NELSON LABORATORIES

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

Test Article:	LOT: 20170602
Study Number:	973401-S01
Study Received Date:	27 Jun 2017
Testing Facility:	Nelson Laboratories, LLC, a Business Unit of Sterigenics International 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: 801-STP0004 Rev 14

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 - 2.7 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 F2101-14 and EN 14683:2014, 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 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 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 ~160 mm
Positive Control Average:	1.7 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.1 µm

ANAB ACCREDITED TESTING LABORATORY

Study Director Trang T. Truong, B.S.

06 Jul 2017
Study Completion Date

973401-S01

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	99.8	2.9	28.6
2	99.5	2.9	28.0
3	99.6	3.0	29.1
4	99.6	3.0	29.7
5	99.8	3.0	29.0

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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Synthetic Blood Penetration Resistance Final Report

Test Article:	LOT: 20170602
Study Number:	973403-S01
Study Received Date:	27 Jun 2017
Testing Facility:	Nelson Laboratories, LLC, a Business Unit of Sterigenics International 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: 801-STP0012 Rev 07

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 canula 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:	21.1°C and 32% 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
1-32	None Seen

Study Director Trang T. Truong, B.S.

10/11/2017
Study Completion Date

973403-S01

510(k) Premarket Notification

Device Classification Name	Mask, Surgical
510(K) Number	K182514
Device Name	Surgical Face Mask
Applicant	Xiantao Zhibo Non-Woven Products Co., Ltd NO.8 In Industrial Park, Hefeng Road Xiantao, CN 430000
Applicant Contact	Yao Sanyu
Correspondent	Shanghai Sungo Management Consulting Company Limited 4th Floor, 1500# Central Avenue Shanghai, CN 200122
Correspondent Contact	Ivy Wang
Regulation Number	878.4040
Classification Product Code	FXX
Date Received	09/12/2018
Decision Date	01/24/2019
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General & Plastic Surgery
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No