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FINAL

843875-20

September 23, 2020

September 8, 2020

Laboratory #:

Report Date:

Received Date:

Report For: Fortec International Inc.

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Mississauga, Ontario

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Attention: Masie Gillingham / Mansha Rashid

#1: Medical Masks Supplier: Xiantao Dingcheng Nonwoven Products CO. LTD. Hubei Specimen:

Province China, Lot#:202007101. Model#: Type IIR EN 14683:2019. Production date: 2020-

07-10 Expiration date: 2022-07-09

TEST REPORT

One specimen, consisting of Medical Masks, was submitted to be tested for bacteria filtration efficiency, differential pressure, particle filtration efficiency, synthetic blood penetration and flame spread to determine acceptability with level barrier classification under ASTM F2100-19 requirements.

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 ₂ O/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		Со	mplete - L	evel 1

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Cambridge Materials Testing Limited

Authorized By Stephen Brown

Anomaria Zojás Pineda.

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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.

Requirements ASTM F2100-19:

Differential Pressure (mmH₂O/cm²)

Level 1 Barrier: <5.0 Level 2 Barrier: <6.0 Level 3 Barrier: <6.0



RESULTS						
<u>Specimen</u> <u>ID</u>	<u>Area ID</u>	Differential Pressure (mmH2O/cm2)	ial Pressure (mmH2O/cm2) Specimen Pass/Fail			
_	1	5.0		RESULT		
	2	4.0				
4.4	3	5.9	D. C.C.			
1-1	4	5.0	PASS			
	5	4.7				
	AVERAGE	4.9				
	1	4.4				
	2	3.8				
4.3	3	4.3	DACC			
1-2	4	4.3	PASS			
	5	4.3				
	AVERAGE	4.2				
	1	4.8				
	2	4.4 5.0 PASS		PASS Any		
1-3	3					
1-3	4	3.8	PASS	Level		
	5	4.5				
	AVERAGE 4.5					
	1	4.4				
	2	4.0				
1-4	3	5.6	PASS			
1-4	4	5.1	PASS			
	5	4.0				
	AVERAGE	4.6				
	1	4.7				
	2	4.3				
1-5	3	4.9	PASS			
1-3	4	4.8	FA33			
	5	4.5				
	AVERAGE	4.6				

Mask Surface Area: 25mm diameter (x5 test areas) (4.9 cm²)

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	FINAL RESULT
1	80	32	32	Pass for Level 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	Xiantao Dingcheng Nonwoven Products CO LTD Hubei Province, China		
Lot number	202007101		
Date of receipt	September 8, 2020		
Date of test	September 15, 2020		
Fluid velocity (cm/s)	453		
Volume of impact fluid (ml)	2		
Angle of pneumatic valve to horizontal	5°		
Description target area mask	Blue ripple area		
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		



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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	Classified as Class 4
#1	1-3	IBE	Classified as Class 1 PASS for ANY LEVEL
	1-4	IBE	PASS IOI ANT LEVEL
	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 (PFE)

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: 22.3°C, 40.2% 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

Specimen #	Average Control Counts	Specimen Counts	Filtration Efficiency (%)	Specimen (Pass/Fail)	FINAL RESULT
1-1	107,035	2,017	98.1	Pass	
1-2	105,449	1,971	98.1	Pass	9
1-3	96,292	952	99.0	Pass	PASS Any Level
1-4	62,167	1,183	98.1	Pass	
1-5	65,530	900	98.6	Pass	

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



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BACTERIA FILTRATION EFFICIENCY (BFE)

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

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 x 10³ – 3.0x10³ 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 cm² 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: 2.298 x 10³ CFU Mean Particle Size: 3.23µm

Requirements ASTM F2100-19:

Bacteria filtration efficiency (%)

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

RESULTS

Specimen	Total CFU	Percent	Specimen	FINAL RESULT
#	Recovered	BFE (%)	(Pass/Fail)	
1-1	2	99.9	Pass	
1-2	1	>99.9	Pass	PASS Any Level
1-3	1	>99.9	Pass	

Note: Only 3 specimens were tested however; 5 specimens are required as per ASTM F2100-19.

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