

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 60°C e determinaram ter as seguintes características:

| | Requirement | New* | After 25 washes* |
|---|-------------------------------------|---|---------------------------------------|
| Particulates Filtra- tion 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



Report No.: \$21020400101E-R1 page 1 of 5

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

Feb. 04, 2021

Date:

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: | Vanly | Reviewed by: | May | N. C. |
|--------------|-----------|--------------|------------|-------|
| Approved by: | New blias | Date: | 2021-02-23 | A. |



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Test Result

Clause 7.9.2 Penetration of Filter Material

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

| | * 3 | Test Requir | ement | + | | Results |
|--------------|--------|--|---|------------|--------------------|---------|
| V - | | filter of the par of the following | ticle filtering half g table. | mask shall | 4 | 407 |
| Classificati | ion So | aximum penetra odium chloride est 95 L/min | tion of test aeros Paraffin o test 95 L/m | Detail re | efer to Appendix 1 | |
| FFP1 | 4 | 20 | 20 | | * | |
| FFP2 | 14 | 6 | 6 | | 47 | |
| FFP3 | 4 | 1 | 1 | * | 3 | 4 |

Appendix 1: Summarization of Test Data

Penetration of filter material

| 4 | . 3 | ~ | Penetrat | ion (%) | | | |
|----------------------|---------------------------------------|------------|----------------|-------------|--|--|--|
| Aerosol | Condition | Sample No. | Average in 30s | Max. during | | | |
| <u> </u> | 7 | + 20 | after 3 min | exposure | | | |
| 4 4 | | 1# | 2.07 | 1分 多 | | | |
| Sodium chloride test | A.R. | 2# | 1.64 | £ 2 | | | |
| | | 3# | 1.19 | 1 | | | |
| 4 5 | A A | 4# | 4.38 | * * | | | |
| Paraffin oil test | A.R. | 5# | 3.86 | 31 | | | |
| 1 | 7 | 6# | 4.39 | 1 | | | |
| , 4 | Flow rate of test aerosol: 95.0 L/min | | | | | | |



Report No.: S21020400101E-R1 page 3 of 5

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 | 4 |
| results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be | 4 3 |
| not greater than: | |
| 25% for FFP1 | |
| 11% for FFP2 | Detail refer to Appendix 2 |
| 5% for FFP3 | Detail Telef to Appendix 2 |
| and, in addition, at least 8 out of the 10 individual wearer arithmetic | |
| means for the total inward leakage shall be not greater than: | A 2 |
| 22% for FFP1 | - L |
| 8% for FFP2 | A Comment of the Comm |
| 2% for FFP3 | 4 5 |

Appendix 2: Summarization of Test Data

| | | | Normal | Head | Head | Speak | Normal 🔏 | Mean |
|---------|--------|-----------|-----------|-----------|---------|--------|-----------|------|
| Subject | Sample | Condition | Breathing | Side/Side | Up/Down | Loudly | Breathing | |
| | 4 | | (%) | (%) | (%) | (%) | (%) | (%) |
| 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 | 7 18# | A.R. | 7.5 | 7.7 | 7.8 | 7.9 | 7.6 | 7.70 |
| L Li 🍣 | 19# | A.R. | 6.2 | 6.3 | 6.4 | 6.6 | 6.4 | 6.38 |



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Facial Dimension:

| Subject | Length of Face | Width of Face | Depth of Face | Width of Mouth |
|---------|----------------|---------------|---------------|----------------|
| Oubject | (mm) | (mm) | (mm) | (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 |
| | 112 | 146 | 112 | 50 |

Clause 7.16 Breathing Resistance

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

| 4 5 | Results | | | | | | | |
|-------------------|--|------------------|------------|---|----------------------------|--|--|--|
| The breathing res | The breathing resistances apply to valved and valveless filtering half | | | | | | | |
| masks and shall m | The second second | | | | | | | |
| L 5 | Maximum pe | ermitted resista | 4 | | | | | |
| Classification | Inhala | ation | Exhalation | | Detail refer to Appendix 3 | | | |
| | 30 L/min | 95 L/min | 160 L/min | | 4 3 | | | |
| FFP1 | 0.6 | 2.1 | 3.0 | 4 | 5 | | | |
| FFP2 | 0.7 | 2.4 | 3.0 | 4 | L 3 | | | |
| FFP3 | 1.0 | 3.0 | 3.0 | | | | | |

Appendix 3: Summarization of Test Data

| Appendix | Appendix of Cammanization of Test Buta | | | | | | | |
|----------|--|------------------|-------|--|------|-----------|--------|------|
| | | Inhalation(mbar) | | Inhalation(mbar) Exhalation resistance(mbar) | | | (mbar) | 70 |
| Specimen | Condition | At 30 | At 95 | 4 | At | 160 L/min | 10 | |
| | | L/min | L/min | Α | В | С | D | Е |
| 12# | 4 | 0.38 | 1.43 | 1.25 | 1.26 | 1.24 | 1.25 | 1.25 |
| 13# | A.R. | 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.

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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.

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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 Subm | itted 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



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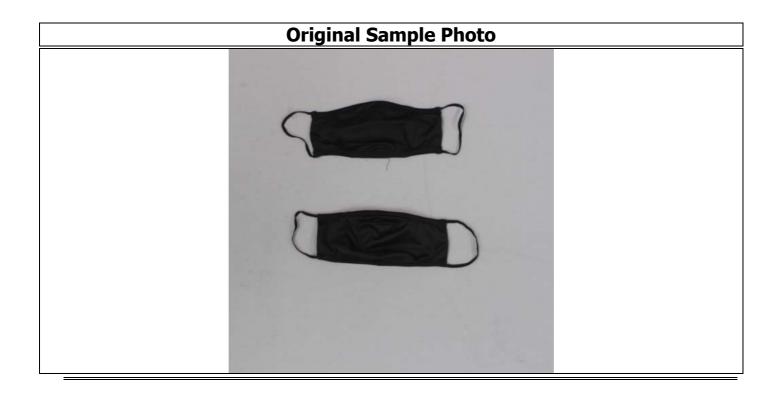
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Number: GZHT02363627-S1



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Lin Lin General Manager

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37 M

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promic & Technological Development District, Guangzhou, China

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(10)



Number: GZHT02363627-S1

Tests Conducted (As Requested By The Applicant)

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

TEST RESULTS:

| | Efficiency of Filter M | laterial | | |
|-----------------|--|-----------------|---------|-------|
| Aerosol | Standard terms Methods | Unit | Resu | ılt |
| | Aerosol particles: NaCl | | #1 | 99.96 |
| Sodium Chloride | Flow rate: 6cm/s | | #2 | 99.94 |
| | Sampling time: 1min | | #3 | 99.98 |
| | Temperature: 22.3℃ | % | #4 | 99.94 |
| | Relative humidity: 36%RH | | #5 | 97.71 |
| | Test area: 56.7cm ² Particle Diameter: around 3 µ m | | Average | 99.51 |
| | Aerosol particles: Paraffin oil | | #1 | 99.98 |
| Paraffin Oil | Flow rate: 6 cm/s | | #2 | 99.93 |
| | Sampling time: 1min | | #3 | 99.23 |
| | Temperature: 22.3°C | % | #4 | 99.76 |
| | Relative humidity: 36%RH | | #5 | 99.91 |
| | Test area: 56.7cm ² Particle Diameter: around 3 µ m | | Average | 99.76 |

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

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Page 3 Of 7

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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 ± 5) °C 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 cm² 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) °C for (20 to 52) h

Number of test specimens: 5

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conomic & Technological Development District, Guangzhou, China



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.
- 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



GZHT02363627-S1 Number:

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 \times 100

where,

C = Average plate counts total for test controls;

T = Plate count total for the test specimen.

Test Result:

| <u>Tested</u> | <u>Result</u> | | |
|-----------------|---------------------------|---------------------------------|--|
| <u>Specimen</u> | The Total Plate Count (T) | Bacterial Filtration Efficiency | |
| - | (CFU) | (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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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

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

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Number: GZHT02368390

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

| 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 Subm | itted 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

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General Manager



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Intertek Testing Services Stienzhen Ltd. Guangzhou Branch

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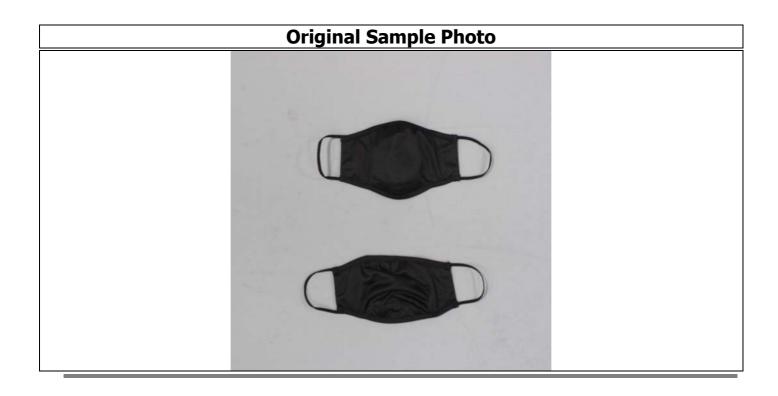
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Number: GZHT02368390



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

Lin Lin

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Tests Conducted (As Requested By The Applicant)

Number: GZHT02368390

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

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

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

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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) °C 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 cm² 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) °C for (20 to 52) h

Number of test specimens: 5

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Tests Conducted (As Requested By The Applicant)

Test Procedure:

- Preparation of the bacterial challenge: Dilute the culture in peptone water to achieve a concentration of approximately 5×10⁵ 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.
- Time the air pressure and cascade impactor to run for 2 min. 7.
- At the conclusion of the positive control run, remove plates from the cascade impactor.
- Place new agar plates into the cascade impactor and clamp the test specimen into the top of the 9. cascade impactor, with the inside oriented toward the challenge as intended.
- 10. Repeat the challenge procedure for each test specimen and positive control sample.
- 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.
- Count each of the six-stage plates of the cascade impactor. 13.
- 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 \times 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:

| <u>Tested</u> | | <u>Result</u> | |
|---------------|---------------------------|---------------------------------|--|
| Specimen | The Total Plate Count (T) | Bacterial Filtration Efficiency | |
| | (CFU) | (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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