

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

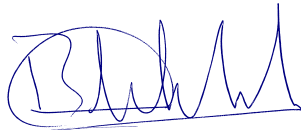
Scope:

Design and development, manufacturing and distribution of Cardiovascular catheters.

Certificate expiry date: 1 January 2026
Certificate effective date: 12 January 2023
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.M.A. McKenzie
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 10
9351 VD Leek
The Netherlands

Design and Development

Warehouse (sterile and non-sterile goods)

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

PendraCare International B.V.
Van der Waalspark 40
9351 VC Leek
The Netherlands

Warehouse (sterile and non-sterile goods)

Addendum expiry date: 1 January 2026
Addendum effective date: 12 January 2023