Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO – UFFICIO 3

DGDMF/III/P/I.5.l.e.1/2019/1729

VISTA la direttiva 93/42/CEE concernente i dispositivi medici;
HAVING REGARD *to Directive 93/42/EEC concerning medical devices;*
VISTO il Decreto Legislativo n. 46/97 e successive modifiche recante il recepimento della direttiva 93/42/CEE;
HAVING REGARD *to the Legislative Decree n. 46/97 and its following amendments implementing Directive 93/42 EEC;*
VISTA la richiesta prot.n. 56510-A-08/10/2019 con integrazione prot. n. 976-A-09/01/2020 presentata dalla Ditta **E.C.S. S.R.L.** con sede in Via I° Maggio, 18/22 – 23881 Airuno (LC) Italia - Partita IVA n. 02207200136;
HAVING REGARD *to the request with ref. 56510-A-08/10/2019 updated to January 09, 2020 ref. 976 submitted by the Company* ***E.C.S. S.R.L.*** *located in Via I° Maggio, 18/22 – 23881 Airuno (LC) Italy - VAT number: 02207200136;*
CONSIDERATO che la ditta richiedente ha effettuato i versamenti richiesti dal D.M. 16 Gennaio 2019;
WHEREAS *the Company paid the fees required by Ministerial Decree January 16, 2019;*
VISTI gli atti d'ufficio;
HAVING REGARD *to the official deeds:*

SI ATTESTA
IT IS ATTESTED

che la Ditta **E.C.S. S.R.L.** con sede in Via I° Maggio, 18/22 – 23881 Airuno (LC) Italia è il fabbricante e ha marcato CE come dispositivi medici, secondo le procedure previste dalla direttiva 93/42 CEE i prodotti:
that, according to Directive 93/42/EEC, the Company ***E.C.S. S.R.L.*** *located in Via I° Maggio, 18/22 – 23881 Airuno (LC) Italy is the manufacturer and has marked CE as medical devices the following products:*
"Non surgical vinyl gloves - Top glove powdered and top glove powder free"; "Decontaminating multi-layer adhesive carpet Tread Step"; "Steril sheet blue line - TNT for sterilization"; "Steryl filter line - cotton, synthetic and medical paper filters for baskets and containers to be sterilized"; "Steriplasma flat rolls and pouches for hydrogen peroxide sterilization"; "Steridiamond – Steriperfect flat rolls, gussetted rolls, flat pouches, gussetted pouches self-sealing pouches for steam, EO and form sterilization"; "SMS Blu line - Sheets for pack to be sterilized"; "Non surgical nytril gloves – nytril star powder free"; " Non surgical latex gloves – Green star powdered and green star powder free"; "Steril sheet green/Blue Line – Creped medical paper for sterilization".

Tali prodotti, in base all'art. 4 della citata direttiva, sono di libera circolazione e possono essere messi in commercio in Italia e in tutto il territorio dell'Unione Europea.
The above mentioned products, according to the art. 4 of Directive 93/42/EEC, can freely circulate and can be placed on the market in Italy and all over the European Union.
Questo documento è rilasciato in unico originale a richiesta del fabbricante ai fini di esportazione di dispositivi medici nei **Paesi al di fuori dell'Unione Europea.**
This document has been issued in a unique original version upon request of the manufacturer in order to export medical devices to ***Countries outside European Union.***
Non è consentita la sua riproduzione o pubblicazione su carta, stampa, supporti elettronici o siti internet.
It is not allowed any reproduction or publication of this document by paper, press, electronic base or websites.
Ne è consentita la sola esibizione o consegna alle autorità doganali o sanitarie del paese di importazione.
It is only allowed to show or to delivery it, upon request of the customs or Health Competent Authorities of the importing country.

Il Dirigente
The Executive Manager
Dr. Marco Musella

MINISTERO DELLA SALUTE
Dir. Gen. Dispositivi Medici e del Servizio Farmaceutico
UFFICIO 03

DDP

CERTIFICATO/ *CERTIFICATE*

NUMERO PC/ *NUMBER PC*: **017N-ECS-Q**

RIFERIRSI AI DOCUMENTI DI SISTEMA PER I DETTAGLI DELLE ESCLUSIONI AI REQUISITI DELLA NORMA
REFER TO SYSTEM DOCUMENTS FOR DETAILS OF EXCLUSIONS TO NORMA REQUIREMENTS

L'AZIENDA/ *THE COMPANY*:

E.C.S. S.r.l.

Partita IVA 02207200136

Sede Legale
Via 1 Maggio, 18/22
23881 Airuno
LECCO
Italy

Sede Operativa
Via Como, 47
23883 Brivio
LECCO
Italy

HA OTTENUTO LA CERTIFICAZIONE DEL SISTEMA DI GESTIONE PER LA QUALITÀ SECONDO LA NORMA

IT IS CERTIFIED OF THE MANAGEMENT SYSTEM FOR THE QUALITY ACCORDING TO

EN ISO 9001:2015

PER I SEGUENTI CAMPI DI ATTIVITÀ

FOR THE FOLLOWING ACTIVITIES FIELDS

Progettazione, fabbricazione e commercializzazione di prodotti per il confezionamento di dispositivi medici monouso da sterilizzare e di dispositivi per il controllo della sterilizzazione.

EA 19 – 29

Design, manufacture and marketing of products for the packaging of disposable medical devices to be sterilized and devices for sterilization control.

EA 19 – 29

Prima Emissione: ***First issue***	**rev. 00**	**12 Marzo 2018**
	Rilasciato da:	**SI Cert S.a.g.l.**
Emissione Corrente: ***Current issue***	**rev. 03**	**07 Maggio 2021**
Scadenza Ciclo: ***Expiration cycle***	**11 Marzo 2024**	

Periodo di non validità del presente certificato: **Dal:** ****
Invalid validity period of this certificate: **Al:** ****

La validità del certificato è confermata dalla presenza del bollino di sicurezza. Le date sotto riportate sono indicative. In caso di assenza del bollino di sicurezza e per avere informazioni certe sulla validità del certificato, vi chiediamo di inviare richiesta all'indirizzo comitatocertificazione@sicert.ch.
The validity of the certificate is confirmed by the presence of the security label. The dates given below are indicative. In the absence of the label security and to have reliable information on the validity of the certificate, send request to comitatocertificazione@sicert.ch.

Certificazione valido fino al
11 Marzo 2022

Sorveglianza 1 valida fino al
11 Marzo 2023

Sorveglianza 2 valida fino al
11 Marzo 2024

SI Cert S.a.g.l.

Per un'informazione puntuale ed aggiornata circa la validità del presente certificato si prega di contattare:
SI Cert s.a.g.l. – Sede Legale
Via Giardino, 12 - 6517 Arbedo – (Svizzera)
e.mail: **comitatocertificazione@sicert.ch** – www.sicert.ch

BUREAU VERITAS
Certification

E.C.S. SRL

VIA 1 MAGGIO 18/22 - 23881 AIRUNO (LC)- ITALY

Certified site:

VIA 1 MAGGIO 18/22 - 23881 AIRUNO (LC) –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

EN ISO 13485:2016

Scope of certification

Design, manufacture and marketing of packaging systems for sterilized medical devices, accessories and chemical and biological indicators for the sterilization process.

Certificate awarded in conformity with the requirements of ACCREDIA DT 02-DC Rev.00

Original cycle start date:	**02 September 2019**
Expiry date of previous cycle:	**n.a.**
Certification / Recertification Audit date:	**10 July 2019**
Certification / Recertification cycle start date:	**02 September 2019**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **01 September 2022**

Certificate No. - Version: IT292706-1 Revision date: **02 September 2019**

ANDREA FILIPPI – Local Technical Manager

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

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

CERTIFICATO/*CERTIFICATE*

NUMERO PC/*NUMBER PC*: **017N-ECS-E**

L'AZIENDA/*THE COMPANY*:

E.C.S. S.r.l.

Partita IVA 02207200136

Via 1 Maggio, 18/22
23881 Airuno
LECCO
Italy

NELLE SEGUENTI UNITÀ OPERATIVE:/*IN THE FOLLOWING OPERATIVE LOCATION*:

Via Como, 47
23883 Brivio
LECCO
Italy

HA OTTENUTO LA CERTIFICAZIONE DEL SISTEMA DI GESTIONE AMBIENTALE

IT IS CERTIFIED OF THE ENVIRONMENTAL MANAGEMENT SYSTEM ACCORDING TO

EN ISO 14001 : 2015

PER I SEGUENTI CAMPI DI ATTIVITÀ

Commercializzazione di prodotti per il confezionamento di dispositivi medici monouso da sterilizzare e di dispositivi per il controllo della sterilizzazione.

EA 29

FOR THE FOLLOWING ACTIVITIES FIELDS

Marketing of products for the packaging of disposable medical devices to be sterilized and devices for sterilization control.

EA 29

Prima Emissione: ***First issue***	**rev. 00**	**12 Marzo 2018**
	Rilasciato da:	**SI Cert S.a.g.l.**
Emissione Corrente: ***Current issue***	**rev. 03**	**07 Maggio 2021**
Scadenza Ciclo: ***Expiration cycle***	**11 Marzo 2022**	

Periodo di non validità del presente certificato: **Dal:** ****
Invalid validity period of this certificate: **Al:** ****

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The validity of the certificate is confirmed by the presence of the security label. The dates given below are indicative. In the absence of the label security and to have reliable information on the validity of the certificate, send request to comitatocertificazione@sicert.ch.

Certificazione valido fino al 11 Marzo 2022

Sorveglianza 1 valida fino al 11 Marzo 2023

Sorveglianza 2 valida fino al 11 Marzo 2024

SI Cert S.a.g.l.

TECHNICAL DATA SHEET STERIDIAMOND-STERIPERFECT POUCHES AND ROLLS (FLAT AND GUSSETTED) AND SELF-SEALING POUCHES	Mod. ST19 EN Rev. 15 May 2021

MANUFACTURER IDENTIFICATION

E.C.S. S.r.l.
Via Como, 71
23883 Brivio (LC)
Italy
Tel. +39.0341.681602
info@ecssrl.com – www.ecssrl.com

PRODUCT IDENTIFICATION

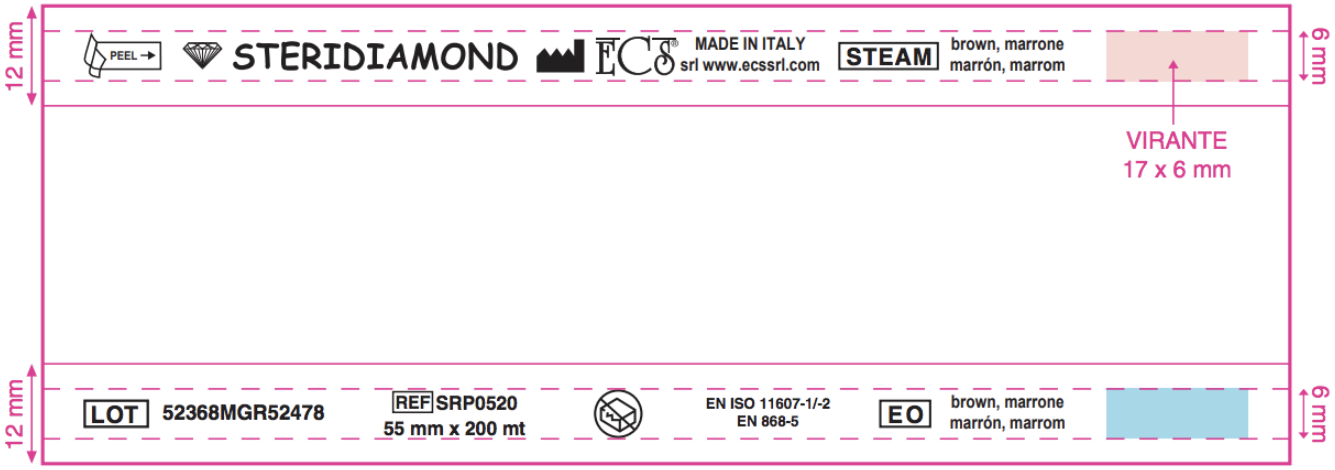
Class / Definition

Non-invasive devices, class I, rule number 1 - ANNEX VIII - of Regulation (EU) 2017/745.

"All non-invasive devices are in Class I, unless one of the following rules applies."

« none of the rules following the rule no.1 are applicable ».

PRODUCT IMAGE



PRODUCT DESCRIPTION

E.C.S. S.r.l. is the manufacturer of the medical devices STERIDIAMOND – STERIPERFECT, pouches and rolls of various sizes including self-sealing pouches.

STERIDIAMOND - STERIPERFECT pouches and rolls have been designed to be used by hospitals and dentists and by anyone wishing to sterilize instruments or other medical devices with Steam and Ethylene oxide (EO). STERIDIAMOND - STERIPERFECT pouches and rolls are disposable so they cannot be reused. The product is made from smooth cellulose medical paper (60g/sqm) and plastic film made of polyester and polypropylene (PET/PP). The product also reports Class 1 process indicators. The indicators, as well as the writings and indications are shown within the polyester / polypropylene film and paper and are enclosed within the sealing bands in order to avoid any contamination of the wrapped medical devices. The employed paper is white colour and resistant to humidity. It has been developed in order to ensure a high level of protection against bacteria.

All prints, including chemical indicators for Steam and Ethylene oxide (EO), are positioned on the paper side in such a way that they do not come into contact with the medical devices contained inside nor release potentially polluting substances towards the product itself (in compliance with EN ISO 11607-1/-2:2014 and UNI EN 868-5:2009 standards) with indications for the interpretation of the results in Italian, English, Spanish and Portuguese.

Pouches and rolls are flat and gussetted and they are designed to be welded. The self-sealing pouches, on the other hand, are equipped with a special system that self-seals the same pouch by replacing the sealing with an adhesive system. The welding on the three sides is multi-line continuous and hot welding with a width equal to / greater than 6 mm, with rounded corners. The multi-line welding on the three sides is always carried out to prevent adhesion of dirt. This reduces the risk of contamination of the product placed inside, during storage in the warehouse and when the packaging is open.

In addition, in compliance to the Regulation (UE) 2017/745, E.C.S. S.r.l. declares that:

1. the family of the medical device “STERIDIAMOND - STERIPERFECT” does not incorporate, as an integral part, a substance or a derivative of human blood;
2. no compound of animal origin has been used during production as per the Directive 2003/32/CE.

Brivio, May 2021 E.C.S. S.r.l.

TECHNICAL CHARACTERISTICS

- Plastic film made of coloured polyester/polypropylene and white medical paper. The plastic film is transparent in order to allow a clear identification of the contents. The medical paper is highly resistant to tearing and humidity.
- All pouches and rolls report, every 15 cm., the name of the manufacturer, the code (REF) and the measures of the product, the lot and the process indicators in conformity with the regulation UNI EN 868-5:2019.
- All pouches and rolls are suitable and compatible for the sterilization with saturated Steam and Ethylene oxide (EO).
- The Class 1 process indicators are present on the products in conformity with the regulation UNI EN 868-5 and as described in the regulation UNI EN ISO 11140-1:2009. The color interpretation is simple, univocal and clear.
- The process indicator for saturated Steam turns from pink to brown (the gusseted rolls turn from light blue to yellow/brown).
- The process indicator for Ethylene oxide (EO) turns from light blue to yellow/brown (gusseted rolls turn from pink to brown).
- The indicator color change is reported in more languages.
- Absence of fine-dust, hair.

- Mechanical and dimensional uniformity of the continuous and multi – line/stripe of 10 or 12 mm. heat-sealing.
- Endurance of the lateral heat-sealing after the sterilization process.
- High peelability of the two layers after the sterilization process: splitting the two layers of the roll/pouch, it is verified their ability to split without laceration and fiber release.
- Absence of sealing interruptions on the length of the roll.
- Resistance to the sterilization: absence of lacerations before and after the sterilization process.
- Lot number for the complete traceability.
- The pouches are easily opening with the specific invitation. The opening management (that also determines the slightest alteration of the fibres) is represented by the coded symbol (PEEL).
- The wording “do not use if the packaging is damaged” is represented by the specific coded symbol.
- STERIDIAMOND-STERIPERFECT pouches and rolls have absence of delamination during the opening.
- Primary packaging with plastic film in order to guarantee the protection from dust also after the opening of the carton and facilitate its transport in areas where the cartons’ entrance isn’t allowed.
- Secondary packaging in carton box.
- Labelling-data:

  Description of the content, product code (REF) quantity and product sizes

  Manufacturer

  Fabrication date and deadline of the product

  Production lot number

  Symbol CE of conformity to the Regulation medical devices 2017/745

  Symbol MD which identifies that the product is a medical device

  Storage symbols

  Barcode 2D Datamatrix

E.C.S. S.r.l. performed at qualified laboratory a "Packaging Validation" (Report n. 02/2015 for pouches and Report n. 03/2015 for rolls) according to which it can be confirmed that the packaging (considering the three pre-welded sides by the manufacturer) do not result to be damaged after the process of accelerated aging compared to samples not put through aging.

After the aging process, simulating 5 years of natural shelf-life, validation tests of the packaging were conformed to requirements of the reference standards UNI EN ISO 868-5:2009, EN ISO 11607-1/-2:2014.

In addition, E.C.S. S.r.l. performed in a qualified laboratory a "printed indicators validation" (Report n. 13/2015) according to standard UNI EN ISO 11140-1:2014 which shows conformity of the indicators operation.

STORAGE CONDITIONS

Avoid direct exposure to sunlight or heat sources and store in low contamination environments.

Keep away from heat, light and humidity sources.

Use in arrival order and handle with care.

HEALTH AND SAFETY

If STERIDIAMOND - STERIPERFECT packaging are correctly used for their intended use, there are no special precautions to observe during their handling and usage.

These packaging do not contain agents or materials today classified as toxic.

Considering the material chosen, it can be declared that the products are free from phthalates, carcinogenic, mutagenic or toxic to reproduction substances.

The products do not contain latex.

Absence of unpleasant smells dry and wet.

The undersigned declines every responsibility regarding possible following contaminations from air pollution or other source, once the product has been removed from its packaging.

E.C.S. S.r.l.

CND CLASSIFICATION – DIRECTORY NUMBER

Commercial name	CND classification	Directory number	Manufacturer
Flat pouches and self-sealing pouches Steridiamond/Steriperfect	S01010101 – Flat pouches in coupled paper/film for sterilization.	96701/R	E.C.S. S.r.l.
Gussetted pouches Steridiamond	S01010102 – Gussetted pouches in coupled paper/film for sterilization	1452804/R	E.C.S. S.r.l.
Flat rolls Steridiamond/Steriperfect	S01020101 – Flat rolls in coupled paper/film for sterilization	96767/R	E.C.S. S.r.l.
Gussetted rolls Steridiamond	S01020102 – Gussetted rolls in coupled paper/film for sterilization	98820/R	E.C.S. S.r.l.

REF, DIMENSIONS AND PACKAGING

STERIDIAMOND LINE

SRP - STERIDIAMOND FLAT ROLLS 100MT

REF	DIMENSIONS	PACKAGING
SRP0510	55 MM. X 100 MT.	8 pieces
SRP7510	75 MM. X 100 MT.	8 pieces
SRP1010	100 MM. X 100 MT.	4 pieces
SRP12510	125 MM. X 100 MT.	4 pieces
SRP1510	150 MM. X 100 MT.	4 pieces
SRP2010	200 MM. X 100 MT.	2 pieces
SRP2510	250 MM. X 100 MT.	2 pieces
SRP3010	300 MM. X 100 MT.	2 pieces
SRP3510	350 MM. X 100 MT.	1 piece
SRP4010	400 MM. X 100 MT.	1 piece
SRP5010	500 MM. X 100 MT.	1 piece

*Other measures available on request

SRP - STERIDIAMOND FLAT ROLLS 200MT

REF	DIMENSIONS	PACKAGING
SRP0520	55 MM. X 200 MT.	8 pieces
SRP7520	75 MM. X 200 MT.	8 pieces
SRP1020	100 MM. X 200 MT.	4 pieces
SRP12520	125 MM. X 200 MT.	4 pieces
SRP1520	150 MM. X 200 MT.	4 pieces
SRP2020	200 MM. X 200 MT.	2 pieces
SRP2520	250 MM. X 200 MT.	2 pieces
SRP3020	300 MM. X 200 MT.	2 pieces
SRP3520	350 MM. X 200 MT.	1 piece
SRP4020	400 MM. X 200 MT.	1 piece
SRP5020	500 MM. X 200 MT.	1 piece

* Other measures available on request

SRS - STERIDIAMOND GUSSETTED ROLLS

REF	DIMENSIONS	PACKAGING
SRS7510	75 MM. X 25 MM. X 100 MT.	8 pieces
SRS1010	100 MM. X 50 MM. X 100 MT.	4 pieces
SRS1510	150 MM. X 65 MM. X 100 MT.	4 pieces
SRS2010	200 MM. X 55 MM. X 100 MT.	2 pieces

SRS2510	250 MM. X 65 MM. X 100 MT.	2 pieces
SRS3010	300 MM. X 80 MM. X 100 MT.	2 pieces
SRS3510	350 MM. X 80 MM. X 100 MT.	1 piece
SRS4010	400 MM. X 80 MM. X 100 MT.	1 piece

* Other measures available on request

SBA - STERIDIAMOND SELF-SEALING POUCHES

REF	DIMENSIONS	PACKAGING	
		CARDBOARD	BOX
SBA60100	60 MM. X 100 MM.	3.600 pieces	200 pieces
SBA7525	75 MM. X 250 MM.	1.800 pieces	200 pieces
SBA90165	90 MM. X 165 MM.	1.800 pieces	200 pieces
SBA0925	90 MM. X 250 MM.	1.800 pieces	200 pieces
SBA1335	130 MM. X 350 MM.	1.200 pieces	200 pieces
SBA1426	140 MM. X 260 MM.	1.200 pieces	200 pieces
SBA1933	190 MM. X 330 MM.	1.200 pieces	200 pieces
SBA1940	190 MM. X 400 MM.	1.200 pieces	200 pieces
SBA3037	300 MM. X 370 MM.	800 pieces	200 pieces
SBA3045	300 MM. X 450 MM.	800 pieces	200 pieces
SBA3050	300 MM. X 500 MM.	800 pieces	200 pieces

* Other measures available on request

SBP - STERIDIAMOND FLAT POUCHES

REF	DIMENSIONS	PACKAGING
SBP7520	75 MM. X 200 MM.	2.000 pieces
SBP7525	75 MM. X 250 MM.	2.000 pieces
SBP7530	75 MM. X 300 MM.	2.000 pieces
SBP7545	75 MM. X 450 MM.	2.000 pieces
SBP1015	100 MM. X 150 MM.	2.000 pieces
SBP1020	100 MM. X 200 MM.	2.000 pieces
SBP1025	100 MM. X 250 MM.	2.000 pieces
SBP1030	100 MM. X 300 MM.	2.000 pieces

REF	DIMENSIONS	PACKAGING
SBP2128	210 MM. X 280 MM.	1.000 pieces
SBP2530	250 MM. X 300 MM.	1.000 pieces
SBP2535	250 MM. X 350 MM.	1.000 pieces
SBP2540	250 MM. X 400 MM.	1.000 pieces
SBP2545	250 MM. X 450 MM.	1.000 pieces
SBP2550	250 MM. X 500 MM.	1.000 pieces
SBP2745	270 MM. X 450 MM.	1.000 pieces
SBP3040	300 MM. X 400 MM.	1.000 pieces

SBP1035	100 MM. X 350 MM.	2.000 pieces
SBP1040	100 MM. X 400 MM.	2.000 pieces
SBP1055	100 MM. X 550 MM.	2.000 pieces
SBP1220	120 MM. X 200 MM.	1.000 pieces
SBP1520	150 MM. X 200 MM.	1.000 pieces
SBP1525	150 MM. X 250 MM.	1.000 pieces
SBP1530	150 MM. X 300 MM.	1.000 pieces
SBP1535	150 MM. X 350 MM.	1.000 pieces
SBP1540	150 MM. X 400 MM.	1.000 pieces
SBP1622	160 MM. X 225 MM.	1.000 pieces
SBP1635	160 MM. X 350 MM.	1.000 pieces
SBP2025	200 MM. X 250 MM.	1.000 pieces
SBP2030	200 MM. X 300 MM.	1.000 pieces
SBP2035	200 MM. X 350 MM.	1.000 pieces
SBP2040	200 MM. X 400 MM.	1.000 pieces
SBP2050	200 MM. X 500 MM.	1.000 pieces
SBP3050	300 MM. X 500 MM.	1.000 pieces
SBP3055	300 MM. X 550 MM.	1.000 pieces
SBP3057	300 MM. X 570 MM.	1.000 pieces
SBP3250	320 MM. X 500 MM.	500 pieces
SBP3260	320 MM. X 600 MM.	500 pieces
SBP3550	350 MM. X 500 MM.	500 pieces
SBP3658	360 MM. X 580 MM.	500 pieces
SBP4050	400 MM. X 500 MM.	500 pieces
SBP4055	400 MM. X 550 MM.	500 pieces
SBP4060	400 MM. X 600 MM.	500 pieces
SBP4250	420 MM. X 500 MM.	500 pieces
SBP4260	420 MM. X 600 MM.	500 pieces
SBP5060	500 MM. X 600 MM.	500 pieces
SBP6060	600 MM. X 600 MM.	500 pieces

* Other measures available on request

Pouches are strapped in bats of 200/250 pieces.

SBS - STERIDIAMOND GUSSETTED POUCHES

REF	DIMENSIONS	PACKAGING
SBS1540	150 MM. X 50 MM. X 400 MM.	500 pieces
SBS2040	200 MM. X 55 MM. X 400 MM.	500 pieces
SBS2050	200 MM. X 55 MM. X 500 MM.	500 pieces
SBS2550	250 MM. X 65 MM. X 500 MM.	500 pieces
SBS3050	300 MM. X 80 MM. X 500 MM.	500 pieces
SBS3058	300 MM. X 80 MM. X 580 MM.	500 pieces
SBS4258	420 MM. X 90 MM. X 580 MM.	500 pieces

* Other measures available on request

STERIPERFECT LINE

RP - STERIPERFECT FLAT ROLLS 100MT

REF	DIMENSIONS	PACKAGING
RP0510	55 MM. X 100 MT.	8 pieces
RP7510	75 MM. X 100 MT.	8 pieces
RP1010	100 MM. X 100 MT.	4 pieces
RP12510	125 MM. X 100 MT.	4 pieces
RP1510	150 MM. X 100 MT.	4 pieces
RP2010	200 MM. X 100 MT.	2 pieces
RP2510	250 MM. X 100 MT.	2 pieces
RP3010	300 MM. X 100 MT.	2 pieces
RP3510	350 MM. X 100 MT.	1 piece
RP4010	400 MM. X 100 MT.	1 piece
RP5010	500 MM. X 100 MT.	1 piece

*Other measures available on request

RP - STERIPERFECT FLAT ROLLS 200MT

REF	DIMENSIONS	PACKAGING
RP0520	55 MM. X 200 MT.	8 pieces
RP7520	75 MM. X 200 MT.	8 pieces
RP1020	100 MM. X 200 MT.	4 pieces
RP12520	125 MM. X 200 MT.	4 pieces
RP1520	150 MM. X 200 MT.	4 pieces
RP2020	200 MM. X 200 MT.	2 pieces
RP2520	250 MM. X 200 MT.	2 pieces
RP3020	300 MM. X 200 MT.	2 pieces
RP3520	350 MM. X 200 MT.	1 piece
RP4020	400 MM. X 200 MT.	1 piece
RP5020	500 MM. X 200 MT.	1 piece

*Other measures available on request

SRSB – STERIDIAMOND GUSSETTED ROLLS BLUE FILM

REF	DIMENSIONS	PACKAGING
SRS7510B	75 MM. X 25 MM. X 100 MT.	8 pieces
SRS1010B	100 MM. X 50 MM. X 100 MT.	4 pieces
SRS1510B	150 MM. X 65 MM. X 100 MT.	4 pieces
SRS2010B	200 MM. X 55 MM. X 100 MT.	2 pieces
SRS2510B	250 MM. X 65 MM. X 100 MT.	2 pieces
SRS3010B	300 MM. X 80 MM. X 100 MT.	2 pieces
SRS3510B	350 MM. X 80 MM. X 100 MT.	1 pieces
SRS4010B	400 MM. X 80 MM. X 100 MT.	1 pieces

*Other measures available on request

BA - STERIPERFECT SELF-SEALING POUCHES

REF	DIMENSIONS	PACKAGING	
		CARDBOARD	BOX
BA60100	60 MM. X 100 MM.	3.600 pieces	200 pieces
BA75250	75 MM. X 250 MM.	1.800 pieces	200 pieces
BA90165	90 MM. X 165 MM.	1.800 pieces	200 pieces
BA90250	90 MM. X 250 MM.	1.800 pieces	200 pieces
BA13350	130 MM. X 350 MM.	1.200 pieces	200 pieces
BA14260	140 MM. X 260 MM.	1.200 pieces	200 pieces
BA19330	190 MM. X 330 MM.	1.200 pieces	200 pieces
BA19400	190 MM. X 400 MM.	1.200 pieces	200 pieces
BA30370	300 MM. X 370 MM.	800 pieces	200 pieces
BA30450	300 MM. X 450 MM.	800 pieces	200 pieces
BA30500	300 MM. X 500 MM.	800 pieces	200 pieces

*Other measures available on request

BP - STERIPERFECT FLAT POUCHES

REF	DIMENSIONS	PACKAGING
BP7520	75 MM. X 200 MM.	2.000 pieces
BP7525	75 MM. X 250 MM.	2.000 pieces
BP7530	75 MM. X 300 MM.	2.000 pieces
BP7545	75 MM. X 450 MM.	2.000 pieces
BP1015	100 MM. X 150 MM.	2.000 pieces
BP1020	100 MM. X 200 MM.	2.000 pieces
BP1025	100 MM. X 250 MM.	2.000 pieces

REF	DIMENSIONS	PACKAGING
BP2128	210 MM. X 280 MM.	1.000 pieces
BP2530	250 MM. X 300 MM.	1.000 pieces
BP2535	250 MM. X 350 MM.	1.000 pieces
BP2540	250 MM. X 400 MM.	1.000 pieces
BP2545	250 MM. X 450 MM.	1.000 pieces
BP2550	250 MM. X 500 MM.	1.000 pieces
BP2745	270 MM. X 450 MM.	1.000 pieces

BP1030	100 MM. X 300 MM.	2.000 pieces
BP1035	100 MM. X 350 MM.	2.000 pieces
BP1040	100 MM. X 400 MM.	2.000 pieces
BP1055	100 MM. X 550 MM.	2.000 pieces
BP1220	120 MM. X 200 MM.	1.000 pieces
BP1520	150 MM. X 200 MM.	1.000 pieces
BP1525	150 MM. X 250 MM.	1.000 pieces
BP1530	150 MM. X 300 MM.	1.000 pieces
BP1535	150 MM. X 350 MM.	1.000 pieces
BP1540	150 MM. X 400 MM.	1.000 pieces
BP1622	160 MM. X 225 MM.	1.000 pieces
BP1635	160 MM. X 350 MM.	1.000 pieces
BP2025	200 MM. X 250 MM.	1.000 pieces
BP2030	200 MM. X 300 MM.	1.000 pieces
BP2035	200 MM. X 350 MM.	1.000 pieces
BP2040	200 MM. X 400 MM.	1.000 pieces
BP2050	200 MM. X 500 MM.	1.000 pieces
BP3040	300 MM. X 400 MM.	1.000 pieces
BP3050	300 MM. X 500 MM.	1.000 pieces
BP3055	300 MM. X 550 MM.	1.000 pieces
BP3057	300 MM. X 570 MM.	1.000 pieces
BP3250	320 MM. X 500 MM.	500 pieces
BP3260	320 MM. X 600 MM.	500 pieces
BP3550	350 MM. X 500 MM.	500 pieces
BP3658	360 MM. X 580 MM.	500 pieces
BP4050	400 MM. X 500 MM.	500 pieces
BP4055	400 MM. X 550 MM.	500 pieces
BP4060	400 MM. X 600 MM.	500 pieces
BP4250	420 MM. X 500 MM.	500 pieces
BP4260	420 MM. X 600 MM.	500 pieces
BP5060	500 MM. X 600 MM.	500 pieces
BP6060	600 MM. X 600 MM.	500 pieces

*Other measures are available on request

Pouches are strapped in bats of 200/250 pieces.

LABELS

Each carton is equipped with a label, printed according to the standards' indications UNI CEI EN ISO 15223-1:2017 and UNI CEI EN 1041:2013, containing all the information as regulation EN ISO 11607-1-2:2014 and UNI EN 868-5:2009.

LIMITATIONS OF USE

STERIDIAMOND - STERIPERFECT packaging are not suitable neither for dry heat sterilization nor for gas plasma sterilization.

WARNINGS

Weld the open side of the pouches and rolls with a heat sealer at the recommended temperature of 160-180 °C; such temperature can vary according to contact time and to the heat sealer's welding speed.

Follow the instructions of the heat sealer's manufacturer.

Pouches and rolls are LATEX FREE

PRODUCT SHELF-LIFE

The product has a 5 (five) years shelf-life from production date.
The product must be kept and stored in dry places at environmental temperature, away from chemical, microbiological and biological pollution sources. Storage places must have a Pest Control program in order to avoid contact with mice, insects and crawling animals.
The product guarantee sterility maintenance only with intact packaging and perfectly stored.

COMPLIANCE TO DIRECTIVES

Sterilization pouches and rolls are manufactured in compliance with the following regulations:

- Regulation (UE) n. 2017/745 related to medical devices
- Standard IEC 61882:2016 Analysis' method of the risks according to the method HAZOP
- Standard CEI EN 61511-1 used for the calculation's method of the remaining risk LOPA
- UNI CEI EN ISO 15223-1:2017 Title: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- UNI CEI EN 1041:2013 information supplied by the manufacturer of the medical devices
- UNI CEI EN 14971:2020 Title: Medical devices - Application of risk management to medical devices
- UNI EN 868-2:2009 Title: Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods
- UNI EN 868-3:2017 Title: 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
- UNI EN 868-5:2009 Title: Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
- EN ISO 11607-1:2014 Title: Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- EN ISO 11607-2:2014 Title: Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- UNI EN ISO 11140-1:2009 Title: Sterilization of health care products - Chemical indicators - Part 1: General requirements
- UNI EN ISO 15882:2009 Title: Sterilization of health care products - Chemical indicators - Guidance for selection, use and interpretation of results

DISPOSAL

Assimilable to a normal urban waste. For big quantities it has to be considered as a special waste.

MARKETING PROCESS

The manufacturer on the basis of the indications reported in the article 53 paragraph 7 set up all the documentation of which annex II and III of the Regulation (UE) n.2017/745

E.C.S. S.r.l.

FILM COMPOSITION AND MEDICAL PAPER

FILM

PRODUCT DESCRIPTION:	The film coat PET/PP GREEN or BLUE consists in a polyester layer and a polypropylene one (2 layers in total).
APPLICATION FIELD:	The film coat PET/PP GREEN or BLUE has been specifically designed for disposable medical devices and for being used with rotary and with impulses welding machines. The film coat PET/PP GREEN or BLUE is suitable to be welded with medical paper, in order to create a unique system usable Steam, Ethylene oxide (EO) sterilization and perfectly peelable at the opening.
TRACEABILITY:	We can provide documentation regarding used materials for a 5 (five) years period from the production date, starting from the production lot.
WASTE-DISPOSAL:	The film coat PET/PP GREEN or BLUE is considered as a normal urban waste in small quantities and a special waste in big quantities.

MEDICAL PAPER

STANDARDS COMPLIANCE:	UNI EN 868-3:2017 Packaging for terminally sterilized medical devices – Part 3: Paper to be used in the manufacturing of paper bags (specified in the EN 868-4) and in the manufacturing of pouches and tubes (specified in the EN 868-5)
PRODUCT DESCRIPTION:	Smooth medical paper 60 g/sqm is moisture-resistant and manufactured with 100% pure pulp. The surface's characteristics guarantee a high resistance at the opening and a peeling without fibres' release. The paper's porosity has been designed for Steam, Ethylene oxide (EO)sterilization and represents a reliable barrier against any bacteria.
APPLICATION:	Medical paper 60 g/sqm is particularly designed for the production of pouches and rolls, printed or neutral, where the paper is hot welded together with a coupled layer made of polyester and polypropylene film. The obtained packaging is suitable for Steam, Ethylene oxide (EO) sterilization.
TRACEABILITY:	We can provide the documentation regarding the materials used for a 5 (five) years period starting from the production lot.
DISPOSAL:	The paper is considered as a normal urban waste in small quantities and a special waste in big quantities.

DECLARATION OF CONFORMITY CE

The undersigned Ivano Redaelli, as General Manager of E.C.S. S.r.l., located in Via Como n.71, 23883 Brivio (LC), VAT 02207200136

Declares under its own responsibility that the products

"FLAT ROLLS, GUSSETTED ROLLS, FLAT POUCHES, GUSSETTED POUCHES, SELF-SEALING POUCHES, STERIDIAMOND – STERIPERFECT LINE WITH PROCESS INDICATORS FOR STEAM AND EO STERILIZATION" Class I disposable not sterile.

have been manufactured according to the following guidelines and regulations in force:

- Regulations (UE) n. 2017/745 related to medical devices
- Standard IEC 61882:2016 Analysis' method of the risks according to the method HAZOP
- Standard CEI EN 61511-1 used for the calculation's method of the remaining risk LOPA
- UNI CEI EN ISO 15223-1:2017 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- UNI CEI EN 1041:2013 information supplied by the manufacturer of the medical devices
- UNI CEI EN 14971:2020 Application of risk management to medical devices
- UNI EN 868-2:2009 Title: Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods
- UNI EN 868-3:2017 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
- UNI EN 868-5:2009 Title: Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
- EN ISO 11607-1:2014 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- EN ISO 11607-2:2014 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- UNI EN ISO 11140-1:2009 Sterilization of health care products - Chemical indicators - Part 1: General requirements
- UNI EN ISO 15882:2009 Sterilization of health care products - Chemical indicators - Guidance for selection, use and interpretation of results

E.C.S. S.r.l. manufacturer of these products, is certified according to the provisions by the rules UNI EN ISO 9001:2015 and UNI EN ISO 13485:2016.

Family products	**Basic UDI-DI**
Steridiamond flat rolls	803298667F00203Q
Steridiamond gussetted rolls	803298667F00303T
Steridiamond flat pouches	803298667F00403W
Steridiamond gussetted pouches	803298667F00503Z
Steridiamond self-sealing pouches	803298667F006044
Steriperfect flat rolls	803298667F00804A
Steriperfect flat pouches	803298667F01003P
Steriperfect self-sealing pouches	803298667F01103S

The current declaration of conformity is released under the manufacturer's exclusive responsibility.

Brivio, May 2021

E.C.S S.r.l.