

855925-21

February 18, 2021

February 10, 2021

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Laboratory #:

Report Date:

Received Date:

**Report For:** Continental Filing System Inc.

2045, rue Berlier Laval, Quebec H7L 3M9

Phone: 450-686-2866 x202 Email: melkon@continental-fs.ca

Attention: Melkon Iskenderian

**Specimen:** #1: Surgical Mask. Item#: 19022 MDEL: 13747 Manufactured by: CONTINENTALFS INC.

Lot#:220221. 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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Cambridge Materials Testing Limited

Authorized By Stephen Brown

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	220221
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 <sub>2</sub> O/cm <sup>2</sup>	<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 2
Flame Spread	Class 1	Class 1	Class 1	Pass any Level
OVERALL PERFORMANCE LEVEL	Complete - Level 2			

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/cm²)
	1	4.5
	2	4.9
1.1	3	5.1
1-1	4	5.2
	5	5.0
	AVERAGE	4.9
	1	4.1
	2	4.3
1-2	3	5.6
1-2	4	4.6
	5	6.0
	AVERAGE	4.9
	1	5.2
	2	5.2
1-3	3	4.7
1-3	4	5.1
	5	4.6
	AVERAGE	4.9
	1	5.3
	2	4.8
1-4	3	5.0
1-4	4	4.7
	5	4.9
	AVERAGE	4.9
1-5	1	5.5
	2	5.0
	3	4.9
	4	4.7
	5	4.7
	AVERAGE	4.9

Mask Surface Area: 25mm diameter (x5 test areas) (4.9 cm<sup>2</sup>)

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 120 mmHg pressure

#### **RESULTS**

Specimen #	Test Pressure	Total Number of	Number of Pass
	(mmHg)	Specimens	Specimens
1	120	32	30

<u>Note</u>: 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	220221
Date of receipt	February 9, 2021
Date of test	February 17, 2021
Fluid velocity (cm/s)	555
Volume of impact fluid (ml)	2
Angle of pneumatic valve to horizontal	3°
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

<u>NOTE</u>: 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
	1-1	IBE	
Specimen	1-2	IBE	
#1	1-3	IBE	Classified as Class 1
	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

Particles: Monodispersed polystyrene latex spheres (PSL)

Particles Counter: TSI scanning mobility particle sizer spectrometer 3082 and CPC

Tested as per ASTM F2299, non-neutralized aerosol challenge measured over 3 minutes (test specimen /

control counts before and after test specimen and averaged)

Test Side: Inside Area Tested: 21.7 cm2 Particle Size: 0.1 µm

Laboratory Conditions: 23°C, 38% relative humidity (RH)

#### Requirements ASTM F2100-19:

Particle filtration efficiency at 0.1 micron (%)

Level 1 Barrier: ≥95 Level 2 Barrier: ≥98 Level 3 Barrier: ≥98

#### **RESULTS**

			KLOOLIO		
Specimen #	Average Control Counts	Specimen Counts	Filtration Efficiency (%)	Specimen (Pass/Fail)	FINAL RESULT
1-1	226,465	658	<99	Pass	
1-2	221,250	1,194	99	Pass	
1-3	253,682	843	<99	Pass	<b>^</b> Pass any Level
1-4	229,770	1,401	99	Pass	
1-5	192,025	745	<99	Pass	

\*Note: Tested under Laboratory#: 850549-20, reported December 17, 2020.

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  $1.7 \times 10^3 - 3.0 \times 10^3$  colony forming units (CFU) per test article with a mean particle size of  $3.0 \pm 0.3$  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<sup>2</sup> Flow Rate: 28.3 LPM

Test Article Conditioning:  $85 \pm 5\%$  RH at  $25.0 \pm 0.5$ °C for a minimum of 4 hours

Challenge Level: 2.9 x 10<sup>3</sup> CFU Mean Particle Size: 2.9 µm

# Requirements ASTM F2100-19: Bacterial filtration efficiency (%)

Level 1 Barrier: ≥95 Level 2 Barrier: ≥98 Level 3 Barrier: ≥98

## **RESULTS**

Specimen #	Total CFU Recovered	Percent BFE (%)	Specimen (Pass/Fail)	FINAL RESULT
1-1	4	99.9	Pass	
1-2	1	>99.9	Pass	<b>^</b> Pass any Level
1-3	4	99.9	Pass	

**^Note:** Tested under Laboratory#: 850549-20, reported December 17, 2020.

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

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