

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



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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