

Certificate



**TUV Rheinland of North America, Inc., a CMDCAS
recognized registrar, certifies that**

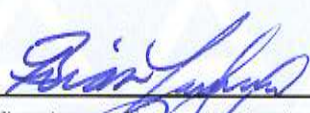
**Boston Scientific Corporation
One Boston Scientific Place
Natick MA 01760-1537
USA**

**has established and maintained a
Quality Management System
according to
ISO 13485:2003**

**Audit Report No.: 31190232 011
Certificate Registration No.: 74 500 4578
Expiry Date: October 08, 2017**

**for the Design and Development and Manufacture of
Medical Devices for Peripheral Interventions,
Minimally Invasive Surgical Procedures,
Endoscopy, Gastrointestinal, Gynecological, Nephrological,
Biliary, Urological and Electrosurgical Applications and
for the Distribution, Service and Installation of
Medical Devices**




Certification Officer: B. Ludovico
**TUV Rheinland of North America, Inc.
Newtown, Connecticut**
Effective Date: October 17, 2014

Attachment
**Quality Management System
according to ISO 13485:2003**

for

**Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA**

The scope of the registration also includes the following sites:

Boston Scientific Limited

Business and Technology Park, Model Farm Road, Cork, Ireland
Scope: Aspects related to manufacture.

Boston Scientific Corporation

47215 Lakeview Boulevard, Fremont, CA 94538
Scope: Aspects related to design and development and manufacture.

Boston Scientific Limited

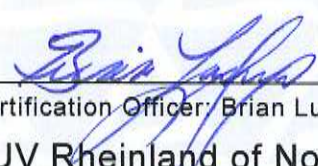
Ballybrit Business Park, Galway, Ireland
Scope: Aspects related to design and development and manufacture.

Boston Scientific Ltd.

6430 Vipond Dr., Mississauga, Ontario, L5T 1W8, Canada
Scope: Aspects related to manufacture and distribution

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Certification Officer: Brian Ludovico
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Newtown, Connecticut
Effective Date: October 17, 2014

Attachment
**Quality Management System
according to ISO 13485:2003**

for

**Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA**

The scope of the registration also includes the following sites:

Boston Scientific Corporation

780 Brookside Drive, Spencer, IN 47460, USA

Scope: Aspects related to manufacture.

Boston Scientific Corporation

100 Boston Scientific Way, Marlborough, MA 01752, USA

Scope: Aspects related to design and development.

Boston Scientific Corporation

Two Scimed Place, Maple Grove, MN 55311, USA

Scope: Aspects related to design and development and manufacture.

Boston Scientific Corporation

302 Parkway, Global Park, Heredia, Costa Rica

Scope: Aspects related to manufacture.

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TUV Rheinland of North America, Inc.
Newtown, Connecticut

Effective Date: October 17, 2014

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, Tel(203) 426-0888 Fax(203)426-4009

Attachment
Quality Management System
according to ISO 13485:2003

for

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA

The scope of the registration also includes the following sites:

Boston Scientific Corporation

2546 First Street Propark; El Coyol, Alajuela, Costa Rica

Scope: Aspects related to manufacture.

Boston Scientific International B.V.

European Distribution Center, Vestastraat 6, 6468 EX Kerkrade, The Netherlands

Scope: Aspects related to manufacture (relabeling) and distribution.


Boston Scientific Corporation

Marina Bay Customer Fulfillment Center, 500 Commander Shea Blvd., Quincy, MA 02171, USA

Scope: Aspects related to (labelling and packaging) and distribution.

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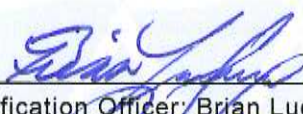
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA

The scope of the registration includes the following product families:

Catheters, dilatation catheters, needles, introducers, adaptors, resorbable material implants, metal implants, grafts, surgical trays, stents, valves, guidewires, lithotripters, sutures, surgical instruments, x-ray and ultrasound systems, syringes, forceps, endoscopic instruments, electrosurgical instruments, embolization coils, irrigation/drainage sets, injection lines, electrodes, gastric feeding devices, radiofrequency generators/devices, radiological devices, inflation devices, polypectomy devices, hemostasis devices, ligators, retrieval devices, snares, stopcocks, tubing sets, prostheses, surgical meshes and patches, rotating hemostatic valve, torque device catheter stylet, power supply, embolization devices, fiberoptic laser delivery unit, heated fluid hyperthermia system and hyperthermia system accessories.

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