

# 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, stent systems, carotid and peripheral stent systems, embolic protection systems, coronary and peripheral guiding catheters, guidewires 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):

A handwritten signature in black ink, appearing to read 'David W. Ford', written over a horizontal line.

David W. Ford, Executive Director, Healthcare and Testing Services

First Issued: 1 Aug 2006

Date: 12 Oct 2010

Expiration Date: 16 Oct 2015

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.

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# Certificate

## List of Significant Subcontractors

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

Certificate No. **CE 510108**  
Date: **12 Oct 2010**  
Issued to: **Abbott Vascular**  
**California 95054**  
**USA**

<b>Subcontractor</b>	<b>Service(s) supplied</b>
Abbott Vascular International BVBA 1831 Diegem Belgium	EU Representative
Creganna Parkmore West Galway Ireland	Manufacture
Abbott Vascular Cashel Road Clonmel Tipperary Ireland	Manufacture
Abbott West Distribution Center 42301 Zevo Drive Temecula California 92590 USA	Distribution Manufacture
Abbott Vascular Devices Holland B.V. Bamfordweg 1 6235 NS Ulestraten The Netherlands	Distribution Labelling Packaging



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<b>Subcontractor</b>	<b>Service(s) supplied</b>
Sterigenics 4900 South Gifford Avenue Los Angeles CA 90058 USA	ETO Sterilization
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 30590 Cochise Circle Murrieta CA 92563 USA	Manufacture

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<b>Subcontractor</b>	<b>Service(s) supplied</b>
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
STERIGENICS 2400 Airport Road Santa Teresa New Mexico 88008 USA	ETO Sterilization



## History of Quality Assurance Certificate

Certificate No: **CE 510108**  
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Date	Reference Number	Action
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.
20 April 2010	7510769	Addition of Creganna-Tactx Medical to list of significant subcontractors for manufacturing activities and addition of Abbott Vascular International BVBA as EU Authorized Representative.
12 October 2010	7581791	Renewal of certification Removal of Sterigenics (Salt Lake City), Abbott Ireland (Galway) and Isotron Ireland as significant subcontractors. Remove Abbott Vascular Sterilization from Clonmel manufacturing site. Addition of Sterigenics (New Mexico) as significant subcontractor. Removal of atherectomy catheters and motor drive units from the scope. Redefine stents as stent systems. Addition of Abbott West Distribution Center and Abbott Vascular Devices Holland B.V. as a significant subcontractor.