

**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

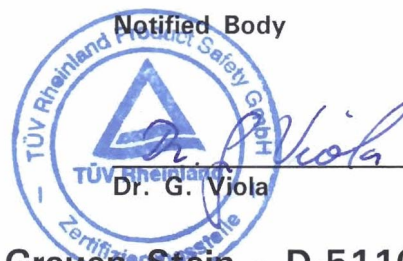
Facilities: See Attachment No. 1

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**

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Registration No.:** DD 60015631 0001  
**Report No.:** 30691113 023

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

**Scope:** Facilities

| Ref. | Facility  | Ref. | Facility  |
|------|---|------|---|
| NAT  | Boston Scientific Corporation<br>One Boston Scientific Place<br>Natick, MA 01760-1537 USA     | SPE  | Boston Scientific Corporation<br>780 Brookside Drive<br>Spencer, IN 47460 USA   |
| GAL  | Boston Scientific Ireland Ltd.<br>Ballybrit Business Park<br>Galway, IRELAND                  | QUI  | Boston Scientific Corporation<br>Marina Bay Customer Fulfillment Center<br>500 Commander Shea Boulevard<br>Quincy, MA 02169 USA |
| MIA  | Boston Scientific Corporation<br>8600 N.W. 41st Street<br>Miami, FL 33166 USA                 | KER  | Boston Scientific International B.V.<br>European Distribution Center<br>Vestastraat 6<br>6468 EX Kerkrade, The Netherlands      |
| COR  | Boston Scientific Cork Ltd.<br>Business & Technology Park<br>Model Farm Road<br>Cork, IRELAND |      |   |

Date, 18.06.2010



**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Registration No.:** DD 60015631 0001  
**Report No.:** 30691113 029

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

**Scope:** Products

| Product Families  | NAT | GAL | MIA | SPE | COR |
|---|-----|-----|-----|-----|-----|
| Accessories   | X   |     | X   | X   |     |
| Biopsy Devices and Accessories                          |     |     |     | X   |     |
| Cannula, Endotherapy,<br>Single use                     | X   |     |     | X   |     |
| Electrophysiology Equipment and<br>Accessories          | X   |     |     |     |     |
| Fluid Administration Devices and Related<br>Accessories | X   |     |     |     |     |
| Inflation Devices                                       | X   |     |     |     | X   |
| Retrieval Balloon Catheter                              |     |     |     |     | X   |
| Uroradiology/<br>Gastroendoscopy Products               |     | X   |     |     |     |
| Ultrasound System, Imaging,<br>Accessories              | X   |     |     |     |     |

**Date 13.12.2010**

