

# EC DESIGN-EXAMINATION CERTIFICATE

Number: 2147915DE01

**Directive 93/42/EEC on Medical devices, Annex II (4)**  
(Devices in Class III)

Manufacturer:

**Medical Concepts Europe B.V.**

**Oost-Om 54  
5422 VZ Gemert  
The Netherlands**

For the product

**Temporary epicardial and myocardial pacing wires including adaptors**

Documents, that form the basis of this certificate:

**Certification Notice 2147915CN, initially dated 3 November 2011**  
**Addendum, initially dated 22 February 2016**

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, 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, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and 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: 22 February 2016  
Reissued: 1 November 2017

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, consisting of a stylized, cursive script.

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of ing. A.A.M. Laan, consisting of a stylized, cursive script.

ing. A.A.M. Laan  
Certification Manager

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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-certification.com Company registration 09085396

# ADDENDUM

Belonging to certificate: 2147915DE01

1/1

## EC DESIGN-EXAMINATION MEDICAL DEVICES

Temporary epicardial and myocardial pacing wires including adaptors

Issued to:

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

This certificate covers the following product(s):

MONOPOLAR WIRE – EPICARDIAL  
BIOPOLAR WIRE – EPICARDIAL  
QUADPOLAR WIRE – EPICARDIAL  
MONOPOLAR WIRE – MYOCARDIAL - ADULT  
BIOPOLAR WIRE – MYOCARDIAL – ADULT  
QUADPOLAR WIRE – MYOCARDIAL – ADULT  
MONOPOLAR WIRE – MYOCARDIAL – PEDIATRIC  
BIOPOLAR WIRE – MYOCARDIAL – PEDIATRIC  
QUADPOLAR WIRE – MYOCARDIAL - PEDIATRIC

PACKS (PACING WIRE + FASTLOCK)

Initial date: 22 February 2016

DEKRA Certification B.V.

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drs. G.J. Zoetbrood  
Managing Director

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

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