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 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 :

- BS EN ISO 13485 ; 2016+A11:2021 Medical devices - Quality management systems – Requirements for regulatory purposes
- EN ISO 14971 ; 2019 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
- 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 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems · EN ISO 11607-2 ; 2020 Validation requirements for forming, sealing and assembly processes
- 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 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
Ridlerstraβe 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 ; 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.

パイオネックス (SEIRIN Pyonex 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 / Cartridge molded from PE resin)

【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)

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
PYONEX	0.3mm	04547248420017	24521A9	侵襲機器、Rule 7 Invasive, Rule 7	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. (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。)
	0.6mm	04547248420024	24530A1			
	0.9mm	04547248420031	24520A9			
	1.2mm	04547248420048	24405A9			
	1.5mm	04547248420062	24403B9			

2024/08/30

作成 Created by	承認 Approved by
T. Amma	Masashi Sekito