



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

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...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory