

EC Certificate - Full Quality Assurance System

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

No.

CE 00500

Issued To:

**Covidien llc
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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Page 1 of 5

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.

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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Page 2 of 5

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This certificate was issued electronically and is bound by the conditions of the contract.

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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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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Page 3 of 5

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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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Page 4 of 5

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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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Page 5 of 5

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

List of Significant Subcontractors

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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 llc Boulevard Insurgentes 19030 Libramiento Tijuana B.C. 22225 Mexico	Control of Sterilization Manufacture
Covidien llc 5920 Longbow Drive Boulder Colorado 80301 USA	Design Finished Device Supplier Labelling Manufacture Packaging
Covidien llc 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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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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Subcontractor:	Service(s) supplied
Lake Region Medical Venusa de Mexico S.A. de C.V. 1525-6 Hertz Street Cuidad 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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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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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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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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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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