

# CERTIFICATE

Number: 2086817

The management system of the organization(s) and locations mentioned on the addendum belonging to:

## PendraCare International B.V.

Van der Waalspark 22  
9351 VC Leek  
The Netherlands

including the implementation meets the requirements of the standard:

## EN ISO 13485:2016

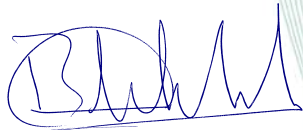
### Scope:

Design and development, manufacturing and distribution of Cardiovascular catheters and Urodynamic Catheters

Certificate expiry date: 1 January 2023  
Certificate effective date: 1 January 2020  
Certified since: 1 January 2006

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



# ADDENDUM

To certificate: 2086817

The management system of the organization(s) and/or location(s) of:

## PendraCare International B.V.

Van der Waalspark 22  
9351 VC Leek  
The Netherlands

Certified organization(s) and/or locations:

Different scope

PendraCare International B.V.  
Kamerlingh-Onnesstraat 6  
9351 VD Leek  
The Netherlands

Warehouse

PendraCare International B.V.  
Stevinstraat 8  
9351 VD Leek  
The Netherlands

Design and Development

PendraCare International B.V.  
Kamerlingh-Onnesstraat 10  
9351 VD Leek  
The Netherlands

Design and Development

Addendum expiry date: 1 January 2023  
Addendum effective date: 1 January 2020