STERIFIT S.R.L

Via Dei Martinitt, 3 - 20146 MILANO (MI) - Italy

Certified site:

Via Lombardia, 10/d - 20098 SAN GIULIANO MILANESE (MI) - Italy

Bureau Veritas Italia S.p.A. certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 9001:2015

Scope of certification

Design, development, production management and marketing of material for the packaging of medical devices to be sterilized.

IAF sector: **23,29**

Original cycle start date:	**16-September-2021**
Expiry date of previous cycle:	**NA**
Certification / Recertification Audit date:	**20-August-2021**
Certification / Recertification cycle start date:	**16-September-2021**
Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on:	**15-September-2024**

Certificate No.: **IT309596** Version: **1** Issue Date: **16-September-2021**

GIORGIO LANZAFAME - Local Technical Manager

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 009A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC mutual Recognition Agreements

Certification body address:
Bureau Veritas Italia S.p.A., Viale Monza, 347 - 20126 Milano, Italia

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.
To check this certificate validity please refer to the website www.bureauveritas.it

Bureau Veritas Certification

STERIFIT S.R.L

Via Dei Martinitt, 3 - 20146 MILANO (MI) - Italy

Certified site:

Via Lombardia, 10/d - 20098 SAN GIULIANO MILANESE (MI) - Italy

Bureau Veritas Italia S.p.A. certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 13485:2016

Scope of certification

Design, development, production management and marketing of material for the packaging of medical devices to be sterilized.

Certificate issued in accordance with the Technical Regulation ACCREDIA DT 02-DC Rev.00

Original cycle start date by a different certification body:	**02-January-2019**
Expiry date of previous cycle:	**01-January-2022**
Certification / Recertification Audit date:	**20-August-2021**
Certification / Recertification cycle start date:	**16-September-2021**
Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on:	**01-January-2025**

Certificate No.: **IT309602** Version: **1** Issue Date: **16-September-2021**

GIORGIO LANZAFAME - Local Technical Manager

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 009A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC mutual Recognition Agreements

Certification body address:

Bureau Veritas Italia S.p.A., Viale Monza, 347 - 20126 Milano, Italia

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DECLARATION OF CONFORMITY

Manufacturer: Address:	**STERIFIT s.r.l.** Via dei Martinitt, 3 - 20146 Milano (MI) Italy
Medical Device:	**POUCHES AND ROLLS "VeriSteril"**
Classification Annex IX D. *Lgs*. 46/97	**Class I** not sterile

STERIIFIT s.r.l. declares that Medical Devices POUCHES AND ROLLS "VeriSteril" in each different models are conforming to the essential requirements described in annex I of the Medical Devices Directive 93/42/CEE, consolidated with the requirements to 2007/47/EC, and to the applicable standards.

STERIIFIT s.r.l. has developed a post sale surveillance procedure of its medical device according to MEDDEV 2.12/1. "guidelines on post sale surveillance of Medical Devices".

Applicable Directives:

- Medical Devices Directive 93/42/CEE, consolidated with the requirements to 2007/47/EC

Applicable Standards:

European standards	Title
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (EN ISO 11607-1:2009/A1:2014)
EN ISO 13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2012)
EN 868-5:2009	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
EN 868-3:2009	Packaging for terminally sterilized medical devices - Part 3: Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) - Requirements and test methods

STERIIFIT s.r.l. put at the Authority disposal the Technical File with all the documentation required by Annex VII of the Directive 93/42/CEE for five years starting from the last production date of the device.

Milano, 08-01-2023

STERIFIT s.r.l.
CEO
Mario Neri

Milano, 27 ottobre 2022

STERILITY DECLARATION

We hereby declare that, based on the results of the tests at the laboratory authorized Crowned Consulting srl (4678-16 and 4679-16 Test reports), the range of products of the family “Veristeril” pouches and rolls, maintain the sterility of the products contained as follows:

STEAM STERILIZATION: 5 years

ETO STERILIZATION: 5 years

The maintenance of sterility requires to preserve the packaged products and sterile, away from direct sources of light and heat, in a dry place and at temperatures between 10 °C and 40 °C (recommended).

STERIFIT s.r.l.
CEO
Mario Neri

STERIIFIT S.r.l.- Via dei Martinitt, 3 - 20146 Milano (MI) Italy
Tel: +39 0250030956 e-mail: info@sterifit.com
VAT: 08969520967 - Shared Capital 75.000€

ROTOLI PIATTI/FLAT REELS

COD/REF	MIS/SIZE	Q.TA'/Q.TY
RP050200	50mm x 200m	8
RP075200	75mm x 200m	8
RP100200	100mm x 200m	4
RP120200	120mm x 200m	4
RP150200	150mm x 200m	4
RP200200	200mm x 200m	2
RP210200 *	210mm x 200m	2
RP250200	250mm x 200m	2
RP300200	300mm x 200m	2
RP320200 *	320mm x 200m	2
RP350200	350mm x 200m	1
RP380200 *	380mm x 200m	1
RP400200	400mm x 200m	1
RP420200 *	420mm x 200m	1
RP450200 *	500mm x 200m	1
RP500200 *	600mm x 200m	1

* DISPONIBILI COME M.O.Q.

GB *INSTRUCTION FOR USE*
VERISTERIL POUCHES AND REELS

1. INSTRUCTIONS FOR USE

Use VERISTERIL pouches and reels to pack medical devices to be sterilized by steam or EO gas.
VERISTERIL with 3 indicators also can be sterilized by formaldehyde.

Seal the open end(s) with a rotary or impulse sealing machine at the recommended temperature (150-180 °C) and following the instructions of the sealing machine manufacturer.

2. ESTERNAL INDICATORS PRINTED ON THE PRODUCTS:

VERISTERIL:
EO gas: Yellow/Brown sterilized
Steam: Brown sterilized

VERISTERIL with 3 indicators:
EO gas: Yellow/Brown sterilized
Steam: Brown sterilized
Formaldehyde: Green sterilized

The packaging is for single use only.
Do not use if pack is damaged.

Report any serious incident involving the device to the manufacturer and the competent authority.

3. STORAGE CONDITIONS

Keep away from direct sunlight and heat. We recommend:
- Store at temperature 10-30 °C before use.
- Relative humidity: 30-60 % before use.

Outer cartons should not suffer physical damage in handling and storage.

EN 868-5 ISO 11607-1

STERIFIT S.r.l.
Via dei Martinitt, 3
20146 Milano - Italia
info@sterifit.com – www.sterifit.com

GB *INSTRUCTION FOR USE*
VERISTERIL SELF SEALING POUCHES

1. INSTRUCTIONS FOR USE

Use VERISTERIL self-sealing pouches to pack medical devices to be sterilized by steam or EO gas.

Sealing instructions

- Unfold flap;
- Insert item into pouch;
- Remove backing from sealing strip;

Refold along crease pressing down firmly from center to each side to form good seal between adhesive strip and paper and plastic.

2. ESTERNAL INDICATORS PRINTED ON THE PRODUCTS:

VERISTERIL:
EO gas: Yellow/Brown sterilized
Steam: Brown sterilized

VERISTERIL with 3 indicators:
EO gas: Yellow/Brown sterilized
Steam: Brown sterilized
Formaldehyde: Green sterilized

The packaging is for single use only.
Do not use if pack is damaged.

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