

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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 dilation catheters, stent systems, including covered stents, drug eluting stents, Bioresorbable Vascular Scaffold (BVS) Systems, carotid and peripheral stent systems, embolic protection systems, coronary and peripheral guiding catheters, arterial vessel closure devices and the related instruments necessary for the deployment of the closure devices, guidewires and associated accessories.

Those aspects of Annex II related to securing and maintaining the sterility of guide wire extensions, torque devices, hemostatic valves, introducers and flushing tools.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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



Frank Lee, EMEA Compliance & Risk Director

First Issued: **01 August 2006**

Date: **07 September 2015**

Expiry Date: **16 October 2020**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. 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.

This certificate was issued electronically and is bound by the conditions of the contract.

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List of Significant Subcontractors

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

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3200 Lakeside Drive
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Subcontractor:	Service(s) supplied
Abbott Ireland Ballytivnan Sligo Ireland	ETO Sterilization
Abbott Vascular International BVBA Park Lane Culliganlaan, 2B 1831 Diegem Belgium	EU Representative
Abbott Vascular Netherlands B.V. Argonstraat 1 6422 PH Heerlen Netherlands	Distribution Labelling Packaging
Abbott Vascular 26531 Ynez Road Temecula California 92591 USA	Design Development E beam Sterilization Manufacture

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Subcontractor:	Service(s) supplied
Abbott Vascular 52 Calle, 3, B31, Coyoil Free Zone El Coyoil Alajuela Costa Rica	Manufacture
Abbott Vascular Building PR-17, Road #2 km. 58.0 Cruce Davila Barceloneta 00617 Puerto Rico	Manufacture
Abbott Vascular Cashel Road Clonmel Tipperary Ireland	Manufacture

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Subcontractor:	Service(s) supplied
Abbott West Distribution Center 42301 Zevo Drive Temecula California 92590 USA	Distribution Manufacture
Acme Monaco 75 Winchell Drive New Britain CT 06052 USA	Manufacture
Ad)medes Schuessler GmbH Rastatter Strasse 15 75179 Pforzheim Germany	Manufacture

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Subcontractor:	Service(s) supplied
Availmed S.A. de C.V. Av. Paseo Reforma No. 8950 Interior B1, C1, E1, E2, F2, G1 (Local A, B, C, G, H) La Mesa Tijuana, 22116 Mexico	Manufacture
LEONI Studer AG Hogenweidstrasse 2+4 CH-4658 Däniken Switzerland	E beam Sterilization
Sterigenics Costa Rica S.R.L. Zona Franca PROPARK Calle Principal, Edificio 10 El Coyal Alajuela Costa Rica	ETO Sterilization

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Subcontractor:	Service(s) supplied
Sterigenics Germany GmbH Kasteler Straße 45 65203 Wiesbaden Germany	ETO Sterilization
Sterigenics UK Limited Cotes Park Estate Somercotes Alfreton DE55 4NJ United Kingdom	ETO Sterilization
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	ETO Sterilization

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Subcontractor:	Service(s) supplied
Sterigenics US, LLC 4900 South Gifford Avenue Los Angeles CA 90058 USA	ETO Sterilization
Sterigenics US, LLC 7695 Formula Place San Diego California 92121 USA	E beam Sterilization
Synergy Health AST, SRL B16, Street 4, Avenue 0 El Coyal Free Zone 20102 El Coyal Alajuela Costa Rica	E beam Sterilization

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Subcontractor:

Service(s) supplied

Synergy Health Ireland Ltd.
IDA Business & Technology Park
Sragh Industrial Estate
Tullamore, Co. Offaly
Ireland

E beam Sterilization
ETO Sterilization

Teleflex Medical OEM
50 Plantation Drive
Jaffrey
NH 03452
USA

Manufacture

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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.

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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 atherctomy 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.
10 November 2011	7765633	Addition of LEONI Studer Hard AG to list of significant subcontractors for E beam sterilization.
13 December 2011	7766500	Addition of the Abbott Vascular Manufacturing Site in Alajuela, Costa Rica as a significant subcontractor.
31 May 2012	7804693	Addition of Synergy Health Ireland Ltd as a significant subcontractor for e-beam sterilization. Name of subcontractor Abbott Vascular Devices Holland B.V. changed to Abbott Vascular Netherlands B.V. and address updated. Administrative changes on certificate.
19 September 2012	7903213	Addition of Accellent as significant subcontractor for TREK family. Addition of Abbott Vascular Costa Rica Main Building as significant subcontractor for manufacturing.

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21 December 2012	7911227	Addition of Abbott (Nutritional) Ireland Sligo to the list of significant subcontractors for the sterilization. Scope updated to include "including covered stents".
02 July 2013	7991114	Removal of Abbott Vascular - Alajuela Costa Rica, as a significant subcontractor. Change name of subcontractor from LEONI Studer Hard AG to LEONI Studer AG. Reclassify Funnel Introducer, Guide Wire Introducer, Duostat Rotating Hemostatic Valve, Rotating Hemostatic Valve, Guide Wire Introducer Accessory Kit and Guide Wire Accessory Kit with CoPilot from Class IIa to Class I (Sterile).
May 28, 2014	8164752	Addition of NovoSci and Sterigenics in Wiesbaden for the service of ETO sterilization, Synergy Health in Costa Rica for the service of E-beam sterilization and Availmed S.A. de C.V. for service of manufacturer due to several product transfers.
05 February 2015	8268209	Update to add Drug Eluting Stents to the scope. Addition of significant subcontractors OK International, LTD and Sterigenics UK Limited.
31 March 2015	8283470	Addition of Vessel Closure Devices to the scope of certification as part of a transfer from the Abbott Vascular Redwood City facility. Addition of significant subcontractors Teleflex Medical and Acme Monoco for manufacture and Synergy Health Ireland Ltd for EO Sterilization.

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Date	Reference Number	Action
13 April 2015	8296689	Addition of Bioresorbable Vascular Scaffold (BVS) Systems to the scope of certification.
08 July 2015	8359594	Addition of Sterigenics Costa Rica S.R.L. as a significant subcontractor for ETO sterilization.
07 September 2015	8411826	Renewal of certification. Removal of subcontractors: Accellent, Inc., Creganna, NovoSci Corp and OK International, LTD. Removal of Abbott Vascular Murrieta site: facility closed down. Typo correction (LEONI Studer AG address, Sterigenics names).