O-BRUSH

Surgical Masks ASTM Level 2

TECHNICAL DATA SHEET

CE

Description

ASTM F2100-19 - Level 2

Bacterial Filtration Efficiency (BFE) ≥ 98%
Particulate Filtration Efficiency at 0.1 micron (PFE) ≥ 98%
Differential Pressure < 6mm H_2O/cm^2
Resistance to penetration by synthetic blood – 120mm Hg
Flame Spread – Class 1

Latex Free
Single Use Only
Manufactured in China

Dimensions

Length: 17.5 cm
Width: 9.5 cm

Directions

- *Clean your hands with soap and water or hand sanitizer before touching the mask.*
- *Remove a mask from the box and make sure there are no obvious tears or holes in either side of the mask.*
- *Determine which side of the mask is the top. The side of the mask that has a stiff bendable edge is the top and is meant to mold to the shape of your nose.*
- *The colored side of the mask is the front and should face away from you, while the white side touches your face.*
- *Hold the mask by the ear loops. Place a loop around each ear.*
- *Mold or pinch the stiff edge to the shape of your nose.*
- *Pull the bottom edge over the mask to cover your chin.*

Sterilisation

These products are non-sterile.
These products cannot be sterilized.

Packaging

Shipping carton of 2000 masks.
50 masks per box and 40 boxes are placed within one carton box
Box Dimensions/Weight
52x39x30cm/ 7.5kg per carton

Regulatory Information

Product CE marked as per 93/42/EEC Directive on Medical Devices.
Class of the device: I.

Storage Information

Store in a dry and cool place, away from intense sources of heat. Keep the masks inside the box.

Shelf Life

5 years

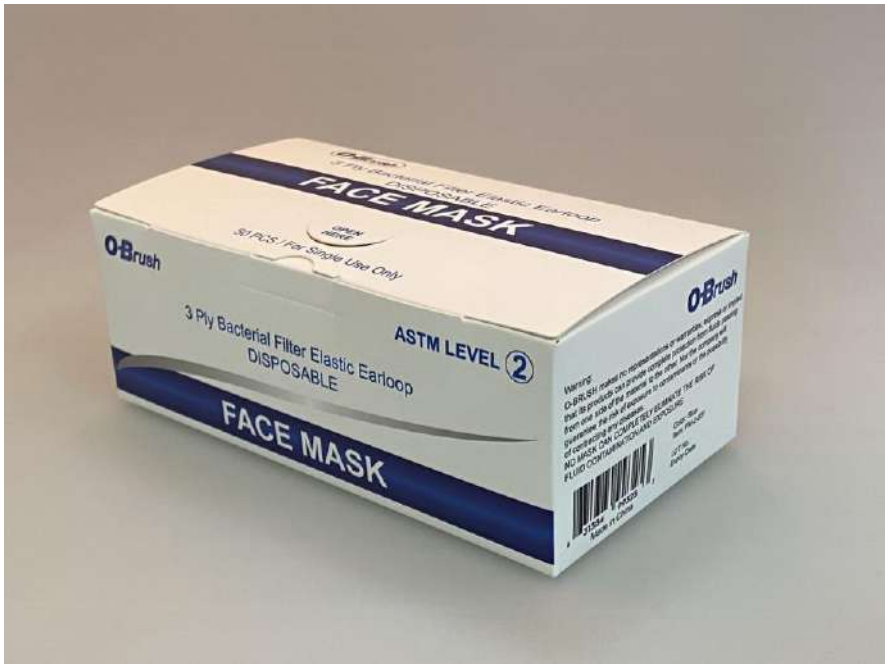
Caution

When properly worn, this mask helps reduce exposure to blood and body fluids and minimize patient contamination. This product is not a respirator and does not eliminate exposure to or the risk of contracting disease or infection. Dispose if damaged or contaminated with blood or body fluids.

The dimensions and properties listed above can vary within pre-established specifications. This document was created using the most recent information. In the interest of continuous improvement, the characteristics of the product may change without prior notice.

Images

ASTM F2100 STANDARD | *ASTM F2100 STANDARD* ESTANDARD ASTM F2100			
ASTM F2100 Test Standard	**Level 1**	**Level 2**	**Level 3**
Particle Filtration Efficiency (PFE) *Efficacité de filtration des particules (EFP)* Eficiencia de filtración de partículas	≥95%	≥98%	≥98%
Bacterial Filtration Efficiency (BFE) *Efficacité de filtration des bactéries (EFB)* Eficiencia de filtración de bacterias	≥95%	≥98%	≥98%
ΔP (mmH_2O/cm^2)	<4.0	<5.0	<5.0
Flame Spread *Classement d'inflammabilité* Clasificación de flamabilidad	Class 1	Class 1	Class 1
Resistance to penetration by synthetic blood *Résistance à la pénétration du sang synthétique* Resistencia a la penetración de sangre sintética	80 mmHg	120 mmHg	160 mmHg



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Sponsor:
[redacted]
CHINA

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

Test Article:	Surgical Face Mask, FM-34EE/MK7200 LOT #191028
Purchase Order:	[redacted]
Study Number:	
Study Received Date:	04 Dec 2019
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:	~173 mm x ~172 mm
Positive Control Average:	1.9 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.0 µm

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Curtis Dersch For Janelle R. Bentz, M.S.
Study Director

18 Dec 2019
Study Completion Date

[redacted]
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bsm

Results:

Test Article Number	Percent BFE (%)
1	99.7
2	99.6
3	99.8
4	99.8
5	>99.9

Test Article Number	Delta P (mm H_2O/cm^2)
1	4.6
2	4.4
3	5.2
4	5.0
5	4.7

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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[redacted]

Latex Particle Challenge GLP Report

Test Article:	Surgical Face Mask,FM-34EE LOT #191028
Purchase Order:	[redacted]
Study Number:	
Study Received Date:	05 Nov 2019
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):	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.

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.

Test Side:	Inside
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	21°C, 23% relative humidity (RH) at 0833; 21°C, 24% RH at 1045
Average Filtration Efficiency:	99.60%
Standard Deviation:	0.270

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Curtis Gerow
Study Director — Curtis Gerow, B.S.

13 Nov 2019
Study Completion Date

[redacted]

[redacted]

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	37	11,434	99.68
2	33	11,749	99.72
3	27	12,991	99.79
4	42	13,815	99.70
5	122	13,994	99.13

Test Method Acceptance Criteria: Ambient background particles detected through the test system must be below 1% of the challenge total (<100 particles).

Procedures:

Test Set-up: Testing was conducted in an ISO Class 5 (class 100) HEPA filtered hood. The inlet air to the test system was filtered through a 0.2 µm rated air filter. The particle generator outlet was clamped off and the number of background particles within the test system was verified to be <100 particles at 1 cubic foot per minute (CFM). The flow rate through the test system was maintained at 1 CFM ± 5%.

An aliquot of the PSL was aerosolized using a particle generator, mixed with additional filtered air, dried and passed through the test system. The particles delivered were enumerated using a laser based particle counter.

Test Procedure: A test article was placed into the holder and the system was allowed to stabilize. The average number of particles being delivered to the test article was determined (no medium in air stream) as triplicate one-minute control readings were taken prior to and after every test article. Control count averages were maintained at a level of 10,000-15,000 particles per cubic foot. Triplicate one-minute counts were recorded for the test article between the control counts.

The PFE of each test article was determined by using the following equation:

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

Where: C = Combined average of the control counts
T = Average test article counts

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[redacted]

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	11 Nov 2019
Phase Inspected by Quality Assurance: Latex Test	12 Nov 2019
Audit Results Reported to Study Director	12 Nov 2019
Audit Results Reported to Management	12 Nov 2019

Scientists	Title
Sarah Smit	Supervisor
Curtis Gerow	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Quality Assurance

15 Nov 2019
Date

Nelson Labs.
A Sotera Health company

Sponsor:
[redacted]
CHINA

Synthetic Blood Penetration Resistance Final Report

Test Article:	Surgical Face Mask,FM-34EE/MK7200 LOT #191028
Purchase Order:	[redacted]
Study Number:	
Study Received Date:	
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:	30
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	21.8°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: 120 mmHg (16.0 kPa)

Test Article Number	Synthetic Blood Penetration
1-7, 9-27, 29-32	None Seen
8, 28	Yes

Curtis Beron For
Study Director — Janelle R. Bentz, M.S.

11 Nov 2019
Study Completion Date

[redacted]