

EC Certificate - Full Quality Assurance System

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

No. CE 701333
Issued To: **Abbott Medical**
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

Design, Development, and Manufacture of Electrophysiology Catheters including Radio Frequency (RF) Ablation Electrodes and Catheters, Return Electrodes, Radio Frequency (RF) Ablation Generators, Introducers and Needles, Catheters, Pacing Catheters, Diagnostic Guidewires, Guidewires, and Accessories.

Those aspects of Annex II related to securing and maintaining the sterility in the manufacture of Sterile Cables/leads for use with Electrophysiology Catheters, Guidewire Torque Devices, Hemostasis and Compression devices.

Those aspects of Annex II related to maintaining the measuring function of FemoStop Pump systems.

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: **2018-12-12**

Date: **2020-10-15**

Expiry Date: **2023-05-15**

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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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Supplementary Information to CE 701333

Issued To:

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Number	Device Name	Intended purpose per IFU
Class III		
---	Fast-Cath Introducers (EP division)	See CE 701338
---	Swartz Braided Transseptal Guiding Introducers	See CE 701340
---	Peel-Away Introducers	See CE 701349
---	Fast-Cath Hemostasis Introducers (Vascular Division)	See CE 701266
---	(Cardiac Mapping/Radio-Frequency Ablation Catheter, Single-Use) (<i>TactiCath Quartz</i>)	See CE 701353
---	FlexAbility Ablation Catheters	See CE 701336
---	PressureWire Diagnostic Guidewire	See CE 701274
---	Advisor Circular Mapping Catheter, Sensor Enabled	See CE 701260
---	Advisor High Density Mapping Catheter, Sensor Enabled	See CE 722347
---	Advisor VL Circular Mapping Catheter, Sensor Enabled	See CE 712356

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Number	Device Name	Intended purpose per IFU
Class III		
---	TigerWire, GuideRight and HydroSteer guide wires	See CE 701265
---	Cardiac Mapping / Radio-Frequency Ablation Catheter, Single-Use (<i>aka TactiCath SE</i>)	See CE 701262
---	FIRMap Catheter	See CE 701225
Class IIb		
35156	IonicRF Generator	<p>The IonicRF™ Generator, in combination with approved compatible electrodes and cannulae, is intended for lesioning of neural tissue in the nervous system as an aid in the management of pain.</p> <p>The IonicRF™ Generator, in combination with approved compatible electrodes and cannulae, is indicated as an aid in the management of pain in the nervous system. Examples include, but are not limited to, facet denervation, rhizotomy, and related functional neurosurgical procedures.</p>

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Number	Device Name	Intended purpose per IFU
Class IIb		
61931	Radiofrequency Disposable Electrodes	Abbott Medical Radiofrequency Electrodes are intended for use in temperature-controlled radiofrequency lesion procedures for the relief of pain. These are single-use-only products.
61931	Simplicity III Radiofrequency Disposable Electrode	The Abbott Medical Simplicity™ III Disposable Radiofrequency Electrode is intended for use in the treatment of chronic pain by the ablation of neural tissue.
58494	Grounding Pad	The model RF-DGP-IS, RF-DGP-S and RF-DGP-L grounding pads are designed for use in electrosurgical procedures. The grounding pad provides a path for radiofrequency (RF) energy produced at the electrode to return to the RF generator.

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Fast-Cath Hemostasis, Percutaneous and Venous Introducer (Abbott Vascular)	--
MD 0106	Maximum Introducer	--
MD 0106	Ultimum Introducer	--
MD 0106	Engage and Engage TR Introducer	--
MD 0106	Introducer Accessories (Vessel dilator, Hemostasis valve adapter, Luer Cap, Protective Cap for Hemostasis Valve, Sheath Obturator, Repositioning Sleeve, Hypodermic Needles)	--
MD 0106	Disposable Radiofrequency Cannulas, needles	--

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Number	Device Name	Intended purpose per IFU
Class Is		
MD 0106	Electrophysiology Cables / Leads	--
MD 0106	Torque Devices	--
MD 0106	Hemostasis / Compression Devices	--
Class Im		
MD 1100 MD 0106	FemoStop Pump Systems	--

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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:

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Subcontractor:	Service(s) supplied
Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem Belgium	EU Representative Labelling Packaging
Abbott Medical 4 Robbins Road Westford Massachusetts 01886 USA	Design
Abbott Vascular 52 Calle 3, B31 Coyol Free Zone El Coyol Alajuela 20102 Costa Rica	Manufacture

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Subcontractor:	Service(s) supplied
Abbott Vascular Netherlands B.V. Argonstraat 1 6422 PH Heerlen The Netherlands	Labelling Packaging
ATL Technology 1335 West 1650 North Springville Utah 84663 USA	Manufacture
ATL Technology DG Limited Kang Le Road Xitou Village Houjie Town Dongguan City Guangdong 523952 China	Manufacture

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Subcontractor:	Service(s) supplied
Corpus Medical 1300 White Oaks Road, Suite 108 Campbell California 95008 USA	Manufacture
GeoTec, Inc 89 Bellows Street Warwick Rhode Island 02888 USA	Manufacture Testing
Irvine Biomedical, Inc a St. Jude Medical Company 2375 Morse Avenue Irvine CA 92614 USA	Manufacture

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Isomedix Operations, Inc. 43425 Business Park Drive Temecula California 92590 USA	ETO Sterilization
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 USA	ETO Sterilization
Lake Region Medical 340 Lake Hazeltine Drive Chaska Minnesota 55318 USA	Control of Sterilization Manufacture Packaging

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Subcontractor:	Service(s) supplied
Lake Region Medical Ltd Butlersland New Ross Co. Wexford Ireland	Control of Sterilization Design Manufacture Packaging
Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan UT 84095 USA	Manufacture
MidWest Sterilization P.O. Box 411 1204 Lenco Avenue Jackson Missouri 63755 USA	ETO Sterilization

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Subcontractor:	Service(s) supplied
Morgan Innovation and Technology Unit 17, Petersfield Business Park Bedford Road Petersfield Hampshire GU32 3QA United Kingdom	Manufacture Testing
St. Jude Medical 14901 DeVeau Place Minnetonka Minnesota 55345-2126 USA	Manufacture
St. Jude Medical 2305 Walnut Street Roseville Minnesota 55113 USA	Labelling Packaging

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Subcontractor:	Service(s) supplied
St. Jude Medical Costa Rica Ltda. Edificio #44B Calle 0, Ave. 2 Zona Franca Coyoil El Coyoil, Alajuela Costa Rica	Manufacture
St. Jude Medical PR LLC Caguas West Industrial Park Lot 20 and 21 Caguas 00726 Puerto Rico	Manufacture
Sterigenics Belgium (Petit- Rechain) SA Zoning Industriel Avenue Andre Enst 21, Verviers Liège B-4800 Belgium	ETO Sterilization

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Subcontractor:	Service(s) supplied
Sterigenics Denmark A/S Aa. Louis Hansens Alle 1 DK-3060 Espergarde Denmark	Radiation (E Beam Sterilization)
Sterigenics US LLC 5725 W. Harold Gatty Drive Salt Lake City Utah 84116 USA	ETO Sterilization
Synergy Health AST SRL B13.1 Street 4, Avenue 1 El Coyal Free Zone 20102 El Coyal Alajuela Costa Rica	ETO Sterilization

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Subcontractor:	Service(s) supplied
Synergy Health Ireland Ltd (Synergy Health - AST - Ireland) IDA Business & Technology Park Tullamore, Co. Offaly Ireland	ETO Sterilization
Technical Services for Electronics Avenida Los Encinos Manzana 1, Lote 3 Parque, Industrial Villa Florida Reynosa Tampaulipas C.P. 88730 Mexico	Manufacture
Venusa de Mexico S. de R.L. de C.V. a Lake Region Medical Company Calle Hertz 1525 Parque Industrial Antonio J. Bermudez Chihuahua 32470 Ciudad Juarez Mexico	Manufacture

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Date	Reference Number	Action
12 th December 2018	9663584	First Issue. Mirror certificate to CE 597699.
01 March 2019	9714804	Addition of subcontractors: GeoTec Inc. for Manufacture and Testing. Typo correction to the Venusa de Mexico address.
05 March 2019	8250541	Traceable to NB 0086.
26 November 2019	9755979	Removal of 'Vascular Closure Systems' from scope statement due to divestiture. Removal of 'Guide Catheters' from scope statement due to product discontinuation. Removal of related subcontractors: Sterigenics US, LLC Gurnee, Illinois and Sterigenics US, LLC Arkansas. Add subcontractors Midwest Sterilization, Jackson, MO and Isomedix Operations, Inc. Temecula, CA as alternative EtO locations.
06 February 2020	3071460	Addition of the Abbott Vascular, 52 Calle 3, B31 Coyol Free Zone location for manufacturing. Administrative addition of certificate product table.

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Date	Reference Number	Action
01 July 2020	3174723	Addition of Return Electrodes to scope; administrative clarification to scope statement. Removal of subcontractors Sterigenics (Willowbrook, Illinois USA) and Minta Medical Ltd. Updates to device table: remove Class III reusable electrodes; update certificate number of Advisor High Density Mapping Catheter; remove Class IIb NT1100 RF Generator, N2000iX RF Generator, and ET20s RF Generator; add Class IIb IonicRF Generator; clarify Class IIa Introducer Accessories to include Hypodermic Needles; administrative updates to table formatting.
Current	3277497	Sterilization change from BIs to parametric release. Change affecting all ETO sterilized products covered by this certificate. Addition of significant subcontractor Abbott Vascular Netherlands B.V. for the activities of labelling and packaging.