

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

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 13485:2003 & EN ISO 13485:2012 for the following scope:

Design and development, manufacturing and distribution of sterile catheters and stents with and without drug-eluting balloon technology for coronary use, catheters for peripheral use and accessories.

For and on behalf of BSI:



Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 22/07/2016

Latest Revision Date: 10/03/2017

Effective Date: 15/03/2017

Expiry Date: 28/02/2019

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