EC CERTIFICATE

Number: 2134831CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Sensimed SA

Route en Rambuz 17
CH-1037 Etagnières
Switzerland

For the product category(ies)

Medical device telemetry applications for monitoring IOP related patterns

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2134831CN, initially dated 7 May 2010
Addendum, initially dated 7 May 2010

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 7 May 2010
Revised: 7 May 2021
Reissued: 1 April 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2134831CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Medical device telemetry applications for monitoring IOP related patterns

Issued to:

Sensimed SA
Route en Rambuz 17
CH-1037 Etagnières
Switzerland

This certificate covers Sensimed Triggerfish system, which contains the following components:

- Sensimed Triggerfish Sensor (configurations steep, flat and medium)
- Sensimed Triggerfish Antenna (left and right)
- Sensimed Triggerfish Data-Cable
- Sensimed Triggerfish Software
- Sensimed Triggerfish Data Recorder

Initial date: 7 May 2010
Revision date: 7 May 2021

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344