By Royal Charter

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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **30 November 1994** Date: **13 December 2015** Expiry Date: **25 November 2019**

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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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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 00340**
Date:	**13 December 2015**
Issued To:	**Cordis Corporation** **14201 North West 60th Avenue** **Miami Lakes** **Florida** **33014** **USA**

Subcontractor:	**Service(s) supplied**
Cordis Cashel Cahir Road Cashel Co. Tipperary Ireland	**EU Representative** **Regulatory Compliance**
Cordis Corporation 6500 Paseo Padre Parkway Fremont CA 94555 USA	**Design** **Development** **Regulatory Compliance**
Cordis de Mexico S.A. de C.V. Calle Circuito Interior Norte #1820 Parque Industrial Salvarcar Ciudad Juarez Chihuahua, CP 32574 Mexico	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Freudenberg Medical MIS Inc. 2301 Centennial Boulevard Jeffersonville IN 47130 USA	**Design** **Manufacture**
GMED Healthcare BVBA European Distribution Center Rue de Luxembourg 5 B-6180 Courcelles Belgium	**Labelling** **Packaging**
Lake Region Medical Limited Butlersland New Ross Co. Wexford Ireland	**Control of Sterilization** **Manufacture**

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Subcontractor:	**Service(s) supplied**
Lake Region Medical 340 Lake Hazeltine Drive Chaska Minnesota 55318 USA	**Control of Sterilization** **Manufacture**
Lake Region Medical 45 Lexington Drive Laconia New Hampshire 03246 USA	**Design** **Manufacture**
Nitinol Device and Components, Inc. 47533 Westinghouse Drive Fremont California 94539 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Norman Noble, Inc Medtech Manufacturing Division 5507 Avion Park Drive Highland Heights OH 44143 USA	**Manufacture**
Schenker Singapore Pte Ltd Megahub 51, Alps Avenue 498783 Singapore	**Labelling** **Packaging**
Sterigenics US, LLC 10821 Withers Cove Park Drive Charlotte NC 28278 USA	**Gamma Sterilization**

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Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	**ETO Sterilization**
Sterigenics US, LLC 5725 West Harold Gatty Drive Salt Lake City Utah 84116 USA	**ETO Sterilization**
STERIS Isomedix Corporation 1435 Isomedix Place El Paso Texas 79936 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
STERIS Isomedix Services 2072 Southport Road Spartanburg South Carolina 29306 Illinois USA	**ETO Sterilization**
Synergy Health AST, LLC 6750 East 46th Avenue Drive Suite 100 Denver Colorado 80216 USA	**E beam Sterilization**

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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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Date	Reference Number	Action
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.