

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																							
<i>declares</i>																							
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 BAXXXX SBSXXXX																							
Class: I disposable GMDN: 13735	<p>Basic UDI-DI:</p> <table border="1"> <thead> <tr> <th>Product family</th> <th>Basic UDI-DI</th> </tr> </thead> <tbody> <tr> <td>Steridiamond flat pouches</td> <td>803298667F00403W</td> </tr> <tr> <td>Steridiamond blue film flat pouches</td> <td>803298667F004344</td> </tr> <tr> <td>Steridiamond gussetted pouches</td> <td>803298667F00503Z</td> </tr> <tr> <td>Steridiamond self- sealing pouches</td> <td>803298667F006044</td> </tr> <tr> <td>Steriperfect self-sealing pouches</td> <td>803298667F01103S</td> </tr> <tr> <td>Steridiamond flat reels</td> <td>803298667F00203Q</td> </tr> <tr> <td>Steridiamond flat reels with FORM</td> <td>803298667F00223U</td> </tr> <tr> <td>Steridiamond gussetted reels</td> <td>803298667F00303T</td> </tr> <tr> <td>Steridiamond blue film gussetted reels</td> <td>803298667F00313V</td> </tr> <tr> <td>Steriperfect flat Reels</td> <td>803298667F00804A</td> </tr> </tbody> </table>	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
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It was built in compliance with the following directives and standards:																							
<ul style="list-style-type: none"> 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

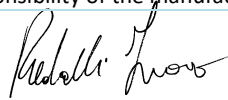
E.C.S.S.R.L., manufacturer of these products, is certified in accordance with the UNI EN ISO 9001:2015 and UNI EN ISO 13485:2016 standards.

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.