

CERTIFICATE

Number: **3805988**

The management system of:

Stryker Neurovascular

47900 Bayside Parkway
Fremont, CA 94538
USA

including the implementation meets the requirements of the standard:

EN ISO 13485:2012 +AC:2012

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, guide catheters, microcatheters, aneurysm-embolization systems, 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.

This certification also includes the locations as identified on the Addendum belonging to this Certificate.

Certificate expiry date: **May 16, 2017**
Certified for the first time: **January 20, 2011**
Certificate effective date: **September 17, 2014**

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM 1/1

to Certificate: **3805988**

concerning the Management System of:

Stryker Neurovascular

List of certified locations:

Location	Certification scope
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, aneurysm-embolization systems, balloon catheters, stents and delivery systems, microcatheters, aneurysm embolization systems, hemostatic valves, shaping mandrels and torque devices.
Stryker Neurovascular 47421 Bayside Parkway Fremont, CA 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, guide catheters, microcatheters, aneurysm embolization systems, power supplies, cables, shaping mandrels, torque devices, catheter introducers and hemostatic valves.
Stryker Neurovascular 3451 Commerce Pkwy Miramar, FL 33025 USA	Design, development, manufacturing and distribution of aneurysm-embolization systems.
Stryker Neurovascular 2405 West Orton Circle West Valley City, UT 84119 USA	Development, production and distribution of manufactured components, guidewires and intravascular product subassemblies. Finished goods release of cables, catheters and InZone detachment system.

Addendum Initial date: January 20, 2011

Addendum Effective date: May 16, 2014