

# Certificate

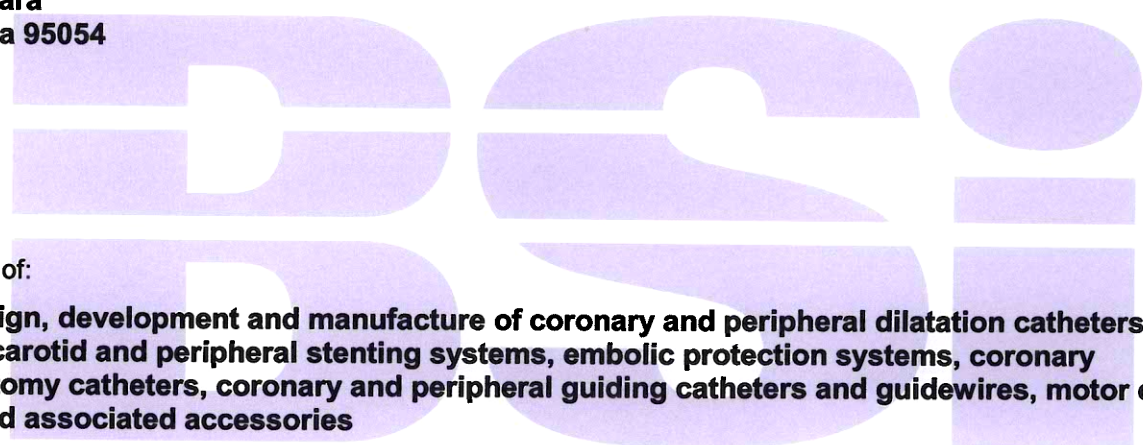
## Full Quality Assurance



No. CE 510108

Issued to:

**Abbott Vascular**  
**3200 Lakeside Drive**  
**Santa Clara**  
**California 95054**  
**USA**

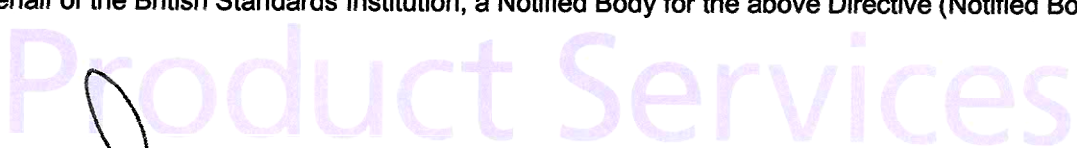


In respect of:

**The design, development and manufacture of coronary and peripheral dilatation catheters and stents, carotid and peripheral stenting systems, embolic protection systems, coronary atherectomy catheters, coronary and peripheral guiding catheters and guidewires, motor drive units and associated accessories**

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 the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):



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David Ford, Managing Director, BSI Product Services

First Issued: 1 Aug 2006

Date: 18 Feb 2009

Expiration Date: 16 Oct 2010

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.

# Certificate

## List of Significant Subcontractors

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

Certificate No. **CE 510108**  
Date: **18 Feb 2009**  
Issued to: **Abbott Vascular**  
**California 95054**  
**USA**

<b>Subcontractor</b>	<b>Service(s) supplied</b>
Abbott Ireland Vascular Division Mervue Business Park Mervue Galway Ireland	Manufacture
Isotron Ireland Ltd IDA Business & Technology Park Sragh Tullamore Offaly Ireland	ETO Sterilization
Sterigenics 4900 South Gifford Avenue Los Angeles CA 90058 USA	ETO Sterilization
Sterigenics 5725 West Harold Gatty Drive Salt Lake City Utah 84116 USA	ETO Sterilization

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**California 95054**  
**USA**

<b>Subcontractor</b>	<b>Service(s) supplied</b>
Sterigenics 7695 Formula Place San Diego CA 92121 USA	E beam Sterilization
Abbott Vascular 26531 Ynez Road Temecula California 92591-4628 USA	Design Development E beam Sterilization Manufacture
Abbott Vascular Cashel Road Clonmel Tipperary Ireland	E beam Sterilization Manufacture
Abbott Vascular 30590 Cochise Circle Murrieta CA 92563 USA	Manufacture

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**USA**

### Subcontractor

### Service(s) supplied

Abbott Vascular  
Building PR-17, Road #2 km. 58.0  
Cruce Davila  
Barceloneta 00617  
Puerto Rico

Manufacture

AD)MEDES Schuessler GmbH  
Rastatter Strasse 15  
75179 Pforzheim  
Germany

Manufacture

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## History of Quality Assurance Certificate

Certificate No: **CE 510108**  
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Issued to **Abbott Vascular**  
**California 95054**  
**USA**

<b>Date</b>	<b>Reference Number</b>	<b>Action</b>
01 August 2006	4068482	First Issue based on CE 00946
13 March 2007	4941821	Isotron Ireland, Ltd added to the list of significant subcontractors
15 November 2007	7104034	Addition of Abbott Ireland (Galway) to the list of significant subcontractors. Addition of design and development of services supplied by Temecula
01 August 2008	7200338	Addition of Abbott Vascular, Murrieta and Abbott Vascular, Barceloneta to list of significant subcontractors for manufacturing activities. Removal of Abbott Vascular, Dorado facility.
18 February 2009	7292729	Transfer of product families from Abbott Vascular, Vascular Solutions FQA certificate CE 525963.  Remove Business Unit name (Cardiac Therapies) from the 'issued to' address and the Abbott Vascular, Murrieta facility address in the list of subcontractors.  Addition of AD)MEDES Schuessler GmbH to list of significant subcontractors for manufacturing activities.