SEIRIN

[Form No. SQAF02503-01-002]

EU-DECLARATION OF CONFORMITY

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
+31.70.345.8570 - phone, +31.70.346.7299 - fax, EmergoEurope@ul.com

Product : Sterile SEIRIN Pyonex Needles (PYONEX)

Basic UDI-DI : 4547248SPN001X6

Intended Purpose : This product is a device intended to pierce the skin in the practice of acupuncture by authorized medical practitioners (specialists) in order to relieve pain and to promote other therapeutic effects.

Classification : Rule 7 , 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 18746 ; 2016	Traditional Chinese medicine - Sterile intradermal 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

Published by SEIRIN CORPORATION
147 Ouchi, Shimizu-ku, Shizuoka-shi, Shizuoka 424-0061 JAPAN
Tel.: +81-(0)54-344-7008 Fax: +81-(0)54-344-7078
www.seirin.jp
customerservice@seirin.jp

SEIRIN

[Form No. SQAF02503-01-002]

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)
- EC-CERTIFICATE : № 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 ; 2025/03/03 <MDR-№2>)

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

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

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

Published by **SEIRIN CORPORATION**
147 Ouchi, Shimizu-ku, Shizuoka-shi, Shizuoka 424-0061 JAPAN
Tel.: +81-(0)54-344-7008 Fax: +81-(0)54-344-7078
www.seirin.jp
customerservice@seirin.jp