Sponsor: Valor Zhu Wellmien Healthcare Tech. (Suzhou) Co., Ltd. 1-3603, Global 188, No.88 Suhui Road Suzhou Industrial Park, Jiangsu, 215021 CHINA

## Differential Pressure (Delta P) Final Report

Test Article: 2020 Wellmien Surgical mask ASTM F2100-19 Level 3

Purchase Order: WM200715 Study Number: 1324348-S01 Study Received Date: 24 Jul 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): None

**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

Test Article Dimensions: ~171 mm x ~164 mm

## Results:

Test Article Number	Delta P (mm H <sub>2</sub> O/cm <sup>2</sup> )	Delta P (Pa/cm²)
1	5.1	50.3
2	5.1	49.8
3	5.0	49.4
4	5.1	49.9
5	5.1	50.2





Leah Tiberius electronically approved for

James Luskin

13 Aug 2020 00:38 (+00:00)

Study Completion Date and Time

Study Director

FRT0004-0001 Rev 22 Page 1 of 1