MODERN AIR FILTERS
CORPORATION

LEVEL 2
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

Site listing begins on the back of this page

Liste des sites commence au verso de cette page

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

Health Canada Santé 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

GAPLAB
Environmental Microbiology

1020 Hargrieve Road, Unit 14
London, Ontario, Canada N6E 1P5
Telephone: (519) 681-0571
Fax: (519) 681-7150
Email: info@gaplab.com
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:	Cjod

These test results relate only to the samples submitted and the analyses requested.
This test report cannot be reproduced except in full, without written permission from GAP.

GroupeCTTGroup

SCC Accredited LAB — LAB Accrédité CCN

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ANALYSIS REPORT
SCC Accreditation No.: 40‡

Mr. Frank Sultan
Modern Air Filters Corporation

Date: July 29, 2020
Report: 5916-001T-8A-en

IDENTIFICATION:	Medical face masks: MAFC masks - Test at 120 mm Hg Received: July 28, 2020
STANDARD:	
TEST:	Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) — ASTM F1862/F1862M-17‡
TEST CONDITIONS:	Conditioning atmosphere: 21±5°C, 85±5% R.H.; Testing atmosphere (<1 minute): 19.9°C : 72% H.R. Distance of the mask from the cannula: 30.5cm Volume of fluid impacting the masks: 2.01ml Blood penetration detection: Naked eye Number of specimens tested: 32 Date of test: July 29,2020

RESULTS:

	Individual Data				
Stream velocity (cm/s):	550				
Corresponding blood pressure (mmHg):	120				
Blood penetration (pass/fail):	PASS	PASS	PASS	PASS	PASS
	PASS	PASS	PASS	PASS	PASS
	PASS	PASS	PASS	PASS	PASS
	PASS	PASS	PASS	PASS	PASS
	PASS	PASS	PASS	PASS	PASS
	PASS	PASS	PASS	PASS	PASS
	PASS	PASS			

Prepared by:
Patrick Dubois,
Technician

Approved by:
Alejandro Maupomé, Eng., Ph.D.
Project Leader

Date: July 29, 2020

For any information concerning this report, please contact Alejandro Maupomé.

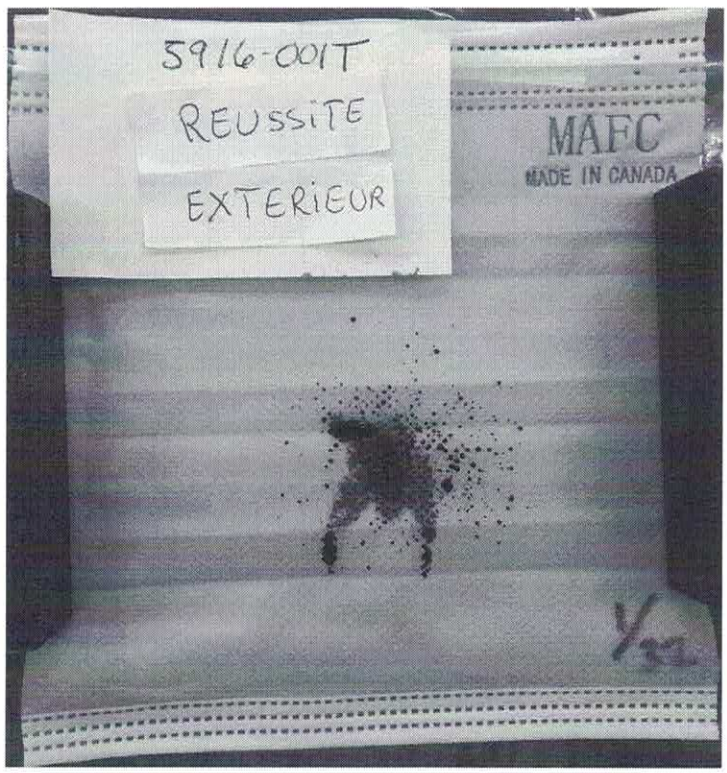
GroupeCTTGroup

ANALYSIS REPORT
SCC Accreditation No.: 40‡

Mr. Frank Sultan
Modern Air Filters Corporation

Date: July 29, 2020
Report: 5916-001T-8A-en

MAFC blue mask PASS OUT 120



Approved by:

A Maupomé

Alejandro Maupomé, Eng., Ph.D.
Project Leader

Date: July 29, 2020

For any information concerning this report, please contact Alejandro Maupomé.**

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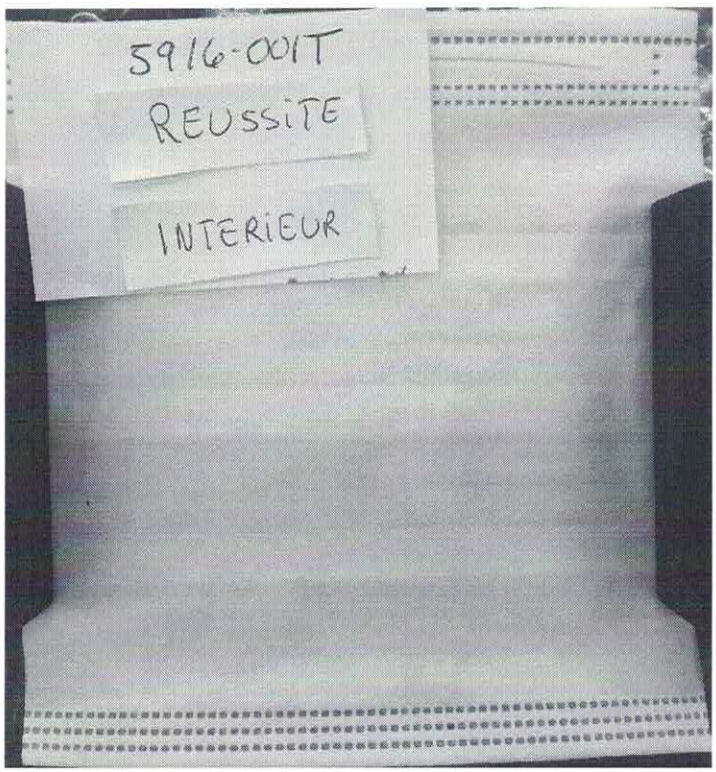
SCC Accredited LAB — LAB Accrédité CCN — ilac-MRA

ANALYSIS REPORT
SCC Accreditation No.: 40‡

Mr. Frank Sultan
Modern Air Filters Corporation

Date: July 29, 2020
Report: 5916-001T-8A-en

MAFC blue mask PASS IN 120



Approved by:

A Maupomé

Alejandro Maupomé, Eng., Ph.D.
Project Leader

Date: July 29, 2020

For any information concerning this report, please contact Alejandro Maupomé.

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ANALYSIS REPORT
SCC Accreditation No.: 40‡

Mr. Frank Sultan
Modern Air Filters Corporation

Date: July 30, 2020
Report: 5916-001T-10A-en

IDENTIFICATION: Medical face masks: MAFC
Received: July 21, 2020

STANDARD:

TEST: Standard for the Flammability of Clothing Textiles - As received — 16 CFR PART 1610 (1-1-16 Edition)

TEST CONDITIONS: Specimens tested as received.
Codes explanation: DNI: Does not ignite; IBE: Ignites but extinguishes;
TSF: Timed surface flash; SF: Surface flash; BB: Base burn.
Classification: Class 1 = Normal flammability; Class 2 = Intermediate flammability;
Class 3 = Rapid and Intense Burning.
Type of fabric: Multi-layers
Surface tested: Face
Direction tested: Length
Date of test: July 30, 2020

RESULTS:	Individual Data					Avg.	S.D.	% CV
Behaviour (code):	DNI	DNI	DNI	DNI	DNI			
Sample classification:	Class 1							

Prepared by:
Annie Laneuville,
Technician

Approved by:
B. Esmaeili
Babak Esmaeili, Jr. Eng.
Project Leader

Date: July 30, 2020

For any information concerning this report, please contact Babak Esmaeili.

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ANALYSIS REPORT
SCC Accreditation No.: 40‡

Mr. Frank Sultan
Modern Air Filters Corporation

Date: August 4, 2020
Report: 5916-001T-11A-en

IDENTIFICATION: Medical face masks: MAFC
Received: July 30, 2020

STANDARD:

TEST: Determination of Breathability (Differential Pressure) — EN 14683:2019, Annex C‡

TEST CONDITIONS: Specimens conditioned for not less than 4 hours at 21°C, 85% R.H.;
Apparatus used: Frazier High Pressure Air Permeability Machine.
Diameter of tested area: 2.5 cm ; Tested surface area: 4.9 cm²;
Air flow rate: 8 L/min;
Sample tested in inhalation configuration.
Date of test: August 3, 2020

RESULTS:	Individual Data					Avg.	S.D.	% CV
TEST SPECIMEN 1 :								
Differential pressure per surface area, Pa/cm²:	45.3	49.8	35.1	37.6	42.2	**42.0**	5.9	**14.0**
Differential pressure per surface area, mm H2O/cm²:	4.6	5.1	3.6	3.8	4.3	**4.3**	0.6	**14.2**
TEST SPECIMEN 2 :								
Differential pressure per surface area, Pa/cm²:	50.3	55.9	54.9	50.9	56.4	**53.7**	2.9	**5.3**
Differential pressure per surface area, mm H2O/cm²:	5.1	5.7	5.6	5.2	5.8	**5.5**	0.3	**5.7**
TEST SPECIMEN 3 :								
Differential pressure per surface area, Pa/cm²:	46.3	46.3	50.3	48.8	52.4	**48.8**	2.6	**5.4**
Differential pressure per surface area, mm H2O/cm²:	4.7	4.7	5.1	5.0	5.3	**5.0**	0.3	**5.3**

Prepared by:
Julien Gagné
Julien Gagné, Tech.
Technician

Approved by:
A Maupomé
Alejandro Maupomé, Eng., Ph.D.
Project Leader

Date: August 4, 2020

For any information concerning this report, please contact Alejandro Maupomé.

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SCC Accredited LAB — LAB Accrédité CCN

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ANALYSIS REPORT
SCC Accreditation No.: 40‡

Mr. Frank Sultan
Modern Air Filters Corporation

Date: August 4, 2020
Report: 5916-001T-11A-en

IDENTIFICATION: Medical face masks: MAFC
Received: July 30, 2020

STANDARD:

TEST: Determination of Breathability (Differential Pressure) — EN 14683:2019, Annex C‡

RESULTS (CONT):	Individual Data					Avg.	S.D.	% CV
TEST SPECIMEN 4 :								
Differential pressure per surface area, Pa/cm²:	44.2	40.2	45.3	49.3	44.2	**44.6**	3.3	**7.3**
Differential pressure per surface area, mm H2O/cm²:	4.5	4.1	4.6	5.0	4.5	**4.5**	0.3	**7.1**
TEST SPECIMEN 5 :								
Differential pressure per surface area, Pa/cm²:	40.2	51.9	45.3	50.3	49.3	**47.4**	4.7	**9.9**
Differential pressure per surface area, mm H2O/cm²:	4.1	5.3	4.6	5.1	5.0	**4.8**	0.5	**9.9**

Prepared by:
Julien Gagné
Julien Gagné, Tech.
Technician

Approved by:
A Maupomé
Alejandro Maupomé, Eng., Ph.D.
Project Leader

Date: August 4, 2020

For any information concerning this report, please contact Alejandro Maupomé.

Cambridge
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www.cambridgematerials.com

Laboratory # 843878-20
FINAL
Modern Air Filters Corporation

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.