



Report For: SMP Manufacturing Ltd.
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Laboratory #: 838117-20
Report Date: June 23, 2020
Received Date: June 11, 2020
FINAL

Attention: Nadheer Rehmtulla
Specimen: #1: ID # SMP-GWN

TEST REPORT

One specimen, consisting of Isolation Medical Gowns, was submitted to be tested for Spray Impact Test and Hydrostatic Pressure Test to determine its level barrier classification under ANSI/AAMI PB70:2012 and CSA Z314-18 requirements.

SPRAY IMPACT TEST (Water Penetration)

According to Test Method AATCC 42-2017

RESULTS

Type of Gown: Isolation

			ANSI/AAMI PB70 REQUIREMENTS		CSA Z314 REQUIREMENTS	
<u>Specimen Area</u>	<u>Specimen ID</u>	<u>Water Penetration (g)</u>	Individual Test Level Barrier Requirement ≤ 4.5 g Level 1 ≤ 1.0 g Level 2 ≤ 1.0 g Level 3 (pass/fail)	Area Test (Pass/Fail)	Individual Test Level Barrier Requirement ≤ 5.5 g Level 1 ≤ 1.0 g Level 2 ≤ 1.0 g Level 3 (pass/fail)	Area Test (Pass/Fail)
A (Front)	1-1	<0.1	PASS	PASS for all Levels	PASS	PASS for all Levels
	1-2	<0.1	PASS		PASS	
	1-3	<0.1	PASS		PASS	
	AVERAGE	<0.1				

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			ANSI/AAMI PB70 REQUIREMENTS		CSA Z314 REQUIREMENTS	
<u>Specimen Area</u>	<u>Specimen ID</u>	<u>Water Penetration (g)</u>	Individual Test Level Barrier Requirement ≤ 4.5 g Level 1 ≤ 1.0 g Level 2 ≤ 1.0 g Level 3 (pass/fail)	Area Test (Pass/Fail)	Individual Test Level Barrier Requirement ≤ 5.5 g Level 1 ≤ 1.0 g Level 2 ≤ 1.0 g Level 3 (pass/fail)	Area Test (Pass/Fail)
B (Sleeve)	1-1	<0.1	PASS	PASS for all Levels	PASS	PASS for all Levels
	1-2	<0.1	PASS		PASS	
	1-3	0.1	PASS		PASS	
	AVERAGE	<0.1				

			ANSI/AAMI PB70 REQUIREMENTS		CSA Z314 REQUIREMENTS	
<u>Specimen Area</u>	<u>Specimen ID</u>	<u>Water Penetration (g)</u>	Individual Test Level Barrier Requirement ≤ 4.5 g Level 1 ≤ 1.0 g Level 2 ≤ 1.0 g Level 3 (pass/fail)	Area Test (Pass/Fail)	Individual Test Level Barrier Requirement ≤ 5.5 g Level 1 ≤ 1.0 g Level 2 ≤ 1.0 g Level 3 (pass/fail)	Area Test (Pass/Fail)
C (Back)	1-1	<0.1	PASS	PASS for all Levels	PASS	PASS for all Levels
	1-2	<0.1	PASS		PASS	
	1-3	<0.1	PASS		PASS	
	AVERAGE	<0.1				

GENERAL CONCLUSION: PASS FOR ALL LEVEL BARRIERS FOR ISOLATION GOWN.

Note 1: The specimen does pass for all levels due to all critical areas (A, B and C) having water penetration less than 1.0 g (ANSI/AAMI PB70/CSA Z314).

Note 2: The entire isolation gown passed level 1 according to the test as per ANSI/AAMI PB70:2012 for ISOLATION GOWN (Section 4.2.3.1) and CSA Z314 (section 19.1.2.3.1). *The entire isolation gown (Areas A, B and C) including seams but excluding cuffs, hems, and bindings, is required to have a barrier performance of at least Level 1.*

Note 3: For a test plan of 3 specimens, no failure is allowed for an Acceptable Quality Limit of 4.0%.

Note 4: Type I tester used.



HYDROSTATIC PRESSURE TEST (Water Resistance)

AATCC 127-2017(2018)e (performed by GroupeCTTGroup, 3000 Ave Boule, Saint-Hyacinthe, Quebec, J2S 1H9)

RESULTS

Type of Gown: Isolation

			ANSI/AAMI PB70 REQUIREMENTS		CSA Z314 REQUIREMENTS	
<u>Specimen Zone</u>	<u>Specimen ID</u>	<u>Pressure (cm)</u>	<u>Individual Test Level 3 Barrier Requirement (≥ 50 cm) (pass/fail)</u>	<u>Area Test (Pass/Fail)</u>	<u>Individual Test Level 3 Barrier Requirement (≥ 50 cm) (pass/fail)</u>	<u>Area Test (Pass/Fail)</u>
A (Front)	1-1	>100 ¹	PASS	PASS for Level 3	PASS	PASS for Level 3
	1-2	>100 ¹	PASS		PASS	
	1-3	>100 ¹	PASS		PASS	
	AVERAGE	>100 ¹				

			ANSI/AAMI PB70 REQUIREMENTS		CSA Z314 REQUIREMENTS	
<u>Specimen Zone</u>	<u>Specimen ID</u>	<u>Pressure (cm)</u>	<u>Individual Test Level 3 Barrier Requirement (≥ 50 cm) (pass/fail)</u>	<u>Area Test (Pass/Fail)</u>	<u>Individual Test Level 3 Barrier Requirement (≥ 50 cm) (pass/fail)</u>	<u>Area Test (Pass/Fail)</u>
B (Sleeves)	1-1	>100 ¹	PASS	PASS for Level 3	PASS	PASS for Level 3
	1-2	>100 ¹	PASS		PASS	
	1-3	>100 ¹	PASS		PASS	
	AVERAGE	>100 ¹				

			ANSI/AAMI PB70 REQUIREMENTS		CSA Z314 REQUIREMENTS	
<u>Specimen Zone</u>	<u>Specimen ID</u>	<u>Pressure (cm)</u>	<u>Individual Test Level 3 Barrier Requirement (≥ 50 cm) (pass/fail)</u>	<u>Area Test (Pass/Fail)</u>	<u>Individual Test Level 3 Barrier Requirement (≥ 50 cm) (pass/fail)</u>	<u>Area Test (Pass/Fail)</u>
C (Back)	1-1	>100 ¹	PASS	PASS for Level 3	PASS	PASS for Level 3
	1-2	>100 ¹	PASS		PASS	
	1-3	>100 ¹	PASS		PASS	
	AVERAGE	>100 ¹				

¹ The test was stopped at 100cm H₂O because it meets the maximum requirement of the standard for Level 3 (≥50cm)

GENERAL CONCLUSION: Based on the Hydrostatic Pressure test, passing for Level 3, and the Water Penetration data, (water penetration ≤ 1.0 g), the final classification for the ISOLATION GOWN is LEVEL 3, due to all critical zones having passed for Hydrostatic Pressure test. (Section 4.2.1.1 of ANSI/AAMI PB70:2012 and Section 19.1.2.1.1 of CSA Z314-18)