

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2017847DE06

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

Manufacturer:

Contract Medical International GmbH
Lauensteiner Straße 37
01277 Dresden
Germany

For the product

Emery Glide™: Single use MR Conditional Guidewire for the introduction and/or the placement of diagnostic or interventional devices in the central circulatory and/or peripheral vasculature using magnetic resonance imaging techniques

Documents, that form the basis of this certificate:

Certification Notice 2017847CN, initially dated 15 May 2002
Addendum, initially dated 31 October 2014

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: 31 October 2014
Revised: 15 December 2017
Reissued: 15 December 2017

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

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ADDENDUM

Belonging to certificate: 2017847DE06

1/1

EC DESIGN-EXAMINATION MEDICAL DEVICES

Emery Glide™: Single use MR Conditional Guidewire for the introduction and/or the placement of diagnostic or interventional devices in the central circulatory and/or peripheral vasculature using magnetic resonance imaging techniques

Issued to:

Contract Medical International GmbH
Lauensteiner Straße 37
01277 Dresden
Germany

This certificate covers the following product(s):

Size 180 cm, Outer diameter 0,035 inch

Initial date: 31 October 2014

DEKRA Certification B.V.

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Managing Director

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