Certificate No.: 2020LM191108

Declaration of Conformity

Manufacturer: Lyncmed Medical Technology (Beijing) Co.,Ltd.

Room 1601, Building No.2, Zhubang 2000 Busniess Building, Balizhuang Xili 99, Chaoyang District, 100022 Beijing, PEOPLE'S REPUBLIC OF CHINA

Product : Face Mask

Class: Class I;

Standards: EN 14683:2019 Type II

Conformity assessment procedure: Annex VII

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Authorized representative:

Lyncmed technology SRL

Italy Milano(MI) Via Procaccini Giulio Cesare 32 Cap 20154

Tel: +39 3778578323

Email: tinatian@lyncmed.com

LyncMed CE

Beijing, 2020.3.23 ,General manager

Lyncmed Medical Technology (Beijing) Co.,Ltd 中国 北京

Place,date Name, function

Nelson Labs
A Sotera Health company

Sponsor:
Mavis CUI
Lyncmed Medical Technical (Beijing) Co., Ltd
Room 119, No. 1111
South Huihe Road, Chaoyang District
Beijing, 100000
CHINA

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

Test Article:	Product Name: Non-woven Face mask LOT No.: CMA4714
Study Number:	1088913-S01
Study Received Date:	23 Aug 2018
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 15
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 - 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, EN 14683:2014, Annex B, and AS4381:2015.

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 and AS4381:2015.

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:	~177 mm x ~158 mm
Positive Control Average:	2.5 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.1 µm

Janelle Bentz
Study Director — Janelle R. Bentz, M.S.

10 Sep 2018
Study Completion Date

1088913-S01

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	99.8	3.6	35.2
2	99.9	3.6	35.6
3	99.7	3.7	35.9
4	>99.9[a]	3.4	33.5
5	99.9	3.8	36.8

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

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

Nelson Labs
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Synthetic Blood Penetration Resistance Final Report

Test Article:	Product Name: Non-woven Face mask LOT #CMA4714
Study Number:	1088912-S01
Study Received Date:	23 Aug 2018
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 08
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 14683:2014 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:	18.8°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
1-18, 20-26, 28-32	None Seen
19, 27	Yes

Janelle Bentz for
Study Director — Brandon L. Williams

10 Sep 2018
Study Completion Date

1088912-S01

Nelson Labs
A Sotera Health company

Sponsor:
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Lyncmed Medical Technical (Beijing) Co., Ltd
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Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	Product Name: Non-woven Face mask LOT #CMA4714
Study Number:	1111909-S01
Study Received Date:	22 Oct 2018
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 14 Customer Specification Sheet (CSS) Number: 201805306 Rev 01
Deviation(s):	None

Summary: The testing was conducted in accordance with EN 14683:2014, 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.

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.3	<3	<3	<6.3	<1.9
2	3.3	<3	<3	<6.1	<1.8
3	3.5	<3	<3	<6.4	<1.8
4	3.5	<3	<3	<6.1	<1.7
5	3.4	<3	<3	<6.0	<1.8
Recovery Efficiency	UTD[a]				

< = No Organisms Detected
UTD = Unable to determine
Note: Sample positive testing was performed using *Bacillus atrophaeus*. The test article was not inhibitory using this test method.
Note: The results are reported as colony forming units (CFU) per mask.
[a] UTD due to zero count on the first rinse. An alternate method or inoculated product recovery efficiency is recommended.

Robert Putnam electronically approved
Study Director Robert Putnam

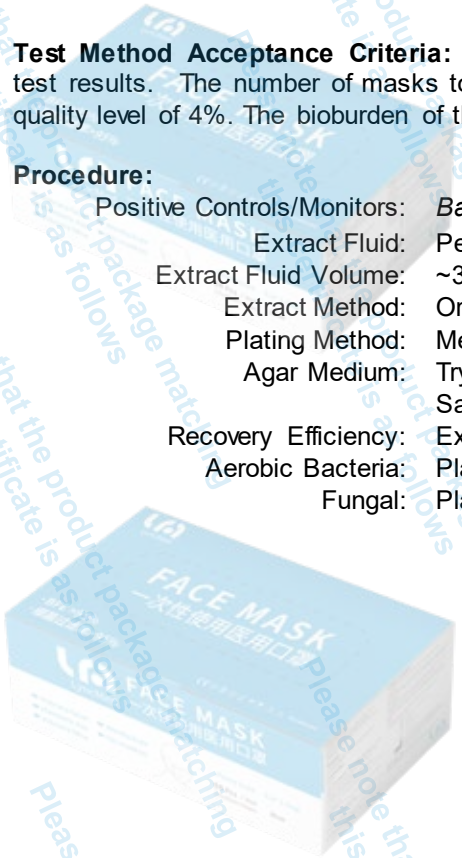
13 Nov 2018 18:39 (+00:00)
Study Completion Date and Time

801-290-7500 | nelsonlabs.com | sales@nelsonlabs.com

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® with Sodium Chloride
Extract Fluid Volume:	~300 mL
Extract Method:	Orbital Shaking for 5 minutes at 250 rpm
Plating Method:	Membrane Filtration
Agar Medium:	Tryptic Soy Agar Sabouraud Dextrose Agar with Chloramphenicol
Recovery Efficiency:	Exhaustive Rinse Method
Aerobic Bacteria:	Plates were incubated 3 days at 30-35°C, then enumerated.
Fungal:	Plates were incubated 7 days at 20-25°C, then enumerated.



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q6 099730 0004 Rev. 01

Holder of Certificate:

Lyncmed Medical Technology (Beijing) Co., Ltd.
Room 1601, Building No. 2
Zhubang 2000 Business Building, Balizhuang Xili 99
Chaoyang District
100022 Beijing
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Lyncmed Medical Technology (Beijing) Co., Ltd.
Room 1601, Building No. 2, Zhubang 2000 Business Building, Balizhuang Xili 99, Chaoyang District, 100022 Beijing, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate:

Distribution, Production and Sales of Dental high speed air turbine handpieces, Dental low speed air turbine hand-pieces, Ultrasonic Scaler, LED Curing Lights, Root Apex locators, Endo motors, Pulp tester, Portable Dental Unit, Dental Implant Systems, Dental Alginate Mixers, Sterile Surgical Gowns, Sterile Surgical Packs, Sterile Surgical Drapes, Sterile Dressing Pouches, Caps, Face mask, Shoe cover, Bed cover, Protective coverall, Urine bag, Foley Catheter, Oxygen Mask, Nebulizer Mask, Laryngeal Mask, Anaesthetic Mask, Wheelchair, Walker, Crutch.

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ19205031
Valid from: 2020-03-19
Valid until: 2020-12-19

Date, 2020-03-19

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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