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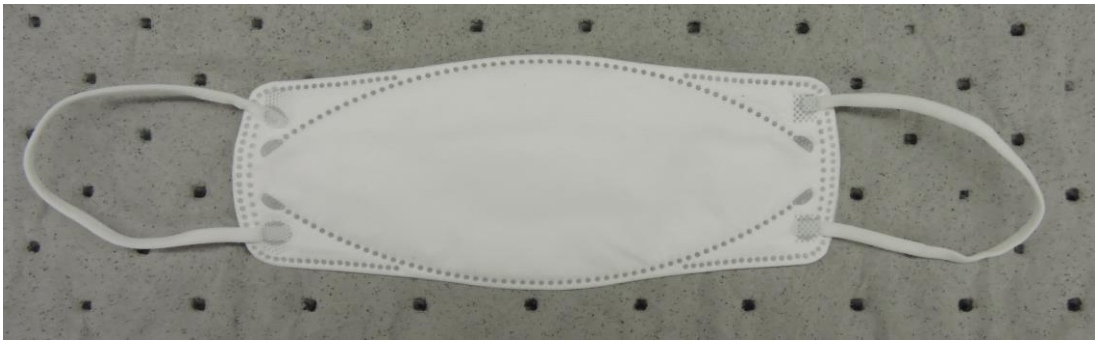
6991 Millcreek Drive, Unit 13
Mississauga, Ontario L5N 6B9
Tel: (905) 812-3856 Fax: (905) 812-3866
www.cambridgematerials.com

Report For:	Dent-X Canada 311 Bowes Road Main Unit Vaughan, Ontario L4K 1J1 Phone: 416-774-2476 Email: angelina@dent-xcanada.com	**Laboratory #:**	856649-21
		Report Date:	February 28, 2021
		Received Date:	February 24, 2021
Attention:	Angelina Wu		
Specimen:	#1: Sample #18 #508/#510H		

TEST REPORT

One specimen, consisting of respirators, identified as #508/#510H, were submitted to CMTL for assessment of particulate filter efficiency, airflow resistance, mechanical strength of headstrap or head harness, fluid resistance, and flammability properties to evaluate acceptability with Health Canada performance criteria for filtering facepiece respirators (Date published: 2020-08-25, Date modified: 2021-02-02).

Testing had also been performed to assess the bacterial filtration efficiency to assess compliance with additional requirements for surgical respirators under 42 CFR 84 and FDA/NIOSH MOU 225-18-006.



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Per _____
Authorized By Stephen Brown

Per _____
Technician, Derek Wild

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Requirement for Filtering Facepiece Respirators per
Health Canada National Standard Specifications for Respirators during COVID-19:
Guidance for Canadian Manufacturers, Date published: 2020-08-25, Date modified: 2021-02-02

Characteristic	**Barrier**	**Summary Results**
Particulate Filter Efficiency (%)	≥95	**Pass**
Mechanical Headstrap Strength, Observations and Proof Load (Newtons)	≥20	**Pass**
Airflow (Inhalation) Resistance, mmH_2O (Pa)	≤35 (343)	**Pass**
Airflow (Exhalation) Resistance, mmH_2O (Pa)	≤25 (245)	**Pass**
Flammability, Class	1	**Pass**
Fluid Resistance maximum pressure in kPa for pass result	21.3	**Pass**

Additional Requirements for Surgical Respirators
Under 42 CFR Part 84 and FDA/NIOSH MOU 225-18-006

Characteristic	**Barrier**	**Summary Results**
Bacterial Filtration Efficiency (%)	≥95	**Pass**

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PARTICULATE FILTER EFFICIENCY

Fourteen submitted specimens were evaluated for particulate filter efficiency based on the TEB-APR-STP-00059 test procedure, with exceptions based on appropriate NRC deviations for maximum expected particle loading being used to filter ambient air in a hospital (medical) or other non-industrial setting.

Seven 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. A remaining seven additional specimens were also tested to evaluate the effect of no conditioning (U), based on NRC recommendations, to assess composition of filtering material.

The particulate filter efficiency was performed on a TSI 8130A automated filter tester, and challenged for 4-minutes under unidirectional airflow at 85 L/min ± 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 ± 0.020 micrometers and a geometric standard deviation not exceeding 1.86. This was equivalent to approximately 7.5 mg of NaCl loading.

Note: The equipment was outsourced and located at University of Toronto, 223 College Street, Toronto, ON, M5T 1R4.

RESULTS

Specimen #	Conditioned	Flow Rate	Initial Filter Resistance (mmH_2O)	Maximum Allowable Leakage (%)	Initial Leakage (%)	Maximum Leakage (%)	Particulate Filtration Efficiency (%)	Requirement (≥95%)	
								Result	Overall Result
1-1	C	85	18.56	5.00	0.62	0.62	99.38	**Pass**	**Pass**
1-2	C	85	21.07	5.00	0.78	0.78	99.22	**Pass**	
1-3	C	85	22.47	5.00	0.76	0.76	99.24	**Pass**	
1-4	C	85	17.73	5.00	0.72	0.72	99.28	**Pass**	
1-5	C	85	17.89	5.00	0.74	0.74	99.26	**Pass**	
1-6	C	85	20.61	5.00	0.80	0.80	99.20	**Pass**	
1-7	C	85	18.08	5.00	0.97	0.97	99.03	**Pass**	
1-8	U	85	16.73	5.00	0.62	0.62	99.38	**Pass**	
1-9	U	85	19.49	5.00	1.56	1.56	98.44	**Pass**	
1-10	U	85	19.58	5.00	0.66	0.66	99.34	**Pass**	
1-11	U	85	21.97	5.00	1.88	1.88	98.12	**Pass**	
1-12	U	85	19.89	5.00	1.42	1.42	98.58	**Pass**	
1-13	U	85	19.7	5.00	1.77	1.77	98.23	**Pass**	
1-14	U	85	17.65	5.00	0.68	0.68	99.32	**Pass**	

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MECHANICAL HEADSTRAP STRENGTH

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: 2020-08-25, Date modified: 2021-02-02). Testing was performed by securing the mask body to the bed of the testing frame. A proof load of 10 N was then applied to the elastomeric strap for 10 seconds. The proof load was then removed and the specimens were examined for failure. Testing machine was operated in accordance with ASTM A370-20 paragraph 8 with a test speed of 75mm/min.

RESULTS

Specimen #	Observations	Result
1-1	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.	**Pass**
1-2	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.	**Pass**
1-3	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.	**Pass**
1-4	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.	**Pass**
1-5	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.	**Pass**
1-6	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.	**Pass**
1-7	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.	**Pass**
1-8	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.	**Pass**
1-9	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.	**Pass**
1-10	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.	**Pass**

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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.

Note: The equipment was outsourced and located at University of Toronto, 223 College Street, Toronto, ON, M5T 1R4.

RESULTS

Specimen #	Maximum Allowable Resistance (mmH_2O) Inhalation	Actual Resistance (mmH_2O) Inhalation	Requirement (≤35)	
			Result	Overall Result
1-1	35	17.3	**Pass**	**Pass**
1-2	35	20.0	**Pass**	
1-3	35	21.0	**Pass**	
1-4	35	17.0	**Pass**	
1-5	35	17.3	**Pass**	
1-6	35	21.3	**Pass**	
1-7	35	18.5	**Pass**	
1-8	35	15.7	**Pass**	
1-9	35	16.5	**Pass**	
1-10	35	16.7	**Pass**	
1-11	35	18.6	**Pass**	
1-12	35	19.0	**Pass**	
1-13	35	15.0	**Pass**	
1-14	35	16.2	**Pass**	
1-15	35	16.2	**Pass**	
1-16	35	17.5	**Pass**	
1-17	35	21.1	**Pass**	
1-18	35	18.9	**Pass**	
1-19	35	18.5	**Pass**	
1-20	35	18.9	**Pass**	

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AIRFLOW (EXHALATION) RESISTANCE

Twenty submitted specimens were evaluated for airflow (inhalation) 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.

Note: The equipment was outsourced and located at University of Toronto, 223 College Street, Toronto, ON, M5T 1R4.

RESULTS

Specimen #	Maximum Allowable Resistance (mmH_2O) Exhalation	Actual Resistance (mmH_2O) Exhalation	Requirement (≤25)	
			Result	Overall Result
1-1	25	14.4	**Pass**	**Pass**
1-2	25	15.0	**Pass**	
1-3	25	14.5	**Pass**	
1-4	25	14.8	**Pass**	
1-5	25	15.4	**Pass**	
1-6	25	14.4	**Pass**	
1-7	25	14.4	**Pass**	
1-8	25	14.5	**Pass**	
1-9	25	13.2	**Pass**	
1-10	25	14.8	**Pass**	
1-11	25	12.8	**Pass**	
1-12	25	13.7	**Pass**	
1-13	25	12.9	**Pass**	
1-14	25	13.5	**Pass**	
1-15	25	15.3	**Pass**	
1-16	25	16.0	**Pass**	
1-17	25	16.5	**Pass**	
1-18	25	16.7	**Pass**	
1-19	25	15.8	**Pass**	
1-20	25	15.9	**Pass**	

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FLAMMABILITY

The submitted specimen, consisting of five filtering facepiece respirators were tested in accordance to 16 CFR 1610 (1-1-16 Edition).

RESULTS

	Specimen #	RESULT	Requirement (Class 1) (PASS/FAIL)
Specimen #1	1-1	IBE	**[2]Pass Classified as Class 1**
	1-2	IBE	
	1-3	IBE	
	1-4	IBE	
	1-5	IBE	

IBE: Ignited but extinguished

Test: Flame Resistance 45˚ angle test. One-Second Flame Impingement.
Type of fabric: Without a raised fiber surface
Surface tested: Face
Type of test: Original State
Direction tested: Length
Testing Conditioning: Specimens conditioned at 105°C for 30 min, then placed in desiccator
Requirements: The flame spread time for textile products without a raised fibre surface must be greater than 3.5 seconds.

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

[2]Note: Sample tested under Laboratory #852155-20 and reported on January 14, 2021.

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FLUID RESISTANCE
ASTM F1862/F1862M-17 at 21.3 kPa pressure

RESULTS

Specimen #	Test Pressure (kPa)	Total Number of Specimens	Number of Pass Specimens	**Requirement**
				FINAL RESULT
1	21.3	32	32	**[2]Pass**

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

Material construction type	Not provided / unknown
Supplier	Dent-X Canada
Lot number	Not provided / unknown
Date of receipt	December 29, 2020
Date of test	January 5, 2021
Fluid velocity (cm/s)	641
Volume of impact fluid (ml)	2
Angle of pneumatic valve to horizontal	2°
Description target area mask	Outer white center area (see Note)
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

Note: The outside surface of the mask was 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).

[2]Note: Sample tested under Laboratory #852155-20 and reported on January 14, 2021.

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BACTERIAL FILTRATION EFFICIENCY

A Bacterial Filtration Efficiency (BFE) test was completed according to the procedure in ASTM F2101-19 to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts recovered downstream. A suspension of S. aureus was aerosolized using a nebulizer and delivered to the test article at a constant rate with a target delivery rate of 1.7 $x10^3$ – $3.0x10^3$ colony forming units (CFU) per test article with a mean particle size of 3.0 ± 0.3 µm. The aerosolized suspension was drawn through the test article which was clamped in a six stage Andersen air sampler, at a constant flow rate of 28.3 liters per minute (LPM), for collection on bacteriological agar plates.

Challenge Microbe: *Staphylococcus aureus* ATCC 6538
Test Side: Blue side
Area Tested: ~38.5 cm^2
Flow Rate: 28.3 LPM
Test Article Conditioning: 85 ± 5% RH at 25.0 ± 0.5°C for a minimum of 4 hours
Challenge Level: 2.2x 10^3 CFU
Mean Particle Size: 3.2 µm
Negative Control Count[9]: <1 CFU

RESULTS

Specimen #	Total CFU Recovered	[2]Percent BFE (%)	Result
1-1	3	99.9	**Pass**
1-2	2	99.9	**Pass**
1-3	1	>99.9	**Pass**
1-4	2	99.9	**Pass**
1-5	2	99.9	**Pass**

[2]Note: Sample tested under Laboratory #852155-20 and reported on January 14, 2021

The filtration efficiency percentages were calculated using the following equation:

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

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

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

Px = 50% effective cut-off diameter for the x^{th} stage as indicated by the manufacturer
Cx = raw count (on stages 1 and 2) or the "probable hit" count determined using the positive hole conversion chart from the cascade impactor manual (for stages 3 through 6) on the x^{th} stage.

Note: Testing performed by GAP EnviroMicrobial Services Ltd., 1020 Hargrieve Road, Unit 14, London, Ontario, Canada, N6E 1P5.