

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
Netherlands

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:

Design and development, manufacturing and distribution of Cardiovascular catheters.

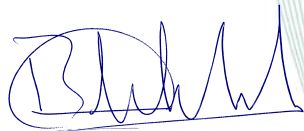
Certificate expiry date: 1 January 2029

Certificate effective date: 1 January 2026

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. 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
Netherlands

Certified organization(s) and/or locations:

Different scope

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

Design and Development

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

Warehouse (storage of raw materials & final products including sterile)

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

Warehouse (storage of raw materials & final products including sterile)

Addendum expiry date: 1 January 2029

Addendum effective date: 1 January 2026