

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Vascular
3200 Lakeside Drive
Santa Clara
California
95054
USA

Holds Certificate No:

FM 72377

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

Design and Development, Manufacture and Distribution of: coronary and peripheral stents and delivery systems, including covered stents; everolimus-eluting coronary and peripheral scaffolding/stent and delivery systems (absorbable/non-absorbable); coronary and peripheral dilation catheters; femoral vessel closure devices and the related deployment instruments; mitral and tricuspid valve repair systems including clip and delivery systems, steerable guide catheters and stabilizer accessories; guidewires and related cardiovascular accessories; carotid stent and delivery systems; embolic protection systems. Manufacture and distribution of diagnostic guidewires. In addition, sterilization by Electron Beam Processor for medical devices.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2002-12-27

Latest Revision Date: 2021-06-21

Effective Date: 2021-01-08

Expiry Date: 2024-01-07

Page: 1 of 2



...making excellence a habit.™

Certificate No: **FM 72377**

Location	Registered Activities
Abbott Vascular Cashel Road Clonmel Tipperary Ireland	Design and development, manufacture and distribution of Everolimus-eluting coronary scaffolding systems (including delivery systems). Manufacture and distribution of coronary and peripheral stents and delivery system, including covered stents, dilatation catheters, femoral vessel closure devices and the related instruments necessary for the deployment of the closure devices, guide wires, and accessories.
Abbott Vascular 3200 Lakeside Drive Santa Clara California 95054 USA	Design and Development, coronary and peripheral stent and delivery systems, including covered stents; everolimus-eluting coronary scaffolding/stent and delivery systems (absorbable/non-absorbable); coronary and peripheral dilation catheters; femoral vessel closure devices and the related deployment instruments; guidewires and related cardiovascular accessories; carotid stent and delivery systems; embolic protection systems. Regulatory and administrative activities.
Abbott Vascular 26531 Ynez Road Temecula California 92591 USA	Design, Development and Manufacture of stent delivery catheters and systems, dilation catheters and guide wires, sterilization by Electron Beam Processor for medical devices. Development of cardiovascular accessories. Design, development and manufacture (including radiation sterilization) of Everolimus-eluting coronary scaffolding systems.
Abbott Vascular 3885 Bohannon Drive Menlo Park California 94025 USA	Design, development and manufacture of sterile mitral and tricuspid valve repair systems and associated accessories.
Abbott Vascular 52 Calle 3, B31 Coyol Free Zone El Coyol Alajuela 20102 Costa Rica	Manufacture of dilatation catheters and diagnostic guidewires.
Abbott Vascular Storage and distribution center 42301 Zevo Drive Temecula California 92590 USA	Warehousing and shipping of finished product. Secondary-level packaging of drug-eluting stent systems; application of country-specific labeling; repackaging and labeling for product branding, identification and shelf life updates.

Original Registration Date: 2002-12-27

Effective Date: 2021-01-08

Latest Revision Date: 2021-06-21

Expiry Date: 2024-01-07

Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.