

## Summary of Surgical Face Mask Testing Results

According to EN 14683

### To whom may concern

We,

### Winner Medical Co., Ltd.

Winner Industrial Park, No. 660 Bulong Road, Longhua District, Shenzhen, China

Hereby declare

The Surgical Face Mask (Type IIR, disposable, earloop, 3ply) manufactured by Winner Medical has been tested according to EN 14683. All test results meet the specified requirements of Type IIR. The detailed information about all testing items refer to the table I and II below.

**Table I Requirements specified in EN 14683**

Test	Type I <sup>a</sup>	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm <sup>2</sup> )	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16.0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

<sup>a</sup> Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professional in an operating room or in other medical setting with similar requirements.

**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 (Type IIR, disposable, earloop, 3ply)	Bacterial filtration efficiency (BFE), (%)	Nelson Labs	1288238-S01	99.5 – 99.9 %	Meet requirement of $\geq 98\%$
2		Differential Pressure (Pa/cm <sup>2</sup> )	Nelson Labs	1288238-S01	34.4 – 36.7 Pa/cm <sup>2</sup>	Meet requirement of $< 60$
3		Splash resistance pressure (16.0 kPa) (120 mm Hg)	Nelson Labs	1288241-S01	31 specimens pass and 1 specimens failed	Meet requirement of $\geq 16$ kPa (120 mm Hg)
4		Microbial cleanliness (cfu/g)	Nelson Labs	1288243-S01	$< 2.0$ cfu/g	Meet requirement of $\leq 30$ cfu/g

**Appendix**

- 1) Test report for Bacterial filtration efficiency (BFE) and Differential pressure
- 2) Test report Splash resistance pressure
- 3) Test report for Microbial cleanliness

**Prepared By:**

Winner Medical Co., Ltd.  
Quality Assurance Department



**Date:**

2020-05-14

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

Test Article: Surgical Face Mask  
Purchase Order: WNNE200402-1  
Study Number: 1288238-S01  
Study Received Date: 14 Apr 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  $1.7 - 3.0 \times 10^3$  colony forming units (CFU) with a mean particle size (MPS) of  $3.0 \pm 0.3 \mu\text{m}$ . 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:  $\sim 40 \text{ cm}^2$   
BFE Flow Rate: 28.3 Liters per minute (L/min)  
Delta P Flow Rate: 8 L/min  
Conditioning Parameters:  $85 \pm 5\%$  relative humidity (RH) and  $21 \pm 5^\circ\text{C}$  for a minimum of 4 hours  
Test Article Dimensions:  $\sim 175 \text{ mm} \times \sim 157 \text{ mm}$   
Positive Control Average:  $3.0 \times 10^3$  CFU  
Negative Monitor Count:  $< 1$  CFU  
MPS:  $2.9 \mu\text{m}$



David Brown electronically approved for  
Study Director

James Luskin

13 May 2020 21:52 (+00:00)  
Study Completion Date and Time

**Results:**

Test Article Number	Percent BFE (%)
1	99.7
2	99.5
3	99.7
4	99.9
5	99.8

Test Article Number	Delta P (mm H <sub>2</sub> O/cm <sup>2</sup> )	Delta P (Pa/cm <sup>2</sup> )
1	3.7	36.0
2	3.5	34.4
3	3.7	36.7
4	3.7	36.3
5	3.7	35.9

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request

## Synthetic Blood Penetration Resistance Final Report

Test Article: Surgical Face Mask  
 Purchase Order: WNNE200402-1  
 Study Number: 1288241-S01  
 Study Received Date: 14 Apr 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  $21 \pm 5^\circ\text{C}$  and a relative humidity of  $85 \pm 10\%$ . 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: 31  
 Test Side: Outside  
 Pre-Conditioning: Minimum of 4 hours at  $21 \pm 5^\circ\text{C}$  and  $85 \pm 5\%$  relative humidity (RH)  
 Test Conditions:  $20.1^\circ\text{C}$  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  $\geq 29$  of 32 test articles show passing results.

Test Pressure: 120 mmHg (16.0 kPa)

Test Article Number	Synthetic Blood Penetration
1-13, 15-32	None Seen
14	Yes



CA FOR JWL  
 Study Director

James W. Luskin

17 APR 2020  
 Study Completion Date



1288241-S01

## Microbial Cleanliness (Bioburden) of Medical Masks Final Report

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Test Article: Surgical Face Mask  
Purchase Order: WNNE200402-1  
Study Number: 1288243-S01  
Study Received Date: 14 Apr 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: STP0036 Rev 15  
Customer Specification Sheet (CSS) Number: 202002092 Rev 01  
Deviation(s): None

**Summary:** The testing was conducted in accordance with EN 14683:2019, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.



Carl Danielson electronically approved for  
Study Director

Robert Putnam

29 Apr 2020 18:44 (+00:00)  
Study Completion Date and Time

**Results:**

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.1	<3	<3	<6.0	<1.9
2	3.2	<3	<3	<5.8	<1.8
3	3.4	<3	<3	<5.7	<1.7
4	3.1	<3	<3	<6.0	<1.9
5	3.0	<3	<3	<6.0	<2.0
Recovery Efficiency	UTD <sup>a</sup>				

< = No Organisms Detected

UTD = Unable to Determine

Note: The results are reported as colony forming units per test article.

<sup>a</sup> UTD due to zero count on the first rinse. An alternative method or inoculated product recovery efficiency is recommended.

**Method Suitability:**

Organism	Percentage
<i>Bacillus atrophaeus</i>	117%

**Test Method Acceptance Criteria:** If applicable, anaerobic controls are acceptable for the bioburden test results. The number of masks to be tested shall be a minimum of 5 or more to meet an acceptable quality level of 4%. The bioburden of the medical mask shall be < 30 CFU/g tested.

**Procedure:**

Positive Controls/Monitors: *Bacillus atrophaeus*  
 Extract Fluid: Peptone Tween<sup>®</sup> with Sodium Chloride  
 Extract Fluid Volume: ~300 mL  
 Extract Method: Orbital Shaking for 15 minutes at 250 rpm  
 Plating Method: Membrane Filtration  
 Agar Medium: Potato Dextrose Agar  
 Tryptic Soy Agar  
 Recovery Efficiency: Exhaustive Rinse Method  
 Aerobic Bacteria: Plates were incubated 3 - 7 days at 30-35°C, then enumerated.  
 Fungal: Plates were incubated 5 - 7 days at 20-25°C, then enumerated.