Government of Canada Gouvernement du Canada

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

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Test Report No. T16962-01-1 Issue 1
N95 Pre-Certification Testing: NIOSH TEB-APR-STP-0003,
NIOSH TEB-APR-STP-0007, and NIOSH TEB-APR-STP-0059
Layfield
Model MLL1970
31 March 2022

A2LA ACCREDITED Test Laboratory Certificate: 1722.01

Authorized by:

Tyler Jenkins
Manager
Respiratory and Chemical Protective Equipment

Performed by:

Ana Guerra
Laboratory Technician
Respiratory and Chemical Protective Equipment

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ICS® INC. LABORATORIES

Issued to: Layfield
11120 Silversmith Place
Richmond, BC V7A 5E4
Canada

Summary:

23 respirators, model MLL 1970, were tested for exhalation resistance, inhalation resistance, and filtration efficiency to NIOSH standards TEB-APR-STP-0003, TEB-APR-STP-0007, and TEB-APR-STP-0059. The samples were submitted by Layfield. All samples met exhalation and inhalation resistance requirements as well as N95 filtration efficiency requirements, having exhalation resistances ≤ 25 mmH_2O, inhalation resistances ≤ 35 mmH_2O, and maximum penetrations ≤ 5%.

Objectives:

Testing to: *NIOSH Procedure TEB-APR-STP-0003 "*Determination of Exhalation Resistance Test, Air-Purifying Respirators Standard Testing Procedure (STP)" Revision: 2.4, 15 March 2019
*NIOSH Procedure TEB-APR-STP-0007 "*Determination of Inhalation Resistance Test, Air-Purifying Respirators Standard Testing Procedure (STP)" Revision: 2.3, 8 March 2019
NIOSH Procedure TEB-APR-STP-0059 "Determination of Particulate Filter Efficiency Level for N95 Series Filters against Solid Particulates for Non-Powered, Air-Purifying Respirators Standard Testing Procedure (STP)" Revision 3.2, 13 December 2019

Materials:

Model No.	*Description*	*Qty*
MLL 1970	95PFE-L3 with headband	40

Date provided by the Client: 03 March 2022
Date Testing Authorized: 02 March 2022
Dates of tests: 16 & 24 - 25 March 2022
Manufacturer/Supplier Layfield

Equipment:

TSI 8130A Filter Tester, test bench configured for sodium chloride aerosol (EQ1325-01)
Flow Meters, Fisher & Porter Co., (EQ0098-01 & EQ0098-02)
Digital Manometer; Dwyer Instruments, (EQ0501)
Humidity chamber, Weiss Technik PharmaEvent C/280 Climate Test Chamber (EQ1329-02)
Vacuum Pumps; Marathon Electric (EQ0088-04-02 &-03)
ISI Headform (EQ0477)
Sodium Chloride, 99+%, VWR Chemicals, (C0015-03)

Procedure:

All tests were conducted in a standard laboratory atmosphere unless otherwise specified. The equipment and instrument calibrations were verified current and within specification prior to use. The materials for assessment were inventoried, numbered, and logged upon receipt.

The exhalation resistance test was performed in general accordance with NIOSH Procedure TEB-APR-STP-0003. A positive 85 LPM airflow through the respirator was established and the pressure difference across the respirator was determined with the digital manometer. The pressure was corrected for systemic resistance and recorded in mmH_2O column height.

Procedure (cont.):

The inhalation resistance test was performed in general accordance with NIOSH Procedure TEB-APR-STP-0007. A negative 85 LPM airflow through the respirator was established and the pressure difference across the respirator was determined with the digital manometer. The pressure was corrected for systemic resistance and recorded in mmH_2O column height.

The filter efficiency test was performed in general accordance with NIOSH Procedure TEB-APR-STP-0059. The respirators were challenged to a sodium chloride aerosol neutralized to a Boltzmann equilibrium state at 25 +/-5°C and a relative humidity of 30 +/- 10%. Particle size distribution was verified to be a count median diameter of 0.075 +/- 0.020 microns, with a geometric standard deviation not exceeding 1.86.

The respirators were conditioned at 85 % +/- 5 % relative humidity and 38°C +/- 2.5°C for 25 hours prior to the filter efficiency test. Three respirators were selected at random from the quantity provided. Each respirator was then assembled into a fixture and subjected to aerosol loading. The filter loading was performed by depositing 200 mg of sodium chloride aerosol at airflow rate of 85 LPM. Flow rate was monitored every 5 - 10 minutes on average and adjusted to maintain a flow rate of 85 LPM +/- 4 LPM. The initial flow rate, initial resistance, initial penetration, and maximum penetration data were recorded.

An aerosol loading graph for each respirator was created to determine the filter type. The respirator was identified as a Type II filter based on the performance graph. As such, the following 17 samples, selected at random, were subjected to instantaneous aerosol loading. The loading was performed by depositing sodium chloride aerosol at an airflow rate of 85 LPM. Flow rate was maintained at 85 LPM +/- 4 LPM. The flow rate, resistance, and penetration data were recorded for each respirator.

Results:

The results for the exhalation and inhalation resistance of the respirators are provided in Table I.

Table I

Breathing Resistance – MLL 1970

Sample ID	*Exhalation Resistance *(mmH_2O)*	*Inhalation Resistance *(mmH_2O)*	*Results*
MLL 1970-21	8	9	Pass
MLL 1970-22	8	9	Pass
MLL 1970-23	8	10	Pass
Specification: **	**≤ 25**	**≤ 35**	

***Resistance corrected for systemic response** ****Specification based on non-powered air purifying respirator**

Table II outlines the results of the full loading tests. All respirators followed the Type II filter profile defined by *NIOSH TEB-APR-STP-0059*.

Results (cont.):

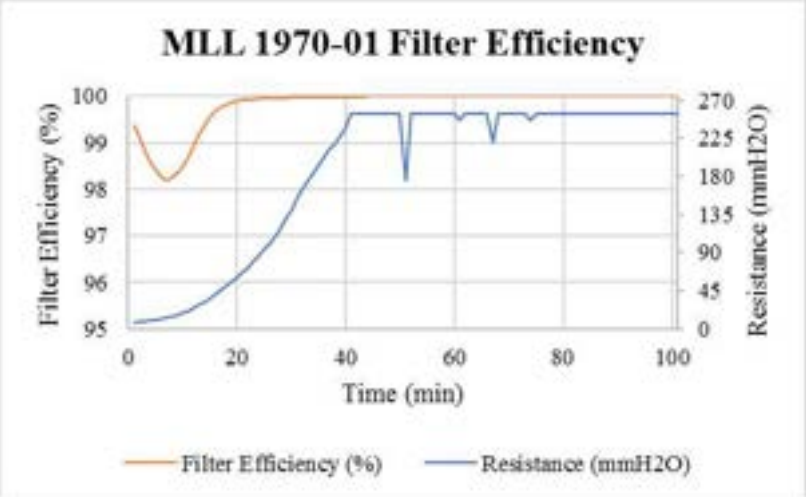
Table II
Full Loading Efficiencies – MLL 1970

Sample ID	*Initial Flow Rate (LPM)*	*Initial Resistance (mmH_2O)*	*Initial Penetration (%)*	*Maximum Penetration (%)*	*Filter Efficiency* (%)*	*Result*
MLL 1970-01	85	7	0.6	1.8	98.2	Pass
MLL 1970-02	85	7	0.5	1.5	98.5	Pass
MLL 1970-03	85	6	0.5	1.8	98.2	Pass
Specification:	**81- 89**		**≤ 5.0**		**≥ 95.0**	

**Filter efficiency percent is based on maximum penetration value.*

Below are the filter efficiency and resistance graphs over the loading time for each test. Raw data tables are located in the appendix of this report.

Filter performance graph, Sample MLL 1970-01



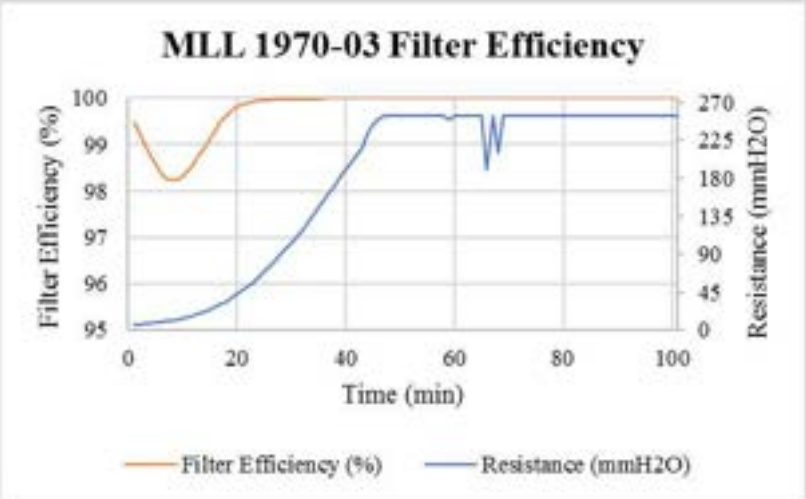
***Note:** Spikes in resistance at 51, 61, 67, and 74 minutes are anomalies caused by the pressure drop across the sample exceeding the instrument's maximum measurable resistance (254 mmH_2O).

Results (cont.):

Filter performance graph, Sample MLL 1970-02

***Note:** Spikes in resistance at 64, 73, 80, 87, 94, and 101 minutes are anomalies caused by the pressure drop across the sample exceeding the instrument's maximum measurable resistance (254 mmH_2O).

Filter performance graph, Sample MLL 1970-03



***Note:** Spikes in resistance at 59, 66, and 68 minutes are anomalies caused by the pressure drop across the sample exceeding the instrument's maximum measurable resistance (254 mmH_2O).

As outlined in TEB-APR-STP-0059, the respirator was identified as Type II filter by its loading profile. Table III outlines the 17 instantaneous aerosol loading test results for each respirator.

Results (cont.):

Table III

Instantaneous Loading Efficiencies – MLL 1970

Sample ID	*Flow Rate (LPM)*	*Resistance (mmH_2O)*	*Penetration (%)*	*Filter Efficiency (%)*	*Result*
MLL 1970-4	85	7	0.4	99.6	Pass
MLL 1970-5	85	7	0.5	99.5	Pass
MLL 1970-6	85	7	0.4	99.6	Pass
MLL 1970-7	85	7	0.5	99.5	Pass
MLL 1970-8	85	7	0.5	99.5	Pass
MLL 1970-9	85	7	0.5	99.5	Pass
MLL 1970-10	85	6	0.4	99.6	Pass
MLL 1970-11	85	7	0.4	99.6	Pass
MLL 1970-12	85	7	0.4	99.6	Pass
MLL 1970-13	85	7	0.5	99.6	Pass
MLL 1970-14	85	6	0.4	99.6	Pass
MLL 1970-15	85	7	0.5	99.5	Pass
MLL 1970-16	85	6	0.4	99.6	Pass
MLL 1970-17	85	7	0.5	99.5	Pass
MLL 1970-18	85	7	0.5	99.5	Pass
MLL 1970-19	85	6	1.4	98.6	Pass
MLL 1970-20	85	6	0.4	99.6	Pass
Specification:	**81- 89**		**≤ 5.0**	**≥ 95.0**	

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Date: 31 March 2022
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Issue: 1

Photographs:

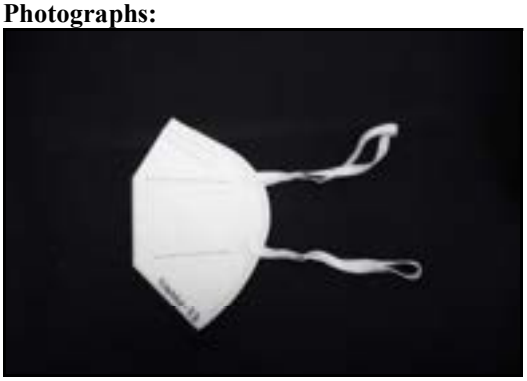

Figure 1: MLL 1970 FFR

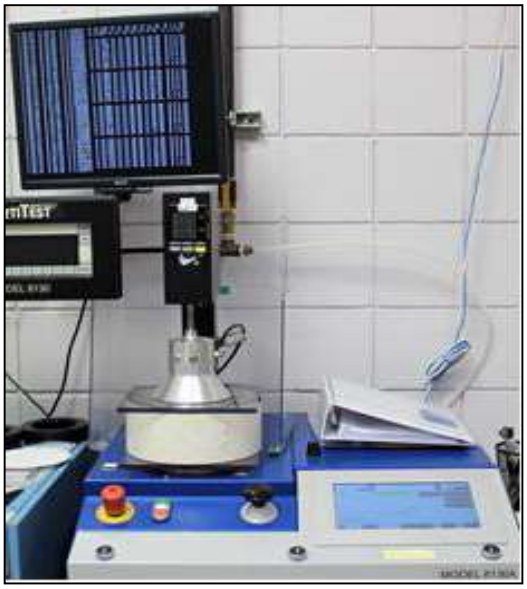

Figure 2. Typical respirator under test

Figure 3. Resistance measurement

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Appendix:

Loading data for Sample MLL 1970-01

Time (min)	Flow (LPM)	Resistance (mmH_2O)	% Penetration	Time (min)	Flow (LPM)	Resistance (mmH_2O)	% Penetration	Time (min)	Flow (LPM)	Resistance (mmH_2O)	% Penetration
1	85.11	7.40	0.62	**35**	83.50	193.77	0.02	**69**	82.44	253.72	0.00
2	85.00	8.27	0.87	**36**	83.41	202.69	0.02	**70**	82.39	253.72	0.00
3	84.99	9.07	1.15	**37**	83.36	210.97	0.02	**71**	82.34	253.72	0.00
4	84.95	9.98	1.40	**38**	83.31	219.15	0.01	**72**	82.29	253.72	0.00
5	84.96	10.86	1.60	**39**	83.24	227.82	0.01	**73**	82.23	253.72	0.00
6	84.96	11.88	1.74	**40**	83.18	238.06	0.01	**74**	82.18	245.89	0.00
7	84.96	13.06	1.82	**41**	84.52	253.72	0.01	**75**	82.13	253.72	0.00
8	84.94	14.46	1.75	**42**	84.43	253.72	0.01	**76**	82.08	253.72	0.00
9	84.93	16.30	1.66	**43**	84.37	253.72	0.01	**77**	82.05	253.72	0.00
10	84.89	18.63	1.51	**44**	84.28	253.72	0.01	**78**	81.98	253.72	0.00
11	84.88	21.17	1.30	**45**	84.17	253.72	0.01	**79**	81.92	253.72	0.00
12	84.88	24.55	1.09	**46**	84.11	253.72	0.01	**80**	81.89	253.72	0.00
13	84.86	28.08	0.86	**47**	84.04	253.72	0.01	**81**	81.85	253.72	0.00
14	84.85	31.94	0.64	**48**	83.93	253.72	0.01	**82**	81.75	253.72	0.00
15	84.79	36.08	0.47	**49**	83.87	253.72	0.01	**83**	81.70	253.72	0.00
16	84.77	40.64	0.33	**50**	83.79	253.72	0.01	**84**	81.66	253.72	0.00
17	84.74	45.34	0.24	**51**	83.74	175.87	0.01	**85**	81.57	253.72	0.00
18	84.68	50.42	0.18	**52**	83.66	253.72	0.01	**86**	81.51	253.72	0.00
19	84.63	55.59	0.14	**53**	83.57	253.72	0.00	**87**	81.47	253.72	0.00
20	84.62	60.87	0.11	**54**	83.50	253.72	0.00	**88**	81.40	253.72	0.00
21	84.58	66.35	0.09	**55**	83.39	253.72	0.00	**89**	81.34	253.72	0.00
22	84.54	72.84	0.07	**56**	83.33	253.42	0.00	**90**	81.27	253.72	0.00
23	84.46	79.27	0.06	**57**	83.27	253.72	0.00	**91**	81.25	253.72	0.00
24	84.41	86.09	0.06	**58**	83.22	253.72	0.00	**92**	81.20	253.72	0.00
25	84.34	93.45	0.05	**59**	83.15	253.72	0.00	**93**	81.15	253.72	0.00
26	84.30	100.98	0.05	**60**	83.09	253.72	0.00	**94**	81.10	253.72	0.00
27	84.22	108.85	0.04	**61**	83.00	245.82	0.00	**95**	81.07	253.72	0.00
28	84.15	118.46	0.04	**62**	82.92	253.72	0.00	**96**	81.01	253.72	0.00
29	84.06	129.14	0.04	**63**	82.85	253.72	0.00	**97**	80.98	253.72	0.00
30	83.95	140.92	0.03	**64**	82.80	253.72	0.00	**98**	80.91	253.72	0.00
31	83.84	153.56	0.03	**65**	82.71	253.72	0.00	**99**	80.87	253.72	0.00
32	83.73	164.18	0.03	**66**	82.64	253.72	0.00	**100**	80.83	253.72	0.00
33	83.67	174.14	0.02	**67**	82.56	220.95	0.00	**101**	80.79	253.72	0.00
34	83.57	184.37	0.02	**68**	82.53	253.72	0.00				

Loading data for Sample MLL 1970-02

Time (min)	Flow (LPM)	Resistance (mmH_2O)	% Penetration	Time (min)	Flow (LPM)	Resistance (mmH_2O)	% Penetration	Time (min)	Flow (LPM)	Resistance (mmH_2O)	% Penetration
1	85.06	6.74	0.50	**35**	83.56	189.99	0.02	**69**	85.04	253.72	0.00
2	85.09	7.49	0.68	**36**	83.51	198.21	0.01	**70**	84.96	253.72	0.00
3	85.08	8.21	0.91	**37**	83.42	206.29	0.01	**71**	84.86	253.72	0.00
4	85.11	8.91	1.11	**38**	83.34	214.38	0.01	**72**	84.78	253.72	0.00
5	85.09	9.68	1.33	**39**	83.28	222.43	0.01	**73**	84.70	250.59	0.00
6	85.09	10.51	1.44	**40**	83.22	230.53	0.01	**74**	84.63	253.72	0.00
7	85.09	11.43	1.51	**41**	83.14	238.43	0.01	**75**	84.56	253.72	0.00
8	85.09	12.61	1.54	**42**	83.08	246.67	0.01	**76**	84.48	253.72	0.00
9	85.09	13.78	1.46	**43**	82.99	253.72	0.01	**77**	84.42	253.72	0.00
10	85.07	15.26	1.37	**44**	82.91	253.72	0.01	**78**	84.35	253.72	0.00
11	85.09	17.20	1.23	**45**	82.84	253.72	0.01	**79**	84.27	253.72	0.00
12	85.06	19.40	1.08	**46**	82.77	253.72	0.01	**80**	84.24	244.36	0.00
13	85.02	22.13	0.93	**47**	82.72	253.72	0.00	**81**	84.18	253.72	0.00
14	84.99	24.96	0.77	**48**	82.66	253.72	0.00	**82**	84.12	253.72	0.00
15	84.96	27.99	0.61	**49**	82.59	253.72	0.00	**83**	84.05	253.72	0.00
16	84.96	31.10	0.50	**50**	82.51	253.72	0.00	**84**	84.02	253.72	0.00
17	84.94	34.61	0.39	**51**	82.47	253.72	0.00	**85**	83.92	253.72	0.00
18	84.90	38.53	0.32	**52**	82.41	253.72	0.00	**86**	83.89	253.72	0.00
19	84.86	43.09	0.25	**53**	82.34	253.72	0.00	**87**	83.81	220.82	0.00
20	84.80	48.11	0.20	**54**	82.27	253.72	0.00	**88**	83.75	253.72	0.00
21	84.76	53.98	0.15	**55**	82.20	253.72	0.00	**89**	83.69	253.72	0.00
22	84.69	62.10	0.12	**56**	82.13	253.72	0.00	**90**	83.66	253.72	0.00
23	84.56	74.96	0.10	**57**	82.05	253.72	0.00	**91**	83.60	253.72	0.00
24	84.46	87.49	0.08	**58**	81.99	253.72	0.00	**92**	83.55	253.72	0.00
25	84.37	99.70	0.07	**59**	81.89	253.72	0.00	**93**	83.49	253.72	0.00
26	84.26	109.85	0.05	**60**	81.82	253.72	0.00	**94**	83.42	215.28	0.00
27	84.15	119.67	0.05	**61**	81.75	253.72	0.00	**95**	83.35	253.72	0.00
28	84.10	129.20	0.04	**62**	81.69	253.72	0.00	**96**	84.31	253.72	0.00
29	83.99	138.22	0.04	**63**	81.63	253.72	0.00	**97**	84.96	253.72	0.00
30	83.93	147.25	0.03	**64**	81.56	237.33	0.00	**98**	84.89	253.72	0.00
31	83.85	156.08	0.02	**65**	81.50	253.72	0.00	**99**	84.82	253.72	0.00
32	83.78	164.82	0.02	**66**	81.45	253.72	0.00	**100**	84.74	253.72	0.00
33	83.70	173.42	0.02	**67**	81.40	253.72	0.00	**101**	84.81	201.94	0.00
34	83.63	181.65	0.02	**68**	81.37	253.72	0.00	**102**			

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Report: T16962-01-1
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Appendix (cont.):

Loading data for Sample MLL 1970-03

Time (min)	Flow (LPM)	Resistance (mmH_2O)	% Penetration	Time (min)	Flow (LPM)	Resistance (mmH_2O)	% Penetration	Time (min)	Flow (LPM)	Resistance (mmH_2O)	% Penetration
1	85.04	6.39	0.53	**35**	83.90	145.92	0.01	**69**	84.84	253.72	0.00
2	85.05	7.02	0.73	**36**	83.81	154.25	0.01	**70**	84.79	253.72	0.00
3	85.05	7.62	0.98	**37**	83.75	163.11	0.01	**71**	84.71	253.72	0.00
4	85.06	8.27	1.22	**38**	83.65	172.24	0.01	**72**	84.69	253.72	0.00
5	85.01	8.91	1.44	**39**	83.56	181.95	0.00	**73**	84.62	253.72	0.00
6	85.00	9.61	1.63	**40**	83.47	190.87	0.00	**74**	84.55	253.72	0.00
7	84.98	10.43	1.74	**41**	83.43	198.35	0.01	**75**	84.51	253.72	0.00
8	84.98	11.26	1.77	**42**	83.34	208.21	0.00	**76**	84.45	253.72	0.00
9	85.02	12.27	1.77	**43**	83.25	216.78	0.00	**77**	84.40	253.72	0.00
10	84.99	13.52	1.67	**44**	85.06	232.75	0.00	**78**	84.33	253.72	0.00
11	84.99	15.10	1.58	**45**	84.93	242.69	0.00	**79**	84.26	253.72	0.00
12	84.99	17.13	1.43	**46**	84.89	249.52	0.00	**80**	84.22	253.72	0.00
13	84.95	19.69	1.25	**47**	84.80	253.72	0.00	**81**	84.15	253.72	0.00
14	84.92	22.26	1.07	**48**	84.76	253.72	0.00	**82**	84.13	253.72	0.00
15	84.90	24.97	0.88	**49**	84.71	253.72	0.00	**83**	84.06	253.72	0.00
16	84.88	28.06	0.71	**50**	84.65	253.72	0.00	**84**	84.02	253.72	0.00
17	84.81	31.11	0.52	**51**	84.60	253.72	0.00	**85**	85.37	253.72	0.00
18	84.79	34.50	0.38	**52**	84.54	253.72	0.00	**86**	85.32	253.72	0.00
19	84.78	38.27	0.27	**53**	84.47	253.72	0.00	**87**	85.27	253.72	0.00
20	84.73	42.41	0.20	**54**	84.42	253.72	0.00	**88**	85.21	253.72	0.00
21	84.70	46.88	0.14	**55**	84.34	253.72	0.00	**89**	85.14	253.72	0.00
22	84.66	51.80	0.10	**56**	84.27	253.72	0.00	**90**	85.08	253.72	0.00
23	84.60	57.18	0.07	**57**	84.24	253.72	0.00	**91**	85.01	253.72	0.00
24	84.57	62.98	0.06	**58**	84.19	253.72	0.00	**92**	84.95	253.72	0.00
25	84.52	68.86	0.04	**59**	84.13	248.98	0.00	**93**	84.89	253.72	0.00
26	84.48	75.77	0.04	**60**	84.08	253.72	0.00	**94**	84.87	253.72	0.00
27	84.40	83.12	0.02	**61**	84.07	253.72	0.00	**95**	84.82	253.72	0.00
28	84.36	89.71	0.02	**62**	83.98	253.72	0.00	**96**	84.74	253.72	0.00
29	84.30	96.45	0.02	**63**	83.93	253.72	0.00	**97**	84.68	253.72	0.00
30	84.24	103.62	0.01	**64**	83.86	253.72	0.00	**98**	84.68	253.72	0.00
31	84.17	110.56	0.01	**65**	83.84	253.72	0.00	**99**	84.60	253.72	0.00
32	84.11	118.05	0.01	**66**	84.92	190.23	0.00	**100**	84.59	253.72	0.00
33	84.05	126.99	0.01	**67**	84.95	253.72	0.00	**101**	84.53	253.72	0.00
34	83.98	136.91	0.01	**68**	84.92	209.37	0.00	**102**			

ICS INC. LABORATORIES

TERMS AND CONDITIONS

1. Client acknowledges that ICS Laboratories (ICS) performs testing services only as specified by Client. ICS does not design, warrant, supervise or monitor compliance of products or services except as specifically agreed to in writing. By their very nature, testing, analysis, and other ICS services are limited in scope and subject to expected measurement variability.
2. Client retains the right to clarify test requests and reasonable access to monitor test work, with reference to test queue and obligations regarding the confidentiality of other clients.
3. ICS shall keep documents and information related to Client confidential and will not disclose any such information to third parties without written consent. ICS will disclose such information in response to compulsory legal process, (only after providing Client with notice-of and/or a copy of such process).
4. ICS Reports apply only to the standards or procedures identified therein and to the sample(s) assessed. Test results are not definitively indicative of the qualities of the lot from which the sample was taken or of apparently identical or similar products.
5. ICS Test Reports and their insignia are for the exclusive use of the Client. Reports, in their entirety, may be utilized at the discretion of Clients and/or their authorized agents for purposes including, but not limited to, research & development, recordkeeping, product packaging, educational and promotional materials in various formats, certification, and compliance. As an accredited independent testing laboratory, ICS maintains an interest in preventing the misrepresentation of the contents of its test reports. As such, Clients may NOT use, reproduce or otherwise disseminate excerpted, partial, redacted or otherwise altered ICS test reports without the prior review of such use by ICS and its granting of approval in writing. Further, Clients are prohibited from manipulating data and/or extrapolating-from-it statistics or conclusions that contradict or eclipse the empirical results of testing as reflected by the totality of the report. Clients are to refrain from utilizing ICS Test Reports and/or the ICS logo in a manner that suggests any extra-report conclusions are provided and/or endorsed by ICS Laboratories.
6. The name(s) listed as the "Issued to" party on test reports may not reflect the actual entity submitting and/or contracting the assessment.
7. ICS shall retain copies of testing job files (including reports) for a period of at least six (6) years and when applicable, evidentiary test samples for a length of time agreed to or deemed appropriate. If Client requests additional copies of Reports during this period, an additional charge will apply for the preparation and delivery of such reports.
8. Test reports are valid for certification purposes for one year from date of issue, inclusive of retest or variant additions, which must be performed within one year of date of issue to avoid full retest.
9. Client is responsible for procuring, at its cost, insurance protecting the value of its property, extending to provided samples.
10. For the safety of our personnel, Client must advise if samples are known or suspected to contain hazardous substances. Safety Data Sheets must be provided upon request.
11. ICS represents that Services shall be performed according to terms and specification agreed to by Client, and in a manner consistent with good laboratory practice. No other Representations to client, express or implied, and no warranty or guarantee is included or intended in this agreement, or in any other report or document related to the services. ICS does not guarantee product performance or compliance.
12. Schedules are confirmed upon acceptance of quotation. All reasonable efforts will be made to comply with provided timeline. Guarantees are neither implied nor promised.
13. Certain work may be subcontracted to ICS-approved laboratories as required or applicable. Client will be notified of this in advance.
14. Client agrees to pay any and all additional costs associated with unexpected or above-standard communications and/or consultations with Client or third parties as designated by Client.
15. Client agrees to pay any and all additional costs for work additional to the original scope of work as agreed to by Client.
16. Client understands and agrees that ICS, in entering into this Contract and by performing services hereunder, does not assume, abridge, abrogate or undertake to discharge any duty or responsibility of Client to any other party or parties. No one other than Client shall have any right to rely on any Report or other representation or conduct of ICS and ICS disclaims any obligations of any nature whatsoever with respect to such third parties.
17. For statements of conformity (pass/fail/"meets") regarding qualitative test results, ICS utilizes simple acceptance as its basis. For most statements of conformity relating to quantitative test results, the decision rule and associated uncertainty is inherent in the standard method. As such, simple acceptance is typically applied. Results on or near pass/fail thresholds or otherwise upon Client request or appeal will be evaluated with reference to the measurement uncertainty of relevant testing practices, equipment and other inputs/variables.
18. Client agrees, in consideration of ICS undertaking to perform the test(s) hereunder, to protect, defend and indemnify ICS from any and all claims, damages, expenses either direct or consequential for injuries to persons or property arising out of or in consequence of the performance of the testing, inspection and reporting hereunder and/or the performance of the products tested or inspected hereunder, unless caused by the negligence of ICS.
19. It is agreed that if ICS should be found liable for any losses or damages attributable to the services hereunder in any respect, its liability shall not exceed the amount of the fee paid by Client for services rendered and Client's sole remedy at law or in equity shall be the right to recover that sum.
20. Quotations are valid for 30 days from date of issue. Standard Terms: 30% Laboratory/Testing fees invoiced and payable upon acceptance of quotation. 15 days net. Any change to these terms requires written approval by the President, Executive Vice President or Accounting Manager. ICS retains the right to require prepayment in full at any time. Cancelled jobs will be invoiced for work performed and/or set-up costs incurred. All jobs will be assessed a $25 sample disposition fee. Shipping costs over $25 incurred by ICS for sample returns will be invoiced at cost +10%.
21. ICS hereby objects to any conflicting terms contained in any order, acceptance or other subsequent correspondence submitted by Client.
22. In the event that payment is not received within 15 days of invoice date, Client agrees to pay a late payment charge on the unpaid balance equal to 1-1/2% per month or the maximum charge allowed by law, whichever is less, and all costs and expenses, including attorney's fees where recovery of the same is not prohibited by law, incurred by ICS in collecting such invoices.
23. All costs associated with compliance with any subpoena (s) for documents, testimony in a court of law, or for any other purpose relating to work performed by ICS in connection with work performed for that Client, shall be paid by Client. Client shall also pay costs related to deposition and trial testimony.
24. Cancelled/discontinued orders: Client responsible for all administrative and testing charges up to point of cancellation.

Mask Testing Services
800 Kipling Ave
Building KJ 135
Toronto, ON
M8Z 5G5
416-207-6000

ANALYTICAL REPORT ID	20-PPE-00055
PRODUCT ID	MLL-1970
DESCRIPTION	White; 3-ply
MATERIAL	SMS
MANUFACTURER	Maple Leaf Laboratories Ltd.
LOT IDENTIFICATION	n/a
DATE RECEIVED	24-Jul-2020
REPORT DATE	7-Aug-2020

MEDICAL MASK TEST SUMMARY

ASTM 2100: 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	99.97	< 95%	≥ 95%	≥ 98%	
Differential Pressure EN 14683 Annex C	2.68	≥ 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	Failure at 80 mmHg	80 mmHg	120 mmHg	160 mmHg

Highlighted box indicates the performance level of the mask for the given test.

The samples tested meet the acceptance criteria for **ASTM F2100 performance LEVEL 3**

Test results only apply to the samples submitted and tested for analysis. For individual mask results, please see the Analytical Test Report. It is the responsilbity of the distributor to ensure the tested batch is compliant to the required sampling methodology as per ANSI/ASQ Z1.4. Additional test information is available upon request.

Reviewed By: Approved By:

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 28-Jul-2020
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 29-Jul-2020

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

Conditioning Parameters 30-50% ± 5% relative humidity and 21 ± 3^oC

Face Velocity 6 to 7 cm/s

Laboratory Conditions 71 % Relative Humidity; 22.5 °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	99.97
2	99.97
3	99.97
4	99.98
5	99.97

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

Average Filtration Efficiency 99.97

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 31-Jul-2020
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: < 4.0 mm H_2O/cm^2
ASTM Level 2,3: < 5.0 mm H_2O/cm^2

TEST LOT NUMBER

Article No.	Delta P (mm H_2O/cm^2)
1	2.77
2	2.7
3	2.67
4	2.78
5	2.5

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 2.68
Standard Deviation 0.113

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 06-Aug-2020

Test Side and Area Inside, Centre (40 cm^2)

Conditioning Parameters 85 ± 5% relative humidity and 21 ± 5^oC for a minimum of 4h

Flow Rate 28.3 L/min

Mean Particle Size (MPS) 3.03 µm

Negative Control Count 0 CFU

Positive Control Average 2517 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

BLOOD PENETRATION RESISTANCE

Test Summary A volume of synthetic blood was disbursed at the mask to simulate the impact (splatter) of blood or other body fluid onto the specimen. Any evidence of synthetic blood penetration on the inner facing of the mask (side contacting the wearer's face) constitutes a failure. Samples are evaluated at one or more velocities of 450, 500, and 635 cm/s, corresponding to the velocity of blood exiting a small arterial puncture at human blood pressures of 80, 120, and 160 mmHg. The distance from the target area to the tip of the cannula is 30.5 cm, with the impact of the spurt normal to the target area. Test results are reported at each tested velocity or corresponding pressure, and the medical face mask is rated at the highest corresponding blood pressure for which the mask demonstrates an acceptable quality limit of 4.0. The test was conducted in accordance with Test Method ASTM F1862.

Date Tested 27-Jul-2020

Test Side and Area Outside, Centre

Conditioning Parameters 85 ± 5% relative humidity and 21 ± 5°C for a minimum of 4h

Laboratory Conditions 65.6 % Relative Humidity; 24.1 °C

Acceptance Criteria The output of synthetic blood before and after 16 articles must be within 2% of theoretical output

29 of 32 tests must show passing result

ASTM Level 1: Pass at 80 mmHg

ASTM Level 2: Pass at 120 mmHg

ASTM Level 3: Pass at 160 mmHg

TEST LOT NUMBER

Article No.	80 mmHg	120 mmHg	160 mmHg	Article No.	80 mmHg	120 mmHg	160 mmHg
1	n/a	n/a	Pass	17	n/a	n/a	Pass
2	n/a	n/a	Pass	18	n/a	n/a	Pass
3	n/a	n/a	Pass	19	n/a	n/a	Pass
4	n/a	n/a	Pass	20	n/a	n/a	Pass
5	n/a	n/a	Pass	21	n/a	n/a	Pass
6	n/a	n/a	Pass	22	n/a	n/a	Pass
7	n/a	n/a	Pass	23	n/a	n/a	Pass
8	n/a	n/a	Pass	24	n/a	n/a	Pass
9	n/a	n/a	Pass	25	n/a	n/a	Pass
10	n/a	n/a	Pass	26	n/a	n/a	Pass
11	n/a	n/a	Pass	27	n/a	n/a	Pass
12	n/a	n/a	Pass	28	n/a	n/a	Pass
13	n/a	n/a	Pass	29	n/a	n/a	Pass
14	n/a	n/a	Pass	30	n/a	n/a	Pass
15	n/a	n/a	Pass	31	n/a	n/a	Pass
16	n/a	n/a	Pass	32	n/a	n/a	Pass

Passes at 80 mmHg n/a

Passes at 120 mmHg n/a

Passes at 160 mmHg 32/32

NOTES

This section is to provide general comments on observations and/or exceptions that were noted during analysis.

No observations or exceptions to report.

Analytical and Environmental Services Laboratory

Test Report

Report Number: 20-PPE-00055
Version: 1
Report Date: 07-Aug-2020

Attn: Arthur Coren
Maple Leaf Laboratories Ltd.
3800 Wesbrook Mall (UBC)
Vancouver, BC
V6S 2L9

Purchase Order: PRE PAID

Sample(s) received: 24-Jul-2020

Authorized by:

Rob Taylor
Service Line Leader - Analytical Chemistry
Rob.Taylor@kinectrics.com

Description: ASTM F2100 FULL SUITE - LEVEL 3

Sample ID	Sample Name	Matrix	Sample Point	Sample Date
20-PPE-00055-1	MLL-1970	Medical Mask		24-Jul-2020

Special Instructions:
Evaluation to ASTM F2100, Standard Specification for Performance of Materials Used in Medical Face Masks"
Target ASTM F2100 Level 3
Refer to summary report for details of the tests performed: KIN-975020-20-PPE-00055-Test Summary

Version comment: Initial report.

Sample ID	Sample Name	Matrix	Sample Point	Sample Date
20-PPE-00055-1	MLL-1970	Medical Mask		24-Jul-2020

Parameter / Analyte	Result	Units	Uncert.	DL	Spec. Limt	Analyzed On dd-mmm-yy	Method
PFE #001	99.97	%				29-Jul-20	ASTM F2299
PFE #002	99.97	%				29-Jul-20	ASTM F2299
PFE #003	99.97	%				29-Jul-20	ASTM F2299
PFE #004	99.98	%				29-Jul-20	ASTM F2299
PFE #005	99.97	%				29-Jul-20	ASTM F2299
Differential Pressure #001	2.77	mm H2O/cm^2				31-Jul-20	EN 14683:2019 - Annex C
Differential Pressure #002	2.7	mm H2O/cm^2				31-Jul-20	EN 14683:2019 - Annex C
Differential Pressure #003	2.67	mm H2O/cm^2				31-Jul-20	EN 14683:2019 - Annex C
Differential Pressure #004	2.78	mm H2O/cm^2				31-Jul-20	EN 14683:2019 - Annex C
Differential Pressure #005	2.5	mm H2O/cm^2				31-Jul-20	EN 14683:2019 - Annex C
BFE #001	100	%				06-Aug-20	ASTM F2101
BFE #002	100	%				06-Aug-20	ASTM F2101
BFE #003	100	%				06-Aug-20	ASTM F2101
BFE #004	100	%				06-Aug-20	ASTM F2101
BFE #005	100	%				06-Aug-20	ASTM F2101
Positive Control Average	2517	CFU				06-Aug-20	ASTM F2101
Negative Control	0	CFU				06-Aug-20	ASTM F2101
Mean Particle Size (MPS)	3.03	micron				06-Aug-20	ASTM F2101
Fluid Resistance @ 160 mmHg #001	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #002	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #003	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #004	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #005	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #006	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #007	Pass					27-Jul-20	ASTM F1862

Parameter / Analyte	Result	Units	Uncert.	DL	Spec. Limt	Analyzed On dd-mmm-yy	Method
Fluid Resistance @ 160 mmHg #008	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #009	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #010	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #011	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #012	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #013	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #014	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #015	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #016	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #017	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #018	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #019	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #020	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #021	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #022	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #023	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #024	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #025	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #026	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #027	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #028	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #029	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #030	Pass					27-Jul-20	ASTM F1862

Analytical and Environmental Services Laboratory

Test Report

Report Number: 20-PPE-00055
Version: 1
Report Date: 07-Aug-2020

Parameter / Analyte	Result	Units	Uncert.	DL	Spec. Limt	Analyzed On dd-mmm-yy	Method
Fluid Resistance @ 160 mmHg #031	Pass					27-Jul-20	ASTM F1862
Fluid Resistance @ 160 mmHg #032	Pass					28-Jul-20	ASTM F1862
Burn Time #001	DNI					28-Jul-20	16 CFR 1610 Flammability
	DNI: Did not ignite						
Burn Time #002	DNI					28-Jul-20	16 CFR 1610 Flammability
Burn Time #003	DNI					28-Jul-20	16 CFR 1610 Flammability
Burn Time #004	DNI					28-Jul-20	16 CFR 1610 Flammability
Burn Time #005	DNI					28-Jul-20	16 CFR 1610 Flammability

Instruments Used

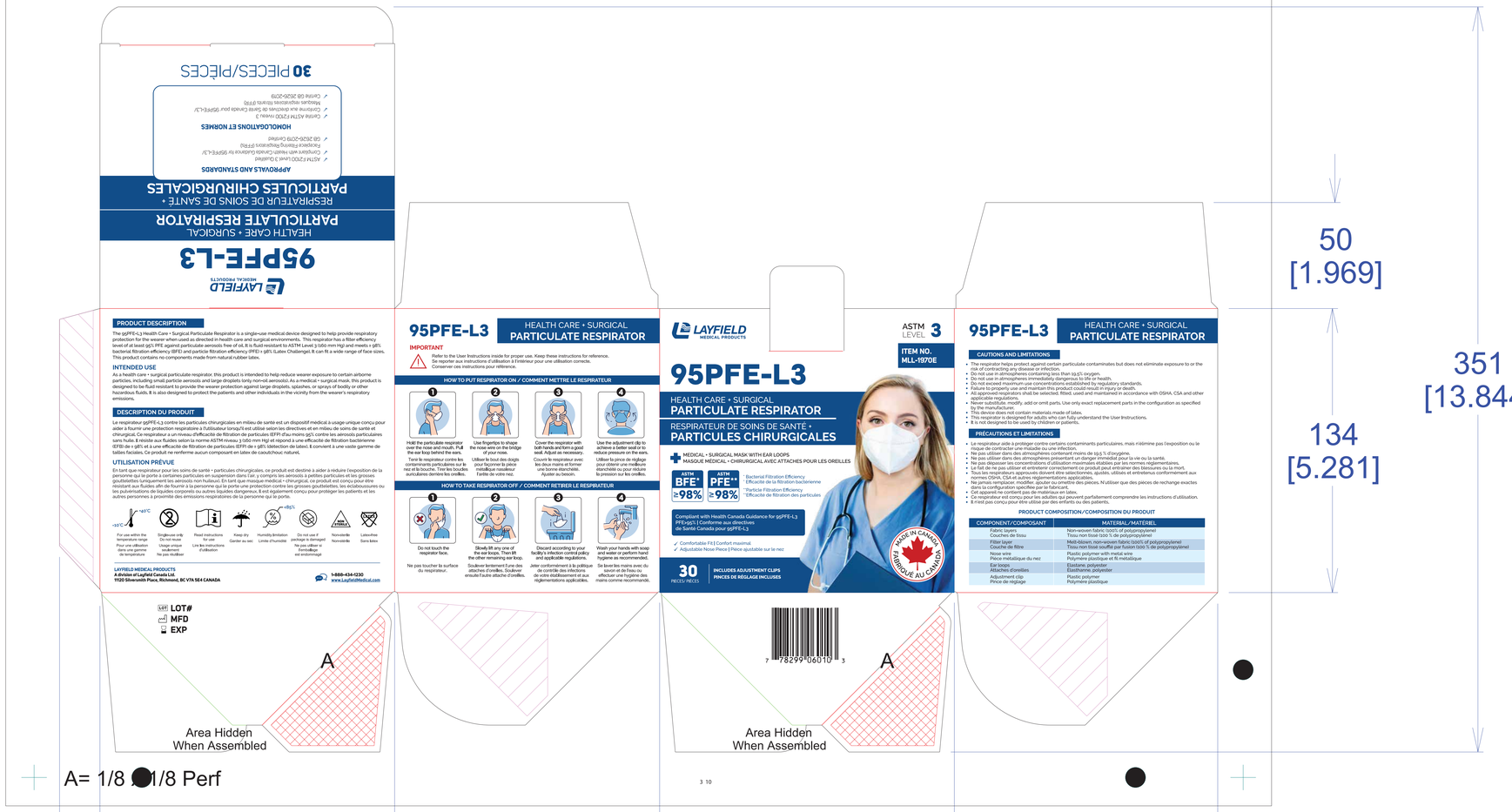
Name	Serial Number	Last Calibration	Calibration Due
SphereFlash Auto Colony Counter	10007000/0171	Calibrated Before Use	
Dispensing Controller	KIN-06377	12-Jun-2020	12-Jun-2021
M015 45 Degree Automatic Flammability Tester	A70031	13-Jul-2020	13-Jul-2023
TSI 4045H Mass Flow Meter #10	KIN-04806	07-Jan-2020	07-Jan-2021
TSI 4000 Series Mass Flow Meter #11	KIN-04570	01-Oct-2019	01-Oct-2020
TSI 4045 Mass Flow Meter #9	KIN-04557	07-Jan-2020	07-Jan-2021
Dwyer Series 475 Mark III Digital Manometer #3	KIN-06373	15-Jun-2020	15-Jun-2021
MET ONE 3411 Particle Counter	2006524001	12-Jun-2020	12-Jun-2021

The Analytical and Environmental Services Laboratory of Kinectrics is accredited by the Standards Council of Canada as conforming with ISO 17025.

The DL is the reported detection limit. All analytical data is subject to uncertainty, and is a function of the sample matrix, method and instrumental variations. As a general guideline, it can be expressed as +/-50% of the result at the detection limit (RDL) and approximately +/-10% of the result at greater than 10 times the RDL. Results in this report relate only to the items/samples tested and to all the items tested, as received. All tests are as defined by our understanding of customer requirements.

TECHNIQUE '*' = ISO 17025 accredited
TECHNIQUE '¤' = Indicates a modified test method
TECHNIQUE '†' = Indicates a sub-contracted analysis

CAD NUMBER: 59571 TTAB

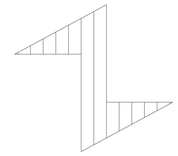

95PFE-L3
HEALTH CARE • SURGICAL
PARTICULATE RESPIRATOR
RESPIRATEUR DE SOINS DE SANTÉ •
PARTICULES CHIRURGICALES
APPROVALS AND STANDARDS
ASTM F2100 Level 3 Cleared
Cleared with Health Canada Licensing as 95PFE-L3/
Évacué avec Health Canada Licence en 95PFE-L3/
GB 2626-2019 Cleared
HOMOLOGATIONS ET NORMES
Approuvé ASTM F2100 niveau 3
Autorisé par Services de Santé Canada pour 95PFE-L3/
Évacué GB 2626-2019
30 PIECES/PIÈCES
PRODUCT DESCRIPTION
The 95PFE-L3 Health Care • Surgical Particulate Respirator is a single-use medical device designed to help provide respiratory protection for the wearer when used as directed in health care and surgical environments. This respirator has a filter efficiency level of at least 95% PFE against particulate aerosols free of oil. 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 health care • surgical 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). As a medical • surgical mask, 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. It is also designed to protect the patients and other individuals in the vicinity from the wearer's respiratory emissions.
DESCRIPTION DU PRODUIT
Le respirateur 95PFE-L3 contre les particules chirurgicales en milieu de santé est un dispositif médical à usage unique conçu pour aider à fournir une protection respiratoire à l'utilisateur lorsqu'il est utilisé selon les directives et en milieu de soins de santé et chirurgical. Ce respirateur a un niveau d'efficacité de filtration de particules (EFP) d'au moins 95% contre les aérosols particulaires sans huile. Il résiste aux fluides selon la norme ASTM niveau 3 (160 mm Hg) et répond à une efficacité de filtration bactérienne (EFB) de ≤ 98% et à une efficacité de filtration de particules (EFP) de ≥ 98% (détection de 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 pour les soins de santé • particules chirurgicales, 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 non huileux). En tant que masque médical • chirurgical, 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. Il est également conçu pour protéger les patients et les autres personnes à proximité des émissions respiratoires de la personne qui le porte.
-10°C +40°C
For use within the temperature range
Pour une utilisation dans la plage de température
Single-use only
Do not reuse
Usage unique
Ne pas réutiliser
Read instructions for use
Lire les instructions d'utilisation
Keep dry
Garder au sec
Humidity limitation
Limite d'humidité
Do not use if package is damaged
Ne pas utiliser si l'emballage est endommagé
Non-sterile
Non-stérile
Latex-free
Sans latex
LAYFIELD MEDICAL PRODUCTS
A division of Layfield Canada Ltd.
1920 Silversmith Pace, Richmond, BC V7A 5E4 CANADA
1-866-434-1230
www.LayfieldMedical.com
LOT LOT#
MFD
EXP
95PFE-L3
HEALTH CARE • SURGICAL
PARTICULATE RESPIRATOR
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.
HOW TO PUT RESPIRATOR ON // COMMENT METTRE LE RESPIRATEUR
1 Hold the particulate respirator over the nose and mouth. Pull the ear loop behind the ears.
Tenir le respirateur contre les contaminants particulaires sur le nez et la bouche. Tirer les boucles auriculaires derrière les oreilles.
2 Use fingertips to shape the nose wire on the bridge of your nose.
Utiliser le bout des doigts pour façonner la pièce métallique nasale sur l'arête de votre nez.
3 Cover the respirator with both hands and form a good seal. Adjust as necessary.
Couvrir le respirateur avec les deux mains et former une bonne étanchéité. Ajuster au besoin.
4 Use the adjustment clip to achieve a better seal or to reduce pressure on the ears.
Utiliser la pince de réglage pour obtenir une meilleure étanchéité ou pour réduire la pression sur les oreilles.
HOW TO TAKE RESPIRATOR OFF // COMMENT RETIRER LE RESPIRATEUR
1 Do not touch the respirator face.
Ne pas toucher la surface du respirateur.
2 Slowly lift any one of the ear loops. Then lift the other remaining ear loop.
Soulever lentement l'une des attaches d'oreilles. Soulever ensuite l'autre attache d'oreilles.
3 Discard according to your facility's infection control policy and applicable regulations.
Jeter conformément à la politique de contrôle des infections de votre établissement et aux réglementations applicables.
4 Wash your hands with soap and water or perform hand hygiene as recommended.
Se laver les mains avec du savoir et de l'eau ou effectuer une hygiène des mains comme recommandé.
A
Area Hidden When Assembled
A= 1/8 ● 1/8 Perf
LAYFIELD MEDICAL PRODUCTS
95PFE-L3
HEALTH CARE • SURGICAL
PARTICULATE RESPIRATOR
RESPIRATEUR DE SOINS DE SANTÉ •
PARTICULES CHIRURGICALES
MEDICAL • SURGICAL MASK WITH EAR LOOPS
MASQUE MEDICAL • CHIRURGICAL AVEC ATTACHES POUR LES OREILLES
ASTM BFE ≥98%
ASTM PFE ≥98%
*Bacterial Filtration Efficiency
Efficacité de la filtration bactérienne
*Particle Filtration Efficiency
Efficacité de filtration des particules
Compliant with Health Canada Guidance for 95PFE-L3
PFE>95% | Conforme aux directives de Santé Canada pour 95PFE-L3
✓ Comfortable Fit | Comfort maximal.
✓ Adjustable Nose Piece | Pièce ajustable sur le nez
30 PIECES / PIÈCES
INCLUDES ADJUSTMENT CLIPS
PINCES DE RÉGLAGE INCLUSES
ASTM LEVEL 3
ITEM NO. MLL-1970E
MADE IN CANADA FABRIQUÉ AU CANADA
7 78299 06010 3
3 10
95PFE-L3
HEALTH CARE • SURGICAL
PARTICULATE RESPIRATOR
CAUTIONS AND LIMITATIONS
• The respirator helps protect against certain particulate contaminates but does not eliminate exposure to or the risk of contracting an illness 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.
• The correct respirator must 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.
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 réglementations 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	Elastanes: polyester Élasthanne: polyester
Adjustment clip Pince de réglage	Plastic polymer Polymère plastique

CAD NUMBER	59571 TTAB
PRODUCT ID	Face Mask Box - TTAB
CUSTOMER NAME	Layfield
SALES PERSON	Lee Barker
CURRENT DESIGNER	Charlie Mitchell
VIEW	Outside Liner
ADHESIVE	Cold Set
GLUE JOINT	Varied
DESIGN SIZE	351 x 546
SHEET SIZE WITH TRIM	0 x 0
NUMBER PER DISPLAY	1
SRD NUMBER	
	DATE LAST SAVED 2020-07-30
L X W X D	139 x 125 x 134
MATERIAL	18 PT (SBS)

RULE USED & LENGTH

Cut	93.21
Crease	64.87
3 3 perf in channel	4.14
TOTAL LENGTH	162.22



NOTES

FILES ON DRAWING

59571 TTAB 139 x 125 x 134
Face Mask Box - TTAB

REVISION DESCRIPTION	REVISION BY

Great Little Box Company | IDEON PACKAGING
BETTER TOGETHER

DRAWING SCALE IS 1:1

Layfield Medical Products
95PFE-L3 Health Care + Surgical Particulate Respirator
Medical + Surgical Mask 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 Health Care + Surgical Particulate Respirator is a single-use medical device designed to help provide respiratory protection for the wearer when used as directed in health care and surgical environments. This respirator has a filter efficiency level of at least 95% PFE against particulate aerosols free of oil. 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 health care + surgical 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). As a medical + surgical mask, 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. It is also designed to protect the patients and other individuals in the vicinity from the wearer's respiratory emissions.

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.

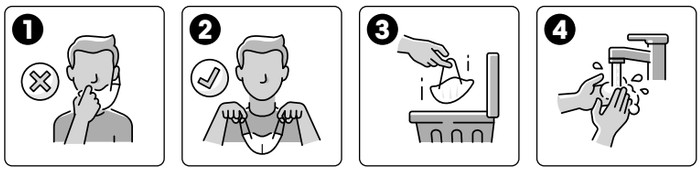
Use Instructions

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

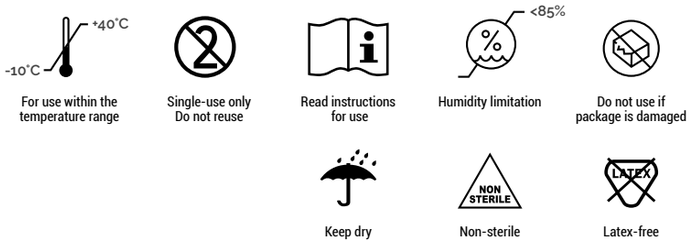
Dispose of respirator according to your facility or institution or employer policy, and local regulations.

Product Details

- Item No. MLL-1970E
- 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)
- GB 2626-2019 Certified

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



For use within the temperature range | Single-use only Do not reuse | Read instructions for use | Humidity limitation | Do not use if package is damaged

Keep dry | Non-sterile | Latex-free

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

LAYFIELD MEDICAL PRODUCTS

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

Produits médicaux Layfield
Respirateur de soins de santé + particules chirurgicales 95PFE-L3
Masque médical + chirurgical avec attaches d'oreilles

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 95PFE-L3 contre les particules chirurgicales en milieu de santé est un dispositif médical à usage unique conçu pour aider à fournir une protection respiratoire à l'utilisateur lorsqu'il est utilisé selon les directives et en milieu de soins de santé et chirurgical. 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 résiste aux fluides selon la norme ASTM niveau 3 (160 mm Hg) et répond à une efficacité de filtration bactérienne (EFB) de ≥ 98% et à une efficacité de filtration de particules (EFP) de ≥ 98% (détection de 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 de soins de santé + particules chirurgicales, ce produit est conçu pour 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 non huileux). En tant que masque médical + chirurgical, 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 d'autres liquides dangereux. Il est également conçu pour protéger les patients et les autres personnes à proximité des émissions respiratoires de la personne qui le porte.

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.

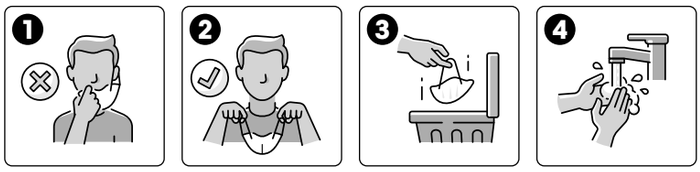
Instructions d'utilisation

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: MLL-1970E
- 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)
- Certifié GB 2626-2019

COMPOSITION DU PRODUIT

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

Pour une utilisation dans une gamme de température

Ne pas réutiliser

Lire les instructions d'utilisation

Limite d'humidité

Ne pas utiliser si l'emballage est endommagé

Garder au sec

NON STÉRILE
Non stérile

LATEX
Sans latex

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, Colombie-Britannique V7A5E4 CANADA

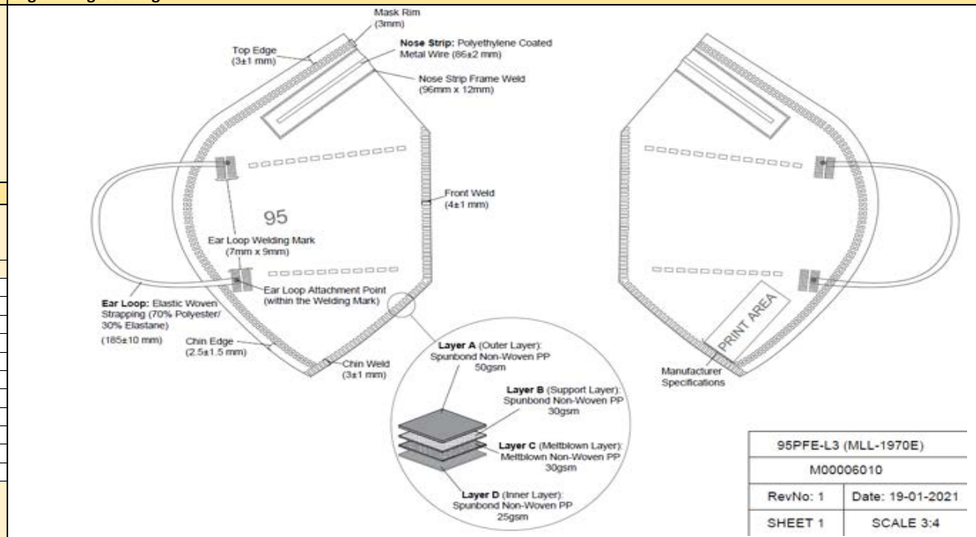
LAYFIELD MEDICAL PRODUCTS

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

General

Stock Code	**M00006010**
Description	**95PFE-L3 with Ear Loop**
Model #	**MLL 1970E**
Mask Type	Vertical Folding
Mask Style	Ear Loop
Mask Machine	MASK01
Certification/ Class	95PFE, ASTM F2100 Performance L3 *IO # 324962*

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

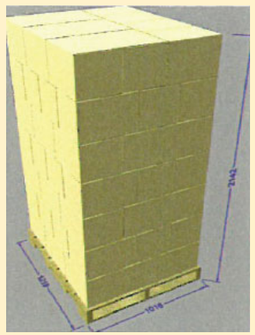
Die	HT-002
Ink Jet Text	M00006010-P0

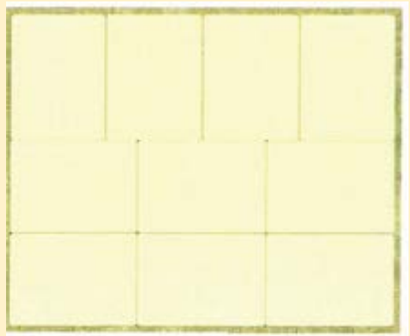
Material Details

	SKU	***Material Description***	***Basis Weight***	***Basis Weight Tolerance***	***TD Width (mm)***	***MD Length (mm)***	***MD Length per mask***	***Attribute Classification***
Layer A (Outer Layer)	**4MSKFSB50**	RESPIRATOR SPUNBOND 50gsm x 260mm	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	**4MSKEARLP5**	MASK EAR LOOPS - ELASTIC WOVEN STRAPPING 5mm	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 M00006010	**4901MSKINTR6010**	1 instructions sheet/ retail box	
MASK HEAD TENSIONER	**4MSKHEADTN**	1 pack of 10 units/retail box	
RETAIL BOX M00006010	**4901MSK6010**	30 masks/ retail box	**Lot Traceability label required**
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 ROYAL BLUE circle sticker applied to box**
PALLET 48x40 4-WAY	**495PA4048**	10 shipper boxes/ layer Max. 7 layers/ pallet (Max. 70 shipper boxes/ pallet)	See palletization diagram





Last Revised: 3/19/2021

中国认可
国际互认
检测
TESTING
CNAS L13034

In Vitro Cytotoxicity Test

MTT Method

Final Report

Verification

Report Number: CSTBB20090368

Article Name: Particulate Respirator

Method Standard: ISO 10993-5：2009

Sponsor

Maple Leaf Laboratories Ltd.

3800 Wesbrook Mall, Vancouver, BC，
CANADA V6S 2L9
Gordon Zhang. Tel: 001 778 846 2285

Test Facility

CCIC Huatongwei international inspection (Suzhou) Co., Ltd

Room 101, Building G, Ruoshui Road 388,
Suzhou, Jiangsu, China

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Notices

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3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The report is only responsible for the test results of the tested samples.
5. The report shall not be reproduced except in full without the written approval of the company.

Abstract

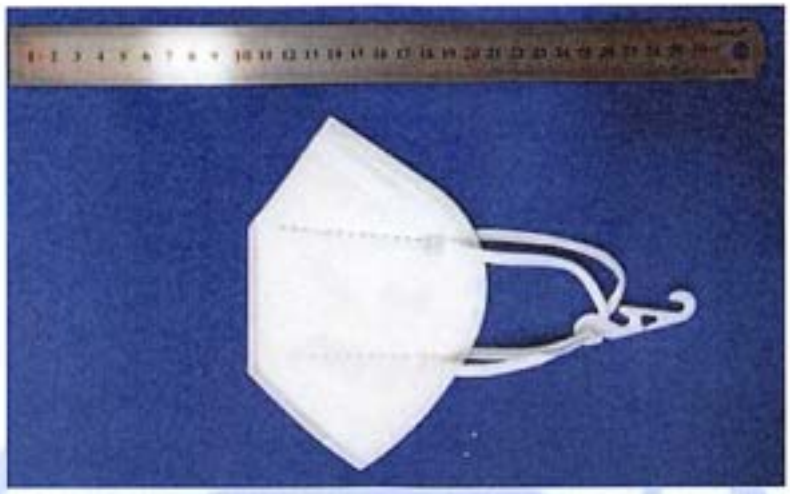
In this study, mammalian L-929 cells were cultured in vitro according to ISO 10993-5:2009 to test the potential cytotoxicity of the test article.

The test articles and the control material were separately placed in MEM medium containing 10% fetal bovine serum, and extracted in a 37 ℃ incubator for 24 hours. After the end of the extraction, the cell culture medium in the 96-well plate (10^4 cells/well) cultured for 24 hours was removed and replaced with the corresponding extract, cultured in 37 ℃, 5% CO_2, >90% humidity for 24 hours. After the culture, the morphology and cell lysis of the cells were observed under the microscope, and the cytotoxicity of the test samples was determined by MTT assay.

The results showed that the cells in the blank control group and the negative control group (high density polyethylene) were well-formed throughout the experiment and showed no cytotoxic reaction. A severe cytotoxic response was shown in the positive control group (ZDEC). The 100% concentration of the test extract retained a normal appearance after 24 hours of incubation, and the cell viability was 70.6%. The data of each group met the acceptance criteria, and the results of this test were valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article have no potential toxicity to L-929 in the MTT method.

Study Verification and Signature



Protocol Number	SST2008016701BB
Protocol Effective Date	2020-09-14
Technical Initiation Date	2020-09-18
Technical Completion Date	2020-09-23
Final Report Completion Date	2020-10-21

Personnel _____ 2020-10-21
Date Completed

Approved
Study Director _____ 2020-10-21
Date Completed

Supervisory
Test Facility Manager _____ 2020-10-21
Date Completed

CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

Quality Assurance Statement and GLP Statement

Quality Assurance Statement

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the HTW's Management.

The final report was reviewed to assure that the report accurately describes the methods and standard operating procedures. The reported results accurately reflect the raw data of the nonclinical study conducted per the protocol.

Phase Inspected	Date	Study Director	Management
Experiment	2020-09-18	2020-09-18	2020-09-18
Raw Data	2020-09-23	2020-09-23	2020-09-23
Final Report	2020-10-21	2020-10-21	2020-10-21

The findings of these inspections have been reported to Management and the Study Director.

Hui Tang
Quality Assurance

2020-10-21
Date

GLP Statement

This study was conducted in compliance with current U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of HTW, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

Study Director

2020-10-21
Date

1.0 Purpose

The purpose of the test is to determine the potential cytotoxicity toxicity of a mammalian cell culture (mouse fibroblast L-929 cells) in response to the test article.

2.0 Reference

Biological evaluation of medical devices-Part 5: Tests for In Vitro Cytotoxicity (ISO 10993-5：2009)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12：2012)

3.0 Test and control articles

Groups	Test article	Negative Control Article	Positive Control Article	Blank Control
Name	Particulate Respirator	High Density Polyethylene Film	ZDEC	MEM medium, with addition 10% FBS
Manufacture	Maple Leaf Laboratories Ltd	Hatano Research Institute. FDSC	Sigma-Aldrich.	Hyclone
Size	Not provided	3 cm×10 cm (5 sheets)	25 g	500 ml
Model	1970E	/	/	/
Lot Batch#	Not provided	C-161	BCBQ6847V	AF29479404
Test Article Material	Not provided	/	/	/
Physical State	Solid	Solid	Solid	Liquid
Color	Not provided	White	White	Pink
Packaging Material	Not provided	/	/	/
Sterilized or Not	No	No	No	Yes
Concentration	/	/	0.1%	/
Total Surface or weight	Not provided	/	/	/
Storage Condition	Room Tep.	Room Tep.	Room Tep.	4℃
Note：The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification and justification of test system

L-929 mouse fibroblast cells obtained from American Type Culture Collection (ATCC).

L-929 cells have been used for cytotoxicity studies because they demonstrate sensitivity to extractable cytotoxic articles. Also, the test article is extracted and administered in vitro to mouse fibroblast L929 cells through a solvent compatible with the test system, which is the optimal route of administration available in this test system as recommended in ISO 10993-5.

5.0 Equipment and reagents

5.1 Instruments

Vertical pressure steam sterilizer (SHB026), Ethylene oxide sterilizer (SHB109), CO_2 Incubator (SHB002), Steel Straight Scale (SHB076), Electronic Balance (SHB016), Clean bench (SHB014), Multiskan Spectrum Microplate Spectrophotometer (SHB003), Bench type low speed centrifuge (SHB022), Inverted microscope (SHB005)

5.2 Reagents

MEM (Hyclone, AF29479404), FBS (Clark, JC65941), Penicillin-Streptomycin (Gibco, 2145469), Trypsin (Gibco, 2085461), PBS (Hyclone, AE27749269), MTT (3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyletrazolium bromide) (Sigma, MKBG2038V), Isopropyl alcohol (Macklin, C10954717)

6.0 Experiment design and dose

6.1 Sample preparation

According to the table below, aseptic extraction of the test article sealed and incubated in MEM medium (10% FBS) at 37 ℃, 5% CO_2 and 60 rpm for 24 hours.

Groups	Sampling		Sterilization	Aseptic Extraction In Inert Container				Final Extract
	Sampling Manner	Actually sampling	Method	Ratio	Extracts	Condition	pH	Clear or Not
Test article	Whole	379.9 cm^2	EO	6 cm^2: 1 ml	63.3 ml	37 ℃ 24 h	7.4	Clear
Negative Control	Random	60.0 cm^2	EO	3 cm^2: 1 ml	20.0 ml	37 ℃ 24 h	7.4	Clear
Positive Control	Random	0.02 g	/	0.1 g: 100 ml	20.0 ml	37 ℃ 24 h	7.4	Clear
Blank Control	/	/	/	/	20.0 ml	37 ℃ 24 h	7.4	Clear

The changes of the leaching solution was observed after extraction. No particulates or color changes were observed in pre- and post-extraction, and immediately be used in the follow-up experiment. The color and pH of the extraction solution did not change before and after use, and the pH value was 7.4 after leaching.

6.2 Test method

Aseptic procedures were used for handling cell cultures. L-929 cells were cultured in MEM medium (10% FBS, 1% Penicillin-Streptomycin solution) at 37 ℃ in a humidified atmosphere of 5% CO_2, then digested by 0.25% trypsin containing EDTA to get single cell suspension. 1×10^5 cells/ml suspension were obtained by centrifuging (1000 rpm, 5 min) and re-dispersing in MEM medium.

The suspended cells were dispensed at 100 µl per well in 96-well plate, and cultured in cell incubator (5% CO_2, 37 ℃, >90% humidity). Cell morphology was evaluated to verify that the monolayer was satisfactory.

After the cells grew to about 70% and form a monolayer, original culture medium was discarded. The 96-well plates were then treated with 100 µl of extract of test article (100%、75%、50%、25%), control article, negative article and positive article respectively. The 96-well plate was incubated at 37 ℃ in cell incubator of 5% CO_2 for 24

h. Six replicates of each test were tested.

After incubation, observe the cell morphology first and then discard the culture medium. Add 50 µl MTT (1mg/ml) to each well and then incubated at 37 ℃ in a humidified atmosphere of 5% CO_2 for 2 hours. The liquid in each well was tipped out and 100 µl Isopropyl alcohol was added to each well to suspend the cell layer.

Evaluate the suspension above with a dual-wavelength spectrophotometer with the measurement wavelength at 570 nm.

7.0 Statistical method

Mean±standard deviation ($\bar{x}$ ±s)

The cell cytotoxicity ratio = OD_{570} of test (or positive or negative) article group/ OD_{570} of blank control group×100%.

8.0 Evaluation criteria

8.1 The 50% extract of the test article should have at least the same or a higher viability than the 100% extract. Otherwise the test should be repeated.

8.2 The lower the Viab.% value, the higher the cytotoxic potential of the test article is.

8.3 If viability is reduced to < 70% of the blank, it has a cytotoxic potential.

8.4 The Viab.% of the 100% extract of the test article is the final result.

9.0 Results of the test

9.1 Results of the cell morphology

Table 1 Observation of the cell morphology

Group	Before inoculation	Before treated with extract	24 h after treatment
Blank control	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
Negative control			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
Positive control			Nearly complete or complete destruction of the cell layers.
100% Test article extract			The cells showed a round shape and a change in cell morphology occasionally, and there were particles in the cytoplasm, occasionally cell lysis and slight growth inhibition.
75% Test article extract			The cells showed a round shape and a change in cell morphology occasionally, and there were particles in the cytoplasm, occasionally cell lysis and slight growth inhibition.
50% Test article extract			The cells showed a round shape and a change in cell morphology occasionally, and there

			were particles in the cytoplasm, occasionally cell lysis and slight growth inhibition.
25% Test article extract			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.

9.2 Results of the cell vitality

Table2 Results of the cell vitality

Group	OD value								Viab. (%)
	1	2	3	4	5	6	$\bar{x}$	s	
Blank control	0.619	0.627	0.626	0.621	0.615	0.616	0.621	0.005	100.0
Negative control	0.609	0.609	0.632	0.627	0.614	0.613	0.617	0.010	99.4
Positive control	0.061	0.056	0.054	0.052	0.052	0.060	0.056	0.004	9.0
100% test article extract	0.444	0.445	0.434	0.427	0.439	0.440	0.438	0.007	70.6
75% test article extract	0.480	0.482	0.480	0.470	0.486	0.480	0.480	0.005	77.3
50% test article extract	0.534	0.514	0.517	0.534	0.525	0.521	0.524	0.009	84.4
25% test article extract	0.593	0.564	0.591	0.576	0.578	0.578	0.580	0.011	93.4

10.0 Conclusion

Under the conditions of this study, the test article have no potential toxicity to L-929 cells.

11.0 Compliance

US FDA Good Laboratory Practice Regulations 21 CFR 58, effective June 20, 1979, as amended 52 FR 33780, Sept. 4, 1987, and subsequent amendments

Standard operating procedure of CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

12.0 Record

All raw data pertaining to this study and a copy of the final report are retained in designated Huatongwei archive.

13.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

191020340175

中国认可
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检测
TESTING
CNAS L13034

Skin Sensitization Test

Guinea Pig Maximization

Final Report

Verification

Report Number: CSTBB20100068

Article Name: Particulate Respirator

Method Standard: ISO 10993-10: 2010

Sponsor

Maple Leaf Laboratories Ltd.

3800 Wesbrook Mall, Vancouver, BC，
CANADA V6S 2L9
Gordon Zhang. Tel: 001 778 846 2285

Test Facility

CCIC Huatongwei international inspection (Suzhou) Co., Ltd

Room 101, Building G, Ruoshui Road 388,
Suzhou, Jiangsu, China

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Abstract

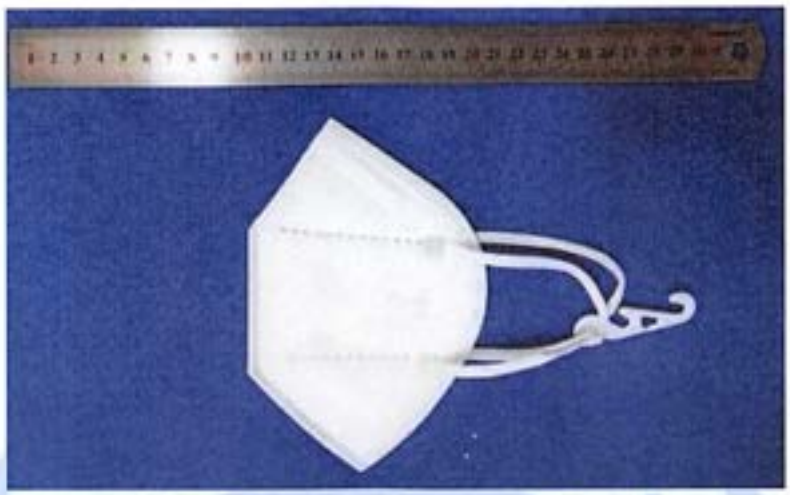
In this study, we took guinea pigs to observe the skin sensitization of the test article according to ISO 10993-10: 2010.

The test article were extracted in Constant Temperature Vibrator at 50 ℃, 60 rpm for 72 h by 0.9 % Sodium Chloride Injection and Sesame Oil. Mix 50:50 (by volume) stable emulsion of Freund's complete adjuvant with selected solvent. Intradermal induction and topical induction were operated in the clipped intrascapular region of each animal. After the topical induction phase was completed on day 14, all test and control animals were challenged with the test sample. The erythema and edema of the challenge site were observed to test the sensitization response of the test article. According to the Magnusson and Kligman scales, the response to erythema and edema at each application site of the skin was described and scored 24 hours and 48 hours after the challenge phase.

The results showed that the guinea pigs in the negative control group (0.9 % Sodium Chloride Injection, Sesame Oil) retained a normal appearance throughout the test and showed no skin irritants. A severe skin reactions for erythema and oedema were shown in the positive control group (DNCB). While in test article group, the response of skin on testing side did not exceed that on the control side. The skin reactions for erythema and oedema were not observed in test article group. The data of each group met the acceptance criteria, and the results of this test were considered valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article has no potential skin sensitization on guinea pigs in the extraction method.

Study Verification and Signature



Protocol Number	SST2008016702BB
Protocol Effective Date	2020-09-14
Technical Initiation Date	2020-09-18
Technical Completion Date	2020-10-16
Final Report Completion Date	2020-10-21

Personnel — Date Completed: 2020-10-21

Approved — Study Director — Date Completed: 2020-10-21

Supervisory — Test Facility Manager — Date Completed: 2020-10-21

CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

Quality Assurance Statement and GLP Statement

Quality Assurance Statement

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the HTW's Management.

The final report was reviewed to assure that the report accurately describes the methods and standard operating procedures. The reported results accurately reflect the raw data of the nonclinical study conducted per the protocol.

Phase Inspected	Date	Study Director	Management
Experiment	2020-09-18	2020-09-18	2020-09-18
Raw Data	2020-10-16	2020-10-16	2020-10-16
Final Report	2020-10-21	2020-10-21	2020-10-21

The findings of these inspections have been reported to Management and the Study Director.

Hui Tian
Quality Assurance

2020.10.21
Date

GLP Statement

This study was conducted in compliance with current U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of HTW, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

Study Director

20-10-21
Date

1.0 Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization. The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it does not establish the actual risk of sensitization.

2.0 Reference

Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization (ISO 10993-10: 2010)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2012)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

3.0 Test and control articles

Groups	Test article	Negative Control Article(Polar)	Negative Control Article(Non-Polar)	Positive Control
Name	Particulate Respirator	Sodium Chloride Injection (SC)	Sesame Oil (SO)	2, 4-Dinitrochlorobenzene (DNCB)
Manufacture	Maple Leaf Laboratories Ltd	Shijiazhuang No.4 Pharmaceutical	Ji'an Lv yuan natural flavor oil refinery, Qingyuan District	TOKYO CHEMICAL INDUSTRY CO., LTD
Size	Not provided	500 ml	5L	25 g
Model	1970E	/	/	/
Lot Batch#	Not provided	1912121907	20200528	H2UKD-DM
Test Article Material	Not provided	/	/	/
Physical State	Solid	Liquid	Liquid	Solid
Color	Not provided	Colorless	Light yellow	Light yellow
Package material	Not provided	/	/	/
Sterilized or Not	No	/	/	/
Concentration	/	0.9 %	/	Induction Concentration: 0.5 % Challenge Concentration: 0.1 % Dissolved in ethanol
Total Surface/Weight	Not provided	/	/	/
Storage Condition	Room Temp.	Room Temp.	Room Temp.	Room Temp.

The information about the test article was supplied by the sponsor wherever applicable.

4.0 Identification of test system

4.1 Test animal

Species: Hartley Guinea Pig (Cavia Porcellus)

Number: 30 (20 Test +10 Control)

Sex: Either sex

Initial body weight: 300.0~500.0 g

Health status: Healthy, not previously used in other experimental procedures. Female animals were nul liparous and not pregnant.

Animal identification: Ear tag

Cages: Plastic cage

Acclimation Period: 7 days under the same conditions as for the actual test

4.2 Justification of test system

The albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1970). The guinea pig is believed to be the most sensitive animal model for this type of study. DNCB is the positive control article recommended in the test instructions. To ensure the sensitivity of the experimental system, the positive control article should be verified every three months.

5.0 Animal Management

Animal purchase: Wuxi hengtai experimental animal breeding co. LTD SCXK (SU) 2020-0003

Bedding: Corncob Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

Feed: Guinea pigs were fed with full-price pellets Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006

Animal room temperature: 18-26 ℃

Animal room relative humidity: 30 %-70 %

Lights: 12 hours light/dark cycle, full-spectrum lighting

Personnel: Associates involved were appropriately qualified and trained

Selection: Only healthy, previously unused animals were selected

There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data.

6.0 Equipment and reagents

6.1 Instruments

Constant Temperature Vibrator (SHB007, calibration data: 2020/3/16), Autoclave (SHB026, calibration data: 2020/3/16), Electronic scale (SHB017, calibration data: 2020/3/16)

6.2 Reagents

Freund’s adjuvant Complete liquid (SIGMA, Lot No: SLCD4457), Sodium dodecyl sulfate (SDS SIGMA, Lot No: SLBL2304V)

7.0 Experiment design

7.1 Sample preparation

The extracts of test article will be prepared according to the following steps:

Aseptic Sampling			Extraction in sterile vessels				
Sampling Manner	Actually sampling	Ratio	Reagent		Temperature	Time	pH
Whole	379.9 cm^2	6 cm^2: 1 ml	SC	63.3 ml	50 ℃	72 h	5.5
	379.9 cm^2		SO	63.3 ml		72 h	/

Both inducements and excitations were prepared by the number of times. The state of the leaching solution did not change visually after the leaching was advanced. After extraction, the samples were stored at room temperature for no more than 24 h. The extraction solution is clear, and the pH value has not been adjusted, filtered, centrifuged, diluted and other processes. The control solution was prepared under the same conditions.

7.2 Test method

7.2.1 Intradermal induction phaseI

A pair of 0.1ml intradermal injections was made for each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.

Site B: The test sample (undiluted extract); the control animals were injected with the solvent alone.

Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent (50 %); the control animals were injected with an emulsion of the blank liquid with adjuvant.

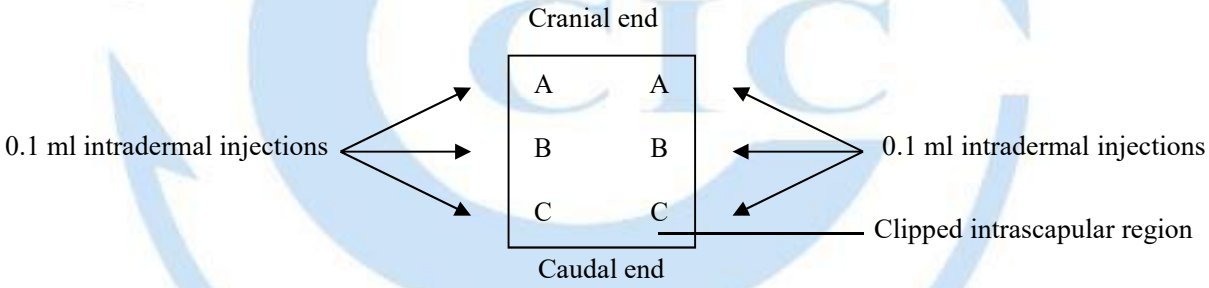


Figure 1 Location of intradermal injection sites

7.2.2 Topical induction phaseII

The maximum concentration that can be achieved in Intradermal induction phase Ⅰ did not produce irritation, animals are pretreated with 10% sodium dodecyl sulfate 24(±2) hours before the topical induction application.

At 7 d after completion of the intradermal induction phase, administer test article extract by topical application to the intrascapular region of each animal, using a patch of area approximately 8 cm^2 (absorbent gauze), so as to cover the intradermal injection sites. Secure the patches with an occlusive dressing. Remove the dressings and patches after (48±2) h.

Treat the control animals similarly, using the blank liquid alone.

7.2.3 Challenge phase

At 14d after completion of the topical induction phase, challenge all test and control animals with the test sample. Absorbent gauzes (2.5 cmx2.5 cm) were soaked respectively with test article and control article. Apply the test article extract and control article topically to two sites that were not treated during the induction stage. Secure

with an occlusive dressing. Remove the dressings and patches after (24±2) h.

8.0 The results observed

The day after challenge exposure, the patch will be removed and the area cleaned gently with gauze if necessary. The site will be wiped gently with a 0.9 % saline soaked gauze sponge prior to each scoring period. The challenge sites will be observed for signs of irritation and sensitization reaction, as indicated by erythema and edema. If necessary, the fur will be shaved or clipped in advance for the convenience of dermal score.

Daily challenge observation scores will be recorded approximately 24, and 48 hours after patch removal in accordance with the following classification system for skin reactions:

Table 1 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

9.0 Evaluation criteria

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals.

If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization.

If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge.

The outcome of the test is presented as the frequency of positive challenge results in test and control animals.

10.0 Results of the test

All animals were survived and no abnormal signs were observed during the study.Individual results of dermal scoring for the challenge appear in Table 2.

11.0 Conclusion

The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor’s responsibility.

12.0 Compliance

US FDA Good Laboratory Practice Regulations 21 CFR 58, effective June 20, 1979, as amended 52 FR 33780, Sept. 4, 1987, and subsequent amendments

Standard operating procedure of CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

13.0 Record

All raw data pertaining to this study and a copy of the final report are retained in designated Huatongwei archive.

14.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

Table 2 Guinea pig Sensitization Dermal Reactions

Group		No.	Pretest weight(g)	Finished weight(g)	The Challenge patch was removed 24h later		The Challenge patch was removed 48h later		Positive rate
					Erythema	Swelling	Erythema	Swelling	
SC	Test	1	312.7	376.1	0	0	0	0	0%
		2	305.0	361.5	0	0	0	0	
		3	307.5	379.2	0	0	0	0	
		4	311.2	351.2	0	0	0	0	
		5	312.3	362.3	0	0	0	0	
		6	303.6	373.4	0	0	0	0	
		7	317.4	356.8	0	0	0	0	
		8	304.4	364.7	0	0	0	0	
		9	315.9	368.2	0	0	0	0	
		10	314.0	372.9	0	0	0	0	
	Control	11	303.3	383.0	0	0	0	0	0%
		12	316.5	377.8	0	0	0	0	
		13	309.9	371.6	0	0	0	0	
		14	316.8	353.2	0	0	0	0	
		15	305.8	381.7	0	0	0	0	
SO	Test	16	303.3	370.9	0	0	0	0	0%
		17	306.3	382.4	0	0	0	0	
		18	316.2	359.1	0	0	0	0	
		19	312.5	373.6	0	0	0	0	
		20	309.2	374.7	0	0	0	0	
		21	306.7	350.3	0	0	0	0	
		22	317.2	372.3	0	0	0	0	
		23	303.0	366.6	0	0	0	0	
		24	306.0	354.5	0	0	0	0	
		25	312.7	358.9	0	0	0	0	
	Control	26	311.4	356.8	0	0	0	0	0%
		27	315.9	366.9	0	0	0	0	
		28	304.2	382.7	0	0	0	0	
		29	316.8	364.0	0	0	0	0	
		30	306.5	383.7	0	0	0	0	

Table 3 Positive control

Group	No.	Pretest weight(g)	Finished weight(g)	The Challenge patch was removed 24 h later		The Challenge patch was removed 48 h		Positive rate
				Erythema	Swelling	Erythema	Swellin	
Test	1	309.8	354.0	1	0	1	0	100%
	2	307.2	352.1	2	0	2	0	
	3	306.3	360.2	1	0	1	0	
	4	314.1	382.9	1	0	1	0	
	5	307.1	351.0	1	0	2	0	
	6	318.7	352.9	1	0	2	0	
	7	312.1	374.0	1	0	1	0	
	8	310.4	358.6	1	0	1	0	
	9	303.3	366.1	2	0	2	0	
	10	308.7	354.2	1	0	2	0	
Control	11	312.9	353.0	0	0	0	0	0%
	12	307.7	359.0	0	0	0	0	
	13	303.7	353.7	0	0	0	0	
	14	307.9	372.3	0	0	0	0	
	15	310.8	380.9	0	0	0	0	

Note：The positive control was CSTBB20080001P1 (Finish date：2020-09-11)

河南省纺织产品质量监督检验院

Henan Textile Products Quality Supervision & Test Institute

检 验 报 告

Test Report

FW202000779

产品名称 Sample Name	Particulate respirator	检验类型 Type of Tests	委托检验 Entrusted Test
规格型号 Size	1970E	样品等级/安全类别 Sample Grade/ Safety Category	KN95/—
商标 Trademark	—	产品款号/货号 Product No.	—
委托单位 Trustor	Maple Leaf Laboratories Ltd.	样品数量 Sample Quantity	50 只 50 Pieces
地址 Address	3800 Wesbrook Mall, Vancouver, BC V6S2L9	送样人/电话 Sender/ Tel.	Gordon Zhang/001 778 846 2285
生产单位 Manufacturer	—	联系人/电话 Contact/ Tel.	—
地址 Address	—	封样状态 Sealed Sample State	—
样品描述 Sample Description	白色 White	受理日期 Date of Accepting Application	2020-07-31
任务来源 Task Source	—	分包项目 Subcontracting Projects	—
检验依据 Testing Standards	GB 2626-2019 《呼吸防护用品-自吸过滤式防颗粒物呼吸器》 GB 2626-2019Respiratory protective equipment—Non-powered air-purifying particle respirator		
检验项目 Test Items	初始过滤效率、吸气阻力、呼气阻力、可燃性、头带 Initial Filter Efficiency, Inspiratory Resistance, Expiratory Resistance, Flammability, Head Harness		
检验结论 Conclusion	样品经检验，所检项目符合 GB 2626-2019 《呼吸防护用品-自吸过滤式防颗粒物呼吸器》标准要求。 After testing , the test items of the samples are qualified according to the Standard GB 2626-2019 Respiratory protective equipment—Non-powered air-purifying particle respirator. 签发日期 2020-08-05		
备注 Remarks	无呼气阀 Without the Exhalation Valve	贴样 Sample	

批准：
Approved by

审核：
Checked by

编制
Edited by

河南省纺织产品质量监督检验院

Henan Textile Products Quality Supervision & Test Institute

检 验 报 告

Test Report

FW202000779

序号 SR No.	检验项目 Test Items		单位 Unit	标准要求 Standard Requirements	实测结果 Results	单项结论 Single Conclusion	备注 Remarks
1	初始过滤效率 Initial Filter Efficiency	NaCl 颗粒物 NaCl Particle	%	≥95.0	97.4	符合 PASS	未经预处理 The sample is not pretreated
2	吸气阻力 Inspiratory Resistance		Pa	≤210	70	符合 PASS	未经预处理 The sample is not pretreated 最大值 Maximum
3	呼气阻力 Expiratory Resistance		Pa	≤210	61	符合 PASS	未经预处理 The sample is not pretreated 最大值 Maximum
4	可燃性 Flammability	续燃时间 Afterflame Time	s	≤5	无续燃 The Masks have not been afterflaming.	符合 PASS	未经预处理 The sample is not pretreated
5	头带 Head Harness	随弃式 Disposable Facepiece	——	无滑脱或断裂 The Head Harnesses shall not be slipped or fractured.	无滑脱、无断裂 The Head Harnesses have not been slipped and fractured.	符合 PASS	未经预处理 10N 持续 10s The sample is not pretreated 10N ,Keeping 10s

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地址：郑州市西四环与建设西路交叉口北300米 邮编：450042 电话：0371-86687921 0371-86687920

Layfield Medical Products
95PFE-L3 Health Care + Surgical Particulate Respirator
Medical + Surgical Mask 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 Health Care + Surgical Particulate Respirator is a single-use medical device designed to help provide respiratory protection for the wearer when used as directed in health care and surgical environments. This respirator has a filter efficiency level of at least 95% PFE against particulate aerosols free of oil. 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 health care + surgical 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). As a medical + surgical mask, 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. It is also designed to protect the patients and other individuals in the vicinity from the wearer's respiratory emissions.

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.

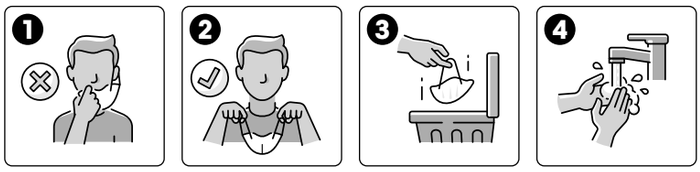
Use Instructions

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

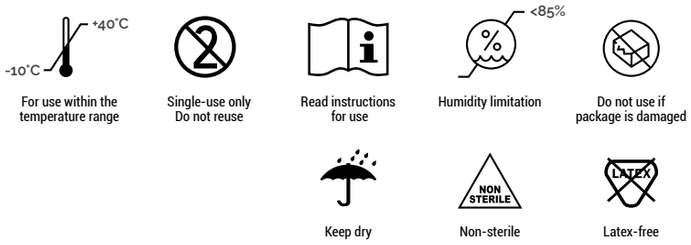
Dispose of respirator according to your facility or institution or employer policy, and local regulations.

Product Details

- Item No. MLL-1970E
- 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)
- GB 2626-2019 Certified

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



For use within the temperature range | Single-use only Do not reuse | Read instructions for use | Humidity limitation | Do not use if package is damaged

Keep dry | Non-sterile | Latex-free

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

LAYFIELD MEDICAL PRODUCTS

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

Produits médicaux Layfield
Respirateur de soins de santé + particules chirurgicales 95PFE-L3
Masque médical + chirurgical avec attaches d'oreilles

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 95PFE-L3 contre les particules chirurgicales en milieu de santé est un dispositif médical à usage unique conçu pour aider à fournir une protection respiratoire à l'utilisateur lorsqu'il est utilisé selon les directives et en milieu de soins de santé et chirurgical. 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 résiste aux fluides selon la norme ASTM niveau 3 (160 mm Hg) et répond à une efficacité de filtration bactérienne (EFB) de ≥ 98% et à une efficacité de filtration de particules (EFP) de ≥ 98% (détection de 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 de soins de santé + particules chirurgicales, ce produit est conçu pour 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 non huileux). En tant que masque médical + chirurgical, 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 d'autres liquides dangereux. Il est également conçu pour protéger les patients et les autres personnes à proximité des émissions respiratoires de la personne qui le porte.

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.

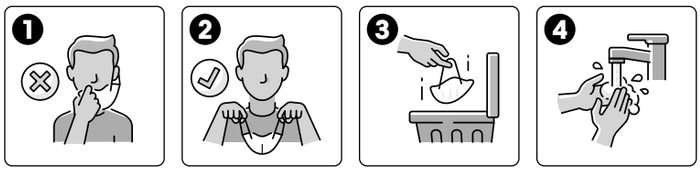
Instructions d'utilisation

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: MLL-1970E
- 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)
- Certifié GB 2626-2019

COMPOSITION DU PRODUIT

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

Pour une utilisation dans une gamme de température

Ne pas réutiliser

Lire les instructions d'utilisation

Limite d'humidité

Ne pas utiliser si l'emballage est endommagé

Garder au sec

NON STÉRILE
Non stérile

LATEX
Sans latex

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, Colombie-Britannique V7A5E4 CANADA

LAYFIELD MEDICAL PRODUCTS

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