

CERTIFICATE

Number: 2134831CE01

CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

Sensimed AG

Route de Chavannes 37

1007 Lausanne

Switzerland

For the product category:

Medical device for continuous intraocular pressure monitoring

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 Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex V in combination with Annex VII for class IIa products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. The necessary information 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: 1 April 2014

Issued for the first time: 7 May 2010

Reissued: 22 April 2011

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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All testing, inspection, auditing and certification activities of the former KEMA Quality are an integral part of the DEKRA Certification Group.

ADDENDUM

Belonging to certificate: 2134831CE01

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CE MARKING OF CONFORMITY MEDICAL DEVICES

Medical device for continuous intraocular pressure monitoring

Issued to:

Sensimed AG
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Switzerland

This CE 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: 13 January 2011

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of ing. A.A.M. Laan.

ing. A.A.M. Laan
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