

CERTIFICATE

Number: 2017847CE05



CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

Contract Medical International, GmbH

Zur Wetterwarte 50, Haus 302

01109 Dresden

Germany

For the product category:

Introducer Sheath Device for percutaneous intravascular introduction

KEMA Quality 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 May 15, 2002

Addendum, initially dated December 23, 2009

KEMA Quality 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 section 3 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: June 1, 2011

Issued for the first time: December 23, 2009

KEMA Quality B.V.

drs. G.J. Zoetbrood
Managing Director

M. McCann
Certification Manager

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ADDENDUM

Belonging to certificate: 2017847CE05

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Introducer Sheath Device for percutaneous intravascular introduction

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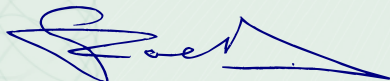
This certificate covers the following product(s):

Introducer Sheath System (Class IIa)

Initial date: December 23, 2009

Revision date: April 20, 2010

KEMA Quality B.V.



drs. G.J. Zoetbrood
Managing Director



M. McCann
Certification Manager

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