

EC Certificate - Full Quality Assurance System

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

No.

CE 00500

Issued To:

**Covidien Ilc
15 Hampshire Street
Mansfield
Massachusetts
02048
USA**

In respect of:

See certificate scope page.



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: **1995-02-01**

Date: **2020-09-18**

Expiry Date: **2024-05-26**

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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.

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Certificate No: CE 00500

Certificate Scope:

The design, development and manufacture of electrosurgical generators and associated sterile and non-sterile accessories; sterile surgical smoke evacuation accessories; electrosurgical vessel sealing systems and associated sterile and non-sterile accessories; RF ablation generators and associated sterile and non-sterile accessories; microwave ablation generators and associated sterile and non-sterile accessories; sterile and non-sterile electromagnetic navigation accessories; ultrasonic surgical systems and associated sterile and non-sterile accessories.

Spanish:

Diseño, desarrollo y manufactura de generadores electroquirúrgicos y accesorios estériles y no estériles relacionados; accesorios estériles de evacuación de humo quirúrgico; sistemas electroquirúrgicos de sellado de vasos sanguíneos y accesorios estériles y no estériles relacionados; generadores de RF de ablación y accesorios estériles y no estériles relacionados; generadores de ablación por microondas y accesorios estériles y no estériles relacionados; accesorios de navegación electromagnética estériles y no estériles; sistemas quirúrgicos ultrasónicos y accesorios estériles y no estériles relacionados.

Portuguese:

Concepção, desenvolvimento e fabricação de geradores eletro-cirúrgicos e acessórios estéreis e não estéreis associados, acessórios estéreis de evacuação de fumaça cirúrgica, sistemas eletro-cirúrgicos de selagem de vasos e acessórios estéreis e não estéreis associados, geradores de ablação por RF e acessórios estéreis e não estéreis associados, geradores de ablação por microondas e acessórios estéreis e não estéreis associados, acessórios de navegação eletromagnética estéreis e não estéreis, sistemas cirúrgicos ultrassônicos e acessórios estéreis e não estéreis associados.



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Supplementary Information to CE 00500

Issued To:

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NBOG code	Device description	Intended purpose per IFU
Class IIb		
MD 1104	Electrosurgical electrodes	Intended to be used to remove tissue and control bleeding by use of high-frequency electrical current.
MD 1104	Electrosurgical and vessel sealing RF generators	Intended for use with monopolar and bipolar accessories for cutting, coagulating, desiccating, and fulgurating tissue and sealing (fusing) vessels.
MD 1104	Electrosurgical smoke evacuation system accessories and electrodes	Intended for use with standard monopolar electrosurgical generators, standard monopolar electrodes, and smoke evacuators
MD 1104 MD 1301 MD 0102	RF ablation generators and accessories	Intended for use in percutaneous, laparoscopic, and intraoperative coagulation and ablation of tissue, including partial or complete ablation of non-resectable liver tumors and osteoid osteoma tumors within bone



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NBOG code	Device description	Intended purpose per IFU
MD 1402	Microwave ablation generators and accessories.	Intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors. It is not for use in cardiac procedures.
MD 1104	Cordless ultrasonic generator and accessories	Indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The device can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open and endoscopic procedures. Can be used to coagulate isolated vessels up to 5 mm in diameter.



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NBOG code	Device description	Intended purpose per IFU
Class IIa		
MD 0102	Smoke evacuation accessories	N/A
MD 1301	Temperature probes for ablation systems	N/A
MD 1402	Electromagnetic navigation accessories	N/A

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Date	Reference Number	Action
01 February 1995		First Issued.
13 December 1996		Addition of Sub-contractors.
22 June 1998		Addition of Sub-contractors.
25 January 1999		Addition of Sub-contractors.
19 April 1999		Addition of Sub-contractors.
28 February 2000		Addition of sterilisation Sub-Contractor.
20 April 2000		Addition of Sub-Contractor.
24 July 2000		Extension to the scope, bipolar monitoring devices added.
12 July 2001		Addition of Sub-Contractors and Certificate renewal.
03 April 2003	4356583	Addition of Sub-Contractors and removal of Sub-Contractors.
5 October 2003	4356583	Extension of scope to include lesion generators and the addition of sub-contractor Ion Beam Applications in Queensbury New York for Ethylene Oxide Sterilisation.
24 February 2005	4647875	Certificate renewal and issue in new format.

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21 March 2006	4799198	Change of address format. Addition of sub-contractors: Gambro BCT (Lakewood), Sterigenics (Willowbrook), Sterigenics (Gurnee) and Linemaster (Woodstock). Change of sub-contractor address: Beam One (Lima). Removal of subcontractors: Steris Isomedix (Sandy), Delphi Medical Systems (Longmont) and Sterigenics (Santa Teresa).
07 February 2008	7068083	Extension to scope for Microwave generator. Addition of significant subcontractors 'Thermo Fisher Scientific', 'HEI Inc' in relation to the manufacture of microwave generators and accessories. Addition of 'Covidien Medical Products (Shanghai) Manufacturing' and 'Buffalo Filters, Buffalo' as a significant subcontractor for manufacturing activities Maintenance of addresses for other significant subcontractors.

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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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18 February 2009	7316357	Certificate re-issue due to: change of company name, removal of subcontractor 'Nellcor Puritan Bennett Mexico', change of subcontractor company name 'Aaron Medical Industries, Inc.' to 'Bovie Medical Corp', change of subcontractor company name 'Gambro BCT, Inc.' to 'Caridian BCT Sterilization Services, Inc.' and addition of "Covidien Ireland Limited" as EU Rep.
27 January 2010	7464667	Certificate renewal – scope amended "ultrasonic surgical aspirators and associated accessories" deleted "Lesion" amended to "ablation". Subcontractors removed: Kendall, a division of Tyco Healthcare Group LP, Norfolk UK– Gamma Sterilization, United States Surgical (USS) North Haven US – Manufacture & Design, HEI Inc, Boulder, US – Manufacture. Address amendment for Bovie Medical Corp and name correction for Cardian BCT. Address change for Design Standards Corporation from 182 Ceda Road to 957 Claremont Road.
16 April 2010	7510978	Change company name from Covidien LP (formerly known as Valleylab a division of Tyco Healthcare Group LP) to Valleylab, a division of Tyco Healthcare Group LP.

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Date	Reference Number	Action
10 November 2010	7603788	Company name change from Valleylab, a division of Tyco Healthcare Group LP to Covidien Energy-based Devices . The addition of Covidien Energy-based Devices as a significant sub contractor for Design and Manufacture. Changes to the format of the address on the certificate and to Covidien Energy-based Devices address.
13 April 2012	7817940	Extension of scope to include "ultrasonic surgical systems and associated accessories."
12 June 2012	7841245	Subcontractor name change from 'Caridian BCT Inc' to 'Terumo BCT'. The addition of Synergy Health (Suzhou) as a significant subcontractor for Sterilisation. Subcontractor name change from 'BeamOne, LLC' to 'Synergy Health Applied Sterilization Technologies, LLC' in 2 places.
07 January 2013	7930922	Addition of subcontractors Accellent Inc, El Paso, Texas and Venusa de Mexico S.A. de C.V., Chihuahua, Mexico both for manufacturing services.

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Date	Reference Number	Action
26 January 2015	8258195	Correction of subcontractor address for, 'Buffalo Filter and New Deantronics Taiwan Ltd.' Addition of subcontractor, 'Buffalo Filter, CEA Medical Manufacturing, DeRoyal Industries, Inc., Modern Medical Equipment Manufacturing Ltd., SEI MEDICAL S.A. DE C.V. and Vanguard AG', for Sterile manufacture. Addition of subcontractor, 'Electrochem Solutions Inc, Contract Medical Manufacturing, LLC, New Deantronics Taiwan Ltd. for Design and manufacture.
26 January 2015	8258496	Certificate renewal.
05 October 2015	8318433	Addition of subcontractor, 'Covidien Ilc., 161 Cheshire Lane Suite 100, Plymouth, Minnesota, 55441-5433, USA', for manufacture and 'Emblation Microwave, Forrester Lodge, Inglewood, Alloa, FK10 2HU, Scotland, UK', for manufacture, design. Change of subcontractor name from Venusa de Mexico S.A. de C.V. an Accellent Company to Lake Region Medical. Amendment to scope.

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Date	Reference Number	Action
30 March 2016	8470731	Removal of subcontractor, 'Electrochem Solutions Inc, 13955 SW Milikan Way, Beaverton, Oregon 97005, USA'. Change of subcontractor name from, 'Covidien Energy-based Devices (Formerly Valleylab, a division of Tyco Healthcare Group LP)', to 'Covidien', for manufacture, design. Addition of subcontractor, 'Greatbatch Medical S. de R.L. de C.V., Calle 5 Norte No. 511, Ciudad Industrial, Tijuana, Baja California, 22444, Mexico', for manufacture. Amendment to scope.
06 May 2016	8524761	Remove duplicate EU representative.
01 March 2019	7794476	Administrative Subcontractor Service wording update for 'Sterile Manufacture' to 'Gamma Sterilization, Manufacture' for Buffalo Filter, division of MEDTEK, 5900 Genesee Street, New York. 'Sterile Manufacture' to 'Gamma Sterilization, ETO Sterilization, Dry Heat Sterilization, Moist Heat Sterilization, Manufacture' for CEA Medical Manufacturing, 1735 Merchants Court, Colorado.

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Date	Reference Number	Action
		'Sterile Manufacture' to 'ETO Sterilization, Manufacture' for DeRoyal Industries, Inc, 200 DeBusk Lane, Tennessee 'Sterile Manufacture' to 'Manufacture' for Modern Medical Equipment, Gold King Ind. Bldg., Hong Kong 'Sterile Manufacture' to 'Manufacture' for SEI MEDICAL S.A. DE C.V., Roberto Fierro y Francisco Sarabia, Juarez 'Sterilization' to 'ETO Sterilization' for Sterigenics US, LLC, 7775 South Quincy, Illinois 'Sterilization' to 'ETO Sterilization' for Synergy Health (Suzhou), 26 Xinchang Road, Jiangsu 'Sterilization' to 'Gamma Sterilization' for Synergy Health Americas, 500 West 4th Street, Ohio 'Sterile Manufacture' to 'Gas Plasma Sterilization, Manufacture' for Vanguard AG, Landsberger Str. 266, Berlin Traceable to NB 0086.

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Date	Reference Number	Action
17 October 2019	8747987	Addition of the subcontractors: Covidien (Plainfield); Medtronic Engineering and Innovation Center Private Ltd; NextPhase Medical Devices, LLC; Covidien (Tijuana); Royal Sterilization Systems; Cadex Electronics Inc.; Bovie Medical Corporation; New Deantronics Taiwan Ltd.; Sterigenics Shanghei ETO Ltd.; Sterigenics US, LLC.; Isomedix Operations, Inc.; Covidien Ilc, GI Solution; Sotera Health LLC; Trelleborg Sealing Solutions Tustin, Inc. Removal of the subcontractors: SEI MEDICAL S.S. DE C.V.; Accellent, Inc.; BOWA-Electronic GmbH & Co. KG; Linemaster Switch Corporation; United States Surgical (USS) A Div of Tyco Healthcare Group LP; CEA Medical Manufacturing; Synergy Health – Applied Sterilization Technologies, LLC (Denver, Co); Synergy Health Americas; Cole-Parmer Instrument Company; Design Standards Corporation; HEI, Inc.; Kendall, a division of Tyco, Nicolay GmbH; Sterigenics US, LLC (Gurnee, IL); Sterigenics (Queensbury, NY); Sutter Medizintechnik GmbH. Clarified scope wording adding to system granularity and an extension to scope to include surgical navigation.

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Date	Reference Number	Action
		Corrected names or addresses of subcontractors to align with ISO certificates: Covidien LLC; Buffalo Filter, LLC.; DeRoyal Industries, Inc.; Emblation Ltd.; Vanguard AG. Maintenance of subcontractor activities to align with BSI subcontractor activities for: Buffalo Filter, division of MEDTEK; DeRoyal Industries, Inc.; Emblation Ltd; Sterigenics US, LLC; Vanguard AG; Covidien LLC; "Finished device supplier" activity added to Emblation Ltd.; "ETO Sterilization" removed from DeRoyal Industries, Inc. activities.
24 January 2020	3061488	Certificate renewal. Amended scope to remove "procedure planning software", "software de planificacion de procedimientos" and "software de planeamento de processos". Removed subcontractors: Contract Medical Manufacturing, LLC, Oxford, USA; DeRoyal Industries, Inc., Powell, USA; Royal Sterilization Systems, New Tazewell, USA; Sterigenics US, LLC, Willowbrook, USA. Changed subcontractors: Covidien, LLC, Tijuana, Mexico to add Control of Sterilization and make a spelling correction to the name; Modern Medical Equipment Manufacturing Ltd to update address;

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Date	Reference Number	Action
		Buffalo Filter, LLC, Lancasters, USA to change "Control of Manufacture" to "Manufacture". Spelling corrections to the names of: Covidien llc, Mansfield, USA; Covidien llc, Plainfield, USA; Covidien llc, Plymouth, USA Added subcontractors: Isomedix Operations, Inc., San Diego, USA for ETO Sterilization; Medtronic B.V., Heerlen, The Netherlands as EU Representative; Midwest Sterilization Corporation, Jackson, USA for ETO Sterilization. Added Product Table.

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Date	Reference Number	Action
18 September 2020	3175231	Removed subcontractor Buffalo Filter, LLC. Added subcontractor ConMed Corporation for Design, Control of Manufacture, Finished Device Supplier and Control of Sterilization. Added subcontractor Consolidated Medical Equipment Company for Manufacture. Correction to subcontractor services supplied: • "Finished Device Supplier" added to Bovie Medical Corporation, New Deantronics Taiwan Ltd. • "Finished Device Supplier" removed from Covidien llc, Plainfield, Covidien llc, Tijuana, Covidien llc, Plymouth, Covidien llc, GI Solutions. • "Assembly" changed to "Manufacture" for Trelleborg Sealing Solutions Tustin, Inc. • "Control of Sterilization" added to Covidien llc, Plymouth and Kirwan Surgical Products LLC Correction to address of Emblation Ltd from FK10 2HU, Scotland to Scotland, FK10 2HU, UK. Correction to address of Medtronic Engineering and Innovation Center Private Ltd, correcting Hyderabad to Hyderabad Removed subcontractor NextPhase Medical Devices. Added subcontractor International Sterilization Laboratory, LLC for ETO Sterilization Added Isomedix Operations, Inc(Chester) for E Beam Sterilization

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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 2021	3479846	Addition of significant subcontractor Sterigenics Radiation Technologies, LLC

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 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

20th July 2021

Covidien llc
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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 00500	93/42/EEC Annex II excluding Section 4	3479846	Addition of significant subcontractor Sterigenics Radiation Technologies, LLC

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,

Gary Slack
Senior Vice President, Medical Devices

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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

Bovie Medical Corporation
 5115 Ulmerton Road
 Clearwater
 Florida 33760
 USA

Design
Finished Device Supplier
Manufacture

Cadex Electronics, Inc.
 22000 Fraserwood Way
 Richmond
 British Columbia
 V6W 1J6
 Canada

Manufacture

ConMed Corporation
 6455 S Yosemite Street
 Greenwood Village
 Colorado
 80111
 USA

Control of Manufacture
Control of Sterilization
Design
Finished Device Supplier

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Subcontractor:	Service(s) supplied
Consolidated Medical Equipment Company Ave. Alejandro Dumas No. 11321 Complejo Industrial Chihuahua Chihuahua Chihuahua 31136 Mexico	Manufacture
Covidien Ireland Limited IDA Business and Technology Park Tullamore Ireland	EU Representative
Covidien llc 2824 Airwest Boulevard Plainfield IN 46168 USA	Labelling Packaging

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Subcontractor:	Service(s) supplied
Covidien Ilc Boulevard Insurgentes 19030 Libramiento Tijuana B.C. 22225 Mexico	Control of Sterilization Manufacture
Covidien Ilc 5920 Longbow Drive Boulder Colorado 80301 USA	Design Finished Device Supplier Labelling Manufacture Packaging
Covidien Ilc 161 Cheshire Lane Suite 100 Plymouth Minnesota 55441-5433 USA	Control of Sterilization Manufacture

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Subcontractor:	Service(s) supplied
Covidien llc, GI Solutions 540 Oakmead Parkway Sunnyvale CA 94085 USA	Manufacture
Covidien Medical Products (Shanghai) Manufacturing, LLC Building #10 789 Puxing Road Shanghai 201114 People's Republic of China	Manufacture
Emblation Ltd. 3 Forrester Lodge Inglewood, Alloa Scotland FK10 2HU United Kingdom	Design Finished Device Supplier Manufacture

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Subcontractor:	Service(s) supplied
Greatbatch Medical S. de R.L. de C.V. Calle 5 Norte No. 511 Ciudad Industrial Tijuana BC CP 22444 Mexico	Manufacture
International Sterilization Laboratory, LLC 217 Sampey Road Groveland Florida 34736 USA	ETO Sterilization
Isomedix Operations, Inc 2 Nucifora Boulevard Chester New York 10918 USA	Radiation (E Beam Sterilization)

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EC Certificate - Full Quality Assurance System

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 00500**
 Date: **2020-09-18**
 Issued To: **Covidien llc**
15 Hampshire Street
Mansfield
Massachusetts
02048
USA



Subcontractor:

Service(s) supplied

Isomedix Operations, Inc.
 1000 S. Sarah Place
 Ontario
 California
 91761
 USA

Radiation (E Beam Sterilization)

Isomedix Operations, Inc.
 7685 Saint Andrews Avenue
 San Diego
 California
 92154
 USA

ETO Sterilization

Kirwan Surgical Products LLC
 180 Enterprise Drive
 Marshfield
 Massachusetts
 02050
 USA

**Control of Sterilization
 Manufacture**

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Mansfield
Massachusetts
02048
USA



Subcontractor:

Service(s) supplied

Lake Region Medical
 Venusa de Mexico S.A. de C.V.
 1525-6 Hertz Street
 Ciudad Juarez
 Chihuahua
 32470
 Mexico

Manufacture

Medtronic B.V.
 Earl Bakkenstraat 10
 6422 PJ Heerlen
 The Netherlands

EU Representative

Medtronic Engineering and Innovation Center Private
 Ltd
 DLF Cyber City, Block No. 3
 APHB Colony, Gachibowli, Telangana
 Ground Floor, Plot No. 129-132, APHB
 Hyderabad
 500019
 India

Design

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Mansfield
Massachusetts
02048
USA



Subcontractor:	Service(s) supplied
Midwest Sterilization Corporation P.O. Box 411 1204 Lenco Avenue Jackson Missouri 63755 USA	ETO Sterilization
Modern Medical Equipment Manufacturing Ltd Flat A, 11/F Mai Wah Ind. Bldg. 1- 7 Wah Sing Street Kwai Chung, New Territories Hong Kong	Manufacture
New Deantronics Taiwan Ltd. 12F, No. 51, Sec. 4, ChongYang Rd. Tu Cheng Dist. New Taipei City 23675 Taiwan	Design Finished Device Supplier Manufacture

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Mansfield
Massachusetts
02048
USA



Subcontractor:	Service(s) supplied
Sterigenics Radiation Technologies, LLC 7695 Formula Place San Diego California 92121 USA	Radiation (E Beam Sterilization)
Sterigenics Shanghai ETO, Ltd. No. 333 Shuang Hui Road Yang Shan Free Port Shanghai 201308 China	ETO Sterilization
Sterigenics US, LLC 4900 Gifford Avenue Los Angeles California 90058 USA	ETO Sterilization

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Mansfield
Massachusetts
02048
USA



Subcontractor:	Service(s) supplied
Synergy Health (Suzhou) Sterilization Technologies Ltd No. 26 Xinchang Road Suzhou Industrial Park Jiangsu 215125 China	ETO Sterilization
Synergy Health AST, LLC 9020 Activity Road, Suite D San Diego California 92126 USA	Radiation (E Beam Sterilization)
Terumo BCT, Inc. 10811 W. Collins Avenue Lakewood Colorado 80215 USA	ETO Sterilization

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Mansfield
Massachusetts
02048
USA



Subcontractor:

Service(s) supplied

Trelleborg Sealing Solutions Tustin, Inc.
 222 Industrial Park Drive
 Elk Rapids
 MI 49629
 USA

Manufacture

Vanguard AG
 Landsberger Str. 266
 Berlin
 12623
 Germany

Gas Plasma Sterilization
Manufacture

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