

# Certificate

## Full Quality Assurance

No. CE 552701



Issued to:

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

In respect of:

**Design, Development, and Manufacturing of Guidewires and Angiographic and Guide Catheters**

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

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

A handwritten signature in black ink, appearing to read 'Rob Wallis'.

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Rob Wallis, Chair Certification Body Management Committee

First Issued: **18 Aug 2009**

Date: **20 Oct 2011**

Expiration Date: **25 Sep 2016**

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*™



## List of Significant Subcontractors

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

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Subcontractor	Service(s) supplied
Boston Scientific Corporation 302 Parkway Global Park Heredia Costa Rica	Manufacture
Isotron Nederland B.V. Faunalaan 38 5928 RZ Venlo Netherlands	ETO Sterilization
Teleflex Medical Unit 7, 8, & 9 Annacotty Business Park Annacotty Limerick Ireland	Manufacture
Availmed S.A. de C.V. Ave. Paseo Reforma No. 8950 C.P. 22116 La Mesa, Tijuana, Baja California Mexico	Manufacture
Boston Scientific Corporation 2546 First Street Propark, El Coyol, Alajuela Costa Rica	Manufacture

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Subcontractor	Service(s) supplied
Boston Scientific Corporation 5905 Nathan Lane Plymouth Minnesota USA 55442	Manufacture
BSC Coventry 8 Industrial Drive Coventry Rhode Island USA 02816	ETO Sterilization
Boston Scientific Corporation Two Scimed Place Maple Grove Minnesota USA 55311	Design

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Subcontractor	Service(s) supplied
Boston Scientific Corporation 8600 N.W. 41st Street Miami Florida USA 33166	Manufacture
STERIS Isomedix Services, Inc 3459 South Clinton Avenue South Plainfield New Jersey 07080 USA	ETO Sterilization
Boston Scientific International S.A. 55 avenue des Champs Pierreux TSA 51101 92729 NANTERRE CEDEX France	EU Representative
STERIS ISOMEDIX Services, Inc 7685 Saint Andrews Avenue San Diego, California 92173 USA	ETO Sterilization

## History of Quality Assurance Certificate

Certificate No: **CE 552701**  
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Date	Reference Number	Action
18 August 2009	7429960	First issue - Transfer from another Notified Body
25 March 2010	7494170	Update scope of certificate to add angiographic catheters and add Teleflex Medical to list of significant subcontractors.
21 April 2010	7521097	Add the Plymouth, MN facility to the list of significant subcontractors for the manufacture of the Kinetix Guide Wires
03 January 2011	7610090	Update scope to of certificate to add guide catheters and add Availmed and Steris Isomedix in San Diego, California to the list of significant subcontractors.
27 June 2011	7698806	Addition of manufacturing sites in Coyol and Heredia. Clarify the scope of the certificate by removing "Coronary and Peripheral".
15 September 2011	7754931	Certificate renewal
20 October 2011	7752928	Addition of Isotron Nederland B.V., Venlo, The Netherlands as a significant subcontractor for ETO sterilization.