6 October 2023 1 March 2024 10555126

Original approval(s): ISO 13485 - 6 October 2023

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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:

Heart Medical: 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.

LRQA Group Limited, its affiliates and subsidiaries and their respective officers, employees or agents are, individually and collectively, referred to in this clause as 'LRQA'

This certificate is a continuation of a previous approval from another certification body as follows:

Previous original ISO 13485 approval on 02-MAR-2021, SGS Belgium NV certificate number BE20/819944143

Paul Graaf

Area Operations Manager, Europe

Issued by: LRQA Limited



liability is exclusively on the terms and conditions set out in that contract Issued by: LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom



Certificate identity number: 10555126

Certificate Schedule

Hallenweg 40, 5683 CT Best, The Netherlands

Location **Activities Heart Medical Europe B.V. (hoofdvestiging)** ISO 13485:2016 Heart Medical: Importing and distribution of (non)- and Hallenweg 40, 5683 CT Best, The Netherlands Sterile implantable medical devices for interventional Cardiology and (non) – sterile active medical devices for (pediatric) Cardiology, interventional Radiology and cardio thoracic surgery. Gerrit van Wageningen B.V. (filiaal) ISO 13485:2016

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

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