postcode: 510663
3/F., Hengyun Building, 235 Kaifa Ave., Guangzhou Economic & 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
Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730

Test Report

Number: GZHT02368390

Original Sample Photo

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

Lin Lin
General Manager

AL / hilaryxu

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Tests Conducted (As Requested By The Applicant)

1 Penetration Test As Received (AFNOR-SPEC-S76-001:2020, Reference to EN 13274-7: 2019 Modified):

Aerosol Particle	Test Parameters	Unit	Result	
Sodium Chloride	Flow Rate: 6 cm/s Sampling Time: 1 min Temperature: 22.1℃ Relative Humidity: 36% RH Test Area: 56.7 cm^2 Particle Diameter: Around 3 μm	%	#1	97.05
			#2	96.35
			#3	98.55
			#4	96.28
			#5	98.71
			Average	97.39
Paraffin Oil	Flow Rate: 6 cm/s Sampling Time: 1 min Temperature: 22.1℃ Relative Humidity: 36% RH Test Area: 56.7 cm^2 Particle Diameter: Around 3 μm	%	#1	84.32
			#2	91.57
			#3	92.47
			#4	91.48
			#5	91.93
			Average	90.63

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

AL / hilaryxu

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Tests Conducted (As Requested By The Applicant)

2 Bacterial Filtration Efficiency (BFE)

Test Method: With reference to 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

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: 2.4×10^3 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

AL / hilaryxu

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Tests Conducted (As Requested By The Applicant)

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.

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.

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Tests Conducted (As Requested By The Applicant)

Test Result:

Tested Specimen	Result		
	The Total Plate Count (T) (CFU)	Bacterial Filtration Efficiency (BFE) (%)	
Specimen (1)	579	75.7	
Specimen (2)	582	75.5	
Specimen (3)	537	77.4	
Specimen (4)	513	78.4	
Specimen (5)	444	81.3	

Remarks:

CFU = Colony Forming Unit

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

End of Report

AL / hilaryxu

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