

# 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.

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



# Certificate Schedule

Location	Activities
<b>Heart Medical Europe B.V. (hoofdvestiging)</b> Hallenweg 40, 5683 CT Best, The Netherlands	<b>ISO 13485:2016</b> 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.
<b>Gerrit van Wageningen B.V. (filiaal)</b> Hallenweg 40, 5683 CT Best, The Netherlands	<b>ISO 13485:2016</b> 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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