CE Declaration of Conformity

Ivano Redaelli

As PRRC of the company E.C.S.S.R.L.

based in Headquarters: Via Como, 71 – 23883 – Brivio (LC)

VAT number: 02207200136 SRN: IT-MF-000036233

declares

that the product: STERIDIAMOND-STERIPERFECT
POUCHES AND REELS (FLAT AND GUSSETTED) AND SELF-SEAL POUCHES

Model and code:
SRPXXXX
SRPFXXXX
RPXXXX
SRSXXXX
SRSXXXXB

SBPXXXX
SBPXXXXB
SBAXXXX
SBAXXXX/100
BAXXXXX
SBSXXXX

Class: I disposable

GMDN: 13735

Basic UDI-DI:

Product family	Basic UDI-DI
Steridiamond flat pouches	803298667F00403W
Steridiamond blue film flat pouches	803298667F004344
Steridiamond gussetted pouches	803298667F00503Z
Steridiamond self- sealing pouches	803298667F006044
Steriperfect self-sealing pouches	803298667F01103S
Steridiamond flat reels	803298667F00203Q
Steridiamond flat reels with FORM	803298667F00223U
Steridiamond gussetted reels	803298667F00303T
Steridiamond blue film gussetted reels	803298667F00313V
Steriperfect flat Reels	803298667F00804A

It was built in compliance with the following directives and standards:

- Regulation (EU) n.745/2017 Regulation on medical devices
- Standard IEC 61882:2016 Risk analysis method according to the HAZOP method
- Standard CEI EN 61511-1 used for the residual risk calculation method LOPA
- UNI CEI EN ISO 15223-1:2021 Title: Medical devices - Symbols to be used in medical device labels, labeling and information to be provided - Part 1: General requirements
- UNI CEI EN 1041:2013 Information supplied by the Manufacturer with medical devices
- UNI CEI EN 14971:2020 Application of risk management to medical devices
- UNI EN 868-2:2017 Title: Packaging for terminally sterilized medical devices - Part 2: Sterilization wraps - Requirements and test methods
- UNI EN 868-3:2017 Title: Packaging for terminally sterilized medical devices - Part 3: Paper to be used in the manufacture of paper pouches (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) - Requirements and test methods

- UNI EN 868-5:2019 Title: Packaging for terminally sterilized medical devices - Part 5: Heat-sealable pouches and tubes consisting of one side of porous material and one side of plastic film - Requirements and test methods
- EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for format, sealing and assembly processes
- UNI EN ISO 11140-1:2015 Sterilization of sanitary products - Chemical indicators - Part 1: general requirements.
- UNI EN ISO 15882:2009 Sterilization of sanitary products - Chemical indicators - Guide for selection, use and interpretation of results
- UNI EN ISO 11737 – 1: 2021 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products

E.C.S.S.R.L., manufacturer of these products, is certified in accordance with the UNI EN ISO 9001:2015 and UNI EN ISO 13485:2016 standards.

And it is therefore compliant with current directives and regulations.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Place: Brivio	Signature:
Date: September 2023	Rev. 20

E.C.S.S.R.L.