

**Sponsor:** Breathe Medical Manufacturing Ltd.  
 #110 – 250 Beaver Lake Road  
 Kelowna, British Columbia  
 V4V 1S7

**Report Date:** July 23, 2020  
**Received Date:** July 20, 2020  
**Purchase Order #:** 12001-24  
**Study #:** BMM-200720  
**Test Class:** ASTM  
 F2100-19

**Attention:**

**Manufacturer:** Breathe Medical Manufacturing Ltd.  
**Specimens:** Surgical Disposable Face Masks  
**Lot #:** 20200720-01-0800

**TEST REPORT**

A set of specimens, consisting of 3-Ply Medical Face Masks, was submitted to be tested for the following tests:

Bacterial Filtration Efficiency	Yes
Particulate Filtration Efficiency	Yes
Differential Pressure	Yes
Synthetic Blood Penetration	Yes
Flame Spread	Yes
Ear Loop Tensile Strength	Yes

3-Ply Medical Face Mask Material Requirements & Results

<u>Test</u>	<u>Level 1 Barrier</u>	<u>Level 2 Barrier</u>	<u>Level 3 Barrier</u>	<u>SUMMARY RESULTS</u>
Bacterial Filtration Efficiency, %	≥95	≥98	≥98	Pass for any Level
Sub-Micron Particulate Filtration Efficiency at 0.1 micron, %	≥95	≥98	≥98	Pass for Level 1
Differential Pressure, mm H <sub>2</sub> O/cm <sup>2</sup>	<5.0	<6.0	<6.0	Pass for Level 2 & 3
Synthetic Blood Penetration minimum pressure in mmHg for pass result	80	120	160	Pass for any Level
Flame Spread	Class 1	Class 1	Class 1	Pass for any Level
Ear loop Resistance Strength	N/A	N/A	N/A	Above 5.00lbs force



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 Technician, Shane Broesky



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 Authorized By, Robert Balazs

July 23, 2020  
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 Study Completion Date

These results apply to the samples as received and relate only to the test articles listed in this report.

### BACTERIA FILTRATION EFFICIENCY (BFE)

**Summary:** 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  $3.0 \pm 0.3 \mu\text{m}$ . 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:	<i>Staphylococcus aureus</i> ATCC 6538
Test Side:	White side
Number of Specimens:	5
Area Tested:	~38.5 cm <sup>2</sup>
Flow Rate:	28.3 L/min
Test Article Conditioning:	85 ± 5% RH at 25.0 ± 0.5°C for a minimum of 4 hours
Challenge Level:	$2.58 \times 10^3$ CFU
Mean Particle Size:	3.04 μm

Requirements ASTM F2101/F2100-19:

Particle filtration efficiency at 0.1 micron (%)

Level 1 Barrier: ≥95

Level 2 Barrier: ≥98

Level 3 Barrier: ≥98

### RESULTS

<u>Specimen #</u>	<u>Total CFU Recovered</u>	<u>Bacterial Efficiency (%)</u>	<u>Specimen (Pass/Fail)</u>	<u>FINAL RESULT</u>
1	10	99.6078	PASS for any Level	<b>PASS for any Level</b>
2	5	99.8059	PASS for any Level	
3	15	99.4137	PASS for any Level	
4	16	99.3748	PASS for any Level	
5	14	99.4525	PASS for any Level	

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

### **PARTICULATE FILTRATION EFFICIENCY (PFE)**

**Summary:** This test method establishes procedures for measuring the initial particle filtration efficiency of materials used in medical face masks using monodispersed polystyrene latex spheres and light scattering particle counting.

Particles:	Monodispersed polystyrene latex spheres (PSL)
Particles Counter:	Thermo Scientific pDR-1500
Area Tested:	21.7 cm <sup>2</sup>
Particle Size:	0.1 µm
Flow Rate:	28.3 L/min
Testing Time:	90 seconds
Number of Specimens:	5
Laboratory Conditions:	21°C, 40.4 relative humidity
Average Filtration Efficiency:	97.17%

**Requirements ASTM F2299/F2100-19:**

Particle filtration efficiency at 0.1 micron (%)

Level 1 Barrier: ≥95

Level 2 Barrier: ≥98

Level 3 Barrier: ≥98

### **RESULTS**

<b><u>Specimen #</u></b>	<b><u>Particle Up Stream</u></b>	<b><u>Particle Down Stream</u></b>	<b><u>Filtration Efficiency (%)</u></b>	<b><u>Specimen (Pass/Fail)</u></b>	<b><u>FINAL RESULT</u></b>
1	13,440	350	97.39%	PASS for Level 1	<b>PASS for Level 1</b>
2	14,060	490	96.52%	PASS for Level 1	
3	14,850	320	97.85%	PASS for Level 1	
4	15,040	390	97.40%	PASS for Level 1	
5	15,070	500	96.68%	PASS for Level 1	

### DIFFERENTIAL PRESSURE (DELTA P)

**Summary:** The Delta P test determines the breathability of medical face masks by measuring the differential air pressure on either side of the test article using a nanometer, at a constant flow rate. The Delta P test complies with EN 14683:2019 Annex C.

Mask Surface Area:	25mm diameter (x5 test areas) (4.9cm <sup>2</sup> )
Air Flow Rate:	8 L/min
Mask Test Location:	Each specimen from the middle of the mask
Number of Specimens:	5
Test Article Conditioning:	85 ± 5% RH at 25.0 ± 0.5°C for a minimum of 4 hours

Requirements ASTM F2100-19:

Differential Pressure (mm H<sub>2</sub>O/cm<sup>2</sup>)

Level 1 Barrier: <5.0

Level 2 Barrier: <6.0

Level 3 Barrier: <6.0

### RESULTS

<u>Specimen #</u>	<u>Differential Pressure (mm H<sub>2</sub>O/cm<sup>2</sup>)</u>	<u>Pass/Fail</u>	<u>FINAL RESULT</u>
1-1	5.20	Pass	PASS for Level 2 & 3
1-2	4.77	Pass	
1-3	4.34	Pass	
1-4	5.55	Pass	
1-5	5.13	Pass	
<b>Average</b>	<b>4.998</b>		

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

### SYNTHETIC BLOOD PENETRATION

**Summary:** This procedure was performed to evaluate medical face mask resistance to synthetic blood penetration that is useful in establishing claims for penetration resistance performance of medical face masks and ranking their performance. The mean human blood pressure generally varies over a range of about 10.7 to 16.0 kPa (80 to 120 mmHg).<sup>8</sup> In this test method, medical face masks are tested at stream velocities corresponding to 10.7 kPa, 16.0 kPa, and 21.3 kPa (80 mmHg, 120 mmHg, and 160 mmHg).

Target Distance:	30.5cm
Test Volume:	2mL
Fluid Velocity (cm/s)	457
Test Side:	Blue side
Number of Specimens:	32
Material:	Polypropylene
Detection Technique:	Visual and Cotton Swab
Test Article Conditioning:	85 ± 5% RH at 25.0 ± 0.5°C for a minimum of 4 hours
Laboratory Conditions:	21°C, 40.4 relative humidity

Requirements ASTM F1862/F2100-19:

Synthetic Blood Penetration (mmHg)

Level 1 Barrier: 80

Level 2 Barrier: 120

Level 3 Barrier: 160

### RESULTS

<u>Specimen #</u>	<u>Test Pressure (mmHg)</u>	<u>Total Number of Specimens</u>	<u>Number of Specimens Passed</u>	<u>FINAL RESULT</u>
1-32	160	32	32	<b>PASS for any Level</b>

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

### FLAME SPREAD

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

Test:	Flame Resistance 45° angle test. One-Second Flame Impingement
Type of Fabric:	Without a raised fiber surface
Number of Specimens:	5
Surface Tested:	Face
Type of Test:	Original State
Direction Tested:	Length
Testing Conditions:	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.

### **RESULTS**

<u>Specimen #</u>	<u>Result</u>	<u>FINAL RESULT</u>
1	IBE	<b>Classified as Class 1 PASS for any Level</b>
2	IBE	
3	IBE	
4	IBE	
5	IBE	

**IBE:** Ignited but extinguished

**Note:** For a test plan of 5 specimens, no failure is allowed for an Acceptable Quality Limit of 4.0%  
 Testing performed by Cambridge Materials Testing Limited., 6991 Millcreek Drive, Unit 13, Mississauga, Ontario, L5N 6B9

### **EAR LOOP TENSILE STRENGTH**

**Summary:** This test method is used to determine the tensile strength of ear loops on medical face masks.

Equipment:	Motorized vertical single column test stand
Force Gauge:	Electronic 2~500N
Number of Specimens:	5

### **RESULTS**

<b><u>Specimen #</u></b>	<b><u>Left Ear Loop (Lbs of Force)</u></b>	<b><u>Right Ear Loop (Lbs of Force)</u></b>
1	6.40	7.10
2	5.20	6.20
3	7.00	7.52
4	6.72	8.10
5	8.20	7.12
<b>Average</b>	<b>6.70</b>	<b>7.21</b>