Summary of Surgical Face Mask Testing Results

According to ASTM F2100 (Level 1)

To whom may concern

We,

Winner Medical Co., Ltd.

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Hereby declare

The Surgical Face Mask (non-sterile, disposable, earloop, 3ply) manufactured by Winner Medical has been tested according to ASTM F2100. All test results meet the specified requirements of Level 1. 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 Medical Face Mask

No.	Sample	Test Item	Test Lab.	Test Report No.	Results	Conclusion
1	Surgical Face Mask	Bacterial filtration efficiency (BFE), (%)	Nelson Laboratories	881751-S01	99.8 – 99.9%	Meet requirement of ≥95%
2		Differential Pressure (mm H_2O/cm^2)	Nelson Laboratories	881751-S01	2.7-2.9	Meet requirement of <5.0
3		Particle filtration efficiency (PFE), (%)	Nelson Laboratories	881755-S01	99.54-99.69%	Meet requirement of ≥95%
4		Synthetic Blood Penetration Resistance (80mm Hg)	Nelson Laboratories	881756-S01	32 specimens PASS	Meet requirement of 80 mm Hg
5		Flammability of Clothing Textiles	Nelson Laboratories	881754-S01	Test Article did not ignite	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 (80mm 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 mask LOT: 20160314
Study Number:	881751-S01
Study Received Date:	21 Mar 2016
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 12

Summary: The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 1.7 - 2.7 x 10^3 colony forming units (CFU) with a mean particle size (MPS) at 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This procedure allows a reproducible bacterial challenge to be delivered to test materials. This test method complies with ASTM F2101-14 and EN 14683:2014, Annex B.

The Delta P test determines the breathability 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 was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C.

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 Area Tested:	~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:	~145 mm x ~157 mm
Positive Control Average:	2.4 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

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30 Mar 2016
Study Completion Date

881751-S01

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	>99.9[a]	2.9	28.0
2	99.8	2.7	26.8
3	99.9	2.9	28.7
4	>99.9	2.7	26.8
5	99.9	2.8	27.1

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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Latex Particle Challenge Final Report

Test Article:	Surgical mask LOT: 20160314
Study Number:	881755-S01
Study Received Date:	21 Mar 2016
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0005 Rev 05

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, dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

Three one-minute counts were performed, with the test article in the system, and the results averaged. Three one-minute control counts were 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 average 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, 24% relative humidity (RH) at 1321; 21°C, 23% RH at 1632
Average Filtration Efficiency:	99.60%
Standard Deviation:	0.057

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30 Mar 2016
Study Completion Date

881755-S01

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	51	11,113	99.54
2	47	11,614	99.59
3	53	12,371	99.57
4	39	12,779	99.69
5	53	13,043	99.60

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Synthetic Blood Penetration Resistance Final Report

Test Article:	Surgical mask LOT: 20160314
Study Number:	881756-S01
Study Received Date:	21 Mar 2016
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0012 Rev 06

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 14683:2014) 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:	32
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	21.9°C and 22% 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: 80 mm Hg

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

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881756-S01

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Flammability of Clothing Textiles Final Report

Test Article: Surgical mask
LOT: 20160314
Study Number: 881754-S01
Study Received Date: 21 Mar 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0073 Rev 06

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

16 CFR Part 1610 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.

Results:

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

DNI = Test Article did not ignite

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