

EU Quality Management System Certificate

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

MDR 759846 R000

Manufacturer: Cordis US Corp.

Address:

14201 North West 60th Avenue
Miami Lakes
Florida
33014
USA

Single Registration Number: US-MF-000020031

EU Authorised Representative: Cordis Cashel

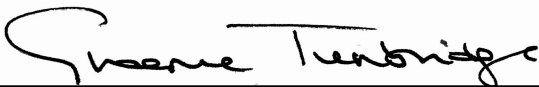
Address:

Cahir Road
Cashel
Co. Tipperary
Ireland

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):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-04-06**

Current Issue Date: **2022-10-07**

Starting Validity Date: **2022-10-07**

Expiry Date: **2027-04-05**

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Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
PRECISE PRO RX™ Nitinol Stent System	See MDR 759862
Class III	Intended purpose
Disposable Biopsy Forceps and BI-PAL 7 Torqueable/Formable Disposable Biopsy Forceps	See MDR 759864
Cordis VISTA BRITE TIP™ Guiding Catheters	See MDR 759861
Cordis AVIATOR™ Plus Percutaneous Transluminal Angioplasty (PTA) Balloon Dilation Catheter	See MDR 759857

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

Device(s)	Risk Classification
Cardiovascular Introducer Sheaths	Class IIa

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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
2022-04-06	3559724	Issued.
2022-06-30	3696124	Amended – Addition of subcontractor Isomedix Operations, Inc., 1441 Don Haskins Drive, El Paso, Texas, 79936, USA. Addition of subcontractor Sterigenics US, LLC, Santa Teresa, New Mexico, 88008, USA. Supplemented – Addition of device category Cardiovascular Introducer Sheaths. Addition of Cordis VISTA BRITE TIP™ Guiding Catheters.
Current	3753556	Amended – Addition of subcontractor Nitinol Devices & Components Costa Rica, S. R. L., Coyol Free Zone, Buildings B14, B15 and B25, El Coyol, Alajuela, 20102, Costa Rica Amended – Addition of subcontractor Synergy Health AST, SRL, B13.1 Street 4, Avenue 1, El Coyol Free Zone, El Coyol, Alajuela, 20102, Costa Rica Supplemented – Addition of Cordis AVIATOR™ Plus Percutaneous Transluminal Angioplasty (PTA) Balloon Dilation Catheter

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List of Critical Subcontractors and Crucial Suppliers

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

MDR 759846 R000

Date: 2022-10-07

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Cardinal Health Mexico 244 S de RL de CV Santiago Troncoso #808 Parque Industrial Salvarcar Ciudad Juarez Chihuahua CP 32574 Mexico	Manufacture
Confluent Medical Technologies Inc. 47533 Westinghouse Drive Fremont California 94539 USA	Manufacture
Isomedix Operations, Inc 1435 Isomedix Place El Paso Texas 79936 USA	ETO Sterilization
Isomedix Operations, Inc. 1441 Don Haskins Drive El Paso Texas 79936 USA	ETO Sterilization

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Nitinol Devices & Components Costa Rica, S. R. L. Coyoil Free Zone, Buildings B14, B15 and B25 El Coyoil Alajuela 20102 Costa Rica	Manufacture
Norman Noble, Inc. 5507 Avion Park Drive Highlands Heights Ohio 44143 USA	Manufacture
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	ETO Sterilization
Synergy Health AST, SRL B13.1 Street 4, Avenue 1 El Coyoil Free Zone El Coyoil Alajuela 20102 Costa Rica	ETO Sterilization

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Critical Subcontractor/Crucial Supplier	Service(s) supplied
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Viant AS&O Holdings, LLC 45 Lexington Drive Laconia New Hampshire 03246 USA	Manufacture
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