

Popieriaus-plastiko sterilizavimo rulonai STERIDIAMOND



Popieriaus-plastiko sterilizacijai skirti rulonai STERIDIAMOND su 1 klasės integruotais garų, EO ir/arba FO proceso poveikio indikatoriais, atitinkančiais EN ISO 11140-1. Rulonai pagaminti iš dviejų sluoksnių: skaidraus plastiko ir sustiprinto krepinio popieriaus (70 g/m²). Ant juostos yra nurodyta visa reikiama informacija: indikatorių spalvos pasikeitimų aprašymai, atidarymo kryptis, gamybinės partijos Nr., gaminio identifikacijos Nr., rulono ilgis, plotis. Rulonai abiejuose kraštuose turi 3 tvirtas užlydymo siūles.

Kiekvienas rulonas įpakotas individualiai į apsauginę plastiko plėvelės pakuotę ir įdėtas į kartono dėžę, todėl rulonai yra pasaugoti nuo dulkių, drėgmės.

Rekomenduojama lydymo temperatūra (160°C - 180°C), geriausias rezultatas pasiekiamas prie 170°C
 Standartiniai dydžiai, prekių kodai ir pakuotės:

| Dydis | Vnt/dėž. |
|------------------------|----------|
| 50 mm x 200 m | 8 |
| 75 mm x 200 m | 8 |
| 100 mm x 200 m | 4 |
| 120 mm x 200 m | 4 |
| 125 mm x 200 m | 4 |
| 150 mm x 200 m | 4 |
| 200 mm x 200 m | 2 |
| 250 mm x 200 m | 2 |
| 300 mm x 200 m | 2 |
| 350 mm x 200 m | 1 |
| 380 mm x 200 m | 1 |
| 400 mm x 200 m | 1 |
| 420 mm x 200 m | 1 |
| 500 mm x 200 m | 1 |
| 75 mm x 25 mm x 100 m | 8 |
| 100 mm x 50 mm x 100 m | 4 |
| 150 mm x 50 mm x 100 m | 4 |
| 200 mm x 55 mm x 100 m | 2 |
| 250 mm x 65 mm x 100 m | 2 |
| 300 mm x 70 mm x 100 m | 2 |
| 350 mm x 80 mm x 100 m | 1 |
| 400 mm x 80 mm x 100 m | 1 |

* PASTABA: galimybė užsakyti kitus dydžius pagal individualų užsakymą

Gamintojas: E.C.S. Srl (Italija)

TECHNICAL DATA SHEET
STERIDIAMOND - STERIPERFECT
ROLLS



STERIDIAMOND - STERIPERFECT rolls have been designed to be used in the hospitals and dental centres by anyone who needs to have the instruments or other medical devices sterilized by STEAM, EO and/or FORM.

STERIDIAMOND - STERIPERFECT rolls made of moisture-resistant medical 70g/m² paper manufactured with 100% pure pulp and plastic transparent layer made of polyester and polypropylene. The thickness of plastic part is: 12µm polyester, 40µm polypropylene and with the resin, it arrive on a total of 55µm. The medical paper and film has a tension strength of 350kPa. Strength of seals min 140 N/m.

Description:

Sterilization flat and/or gusseted rolls. Preformed Sterile Barrier System according to EN ISO 11607-1

REF No's:

| | |
|---------------------------|---------------------------|
| STERIDIAMOND | STERIDIAMOND WITH FO |
| SRPXXXXX (flat reels) | SRPFXXXX (flat reels) |
| SRSXXXXX (gusseted reels) | SRSFXXXX (gusseted reels) |

Conformity:

CE mark according MDD 93/42/EEC (Class I), 2003/32/CE, EN 868-3, EN 868-4, EN 868-5, EN ISO 11607-1, EN ISO 11607-2, EN ISO 15223-1:2012, EN 1041:2013, EN ISO 14971:2012, process indicators according ISO11140-1, ISO15882:2009

Recommended sealing parameters:

160 – 180°C (best performance in 170 °C)

Storage:

Products should be stored in dry areas away from light and heat. Temperature range 10°C - 30°C. Relative humidity: 30-60 %

Packaging:

Rolls are sealed in a transparent film in order to ensure their protection against dust.

Shelf life:

The product has a 5 years shelf-life from production date.

Country of Origin:

Italy



E.C.S. srl - Euro Clinical Service

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TECHNINIS DUOMENŲ LAPAS
STERIDIAMOND - STERIPERFECT
RULONAI



Vertimas iš anglų kalbos
Vertė: Jekaterina Baratinskienė

STERIDIAMOND - STERIPERFECT rulonai skirti instrumentų ir kitų medicinos prietaisų sterilizacijai garų, EO ir formaldehidu lignoninėse ir odontologijos centruose

STERIDIAMOND - STERIPERFECT rulonai pagaminti iš drėgmei atsparaus 70g/m² medicinos popieriaus, pagaminto iš 100% grynų masės ir plastiko skaidraus sluoksnio iš poliesterio ir polipropileno. Plastikinės dalies storis yra: 12µm poliesteris, 40µm polipropilenas kartu su kitais priedais, viso 55µm. Medicininis popierius ir plastikinė dalis turi atsparumą tempimui 350kPa. Siūlių stiprumas yra min 140 N/m.

Aprašymas:

Sterilizacija plokščiuose rulonuose ir rulonuose su kliste. Sterilus barjero sistema pagal EN ISO 11607-1 standartą.

Prekės kodai:

| STERIDIAMOND | STERIDIAMOND SU FO INDIKATORIUMI |
|------------------------------|----------------------------------|
| SRPXXXX (rulonai be klostės) | SRPFXXXX (rulonai be klostės) |
| SRSXXXX (rulonai su kliste) | SRSFXXXX (rulonai su kliste) |

Atitikimai:

CE ženklas pagal MDD 93/42/EEB (I klasė), 2003/32/CE, EN 868-3, EN 868-4, EN 868-5, EN ISO 11607-1, EN ISO 11607-2, EN ISO 15223-1:2012, EN 1041:2013, EN ISO 14971:2012, proceso indikatoriai pagal ISO11140-1, ISO15882:2009

Rekomendacijos dėl užlydymo temperatūros:

160 – 180°C (geriausi rezultatai prie 170 °C)

Saugojimas:

Produktai turi būti laikomi sausose vietose, esant šviesai ir šilumai. Temperatūros diapazonas 10 °C - 30 °C. Santykinis drėgnumas: 30-60%

Pakuotė:

Rulonai yra sandariai uždaryti permatomoje plėvelėje, kad būtų apsaugota nuo dulkių.

Galiojimo laikas:

5 metai nuo pagaminimo datos.

Kilmės šalis:

Italija



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STERIDIAMOND® - STERIPERFECT® POUCHES AND ROLLS

PRODUCT DESCRIPTION

- Medical devices belonging to class 1.
- Disposable devices designed for STEAM, EO gas and FORM sterilization.
- Not suitable neither for dry heat sterilization at temperatures higher than 140°C nor gas plasma sterilization.
- Medical paper (60g/mq) and plastic film made of polyester and polypropylene.
- The paper employed is white colour and resistant to humidity. It has been developed in order to grant a high level of protection against bacteria.
- All the printing indications, including the chemical indicators STEAM, EO gas and FORM sterilization, are positioned on the paper 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 EN ISO 11607 and EN 868 standards).
- The product is designed to be welded together.
- The multi-line, hot welding is continuous with rounded corners in order to prevent any deposit of dirt, thus reducing the risk of contamination of the content during stocking and upon package opening.
- STERIDIAMOND® - STERIPERFECT® pouches and rolls are in compliance to European Directive 93/42/CEE.

INSTRUCTIONS FOR USE

- Never use in case the packaging is damaged
- Evaluate the dimension of the product to be sterilized and choose the proper size
- Insert the product to be sterilized, securing sharp parts. Put instrument up to 75% of all spece to allow air flowing.
- Remove most air from the packaging before seeling.
- Ensure that the packaging is well sealed
- Start sterilization process.
- The steam process indicator turns from pink to brown. The EO process indicator turns from green/blue to brown.
- Indications of the process indicator are described in several languages and explained through international symbols
- Minimal release of fiber during opening thanks to the features of the medical paper.

CONDITIONS OF STORAGE

- Avoid direct exposure to sunlight or heat sources and store in environments avoiding any contamination.
- Keep far from heat, light and humidity. Rotate your stock accordingly to arrival order and handle with care.
- Shelf-life: 5 years from date of production
- Batch and production number for a complete traceability.

HEALTH AND SAFETY

When STERIDIAMOND® - STERIPERFECT® pouches and rolls are correctly used, there are no special precautions to adopt during their handling and use.

These products do not contain toxic or irritating agents or material.



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DECLARATION OF CE CONFORMITY

In compliance with Annex VII, Directive 93/42 CEE and further modifications and integrations, such as those provided to DL n. 37 of 25/01/2010, acknowledging the European Directive 2007/47/CE.

ECS[®] SRL
Via I° Maggio, 18/22
23881 Airuno (LC)
Italy

Declares under its own responsibility that the products, designed as:

"STERIDIAMOND[®] - STERIPERFECT[®] FLAT ROLLS, GUSSETTED ROLLS, FLAT POUCHES, GUSSETTED POUCHES, SELF-SEALING POUCHES for STEAM, EO gas and FORM sterilization" satisfy all the requirements applicable to European Directive 93/42/CEE and further modifications such as those provided by the D.L. n. 37 of 25/01/2010, acknowledging the European Directive 2007/47/CE, concerning the medical devices and are registered to the Italian Ministry of Health.

For this purpose, E.C.S. s.r.l. grants and declares under its own responsibility that:

- The range of the products referred to subject satisfies the essential requirements as per Annex I of the European Directive 93/42/CEE and further modifications such as those provided by the D.L. n. 37 of 25/01/2010, acknowledging the European Directive 2007/47/CE;
- The range of the products referred to subject belongs to Class I - non sterile;
- The devices referred to subject are not measurement instruments;
- The devices referred to subject are not designed for clinical trials purposes;

- The devices referred to subject comply to the European standards provided by UNI EN ISO 11607-1/-2 and UNI EN 868 - Packaging for medical devices terminally sterilized - part 3: paper to be used in the manufacturing of paper pouches (specified in the EN 868-4) and in the manufacturing of pouches and rolls (specified in the EN 868-5) - requirements and test methods
- ECS srl, manufacturer of these products, is certified according to the rules UNI EN ISO 9001:2008 and UNI EN ISO 13485:2012.

E.C.S. s.r.l. declares that the documentation according to the Annex VII of the European Directive 93/42/CEE and further modifications such as those provided by the D.L. n. 37 of 25/01/2010, acknowledging the European Directive 2007/47/CE, will be held at disposal during a period of five years starting from the last manufacturing batch of the devices referred to subject.

Airuno, April 2015

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



Sterilizavimo sprendimai

CE ATITIKTIES DEKLARACIJA

Pagal Direktyvos 93/42 VII priedą ir tolesnius pakeitimus bei integracijas, pvz., DL Nr. 37/01/2010, pripažįstant Europos direktyvą 2007/47 / EB.

ECS Srl
Via I° Maggio 18/22,
23881 Airuno (LC)
Italija

Deklaruoja, kad produktai, sukurti taip:

„STERIDIAMOND® - STERIPERFECT® rulonai be klostės, rulonai su klostė, maišeliai be klostės, maišeliai su klostė, saviklijai maišeliai skirti garų, EO dujų ir FORM sterilizavimui atitinka visus Europos direktyvos 93/42 / EEB reikalavimus ir kitus pakeitimus, pvz. DL Nr. 37/01/2010, pripažįstant Europos Direktyvą 2007/47 / EB dėl Medicinos Prietaisų ir yra registruoti Italijos sveikatos ministerijoje.

Šiuo tikslu E.C. s.r.l. suteikia ir deklaruoja savo atsakomybe, kad:

- Išvardintų produktų asortimentas atitinka esminius Europos Direktyvos 93/42 / EEB I ir II priedų reikalavimus ir tolesnius pakeitimus, pvz. Nr. 37/01/2010, pripažįstant Europos direktyvą 2007/47 / EB;
- Produktų, kuriems taikomas šis dokumentas, asortimentas priklauso I klasei - nesterilūs;
- Produktai, kuriems taikomas šis dokumentas, nėra matavimo priemonės;
- Produktai, kuriems taikomas šis dokumentas, nėra skirtos klinikinių tyrimų tikslams;
- Produktų kuriems taikomas šis dokumentas, asortimentas atitinka UNI EN ISO 11607-1/ -2 ir UNI EN 868 - Galutinai sterilizuotų medicinos prietaisų pakuotė - 3 dalis: popierius, naudojamas popieriniams maišeliams gaminti (nurodyti EN 868-4) ir maišelių ir ritinių gamybai (nurodyti EN 868-5) - reikalavimai ir bandymo metodai
- Šių produktų gamintojas - ECS srl - yra sertifikuotas pagal UNI EN ISO 9001: 2008 ir UNI EN ISO 13485: 2012 taisyklės.

E.C. s.r.l. pareiškia, kad dokumentacija paruošta pagal Europos direktyvos 93/42 / EEB VII priedą ir tolesni pakeitimai, pvz. Nr. 2010 m. Sausio 25 d. 37, pripažįstant Europos direktyvą 2007/47 / EB, bus laikomi per penkerius metus nuo paskutinės gaminių, nurodytų minėtame straipsnyje, gamybos partijos.

Airuno, 2015-04

Direktorė

Baramedia

E.C.S. s.r.l