

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Blue Medical Devices B.V
Panovenweg 7
5708 HR Helmond
The Netherlands

Holds Certificate Number:

MD 597020

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, manufacture and distribution of sterile and non-sterile (Balloon) Catheter with or without drug coating or other coatings, and (sub-) assemblies for coronary and peripheral devices.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2016-07-22

Latest Revision Date: 2023-02-27

Effective Date: 2023-03-15

Expiry Date: 2026-03-14

Page: 1 of 1



...making excellence a habit.™