KROSS DIRECT

TECHNICAL DATA SHEET

N95

Description

• KROSS N95 respirator has a superior micro fine filter media technology which protects against reparable suspended particulate matter and consists of multiple layers - pre-filter, fine filter and skin comfort layer.
• This filtering face piece respirator is a flat fold "C" style
• KROSS N95 series of respirators have unique fit adjustors which provide optimum fit & comfort. They also have dotted pattern edges for soft feel.
• KROSS N95 series of respirators has latex free knitted textile elastic which has a long life, is skin friendly and does not deform in high temperature.
• The respirator headstrap is stapled outside filter media which avoids puncture in filter that make it leakproof.
• KROSS N95 respirator noseclip is embedded inside the mask and the respirator has no metal exposure or loose parts.

Materials

The following materials are used in the production of KROSS N95 respirator.

STRAPS:	Knitted Elastic
NOSE FOAM:	Polyester
NOSE CLIP:	Aluminum
FILTER:	Electrostatic PP-Meltblown
OUTER LAYER:	Non Woven Spunbound
INNER LAYER:	Non Woven Spunbound

These products do not contain components made from natural rubber latex

Minimum mass of products

KROSS N95 - 9.00 g

KROSS DIRECT

Standards

KROSS N95 respirator complies with CDN 95, NIOSH95 Standards.

These respirators should be used to protect the wearer from solid and non-volatile liquid particles.

KROSS N95 respirator are classified by filtering 95% efficiency and maximum total inward leakage performance & also by inhalation resistance.

The respirator has filters that can help reduce breathing in pathogenic biological airborne particulates.

Approvals

KROSS N95 respirator has been evaluated in the laboratory and found to comply with all of the requirements of Title 42, Code of Federal Regulations, Part 84 for NIOSH certification.

Limitations

1. Do not use for protection against Gases, Vapor or in atmospheres containing less than 19.5% Oxygen.
2. Do not use when concentrations of contaminants are immediately dangerous to life and health, are unknown, or when particulate concentration exceed the maximum use level / or other levels determined by your National Occupational Safety and Health Authorities.

Fit Check

1. Cover the front of the respirator with both hands being careful not to disturb the respirator.
2. Exhale sharply into the respirator.
3. If air leaks around the nose, readjust the nose clip to eliminate leakage. Repeat the above fit check
4. If air leaks at the respirator edges, work the straps back along the sides of the head to eliminate leakage. Repeat the above fit check.

If you cannot achieve a proper fit DO NOT enter the hazardous area. See your supervisor.
For information regarding fit testing procedure please contact Kross Direct.

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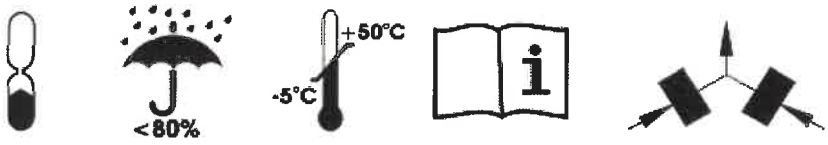
Storage & Shelf Life

KROSS N95 respirator until use shall be stored in the sealed pack to retain its properties. For transport such packs shall be suitably packed in outer cartons to protect from climatic hazards and mechanical shocks.

The shelf life of the product is 60 months from the date of manufacture. (If stored be-between –50C and +500C & Humidity not over 80%).The date of manufacture is mentioned on the pack of the respirator.

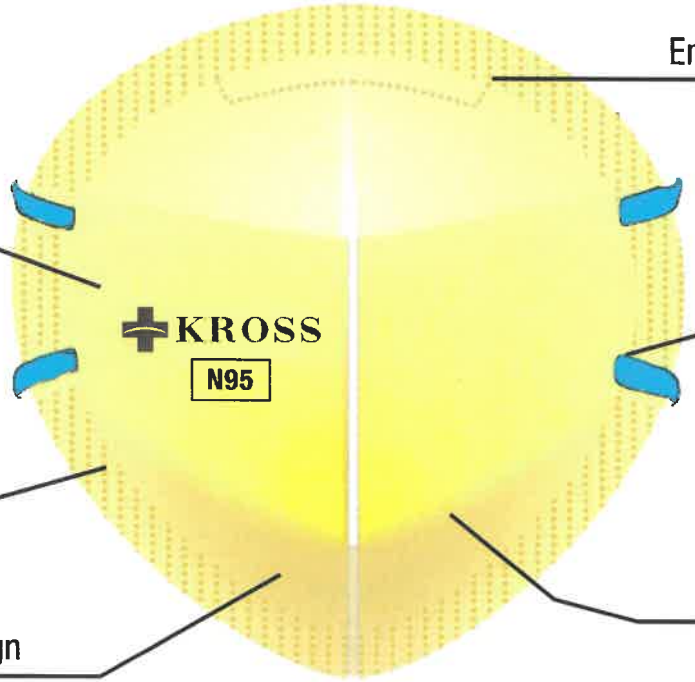


User Instructions

1. Failure to follow all instructions and limitations on the use of this respirator and / or failure to wear this respirator during all times of exposure can reduce respirator effectiveness and result in sickness or death.
2. Before use, wearer must first be trained by the employer for proper respirator use in accordance with applicable Safety and Health Standards. Respiratory protection appliances are to be selected depending on the type and concentration of the hazardous substances.
3. The respirator may only be used if the type and concentration of the harmful substances are known. In case of unknown substances or concentrations or variable conditions, breathing apparatus should be used.
5. If the respirator becomes damaged or breathing becomes difficult, leave the contaminated area, discard and replace the respirator. Also leave the contaminated area immediately if dizziness or other distress occurs.
6. Never alter or modify this respirator. Respiratory protection appliances are to be selected depending on the type and concentration of the hazardous substances.

KROSS DIRECT

N95 RESPIRATOR MASK



Embedded adjustable nose clip

No metal exposure or loose parts

improved breathability

stretchable elastic headband

latex free knitted textile elastic

filtering power

Filters at least ≥95% solid
air borned particles

4/5 protective layers

Composite of multiple layers
(pre filter, fine filter & skin comfort layer)

optimised design

Flat fold "C" style with dotted
pattern edges for soft feel

N95 | 5-LAYER FILTRATION

LAYERED N95 SURGICAL MASK

Five Filter Layer Mask

1. Non Woven Skin Friendly Layer
2. Meltblown Layer
3. Meltblown Layer
4. Electrostatic Cotton
5. Non-Woven

HIGH PROTECTION

FIVE LAYERED

HIGH QUALITY MATERIALS

ANTI MICROBIAL

WATER REPELLENT

BREATHABLE

ADJUSTABLE NOSE BRIDGE

COMFORTABLE

COVID-19 Medical Device Authorization with Conditions for Importation or Sale

Autorisation d'importation ou de mise en vente d'un instrument médical relatif au COVID-19 avec conditions

Authorization Reference Number : 330068 **Numéro de référence de l'autorisation**

Issue Date: 2021-05-06 **Date de délivrance:**

Device Class/Classe de l'instrument : 1

Pursuant to section 5 of the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, made by the Minister of Health on March 18, 2020, the medical device listed below is now authorized for sale or importation in Canada.

Each shipment of a COVID-19 medical device that is imported into Canada must be accompanied by a copy of this authorization document. Please ensure to highlight the **Authorization reference number** during the import declaration process to facilitate port entry without any delays.

This authorization is only valid for so long as the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 is in effect.

Conformément à l'article 5 de *l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid*-19, réalisé par la ministre de la Santé le 18 mars 2020, les instruments indiqués ci-dessous sont présentement autorisés pour la mise en vente ou l'importation au Canada.

Tout envoi d'un instrument médical relatif au COVID-19 doit être accompagné d'une copie de la présente autorisation. Veuillez vous assurez de souligner le **numéro de référence de l'autorisation** durant le processus de déclaration d'importation pour faciliter l'entrée sans délais aux points de contrôle frontalier.

Cette autorisation est uniquement valide tant que *l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid*-19 est en vigueur, ou l'autorisation est annulée.

Device Name(s) Nom de l'instrument

KROSS DIRECT N95P PARTICULATE RESPIRATOR

Name & Address of Authorization Holder/Nom & adresse du titulaire de l'autorisation

2109971 ONTARIO INC. DBA KROSS DIRECT
96-100 CARRIER DRIVE
ETOBICOKE, ONTARIO
CANADA
M9W 5R1

David Boudreau, ing., Director General, Medical Devices Directorate
Directeur général, Direction des instruments médicaux

David Boudreau

Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

KROSS DIRECT N95P PARTICULATE RESPIRATOR

Device ID/No de l'instrument: 1030655
Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):
N95PR

COVID-19 Medical Device Authorization with Conditions for Importation or Sale

Autorisation d'importation ou de mise en vente d'un instrument médical relatif au COVID-19 avec conditions

Authorization Reference Number : 327682 **Numéro de référence de l'autorisation**

Issue Date: 2021-05-06 **Date de délivrance:**

Device Class/Classe de l'instrument : 1

Pursuant to section 5 of the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, made by the Minister of Health on March 18, 2020, the medical device listed below is now authorized for sale or importation in Canada.

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Device Name(s) Nom de l'instrument

KROSS DIRECT N95 SURGICAL RESPIRATOR

Name & Address of Authorization Holder/Nom & adresse du titulaire de l'autorisation

2109971 ONTARIO INC. DBA KROSS DIRECT
96-100 CARRIER DRIVE
ETOBICOKE, ONTARIO
CANADA
M9W 5R1

David Boudreau, ing., Director General, Medical Devices Directorate
Directeur général, Direction des instruments médicaux

David Boud

Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

KROSS DIRECT N95 SURGICAL RESPIRATOR

Device ID/No de l'instrument: 1030654
Device Identifier / Identificateur de l'instrument (Model/Catalog Detail/No de modèle/Catalogue):
N95SR

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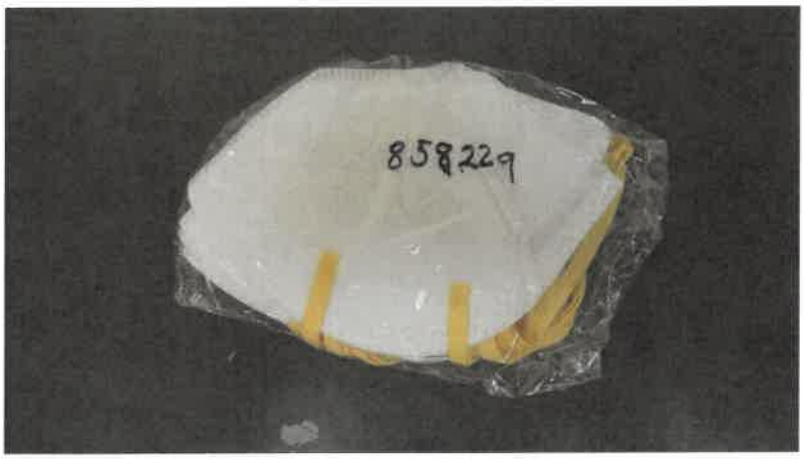
Report For:	Kross Direct 96-100 Carrier Drive Etobicoke, Ontario M9W 5R1 Phone: 647-500-9961 Email: william@softtech-inc.com	**Laboratory #:** **Report Date:** **Received Date:**	858229-21 REVISION 2 May 21, 2021 March 17, 2021
Attention:	William Curry		
Specimen:	#1: Kross Direct N95 Surgical (id N95SR) and Particulate Respirator (id N95PR) with white and yellow straps, identical to ones produced by Kross Direct, Made in Etobicoke, Ontario		

TEST REPORT

One specimen, consisting of respirators was submitted to CMTL for assessment of particulate filter efficiency, airflow resistance, mechanical strength of headstrap or head harness, fluid resistance, and flammability properties to evaluate acceptability with Health Canada performance criteria for filtering facepiece respirators (Date published: 2020-08-25, Date modified: 2021-02-02).

Testing had also been performed to assess the bacterial filtration efficiency to assess compliance with additional requirements for surgical respirators under 42 CFR 84 and FDA/NIOSH MOU 225-18-006.



Revision: Specimen identification updated as per customer request.
Revision Date: April 28, 2021
Revision 2: White and yellow straps added to specimen identification, white strap reference included under mechanical headstrap strength
Revision Date: May 21, 2021

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Per _____
Authorized By Stephen Brown

Per _____
Technician, Derek Wild

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Laboratory # 858229-21 REVISION 2
Kross Direct

Requirement for Filtering Facepiece Respirators per
Health Canada National Standard Specifications for Respirators during COVID-19:
Guidance for Canadian Manufacturers, Date published: 2020-08-25, Date modified: 2021-02-02

Characteristic	Barrier	Summary Results
Particulate Filter Efficiency (%)	≥95	**Pass**[1]
Mechanical Headstrap Strength, Observations and Proof Load (Newtons)	≥20	**Pass**[1]
Airflow (Inhalation) Resistance, mmH_2O (Pa)	≤35 (343)	**Pass**[1]
Airflow (Exhalation) Resistance, mmH_2O (Pa)	≤25 (245)	**Pass**[1]
Flammability, Class	1	**Pass**[1]
Fluid Resistance maximum pressure in kPa for pass result	21.3	**Pass**[1]

[1]Note: Results are represented by Laboratory Number 856214-21

Additional Requirements for Surgical Respirators
Under 42 CFR Part 84 and FDA/NIOSH MOU 225-18-006

Characteristic	Barrier	Summary Results
Bacterial Filtration Efficiency (%)	≥95	**Pass**

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PARTICULATE FILTER EFFICIENCY

Fourteen submitted specimens were evaluated for particulate filter efficiency based on the TEB-APR-STP-00059 test procedure, with exceptions based on appropriate NRC deviations for maximum expected particle loading being used to filter ambient air in a hospital (medical) or other non-industrial setting.

Seven of the specimens were conditioned (C) within a CSZ environmental control chamber for 25±1 hour at a 85±5% relative humidity and 38°C ± 2.5°C, then tested within 10 hours of extraction from the chamber as indicated in NIOSH standard procedure TEB-APR-STP-0059. A remaining seven additional specimens were also tested to evaluate the effect of no conditioning (U), based on NRC recommendations, to assess composition of filtering material.

The particulate filter efficiency was performed on a TSI 8130A automated filter tester, and challenged for 4-minutes under unidirectional airflow at 85 L/min ± 4 L/min with an aerosol of sodium chloride (NaCl) particles. The particles were generated by an aerosol generator and neutralized to their Boltzmann equilibrium state. The particles were considered to have an average count median diameter of 0.075 ± 0.020 micrometers and a geometric standard deviation not exceeding 1.86. This was equivalent to approximately 7.5 mg of NaCl loading.

Note: The equipment was outsourced and located at University of Toronto, 223 College Street, Toronto, ON, M5T 1R4.

RESULTS

Specimen #	Conditioned	Flow Rate	Initial Filter Resistance (mmH_2O)	Maximum Allowable Leakage (%)	Initial Leakage (%)	Maximum Leakage (%)	Particulate Filtration Efficiency (%)	Requirement (≥95%)	
								Result	Overall Result
1-1	C	85	12.0	5.00	0.501	0.501	99.5	Pass	Pass[1]
1-2	C	85	14.2	5.00	0.659	0.659	99.3	Pass	
1-3	C	85	12.2	5.00	0.461	0.461	99.5	Pass	
1-4	C	85	12.7	5.00	0.456	0.456	99.5	Pass	
1-5	C	85	13.0	5.00	0.440	0.440	99.6	Pass	
1-6	C	85	11.7	5.00	0.401	0.401	99.6	Pass	
1-7	C	85	12.8	5.00	0.456	0.456	99.5	Pass	
1-8	U	85	10.9	5.00	0.388	0.388	99.6	Pass	
1-9	U	85	11.8	5.00	0.370	0.370	99.6	Pass	
1-10	U	85	11.6	5.00	0.488	0.488	99.5	Pass	
1-11	U	85	12.8	5.00	0.454	0.454	99.5	Pass	
1-12	U	85	11.9	5.00	0.384	0.384	99.6	Pass	
1-13	U	85	12.8	5.00	0.497	0.497	99.5	Pass	
1-14	U	85	13.5	5.00	0.464	0.464	99.5	Pass	

[1]Note: Results are represented by Laboratory Number 856214-21

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MECHANICAL HEADSTRAP STRENGTH

Ten submitted specimens, with white straps, were subjected to proof load testing in accordance with Health Canada National Standard Specifications for Respirators during COVID-19: Guidance for Canadian Manufacturers (Date published: 2020-08-25, Date modified: 2021-02-02). Testing was performed by securing the mask body to the bed of the testing frame. A proof load of 10 N was then applied to the elastomeric straps for 10 seconds. The proof load was then removed and the specimens were examined for failure. Testing machine was operated in accordance with ASTM A370-20 paragraph 8 with a test speed of 75mm/min.

RESULTS

Specimen #	Observations	Result
1-1	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.	**Pass[1]**
1-2	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.	**Pass[1]**
1-3	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.	**Pass[1]**
1-4	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.	**Pass[1]**
1-5	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.	**Pass[1]**
1-6	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.	**Pass[1]**
1-7	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.	**Pass[1]**
1-8	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.	**Pass[1]**
1-9	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.	**Pass[1]**
1-10	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.	**Pass[1]**

[1]Note: Results are represented by Laboratory Number 856214-21

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AIRFLOW (INHALATION) RESISTANCE

Twenty submitted specimens were evaluated for airflow (inhalation) resistance based on TEB-APR-STP-0007 using a TSI 8130A automated filter tester considered by NIOSH to be an acceptable pressure drop measurement.

Tests were performed with the salt generator turned-off under no loading conditions. Using hot-melt glue the filtering facepiece respirators were sealed onto flat plates with joint for connection to the resistance apparatus for measurements of pressure drop.

Note: The equipment was outsourced and located at University of Toronto, 223 College Street, Toronto, ON, M5T 1R4.

RESULTS

Specimen #	Maximum Allowable Resistance (mmH_2O) Inhalation	Actual Resistance (mmH_2O) Inhalation	Requirement (≤35)	
			Result	Overall Result
1-1	35	11.0	Pass	Pass[1]
1-2	35	12.0	Pass	
1-3	35	13.1	Pass	
1-4	35	11.8	Pass	
1-5	35	11.5	Pass	
1-6	35	10.6	Pass	
1-7	35	11.8	Pass	
1-8	35	10.4	Pass	
1-9	35	10.8	Pass	
1-10	35	10.7	Pass	
1-11	35	11.8	Pass	
1-12	35	11.2	Pass	
1-13	35	11.8	Pass	
1-14	35	13.1	Pass	
1-15	35	13.1	Pass	
1-16	35	11.6	Pass	
1-17	35	11.2	Pass	
1-18	35	10.7	Pass	
1-19	35	11.4	Pass	
1-20	35	11.5	Pass	

[1]Note: Results are represented by Laboratory Number 856214-21

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AIRFLOW (EXHALATION) RESISTANCE

Twenty submitted specimens were evaluated for airflow (inhalation) resistance based on TEB-APR-STP-0003 using a TSI 8130A automated filter tester considered by NIOSH to be an acceptable pressure drop measurement.

Tests were performed with the salt generator turned-off under no loading conditions. Using hot-melt glue the filtering facepiece respirators were sealed onto flat plates and mounted in reverse with joint for connection to the resistance apparatus for measurements of pressure drop.

Note: The equipment was outsourced and located at University of Toronto, 223 College Street, Toronto, ON, M5T 1R4.

RESULTS

Specimen #	Maximum Allowable Resistance (mmH_2O) Exhalation	Actual Resistance (mmH_2O) Exhalation	Requirement (≤25)	
			Result	Overall Result
1-1	25	10.8	Pass	Pass[1]
1-2	25	10.8	Pass	
1-3	25	10.6	Pass	
1-4	25	10.5	Pass	
1-5	25	10.4	Pass	
1-6	25	10.3	Pass	
1-7	25	10.6	Pass	
1-8	25	10.1	Pass	
1-9	25	10.4	Pass	
1-10	25	10.6	Pass	
1-11	25	10.5	Pass	
1-12	25	10.6	Pass	
1-13	25	10.9	Pass	
1-14	25	10.8	Pass	
1-15	25	10.7	Pass	
1-16	25	10.8	Pass	
1-17	25	10.9	Pass	
1-18	25	10.4	Pass	
1-19	25	10.4	Pass	
1-20	25	10.5	Pass	

[1]Note: Results are represented by Laboratory Number 856214-21

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FLAMMABILITY

The submitted specimen, consisting of five filtering facepiece respirators were tested in accordance to 16 CFR 1610 (1-1-16 Edition).

RESULTS

	Specimen #	RESULT	Requirement (Class 1) (PASS/FAIL)
Specimen #1	1-1	8 seconds	**Pass[1] Classified as Class 1**
	1-2	6 seconds	
	1-3	8 seconds	
	1-4	9 seconds	
	1-5	8 seconds	

Test: Flame Resistance 45° angle test. One-Second Flame Impingement.
Type of fabric: Without a raised fiber surface
Surface tested: Face
Type of test: Original State
Direction tested: Length
Testing Conditioning: Specimens conditioned at 105°C for 30 min, then placed in desiccator
Requirements: The flame spread time for textile products without a raised fibre surface must be greater than 3.5 seconds.

Note: For a test plan of 5 specimens, no failure is allowed for an Acceptable Quality Limit of 4.0%.

[1]Note: Results are represented by Laboratory Number 856214-21

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FLUID RESISTANCE
ASTM F1862/F1862M-17 at 21.3 kPa pressure

RESULTS

Specimen #	Test Pressure (kPa)	Total Number of Specimens	Number of Pass Specimens	Requirement
				FINAL RESULT
1	21.3	32	32	**Pass[1]**

Note: Acceptable Quality Limit of 4.0% is met for single sampling plan when 29 or more of the 32 tested specimens show pass results.

Material construction type	Not provided / unknown
Supplier	Not provided / unknown
Lot number	Not provided / unknown
Date of receipt	February 11, 2021
Date of test	February 22, 2021
Fluid velocity (cm/s)	639
Volume of impact fluid (ml)	2
Angle of pneumatic valve to horizontal	2°
Description target area mask	Outer white center area (see Note)
Distance from tip cannula to mask (in)	12
Technique to enhance visual detection	Cotton swab used to lightly daub on the surface
Conditioning parameters	21±5°C, 85±5% R.H for minimum of 4 hours

Note: The outside surface of the mask was exposed to the blood stream in order to observe whether penetration occurred on the inner surface of the mask that could be contacting the wearer's face. Penetration on the inner facing of the mask constitutes failure (ASTM F1862/F1862M-17 section 4.2).

[1]Note: Results are represented by Laboratory Number 856214-21

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BACTERIAL FILTRATION EFFICIENCY

A Bacterial Filtration Efficiency (BFE) test was completed according to the procedure in ASTM F2101-19 to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts recovered downstream. A suspension of S. aureus was aerosolized using a nebulizer and delivered to the test article at a constant rate with a target delivery rate of 1.7 $x10^3$ – 3.0$x10^3$ colony forming units (CFU) per test article with a mean particle size of 3.0 ± 0.3 µm. The aerosolized suspension was drawn through the test article which was clamped in a six stage Andersen air sampler, at a constant flow rate of 28.3 liters per minute (LPM), for collection on bacteriological agar plates.

Challenge Microbe: *Staphylococcus aureus* ATCC 6538
Test Side: User side facing challenge
Area Tested: ~38.5 cm^2
Flow Rate: 28.3 LPM
Test Article Conditioning: 85 ± 5% RH at 25.0 ± 0.5°C for a minimum of 4 hours
Challenge Level: 3.0 x 10^3 CFU
Mean Particle Size: 2.7 µm
Negative Control Count: <1 CFU

RESULTS

Specimen #	Total CFU Recovered	Percent BFE (%)
1-1	<1	>99.9
1-2	1	>99.9
1-3	<1	>99.9

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} \times 100$$

C = Challenge Level
T = Total CFU recovered downstream of test article

$$MPS = \frac{(P1 \times C1) + (P2 \times C2) + (P3 \times C3) + (P4 \times C4) + (P5 \times C5) + (P6 \times C6)}{C1 + C2 + C3 + C4 + C4 + C6}$$

Px = 50% effective cut-off diameter for the x^{th} stage as indicated by the manufacturer
Cx = raw count (on stages 1 and 2) or the "probable hit" count determined using the positive hole conversion chart from the cascade impactor manual (for stages 3 through 6) on the x^{th} stage.

Appendix

Table 1: Raw counts from each stage of the 6 stage cascade air sampler. The numbers presented for stage 1 and 2 represent the total bacterial colonies present and stages 3 through 6 represent a "positive-hole" count. or stages 3 through 6, the air flow through the impactor follows the jet pattern produced by the 400-holes present in these stages. As a result, the count must be corrected using a positive hole correction table based on the principle where the chance of a viable cell/particle impacting in a new, unoccupied, "jet" hole decreases as the total viable particles increase.

Stage Number	Test Article		
	1	2	3
1 - Raw Count	0	0	0
2 - Raw Count	0	0	0
3 - Positive Hole	0	0	0
4 - Positive Hole	0	1	0
5 - Positive Hole	0	0	0
6 - Positive Hole	0	0	0

Table 2: Counts obtained from each stage, including the "positive-hole" correction for stages 3 through 6

Stage Number	Test Article		
	1	2	3
1 - Raw Count	0	0	0
2 - Raw Count	0	0	0
3 - Positive Hole	0	0	0
4 - Positive Hole	0	1	0
5 - Positive Hole	0	0	0
6 - Positive Hole	0	0	0

Note: Testing performed by GAP EnviroMicrobial Services Ltd., 1020 Hargrieve Road, Unit 14, London, Ontario, Canada, N6E 1P5