

# CERTIFICATE

Number: 2017847CE14

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

**Contract Medical International, GmbH**

Zur Wetterwarte 50, Haus 302

01109 Dresden

Germany

For the product category:

**Cardiac Ablation Catheter System**

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 2017847CN, initially dated 15 May 2002**  
**Addendum, initially dated 6 June 2011**

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 II for class III products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II, section 4 is mandatory. 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 June 2012

Issued for the first time: 6 June 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: 2017847CE14

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

Cardiac Ablation Catheter System

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Germany

This certificate covers the following product(s):

- ACT Tempasure Cardiac Ablation Catheter (Class III)
- ACT Cardiac Ablation Temperature Monitor Display (CATMD) Interface Box (Class IIb)
- ACT Patient Interface Module (PIM) Extension Cable (Class IIb)

Initial date: 6 June 2011

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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