

Current issue date: Expiry date: Certificate identity number: 2 March 2024 1 March 2027 10575158 Original approval(s): ISO 13485 - 6 October 2023

## **Certificate of Approval**

This is to certify that the Management System of:

## Heart Medical Europe B.V.

Hallenweg 40, 5683 CT Best, The Netherlands

has been approved by LRQA to the following standards:

## ISO 13485:2016

Approval number(s): ISO 13485 - 00042141

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

## The scope of this approval is applicable to:

Importing and distribution of (non)- and Sterile implantable medical device for interventional Cardiology and (non) – sterile active medical devices for (pediatric) Cardiology, interventional Radiology and cardio thoracic surgery.

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Area Operations Manager, Europe

Issued by: LRQA Limited

Paul Graaf



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Certificate identity number: 10575158

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Activities	LRQ/
<b>ISO 13485:2016</b> Importing and distribution of (non)- and Sterile implantable medical device for interventional Cardiology and (non) – sterile active medical devices for (pediatric)	LRQ/
Cardiology, interventional Radiology and cardio thoracic surgery.	LRQ/
<b>ISO 13485:2016</b> Acting as European Authorized Representative for the medical device industry.	LRQ/
	LRQ/
MANGEMENT SYSTEMS 0001	LRQ/
	ISO 13485:2016 Importing and distribution of (non)- and Sterile implantable medical device for interventional Cardiology and (non) – sterile active medical devices for (pediatric) Cardiology, interventional Radiology and cardio thoracic surgery. ISO 13485:2016 Acting as European Authorized Representative for the medical device industry.

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