

Report For: O-Medical Corporation
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Laboratory #: 843487-20
Report Date: September 8, 2020
Received Date: September 1, 2020
FINAL

Attention: Carmela Dimaria
Specimen: #1: Medical Masks

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 Level 3 |
| Synthetic Blood Penetration minimum pressure in mmHg for pass result | 80 | 120 | 160 | Pass Level 3 |
| Flame Spread | Class 1 | Class 1 | Class 1 | Pass any Level |
| OVERALL PERFORMANCE LEVEL | Complete | | | |

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Per Steve Brown
Authorized By Stephen Brown
Per Anomaria Rojas Pineda
Technician, Anamaria Rojas-Pineda



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

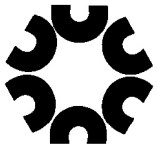
| <u>Specimen #</u> | <u>Area ID</u> | <u>Differential Pressure (mmH₂O/cm²)</u> | <u>Specimen Pass/Fail</u> | <u>FINAL RESULT</u> |
|-------------------|----------------|--|---------------------------|---------------------|
| 1-1 | 1 | 1.5 | PASS | PASS Any Level |
| | 2 | 1.6 | | |
| | 3 | 1.3 | | |
| | 4 | 1.3 | | |
| | 5 | 1.6 | | |
| | AVERAGE | 1.5 | | |
| 1-2 | 1 | 1.7 | PASS | |
| | 2 | 1.7 | | |
| | 3 | 1.7 | | |
| | 4 | 1.4 | | |
| | 5 | 2.0 | | |
| | AVERAGE | 1.7 | | |
| 1-3 | 1 | 1.7 | PASS | |
| | 2 | 1.7 | | |
| | 3 | 1.4 | | |
| | 4 | 1.4 | | |
| | 5 | 1.9 | | |
| | AVERAGE | 1.6 | | |
| 1-4 | 1 | 1.8 | PASS | |
| | 2 | 2.0 | | |
| | 3 | 1.5 | | |
| | 4 | 1.4 | | |
| | 5 | 1.9 | | |
| | AVERAGE | 1.7 | | |
| 1-5 | 1 | 1.7 | PASS | |
| | 2 | 1.9 | | |
| | 3 | 1.3 | | |
| | 4 | 1.4 | | |
| | 5 | 1.8 | | |
| | AVERAGE | 1.6 | | |

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

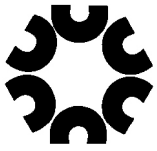
ASTM F1862/F1862M-17 at 160 mmHg pressure

RESULTS

| Specimen # | Test Pressure (mmHg) | Total Number of Specimens | Number of Pass Specimens | FINAL RESULT |
|------------|----------------------|---------------------------|--------------------------|-------------------------|
| 1 | 160 | 32 | 31 | Pass for Level 3 |

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 | O-Medical |
| Lot number | Not provided/Unknown |
| Date of receipt | September 1, 2020 |
| Date of test | September 3, 2020 |
| Fluid velocity (cm/s) | 648 |
| Volume of impact fluid (ml) | 2 |
| Angle of pneumatic valve to horizontal | 2° |
| 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

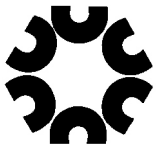
The specimen, consisting of 5 masks, was tested in accordance to 16 CFR 1610 (1-1-16 Edition).

| | Specimen # | RESULT | CONCLUSION |
|--------------------|------------|--------|---|
| Specimen #1 | 1-1 | IBE | Classified as Class 1 PASS for ANY LEVEL |
| | 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 (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: 22.7°C, 45.1% 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 | 50,900 | 559 | 98.9 | Pass | Pass Level 3 |
| 1-2 | 74,441 | 1,191 | 98.4 | Pass | |
| 1-3 | 78,940 | 1,027 | 98.7 | Pass | |
| 1-4 | 46,012 | 369 | 99.2 | Pass | |
| 1-5 | 67,398 | 1,078 | 98.4 | 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 $1.7 \times 10^3 - 3.0 \times 10^3$ 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: *Staphylococcus aureus* ATCC 6538

Test Side: User side facing challenge

Area Tested: $\sim 38.5 \text{ cm}^2$

Flow Rate: 28.3 LPM

Test Article Conditioning: $85 \pm 5\%$ RH at $25.0 \pm 0.5^\circ\text{C}$ for a minimum of 4 hours

Challenge Level: 3.214×10^3 CFU *

Mean Particle Size: $3.30 \mu\text{m}$

* Note: A challenge level of $>3.0 \times 10^3$ CFU was accepted, as control plates remained in a countable range and particle size remained within limits.

Requirements ASTM F2100-19:

Bacteria 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 | 40 | 98.95 | Pass | PASS Level 3 |
| 1-2 | 42 | 98.70 | Pass | |
| 1-3 | 58 | 98.21 | Pass | |
| 1-4 | 44 | 98.62 | Pass | |
| 1-5 | 46 | 98.57 | Pass | |

The filtration efficiency percentages were calculated using the following equation:

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

C = Challenge Level

T = Total CFU recovered downstream of test article