EC Certificate - Full Quality Assurance System

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

No. **CE 00340**

Issued To: **Cordis Corporation**
14201 North West 60th Avenue
Miami Lakes
Florida
33014
USA

In respect of:

The design, development and manufacture of sterile intravascular diagnostic and interventional catheters, biopsy forceps, needles, catheter extensions, coronary and peripheral guidewires, embolic capture guidewire systems, introducer guides, metallic vascular and biliary stents and delivery systems and vascular closure devices.

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):

Digitally signed by Ostapciuc Alexandr
Date: 2023.07.07 15:58:42 EEST
Reason: MoldSign Signature
Location: Moldova

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **1994-11-30** Date: **2021-01-14** Expiry Date: **2024-05-26**

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Supplementary Information to CE 00340

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Number	Device Name	Intended purpose per IFU
Class III		
MD 0106	Angioguard XP and RX Emboli Capture Guidewire System	See CE 02410
MD 0106	Cordis Guiding Catheters	See CE 01110
MD 0106	Cordis 6F 0.070" Vista Brite Tip® Guiding Catheters	See CE 69002
MD 0106	Cordis Adroit™ guiding Catheter (5F and 6F product codes)	See CE 598873
MD 0106	Diagnostic Angiography catheters for Cardiology and Radiology use	See CE 636846
MD 0201	Cordis EXOSEAL® Vascular Closure Device	See CE 552677
MD 0106	Cordis Steerable Guidewires, Cordis Diagnostic Guidewires and Cordis Short Transition Steerable Guidewires	See CE 01439
MD 0201	PRECISE™ Nitinol Stent System PRECISE™ RX Nitinol Stent System PRECISE™ PRO RX Nitinol Stent System	See CE 60926
MD 0106	Cordis Disposable Biopsy Forceps; Cordis BI-PAL 7 Formable/Torquable Disposable Biopsy Forceps	See CE 01567
MD 0106	Cordis OptEase Retrieval Catheter	See CE 526303
MD 0106	Long Sheath and Long Sheath Set	See CE 79729

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Class IIb		
43691, 47932, 44279, 46689 MD 0201	Vascular and Biliary Self expanding Stents	For use in peripheral arteries for TIPSS™ procedures and for palliation of malignant neoplasms in the biliary tree.
47932 MD 0201	Stainless steel balloon expandable stent	For use in peripheral vessels below the aortic arch for percutaneous transluminal angioplasty.
Class IIa		
MD 0106	Intravascular Catheters	Intended Purpose is per IFU
MD 0106	Accessories	Intended Purpose is per IFU
MD 0106	Steerable Guidewires	Intended Purpose is per IFU

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Date	Reference Number	Action
30 November 1994		First Issue.
08 February 1995		Statement added concerning the Annex II Section 3.2 certificate of Cordis Europa NV in Roden, Netherlands.
29 November 1995		Coronary and peripheral metallic stents and delivery systems added to the scope.
17 June 1996		Isomedix Inc. (Spartanburg, South Carolina) and Isomedix Inc (Northborough, Massachusetts) added to the list of sub-contractors carrying out sterilization activities.
04 July 1997		Cordis (Warren), Cordis Endovascular Systems Inc (Miami Lakes), Lake Region Manufacturing Co Inc (New Ross) added to the list of sub-contractors.
27 October 1998		Royal Sterilization Systems (New Tazewell) added to the list of sub-contractors.

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Date	Reference Number	Action
09 March 1999		Cordis Endovascular Systems Inc (Miami Lakes), Lake Region Manufacturing Co Inc (Ireland) removed from sub-contractors listing. Ethicon Inc (Somerville), Cordis De Mexico and Norman Noble Inc (Ohio) added to the list of sub-contractors.
21 December 1999		Peripheral guidewires added to the scope. Lake Region Manufacturing Co Ltd (Ireland) and Quality Sterilization Services (Coon Rapids) added to the sub-contractor listing.
12 May 2000		Umm Electronics Inc (Indianapolis), Best Industries Inc (Springfield) and Portlyn Corporation (Moultonboro) added to the sub-contractor listing.
11 July 2001		5 year renewal of certificate. Address details for Cordis Europa NV adjusted. Isomedix Inc's name changed to Steris Corporation, Isomedix Services. Isomedix Inc (Northboro) and Royal Sterilization System (New Tazewell) removed from the sub-contractor listing. Steris Isomedix Services (Minneapolis) and Steris Isomedix Corporation (El Paso) added to the list of sub-contractors.

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26 February 2002		IBA Sterilization and Ionization (The Netherlands) added to the list of sub-contractors.
27 March 2003		Hemostasis valves, torque devices, needles and catheter extensions added to the scope. Reference to endovascular stend graft systems made. Ethicon Inc (Somerville) removed from the sub-contractor listing. Ethicon Inc (San Angelo), Ion Beam Applications (Charlotte) and Teramed Inc (Maple Grove) added to the list of sub-contractors.
27 August 2003		Address details changed for some sub-contractors. Teramed Inc (Maple Grove) removed and Sterigenics – IBA (Willowbrook) added to the list of sub-contractors.
07 November 2003		Address details changed for some sub-contractors. Medsource Technologies LLC in Norwell, Laconia, Trenton and Corry added to the list of sub-contractors.
12 November 2004	4640516	Renewal of certificate.
03 December 2004	4646625	Addition of gastrointestinal catheters to scope and clarification of scope for vascular and biliary stents.

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07 February 2006	4787639	Introducer Guides added to the scope.
08 May 2007	7046514	Sterigenics, Utah added as a sterilizer to the list of significant subcontractors. Umm Electronics Inc, Best Industries Inc, Sterigenics Willowbrook removed from the list of significant subcontractors. Ion Beam Appliances change of company name to Sterigenics.
07 March 2008	7163595	MedVenture Technology Corporation added to the list of significant subcontractors for the activity of Design and Manufacture.
23 March 2009	7324860	Change of significant subcontractor company name from Lake Region Manufacturing Co. Ltd. to Lake Region Medical Limited and addition of the activity of Control of Sterilization for this site. Change of significant subcontractor company name from Lake Region Manufacturing, Inc. to Lake Region Medical.
26 November 2009	7455657	Certificate renewal and list of sub-contractors update.
30 April 2010	7523419	Extension to scope to add "Vascular Closure Devices" and addition of significant subcontractor, Beam One for the activity of Gamma Sterilization.

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14 May 2010	7532756	Change typographically error for the activity type of Beam One from Gamma to E Beam Sterilization.
12 October 2010	7570843	Add new activity to significant subcontractor, Lake Region Medical, Chaska, MN "Control of Sterilization".
08 March 2012	7771082	Update EU Authorised Representative. Update and addition of Significant Subcontractors. Clarify scope to explicitly include Biopsy Forceps.
10 September 2012	7870783	Various edits to subcontractors including: update zip code of Cordis de Mexico to CP 32574; remove Cordis, Warren, NJ; change responsibilities of Cordis, Brigdewater, NJ; remove Argon Medical and Medinol, Israel; change name of Beam One to Synergy Health, LLC; correct address of Cordis, Cashel, Ireland; change name of Conor Medsystems, LLC to Cordis Corporation and add Nitinol Medical Device as "Manufacture".
05 March 2013	7945072	Edits to scope to remove obsolete products/families, "gastrointestinal diagnostic" catheters and "hemostasis valves, torque devices". Removal of "endovascular stent graft systems" as these are no longer in the current scope of certification.

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25 April 2014	8137437	Addition of significant subcontractors Schenker Singapore Pte Ltd and GMED Healthcare BVBA. Removal of significant subcontractor Cordis Corporation in Bridgewater, NJ, USA. Addition of service "Regulatory Compliance" to Cordis Corporation in Fremont, CA, USA.
20 November 2014	8207871	Certificate renewal. Scope update to explicitly list "Embolic Capture Guidewire Systems" and devices being sold sterile. Minor updates to list of significant subcontractors.
03 July 2015	8346587	Change to subcontractor company name from "Accellent Inc." to "Lake Region Medical".
13 December 2015	8430638	Medventure Technology Corporation name replaced by Freudenberg Medical MIS Inc. Distribution centers removed from the certificate since the distribution and warehousing activities are not required to be listed on Annex II.3 certificate. Ethicon Inc., San Angelo, TX removed from the list of significant subcontractors.
10 October 2017	8792895	Replaced significant subcontractor Cordis Fremont, CA with Cordis Milpitas, CA location.
4 December 2017	8760268	Addition of new sterilization site Synergy Health Costa Rica and NDC Alajuela Costa Rica for the manufacture of PTA catheters.
07 March 2018	8895907	New e-beam sterilization subcontractor, Steri-Tek. Subcontractor name change: from Nitinol Device and Components, Inc. to Confluent Medical Technologies Inc.

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04 February 2019	9653349	Addition of sterilization sites: Synergy Health, Tullamore, Ireland and Synergy Health, Thorne, UK contracted by Lake Region Medical for Steerable Guidewires, Diagnostic Guidewires and Short Transition Guidewires.
06 March 2019	7780552	Traceable to NB 0086.
10 June 2019	9672072	Addition of a new alternative sterilization site: Steris Isomedix Operations, Inc. 1441 Don Haskins Drive El Paso, USA.
14 October 2019	9684749	Certificate renewal. Removal of Cordis Corporation Milpitas, CA location. Removal of GMED Healthcare BVBA. Removal of Schenker Singapore Pte Ltd. Removal of Synergy Health AST, LLC Denver, CO location. Removal of Synergy Health Sterilisation UK Ltd. Change name of Cordis de Mexico to Cardinal Health Cordis and change address. Change name of Lake Region Medical in New Hampshire to Viant AS&O Holdings. Addition of buildings B14 and B25 to Nitinol Devices and Components. Correction of address for Sterigenics US, LLC in North Carolina to 10811 Withers Cove Park Drive. Change name of Steris Isomedix Corporation to Isomedix Corporation. Addition of Device Table.
14 January 2021	3338625	Removal of Sterilization subcontractor Isomedix Corporation, facility located in Spartanburg, South Carolina, USA.

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Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
20 July 2022	3698546	Removal of "biopsy forceps" from Scope Removal of Precise Nitinol Stent System and Disposable Biopsy Forceps, BIPAL 7 Formable / Torquable Disposal Biopsy Forceps from Class III devices of Device table Removal of subcontractor Viant AS&O Holdings, LLC
22 February 2023	3772573	Subcontractor pages removal

Inspiring trust for a more resilient world.

22 February 2023

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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	**Directive and Annex**	**Reference Number**	**Changes approved**
CE 00340	93/42/EEC Annex II excluding Section 4	3772573	Subcontractor pages removal

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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