Sponsor: Raymond Tang PT. SM Engineering Lot.8, Citra Buana Centre Park III, Batam Centre Batam, Kepulauan Riau, 29464 **INDONESIA** 

## Differential Pressure (Delta P) Final Report

GRACE 3PLY EARLOOP FACE MASK Test Article:

BFE101C+DP

Study Number: 1349962-S01 Study Received Date: 07 Oct 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

## Results:

Test Article Number	Delta P (mm H <sub>2</sub> O/cm <sup>2</sup> )	Delta P (Pa/cm <sup>2</sup> )
1	4.9	47.7
2	4.8	47.0
3	5.3	51.5
4	5.6	54.8
5	4.8	47.4





Leah Tiberius electronically approved for

James Luskin

27 Oct 2020 02:18 (+00:00)

Study Completion Date and Time

Study Director