MODERN AIR FILTERS
CORPORATION

LEVEL 3
CERTIFICATES

Health Canada / Santé Canada

id: 156140

Licence Number **12939** Numéro de la licence

Medical Device Establishment Licence

Licence d'établissement pour les instruments médicaux

MODERN AIR FILTER CORPORATION

15 MELANIE DRIVE, SUITE 2
BRAMPTON, ONTARIO
CANADA
L6T 4K8

This licence is issued in accordance with the Medical Devices Regulations of the Food and Drugs Act for the following activities:

Cette licence est délivrée conformément à la Loi sur les aliments et drogues, règlement sur les instruments médicaux pour les activités qui suivent:

	Distributor / Distributeur	Importer / Importateur	Manufacture Devices for Distribution / Fabricant d'instruments médicaux pour distribution
Class I / Classe I	No / Non	No / Non	Yes / Oui
Class II / Classe II	No / Non	No / Non	
Class III / Classe III	No / Non	No / Non	
Class IV / Classe IV	No / Non	No / Non	

Attestation made :

Attestations faites :

The establishment has documented procedures in place in respect of:		L'établissement a mis en oeuvre une procédure écrite concernant:
• distribution records	[Y]	• les registres de distribution
• complaint handling	[Y]	• les plaintes
• recalls	[Y]	• les rappels
• mandatory problem reporting	[Y]	• rapports d'incident obligatoires
• handling, storage, delivery	[N]	• la manutention, le stockage, la livraison
• installation	[N]	• l'installation,
• corrective action	[N]	• les mesures correctives
• servicing	[N]	• l'entretien

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Issue Date, date de délivrance: 2020-05-20

Minister of Health Ministre de la santé	Countersigned: Director, Medical Devices Compliance Program or delegated authority Contresigné par: Directrice, Programme de la conformité des matériels médicaux ou autoritée déléguée Anik Michelle Chartrand

This licence is the property of the Medical Devices Compliance Program and must be returned upon demand.
Cette licence appartient au Programme de la conformité des matériels médicaux et doit être retournée sur demande.

Canada

Sites

MODERN AIR FILTER CORPORATION
15 MELANIE DRIVE, SUITE 2
BRAMPTON, ONTARIO
CANADA
L6T 4K8

Company ID

156140

No. d'identification de la société

Cambridge
materials testing limited

6991 Millcreek Drive, Unit 13
Mississauga, Ontario L5N 6B9
Tel: (905) 812-3856 Fax: (905) 812-3866
www.cambridgematerials.com

Laboratory # 843878-20
FINAL
Modern Air Filters Corporation

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 (mmH_2O/cm^2)
Level 1 Barrier: <5.0
Level 2 Barrier: <6.0
Level 3 Barrier: <6.0

RESULTS

Specimen ID	Area ID	Differential Pressure (mmH2O/cm2)	Specimen Pass/Fail	FINAL RESULT
1-1	1	4.6	PASS	PASS Any Level
	2	4.9		
	3	4.2		
	4	4.3		
	5	3.8		
	AVERAGE	4.4		
1-2	1	4.9	PASS	
	2	4.8		
	3	4.7		
	4	4.7		
	5	4.0		
	AVERAGE	4.6		
1-3	1	4.8	PASS	
	2	4.8		
	3	4.5		
	4	5.0		
	5	3.9		
	AVERAGE	4.6		
1-4	1	5.0	PASS	
	2	4.8		
	3	4.6		
	4	4.3		
	5	4.0		
	AVERAGE	4.5		
1-5	1	4.6	PASS	
	2	4.6		
	3	4.0		
	4	4.5		
	5	3.9		
	AVERAGE	4.3		

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 160 mmHg pressure

RESULTS

Specimen #	Test Pressure (mmHg)	Total Number of Specimens	Number of Pass Specimens	**FINAL RESULT**
1	160	32	32	**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	Modern Air Filters Corporation
Lot number	Not provided/unknown
Date of receipt	September 10, 2020
Date of test	September 15, 2020
Fluid velocity (cm/s)	647
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 cm^2
Particle Size: 0.1 µm
Laboratory Conditions: 23.2°C, 46.5% 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	75,607	1,040	98.6	Pass	PASS Any Level
1-2	75,511	671	99.1	Pass	
1-3	73,651	952	98.7	Pass	
1-4	77,703	1,547	98.0	Pass	
1-5	74,380	990	98.7	Pass	

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

GAPLAB
Environmental Microbiology

1020 Hargrieve Road, Unit 14
London, Ontario, Canada N6E 1P5
Telephone: (519) 681-0571
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Website: www.gaplab.com

GAP Project #A14549

August 18, 2020

Modern Air Filters
Attn: Frank Sultan
15 Melanie Dr.
Brampton, ON L6T 4K8
Tel: 416-728-7735
Fax:
Email: frank@modernairfilters.com

ASTM F2101-19: Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using Biological Aerosol of *Staphylococcus aureus*
and
EN 14683:2019+AC: Medical Face Masks – Requirements and Test Methods Section 5.2.2 Bacterial Filtration Efficiency (BFE)

GAP Sample Number: 5491
Test Article: MAFC
Received Date: August 12, 2020
Test Date: August 17, 2020
Challenge Microbe: *Staphylococcus aureus* ATCC 6538
Test Side: User side facing challenge
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

A Bacterial Filtration Efficiency (BFE) test was completed according to the procedure in ASTM F2101 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 1.7×10^3 – 3.0×10^3 colony forming units (CFU) per test article with a mean particle size (MPS) 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 Level: 7.562×10^2 CFU(1)
Mean Particle Size: 2.71 µm

Results:

Test Article	Total CFU Recovered	Filtration Efficiency (%)
1	<1	>99.87
2	<1	>99.87
3	<1	>99.87
4	<1	>99.87
5	<1	>99.87

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GAP Project #A14549

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

C = Challenge Level
T = Total CFU recovered downstream of test article

$$MPS = \frac{(P1 \times C1) + (P2 \times C2) + (P3 \times C3) + (P4 \times C4) + (P5 \times C5) + (P6 \times C6)}{C1 + C2 + C3 + C4 + C5 + C6}$$

Where: Px = 50% effective cut-off diameter for the xth 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 xth stage.

1. A challenge level of <1.7x10^3 CFU was accepted as we were still able to determine a filtration efficiency of ≥98% as required in ASTM F2100-19 for a "Level 3 Barrier."

If you have any questions regarding the analysis, please do not hesitate to call the lab anytime at (519) 681-0571.

Analyst:	Shawn Verhoeven	Manager Approval:	Conrad Odegaard
Position:	Technical Manager	Position:	Technical Manager
Signature:	S. Verh	Signature:	Cgd

These test results relate only to the samples submitted and the analyses requested.
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