Euro Clinical Service

TECHNICAL DATA SHEET STERIPLASMA POUCHES AND ROLLS	Mod. ST19/TY EN
	Rev. 9
	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, belonging to Class I, applicable rule n°1 of the Annex VIII of the Regulation (UE) 2017/745.

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

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

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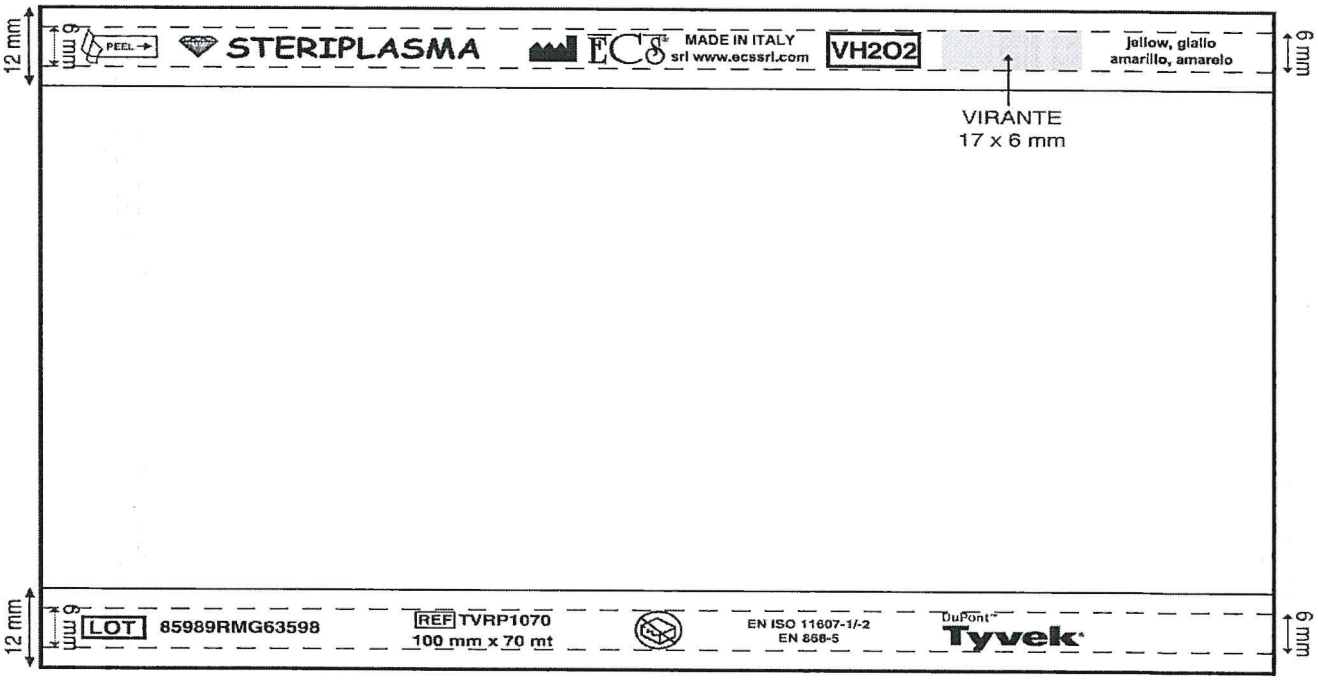
PRODUCT IMAGE



PRODUCT DESCRIPTION

E.C.S. S.r.l. is the manufacturer of STERIPLASMA pouches and rolls.
STERIPLASMA pouches and rolls have been designed to be used by workers who need to have the instruments or other medical devices sterilized by hydrogen peroxide VH2O2 (GAS PLASMA).
STERIPLASMA pouches and rolls are disposable and they shall not be reused.
The product is made of TYVEK® which is a highly resistant material and a coupled Polyester/ polyethylene (PET/PE) film.
All printings, including the chemical indicators for hydrogen peroxide VH2O2, are positioned on the TYVEK® side in order to prevent the contamination of the medical devices with the ink and avoiding any release of potentially polluting substances on the product itself (in compliance with the standard EN ISO 11607-1-2: 2014 and UNI EN 868-5:2009). The indications for the interpretation of the results are in Italian, English, French, German, Spanish and Portuguese.
The product is designed to be heat-sealed.
The multi-line, hot welding is continuous with rounded corners in order to prevent any deposit of dirt. This reduces the risk of contamination of the content during stocking 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 "STERIPLASMA does not contain, as integrant part, any substance or derivative of the human blood;
2. no compound of animal origin has been used during production as per the Directive 2003/32/CE.

Brivio, May 2021

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Sterilization Solutions
E.C.S. s.r.l.
Via Como, 71
23853 BRIVIO (LC) ITALY
C.F. e P. IVA 02207200136
www.ecssrl.com
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TECHNICAL CHARACTERISTICS

- Compliance to the normative series ISO 11607 and EN 868.
- The product is manufactured with high-resistant TYVEK® material with uniform texture in transparency and a coupled transparent and uniform polyester/ polyethylene (PET/PE) film.
- Mechanical and dimensional uniformity of continuous type an 10 or 12 mm multi-line heat-sealing.
- Suitable for hydrogen peroxide VH202 sterilization.
- The colour indicator turns to yellow. The process indicator changing is reported in more languages.
- The pouches can be easily opened by using the specific invitation. The opening direction (which in addition determines the slightest fibres' alteration) is represented by the codified symbol (PEEL).
- All pouches and rolls report the name of the manufacturer, the product code (REF), dimensions, batch and the process indicators in compliance with the standard UNI EN 868-5:2009 every 15 cm.
- The wording " do not use if the packaging is damaged" is represented by the specific codified symbol.
- Absence of interruptions on the bigger side of the roll, unrolling the roll interruptions on the bigger side are not present.
- Resistance to the sterilization: absence of lacerations before and after the sterilization process.
- High peelability of the two layers after the sterilization process: splitting the two layers of the roll/pouch, it verifies their ability to split without lacerations and fibres' release.
- TYVEK® has a sealing point that happens between 128°C and 130°C for about one second.
- STERIPLASMA pouches and rolls are suitable for the used with any brand of plasma sterilizers available on the market.
- Primary packaging with a plastic film in order to guarantee its protection from dust also after the carton opening and facilitate its transport in areas where the entrance of the cartons is not allowed.
- Secondary packaging in carton box.

- Labelling-data:
  Description of the content, product code (REF) quantity and product dimensions
  Manufacturer
  Product manufacturing date and deadline
  Production lot number
  Symbol CE in conformity to the medical devices Regulation 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. 04/2015 for pouches and Report n. 05/2015 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 conform to requirements of the reference standards UNI EN ISO 686-5, UNI EN ISO 11607-1 and 11607-2.

STORAGE CONDITIONS

Avoid direct exposure to sunlight or heat sources and store in environments with low contamination.
Keep away from light and humidity sources.
Use in arrival order and handle with care.
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.

HEALTH AND SAFETY

If STERIPLASMA® packaging are correctly used for their intended use, there are no special precautions to adopt during their handling and use.
These packaging do not contain agents or materials today considered as toxic.
Considering the materials chosen, it can be declared that the products are without phthalates or carcinogenic, mutagenic or toxic to reproduction substances.
In addition, it is declared that the products do not contain latex.
Absence of unpleasant smells dry and wet.
The undersigned declines every responsibility regarding the possible following contaminations from air pollution or from another source, once the product has been removed from its packaging.
Brivio, May 2021

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CND CLASSIFIFATION – DIRECTORY NUMBER

Commercial name	CND Classification	Directory number	Manufacturer
Flat pouches and Steriplasma self-sealing pouches	S01010201 – flat pouches in coupled plastic tyvek /film for sterilization	212834/R	E.C.S. S.r.l.
Steriplasma flat rolls	S01010201 – flat rolls in coupled plastic tyvek /film for sterilization	212831/R	E.C.S. S.r.l.

REF, DIMENSIONS AND PACKAGING

TVRP-Flat rolls

REF	DIMENSIONS	PACKAGING
TVRP7570	75 MM. X 70 MT.	8 pieces
TVRP1070	100 MM. X 70 MT.	4 pieces
TVRP1570	150 MM. X 70 MT.	4 pieces
TVRP2070	200 MM. X 70 MT.	2 pieces
TVRP2570	250 MM. X 70 MT.	2 pieces
TVRP3070	300 MM. X 70 MT.	2 pieces
TVRP3570	350 MM. X 70 MT.	1 piece
TVRP4070	400 MM. X 70 MT.	1 piece
TVRP4270	420 MM. X 70 MT.	1 piece
TVRP5070	500 MM. X 70MT.	1 piece

VBP-Flat pouches

REF	Dimensions	Packaging
TVBP7520	75 MM. X 200 MM.	1.000 pieces
TVBP1025	100 MM. X 250 MM.	500 pieces
TVBP1030	100 MM. X 300 MM.	500 pieces
TVBP1530	150 MM. X 300 MM.	500 pieces
TVBP1535	150 MM. X 350 MM.	500 pieces
TVBP2040	200 MM. X 400 MM.	500 pieces
TVBP2550	250 MM. X 500 MM.	500 pieces
TVBP3060	300 MM. X 600 MM.	400 pieces
TVBP4060	400 MM. X 600 MM.	400 pieces

LABELS

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

LIMITATIONS OF USE

STERIPLASMA packaging are not suitable for steam and hot-air sterilization.

WARNINGS

Seal the pouches and rolls open side with a heat-seal at the suggested temperature of 160-180°C, that temperature can vary depending on contact times and the sealing speed of the heat-sealer.
Follow the heat-sealer's manufacturer instructions.
Pouches and rolls are LATEX FREE.

PRODUCT SHELF-LIFE

The product has 5 years shelf-life from production date.
The product has to 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 guarantees the sterility maintenance exclusively at 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 regarding 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 Title: 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.

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FILM

ANALYSIS	STANDARD	VALUE	RESULT
Grammage		G/m2	65
Tensile strength MD	ASTM D 882	N/15mm	>45
Tensile strength CD	ASTM D 882	%	>45
Breaking load MD	ASTM D 882	%	>150
Breaking load CD	ASTM D 882	%	>165
Permeability to steam H2O	ASTM E96	g/sqm d-24 H	11
Permeability to steam O2	ASTM D3985	cc/sqm d-24 H	130

COMPLIANCE TO DIRECTIVES: the film conforms to FDA CFR21 standards.

PRODUCT DESCRIPTION: The film consists in a layer of PET and a layer of PE.
Excellent transparency
Excellent peelability (sealing characterised by endurance values responding to the need of guaranteeing the integrity of the packaging and at the same time of offering an easy opening).

APPLICATION:

the coat film has been specifically designed for the application with disposable medical devices.
The coat film is suitable to be welded with TYVEK®, in order to create a unique product to be used during hydrogen peroxide VH202 sterilization.

TRACEABILITY:

We can provide the documentation concerning the materials used for the manufacturing of our products during a period of 5 years starting from the production lot.

DISPOSAL:

The coat film is considered as a normal urban waste (in small quantities) and a special waste (in big quantities).

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TYVEK®

FEATURE	STANDARD	VALUE	RESULT
Grammage	EN ISO 536	G/m2	74.7
Exfoliation	ASTM D2724	N/2.54 CM	2.3
Porosity Gurley Hill	ISO 5636-5	Sec/100 cc	22
Permeability Bendtsen	ISO 5636-3	mL/min	572
Hydrostatic pressure test	DIN EN 20811	Cm H2O	147
Tensile strength MD	DIN EN ISO 1924-2	N/2.54 CM	196
Tensile strength CD	DIN EN ISO 1924-2	N/2.54 CM	200
Blast strength longitudinal	DIN EN 21974	mN	3,3
Blast strength transverse	DIN EN 21974	mN	3,5
Muller Burst	ISO 2758	Kpa	1213
Thickness	DIN EN 20534	um	178
Opacity	ISO 2471	%	91

COMPLIANCE TO DIRECTIVES: TYVEK® conforms to UNI EN ISO 11607 standards

APPLICATION: TYVEK® represents an excellent barrier against the penetration of bacterial spores and other contaminating micro-organisms.

TYVEK® pouches and rolls are suitable for hydrogen peroxide VH202 sterilization

TRACEABILITY: we can trace the documentation concerning the materials used for a period of 5 years starting from the lot production

DISPOSAL: TYVEK® is considered as a normal urban waste (in small quantities) and a special waste (in big quantities).

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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 ID 02207200136

Declares under its own responsibility that the products

"FLAT ROLLS AND FLAT POUCHES STERIPLASMA STERILIZATION LINE WITH PROCESS INDICATORS FOR GAS PLASMA VH2O2 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 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 Title: 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

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.

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Family products	Basic UDI-DI
Steriplasma flat rolls	803298667F01213X
Steriplasma flat pouches	803298667F01303Y

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

Brivio, May 2021

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