



APPROVAL
EC Directive 93/42/EEC Annex V, Article 3
Quality Assurance System Production

Registration No.: DD 60015631 0001

Report No.: 30691113 004

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

Scope: For the Aspects of Manufacture Concerned with Securing
and Maintaining Sterile Conditions

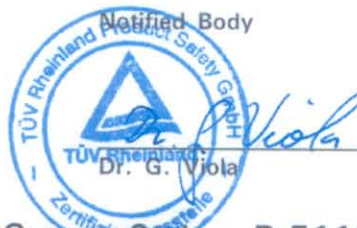
Facilities: See Attachment No. 1

Products: See Attachment No. 2

Date of Expiry: 25.09.2011

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 23.07.2007



TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE



TÜVRheinland

Attachment No. 1

Doc. 1/1 Rev. 1

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: DD 60015631 0001
Report No.: 30691113 005

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

Scope: Facilities

Ref.	Facility	Ref.	Facility
NAT	Boston Scientific Corporation One Boston Scientific Place Natick, MA 01760-1537 USA	MIA	Boston Scientific Corporation 8600 N W 41st Street Miami, FL 33166 USA
SJ1	Boston Scientific Corporation 2710 Orchard Parkway San Jose, CA 95134 USA	SPE	Boston Scientific Corporation 780 Brookside Drive Spencer, IN 47460 USA
GAL	Boston Scientific Ireland Ltd Ballybrit Business Park Galway, IRELAND	QUI	Boston Scientific Corporation Marina Bay Customer Fulfillment Center 500 Commander Shea Boulevard Quincy, MA 02169 USA
GFA	Boston Scientific Corporation 10 Glens Falls Technical Park Glens Falls, NY 12801 USA	KER	Boston Scientific International B.V. European Distribution Center Vestastraat 6 6468 EX Kerkrade, The Netherlands
TUL	Boston Scientific Tullamore Ltd Sragh Industrial Estate Tullamore, County Offaly IRELAND		

Cologne, 20.09.2007





TÜVRheinland®

Attachment No. 2

Doc. 1/1, Rev. 2

**TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln**

**Attachment to
Registration No.:** DD 60015631 0001
Report No.: 30691113 006

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

Scope: Products

Product Families	NAT	SJ1	GAL	GFA	MIA	SPE	TUL
Accessories	X			X	X	X	X
Cable, Electrophysiology		X					
Cannula, Endotherapy, Single use						X	
Inflation Devices				X			X
Magnet Exchange Devices					X		
Tubing Set, Electrophysiology		X					
Uroradiology/ Gastroendoscopy Products			X				

Cologne, 07.01.2008

