

CERTIFICATE

Number: 2020764DE01

EC DESIGN-EXAMINATION MEDICAL DEVICES

Issued to:

PendraCare International B.V.

Van der Waalspark 22

9351 VC Leek

The Netherlands

For the product(s) / product category:

Angiographic Catheters (GMDN 10688)

Documents, that form the basis of this certificate:

Certification Notice 2020764CN, initially dated 30 June 2003

CE Marking of Conformity 2020764CE01

Addendum, initially dated 15 November 2013

DEKRA hereby certifies 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 the design of the product(s) falling within the product category mentioned above, conforms to the provisions of the Council Directive 93/42/EEC of June 14, 1993, in accordance with Annex II, section 4 of this Directive. 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 January 2018

Issued for the first time: 19 March 2010

Reissued: 15 November 2013

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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