# Masques chirurgicaux 3 plis
## avec élastiques auriculaires

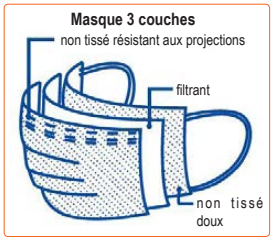
**Cat. I**

**EN 14683 Type IIR**

certification
**DM 93/42/CE**

- masques 3 couches 175 x 95 mm
- revêtement intérieur en tissu non tissé doux et conformable, coloris blanc
- couche filtrante haute densité
- revêtement extérieur en tissu non tissé résistant aux projections, coloris bleu
- attache par 2 bandes auriculaires en nylon élastique
- clip de nez : bande métallique 100 mm, entièrement enfermée, réglable facilement
- filtration bactérienne ≥ 98%
- résistance à la traction entre la bande et le corps du masque ≥ 10N
- minimisent la contamination causée par les micro-organismes expirés et réduisent l'exposition potentielle du porteur aux fluides corporels
- en boîte distributrice de 50






| référence | Prix HT |
|---|---|
| **RU1080** Masques médicaux 3 plis, type IIR, BFE 98%, les 50 | |

TÜVRheinland®

# EC Certificate

## Directive 93/42/EEC Annex V
## Production Quality Assurance
## Medical Devices

**Registration No.:** DD 60111758 0001

**Report No.:** 15095978 001

**Manufacturer:**
Sunsmed Protective Products Ltd.
No. 18, Industrial Park, Maozui Town
Xiantao City
433000 Hubei
China

**Products:**
Aspects of manufacture concerned with securing and maintaining sterile conditions:
Sterile Surgical Caps, Sterile Surgical Face Masks, Sterile Surgical Gowns, Sterile Bed Protections, Sterile Surgical Drapes, Sterile Surgical Packs

**Expiry Date:** 2021-08-11

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Notified Body

**Effective Date:** 2016-08-12

**Date:** 2016-08-12

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Nelson Labs
A Sotera Health company

Sponsor:
Joyce Lee
Sunsmed Protective Products Ltd.
Industrial Park, Maozui Town
Xiantao City
Hubei Province, 433000
CHINA

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

| | |
|---|---|
| Test Article: | Surgical Face Mask |
| Purchase Order: | SHLAB2003160001A |
| Study Number: | 1277685-S01 |
| Study Received Date: | 16 Mar 2020 |
| Testing Facility: | Nelson Laboratories, LLC<br>6280 S. Redwood Rd.<br>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 Liters per minute (L/min) |
| Conditioning Parameters: | 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours |
| Test Article Dimensions: | ~175 mm x ~150 mm |
| Positive Control Average: | 2.0 x $10^3$ CFU |
| Negative Monitor Count: | <1 CFU |
| MPS: | 3.2 µm |

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Study Director James W. Luskin

23 MAR 2020
Study Completion Date

1277685-S01

**Results:**

| Test Article Number | Percent BFE (%) |
|---|---|
| 1 | 99.8 |
| 2 | >99.9 |
| 3 | >99.9[a] |
| 4 | 99.9 |
| 5 | >99.9 |

[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 | 3.8 | 37.5 |
| 2 | 4.0 | 39.5 |
| 3 | 4.1 | 40.0 |
| 4 | 4.2 | 40.9 |
| 5 | 4.1 | 40.2 |

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

Nelson Labs.
A Sotera Health company

Sponsor:
Joyce Lee
Sunsmed Protective Products Ltd.
Industrial Park, Maozui Town,
Xiantao City, 433000
Hubei Province,
CHINA

# Synthetic Blood Penetration Resistance Final Report

| | |
|---|---|
| Test Article: | Surgical Face Mask |
| Purchase Order: | SHLAB2003160001A |
| Study Number: | 1277684-S01 |
| Study Received Date: | 16 Mar 2020 |
| Testing Facility: | Nelson Laboratories, LLC<br>6280 S. Redwood Rd.<br>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: | 29 |
| Test Side: | Outside |
| Pre-Conditioning: | Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH) |
| Test Conditions: | 22°C and 22% RH |

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Study Director James W. Luskin

23 Mar 2020
Study Completion Date

1277684-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: 160 mmHg (21.3 kPa)

| Test Article Number | Synthetic Blood Penetration |
|---|---|
| 1-8, 10-13, 15-27, 29-32 | None Seen |
| 9, 14, 28 | Yes |

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## Certificate No. 60111758

| | |
|---|---|
| **Certificate Number:** | 60111758 |
| **Certificate Holder:** | **Sunsmed Protective Products Ltd.**<br>No. 18, Industrial Park, Maozui Tow<br>Xiantao City<br>433000 Hubei<br>China (Mainland) |
| **Scope:** | Aspects of manufacture concerned with securing and maintaining sterile conditions:<br>Sterile Surgical Caps, Sterile Surgical Face Masks, Sterile Surgical Drapes, Sterile Surgical Packs<br>Sterile Surgical Gowns, Sterile Bed Protections, |
| **Fulfilled Standards:** | Richtlinie 93/42/EWG |
| **Certificate Type:** | QMS Produktion, Anhang V MDD<br>The Notified Body authorizes the quality management System established and applied by the Company mentioned in the certificate. The requirements of Annex V, Article 3 of the EC directive 93/42/EEC, referred to as the Medical Device Directive (MDD), have been met. This approval is subject to periodic surveillance, defined in Annex V, Article 4 of the aforementioned EC-Directive, and can be used by the Company with the manufacturer's declaration of conformity. |