Document Title	DOC-002
Revision Date	28/04/20
Page	1

CE DECLARATION OF CONFORMITY

Product Family Name: Surgical Face Masks

Device Name, Part Number: Single Use, Type IIR Surgical Face Mask, REF SP
Single Use, Type IIR Surgical Face Mask, REF SP01
Single Use, Type IIR Surgical Face Mask, REF SP02

GMDN Code: 35177 Surgical Face Mask, Single-Use
UMDNS Code: 12458 Masks, Surgical

Applicable Council Directives: Medical Device Directive 93/42/EEC amended by 2007/47/EC

Risk Classification: Class I, Non-Sterile (Rule 1, MDD Annex IX)

Harmonized Standards to which conformity is declared:

Safety/Efficacy:	BS EN 14683:2019
Medical Device QMS:	EN ISO 13485:2016

Manufacturer: Spro Medical Products (Xiamen) Co., Ltd
139 Factory Building, Tongan Garden, Tongan Industrial Area
Tongan, Xiamen, 361100
P.R. China

Authorized Representative in the UK: Element Packaging LTD
Tallis House, 2 Tallis Street
London, EC4Y 0AB, United Kingdom

Notified Body: SGS United Kingdom Ltd (N.B. No. 0120)
Unit 202B, Worle Parkway, Weston-super-Mare,
Somerset, BS22 6WA, United Kingdom

This Device Family has been assessed with respect to the conformity assessment procedures described in Annex II excluding section 7 of Council Directive 93/42/EEC, as amended, and found to comply.

We declare, under our sole responsibility, that the above-mentioned products conform to the specified Directives and Standards and is eligible to carry the CE Mark. The Device History File is retained at the premises of the Manufacturer and its Authorized Representative.

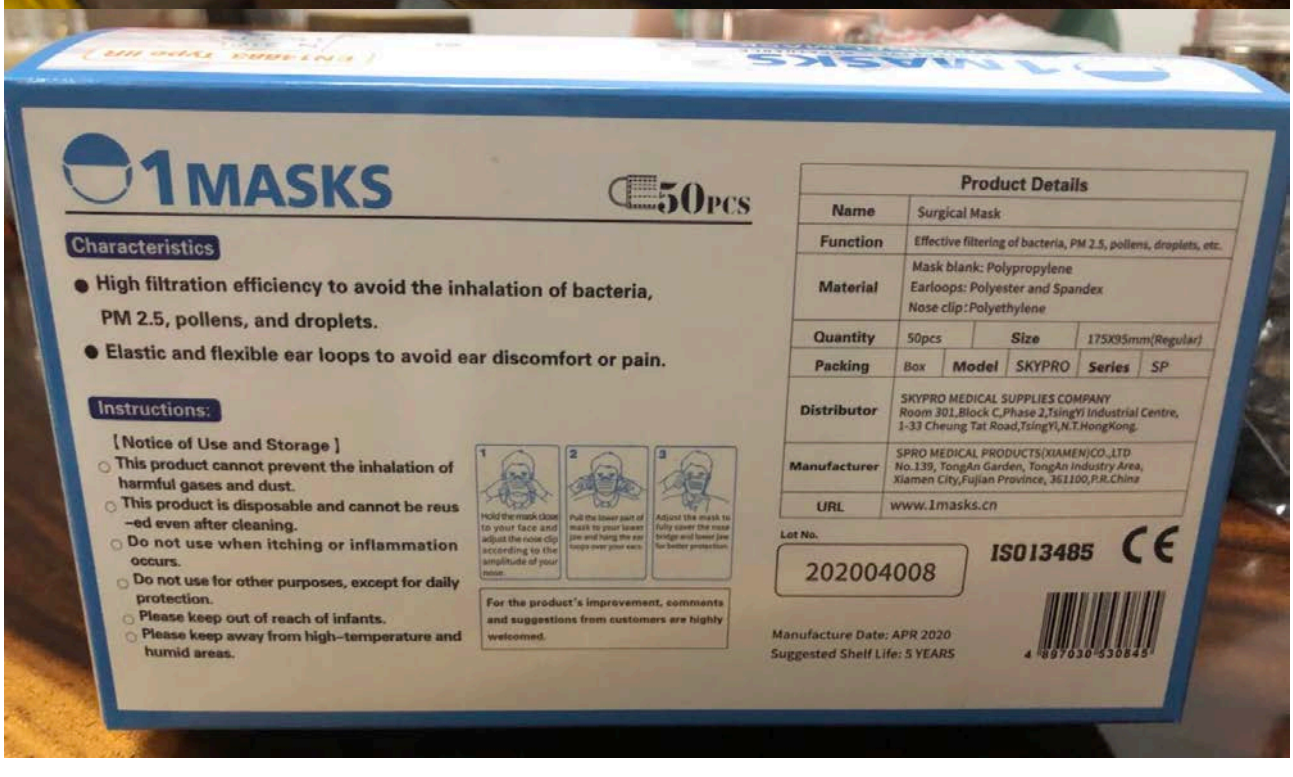
Signature of Authorized Person:

Name:
Head Quality & Regulatory Affairs/
Management Representative
Spro Medical Products (Xiamen) Co., Ltd

7th May 2020
Date Signed


TESTED BY NELSON LABS
1MASKS
SAFE · RELIABLE · PROTECTIVE · BREATHABLE
SURGICAL MASK
EFFECTIVE PM 2.5 FILTER
EN14683 Type IIR
3 PLY
BFE 99%
PFE 99%
VFE 99%
COMFORT EARLOOP
FACE FITTING
TESTED BY NELSON LABS
50PCS
CLASSIC


1MASKS
SAFE · RELIABLE · PROTECTIVE · BREATHABLE
SURGICAL MASK
EFFECTIVE PM 2.5 FILTER
EN14683 Type IIR
BFE 99%
PFE 99%
VFE 99%
TESTED BY NELSON LABS
THANK YOU FOR SELECTING


1MASKS
50PCS
Characteristics
● High filtration efficiency to avoid the inhalation of bacteria, PM 2.5, pollens, and droplets.
● Elastic and flexible ear loops to avoid ear discomfort or pain.
Instructions:
【Notice of Use and Storage】
○ This product cannot prevent the inhalation of harmful gases and dust.
○ This product is disposable and cannot be reus-ed even after cleaning.
○ Do not use when itching or inflammation occurs.
○ Do not use for other purposes, except for daily protection.
○ Please keep out of reach of infants.
○ Please keep away from high-temperature and humid areas.
For the product's improvement, comments and suggestions from customers are highly welcomed.
Product Details
Name: Surgical Mask
Function: Effective filtering of bacteria, PM 2.5, pollens, droplets, etc.
Material: Mask blank: Polypropylene; Earloops: Polyester and Spandex; Nose clip: Polyethylene
Quantity: 50pcs
Size: 175X95mm(Regular)
Packing: Box
Model: SKYPRO
Series: SP
Distributor: SKYPRO MEDICAL SUPPLIES COMPANY Room 301,Block C,Phase 2,TsingYi Industrial Centre, 1-33 Cheung Tat Road,TsingYi,N.T.HongKong.
Manufacturer: SPRO MEDICAL PRODUCTS(XIAMEN)CO.,LTD No.139, TongAn Garden, TongAn Industry Area, Xiamen City,Fujian Province, 361100,P.R.China
URL: www.1masks.cn
Lot No.
202004008
ISO13485
CE
Manufacture Date: APR 2020
Suggested Shelf Life: 5 YEARS

Statement of Compliance

This is to state that Technical Documentation (SPRO-TF01, SPRO-TF02, SPRO-TF03, SPRO-TF04, SPRO-TF05) for Product(s)

No-sterile single use Surgical Mask, No-sterile single use Coverall, No-sterile single use Shoe Cover, No-sterile single use Surgical Cap and No-sterile single use Surgical Bed Sheet
(Class I not sterile or measuring via Annex IX Rule I)

Manufactured by

SPRO Medical Products (Xiamen) Co., Ltd.

West of 1-5th Floor, No.139 Factory Bldg, TongAn Garden, TongAn Industry Area, Xiamen, 361000, China

Has been assessed as meeting the Essential Requirements and relevant provisions of EC Directive 93/42/EEC as amended by 2007/47 for Medical Devices

Date of review: May 23, 2015
Reference No: CN/XMN6395

For SGS-CSTC Standards Technical Services Co., Ltd.
System & Services Certification Division

CE

While all due care and skill was exercised in carrying out this assessment, SGS-CSTC accepts responsibility only for proven gross negligence. This certificate relates only to the medical device as described in the technical file reviewed on the date shown. Conformance to all the regulatory requirements is the sole responsibility of the manufacturer including the manufacture and quality control of the products. This is not a legal document and cannot be used as such. This certificate remains the property of SGS-CSTC Standards Technical Services Co., Ltd. to whom it must be returned on request.

SGS-CSTC Standards Technical Services Co., Ltd. Shenzhen Branch
Bldg, No. 4 , Jianghao Industrial Park, No. 430 ,Jihua Road, Bantian , Longgang District ,
Shenzhen, CHINA 518129

Certificate CN15/30182

The management system of

SPRO Medical Products (Xiamen) Co., Ltd.

West of 1-5th Floor, No.139 Factory Bldg, Tong'an Garden, Tong'an Industry Area,
Xiamen City, Fujian Province, 361000, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Manufacture of non-sterile Examination glove, sterile and non-sterile Coverall, sterile and non-sterile surgical face mask, sterile and non-sterile Surgical cap, sterile and non-sterile Alcohol pad, sterile and non-sterile Shoe cover, sterile and non-sterile Surgical gown, sterile and non-sterile Non woven sponge, sterile Surgical glove, Sterile Surgical kits, Non-sterile Disposable isolation gown, Sterile and non-sterile Cotton tipped applicators, Sterile and Non-sterile Gauze swab, Sterile nursing kit, Sterile examination glove, Medical adhesive tape and Sterile suction kit

This certificate is valid from 09 July 2019 until 28 January 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 24 May 2020
Issue 5. Certified since 28 January 2015

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

Nelson Labs
A Sotera Health company

Sponsor:
Cyrus Wong
Skypro Medical Supplies Company
Workshop C301-303, 3/F, BLK C
Tsing YI
Industrial Centre Phase 2, 1-33
Cheung T
Tsing YI, NT Hong Kong, CN 999077
CHINA

Spro Medical Products
(Xiamen) Company Limited
139 Factory Building
Tongan Garden,
Tongan Industrial Area,
Tongan, Xiamen, 361100
CHINA

Synthetic Blood Penetration Resistance GLP Report

Test Article:	Skypro, SP02 Mask
Study Number:	1279089-S01.1 Amended
Study Received Date:	20 Mar 2020
Study Completion Date:	10 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.

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:	20.1°C and 22% RH

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Study Director James W. Luskin

17 Apr 2020
Amended Report Date

1279089-S01

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

Test Method Acceptance Criteria: The output of synthetic blood passing through the targeting hole before and after every set of test articles must be ≤5% (±0.10 g) in difference from the theoretical output of 2 mL.

Procedure: A clean cannula was fixed onto the front of the valve and the reservoir was filled with synthetic blood. The reservoir pressure and timer were set to allow a differential weight of 95-102%. This was achieved by setting the valve timer to 0.5 seconds and 1.5 seconds, collecting and weighing the amount of fluid before and after the targeting hole, and then calculating the weight differences for the deliveries. After the reservoir pressure and timer duration had been adjusted, the 2 mL spray was verified by dispensing three spurts in a row through the targeting hole into a graduated cylinder and weighing. After every 16 test articles, synthetic blood was delivered into a graduated cylinder and weighed to ensure the test apparatus was still delivering 2 mL of synthetic blood.

Each test article was tested within one minute of removal from the conditioning chamber. The facemask was mounted on the test article(s) holding fixture and positioned 305 mm (12 in) from the cannula. The mask was then subjected to the 2 mL volume spray, which moved from the cannula in a horizontal path perpendicular to the facemask. This procedure used a targeting hole that blocked the initial, high-pressure portion of the synthetic blood stream and allowed only the fluid traveling at the target velocity to hit the center of the mask. Each test article was observed for penetration within 10 seconds of dispensing the synthetic blood against the target area.

Amendment Justification: To reflect the sponsor's original request, the manufacturer's information for Spro Medical Products was added to the top of the report.

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	02 Apr 2020
Phase Inspected by Quality Assurance: Sample Preparation / Conditioning	07 Apr 2020
Audit Results Reported to Study Director	09 Apr 2020
Audit Results Reported to Management	09 Apr 2020

Scientists	Title
Sarah Smit	Supervisor
James Luskin	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.

Camille Coffey
Quality Assurance

17 Apr 2020
Date

Nelson Labs
A Sotera Health company

Manufacturer:
Spro Medical Products
(Xiamen) Company Limited
139 Factory Building,
Tongan Garden,
Tongan Industrial Area
Tongan, Xiamen, 361100
CHINA

Sponsor:
Skypro Medical Supplies Company
Workshop C301-303, 3/F, BLK C
Tsing YI
Industrial Centre Phase 2, 1-33
Tsing YI, NT Hong Kong, CN 999077
CHINA

Flammability of Clothing Textiles GLP Report

Test Article:	Skypro, SP02 Mask
Study Number:	1279092-S01
Study Received Date:	20 Mar 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: STP0073 Rev 06
Deviation(s):	None

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state*. Step 2 - *Refurbishing and testing after refurbishing*, was not performed. All test method acceptance criteria were met.

Test Article Side Tested: Outside Surface
Orientation: Machine

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≥3.5 seconds
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

The 16 CFR Part 1610 standard specifies that 10 replicates are to be tested if, during preliminary testing, only 1 test article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an average flame spread less than 3.5 seconds. Five replicates are to be tested if no flame spread is observed upon preliminary testing, if only 1 test article exhibits flame spread and it is equal to or greater than 3.5 seconds, or if the average flame spread is equal to or greater than 3.5 seconds. In accordance with the standard, 5 replicates were tested for this study.

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

13 Apr 2020
Study Completion Date

1279092-S01

Results:

Replicate Number	Time of Flame Spread
1	IBE
2	IBE
3	IBE
4	IBE
5	IBE

IBE = Test Article ignited, but extinguished

Test Method Acceptance Criteria: Flame length must be approximately 16 mm (~⅝ in) from the flame tip to the opening in the gas nozzle.

Procedure: Test articles were prepared by cutting the material into approximately 50 x 150 mm swatches. Preliminary testing to establish the orientation and side of the test article to test was performed. The side and orientation that burned the fastest was used to test the test articles. Each test article was clamped into the specimen holder and placed in an oven maintained at 105 ± 3°C for 30 ± 2 minutes. The test articles were then placed in a desiccator for a minimum of 15 minutes prior to testing.

The flame length of the flammability tester was adjusted to approximately 16 mm prior to testing. Test articles were placed on the flammability rack and the stop cord was strung through the guides. The flammability timer was zeroed and testing was started. When the flame reached the stop cord, the timer stopped, and the results were recorded. Testing was terminated for test articles that did not exhibit flame spread beyond the initial application of the flame.

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	01 Apr 2020
Phase Inspected by Quality Assurance: Flammability Test	08 Apr 2020
Audit Results Reported to Study Director	08 Apr 2020
Audit Results Reported to Management	08 Apr 2020

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

14 Apr 2020
Date

Nelson Labs
A Sotera Health company

Sponsor:
Skypro Medical Supplies Company
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NT Hong Kong, CN 999077
CHINA

Spro Medical Products
(Xiamen) Company Ltd
139 Factory Building
Tongan Garden
Tongan Industrial Area
Tongan, Xiamen
361100
CHINA

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

Test Article:	Skypro, SP02 Mask
Study Number:	1279095-S01
Study Received Date:	20 Mar 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.

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 ~165 mm
Positive Control Average:	2.7 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.8 µm

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Study Director James W. Luskin

24 APR 2020
Study Completion Date

1279095-S01

Results:

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

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	5.9	57.7
2	5.4	52.6
3	5.5	53.7
4	5.8	56.6
5	5.5	54.3

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

Test Article Preparation: The test articles were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% RH, prior to BFE and Delta P testing.

Test Method Acceptance Criteria: The BFE positive control average shall be maintained at 1.7 – 3.0 x 10^3 CFU.

The MPS control average of the challenge aerosol shall be maintained at 3.0 ± 0.3 µm.

The Delta P test flow rate shall be maintained at 8 L/min throughout the testing.

Procedure:

BFE: A culture of *S. aureus*, ATCC #6538, was diluted in peptone water (PEPW) to yield challenge level counts of 1.7 – 3.0 x 10^3 CFU per test article. The bacterial culture suspension was pumped through a nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery, at a fixed air pressure, formed aerosol droplets with a MPS of approximately 3.0 µm. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. Test articles, positive controls, and reference material received a one minute challenge followed by a one minute vacuum cycle.

The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six soybean casein digest agar (SCDA) plates based on the size of each droplet. The agar plates were incubated at 37 ± 2°C for 48 ± 4 hours and the colonies formed by the bacteria laden aerosol droplets were then counted and converted to probable hit values using the positive hole conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test articles. The distribution ratio of the colonies on each of the six agar plates was used to calculate the MPS of the challenge aerosol.

Delta P: The Delta P test simply measured the differential air pressure on either side of the test article using an incline, "U" tube, or digital manometer. Testing was conducted at a flow rate of 8 L/min (volumetric). At least one reference material is included with each set of test articles.

The Delta P values were reported in mm water/cm^2 and Pa/cm^2 of test area and calculated using the following equation:

$$Delta\ P = \frac{\bar{M}}{A}$$

Where: $\bar{M}$ = Average mm of water of the test replicates per test article
A = Area of the test article holder (cm^2)

The test article holder used in the Delta P test has a test area of 4.9 cm^2.

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	02 Apr 2020
Phase Inspected by Quality Assurance: BFE Challenge Procedure	09 Apr 2020
Audit Results Reported to Study Director	21 Apr 2020
Audit Results Reported to Management	22 Apr 2020

Scientists	Title
Sarah Smit	Supervisor
James Luskin	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.

E [illegible]
Quality Assurance

24 Apr 2020
Date

Nelson Labs
A Sotera Health company

Sponsor:
Cyrus Wong
Skypro Medical Supplies Company
Workshop C301-303, 3/F Blk C Tsing Yi Industrial Centre Phase 2,
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Spro Medical Products (Xiamen) Co., Ltd
139 Factory Bldg.
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CHINA

MEM Elution GLP Report

Test Article:	Skypro, SP02 masks
Study Number:	1279101-S01.1 Amended
Study Received Date:	20 Mar 2020
Study Completion Date:	06 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: STP0032 Rev 10
Deviation(s):	None

Summary: The Minimal Essential Media (MEM) Elution test was designed to determine the cytotoxicity of extractable substances. An extract of the test article was added to cell monolayers and incubated. The cell monolayers were examined and scored based on the degree of cellular destruction. All test method acceptance criteria were met.

Results:

Test Article:

Results Pass/Fail	Scores				Extraction Ratio	Amount Tested / Extraction Solvent Amount
	#1	#2	#3	Average		
Pass	1	1	1	1	3 cm^2/mL	606.1 cm^2 / 202 mL

Note: An additional 7 mL of media was added to account for absorbency.

Controls:

Identification	Scores				Extraction Ratio	Amount Tested / Extraction Solvent Amount
	#1	#2	#3	Average		
Negative Control - Polypropylene Pellets	0	0	0	0	0.2 g/mL	4 g / 20 mL
Media Control	0	0	0	0	N/A	20 mL
Positive Control - Latex Natural Rubber	4	4	4	4	0.2 g/mL	4 g / 20 mL

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Danielle Short electronically approved — 15 Apr 2020 15:04 (+00:00)
Study Director Danielle Short — Amended Report Date and Time

Test Method Acceptance Criteria: The United States Pharmacopeia & National Formulary (USP <87>) states that the test article meets the requirements, or receives a passing score (**Pass**) if the reactivity grade is not greater than grade 2 or a mild reactivity. The ANSI/AAMI/ISO 10993-5 standard states that the achievement of a numerical grade greater than 2 is considered a cytotoxic effect, or a failing score (**Fail**).

Nelson Laboratories acceptance criteria was based upon the negative and media controls receiving "0" reactivity grades and positive controls receiving a 3-4 reactivity grades (moderate to severe). The test was considered valid as the control results were within acceptable parameters.

The cell monolayers were examined microscopically. The wells were scored as to the degree of discernable morphological cytotoxicity on a relative scale of 0 to 4:

Conditions of All Cultures	Reactivity	Grade
No cell lysis, intracytoplasmic granules.	None	0
Less than or equal to 20% rounding, occasional lysed cells.	Slight	1
Greater than 20% to less than or equal to 50% rounding, no extensive cell lysis.	Mild	2
Greater than 50% to less than 70% rounding and lysed cells.	Moderate	3
Nearly complete destruction of the cell layers.	Severe	4

The results from the three wells were averaged to give a final cytotoxicity score.

Procedure: The amount of test material extracted was based on ANSI/AAMI/ISO and USP surface area or weight recommendations. Test articles and controls were extracted in 1X Minimal Essential Media with 5% bovine serum for 24-25 hours at 37 ± 1°C with agitation. Multiple well cell culture plates were seeded with a verified quantity of industry standard L-929 cells (ATCC CCL-1) and incubated until approximately 80% confluent. The test extracts were held at room temperature for less than four hours before testing. The extract fluids were not filtered, centrifuged or manipulated in any way following the extraction process. The test extracts were added to the cell monolayers in triplicate. The cells were incubated at 37 ± 1°C with 5 ± 1% CO_2 for 48 ± 3 hours.

Pre and Post Extract Appearance		
Test Article	Pre extract	Clear with no particulates present
	Post extract	Clear with no particulates present No color change noted
Controls	Pre extract	Clear with no particulates present
	Post extract	Clear with no particulates present No color change noted

Amendment Justification: To reflect the sponsor's original request, the sponsor's address was corrected and the manufacturer's information for Spro Medical Products was added to the top of the report. Additionally, the study number was updated from "1279101" to "1279101-S01" to reflect the correct study number.

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	25 Mar 2020
Phase Inspected by Quality Assurance: Interpretation	02 Apr 2020
Audit Results Reported to Study Director	02 Apr 2020
Audit Results Reported to Management	03 Apr 2020

Scientists	Title
Chad Summers	Supervisor
Danielle Short	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.

Megan Still electronically approved
Quality Assurance

14 Apr 2020 23:35 (+00:00)
Date and Time

Nelson Labs
A Sotera Health company

Sponsor:
Cyrus Wong
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CHINA

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139 Factory Building.
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CHINA

Microbial Cleanliness (Bioburden) of Medical Masks GLP Report

Test Article:	Skypro, SP02 Mask
Study Number:	1279094-S01
Study Received Date:	20 Mar 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: STP0036 Rev 15 Customer Specification Sheet (CSS) Number: 202001675 Rev 01
Deviation(s):	None

Summary: The testing was conducted in accordance with EN 14683:2019, 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.

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.3	6	<3	<9.2	<2.8
2	3.3	<3	<3	<6.1	<1.8
3	3.4	<3	<3	<6.2	<1.8
4	3.3	<3	<3	<6.1	<1.9
5	3.3	<3	<3	<6.1	<1.9
Recovery Efficiency	UTD[a]				

< = No Organisms Detected
UTD = Unable to Determine
Note: The results are reported as colony forming units per test article.
[a] UTD due to zero count on the first rinse. An alternative method or inoculated product recovery efficiency is recommended.

Robert Putnam electronically approved — 16 Apr 2020 18:10 (+00:00)
Study Director — Robert Putnam — Study Completion Date and Time

Method Suitability:

Organism	Percentage
Bacillus atrophaeus	90%

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®
Extract Fluid Volume:	~300 mL
Extract Method:	Orbital Shaking for 15 minutes at 250 rpm
Plating Method:	Membrane Filtration
Agar Medium:	Potato Dextrose Agar Tryptic Soy Agar
Recovery Efficiency:	Exhaustive Rinse Method
Aerobic Bacteria:	Plates were incubated 3 - 7 days at 30-35°C, then enumerated.
Fungal:	Plates were incubated 5 - 7 days at 20-25°C, then enumerated.

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	26 Mar 2020
Phase Inspected by Quality Assurance: Aerobic Counting	03 Apr 2020
Audit Results Reported to Study Director	09 Apr 2020
Audit Results Reported to Management	09 Apr 2020

Scientists	Title
Carl A. Danielson	Supervisor
Robert Putnam	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.

Loxane Konesavanh electronically approved
Quality Assurance

16 Apr 2020 18:06 (+00:00)
Date and Time