

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 717274 R000

**Manufacturer:** Abbott Medical

**Address:**

3200 Lakeside Drive  
Santa Clara  
California  
95054  
USA

**Single Registration Number:** US-MF-000003851

**EU Authorised Representative:** Abbott Vascular International BVBA

**Address:**

Park Lane, Culliganlaan 2B  
1831 Diegem  
Belgium

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-11-06**

Date: **2021-12-17**

Expiry Date: **2025-11-05**

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### Device Schedule: Class III and Class IIb devices

<b>Class III, Implantable</b>	<b>Intended purpose</b>
XIENCE V Everolimus Eluting Coronary Stent System	See MDR 735423
XIENCE PRIME Everolimus Eluting Coronary Stent System	See MDR 735435
XIENCE Prime BTK Everolimus Eluting Peripheral Stent System	See MDR 735436
XIENCE Xpedition Everolimus Eluting Coronary Stent System	See MDR 735426
XIENCE Xpedition 48 Everolimus Eluting Coronary Stent System	See MDR 735426
XIENCE Alpine Everolimus Eluting Coronary Stent System	See MDR 735433
XIENCE Sierra Everolimus Eluting Coronary Stent System	See MDR 735434
XIENCE PRO 48 Everolimus Eluting Coronary Stent System	See MDR 735427
XIENCE PRO <sup>A</sup> Everolimus Eluting Coronary Stent System	See MDR 735427
XIENCE PRO <sup>S</sup> Everolimus Eluting Coronary Stent System	See MDR 735427
XIENCE Skypoint Everolimus Eluting Coronary Stent System	See MDR 729166
<b>Class III</b>	<b>Intended purpose</b>
Coronary Artery Guidewires – 0.014" Stainless Steel	See MDR 718160
Coronary Artery Guidewires - 0.014" Nitinol	See MDR 729169
Coronary Artery Guidewires - 0.014" Polymer	See MDR 729170
<b>Class IIb, Implantable</b>	<b>Intended purpose</b>
Perclose ProGlide Suture-Mediated Closure System	See MDR 729164

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### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Cardiovascular Peripheral Guidewires	Class IIa
Cardiovascular Guidewires - Accessories	Class Is
Hemostasis Valves	Class Is
Arterial Introduction Sets	Class Is
Cardiac Angiography Devices - Accessories	Class Is/Im

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.



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### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

Date	Reference number	Action
2020-11-06	3319729	Issued.
2021-03-23	3340090	Amended – Minor update to 0.014” stainless steel guidewire description. Change of Subcontractor site name to “Sterigenics Radiation Technologies.” Addition of the associated subcontractors to Critical Subcontractor list: Abbott Vascular (Clonmel), Abbott Vascular Netherlands B.V. (Heerlen), Availmed (C. Industrial), Sterigenics Costa Rica, Sterigenics US (Los Angeles), Sterigenics UK (Alfreton), and Synergy Health Ireland Ltd. (Tullamore).  Supplemented – Addition of various Accessory Products and Perclose ProGlide to the Device Schedule.
2021-06-16	3445639	Amended – Addition of SRN number. Addition of Abbott Vascular Barceloneta site as critical subcontractor for manufacturing. Administrative update to prior history entry.  Supplemented – Addition of Cardiovascular Peripheral Guidewires to the Device Schedule.
2021-12-01	3409821	Amended – Addition of the associated subcontractors to Critical Subcontractor list: Abbott Vascular (Coyol), Abbott Vascular (Zevo – Temecula), and Novartis Pharma AG. Administrative update to prior history entry.  Supplemented – Addition of the XIENCE Family of Devices (V, PRIME, Prime BTK, Xpedition, Alpine, Sierra, PRO 48, PRO <sup>A</sup> , PRO <sup>S</sup> , and Skypoint) to the Device Schedule.

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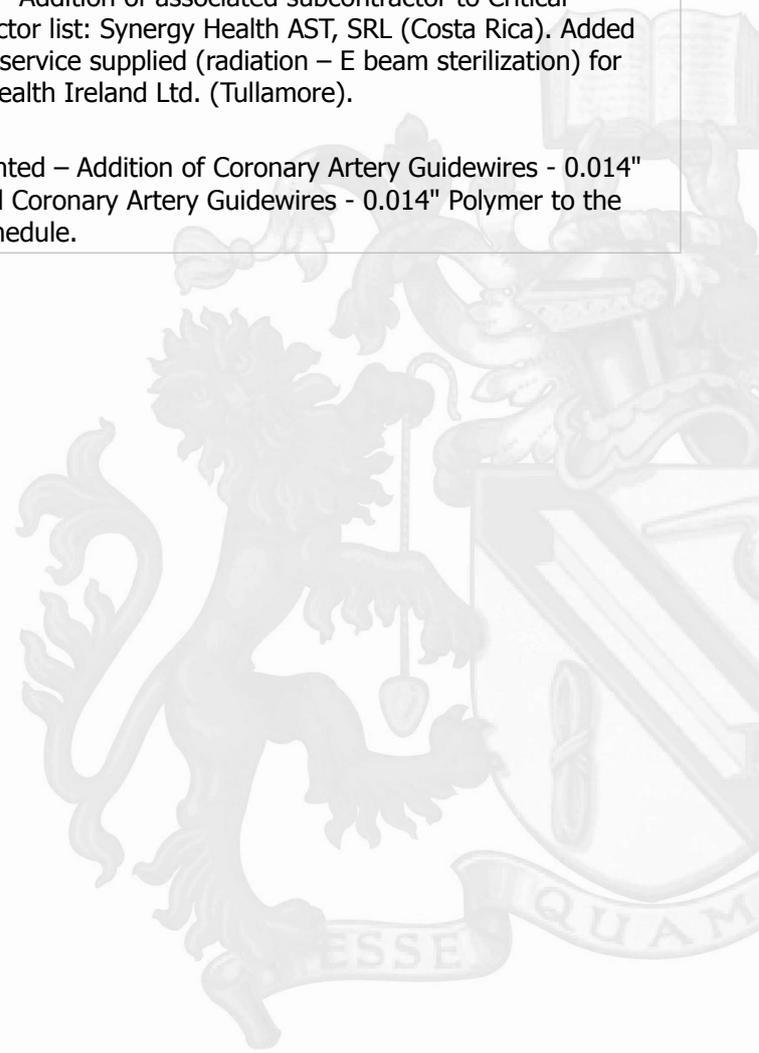
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Current	3584707	<p>Amended – Addition of associated subcontractor to Critical Subcontractor list: Synergy Health AST, SRL (Costa Rica). Added additional service supplied (radiation – E beam sterilization) for Synergy Health Ireland Ltd. (Tullamore).</p> <p>Supplemented – Addition of Coronary Artery Guidewires - 0.014" Nitinol and Coronary Artery Guidewires - 0.014" Polymer to the Device Schedule.</p>
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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
A Member of the BSI Group of Companies.

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

### MDR 717274 R000

Date: 2021-12-17

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Abbott Vascular 26531 Ynez Road Temecula California 92591 USA	<b>Design Manufacture Radiation (E Beam Sterilization)</b>
Abbott Vascular Cashel Road Clonmel, Tipperary Ireland	<b>Design Manufacture Packaging</b>
Abbott Vascular Building PR-17, Road #2 km. 58.0 Cruce Davila Barceloneta 00617 Puerto Rico	<b>Manufacture</b>
Abbott Vascular 52 Calle 3, B31 Coyol Free Zone El Coyol Alajuela 20102 Costa Rica	<b>Manufacture</b>

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## List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

### MDR 717274 R000

Date: 2021-12-17

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Abbott Vascular Storage and distribution Center 42301 Zevo Drive Temecula California 92590 USA	<b>Labelling</b> <b>Secondary Packaging</b>
Abbott Vascular Netherlands B.V. Argonstraat 1 6422 PH Heerlen The Netherlands	<b>Labelling</b>
Availmed S.A. de C.V. C. Industrial Lt. 001 Mz.105 No. 20905 Int. A Col. Cd. Industrial Tijuana Baja California C.P. 22444 Mexico	<b>Manufacture</b>
Novartis Pharma AG Lichstrasse 35 4056 Basel Switzerland	<b>Medicinal Substances</b>

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Date: 2021-12-17

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Sterigenics Costa Rica S.L.R. Zone Franca PROPARK Calle Principal, Edificio 10 El Coyal Alajuela 20101 Costa Rica	<b>ETO Sterilization</b>
Sterigenics Radiation Technologies, LLC 7695 Formula Place San Diego California 92121 USA	<b>Radiation (E Beam Sterilization)</b>
Sterigenics UK Ltd Cotes Park Lane Somercotes Alfreton, DE55 4NJ United Kingdom	<b>ETO Sterilization</b>
Sterigenics US, LLC 4900 Gifford Avenue Los Angeles California 90058 USA	<b>ETO Sterilization</b>

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Date: 2021-12-17

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Synergy Health AST, SRL B16, Street 4, Avenue O El Coyal Free Zone El Coyal Alajuela 20102 Costa Rica	<b>Radiation (E Beam Sterilization)</b>
Synergy Health Ireland Ltd. IDA Business & Technology Park Tullamore Co. Offaly Ireland	<b>ETO Sterilization Radiation (E Beam Sterilization)</b>

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