

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2238714DE04

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:

IMDS Operations B.V.
Ceintuurbaan Noord 150
9301 NZ Roden
The Netherlands

For the product

ReCross OTW Dual Lumen Guide Wire Support Catheter

Documents, that form the basis of this certificate:

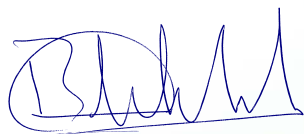
Certification Notice 2238714CN, initially dated 10 September 2019
CE Marking of Conformity 2238714CE01
Addendum, initially dated 20 December 2019

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 17 April 2024
Issued for the first time: 10 September 2019
Revised: 20 December 2019

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping letters.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, flowing initial 'J' followed by the name.

J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2238714DE04

1/1

EC DESIGN-EXAMINATION MEDICAL DEVICES

ReCross OTW Dual Lumen Guide Wire Support Catheter

Issued to:

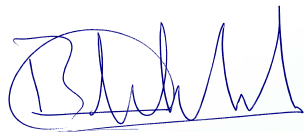
IMDS Operations B.V.
Ceintuurbaan Noord 150
9301 NZ Roden
The Netherlands

This certificate covers the following product(s):

<i>Product code</i>
RC1414025

Initial date: 20 December 2019

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of a stylized, cursive script.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, consisting of a stylized, cursive script.

J.A. van Vugt
Certification Manager

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