Lyncmed Product Profile

Glocal Linker, Healthcare Better; Dream Maker, Win Together >>>

LyncMed

Disposable Face Mask
Product Profile

KA International Business Dept

Lyncmed Medical Group

Face Mask Packing & Artwork

New Box Design Artwork

Previous LM Face Mask Box Picture

Face Mask Carton Design Artwork

Face Mask Carton Design Artwork

Face Mask Certificates –EN14683 BEF Test Report

Nelson Labs.
A Sotera Health company

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

Nelson Labs.
A Sotera Health company

Results:

Test Article Number	Percent BFE (%)	Delta P (mmH2O/cm²)	Delta P (kPa/cm²)
1	99.6	3.6	35.3
2	99.6	3.6	35.6
3	99.7	3.7	36.9
4	>99.9*	3.4	33.5
5	99.6	3.6	35.9

* 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.

Lyncmed Company Certificate

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

Lyncmed Medical Technology
(Beijing) Co., Ltd.
Room 119, Floor 1
GUOTOUSHANGKE Building
No. 1111, South Huihe Road
ChaoYang District
100022 Beijing
China

Manufacture and Distribution of Medical Devices
(see attachment for products included)

EN ISO 13485:2016

Effective Date: 2018-12-04
Certificate Registration No.: SX 60133386 0001
An audit was performed, Report No.: 501801/80 002
This Certificate is valid until: 2021-12-03

Certification Body

Herbert Zhong

Date: 2018-12-04

TÜV Rheinland LGA Products GmbH · Tillystraße 2 · 90431 Nürnberg

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60133386 0001
Report No.: 501801/80 002

Organization: Lyncmed Medical Technology (Beijing) Co., Ltd.
Room 119, Floor 1
GUOTOUSHANGKE Building
No. 1111, South Huihe Road
ChaoYang District
100022 Beijing
China

Scope:

Products:

Sterile Latex Surgical Gloves, Non-sterile Examination Latex gloves, Dental High Speed Air Turbine Handpiece, Dental Low Speed Air Turbine Handpiece, Patient Examination Gloves, Ultrasonic Scaler, Endo motor, Apex Locator, Pulp tester, Mask, Laryngeal Mask Airway, Overall, Isolation Gown, Sterile Surgical Gowns, Sterile Surgical Kits, Sterile Surgical Caps, Sterile face masks, Sterile Shoe covers, Alcohol Swabs, Diapers and Adult Diapers, Disposable Under Pad, Medical Tape, Urine bag for Single Use, Foley Catheter Silicone, Dental Alginate Mixers, Vinyl Examination Gloves, Sterile Gauze Sponges

Certification Body

Herbert Zhong

Date: 2018-12-04

ISO-13485 Certificate

3 Layer Non-woven Disposable Face Mask

Disposable Face Mask Key Features:

-Skin Friendly High Quality PP Material, 3-Ply

-Low Breathing Resistance, Bacterial Filtration Efficiency(BEF)>98%

-Ear Loop, Elastic Band, Latex Free

-Anatomic Adjustable Integrated nose bridge

-Size:17.5*9.5cm

Face Mask CE Certificate

EC DECLARATION OF CONFORMITY

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

Room 110, No.1111 South Huihe Rd, Chaoyang District 100022 Beijing, China

whose single Authorized Representative: SUNSO Certification Company Limited

HM101, MAPLE HOUSE, 118 HIGH STREET, PURLEY, LONDON, ENGLAND

We declare under our sole responsibility that :

the medical device: -Non-woven products:Surgical gowns, Surgical drapes, Surgical patchs, Pouches,Caps,Coveralls,Facemasks,Suits,Underpad,Gloves, Towels,Wipes, Sheets, Packs, Mice covers, Aprons, Gowns, Trousers,Sleeve covers, Pillow covers, Board covers, Bags,Bibs, Rolls,Briefs, Hair bands; -Disposable PE products:Shoe covers, Tray covers, Pouches, Caps, Gloves, Aprons, Gowns, Sleeve covers, Bags, Sheets, Pillow case, Pallet covers, Bibs; -Disposable Vinyl examination gloves -Disposable Nitrile examination gloves -Disposable Latex examination gloves -Urine Cup for single use -Urine Bag for single use

(Name, type or model, batch or serial number, possibly purpose and number of items)

of class: Class I

according to annex IX of Council 93/42/EEC

meets all the provisions of the directive 93/42/EEC (or 90/385/EEC) which apply to it.

Conformity assessment procedure: 93/42/EEC, Annex V

The above mentioned declaration of conformity is exclusively under the responsibility of: Lynxmed Medical Technology(Beijing) Co., Ltd.

Place , date: Beijing 20th Dec. 2017

Wang Peng, Management Representative

Legally binding signature / function

EC Declaration of Conformity

CE Certificate

Face Mask Certificates –EN14683 SBPR & EN14683 Blood Penetration Resistance Report

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

Synthetic Blood Penetration Resistance Final Report

Test Article: Product Name: Non-woven Face mask
LOT #C844714
Study Number: 108912-001
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 n2/n 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

Study Director: Brandon L. Williams
Study Completion Date:

108912-001

NELSON LABORATORIES

Sponsor
Donna Dong
LyncMed Group
No. 1111, South Huihe Road,
100025, Beijing CHINA

EN 14683:2005 Synthetic Blood
Penetration Resistance Final Report

Test Article: Non-woven Facemask
Laboratory Number: 735514
Study Received Date: 27 Jan 2016
Test Procedure(s): Standard Test Protocol (STP) Number STP0012 Rev 05

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 material 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. This test method was designed to comply with ASTM F1862 and EN 14683:2005. All test method acceptance criteria were met.

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: 22.5°C and 21% RH

Study Director: Brandon L. Williams
Study Completion Date:

Face Mask Certificates –EN14683 MC Test Report

Nelson Labs.
A Sotera Health company

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

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article: Product Name: Non-woven Face mask
LOT #CB64714
Study Number: 1088914-S01
Study Received Date: 23 Aug 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: STP0036 Rev 14
Customer Specification Sheet (CSS) Number: 20160036 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	3.2	88	12*	99.7	31.1
2	3.3	49	3*	51.5	15.7
3	3.3	33	3*	35.0	10.9
4	3.4	51	<2	54.2	15.9
5	3.4	69	9*	77.5	22.9
Recovery Efficiency			69.7%		

< = No Organisms Detected
Note: The results are reported as colony forming units (CFU) per mask.
Note: Sample positive testing was performed using *Bacillus atrophaeus*. The test article was not inhibitory using this test method.
* Spreader: Count is considered a minimum estimate due to swarming of certain colonies on the membrane.

Study Director: Robert J. Putnam, B.S. — Study Completion Date: 14SEP2019

Study Number 1088914-S01
Microbial Cleanliness (Bioburden) of Medical Masks Final Report

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 23-28°C, then enumerated.