SEIRIN

[Form No. SQAF02503-01-001]

EU-DECLARATION OF CONFORMITY(MDR)

Manufacturer : SEIRIN Corporation (SRN ; JP-MF-000012274)
147 Ouchi, Shimizu-ku, Shizuoka-shi, Shizuoka, 424-0061, JAPAN

European Representative : Emergo Europe B.V. (SRN ; NL-AR-000000116)
Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
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Product : Sterile SEIRIN Acupuncture Needles
(J type ・ L type ・ J15 ・ J-ProPak10 ・B type ・ G type ・ ELIPEAS)

Basic UDI-DI : 4547248SAN001RZ

Intended Purpose : This product is a device intended to pierce the skin in the practice of acupuncture and/or moxibustion in order to relieve pain and to promote other therapeutic effects.

Classification : Rule 6 , Class Ⅱa

Conformity assessment Route : Medical Device Regulation
The device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745 Annex IX

Standards applied :

・EN ISO 13485:2016+A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
・EN ISO 14971:2019+A11:2021	Application of risk management to medical devices
・EN 62366-1:2015	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
・EN ISO 10993-7:2008+A1:2022	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals – Amendment 1: Applicability of allowable limits for neonates and infants
・EN ISO 10993-10:2023	Biological evaluation of medical devices – Part 10: Tests for skin sensitization
・EN ISO 10993-11:2018	Biological evaluation of medical devices – Part 11 : Tests for systemic toxicity
・EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
・ISO 17218:2014	Sterile acupuncture needles for single use
・JIS T 9301:2016	Acupuncture needle for single use
・EN ISO 11607-1:2020+A1:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
・EN ISO 11607-2:2020+ A1:2023	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+A1:2021	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 14644-1:2015	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration

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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.03 (Valid until; 2027/07/10)
- EU Quality Manegement System Cetificate (MDR) : №. G10 025129 0050 Rev.01 (Valid until; 2028/08/23)
- CERTIFICATE (MDSAP) : №. QS6 025129 0049 Rev.03 (Expiry Date; 2027/06/20)

Products covered :

Listing reference (List of CE marked product ; 2025/03/04 <MDR-№2、MDR-№3>)

Signature : Ken. Kubota

Name: Ken Kubota
Position: Management representative

Place : **Shizuoka, Japan** **Date of Issue** : **2025-03-04**

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

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