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Purpose	Testing was performed in accordance with *16 CFR Part 1610: Standard for the Flammability of Clothing Textiles, October 2008.*

Griffin Care, Surgical Mask Level II; UY-MAT-URLK-20-212-0441:a

Date of Analysis: **31Jul2020**

Preliminary Testing

Sample Number	Burn Time (s)
1	Did not ignite
2	Did not ignite
3	Did not ignite
4	Did not ignite

Performance Testing

Sample Number	Burn Time (s)
1	Did not ignite
2	Did not ignite
3	Did not ignite
4	Did not ignite
5	Did not ignite
6	Did not ignite
7	Did not ignite
8	Did not ignite
9	Did not ignite
10	Did not ignite
Maximum	N/A
Minimum	N/A
Mean*	N/A
Standard Deviation*	N/A

*Calculated using unrounded values

Conclusion	None of the tested samples ignited. The average burn time for the tested samples meets the requirements for a Class 1 flammability rating.

Reviewed and electronically signed for Study Quality Assurance Release by
Caleb Faboye, Quality Assurance
for Eurofins Lancaster Laboratories Inc., on 03-Aug-2020 18:17:16 UTC-04:00

eurofins | Medical Device Testing

Purpose	Testing was performed in accordance with *ASTM F1862/F1862M-17, Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity), June 1, 2017* and *ASTM F2100-19, Standard Specification for Performance of Materials Used in Medical Face Masks, Aug 1, 2019.* **Testing Parameters** Pre-Conditioning: Minimum of 4 hours at 21 ± 5C and 85 ± 10% RH Distance from target area surface to tip of cannula: 30.5 cm Test Volume of Synthetic Blood: 2 mL

Griffin Care, SURGICAL FACE MASK MK2000; UY-MAT-URLK-20-196-0413:a

Date of Analysis: **03Aug2020**

Sample Number	Fluid Penetration
1	Pass
2	Pass
3	Pass
4	Pass
5	Pass
6	Pass
7	Pass
8	Pass
9	Pass
10	Pass
11	Pass
12	Pass
13	Pass
14	Pass
15	Pass
16	Pass

Sample Number	Fluid Penetration
17	Pass
18	Pass
19	Pass
20	Pass
21	Pass
22	Pass
23	Pass
24	Pass
25	Pass
26	Pass
27	Pass
28	Pass
29	Pass
30	Pass
31	Pass
32	Pass

Conclusion	None of the tested samples experienced any fluid penetration. The masks meet the blood penetration resistance requirements for a Level 2 Barrier rating from synthetic blood delivered at 550 cm/s (Test Pressure = 120 mmHg) according to *ASTM F2100*.

Reviewed and electronically signed for Study Quality Assurance Release by
Caleb Faboye, Quality Assurance
for Eurofins Lancaster Laboratories Inc., on 03-Aug-2020 18:26:46 UTC-04:00

Nelson Labs
A Sotera Health company

Sponsor:
Kristina Prattis
Griffin Care
80 Manheim Ave
Bridgeton, NJ 08302

Differential Pressure (Delta P) Final Report

Test Article:	Mask MK2000 Surgical Mask
Study Number:	1331436-S01
Study Received Date:	14 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):	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:	~167 mm x ~159 mm

Results:

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	5.1	50.1
2	5.5	53.7
3	5.0	48.6
4	5.1	50.0
5	5.3	52.2

Sarah Guzman electronically approved for James Luskin
Study Director

31 Aug 2020 19:20 (+00:00)
Study Completion Date and Time

Nelson Labs
A Sotera Health company

Sponsor:
Michelle Patterson
Monadnock Non-Wovens LLC
5110 Park Court
Mount Pocono, PA 18344

Latex Particle Challenge Final Report

Test Article:	PD-6913 1-5
Purchase Order:	75249
Study Number:	1318038-S01
Study Received Date:	08 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: STP0005 Rev 08
Deviation(s):	None

Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

A one-minute count was performed, with the test article in the system. A one-minute control count was performed, without a test article in the system, before and after each test article. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the number of particles penetrating the test article compared to the average of the control values. During testing and controls, the air flow rate is maintained at 1 cubic foot per minute (CFM) ± 5%.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. 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:	Side with the numbers facing up
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	21°C, 27% relative humidity (RH) at 1753; 21°C, 27% RH at 1848
Average Filtration Efficiency:	99.73%
Standard Deviation:	0.053

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McKenna Wild electronically approved for — 07 Aug 2020 20:05 (+00:00)
Study Director — Curtis Gerow — Study Completion Date and Time

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	23	11,711	99.80
2	36	11,687	99.69
3	38	11,966	99.68
4	29	11,973	99.76
5	37	12,024	99.69

Nelson Labs
A Sotera Health company

Sponsor:
Michelle Patterson
Monadnock Non Wovens LLC
5110 Park Court
Mt Pocono, PA 18344

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article:	PD-6913
Purchase Order:	75245
Study Number:	1303738-S01
Study Received Date:	27 May 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 BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

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:	Belt Pattern Side
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Positive Control Average:	2.9 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.8 µm

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David Brown electronically approved for — 20 Jun 2020 01:22 (+00:00)
Study Director — James Luskin — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	98.0
2	98.6
3	98.6
4	97.7
5	98.7

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	2.6	25.4
2	3.2	31.8
3	2.4	24.0
4	2.8	27.1
5	2.6	25.9

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request