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Katerina Baratinskienė

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

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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.

Vertimas iš anglų kalbos
Vertė: Jekaterina Baratinskienė

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 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

E.C.S. s.r.l

Euro Clinical Service

Sterilization Solutions

DECLARATION OF CONFORMITY

Airuno, January 2017

The undersigned E.C.S. SRL having its legal premises in Via I° Maggio n. 18/22 – 23881 Airuno (LC), in the name of Mr. IVANO REDAELLI, as CEO

DECLARES

That the sterilization roll tapes (V12 – V19/50MT – V19/55MT – V25) complies to directive UNI EN ISO 11140-1:2009 (Non biological systems for use in sterilizers – general requirements) for the parts applicable to the process indicators belonging to CLASS 1.

E.C.S. srl also declares that this product is not a medical device and, therefore, the European Directive 93/42/CEE and further modifications are not applicable.

Vertimas iš anglų kalbos
Vertė: Jekaterina Baratinskienė

Sterilization Solutions
ECS
S.r.l.
Euro Clinical Service

Sterilizavimo sprendimai

ATITIKTIES DEKLARACIJA

Airuno, 2017 Sausis

Aš, įmonės E.C.S. SRL, registruotos adresu Via I° Maggio 18/22, 23881 Airuno (LC), vadovas IVANO REDAELLI

DEKLARUOJU, kad

Sterilizavimui skirtos juostos (V12 – V19/50m – V19/55m – V25) atitinka UNI EN ISO 11140-1:2009 (ne biologinės kilmės sistemos, skirtos naudoti sterilizatoriuose – bendrieji reikalavimai) naudojami proceso indikatoriai atitinka 1 klasę.

E.C.S. srl taip pat deklaruoja, kad šie produktai yra priskirti medicinos prietaisams, Europos Direktyvai 93/42/EEB ir tolesni pakeitimai netaikomi.

Liudytojas
ECS srl
parašas/spaudas

Jekateri