

Differential Pressure (Delta P) Final Report

Test Article: 2020 Wellmien Surgical mask ASTM F2100-19 Level 2

Purchase Order: WM200715-1 Study Number: 1333188-S01 Study Received Date: 19 Aug 2020

> Testing Facility: Nelson Laboratories, LLC 6280 S. Redwood Rd.

> > Salt Lake City, UT 84123 U.S.A.

Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 18

Deviation(s):

Summary: The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Inside

Delta P Flow Rate: 8 Liters per minute (L/min)

Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours

Results:

Test Article Number	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	4.3	42.0
2	4.3	42.0
3	4.4	43.0
4	4.4	43.3
5	4.6	44.7





Sean Shepherd electronically approved for

15 Sep 2020 16:55 (+00:00)

Study Completion Date and Time

Study Director

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