**Popieriaus-plastiko sterilizavimo rulonai STERIDIAMOND**

i

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

# 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.

Vertimas iš anglų kalbos
Vertė: Jekaterina Baratinskienė

Sterilizavimo sprendimai

Euro Clinical Service

# 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 kloste, maišeliai be klostės, maišeliai su kloste, 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 taisykles.

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
Jekaterina Baratinskienė

„Barameda"

E.C.S. s.r.l

**PRODUCT SHELF-LIFE**

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

**COMPLIANCE TO DIRECTIVES:**

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

- MDD 93/42;
- UNI CEI EN ISO 14971: 2012 « Application of risks management of medical devices »;
- ISO 11607 standards;
- EN 868 standards – 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;
- UNI EN ISO 11140-1:2009; "Sterilization of healthcare products – Chemical Indicators – Part 1: general requirements"
- UNI EN ISO 15882:2009 "Sterilization of healthcare products – Chemical Indicators – Guidelines for the selection, use and interpretation of results";

**PROCEDURES FOR CERTIFICATION:**

Annex VII of MDD 93/42.

Refer to the responsibility management included in the "Declaration of conformity"

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