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Report For: Dent-X Canada

Attention:

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Angelina Wu

Specimen: #2: FN-N95-508 Respirator

Laboratory #: 877327B-21

FINAL

Report Date: December 24, 2021 **Received Date:** December 10, 2021

Customer P.O. #: 3655

TEST REPORT

One specimen, consisting of respirators were submitted to CMTL for assessment of mechanical headstrap strength to evaluate acceptability with both Health Canada performance criteria for filtering face piece respirators (Date published: 2020-08-25, Date modified: 2021-02-02) and 42 CFR Part 84 Subpart K, Sections 174 and 172 respectively.

Testing had also been conducted for particulate filter efficiency, airflow resistance, fluid resistance and flammability with results reported below from laboratory #877327D-21.



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Per Authorized By Stephen Brown

Technician, Derek Wild



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Requirement for Filtering Facepiece Respirators per both
Health Canada National Standard Specifications for Respirators during COVID-19:
Guidance for Canadian Manufacturers (Date published: 2020-08-25, Date modified: 2021-02-02)
and 42 CFR Part 84 Subpart K, Sections 172 and 174

Characteristic	Barrier	Summary Results
Particulate Filter Efficiency (%)	≥95	Pass*
Airflow (Inhalation) Resistance, mmH₂O (Pa)	≤35 (343)	Pass*
Airflow (Exhalation) Resistance, mmH ₂ O (Pa)	≤25 (245)	Pass*
Fluid Resistance maximum pressure in kPa for pass result	21.3	Pass*
Flammability, Class	1	Pass*
Mechanical Headstrap Strength, Observations and Proof Load (Newtons)	≥20	Pass

^{*} Test results reported under Laboratory #877327D-21 on December 17, 2021.

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Laboratory #877327B-21 FINAL Dent-X Canada

PARTICULATE FILTRATION EFFICIENCY*

Twenty submitted specimens were evaluated for particulate filtration efficiency in accordance with TEB-APR-STP-0059 test procedure to evaluate acceptability with Health Canada and 42 CFR 84 Subpart K requirements for N95 respirators.

All twenty of the specimens were conditioned (C) within a CSZ environmental control chamber for 25±1 hour at a 85±5% relative humidity and 38°C ± 2.5°C, then tested within 10 hours of extraction from the chamber as indicated in NIOSH standard procedure TEB-APR-STP-0059.

The particulate filter efficiency was performed on a TSI 8130A automated filter tester, and challenged under unidirectional airflow at 85 L/min \pm 4 L/min with an aerosol of sodium chloride (NaCl) particles. The particles were generated by an aerosol generator and neutralized to their Boltzmann equilibrium state. The particles were considered to have an average count median diameter of 0.075 \pm 0.020 micrometers and a geometric standard deviation not exceeding 1.86.

RESULTS

Specimen	Conditioned	Flow	Initial Filter	Maximum Allowable	Initial	Maximum	Particulate Filtration	Requir (≥9	rement 5%)
#	Conditioned	Rate	Resistance (mmH ₂ O)	Leakage (%)	Leakage (%)	Leakage (%)	Efficiency (%)	Result	Overall Result
1	С	85	9.7	5.00	1.755	1.755	98.2	Pass	
2	С	85	9.1	5.00	1.966	1.966	98.0	Pass	
3	С	85	9.1	5.00	2.144	2.144	97.9	Pass	
4	С	85	9.6	5.00	1.670	1.670	98.3	Pass	
5	С	85	12.6	5.00	2.160	2.160	97.8	Pass	
6	С	85	9.2	5.00	1.997	1.997	98.0	Pass	
7	С	85	9.8	5.00	1.855	1.855	98.1	Pass	
8	С	85	12.2	5.00	2.172	2.172	97.8	Pass	
9	С	85	10.6	5.00	1.821	1.821	98.2	Pass	
10	С	85	9.6	5.00	1.991	1.991	98.0	Pass	Door
11	С	85	10.3	5.00	1.774	1.774	98.2	Pass	Pass
12	С	85	10.5	5.00	1.887	1.887	98.1	Pass	
13	С	85	9.5	5.00	1.933	1.933	98.1	Pass	
14	С	85	9.4	5.00	1.723	1.723	98.3	Pass	
15	С	85	10.5	5.00	2.106	2.106	97.9	Pass	
16	С	85	12.4	5.00	2.294	2.294	97.7	Pass	
17	С	85	10.0	5.00	2.197	2.197	97.8	Pass	
18	С	85	9.9	5.00	1.920	1.920	98.1	Pass	
19	С	85	9.5	5.00	1.984	1.984	98.0	Pass	
20	С	85	9.7	5.00	1.893	1.893	98.1	Pass	

Note: As per Health Canada and 42 CFR Part 84 Subpart K, section 174(i) the minimum efficiency for each of the 20 filters will be determined and recorded and must be equal to or greater than 95% filtration efficiency.

^{*} Test results reported under Laboratory #877327D-21 on December 17, 2021.

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AIRFLOW (INHALATION) RESISTANCE*

Twenty submitted specimens were evaluated for airflow (inhalation) resistance based on TEB-APR-STP-0007 using a TSI 8130A automated filter tester considered by NIOSH to be an acceptable pressure drop measurement.

Tests were performed with the salt generator turned-off under no loading conditions. Using hot-melt glue the filtering facepiece respirators were sealed onto flat plates with joint for connection to the resistance apparatus for measurements of pressure drop.

RESULTS

Spesimen	Maximum Allowable	Actual Resistance	Requirer	nent (≤35)
Specimen #	Resistance (mmH₂O) Inhalation	(mmH₂O) Inhalation	Result	Overall Result
1	35	8.7	Pass	
2	35	8.8	Pass	
3	35	9.0	Pass	
4	35	10.0	Pass	
5	35	10.0	Pass	
6	35	10.3	Pass	
7	35	11.9	Pass	
8	35	9.4	Pass	
9	35	9.1	Pass	
10	35	10.2	Pass	Door
11	35	10.7	Pass	Pass
12	35	10.3	Pass	
13	35	10.4	Pass	
14	35	10.2	Pass	
15	35	12.5	Pass	
16	35	11.4	Pass	
17	35	12.1	Pass	
18	35	10.3	Pass	
19	35	10.1	Pass	
20	35	10.8	Pass	

^{*} Test results reported under Laboratory #877327D-21 on December 17, 2021.



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Laboratory #877327B-21 FINAL Dent-X Canada

AIRFLOW (EXHALATION) RESISTANCE*

Twenty submitted specimens were evaluated for airflow (exhalation) resistance based on TEB-APR-STP-0003 using a TSI 8130A automated filter tester considered by NIOSH to be an acceptable pressure drop measurement.

Tests were performed with the salt generator turned-off under no loading conditions. Using hot-melt glue the filtering facepiece respirators were sealed onto flat plates, and mounted in reverse, with joint for connection to the resistance apparatus for measurements of pressure drop.

RESULTS

Specimen	Maximum Allowable	Actual Resistance	Requirer	ment (≤25)
Specimen #	Resistance (mmH₂O) Exhalation	(mmH₂O) Exhalation	Result	Overall Result
1	25	8.8	Pass	
2	25	8.8	Pass	
3	25	9.0	Pass	
4	25	9.5	Pass	
5	25	9.3	Pass	
6	25	9.4	Pass	
7	25	9.5	Pass	
8	25	9.3	Pass	
9	25	9.0	Pass	
10	25	8.9	Pass	Door
11	25	9.1	Pass	Pass
12	25	9.4	Pass	
13	25	9.4	Pass	
14	25	9.1	Pass	
15	25	9.8	Pass	
16	25	9.4	Pass	
17	25	9.7	Pass	
18	25	9.3	Pass	
19	25	9.4	Pass	
20	25	9.4	Pass	

^{*} Test results reported under Laboratory #877327D-21 on December 17, 2021.



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FLUID RESISTANCE

ASTM F1862/F1862M-17 at 21.3-kPa (160mmHg) Pressure

RESULTS

Specimen #	Test Pressure	Total Number of	Number of Pass
	(mmHg)	Specimens	Specimens
4	160	32	32

<u>Note</u>: Acceptable Quality Limit of 4.0% is met for single sampling plan when 29 or more of the 32 tested specimens show pass results.

Material construction type	FN-N95-510H
Supplier	Dent-X Canada
Lot number	A10B7CW11/29/2021 1577
Date of receipt	December 10, 2021
Date of test	December 17, 2021
Fluid velocity (cm/s)	647
Volume of impact fluid (ml)	2
Angle of pneumatic valve to horizontal	3°
Description target area mask	Outer Surface
Distance from tip cannula to mask (in)	12
Technique to enhance visual detection	Cotton swab used to lightly daub on the surface
Conditioning parameters	21±5°C, 85±5% R.H for minimum of 4 hours

<u>NOTE</u>: The outside surface of the mask is exposed to the blood stream in order to observe whether penetration occurred on the inner surface of the mask that could be contacting the wearer's face. Penetration on the inner facing of the mask constitutes failure (ASTM F1862/F1862M-17 section 4.2).

^{*} Test results reported under Laboratory #877327D-21 on December 17, 2021.



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FLAMMABILITY

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

RESULTS

	Specimen #	RESULT	CONCLUSION
	4-1	IBE	
Specimen	4-2	IBE	
#4	4-3	IBE	Classified as Class 1
	4-4	IBE	
	4-5	IBE	

IBE: Ignited but extinguished

Test: Flame Resistance 45° angle test. One-Second Flame Impingement.

Type of fabric: Without a raised fiber surface

Surface tested: Face

Type of test: Original State

Direction tested: Length

Testing Conditioning: Specimens conditioned at 105°C for 30 min, then placed in desiccator

Requirements: The flame spread time for textile products without a raised fibre surface must be

greater than 3.5 seconds.

Date of Receipt: December 10, 2021

Date of Test: December 17, 2021

Note: For a test plan of 5 specimens, no failure is allowed for an Acceptable Quality Limit of 4.0%.

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MECHANICAL HEADSTRAP STRENGTH

Attention:



1177 Franklin Boulevard, Cambridge, Ontario N1R 7W4 Tel: (519) 621-6600 Fax: (519) 621-6082 www.cambridgematerials.com

879175-21

Report Date: December 24, 2021

Received Date: December 15, 2021

Report For: Cambridge Materials Testing Limited

> 6991 Millcreek Drive, Unit 13 MISSISSAUGA, Ontario

L5N 6B9

Derek Wild

Customer P.O.#:

Respirators, CMTL Mississauga Lab # 877327, Customer: Dent-X Canada, Identified as #2-FN-Specimen:

Laboratory #:

N95-508 Respirator

PROOF LOAD TEST REPORT

Ten submitted specimens were subjected to proof load testing in accordance with Health Canada National Standard Specifications for Respirators during COVID-19: Guidance for Canadian Manufacturers, Date Published: February 2, 2021. Testing was performed by donning the mask body on to a head form. A proof load of 10 N was then applied to the elastomeric strap for 10 seconds. The proof load was then removed and the specimen was examined for failure. Testing machine was operated in accordance with ASTM A370-20 paragraph 8 with a test speed of 75mm/minute.

RESULTS

Specimen	Observations
1	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.
2	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.
3	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.
4	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.
5	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.
6	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.
7	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.
8	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.
9	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.
10	There was no evidence of breakage, tearing, separation from the point of fixation to the respirator body, permanent deformation or other obvious loss of function in the securing mechanism.

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