

EC CERTIFICATE

Number: 2147915CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class IIa, IIb or III and Devices in Class I in sterile conditions and sterilised systems or procedure packs)

Manufacturer:

Medical Concepts Europe B.V.

Oost-Om 54
5422 VZ Gemert
The Netherlands

For the product category(ies)

Temporary epicardial and myocardial pacing wires including adaptors, and patient cables

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 2147915CN, initially dated 3 November 2011 Addendum, initially dated 11 May 2012

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, that covers the aspects of manufacture concerned with securing and maintaining sterile conditions, for the above mentioned product category in accordance to the provisions of Annex II 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: 1 November 2022
Issued for the first time: 3 November 2011
Reissued: 1 November 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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

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ADDENDUM

Belonging to certificate: 2147915CE01

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Temporary epicardial and myocardial pacing wires including adaptors, and patient cables

Issued to:

Medical Concepts Europe B.V.
Oost-Om 54
5422 VZ Gemert
The Netherlands

This certificate covers the following product(s):

- Temporary pacing wires including adaptors (class III)
- Patient cables: FastLock (class Is)

Initial date: 11 May 2012

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of ing. A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan
Certification Manager

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