Licence

From Health Canada

Holders of an active medical devices establishment licence

Licence number (maximum of 6 numbers): 13512

New search

Company Id (maximum of 6 numbers):

157719

Company name :

Layfield Canada Ltd.

Address:

11131 Hammersmith Gate
Richmond, British Columbia, Canada, V7A 5E6

Senior official name :

AAMIR SIDDIQUI

Filter items Showing 1 to 4 of 4 entries

Activities for device classes:

Device classes	Distribute	Import	Manufacture Devices for Distribution
Class I	Yes	Yes	Yes
Class II	No	No	
Class III	No	No	
Class IV	No	No	

New search

Related links

Guidance on Medical Device Establishment Licence (GUI-0016)

COVID-19 Medical Device Establishment Licence (MDEL) suspensions

Contact us

Contact establishment licensing section

Vancouver Coastal Health PPE Testing Lab

Protecting People

Room G8, LB Pavilion 902 W 10TH Avenue
Vancouver, BC, Canada V5Z 1M9

Lab Phone 604 875 4111 Ext 67418
Email PPEtesting@vch.ca
Website http://www.vch.ca/PPETesting

Test Report for Medical Masks – ATSM F1862 Resistance to Penetration by Synthetic Blood

Prepared for:

Client Name: Layfield Canada Ltd.

Client Contact: Jessica Dominguez

Email Address: Jessica.Dominguez@layfieldgroup.com

Job ID: 220914-LFC-A

Quote ID: PTL-Q-2022-1021

Date: 9/28/2022

Report Version: 2

Contents

Test Report for Medical Masks – ASTM F1862 Resistance to Penetration by Synthetic Blood

Client Name: Layfield Canada Ltd.
Client Contact: Jessica Dominguez
Email Address: Jessica.Dominguez@layfieldgroup.com
Job ID: 220914-LFC-A
Quote Number: PTL-Q-2022-1021
Date: 9/28/2022
Report Version: 2

Executive Summary

Thirty-two M6060 respirator samples were tested for resistance to penetration by synthetic blood in accordance with ASTM F1862/F1862-M-17 at a test pressure of 160 mm Hg. All testing were performed in the VCH PPE testing laboratory. Calibration of instruments and equipment were verified to be current, and within operation specifications prior to use. Samples were catalogued upon receipt and inventoried after visual inspection.

Two samples exhibited penetration of synthetic blood on the interior of the respirator when tested at a pressure of 160 mm Hg (Table 4), meeting the acceptable quality limit of 4% for level 3 barrier specified in ASTM F1862/F1862-M-17 and ASTM F2100-21.

Materials

Table 1. Sample and testing info.

Sample Name	Number of Samples	Analysis ID	Date Samples Received	Sample Prep and Test Date
M6060	32	220914-LFC-A-1	9/14/2022	9/15/2022

Methods

Test Standard: ASTM F2100-21[1]
Test: ASTM F1862/F1862-M-17[2]
Test Apparatus: *Conditioning environment: 21 ± 5 °C, 85 ± 5 % relative humidity*
Apparatus: ASTM 1862 Facemask Blood Penetration Test Apparatus

Procedures:

Testing were performed in accordance with ASTM F1862/F1862-M-17. The distance from the target area to the tip of the cannula is 30.5 cm. Visual inspection of the inner surface of the respirator for detecting the presence of synthetic blood penetration was performed within 10 seconds of testing. All equipment had a valid calibration at the time of testing.

Sample conditioning environment: *21 ± 5 °C, 85 ± 5 % relative humidity; samples were conditioned for a minimum of four hours prior to testing.*

Equipment:

Table 2. Equipment calibration due dates.

Equipment	Calibration Due Date
ASTM 1862 Facemask Blood Penetration Test Apparatus	N/A
Precision Balance (C021452358)	June 30 2023
Climate Chamber (W819.0119)	October 15 2022
Timer (210779774)	September 13 2023

Lab Environmental Conditions:

Table 3. Laboratory environmental conditions.

Date	*Temperature (°C)*	*Relative Humidity (%)*
9/15/2022	21.3	56

Results

Table 4. ASTM F1862/F1862-M-17 test results for M6060 N95-Style Respirator tested at a pressure of 160 mm Hg.

Sample ID	Pass/Fail
220914-LFC-A-1-1	Pass
220914-LFC-A-1-2	Pass
220914-LFC-A-1-3	Pass
220914-LFC-A-1-4	Pass
220914-LFC-A-1-5	Fail
220914-LFC-A-1-6	Fail
220914-LFC-A-1-7	Pass
220914-LFC-A-1-8	Pass
220914-LFC-A-1-9	Pass
220914-LFC-A-1-10	Pass
220914-LFC-A-1-11	Pass
220914-LFC-A-1-12	Pass
220914-LFC-A-1-13	Pass
220914-LFC-A-1-14	Pass
220914-LFC-A-1-15	Pass
220914-LFC-A-1-16	Pass
220914-LFC-A-1-17	Pass
220914-LFC-A-1-18	Pass
220914-LFC-A-1-19	Pass
220914-LFC-A-1-20	Pass
220914-LFC-A-1-21	Pass
220914-LFC-A-1-22	Pass
220914-LFC-A-1-23	Pass
220914-LFC-A-1-24	Pass
220914-LFC-A-1-25	Pass
220914-LFC-A-1-26	Pass
220914-LFC-A-1-27	Pass
220914-LFC-A-1-28	Pass
220914-LFC-A-1-29	Pass
220914-LFC-A-1-30	Pass
220914-LFC-A-1-31	Pass
220914-LFC-A-1-32	Pass
Summary	**30 Pass 2 Fail**

Table 5. ASTM F2100 Medical Face Mask material Requirements by Performance Level[1] classification of barrier performance.

Characteristic	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier
Resistance to penetration by synthetic blood	80 mm Hg	120 mm Hg	160 mm Hg

References

1. American Society for Testing and Materials. (2021). *Standard Specification for Performance of Materials Used in Medical Face Masks* (ASTM F2100 – 21). Retrieved from https://www.astm.org/f2100-21.html
2. American Society for Testing and Materials. (2017). *Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)* (ASTM F1862/F1862M – 17). Retrieved from https://www.astm.org/f1862_f1862m-17.html

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These data are representative of only the samples tested. This report may be copied only in its entirety.

Reports ("**Reports**") contain the results of testing the samples submitted by the client to whom the Report is addressed ("**Client**"). Client acknowledges the following:

(a) Reports are limited in scope. Reports only relate to samples as received and tested by VCH at the time of testing, and not from any lot(s) from which the samples may have been taken, or any apparently identical or similar products. Reports reflect the test results as recorded by VCH at the time of testing and are subject to expected measurement variability.

(b) The interpretation of the Reports and any decisions to be made on the basis of any information contained in the Reports are the sole responsibility of Client. VCH does not provide any interpretation of, or any opinion with respect to, the information contained in the Reports.

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Prepared by: *Jesse Cooper*, MSc. VCH PPE Testing Lab Manager
Reviewed by: *Titus Wong*, MD, Medical Director

Version	Replaces	Change	Description	Approved by	Release Date
2	220914-LFC-A	Editorial	Reference to model name, M6060, added. Added statement referencing AQL of 4% met. Job ID updated on page 1 and 3 to 220914-LFC-A.	TW	9/28/2022

End of Report

Mask Testing Services
800 Kipling Ave, Unit 2
Toronto, ON M8Z 5G5
416-207-6000

ANALYTICAL REPORT ID	22-PPE-00337	PRODUCT ID	95PFE-L3 Particulate Respirator
DATE RECEIVED	02-Aug-2022	LOT/BATCH#	95PFE-L3 Particulate Respirator
REPORT DATE	8-Aug-2022	MATERIAL	SMS
MANUFACTURER	Layfield Canada Ltd.	DESCRIPTION	Black Masks

MEDICAL MASK TEST SUMMARY

ASTM F2100: Standard Specification for Performance of Materials used in Medical Face Masks

			ASTM F2100		
Test Method	**AVERAGED RESULT**	Not Rated	Level 1	Level 2	Level 3
Flammability 16 CFR 1610	Class 1	Class 3	Class 1		
Particulate Filtration Efficiency ASTM F2299	99.98	< 95%	≥ 95%	≥ 98%	
Differential Pressure EN 14683 Annex C	1.83	≥ 6.0 mm H_2O/cm^2	< 5.0 mm H_2O/cm^2	< 6.0 mm H_2O/cm^2	
Bacterial Filtration Efficiency ASTM F 2101	100.00	< 95%	≥ 95%	≥ 98%	
Fluid Resistance to Synthetic Blood ASTM F1862	160 mmHg *	Retested by VCH ; see separate report			

Test results only apply to the samples submitted for analysis. Samples are randomly selected for each test from the submitted batch. It is the responsibility of the distributor to ensure the tested batch is compliant to the required sampling methodology as per ANSI/ASQ Z1.4 or ISO 2859-1. Additional test information is available upon request. Kinectrics is accredited to ISO 17025:2017 by the Standards Council of Canada for ASTM F2100

FLAMMABILITY

Test Summary A conditioned mask or test specimen was affixed to a sample holder and placed in a flammability test chamber. The specimen was exposed to a 16 mm flame for 1 second at an angle of 45°. If the material ignited during this exposure, it was noted whether the flame extinguished before spreading, or if it continued to burn. If the specimen continued to burn, the time of flame spread was measured. Any observations of burning behavior were also recorded. The specimen was tested in its original state as directed in 16 CFR Part 1610.6 (a) step 1 - 'Testing in the original state', (2) 'Plain surface textile fabrics'. As medical masks are intended for one-time use 16 CFR Part 1610.6 (b) step 2- 'Refurbishing and testing after refurbishing' was not performed. The tests were performed in accordance with 16 CFR Part 1610 'Standard for the Flammability of Clothing Textiles'

Date Tested 05-Aug-2022
Test Side: Outside
Test Type Original State
Direction Tested: Length
Conditioning Parameters 105 +/- 3°C for 30 +/- 2 minutes
Acceptance Criteria Class 1: Burn time ≥ 3.5s
Class 3: Burn time < 3.5s

TEST LOT NUMBER

Article No.	Time of Flame Spread
1	DNI
2	DNI
3	DNI
4	DNI
5	DNI

Article No.	Time of Flame Spread
6	n/a
7	n/a
8	n/a
9	n/a
10	n/a

DNI: Did not ignite
IBE: Ignited, but extinguished

PARTICULATE FILTRATION EFFICIENCY (PFE)

Test Summary Filtered and dried air was passed through an atomizer to produce an aerosol containing suspended polystyrene latex (PSL) spheres. The aerosol was then mixed and diluted with additional preconditioned air to produce a stable, non-neutralized, and dried aerosol of latex spheres. The aerosol was passed through the mask material. An optical particle counter was used to sample upstream and downstream aerosol concentrations to determine the particulate filtration efficiency of the mask. The test was conducted in accordance with Test Method ASTM F2299 with the exception that a non-neutralized particle challenge was used in place of a neutralized challenge as per FDA guidance document on surgical facemasks (FDA- 2003-D-0305)

Date Tested 05-Aug-2022

Test Side and Area Inside, Centre (28.3 cm^2)

Conditioning Parameters 30-50% ± 5% relative humidity and 21 ± 3°C

Face Velocity 6 to 7 cm/s

Laboratory Conditions 73 % Relative Humidity; 25 °C

Particle Size 0.1 µm

Acceptance Criteria ASTM Level 1: ≥ 95% PFE
ASTM Level 2,3: ≥ 98% PFE

TEST LOT NUMBER

Article No.	PFE %
1	99.98
2	99.98
3	99.97
4	99.98
5	99.98

Article No.	PFE %
6	n/a
7	n/a
8	n/a
9	n/a
10	n/a

Average Filtration Efficiency 99.98

Standard Deviation 0.004

DIFFERENTIAL PRESSURE

Test Summary Differential pressure testing was performed to determine the breathability of the sample material. Air was passed through a prescribed surface area of the sample material at a constant air flow rate of 8 litres per minute, measured by a calibrated flow meter. A manometer was used to measure the differential pressure across the sample. The test was conducted as directed in EN 14683:2019 Annex C

Date Tested 05-Aug-2022
Test Side and Area Inside, Centre (4.9 cm^2)
Conditioning Parameters 85 ± 5% relative humidity and 21 ± 5°C for a minimum of 4h
Flow Rate 8 L/min
Acceptance Criteria Flow rate must be maintained at 8 L/min throughout testing
ASTM Level 1: < 5.0 mm H_2O/cm^2
ASTM Level 2,3: < 6.0 mm H_2O/cm^2

TEST LOT NUMBER

Article No.	Delta P (mm H_2O/cm^2)
1	1.65
2	1.89
3	1.65
4	2.03
5	1.95

Article No.	Delta P (mm H_2O/cm^2)
6	n/a
7	n/a
8	n/a
9	n/a
10	n/a

Average Delta P 1.83
Standard Deviation 0.175

BACTERIAL FILTRATION EFFICIENCY (BFE)

Test Summary The mask was clamped between a six-stage cascade impactor and an aerosol chamber. A bacterial suspension of *Staphylococcus aureus* was introduced into the aerosol chamber using a four-Jet atomizer. The aerosol was drawn through the sample material using a vacuum pump attached to the cascade impactor. The cascade impactor collects aerosol droplets that penetrate the mask material onto agar plates and sorts them by particle size. Positive control samples were also collected with no test specimen clamped in the test apparatus to verify the bacterial challenge rate (upstream counts). Following the incubating period, the colony forming units (CFU) on the agar plates were counted (downstream counts). The ratio of the upstream counts from the positive control, to the downstream counts collected for the test specimen, was calculated and reported as the bacterial filtration efficiency (BFE). This test was conducted in accordance with Test Method ASTM F2101.

Date Tested	04-Aug-2022
Test Side and Area	Inside, Centre (40 cm^2)
Conditioning Parameters	85 ± 5% relative humidity and 21 ± 5°C for a minimum of 4h
Flow Rate	28.3 L/min
Mean Particle Size (MPS)	3 µm
Negative Control Count	0 CFU
Positive Control Average	2251 CFU
Acceptance Criteria	Control average must be 1.7 to 3.0 x 10^3 CFU MPS of aerosol must be 3.0 ± 0.3 µm ASTM Level 1: ≥95% BFE ASTM Level 2 and 3: ≥98% BFE

TEST LOT NUMBER

Article No.	BFE %
1	100
2	100
3	100
4	100
5	100

Article No.	BFE %
6	n/a
7	n/a
8	n/a
9	n/a
10	n/a

Average Filtration Efficiency 100
Standard Deviation 0.000

APPROVALS AND STANDARDS

ASTM F2100 Level 3 qualified
Compliant with Health Canada Guidance for 95PFE-L3
Facepiece Filtering Respirators (FFRs)

HOMOLOGATIONS ET NORMES

Certifié ASTM F2100 niveau 3
Conforme aux directives de Santé Canada pour 95PFE-L3
Masques respiratoires filtrants (FFR)

30

PIECES / PIÈCES

ASTM LEVEL 3

Item No.M6060

MEDICAL GRADE
BLACK PARTICULATE RESPIRATOR

QUALITÉ MÉDICALE
RESPIRATEUR NOIR À PARTICULES

95PFE-L3

LAYFIELD

PRODUCT DESCRIPTION

The 95PFE-L3 Medical Grade Particulate Respirator is a single-use particulate respirator designed to help provide respiratory protection for the wearer. This respirator has a filter efficiency level of at least 95% PFE against particulate aerosols free of oil (NaCl Challenge). It is fluid resistant to ASTM Level 3 (160 mm Hg) and meets ≥ 98% bacterial filtration efficiency (BFE) and particle filtration efficiency (PFE) ≥98% (Latex Challenge). It can fit a wide range of face sizes. This product contains no components made from natural rubber latex.

INTENDED USE

As a Medical Grade Particulate Respirator, this product is intended to help reduce wearer exposure to certain airborne particles, including small particle aerosols and large droplets (only non-oil aerosols). This product is designed to be fluid resistant to provide the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids.

DESCRIPTION DU PRODUIT

Le respirateur à particules de qualité médicale 95PFE-L3 est un respirateur à particules à usage unique conçu pour aider à fournir une protection respiratoire à l'utilisateur. Ce respirateur a un niveau d'efficacité de filtration de particules (EFP) d'au moins 95% contre les aérosols particulaires sans huile (détection d'aérosol NaCl). Il est résistant aux fluides selon la norme ASTM Niveau 3 (160mm Hg) et répond à une efficacité de filtration bactérienne (EFB) ≥ 98%, ainsi qu'une efficacité de filtration des particules (EFP) ≥ 98% (détection d'aérosol Latex) . Il convient à une vaste gamme de tailles faciales. Ce produit ne renferme aucun composant en latex de caoutchouc naturel.

UTILISATION PRÉVUE

En tant que respirateur à particules de qualité médicale, ce produit est destiné à aider à réduire l'exposition de la personne qui le porte à certaines particules en suspension dans l'air, y compris les aérosols à petites particules et les grosses gouttelettes (uniquement les aérosols exempts d'huile). Ce produit est conçu pour être résistant aux fluides afin de fournir à la personne qui le porte une protection contre les grosses gouttelettes, les éclaboussures ou les pulvérisations de liquides corporels ou autres liquides dangereux.

LAYFIELD
MEDICAL PRODUCTS

11120 SILVERSMITH PLACE, RICHMOND, BC V7A 5E4
1-888-434-1230
WWW.LAYFIELDGROUP.COM/

LOT LOT#
MFD
EXP

A

Area Hidden
When Assembled

95PFE-L3

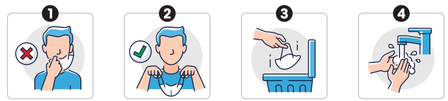
MEDICAL GRADE
BLACK PARTICULATE RESPIRATOR

QUALITÉ MÉDICALE
RESPIRATEUR NOIR À PARTICULES

HOW TO PUT RESPIRATOR ON | COMMENT METTRE LE RESPIRATEUR

Refer to the **User Instructions** inside under the Fitting Instructions for proper use.
Consultez **les instructions d'utilisation** à l'intérieur et lisez les instructions de montage pour une bonne utilisation.

HOW TO TAKE THE RESPIRATOR OFF | COMMENT RETIRER LE RESPIRATEUR



Refer to the **User Instructions** inside under the Removing Instructions for proper use.
Consultez **les instructions d'utilisation** à l'intérieur et lisez les instructions d'enlèvement pour une bonne utilisation.

IMPORTANT
Refer to the User Instructions inside for proper use. Keep these instructions for reference.
Se reporter aux instructions d'utilisation à l'intérieur pour une utilisation correcte.
Conserver ces instructions pour référence

LAYFIELD

95PFE-L3

MEDICAL GRADE
BLACK PARTICULATE RESPIRATOR

QUALITÉ MÉDICALE
RESPIRATEUR NOIR À PARTICULES

Comfortable fit | Confort maximal
Adjustable nose piece | Pièce ajustable sur le nez

ASTM BFE* ≥ 98%
ASTM PFE** ≥ 98%

* Bacterial Filtration Efficiency
* Efficacité de filtration bactérienne
**Particle Filtration Efficiency
**Efficacité de filtration des particules

BLACK PARTICULATE RESPIRATOR WITH EAR LOOPS
RESPIRATEUR NOIR À PARTICULES AVEC BOUCLES LATÉRALES

MADE IN CANADA

30 PIECES

7 78299 06060 8

A

Area Hidden
When Assembled

ASTM Level 3

ITEM NO. M6060

95PFE-L3

MEDICAL GRADE
BLACK PARTICULATE RESPIRATOR

QUALITÉ MÉDICALE
RESPIRATEUR NOIR À PARTICULES

CAUTIONS AND LIMITATIONS

- The respirator helps protect against certain particulate contaminates but does not eliminate exposure to or the risk of contracting any disease or infection.
- Do not use in atmospheres containing less than 19,5% oxygen.
- Do not use in atmospheres immediately dangerous to life or health.
- Do not exceed maximum use concentrations established by regulatory standards.
- Failure to properly use and maintain this product could result in injury or death.
- All approved respirators shall be selected, fitted, used and maintained in accordance with OSHA, CSA and other applicable manufacturer.
- Never substitute, modify, add or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- This device does not contain materials made of latex.
- This respirator is designed for adults who can fully understand the user instructions.
- It is not designed to be used by children or patients.

PRÉCAUTIONS ET LIMITATIONS

- Le respirateur aide à protéger contre certains contaminants particulaires, mais n'élimine pas l'exposition ou le risque de contracter une maladie ou une infection.
- Ne pas utiliser dans des atmosphères contenant moins de 19,5% d'oxygène.
- Ne pas utiliser dans des atmosphères présentant un danger immédiat pour la vie ou la santé.
- Ne pas dépasser les concentrations d'utilisation maximales établies par les normes réglementaires.
- Le fait de ne pas utiliser et entretenir correctement ce produit peut entraîner des blessures ou la mort.
- Tous les respirateurs approuvés doivent être sélectionnés, ajustés, utilisés et entretenu conformément aux normes OSHA, CSA et autres réglementations applicables.
- Ne jamais remplacer, modifier, ajouter ou omettre des pièces. N'utiliser que des pièces de rechange exactes dans la configuration spécifiée par le fabricant.
- Cet appareil ne contient pas de matériaux en latex.
- Ce respirateur est conçu pour les adultes qui peuvent parfaitement comprendre les instructions d'utilisation.
- Il n'est pas conçu pour être utilisé par des enfants ou des patients.

PRODUCT COMPOSITION / COMPOSITION DU PRODUIT

COMPONENT/COMPOSANT	MATERIAL / MATÉRIEL
Fabric layers / Couches de tissu	Non-woven fabric (100% of polypropylene) / Tissu non tissé (100% de polypropylène)
Filter layer / Couche de filtre	Melt-blown, non-woven fabric (100% of polypropylene)/ Tissu non tissé soufflé par fusion (100% de polypropylène)
Nose wire / Pièce métallique du nez	Plastic polymer with metal wire / Polymère plastique et fil métallique
Ear loops / Attaches d'oreilles	Elastane, polyester / Élasthanne, polyester
Adjustment clip / Pince de réglage	Plastic polymer / Polymère plastique

Layfield Medical Products
95PFE-L3 Medical Grade
Black Particulate Respirator with Ear Loops

USER INSTRUCTION

Important: Before use, the wearer must read and understand these User Instructions. Keep these User Instructions for reference.

Cautions and limitations
- The respirator helps protect against certain particulate contaminates but does not eliminate exposure to or the risk of contracting any disease or infection.
- Do not use in atmospheres containing less than 19.5% oxygen.
- Do not use in atmospheres immediately dangerous to life or health.
- Do not exceed maximum use concentrations established by regulatory standards.
- Failure to properly use and maintain this product could result in injury or death.
- All approved respirators shall be selected, fitted, used and maintained in accordance with OSHA, CSA and other applicable regulations.
- Never substitute, modify, add or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- This device does not contain materials made of latex.
- This respirator is designed for adults who can fully understand the User Instructions.
- It is not designed to be used by children or patients.

Product Description
The 95PFE-L3 Medical Grade Particulate Respirator is a single-use particulate respirator designed to help provide respiratory protection for the wearer. This respirator has a filter efficiency level of at least 95% PFE against particulate aerosols free of oil (NaCl Challenge). It is fluid resistant to ASTM Level 3 (160 mm Hg) and meets ≥ 98% bacterial filtration efficiency (BFE) and particle filtration efficiency (PFE) ≥98% (Latex Challenge). It can fit a wide range of face sizes. This product contains no components made from natural rubber latex.

Intended Use
As a Medical Grade Particulate Respirator, this product is intended to help reduce wearer exposure to certain airborne particles, including small particle aerosols and large droplets (only non-oil aerosols). This product is designed to be fluid resistant to provide the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids.

Contraindications
This respirator is designed for adults who can fully understand the User Instructions. It is not designed to be used by children. Not for use with beards or other facial hair or conditions that prevent a good seal between the face and the sealing edge of the respirator. Does not protect against gases or vapors. Check local regulations and requirements to be certain that this respirator is appropriate for your workplace.

Use Instructions
1. Select and use respirator in accordance with all applicable laws, regulations, standards and professional guidance.
2. Follow all instructions and limitations on the use of this respirator and continue to wear this respirator during all times of exposure. Failure to follow all instructions may reduce the effectiveness of the respirator and result in sickness or death.
3. Before use of this respirator, the wearer must be fit tested in accordance with the Fitting and Use Instructions and any local regulations or guidelines specified for the proper use of this respirator.
4. Use the respirator only in adequately ventilated areas containing sufficient oxygen to support life. It does not supply oxygen.
5. Inspect the respirator before each use to ensure it is in good working condition. Examine all the respirator parts for signs of damage including the two straps, the nose clamp, and the cover body. The respirator should be disposed of immediately upon observation of damaged or missing parts.
6. Leave the contaminated area and contact your supervisor if dizziness, irritation, or other distress occurs.
7. Discard the respirator and replace with a new one if it is damaged, excessively clogged, or contaminated with blood or body fluids or breathing becomes difficult while using it. Discard after every use when used for surgical procedures. Follow national, provincial, state, local and facility infection control guidance and policies.
8. Dispose of used product in accordance with applicable regulations.

Fitting Instruction

1. Wash your hands. Pull the ear loops to open the mask.
2. Flatten the nose bridge wire and gently curve to form a nose shape.
3. Place respirator under chin and position on face.
4. Pull the strap over your ears. Position the mask so it is comfortable.
5. Use fingertips to shape the nose wire to the bridge of your nose. Start at the top and move downwards.It is very important to press the nose piece firmly to the bridge to form a good seal. Pinching the nose piece using one hand may result in improper fit and less effective respirator performance (Use two hands).
6. Your mask should have a good fit at the chin and cheeks. Make sure hair, facial hair, jewelry and clothing are not between your face and the respirator as they will interfere with fit.
7. Perform a Wearer Seal Check. Without disturbing the position, cover the respirator with both hands. Exhale sharply. If air leaks around the edges of the respirator, adjust position of straps and ensure the respirator edges fit tightly against the face. If necessary, readjust nose piece and straps to form a good seal. If you CANNOT achieve a proper seal, DO NOT enter the contaminated area. See your supervisor.
8. Use the adjustment clip to achieve a better seal or to reduce pressure on the ears.
9. If no leaks are detected, you are ready to work. Please continue to monitor the fit of your mask and obey all other instructions.

Removal Instruction

1. Do not touch the respirator face.
2. Slowly lift any one of the ear loops. Then lift the other remaining ear loop.
3. Discard according to your facility's infection control policy and applicable regulations.
4. Wash your hands with soap and water or perform hand hygiene as recommended.

Use Limitations
1. The respirator provides protection against certain particles. It does not eliminate the risk of any infection or contracting any disease.
2. Do not use when concentrations of contaminants are immediately dangerous to life and health, are unknown, or when concentrations exceed the allowed exposure limit or the limit according to any applicable standards or regulations, whichever is lower.
3. The respirator can protect you from particulate entry through the nose and mouth. It cannot prevent entry through other ways such as skin and eyes which should be protected by other personal protective equipment(s).
4. This respirator is designed for adults who can fully understand the User Instructions. It is not designed to be used by children or patients.
5. Persons having problem(s) with the respiratory system should consult a physician before use.

Warnings
1. The wearer must conduct a fit check in accordance with Fitting and Use Instructions and any applicable regulations prior to use.
2. This respirator shall not be used for more than one shift of up to 12 hours. Do not alter, wash, reuse or misuse respirator in any way.
3. When the respirator is contaminated or damaged, or breathing becomes difficult, replace it with a new one.
4. It is possible that the requirements for leakage effectiveness may not be achieved in for users with beards, facial hair or other similar features.
5. Do not use the respirator or enter or stay in a contaminated area under the following circumstance:
   a) Atmosphere contains less than 19.5% oxygen.
   b) If you smell or taste contaminant.
   c) For protection against gases or vapors.
   d) Contaminants or their concentrations are unknown or immediately dangerous to life or health.
   e) For sandblasting, paint-spray operations and asbestos.
   f) In explosive atmospheres.

Storage and Transportation
- Product should be stored in clean, dry conditions within the temperature range: –10°C to +40°C with a maximum relative humidity of <85%.
- When storing or transporting this product, use original packaging provided.
- Keep away from fire.

Period of Use
- Shelf life: 3 years from the manufacturing date.
- Subject to the Storage Conditions specified above, the respirator may be used until the expiry date printed on the packaging.
- One-time use only.

Disposal
Dispose of respirator according to your facility or institution or employer policy, and local regulations.

Product Details
- Item No. M6060
- ASTM F2100 Level 3: BFE and PFE ≥ 98%; Synthetic Blood Resistance ≥ 160mmHg
- Particle Filtration Efficiency ≥ 95%
- Compliant with Health Canada Guidance for 95PFE-L3/ Facepiece Filtering Respirators (FFRs)

PRODUCT COMPOSITION

COMPONENT	MATERIAL
Fabric layers	Non-woven fabric (100% of polypropylene)
Filter layer	Melt-blown, non-woven fabric (100% of polypropylene)
Nose wire	Plastic polymer with metal wire
Ear loops	Elastane, polyester
Adjustment clip	Plastic polymer

LAYFIELD MEDICAL PRODUCTS

MDEL (Medical Device Establishment License).
Company ID# 157719 License# 13512

More information
For more information about this product, please contact the manufacturer using any of the following methods:

Website: Layfieldmedical.com
Phone: 1-888-434-1230
Mail: 11120 Silversmith Place, Richmond, BC V7A5E4 CANADA

Produits médicaux Layfield
95PFE-L3 Qualité médicale
Respirateur noir à particules avec boucles latérales

INSTRUCTIONS D'UTILISATION

Important : Avant l'utilisation, la personne qui le porte doit lire et comprendre ces instructions d'utilisation. Conservez ces instructions d'utilisation pour référence.

Précautions et limitations
- Le respirateur aide à protéger contre certains contaminants particulaires, mais n'élimine pas l'exposition ou le risque de contracter une maladie ou une infection.
- Ne pas utiliser dans des atmosphères contenant moins de 19,5 % d'oxygène.
- Ne pas utiliser dans des atmosphères présentant un danger immédiat pour la vie ou la santé.
- Ne pas dépasser les concentrations d'utilisation maximales établies par les normes réglementaires.
- Le fait de ne pas utiliser et entretenir correctement ce produit peut entraîner des blessures ou la mort.
- Tous les respirateurs approuvés doivent être sélectionnés, ajustés, utilisés et entretenus conformément aux normes OSHA, CSA et autres réglementations applicables.
- Ne jamais remplacer, modifier, ajouter ou omettre des pièces. Utiliser uniquement des pièces de rechange exactes dans la configuration spécifiée par le fabricant.
- Cet appareil ne contient pas de matériaux en latex.
- Ce respirateur est conçu pour les adultes qui peuvent parfaitement comprendre les instructions d'utilisation.
- Il n'est pas conçu pour être utilisé par des enfants ou des patients.

Description du produit
Le respirateur à particules de qualité médicale 95PFE-L3 est un respirateur à particules à usage unique conçu pour aider à fournir une protection respiratoire à l'utilisateur. Ce respirateur a un niveau d'efficacité de filtration de particules (EFP) d'au moins 95% contre les aérosols particulaires sans huile (détection d'aérosol NaCl). Il est résistant aux fluides selon la norme ASTM Niveau 3 (160mm Hg) et répond à une efficacité de filtration bactérienne (EFB) ≥ 98%, ainsi qu'une efficacité de filtration des particules (EFP) ≥ 98% (détection d'aérosol Latex) . Il convient à une vaste gamme de tailles faciales. Ce produit ne renferme aucun composant en latex de caoutchouc naturel.

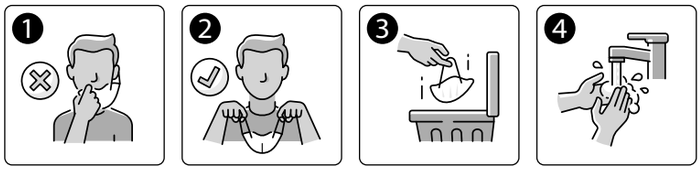
Utilisation prévue
En tant que respirateur à particules de qualité médicale, ce produit est destiné à aider à réduire l'exposition de la personne qui le porte à certaines particules en suspension dans l'air, y compris les aérosols à petites particules et les grosses gouttelettes (uniquement les aérosols exempts d'huile). Ce produit est conçu pour être résistant aux fluides afin de fournir à la personne qui le porte une protection contre les grosses gouttelettes, les éclaboussures ou les pulvérisations de liquides corporels ou autres liquides dangereux.

Contre-indications
Ce respirateur est conçu pour les adultes qui peuvent parfaitement comprendre les instructions d'utilisation. Il n'est pas conçu pour être utilisé par des enfants. Ne pas utiliser avec des barbes ou d'autres poils du visage ou des conditions qui empêchent une bonne étanchéité entre le visage et le bord d'étanchéité du respirateur. Ne protège pas contre les gaz ou vapeurs. Vérifiez les réglementations et les exigences locales pour vous assurer que ce respirateur est approprié pour votre lieu de travail.

Instructions d'utilisation
1. Sélectionner et utiliser un respirateur conformément à toutes les lois, réglementations, normes et directives professionnelles applicables.
2. Suivre toutes les instructions et limitations sur l'utilisation de ce respirateur et continuer à porter ce respirateur pendant toutes les périodes d'exposition. Le non-respect de toutes les instructions peut réduire l'efficacité du respirateur et causer des maladies ou la mort.
3. Avant d'utiliser ce respirateur, la personne qui le porte doit subir un test d'ajustement conformément aux instructions de montage et d'utilisation et aux réglementations ou directives locales spécifiées pour l'utilisation correcte de ce respirateur.
4. N'utiliser le respirateur que dans des zones correctement ventilées contenant suffisamment d'oxygène pour permettre de vivre. Il ne fournit pas d'oxygène.
5. Inspecter le respirateur avant chaque utilisation pour vous assurer qu'il est en bon état de fonctionnement. Examiner toutes les pièces du respirateur pour chercher s'il y a des signes de dommages, y compris les deux attaches, la pince nasale et le couvercle du corps. Le respirateur doit être jeté immédiatement si vous avez remarqué des pièces endommagées ou manquantes.
6. Quitter la zone contaminée et contacter votre superviseur si des étourdissements, une irritation ou une autre détresse surviennent.
7. Jeter le respirateur et le remplacer par un neuf s'il est endommagé, excessivement obstrué ou contaminé par du sang ou des liquides organiques ou si la respiration devient difficile lors de son utilisation. Jeter après chaque utilisation lorsqu'il est utilisé pour des interventions chirurgicales. Suivre les directives et politiques nationales, provinciales, étatiques, locales et des établissements de contrôle des infections.
8. Éliminer le produit usagé conformément aux réglementations applicables.

Instructions de montage


1. **Lavez vos mains. Tirez sur les attaches d'oreilles pour ouvrir le masque.**
2. **Aplatissez la pièce métallique du pont de nez et courbez-la doucement pour faire une forme de nez.**
3. **Placer le respirateur sous le menton et le positionner sur le visage.**
4. **Tirez les attaches sur vos oreilles. Positionnez le masque de manière à ce qu'il soit confortable.**
5. Utilisez le bout des doigts pour façonner la pièce métallique du nez à l'arête de votre nez. Commencez par le haut et descendez. Il est très important d'appuyer fermement la pièce du nez contre le pont pour former une bonne étanchéité. Le fait de pincer l'embout nasal d'une seule main peut causer un ajustement incorrect et des performances moins efficaces du respirateur (utilisez les deux mains).
6. Votre masque doit être bien ajusté au niveau du menton et des joues. Assurez-vous que des cheveux, des poils du visage, des bijoux et des vêtements ne se trouvent pas entre votre visage et le respirateur, car ils gêneront l'ajustement.
7. La personne qui porte le masque doit vérifier l'étanchéité. Sans changer la position, couvrez le respirateur avec les deux mains. Expirez fort. Si de l'air fuit sur les bords du respirateur, ajustez la position des attaches et assurez-vous que les bords du respirateur sont bien ajustés contre le visage. Si nécessaire, réajuster le nez et les attaches pour former une bonne étanchéité. Si vous NE POUVEZ PAS obtenir une bonne étanchéité, NE PAS entrer dans la zone contaminée. Consultez votre superviseur.
8. **Utiliser la pince de réglage pour obtenir une meilleure étanchéité ou pour réduire la pression sur les oreilles.**
9. **Si aucune fuite n'est détectée, vous êtes prêt à travailler.**
   Veuillez continuer à surveiller l'ajustement de votre masque et obéir à toutes les autres instructions.

Instructions d'enlèvement


1. Ne pas toucher la surface du respirateur.
2. Soulever lentement l'une des attaches d'oreilles. Soulever ensuite l'autre attache.
3. Jeter conformément à la politique de contrôle des infections de votre établissement et aux réglementations applicables.
4. Se laver les mains avec du savon et de l'eau ou effectuer l'hygiène de mains recommandée.

Limitations d'utilisation
1. Le respirateur offre une protection contre certaines particules. Il n'élimine pas le risque de contracter une infection ou une maladie.
2. Ne pas utiliser lorsque les concentrations de contaminants sont instantanément dangereuses pour la vie et la santé, sont inconnues ou lorsque les concentrations dépassent la limite d'exposition autorisée ou la limite selon les normes ou réglementations applicables, selon la valeur la plus basse.
3. Le respirateur peut vous protéger contre l'entrée de particules par le nez et la bouche. Il ne peut pas empêcher l'entrée par d'autres moyens tels que la peau et les yeux qui devraient être protégés par d'autres équipements de protection individuels.
4. Ce respirateur est conçu pour les adultes qui peuvent parfaitement comprendre les instructions d'utilisation. Il n'est pas conçu pour être utilisé par des enfants ou des patients.
5. Les personnes qui ont des problèmes avec le système respiratoire doivent consulter un médecin avant de l'utiliser.

Avertissements
1. La personne qui porte le masque doit vérifier l'ajustement conformément aux instructions de montage et d'utilisation et conformément à toutes les réglementations applicables avant l'utilisation.
2. Ce respirateur ne doit pas être utilisé pendant plus qu'un quart de travail de 12 heures maximum. Ne pas modifier, laver, réutiliser ou faire un abus du respirateur de quelque manière que ce soit.
3. Lorsque le respirateur est contaminé ou endommagé ou que la respiration devient difficile, remplacez-le par un nouveau.
4. Il se peut que les exigences concernant l'efficacité des fuites ne puissent être atteintes chez les utilisateurs qui ont une barbe, des poils de visage ou d'autres caractéristiques similaires.
5. Ne pas utiliser le respirateur et ne pas entrer ou rester dans une zone contaminée dans les circonstances suivantes :
   a) L'atmosphère contient moins de 19,5 % d'oxygène.
   b) Si vous sentez ou goûtez un contaminant.
   c) Pour une protection contre les gaz ou vapeurs.
   d) Les contaminants ou leurs concentrations sont inconnus ou instantanément dangereux pour la vie ou la santé.
   e) Pour le sablage, les opérations de pulvérisation de peinture et l'amiante.
   f) Dans des atmosphères explosives.

Stockage et transport
- Le produit doit être stocké dans des conditions propres et sèches dans la gamme de température : – 10° C à + 40° C avec une humidité relative maximale de < 85 %.
- Lors du stockage ou du transport de ce produit, utiliser l'emballage original fourni.
- Tenir à l'écart du feu

Période d'utilisation
- Durée de conservation : 3 ans à compter de la date de fabrication.
- Sous réserve des conditions de stockage spécifiées ci-dessus, le respirateur peut être utilisé jusqu'à la date d'expiration imprimée sur l'emballage.
- Utilisation unique seulement.

Élimination
Éliminer le respirateur conformément à la politique de votre établissement ou institution ou de votre employeur et aux réglementations locales.

Détails du produit
- Numéro d'article: ML6060
- Norme ASTM F2100 niveau 3 : EFB et EFP≥ 98%; Résistance sanguine synthétique ≥ 160 mm Hg
- Efficacité de filtration des particules ≥ 95% (détection d'aérosol NaCl)
- Conforme aux directives de Santé Canada pour 95PFE-L3/masques filtrants respiratoires (FFR)

PRODUCT COMPOSITION

COMPOSANT	MATÉRIEL
Couches de tissu	Tissu non tissé (100 % de polypropylène)
Couche de filtre	Tissu non tissé soufflé par fusion (100 % de polypropylène)
Pièce métallique du nez	Polymère de plastique avec fil métallique
Attaches d'oreilles	Élasthanne, Polyester
Clip de réglage	Polymère de plastique

LAYFIELD MEDICAL PRODUCTS

MDEL (Licence d'établissement de dispositifs médicaux).
Numéro d'identification de l'entreprise # 157719
Licence # 13512

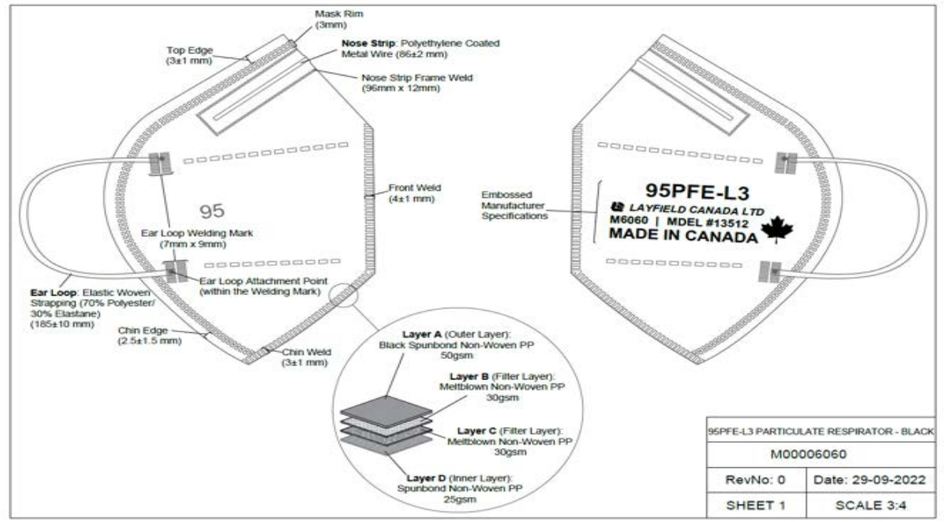
Plus d'informations
Pour plus d'informations sur ce produit, veuillez contacter le fabricant en utilisant l'une des méthodes suivantes :

Site Web: Layfieldmedical.com
Phone: 1-888-434-1230
Courrier: 11120 Silversmith Place, Richmond, BC V7A5E4 CANADA

General

Stock Code	**M00006060** *30 pieces*
Description	**95PFE-L3 PARTICULATE RESPIRATOR – BLACK**
Model #	**M6060**
Mask Type	Vertical Folding
Mask Style	Ear Loop
Mask Machine	MASK01
Certification/ Class	95PFE, ASTM F2100 Performance L3

Engineering Drawing



Mask Dimensions

Die

Repeat Length (MD) (mm)	130

Finished Mask		***Tolerance***	***Attribute Classification***
Nose Strip Length (mm)	86	+/-2mm	Non-Critical
Nose Strip Frame Weld Length (mm)	96	+/-0mm	Non-Critical
Nose Strip Frame Weld Width (mm)	12	+/-0mm	Non-Critical
Ear Loop Length (mm)	185	+/-10mm	Critical
Front Weld Width (mm)	4	+/-1mm	Non-Critical
Chin Weld Width (mm)	3	+/-1mm	Non-Critical
Top Edge Width (mm)	3	+/-1mm	Non-Critical
Chin Edge Width (mm)	2.5	+/- 1.5mm	Non-Critical
Mask Rim Weld Width (mm)	3	+/-0mm	Non-Critical
Ear Strap Weld Width (mm)	7	+/-0mm	Non-Critical
Ear Strap Weld Height (mm)	9	+/-0mm	Non-Critical

Mask Identification

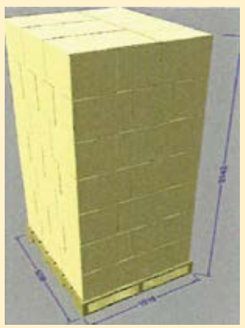
Die	Embossing Die M6060
Ink Jet Text	N/A

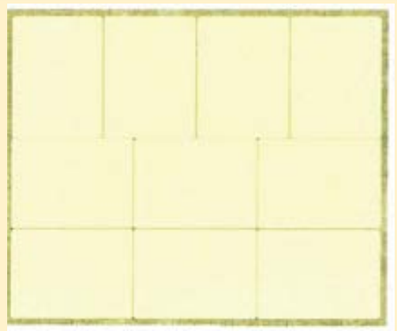
Material Details

	SKU	***Material Description***	***Basis Weight***	***Basis Weight Tolerance***	***TD Width (mm)***	***MD Length (mm)***	***MD Length per mask***	***Attribute Classification***
Layer A (Outer Layer) (Black)	**4MSKFSB50B**	RESPIRATOR SPUNBOND 50gsm x 260mm - BLACK	50 gsm	+/- 10%	260	130	1	Critical
Layer B (Support Layer)	**4MSKFSB30**	RESPIRATOR SPUNBOND 30gsm x 260mm	30 gsm	+/- 10%	260	130	1	Critical
Layer C (Melt Blown Layer)	**4MSKFMB30**	RESPIRATOR MELTBLOWN 30gsm x 250mm	30 gsm	+/- 10%	250	130	1	Critical
Layer D (Inner Layer)	**4MSKFSB25**	RESPIRATOR SPUNBOND 25gsm x 260mm	25 gsm	+/- 10%	260	130	1	Critical
Ear Loop	**4MSKEARLPBLK5**	MASK EAR LOOPS - ELASTIC WOVEN STRAPPING 5mm - BLACK	2 g/m	+/-50%	5	185	2	Critical
Nose Strip	**4MSKNOSEB4**	RESPIRATOR METAL NOSE BRIDGE 4mm	4.34 gr	+/- 5%	4	86	1	Non-critical

Packaging Details

Part Name	***SKU***	***Packaging Specification***	***Notes***
OVERWRAP BAG	**4MSK3081BAG**	10 masks/overwrap bag	Each bag to be heat sealed
USER INSTRUCTIONS M00006060	**4901MSKINTR6060**	1 instructions sheet/ retail box	
MASK HEAD TENSIONER	**4MSKHEADTN**	1 pack of 10 units/retail box	
RETAIL BOX M00006060	**4901MSK6060-30**	30 masks/ retail box	**1 Lot Traceability sticker label on the bottom of the box**
TAMPER TAPE	**4901MSK5502**	1 applied at box closure	
RESPIRATOR SHIPPER BOX	**4901MSKSB**	12 retail boxes/ shipper box	**2 traceability labels applied per shipper box-1 Yellow circle sticker to apply on the box (black mask identification)**
PALLET 48x40 4-WAY	**495PA4048**	10 shipper boxes/ layer Max. 7 layers/ pallet (Max. 70 shipper boxes/ pallet)	See palletization diagram





Last Revised: 9/30/2022

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TEST REPORT

GB 2626 Testing for Filter Efficiency, Breathing Resistance, and Total Inward Leakage on Layfield Canada Ltd. M6060 MDEL #13512 Respirators

Client **Layfield Canada Ltd.**

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Quality Manager, Flexible Films
Layfield Canada Ltd.
Richmond, BC, V7A 5E4

Compiled By Ian Polyzois, PhD, EI
Tech Lead, PPE

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This document has been reviewed and authorized for release by:

Director of Engineering Operations	2023-02-14 X  Meaghan Coates Director of Engineering Operations	Digitally Signed by Meaghan Coates, B.Sc., P.Eng

Notes:

This document contains the professional opinion of the Orthopaedic Innovation Centre (OIC) according to the matters set out herein, using its professional judgment and reasonable care based on the information available, the methodology, procedures, and techniques used, and OIC's assumptions and constraints in place at the time of preparation.

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1 TESTING SUMMARY

The testing described in this report for 38 Layfield Canada Ltd. M6060 MDEL# 13512 respirators show the below performance.

Table 1.1: Layfield Canada Ltd. M6060 MDEL# 13512 respirators performance summary

Test Method	Average Results	GB 2626-2019 Minimum Requirements		
		KN90	KN95	KN100
Filter Efficiency GB 2626-2019 Section 6.3.2.1	*99.72%* *Pass KN95*	≥ 90.0 %	≥ 95.0 %	≥ 99.97%
Breathing Resistance GB 262-2019 Section 5.5 (Disposable facepiece, without exhalation valve)	*Inhalation: 76.25 Pa* *Exhalation: 66.69 Pa* *Pass All*	≤ 170 Pa	≤ 210 Pa	≤ 250 Pa
Total Inward Leakage GB 2626-2019 Section 5.4.1 (Disposable facepiece)	TIL of Each Action[1] Fail (24/21/11)[2]	< 13 %	< 11 %	< 5 %
	Overall TIL[3] Fail (5/4/0)[2]	< 10 %	< 8 %	< 2 %

[1] When using the total inward leakage of each action (i.e. 10 people x 5 actions) as the basis for evaluation, the TIL of at least 46 of 50 actions must be less than the listed % for each KN level

[2](# of TIL results which satisfied the requirements for KN90/ KN95/ and KN100 respectively)

[3]When using the overall total inward leakage as the basis for evaluation, the overall TIL of at least 8 out of 10 persons under each test must be less than the listed % for each KN level

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2 FILTER EFFICIENCY

2.1 Test Summary

The respirator samples were tested for particulate filtration efficiency in accordance with the testing methods in GB 2626-2019 Section 6.3.2 using an NaCl particle filter efficiency testing system. Dried and filtered compressed air was passed into an ATI 100XS Automated Filter Tester, manufactured by Air Techniques International. The testing system was filled as required with 4% concentration of NaCl solution, which is then aerosolized, neutralized, and then passed over the filter material at a 85.0 L/min challenge flow rate. The gravimetric concentration of the aerosolized solution is calibrated along with the sensitivity of the laser scattering chamber; and 100% penetration and 0% penetration baselines are measured prior to testing according to the manufacturer specifications. The measurable particle size was, per GB 2626-2019, specified as 0.075 ±0.020 µm. Respirator samples were sealed onto a respirator filter holder using hot-melt glue and thoroughly inspected to reduce the risk of leaks causing false negative PFE ratings.

2.2 Test Results

Table 2.1: PFE test details

Testing Dates	2023-02-01 Unconditioned 2023-02-08 Mech. Conditioned 2023-02-10 T&H Conditioned
Manufacturer	Layfiled Canada Ltd.
Model	M6060 MDEL# 13512
Testing Standard	GB 2626-2019
Required Pre-treatment	Temperature and Humidity Pre-Treatment: 5 samples: • Condition at 38°C ± 2.5°C & 85% ± 5% RH for 24 ± 1 hrs; • Dry at 70°C ± 3°C for 24 ± 1 hrs; • Store at -30 ± 3°C for 24 ± 1 hrs; • Acclimate to lab conditions for minimum 4 hrs Mechanical Strength Pre-Treatment: 5 samples, 20 mins 10 Un-treated samples
Test Flow Rate	85 litres/min
Aerosol	Sodium Chloride (NaCl)
Equipment Used	ATI 100X
Acceptance Criteria	≥ 90.0 % KN90 ≥ 95.0 % KN95 ≥ 99.97 % KN100

Table 2.2: PFE test results

Sample #	Pre-treatment	Test Chamber		Eff. (%)
		Temp (°C)	RH (%)	
1	**Untreated**	20.7	30.5	99.39
2		20.9	31.0	99.82
3		20.5	30.5	99.77
4		21.4	30.5	99.78
5		20.5	30.5	99.82
6		21.7	31.0	99.84
7		20.9	31.0	99.79
8		21.0	30.5	99.80
9		21.2	30.5	99.83
10		20.9	31.0	99.63
11	**Mechanical**	20.6	31.5	99.83
12		21.6	31.0	99.81
13		21.7	30.5	99.83
14		21.5	31.0	99.84
15		21.7	31.5	99.21
16	**Temperature & Humidity**	21.4	30.5	99.60
17		21.0	31.0	99.65
18		21.1	30.5	99.75
19		20.5	31.0	99.72
20		21.2	31.0	99.68

Expanded Measurement Uncertainty Using a Coverage Factor k=2			
Measurand	**Value ±**	**Units**	**Absolute or Relative**
Efficiency	0.04	%	Absolute

All respirator samples passed the minimum filtration efficiency requirement for a KN95 designation.

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3 BREATHING RESISTANCE

3.1 Test Summary

Inhalation and exhalation breathing resistance of the respirator was tested to determine the ease or difficulty of breathing the user would experience while wearing the respirator. Air was pulled through a respirator sample secured to a respirator filter holder using hot-melt glue within the ATI 100 X testing machine. The volumetric flow rate was prescribed at 85 l/min and was controlled by a calibrated AliCat flow controller Model MCR-250SLPM-D contained within the ATI 100X. The test was conducted following GB 2626-2019 Part 6.5 and 6.6.

3.2 Test Results

Table 3.1: Breathing Resistance Test Details

Testing Date	2023-02-08 Unconditioned 2023-02-10 Conditioned
Manufacturer	Layfield Canada Ltd.
Model	M6060 MDEL# 13512
Testing Standard	GB 2626-2019
Required Pre-Treatment	Per breathing direction: 2 samples un-treated 2 samples pre-treated • Condition at 38°C ± 2.5°C & 85% ± 5% RH for 24 ± 1 hrs; • Dry at 70°C ± 3°C for 24 ± 1 hrs; • Store at -30 ± 3°C for 24 ± 1 hrs; • Acclimate to lab conditions for minimum 4 hrs
Test Flow Rate	85 litres/min
Equipment Used	ATI 100X
Acceptance Criteria	≤ 170 Pa for KN90 ≤ 210 Pa for KN95 ≤ 250 Pa for KN100

Table 3.2: Breathing Resistance Test Results

Sample #	Pre-treatment	Direction	Resistance [Pa]
1	Unconditioned	Inhalation	80.41
2			81.40
3		Exhalation	67.67
4			71.59
5	Conditioned	Inhalation	68.65
6			74.53
7		Exhalation	63.74
8			63.74

Expanded Measurement Uncertainty Using a Coverage Factor k=2			
Measurand	**Value ±**	**Units**	**Absolute or Relative**
Pressure	0.02	Pa	Absolute

All respirator samples passed the minimum breathing resistance requirements for a KN90, KN95, or KN100 designation

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4 TOTAL INWARD LEAKAGE

4.1 Test Summary

Total inward leakage (TIL) is an estimate of the performance of a respirator measured as the leakage of contaminants through the filter media and through the face-seal interface and exhalation valve (if applicable) under laboratory conditions. In accordance with GB 2626-2019 Section 6.4, five untreated and five pre-treated respirator samples are tested on 10 subjects. Each subject donning a respirator performs a series of exercises during which the total inward leakage is measured in % as a function of particle concentrations inside and outside of the device. These exercises consist of 2 minutes each of sitting still and breathing normally, moving head side to side, moving head up and down, and talking out loud. Facial length and width of each individual was measured following the requirements of GB/T 5703. Testing was performed on using a TSI PortaCount Pro Respirator Fit Tester 8038.

4.2 Test Results

Table 4.1: Total Inward Leakage Test Details

Testing Date	2023-02-08 to 2023-02-14
Manufacturer	Layfield Canada Ltd.
Model	M6060 MDEL# 13512
Testing Standard	GB 2626-2019 Section 6.4
Test Flow Rate	85 litres/min
Equipment Used	TSI PortaCount Respirator Fit Tester 8038
Acceptance Criteria	TIL of Each Action: 46/50 actions < 13 % for KN90 < 11 % for KN95 < 5 % for KN100 Overall TIL: 8/10 people < 10 % for KN90 < 8 % for KN95 < 2% for KN 100

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Table 4.2: Total Inward Leakage Test Results

Subject #	Face length[1] [mm]	Face width[2] [mm]	Respirator Condition	Excercises[3] Total Inward Leakage [%]					Overall TIL by Person (Avg. TIL) [%]
				a	b	c	d	e	
1	130	143.5	Untreated	5.50	6.79	13.40	11.23	11.93	9.77
2	130	142.5	Untreated	19.81	12.24	27.29	17.66	14.57	18.31
3	90	136	Untreated	17.33	38.79	33.39	20.67	25.11	27.06
4	115	125	Untreated	1.51	6.32	7.38	13.96	6.88	7.21
5	96	126	Untreated	29.55	39.04	35.55	27.21	51.57	36.58
6	135	136	Pre-Treated	1.70	4.15	2.64	6.75	1.43	3.33
7	135	110	Pre-Treated	45.66	38.54	39.10	23.16	40.12	37.31
8	110	125	Pre-Treated	26.65	14.84	20.77	17.02	17.01	19.26
9	120	130	Pre-Treated	1.36	1.52	1.58	6.38	0.87	2.34
10	130	130	Pre-Treated	9.32	7.45	5.18	4.66	2.93	16.70

[1] Face length is the distance as measured with a sliding caliper in the midsagittal plane between the menton landmark and the sellion landmark (i.e. between the bridge of the nose at eye level and the bottom of the chin)
[2]Face width is the maximum horizontal breadth of the face as measured with a spreading caliper between the zygomatic arches (i.e. between the cheek bones)
[3]Excercises include a) holding head still and not talking for 2 minutes; b) turning head left and right about 15 times over 2 minutes; c) looking up and down to the ceiling and floor about 15 times over 2 minutes; d) reading text, counting, or speaking aloud for 2 minutes; d) holding head still and not talking for 2 minutes

Table 4.3: Total Inward Leakage Test Results Summary

Filter Grade	Minimum Requirement		Number of Action-based TIL Results satisfying Requirements	Number of Subject-Based TIL Results Satisfying Requirements
	*When using the TIL of each action (i.e. 10 people x 5 actions) as the basis for evaluation, the TIL of at **least 46 of the 50 actions***	*When using the overall TIL as the basis for evaluation, the overall TIL of at **least 8 persons of the 10** persons under test*		
KN90	< 13%	< 10%	24	5
KN95	< 11%	< 8%	21	4
KN100	< 5%	< 2%	11	0

The respirators did not pass total inward leakage testing for any KN respirator designation.

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5 CHANGES TO DOCUMENT

Rev. To	Rev. From	Sec/Paragraph Changed	Change(s) Made	Date Implemented	Approval
A	N/A	N/A	Initial Release.	2023-02-14	M.C.