DECLARATION OF CONFORMITY
to
Directive 93/42/EEC concerning Medical Devices

Name of Product: **Climber™ Guiding Catheter**

Legal (labelled) Manufacturer:
PendraCare International B.V.
Van der Waalspark 22
9351 VC Leek
The Netherlands
Dutch Chamber of Commerce - Registration Number 02086018

Declaration:

I hereby declare that the medical device specified in this declaration conforms to the provisions of the *current* European Council (EC) Directive 93/42/EEC of June 14, 1993 concerning Medical Devices and therefore bears the CE mark of conformity on its labelling in combination with the Notified Body Identification number **0344** of DEKRA Certification B.V., Arnhem, The Netherlands.

- The product conforms to the applicable Essential Requirements for Safety and Performance per *current* Directive 93/42/EEC, **Annex I**: "Essential Requirements",
- The device classification (i.e., **Class IIa**) has been determined per *current* Directive 93/42/EEC, Annex IX: Classification Criteria,
- The appropriate Conformity Assessment module per article 11 of the *current* Directive 93/42/EEC, i.e., **Annex II excluding (4)** Full Quality Management System has been followed as indicated on the "CE-marking of Conformity" Certificate (2020764CE01) in combination with this Declaration of Conformity,
- PendraCare's Quality Management System (QMS) fulfils the requirements described in the *current* Directive 93/42/EEC and EN-ISO 13485: 2012 as evidenced by the "CE Marking of Conformity" Certificate [2020764CE01- Full Quality Assurance System per **Annex II excluding (4)**] and its accompanying Certification Notice (2020764CN) and by the Certificate of Registration (2086817). The specified medical device falls within the scope of PendraCare's QMS as indicated in the certificates.

GMDN: GMDN Term*: Intravascular Guiding Catheter GMDN Code*: **17846**
* per GMDN agency database

Valid until: This Declaration of Conformity is valid until **January 1, 2018**, i.e., the validity date indicated on the CE-marking of Conformity Certificate.

Reference: **RA DoCa-020 Rev. 05** - Annex to the Declaration of Conformity.

Place of issue: Leek, The Netherlands

Date: **2014-01-14**

Declared by:

A. Roossien, MSc., PhD.
Manager Quality Assurance & Regulatory Affairs