

# DECLARATION OF CONFORMITY

**Manufacturer :**

SEIRIN Corporation  
1007-1 Sodeshi-cho Shimizu-ku Shizuoka-shi Shizuoka-ken 424-0037 Japan  
SEIRIN Corporation Shimizu Division  
13-7 Yokosunanishi-machi Shimizu-ku Shizuoka-shi Shizuoka-ken 424-0036 Japan

**European Representative :**

Scanlan Group BV  
Postbus 75664,1118 ZS Schiphol Triport, The Netherlands

**Product :**

Sterile SEIRIN Acupuncture Needles  
( Jtype , Ltype , Mtype , J15 , J-Propak10 , JSP  
Btype , Dtype , J15SP , Nanshin , Gtype , Mtype SP )

**Classification :**

Rule 6 , Class II a

**Conformity assessment Route :**

MDD 93/42/EEC ( 2007/47/EC )  
· AnnexI · AnnexV · AnnexVII · AnnexIX

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
- JIS T 9301 ; 2016 Acupuncture needle for single use
- ISO 17218 ; 2014 Sterile acupuncture needles for single use
- EN ISO 15223-1 ; 2016 Symbols to be used with medical device labels, labelling and information to be supplied

**Notified Body :**

TÜV SÜD Product Service GmbH  
Zertifizierstelle Ridlerstr. 65 · 80339 München Germany CE 0123

**(EC)Certificate(s) :**

- CERTIFICATE ( Quality Management System ) : № Q1N 17 01 25129 040 (Valid until; 2020/5/31)
- EC-CERTIFICATE : № G2 17 03 25129 041 (Valid until; 2022/9/23)
- CERTIFICATE ( Health Canada ) : № QS1 17 06 25129 046 (Expiry Date; 2018/12/31)

**Products covered :**

Listing reference (List of CE marked product ; 2017/10/25 <№1, №2, №3> )  
(List of CE marked product ; 2018/2/27 <№4> )

**Place, Date of Issue :**

2018/2/27

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

Signature :

  
Name : Ken Kubota  
Position : Management representative