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6991 Millcreek Drive, Unit 13
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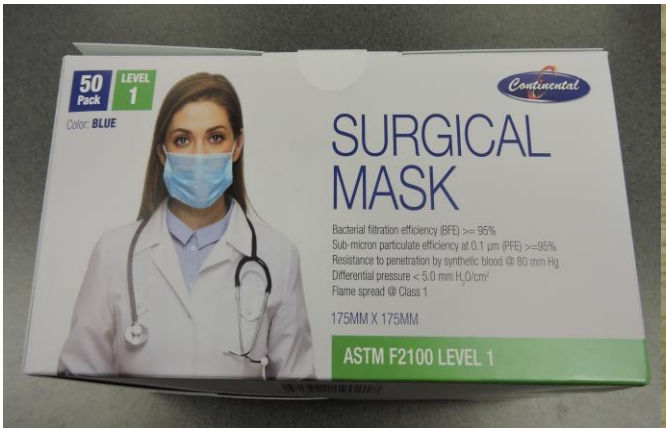
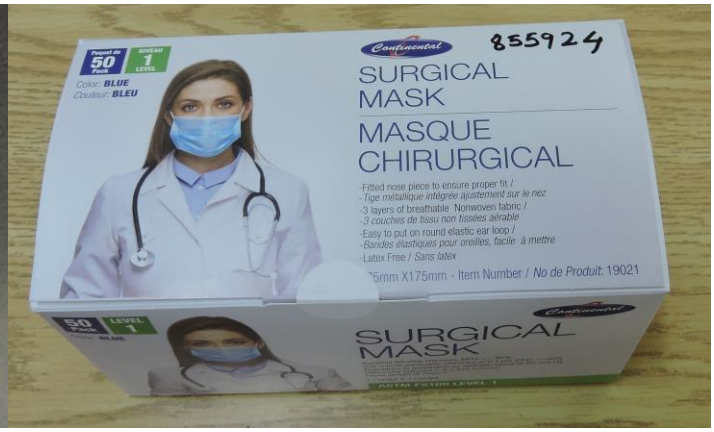
Report For:	Continental Filing System Inc. 2045, rue Berlier Laval, Quebec H7L 3M9 Phone: 450-686-2866 x202 Email: melkon@continental-fs.ca	**Laboratory #:**	855924-21
		Report Date:	February 18, 2021
		Received Date:	February 10, 2021
Attention:	Melkon Iskenderian		
Specimen:	#1: Surgical Mask. Item#: 19021 MDEL: 13747 Manufactured by: CONTINENTALFS INC. Lot#:210221. Expiration date: March 2023.		

TEST REPORT

One specimen, consisting of face masks, was submitted to be tested for bacteria filtration efficiency, differential pressure, particle filtration efficiency, synthetic blood penetration and flame spread to determine barrier classification level as per ASTM F2100-20 requirements.





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Per _____
Authorized By Stephen Brown

Per _____
Technician, Diana Kalinowski

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Medical Face Mask Packaging Requirements

Package Information	**Packaging Displayed Information**
Manufacturer Name	CONTINENTALFS INC
Product / Style Name	Surgical Mask/Masque Chirurgical
Lot Number	210221
Graphical representation indicating the performance level met with the technical requirements of the indicated performance level including a prominent visual indication of the performance level.	Yes
Requirements (Pass / Fail)	**Pass**

Note: ASTM F2100-20 requires verification of packaging, which prominently displays the above packaging information.

Medical Face Mask Material Requirements

Characteristic	**Level 1 Barrier**	**Level 2 Barrier**	**Level 3 Barrier**	**Summary Results**
Bacterial Filtration Efficiency, %	≥95	≥98	≥98	**Pass any Level**
Differential Pressure, mm H_2O/cm^2	<5.0	<6.0	<6.0	**Pass any Level**
Sub-Micron Particulate Filtration Efficiency at 0.1 micron, %	≥95	≥98	≥98	**Pass any Level**
Synthetic Blood Penetration minimum pressure in mmHg for pass result	80	120	160	**Pass Level 1**
Flame Spread	Class 1	Class 1	Class 1	**Pass any Level**
OVERALL PERFORMANCE LEVEL	**Complete - Level 1**			

Note: All five tests must be performed and meet with the requirements of ASTM F2100-20 in order to determine the final overall performance level of the mask, otherwise, the performance level is deemed, "Undetermined".

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DIFFERENTIAL PRESSURE
EN 14683:2019 edition Annex C
Each specimen was conditioned for 4 hours minimum at 21+/-5 C and 85+/-5 % R.H.

RESULTS

Specimen ID	Area ID	Differential Pressure (mmH2O/cm^2)
1-1	1	3.0
	2	3.0
	3	3.0
	4	2.7
	5	3.0
	AVERAGE	2.9
1-2	1	3.0
	2	3.0
	3	2.7
	4	3.4
	5	2.8
	AVERAGE	3.0
1-3	1	3.0
	2	2.5
	3	2.7
	4	3.0
	5	3.0
	AVERAGE	2.8
1-4	1	3.0
	2	3.0
	3	2.9
	4	3.5
	5	3.2
	AVERAGE	3.1
1-5	1	3.0
	2	3.0
	3	2.7
	4	3.0
	5	3.5
	AVERAGE	3.0

Mask Surface Area: 25mm diameter (x5 test areas) (4.9 cm^2)
Air Flow Rate: 8 L/min
Mask Location Specimen taken from: 5 Areas from each specimen distributed all surface wide
Note: For a test plan of 5 specimens, no failure is allowed for an Acceptable Quality Limit of 4.0%.

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SYNTHETIC BLOOD PENETRATION
ASTM F1862/F1862M-17 at 80 mmHg pressure

RESULTS

Specimen #	Test Pressure (mmHg)	Total Number of Specimens	Number of Pass Specimens
1	80	32	32

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	Non-woven fabric
Supplier	CONTINENTALFS INC
Lot number	210221
Date of receipt	February 9, 2021
Date of test	February 11, 2021
Fluid velocity (cm/s)	455
Volume of impact fluid (ml)	2
Angle of pneumatic valve to horizontal	5°
Description target area mask	Outer blue ripple 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 is 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).

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FLAME SPREAD

The specimen, consisting of 5 masks, was tested in accordance to 16 CFR 1610 (1-1-16 Edition).

	Specimen #	RESULT	CONCLUSION
Specimen #1	1-1	IBE	**Classified as Class 1**
	1-2	IBE	
	1-3	IBE	
	1-4	IBE	
	1-5	IBE	

IBE: Ignited but extinguished

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%.

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PARTICLE FILTRATION EFFICIENCY

Description of Material Tested
Material Identification: Non woven fabric
Material Description: Non woven fabric
Manufacturer: CONTINENTALFS INC
Lot # : 210221
Thickness: 0.72 mm
Basis Weight: 77.8 g/m^2
Treatment Prior to Testing: None

Challenge Particles
Challenge Particle Composition: Monodispersed polystyrene latex spheres (PSL)
Particle Size Distribution:
Particle Size: 0.100 um
% Concentration: 0.01 nm sd.
Source: Nanobead NIST traceable 100NM, Cat# 64010
Lot Identification: Lot#: A776757

Aerosol Generator
System Flow Meters: MKS Mass Flow Meter 0558A/247D (calibrated Jan-2021)
Particle Counter: TSI scanning mobility particle sizer spectrometer 3082 and CPC (calibrated Jun-2020)

Test Method
Standard Test Method Used: ASTM F2299/F2299M-03 (2017)
Deviation from Standard Test Method: non-neutralized aerosol challenge measured over 3 minutes,
Temperature and Humidity: 21.3°C, 37.2% relative humidity (RH)
Test Parameters:
Exposed Specimen Area: 21.7 cm^2 with a cross-sectional diameter of 5.25 cm
Flowrate: 10.0 L/min

Test Duration: 3 minutes
Test Sensitivity: 0.1 % detectable percentage penetration
Control Used: Two sampling upstream intervals counted and averaged with a deviation demonstrating reproducibility of the test.

Test Results
Date Tested: February 17, 2021
Number of Specimens Tested: 5
Location of Specimens: Inside

RESULTS

Specimen #	Challenge Particle Diameter / Standard Deviation*	Average Control Counts	Specimen Counts	Face Velocity (cm/s)	Filtration Efficiency (%)
1-1	99.9 nm / 0.01 nm	373,128	3,455	8	99.1
1-2	99.9 nm / 0.01 nm	401,112	4,958	8	98.8
1-3	99.9 nm / 0.01 nm	415,811	3,812	8	99.1
1-4	99.9 nm / 0.01 nm	436,687	5,227	8	98.8
1-5	99.9 nm / 0.01 nm	441,478	5,327	8	98.8

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

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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: Blue side
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: 2.9 x 10^3 CFU
Mean Particle Size: 3.1 µm
Negative Control Count[g]: <1 CFU

RESULTS

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

The filtration efficiency percentages were calculated using the following equation:

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

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	1	0
2 - Raw Count	0	0	0
3 - Positive Hole	0	1	0
4 - Positive Hole	0	0	0
5 - Positive Hole	2	0	0
6 - Positive Hole	1	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	1	0
2 - Raw Count	0	0	0
3 - Positive Hole	0	1	0
4 - Positive Hole	0	0	0
5 - Positive Hole	2	0	0
6 - Positive Hole	1	0	0

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