Summary of Surgical Face Mask (WNL2) Testing Results

According to ASTM F2100 (Level 2)

To whom may concern

We,

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Hereby declare

The Surgical Face Mask (WNL2) (Disposable, earloop, 3ply) manufactured by Winner Medical has been tested according to ASTM F2100. All test results meet the specified requirements of Level 2. The detailed information about all testing items refer to the table I and II below.

Table I Requirements specified in ASTM F2100

Characteristic	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier
Bacterial filtration efficiency, %	≥95	≥98	≥98
Differential pressure, mm H_2O/cm^2	<5.0	<6.0	<6.0
Sub-micron particulate filtration efficiency at 0.1 micron, %	≥95	≥98	≥98
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	80	120	160
Flame spread	Class 1	Class 1	Class 1

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Table II Test Results Summary for Winner Surgical Face Mask

No.	Sample	Test Item	Test Lab.	Test Report No.	Results	Conclusion
1	Surgical Face Mask	Bacterial filtration efficiency (BFE), (%)	Nelson Laboratories	1316619-S01	99.7 – 99.9%	Meet requirement of ≥98 %
2		Differential Pressure (mm H_2O/cm^2)	Nelson Laboratories	1316619-S01	4.6-5.0	Meet requirement of <6.0
3		Particle filtration efficiency (PFE), (%)	Nelson Laboratories	1316621-S01	99.84-99.910 %	Meet requirement of ≥98 %
4		Synthetic Blood Penetration Resistance (120mm Hg)	Nelson Laboratories	1316622-S01	29 specimens pass and 3 specimens failed	Meet requirement of 120 mm Hg
5		Flammability of Clothing Textiles	Nelson Laboratories	1316620-S01	Test Article ignited, but extinguished	Meet requirement of class 1

Appendix

1) Test report for Bacterial filtration efficiency (BFE) and Differential pressure
2) Test report for Particle filtration efficiency (PFE)
3) Test report for Synthetic Blood Penetration Resistance (120mm Hg)
4) Test report for Flammability of Clothing Textiles

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

Test Article:	Surgical Face Mask (WNL2)
Purchase Order:	WNNE2000624-1
Study Number:	1316619-S01
Study Received Date:	02 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 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:	Inside
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
Test Article Dimensions:	~175 mm x ~155 mm
Positive Control Average:	1.9 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.8 µm

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Study Director

29 Jul 2020 17:10 (+00:00)
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Results:

Test Article Number	Percent BFE (%)
1	99.7
2	>99.9[a]
3	99.8
4	>99.9
5	99.7

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	5.0	49.2
2	4.8	47.5
3	4.8	47.0
4	4.9	48.1
5	4.6	45.4

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

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Flammability of Clothing Textiles Final Report

Test Article:	Surgical Face Mask (WNL2)
Purchase Order:	WNNE2000624-1
Study Number:	1316620-S01
Study Received Date:	02 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: STP0073 Rev 06
Deviation(s):	None

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state*. Step 2 - *Refurbishing and testing after refurbishing*, was not performed. 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 Article Side Tested:	Outside Surface
Orientation:	Machine

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≥3.5 seconds
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

The 16 CFR Part 1610 standard specifies that 10 replicates are to be tested if, during preliminary testing, only 1 test article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an average flame spread less than 3.5 seconds. Five replicates are to be tested if no flame spread is observed upon preliminary testing, if only 1 test article exhibits flame spread and it is equal to or greater than 3.5 seconds, or if the average flame spread is equal to or greater than 3.5 seconds. In accordance with the standard, 5 replicates were tested for this study.

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Results:

Replicate Number	Time of Flame Spread
1	IBE
2	IBE
3	IBE
4	IBE
5	IBE

IBE = Test Article ignited, but extinguished

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Latex Particle Challenge Final Report

Test Article:	Surgical Face Mask (WNL2)
Purchase Order:	WNNE2000624-1
Study Number:	1316621-S01
Study Received Date:	02 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 07
Deviation(s):	Quality Event (QE) Number(s): QE22125

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 and the counts were averaged. 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.

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:	Inside
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	21°C, 30% relative humidity (RH) at 1026; 22°C, 30% RH at 1324
Average Filtration Efficiency:	99.87%
Standard Deviation:	0.030

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Deviation Details: Controls and sample counts were conducted for one minute instead of an average of three one minute counts. This change shortens the total test time for each sample but will still provide an accurate determination of the particle counts. An equilibrate is a dwell period where the challenge is being applied to the test article for a certain period of time before test article counts are counted. The equilibrate period was reduced from 2 minutes to a minimum of 30 seconds which is sufficient time to clear the system of any residual particles, and establish a state of stable equilibrium before sample counts are taken. Test method acceptance criteria were met, results are valid.

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	10	11,149	99.910
2	18	11,397	99.84
3	19	11,973	99.84
4	17	12,509	99.86
5	14	12,620	99.89

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Synthetic Blood Penetration Resistance Final Report

Test Article:	Surgical Face Mask (WNL2)
Purchase Order:	WNNE2000624-1
Study Number:	1316622-S01
Study Received Date:	02 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: STP0012 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

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.

Number of Test Articles Tested:	32
Number of Test Articles Passed:	29
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	23.6°C and 21% RH

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 120 mmHg (16.0 kPa)

Test Article Number	Synthetic Blood Penetration
1-4, 6-20, 22-23, 25-32	None Seen
5, 21, 24	Yes

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Study Director

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