

# 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, manufacturing and distribution of sterile PTCA (Balloon) Catheters, Drug-Eluting Balloon Catheters and Stent Delivery Systems with or without drug eluting balloons for coronary and peripheral use. Design, development, manufacturing and distribution of non-sterile (Balloon) Catheters, Stent Delivery Systems and (sub-) assemblies.

Previous certificate expires on March 14, 2020  
Recertification audit ended December 11, 2019

For and on behalf of BSI:

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Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-07-22

Latest Revision Date: 2020-05-12

Effective Date: 2020-05-12

Expiry Date: 2023-03-14

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