SEIRIN®

DECLARATION OF CONFORMITY

Manufacturer : SEIRIN Corporation
1007-1 Sodeshi-cho Shimizu-ku Shizuoka-shi Shizuoka-ken Japan

SEIRIN Corporation Shimizu Division
13-7 Yokosunanishi-machi Shimizu-ku Shizuoka-shi Shizuoka-ken Japan

European Representative :
Emergo Europe
Prinsessegracht 20, 2514 AP The Hague, The Netherlands
+31.70.345.8570 - phone, +31.70.346.7299 - fax, EmergoEurope@ul.com

Product : Sterile SEIRIN Pyonex Needles (PYONEX)

Classification : Rule 7 , Class II a

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

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 :

- EN ISO 13485 ; 2016 Quality management systems
- EN ISO 14971 ; 2012 Application of risk management to medical devices
- EN ISO 11607-1 ; 2009 Requirements for materials, sterile barrier systems and packaging systems
- EN ISO 11607-2 ; 2006 Validation requirements for forming, sealing and assembly processes
- EN ISO 10993-1 ; 2009 Evaluation and testing within a risk management process
- EN ISO 10993-7 ; 2008 Ethylene oxide sterilization residuals
- ISO 18476 ; 2015 Traditional Chinese medicine - Sterile intradermal acupuncture needles for single use
- EN ISO 15223-1 ; 2016 Symbols to be used with medical device labels, labelling and information to be supplied
- EN1041 ; 2008 Information supplied by the manufacturer with medical devices
- EN ISO 11135 ; 2014 Sterilization of health care products - Ethylene oxide -
- EN ISO 11737-1 ; 2006 Sterilization of medical devices - Microbiological methods - Part:1
- EN ISO 11737-2 ; 2009 Sterilization of medical devices - Microbiological methods - Part:2
- ISO 14644-1 ; 2015 Cleanrooms and associated controlled environments

Notified Body : TÜV SÜD Product Service GmbH
Zertifizierstelle Ridlerstr. 65・ 80339 München Germany CE 0123

(EC)Certificate(s) :

- CERTIFICATE (Quality Management System) : № Q5 025129 0048 Rev.00 (Valid until; 2021/07/10)
- EC-CERTIFICATE : № G2 025129 0041 Rev.02 (Valid until; 2024/05/26)
- CERTIFICATE (MDSAP) : № QS6 025129 0049 Rev.00 (Expiry Date; 2021/08/12)

Products covered :
Listing reference (List of CE marked product ; 2017/12/26 <№1)
Listing reference (List of CE marked product ; 2020/10/14 <№2)

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

Place : Shizuoka. Japan **Date of Issue** : 2020-10-14

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

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