

Certificate

Production Quality Assurance

No. CE 552703



Issued to:

Boston Scientific Corporation
One Boston Scientific Place
Natick
Massachusetts
01760-1537
USA

In respect of:

Those aspects of Annex V related to securing and maintaining the sterility in the manufacture of Magnet Exchange Devices

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

A handwritten signature in black ink, appearing to read 'David Ford', with a horizontal line underneath it.

David Ford, Director, Healthcare and Testing Services

First Issued: 18 Aug 2009

Date: 18 Aug 2009

Expiration Date: 25 Sep 2011

Page: 1 of 1

Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate unless specifically agreed with BSI.

*raising standards worldwide*TM



List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No. **CE 552703**
Date: **18 Aug 2009**
Issued to: **Boston Scientific Corporation**
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Natick
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Subcontractor	Service(s) supplied
Boston Scientific International S.A. TSA 51101 55 avenue des Champs Pierreux 92729 NANTERRE CEDEX France	EU Representative
Boston Scientific Corporation 8600 N.W. 41st Street Miami Florida 33166 USA	Manufacture
BSC Coventry 8 Industrial Drive Coventry Rhode Island 02816 USA	ETO Sterilization

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Subcontractor	Service(s) supplied
Boston Scientific Corporation Two Scimed Place Maple Grove Minnesota 55311 USA	Design
STERIS Isomedix Services, Inc 3459 South Clinton Avenue South Plainfield NJ 07080 USA	ETO Sterilization

Please Note:

**The history page is not part
of the official BSI certificate**

**If copies are used as part of
any regulatory submission,
do not include the history
page**

History of Quality Assurance Certificate

Certificate No: **CE 552703**
Date: **18 Aug 2009**
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Date	Reference Number	Action
18 August 2009	7430042	First issue - Transfer from another Notified Body