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 Sterile Coronary and Peripheral Dilatation Catheters, Stent Systems including Covered Stents, Drug Eluting Stents, Coronary Stents, Carotid Stents, and Peripheral Stents, Embolic Protection Systems, Femoral Vessel Closure Systems, Guidewires, Mitral and Tricuspid Valve Repair Systems, Inflation Devices, and Inflation Accessories.

Those aspects of Annex II related to securing and maintaining the sterility of Guide Wire Extensions, Guide Wire Introducers, Torque Devices, Hemostatic and Control Valves, and Guidewire Accessories.

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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2006-08-01** Date: **2020-06-02** Expiry Date: **2024-05-26**

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Supplementary Information to CE 510108

Issued To:

Abbott Vascular
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Number	Device Name	Intended purpose per IFU
Class III		
---	HI-TORQUE Guide Wires – Including AllStar, Extra S'port, Balance, Balance Middleweight, Intermediate, Standard, Extra S'port, Floppy II, Floppy II Extra Support, Traverse, Iron Man, and Wiggle	See CE 01497
---	HI-TORQUE Guide Wires with Hydrocoat Hydrophilic Coating and HI-TORQUE Guide Wires with Hydrophilic Coating – Including Cross-IT XT, Flexi Wire, Floppy II, Floppy II Extra Support, Standard, Intermediate, Traverse, Balance, Balance Middleweight, Whisper, Balance Heavyweight, and Balance Middleweight Universal	See CE 01753
---	Multi-Link RX Ultra Coronary Stent System	See CE 01834
---	Multi-Link Vision RX and Multi-Link Mini-Vision RX Coronary Stent System	See CE 71619
---	HI-TORQUE Pilot Guide Wire with Hydrophilic Coating	See CE 73066

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Number	Device Name	Intended purpose per IFU
Class III		
---	X.ACT Carotid Stent System	See CE 503252
---	Emboshield NAV 6 Embolic Protection System and BareWire Filter Delivery Wires	See CE 504490
---	RX Accunet Embolic Protection System	See CE 518026
---	RX Acculink Carotid Stent System	See CE 518027
---	HI-TORQUE Guide Wires – Including SpartaCore, SteelCore 18, SteelCore 18 LT, and SupraCore	See CE 518028
---	HI-TORQUE Balance Middleweight Universal II Guide Wire	See CE 534263
---	HI-TORQUE Advance & HT Advance Lite Guide Wire	See CE 546723
---	HI-TORQUE Progress Guide Wire	See CE 553292
---	Trek and Mini Trek RX, TREK OTW and Mini TREK II OTW Coronary Dilatation Catheters	See CE 561260
---	HI-TORQUE Winn Guide Wire	See CE 564179
---	NC TREK RX Coronary Dilatation Catheter	See CE 565938

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Number	Device Name	Intended purpose per IFU
Class III		
---	HI-TORQUE Balance Middleweight Elite Guide Wire	See CE 568482
---	HI-TORQUE Powerturn Guide Wires	See CE 581813
---	NC TREK OTW Coronary Dilatation Catheter	See CE 584431
---	HI-TORQUE JET Guide Wires	See CE 591655
---	Graftmaster RX Coronary Stent Graft System	See CE 592549
---	TRAVELER RX Coronary Dilatation Catheter	See CE 602426
---	NC TRAVELER Coronary Dilatation Catheter	See CE 609165
---	HI-TORQUE VersaTurn Guide Wire	See CE 615774
---	Everolimus Eluting Coronary Stent System XIENCE V	See CE 629247
---	Everolimus Eluting Coronary Stent System XIENCE PRIME SV, XIENCE PRIME, XIENCE PRIME LL	See CE 629248
---	Everolimus Eluting Peripheral Stent System XIENCE PRIME BTK	See CE 629249

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Number	Device Name	Intended purpose per IFU
Class III		
---	MULTI-LINK 8 Coronary Stent System	See CE 629250
---	XIENCE Xpedition Everolimus Eluting Coronary Stent System	See CE 632826
---	XIENCE Pro Everolimus Eluting Coronary and Peripheral Stent Systems	See CE 632827
---	XIENCE Alpine Everolimus Eluting Coronary Stent Systems	See CE 632828
---	MitraClip NT/NTR/XTR Delivery System and Steerable Guide Catheter	See CE 643983
---	HI-TORQUE TurnTrac Guide Wire	See CE 679931
---	XIENCE Sierra Everolimus Eluting Coronary Stent System	See CE 680375
---	TriClip Delivery System and Steerable Guide Catheter	See CE 712450

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Number	Device Name	Intended purpose per IFU
Class IIb		
47932	Stent Systems	Stent Systems are implants intended to open lumen restrictions in arteries and biliary structures.
52747	Vessel Closure Devices	Vessel Closure Devices are intended to percutaneously deliver sutures or clips to close vascular access sites.
Class IIa		
MD 0106	Inflation Devices	N/A
MD 0106	Inflation Device Accessory Kits	N/A
MD 0106	Percutaneous Transluminal Angioplasty (PTA) Catheters	N/A
MD 0106	Guidewires	N/A

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Number	Device Name	Intended purpose per IFU
Class Is		
MDS 7006	Torque Device	N/A
MDS 7006	COPILOT Bleedback Control Valve	N/A
MDS 7006	DOC Guide Wire Extension	N/A
MDS 7006	Rotating Hemostatic Valve .096 and .115	N/A
MDS 7006	Guide Wire Introducer	N/A
MDS 7006	Guide Wire Accessory kit	N/A
MDS 7006	Guide Wire Accessory kit with COPILOT Bleedback Control Valve	N/A
MDS 7006	LOC .035 Guide Wire Extension	N/A

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 510108**
Date:	**2020-06-02**
Issued To:	**Abbott Vascular** **3200 Lakeside Drive** **Santa Clara** **California** **95054** **USA**

Subcontractor:	**Service(s) supplied**
Abbott Vascular 26531 Ynez Road Temecula California 92591 USA	**Design** **Development** **Manufacture** **Radiation (E Beam Sterilization)**
Abbott Vascular 3885 Bohannon Drive Menlo Park CA 94025 USA	**Design** **Development** **Manufacture**
Abbott Vascular 52 Calle, 3, B31, Coyol Free Zone El Coyol Alajuela Costa Rica	**Manufacture**
Abbott Vascular Building PR-17, Road #2 km. 58.0 Cruce Davila Barceloneta 00617 Puerto Rico	**Manufacture**

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

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Date:	**2020-06-02**
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Subcontractor:	**Service(s) supplied**
Abbott Vascular Cashel Road Clonmel Tipperary Ireland	**Design** **Development** **Manufacture**
Abbott Vascular International BVBA Park Lane Culliganlaan, 2B 1831 Diegem Belgium	**EU Representative**
Abbott Vascular Netherlands B.V. Argonstraat 1 6422 PH Heerlen The Netherlands	**Labelling** **Packaging**
Abbott West Distribution Center 42301 Zevo Drive Temecula CA 92590 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
ADMEDES GmbH Rastatter Str. 15 75179 Pforzheim Germany	**Manufacture**
Availmed S.A. de C.V. C. Industrial Lt. 001 Mz.105 No. 20905 Int. A Col. Cd. Industrial Tijuana Baja California 22444 Mexico	**Manufacture**
Novartis Pharma AG Lichstrasse 35 Basel CH-4056 Switzerland	**Crucial Supplier**

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

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Subcontractor:	**Service(s) supplied**
Parter Sterilization Services LLC 17115 Kingsview Ave Carson CA 90746 USA	**ETO Sterilization**
Sterigenics Costa Rica S.R.L. Zona Franca PROPARK Calle Principal, Edificio 10 El Coyol Alajuela Costa Rica	**ETO Sterilization**
Sterigenics Germany GmbH Kasteler Strasse 45 Wiesbaden 65203 Germany	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Sterigenics UK Limited Cotes Park Estate Somercotes Alfreton DE55 4NJ United Kingdom	**ETO Sterilization**
Sterigenics US, LLC 4900 Gifford Avenue Los Angeles California 90058 USA	**ETO Sterilization**
Sterigenics US, LLC 7695 Formula Place San Diego California 92121 USA	**Radiation (E Beam Sterilization)**

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List of Significant Subcontractors

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Subcontractor:	**Service(s) supplied**
Synergy Health AST, SRL B16, Street 4, Avenue 0 20102 El Coyol Alajuela Costa Rica	**Radiation (E Beam Sterilization)**
Synergy Health Ireland Ltd. IDA Business & Technology Park Sragh Industrial Estate Tullamore, Co. Offaly Ireland	**ETO Sterilization** **Radiation (E Beam Sterilization)**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 510108**

Date: **2020-06-02**

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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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Date	Reference Number	Action
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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Date	Reference Number	Action
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 subcontactor. 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).
19 December 2015	8427566	Scope extension to include the MitraClip NT System under Abbott Vascular's Quality System.
13 July 2016	8558860	Removal of "coronary and peripheral guiding catheters" from scope of certification and the addition of Availmed S.A. de C.V. Baja California location as significant subcontractor.
22 December 2017	8863184	Scope change from "Arterial" to "Femoral" for vessel closure devices. Removal of Availmed in La Mesa, Tijuana, Mexico for manufacturing services, and LEONI in Switzerland for Ebeam Sterilization. Addition of NOVARTIS as a crucial supplier. Add design and development services to Abbott in Clonmel, Ireland.
27 February 2019	7780598	Traceable to NB 0086.

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Date	Reference Number	Action
12 February 2020	3042205	Remove "Bioresorbable Vascular Scaffold (BVS) Systems" from the scope. Remove subcontractors "Abbott Ireland" Ballytivnan location and "Sterigenics US, LLC" New Mexico location. Update address for Sterigenics US, LLC in Los Angeles.

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Date	Reference Number	Action
Current	9718057	Certificate Renewal. Scope rewrite for clarity. Clearly denoting what devices are sterile in scope, changing "dilation" to "dilatation", listing inflation devices and inflation accessories (Class IIa) in the first paragraph, noting that "systems" applies to all stent types, noting specific device categories as Class Is in the second paragraph, noting femoral vessel closure devices are systems, and corrected capitalization of proper names throughout. Scope change to add the word "tricuspid" to "mitral valve repair systems" to cover new device TriClip NT/XT CE 712450. Added Product Table. Removed Subcontractors: Nitinol Devices and Components, Fremont, CA and Costa Rica locations, Rose Technologies, Grand Rapids, MI, Acme Monaco, New Britain, CT and Teleflex, Jaffrey, NH. Update Subcontractor Name and Addresses to match ISO certificate – ADMEDES GmbH, Rastatter Str. 15, 75179 Pforzheim, Germany and Synergy Health AST, SRL, B16 Street 4, Avenue 0, 20102 El Coyol Alajuela, Costa Rica. Remove "Distribution" service supplied for subcontractors Abbott Vascular (Menlo Park), Abbott Vascular Netherlands B.V., and Abbott West Distribution Center.