

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

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 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, manufacture and distribution of guidewires, manufactured components, intravascular product subassemblies, embolization coils, stents, endovascular retrieval wires, flow diverters, balloon catheters, microcatheters, delivery catheter systems, detachment system power supplies, 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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2015-11-23

Latest Revision Date: 2022-01-28

Effective Date: 2021-08-01

Expiry Date: 2024-07-31



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Location	Registered Activities
Stryker Neurovascular 47900 Bayside Parkway Fremont California 94538 USA	Design and development of guidewires, manufactured components, intravascular product subassemblies, embolization coils, stents, endovascular retrieval wires, flow diverters, balloon catheters, microcatheters, delivery catheter systems, detachment system power supplies, shaping mandrels, torque devices, catheter introducers and hemostatic valves.
Stryker Neurovascular Business & Technology Park Model Farm Road Cork Ireland	Manufacture of and distribution of embolization coils, flow diverters, stents, balloon catheters, microcatheters, delivery catheter systems, hemostatic valves, shaping mandrels and torque devices.
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, stents, endovascular retrieval wires, flow diverters, balloon catheters, microcatheters, delivery catheter systems, detachment system power supplies, shaping mandrels, torque devices, catheter introducers and hemostatic valves.
Stryker Neurovascular 4870 West 2100 South Salt Lake City Utah 84120 USA	Manufacture and distribution of manufactured components, guidewires, endovascular retrieval wires, stent subassembly, balloon catheters, microcatheters, delivery catheter systems and intravascular product subassemblies. Finished goods release of catheters and detachment system power supplies.

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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 [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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