S&C IMPORTS KN95 MASKS

KEY FEATURES

01 3-ply disposable face mask

02 >95% filtration efficiency

03 Independently laboratory tested in USA

03 Packaged in sealed plastic bags to reduce packaging and freight costs

UNITED LASER

CONTACT UNITED LASER AT (888) 487-8775
to learn about product information

BENEFITS OF S&C IMPORTS KN95 MASKS

BACKGROUND

S&C Imports wanted to bring in a high quality mask to support our customers need in this unprecedented time. There is a lot of confusion surrounding the importing of masks.

FDA CONFUSION

We have seen a lot of confusion on how people interpret FDA approval on masks. Some importers and Chinese manufacturers have attempted to "skirt" the system by getting authorizations for non medical masks (such as scavenging masks) and then point to that authorization as proof they are FDA certified and that the masks are approved for medical use. This is not the case, these masks are not approved for medical use.

Here is what the EUA states about authorized face masks.

AUTHORIZED FACE MASKS

Face masks are authorized under this EUA when they are intended for use as source control, by members of the general public as well as HCPs in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of SARSCoV- 2 during the COVID-19 pandemic.

Authorized face masks must meet the following requirements:

- The product is labeled accurately to describe the product as a face mask and includes a list of the body contacting materials (which does not include any drugs or biologics)
- The product is labeled accurately so that it does not claim to be intended for use as a surgical mask or to provide liquid barrier protection
- The product labeling includes recommendations against use in a clinical setting where the infection risk level through inhalation exposure is high
- The product is not labeled as a respiratory protective device, and therefore should not be used for particulate filtration
- The product is not labeled in such a manner that would misrepresent the product's intended use; for example, the labeling must not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction
- The product is not labeled for use in high risk aerosol generating procedures

WHY S&C MASKS

- Partnered with a large respected manufacturer
- Utilized FDA specialized lawyers to insure no steps were missed.
- Partnered with a premier testing laboratory in the USA that can be independently validated.
- Secured space with freight companies to maximize imports

FDA EUA BACKGROUND

- KN95 for general use are governed under the EUA (emergency use authorization) for use temporarily.
- **The link to the FDA EUA:** www.fda.gov/media/137121/download

TESTING RESULTS

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Nelson Labs.
A Sotera Health company

Sponsor:
Frank Espinoza
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45 New Abbey Drive
Inveness, IL 60011

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

Test Article:	202003006
Purchase Order:	1979
Study Number:	1288404-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 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:	~208 mm x ~155 mm
Positive Control Average:	2.1 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

ilac-MRA ANAB ACCREDITED TESTING LABORATORY

(RWJ) for
Study Director James W. Luskin

07 May 2020
Study Completion Date

1288404-S01

TESTING RESULTS

Nelson Labs.
A Sotera Health company

Study Number 1288404-S01
Bacterial Filtration Efficiency (BFE)
and Differential Pressure (Delta P) Final Report

Results:

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

[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	4.8	47.5
2	5.0	48.8
3	5.0	49.0
4	5.2	50.7
5	5.0	48.6

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

TESTING RESULTS

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Nelson Labs.
A Sotera Health company

Sponsor:
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Synthetic Blood Penetration Resistance Final Report

Test Article:	202003006
Purchase Order:	1979
Study Number:	1288401-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 ± 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:	26
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	20.4°C and 23% 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 mmHg (10.7 kPa)

Test Article Number	Synthetic Blood Penetration
1-7, 10-14, 16-24, 27-28, 30-32	None Seen
8-9, 15, 25-26, 29	Yes

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Study Director — (RWJ) for James W. Luskin — 27 Apr 2020 Study Completion Date

1288401-S01