

Mascarilla Sky Xtra: características clave de rendimiento

Nota: Este documento es una traducción del documento original disponible en inglés https://www.flashbay.com/images/certificates/Sky_Xtra_Performance.pdf y en el caso de cualquier diferencia de significado entre esta traducción y el documento original, el significado del documento original tendrá prioridad.

El rendimiento de la mascarilla Sky Xtra frente a los requisitos de eficacia de filtración de partículas y transpirabilidad dentro de los estándares más reconocidos para mascarillas se ha determinado de forma independiente de la siguiente manera:

	FFP2	CWA 17553:2020 - Level 90%
Filtration EN 149:2001+A1:2009, Clause 8.11 & AFNOR-SPEC-S76-001:2020, Reference to EN13274-7: 2019 Modified	PASS	PASS
Breathability EN 149:2001+A1:2009, článek 8.9 & EN ISO 9237-1995	PASS	PASS

Testing against FFP2 functional performance requirements

The Sky Xtra Face Mask has been independently tested by NTEK against the functional performance requirements of the FFP2 standard and determined to have the following key characteristics when new:

Requirement	Result*
Penetration of Filter Material (EN 149:2001+A1:2009, Clause 8.11) Maximum penetration of test aerosol: Sodium chloride @ 95 L/m ≤ 6% Paraffin oil @ 95 L/m ≤ 6%	Sodium chloride ≤ 2.07% Paraffin oil ≤ 4.39% PASS
Breathing Resistance (EN 149:2001+A1:2009, Clause 8.9) Maximum permitted resistance (mbar): Inhalation @ 30 L/min ≤ 0.7 Inhalation @ 95 L/min ≤ 2.4 Exhalation @ 160 L/min ≤ 3.0	Inhalation @ 30 L/min ≤ 0.4 Inhalation @ 95 L/min ≤ 1.46 Exhalation @ 160 L/min ≤ 1.27 PASS
Total Inward Leakage (EN 149:2001+A1:2009 Clause 8.5) Total inward leakage ≤ 8%	Total inward leakage < 8% PASS

*NTEK test reports included as appendix

Testing for conformity with CWA 17553:2020

Additionally, the Sky Xtra Face Mask has been independently tested by Intertek according to commonly used standards of Particle Filtration Efficiency (PFE) both new and after 25 60°C machine wash cycles and determined to have the following key characteristics:

	Requirement	New*	After 25 washes*
Particulates Filtration Efficiency (PFE) (AFNOR-SPEC-S76-001:2020, Reference to EN13274-7: 2019 Modified)	Level 90%: $\geq 90\%$ Level 70: $\geq 70\%$	> 99.5% (Average) PASS - Level 90%	> 90% (Average) PASS - Level 90%

* Intertek test reports included as appendix

In addition to NTEK's measurement of Breathing Resistance according to EN 149:2001 + A1:2009 Intertek have measured Air Permeability according to EN ISO 9237-1995 and with a test pressure of 100 Pa and a test area of 20 cm² the Sky Xtra was determined to have an Air Permeability of 153.0 L/s/m² when new, comfortably in excess of the CWA 17553:2020 requirement of greater than or equal to 96 L/s/m².

The test results for the Sky Xtra Face Mask are presented on the following pages.

Flashbay

February 2021

Test Result

Clause 7.9.2 Penetration of Filter Material

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

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

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
<p>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:</p> <p style="padding-left: 40px;">25% for FFP1 11% for FFP2 5% for FFP3</p> <p>and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than:</p> <p style="padding-left: 40px;">22% for FFP1 8% for FFP2 2% for FFP3</p>	<p>Detail refer to Appendix 2</p>

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)

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

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****

The test report is effective only with both signature and specialized stamp, the result(s) shown in this report refer only to the sample(s) tested. Without written approval of NTEK, this report can't be reproduced except in full; The laboratory is not responsible for the authenticity of the sample information provided by the customer; The laboratory is not responsible for any deviation of results due to methods/standards provided by the customer.

Test Report

Number: GZHT02363627-S1

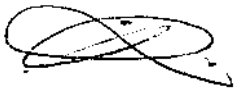
Report Ref:	GZHT02363627-S1	THIS IS TO SUPERSEDE REPORT NO. GZHT02363627 DATED Dec 01, 2020	
Date received:	Nov 16, 2020	Date Issued:	Dec 10, 2020

Company Name:	FLASHBAY ELECTRONICS		
Address:	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



Page 1 Of 7

QIN / hilaryxu

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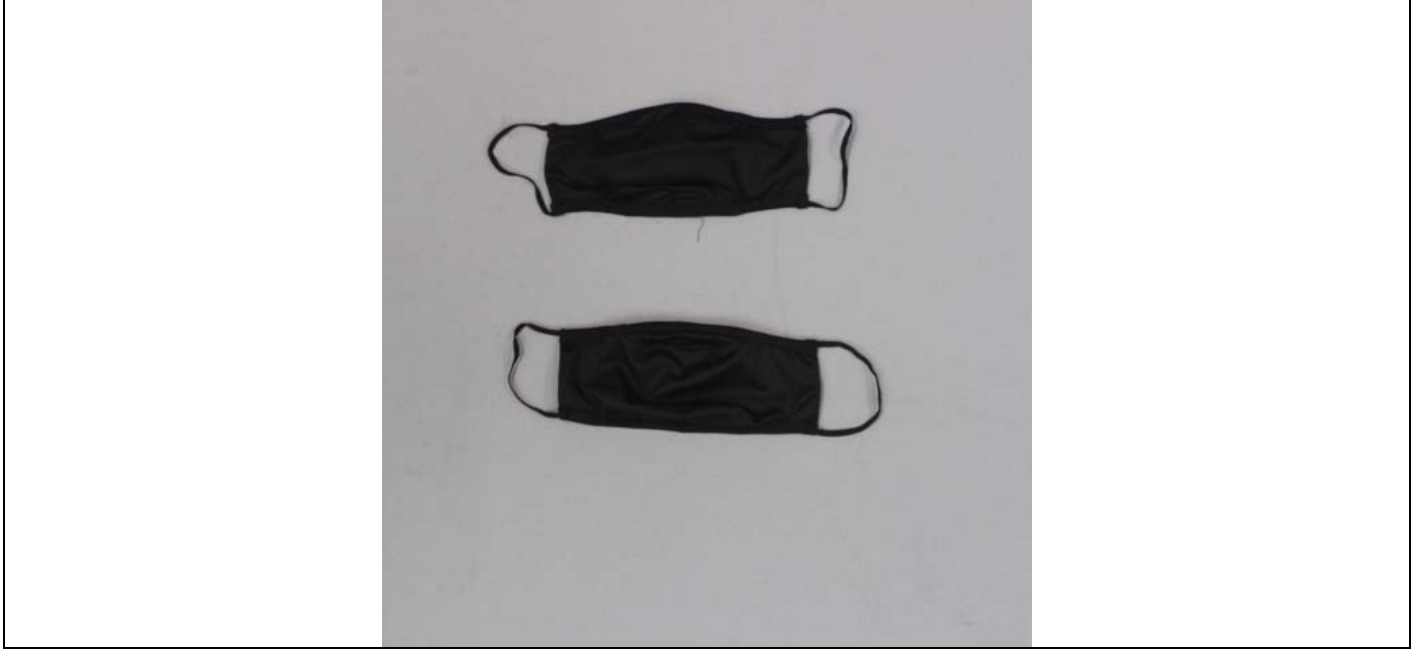
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Original Sample Photo



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General Manager

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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°C Relative humidity: 36%RH Test area: 56.7cm ² Particle Diameter: around 3 μ m	%	#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°C Relative humidity: 36%RH Test area: 56.7cm ² Particle Diameter: around 3 μ m	%	#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.

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Test Report

Number: GZHT02363627-S1

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 $(21 \pm 5) ^\circ\text{C}$ and $(85 \pm 5) \%$ 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: 2.5×10^3 CFUThe average plate count results of the negative controls: < 1 CFUMean particle size (MPS): $2.7 \mu\text{m}$ Incubation condition: $(37 \pm 2) ^\circ\text{C}$ for (20 to 52) h

Number of test specimens: 5

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Page 4 Of 7

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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.

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Page 5 Of 7

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Test Report

Number: GZHT02363627-S1

Tests Conducted (As Requested By The Applicant)

Calculation:

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

$$\% \text{ BFE} = (C-T)/C \times 100$$

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.

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Page 6 Of 7

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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/m²Remark: Test Pressure = 100 Pa
Test Area = 20 cm²

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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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

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Test Report

Number: GZHT02368390

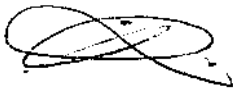
Report Ref:	GZHT02368390		
Date received/ Test Started:	Nov 26, 2020	Date Issued:	Dec 09, 2020

Company Name:	FLASHBAY ELECTRONICS		
Address:	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



Page 1 Of 6

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Original Sample Photo



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Test Report

Number: GZHT02368390

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°C 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°C 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.

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Test Report

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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 $(21 \pm 5) ^\circ\text{C}$ and $(85 \pm 5) \%$ 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 CFUThe average plate count results of the negative controls: < 1 CFUMean particle size (MPS): $2.7 \mu\text{m}$ Incubation condition: $(37 \pm 2) ^\circ\text{C}$ for (20 to 52) h

Number of test specimens: 5

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Page 4 Of 6

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Test Report

Number: GZHT02368390

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:

$$\% \text{ BFE} = (C-T)/C \times 100$$

where,

C = Average plate counts total for test controls;

T = Plate count total for the test specimen.

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Page 5 Of 6

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Test Report

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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

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Page 6 Of 6

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