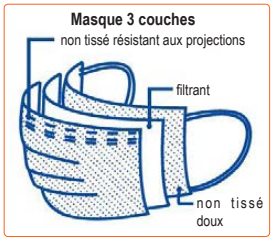
Masques chirurgicaux 3 plis
avec élastiques auriculaires

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 confortable, 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
MA5010 Masques médicaux 3 plis, type IIR, BFE 98%, les 50	

ansm
Agence nationale de sécurité du médicament et des produits de santé

Saint-Denis, le 18 FEV. 2015

Direction de l'inspection
Pôle inspection en surveillance du marché
Personne chargée du dossier : Sandrine HALL
Tél. : +33 (0)1 55 87 37 33
Fax : +33 (0)1 55 87 40 52
E-mail : sandrine.hall@ansm.sante.fr

N/Réf. : 15 DDM 038

Labo Moderne
Monsieur Alain REFET
37 rue Dombasle
75015 PARIS

Objet : Recevabilité de déclaration d'activité
Référence à rappeler : 2014-DI-1404

Monsieur,

Vous avez adressé à l'ANSM en date du 4 Novembre 2014 votre déclaration d'activité, en application de l'article L. 5211-3-1 du code de la santé publique, à l'aide du formulaire mis à votre disposition sur le site internet de l'ANSM.

Je vous informe par la présente de la recevabilité de votre dossier.
Cet accusé de réception ne préjuge pas de la conformité de vos activités ou de vos produits au regard de la législation en vigueur.

Par ailleurs, il n'est pas délivré de copie de votre déclaration ni du présent courrier qu'il vous appartient donc de conserver à toutes fins utiles.

Je vous prie d'agréer, Monsieur, l'expression de mes salutations distinguées.

L'inspecteur référent du pôle
inspection en surveillance du marché

Olivier PIAT

CE certificate:

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.

Effective Date: 2016-08-12

Date: 2016-08-12

Notified Body

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.

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Certificate No. 60111758

Certificate Number:	60111758
Certificate Holder:	**Sunsmed Protective Products Ltd.** No. 18, Industrial Park, Maozui Tow Xiantao City 433000 Hubei China (Mainland)
Scope:	Aspects of manufacture concerned with securing and Sterile Surgical Caps, Sterile Surgical Face Masks, Sterile Surgical Drapes, Sterile Surgical Packs maintaining sterile conditions: Sterile Surgical Gowns, Sterile Bed Protections,
Fulfilled Standards:	Richtlinie 93/42/EWG
Certificate Type:	QMS Produktion, Anhang V MDD 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.

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 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 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

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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 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:	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