

Certificate of Registration

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

This is to certify that:

Stryker Neurovascular
47900 Bayside Parkway
Fremont
California
94538
USA

Holds Certificate Number:

MD 638383

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

Design, development, manufacturing and distribution of guidewires, manufactured components, intravascular product subassemblies, embolization coils and delivery systems, balloon catheters, stents and delivery systems, delivery catheter systems, microcatheters, flow diverters, power supplies, cables, shaping mandrels, torque devices, catheter introducers and hemostatic valves, for the areas of Neurovascular, Cardiovascular and Peripheral Vascular minimally invasive surgical procedures.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2015-11-23

Latest Revision Date: 2017-05-12

Effective Date: 2017-05-17

Expiry Date: 2019-02-28

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Location	Registered Activities
Stryker Neurovascular 47900 Bayside Parkway Fremont California 94538 USA	Design, development, manufacturing and distribution of guidewires, manufactured components, intravascular product subassemblies, embolization coils and delivery systems, balloon catheters, stents and delivery systems, delivery catheter systems, microcatheters, flow diverters, power supplies, cables, shaping mandrels, torque devices, catheter introducers and hemostatic valves, for the areas of Neurovascular, Cardiovascular and Peripheral Vascular minimally invasive surgical procedures.
Stryker Neurovascular Business & Technology Park Model Farm Road Cork Ireland	Design, development, manufacturing and distribution of medical devices for minimally invasive neurovascular surgical and interventional procedures: embolization coils and delivery systems, flow diverters, balloon catheters, stents and delivery systems, microcatheters, hemostatic valves, shaping mandrels and torque devices.
Stryker Neurovascular 2405 West Orton Circle West Valley City Utah 84119 USA	Development, production and distribution of manufactured components, guidewires and intravascular product subassemblies. Finished goods release of cables, catheters and InZone detachment system.
Stryker Neurovascular 47421 Bayside Parkway Fremont California 94538 USA	Administrative activities to support the Quality Management System for guidewires, manufactured components, intravascular product subassemblies, embolization coils and delivery systems, balloon catheters, stents and delivery systems, delivery catheter systems, microcatheters, flow diverters, power supplies, cables, shaping mandrels, torque devices, catheter introducers and hemostatic valves.

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An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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