SEIRIN

[Form No. SQAF02503-01-001]

EU-DECLARATION OF CONFORMITY(MDD)

Manufacturer : SEIRIN Corporation (SRN ; JP-MF-000012274)
1007-1 Sodeshi-cho, Shimizu-ku, Shizuoka-shi, Shizuoka, 424-0037 JAPAN

SEIRIN Corporation Shimizu Division
13-7 Yokosunanishi-cho, Shimizu-ku, Shizuoka-shi, Shizuoka, 424-0036 JAPAN

European Representative : Emergo Europe (SRN ; NL-AR-000000116)
Prinsessegracht 20, 2514 AP The Hague, The Netherlands
+31.70.345.8570 - phone, +31.70.346.7299 - fax, EmergoEurope@ul.com

Product : Sterile SEIRIN Acupuncture Needles
(Jtype 、 Ltype 、 Mtype 、 J15 、 J-ProPak10 、 JSP 、 Btype 、 Dtype Gtype)

Basic UDI-DI : 4547248SAN001RZ

Intended Purpose : This product is intended to be used for acupuncture and/or moxa heat treatment. This product is designed to be used only by authorized medical practitioners (specialists).
Since this product is sterile, it is not intended for reuse or re-sterilization.
There are no contraindications other than re-sterilization and re-use.

Classification : Rule 6 , Class Ⅱa

Conformity assessment Route : MDD 93/42/EEC (2007/47/EC) AnnexⅤ

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC(2007/47/EC) for medical devices as transposed into national law.
All supporting documentation is retained under the premises of the manufacturer.

Standards applied :

- BS EN ISO 13485;2016+A11:2021 Medical devices - Quality management systems – Requirements for regulatory purposes
- EN ISO 14971 ; 2019 Medical devices - Application of risk management to medical devices
- EN 62366-1 ; 2015+A1:2020 Medical devices – Part 1: Application of usability engineering to medical devices
- EN ISO 15223-1 ; 2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
- EN ISO 20417 ; 2021 Medical devices – Information to be supplied by the manufacturer
- EN ISO 10993-1 ; 2020 Biological evaluation of medical devices – Part 1:Evaluation and testing within a risk management process
- EN ISO 10993-5 ; 2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-7 ; 2008+AMD1:2019 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals – Amendment 1: Applicability of allowable limits for neonates and infants
- EN ISO 10993-10 ; 2013 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- EN ISO 10993-11 ; 2018 Biological evaluation of medical devices – Part 11 : Tests for systemic toxicity
- 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 forming, sealing and assembly processes
- EN ISO 11135 ; 2014 +A1:2019 Sterilization of health-care products – Ethylene oxide- Requirements for the development, validation, and routine control of a sterilization process for medical devices – Amendment 1: Revision of Annex E, Single batch release
- EN ISO 11737-1 ; 2018+Amd1:2021 Sterilization of health care products - Microbiological methods - Part:1 Determination of a population of microorganisms on products – Amendment 1
- EN ISO 11737-2 ; 2020 Sterilization of health care products - Microbiological methods - Part:2 Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 17218 ; 2014 Sterile acupuncture needles for single use
- JIS T 9301 ; 2016 Acupuncture needle for single use
- ISO 14644-1 ; 2015 Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration

Published by SEIRIN CORPORATION
1007-1 Sodeshi cho, Shimizu-ku, Shizuoka-shi, Shizuoka 424-0037 JAPAN
Tel.: +81-54-365-5322 Fax: +81-54-365-2927
www.seirin.jp
customerservice@seirin.jp

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Notified Body : TÜV SÜD Product Service GmbH
Ridlerstraße 65・80339 Munich・Germany CE 0123

(EC)Certificate(s) :

- CERTIFICATE (Quality Management System) : № Q5 025129 0048 Rev.01 (Valid until; 2024/07/10)
- EC-CERTIFICATE : № G2 025129 0041 Rev.02 (Valid until; 2024/05/26)
- CERTIFICATE (MDSAP) : № QS6 025129 0049 Rev.01 (Expiry Date; 2024/06/20)

Products covered :

Listing reference (List of CE marked product ; 2022/04/13
<MDD-№1、MDD-№2、MDD-№3>)
Listing reference (List of CE marked product ; 2022/08/30
<MDD-№4>)

Signature : Ken. Kubota.
Name: Ken Kubota
Position: Management representative

Place : **Shizuoka, Japan** **Date of Issue** : **2022-08-30**

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

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