SEIRIN

[Form No. SQAF02503-01-001]



# EU-DECLARATION OF CONFORMITY(MDR)

**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
SEIRIN Corporation Shizuoka Division
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 Acupuncture Needles
(Jtype ・J15 ・Btype ・ Gtype ・ 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+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 10993-10:2023 | 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+A11:2022 | Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems |
| ・EN ISO 11607-2:2020+A11:2022 | 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 14644-1:2015 | Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration |

Published by **SEIRIN CORPORATION**
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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 ; 2024/08/30 <MDR-№1> )

**Signature** : Ken. Kubota

Name: Ken Kubota
Position: Management representative

**Place** : **Shizuoka, Japan** **Date of Issue** : **2024-08-30**

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

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# CEマーク貼付製品一覧表 (MDR)

## List of CE marked Product (MDR)

## EC-Rep : Emergo Europe B.V.

セイリン鍼 (SEIRIN Acupuncture Needles)

【Common items】

MDA/MDN/MDS/MDT Code;【MDN 1208】,【MDS 1005】,【MDT 2001】,【MDT 2002】,【MDT 2008】,【MDT 2011】

EMDN Code;【A019002】

Incorporating a substance as an integral part which, if used separately, may be considered to be a medicinal product etc.; No

Without indented medical purpose according to MDR Annex XVI; No

Reusable/ Re-processing and System or Procedure pack; N/A

A part of a configurable device/system; No

Packaging description/ material/ technology (Sterile papar / PVC/PE film)

【Manufacturing site】

(1) SEIRIN Corporation

Address; 1007-1 Sodeshi-cho, Shimizu-ku, Shizuoka-shi, Shizuoka, Japan

(2) SEIRIN Corporation Shimizu Division

Address; 13-7 Yokosunanishi-cho, Shimizu-ku, Shizuoka-shi, Shizuoka, Japan

(Including packaging process and sterilization process/ Sterilization Method: ETO / Product Family: Acupuncture Needle)

【External Manufacturing (Sterilization) Site】

(1) Steri-Tech Co., Ltd.

Address 13-1 Hanasaki 5 chome, Kazo-shi Saitama, Japan

(Sterilization Method: ETO / Product Family: Acupuncture Needle)

(2) Steri-Tech Co.,Ltd. West Japan Office

Address; 4-7 Mitsugaoka 2 chome, Kobe-shi, Hyogo, Japan

(Sterilization Method: ETO / Product Family: Acupuncture Needle)

| タイプ Type | サイズ Size | UDI-DI | 初期 Lot Initial Lot | 分類の判断基準 Standard of classification | | 備考 Note |
|---|---|---|---|---|---|---|
| Jtype | №1(φ0.16)× 30 ㎜ | 04547248110116 | 24326G1 | 侵襲機器、Rule 6 Invasive, Rule6 | Ⅱa | For MDR Article 54 clinical evaluation consultation procedures for certain Class III and Class IIb equipment. All devices are Class IIa. Therefore, they are not subject to Article 54.<br><br>(MDR 54 条クラスⅢ及びクラスⅡb 機器の臨床評価協議手続きについて、全ての機器はクラスⅡa である。従って 54 条の対象ではない。) |
| | №3(φ0.20)× 30 ㎜ | 04547248110215 | 24318H1 | | | |
| | №8(φ0.30)× 30 ㎜ | 04547248110482 | 24401G1 | | | |
| | №8(φ0.30)× 50 ㎜ | 04547248110505 | 24319J1 | | | |
| | №8(φ0.30)× 60 ㎜ | 04547248110512 | 24306H1 | | | |
| $J_{15}$ | №02(φ0.12)× 15 ㎜ | 04547248131043 | 24506D1 | 侵襲機器, Rule 6 Invasive, Rule6 | Ⅱa | |
| | №01(φ0.14)× 15 ㎜ | 04547248131074 | 24604B1 | | | |
| | №1(φ0.16)× 15 ㎜ | 04547248131104 | 24506B1 | | | |
| | №2(φ0.18)× 15 ㎜ | 04547248131159 | 24513D1 | | | |
| Btype | №1(φ0.16)× 15 ㎜ | 04547248011109 | 24311A9 | 侵襲機器, Rule 6 Invasive, Rule6 | Ⅱa | |
| | №3(φ0.20)× 15 ㎜ | 04547248011208 | 24311B9 | | | |
| | №5(φ0.25)× 30 ㎜ | 04547248011390 | 24507B1 | | | |
| | №5(φ0.25)× 40 ㎜ | 04547248011406 | 24603B1 | | | |
| | №8(φ0.30)× 30 ㎜ | 04547248011482 | 24412B1 | | | |
| | №8(φ0.30)× 50 ㎜ | 04547248011505 | 24327B1 | | | |
| | №10(φ0.35)× 50 ㎜ | 04547248011598 | 24326B9 | | | |
| Gtype | №8(φ0.30)× 75 ㎜ | 04547248116521 | 24514G1 | 侵襲機器, Rule 6 Invasive, Rule6 | Ⅱa | |
| ELIPEAS | №02(φ0.12)×7 ㎜ | 04547248140045 | 24610A1 | 侵襲機器, Rule 6 Invasive, Rule6 | Ⅱa | |
| | №01(φ0.14)×7 ㎜ | 04547248140076 | 24523A1 | | | |
| | №1 (φ0.16)×7 ㎜ | 04547248140106 | 24522A1 | | | |

2024/08/30

| 作成 Preparation | 確認 Approval |
|---|---|
| T. Amma | Masashi Schoto |