

# EU Quality Management System Certificate

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

## MDR 728352 R000

**Manufacturer:** Covidien llc

**Address:**

15 Hampshire Street  
Mansfield  
Massachusetts  
02048  
USA

**Single Registration Number:** Not Available

**EU Authorised Representative:** Medtronic B.V.

**Address:**

Earl Bakkenstraat 10  
6422 PJ Heerlen  
The Netherlands

**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):



First Issued: **2021-09-01**

Date: **2021-09-01**

Expiry Date: **2026-08-31**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
A Member of the BSI Group of Companies.

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### Device Schedule: Class IIb devices

Class IIb	Intended purpose
Microwave ablation generators (CAGEN1, CAGENHP)	Intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, such as lung, kidney, and liver, including partial or complete ablation of non-resectable liver tumors.
Percutaneous Antennas (CA15L1, CA20L1, CA30L1, CA15L2, CA20L2, CA30L2)	Intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, such as lung, kidney, and liver, including partial or complete ablation of non-resectable liver tumors.

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

Class IIa	Risk Classification
ABLATION PUMP (CAPUMP1)	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
Current	3202882	Issued



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## List of Critical Subcontractors and Crucial Suppliers

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

### MDR 728352 R000

Date: 2021-09-01

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Covidien LLC 5920 Longbow Drive Boulder Colorado 80301 USA	Design
Covidien llc, GI Solutions 540 Oakmead Parkway Sunnyvale CA 94085 USA	Manufacture
Covidien Medical Products (Shanghai) Manufacturing L.L.C. Building#10, 789 Puxing Road Shanghai 201114 People's Republic of China	Manufacture
Emblation Limited 3 Forrester Lodge Inglewood Alloa Scotland FK10 2HU UK	Design Manufacture

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## List of Critical Subcontractors and Crucial Suppliers

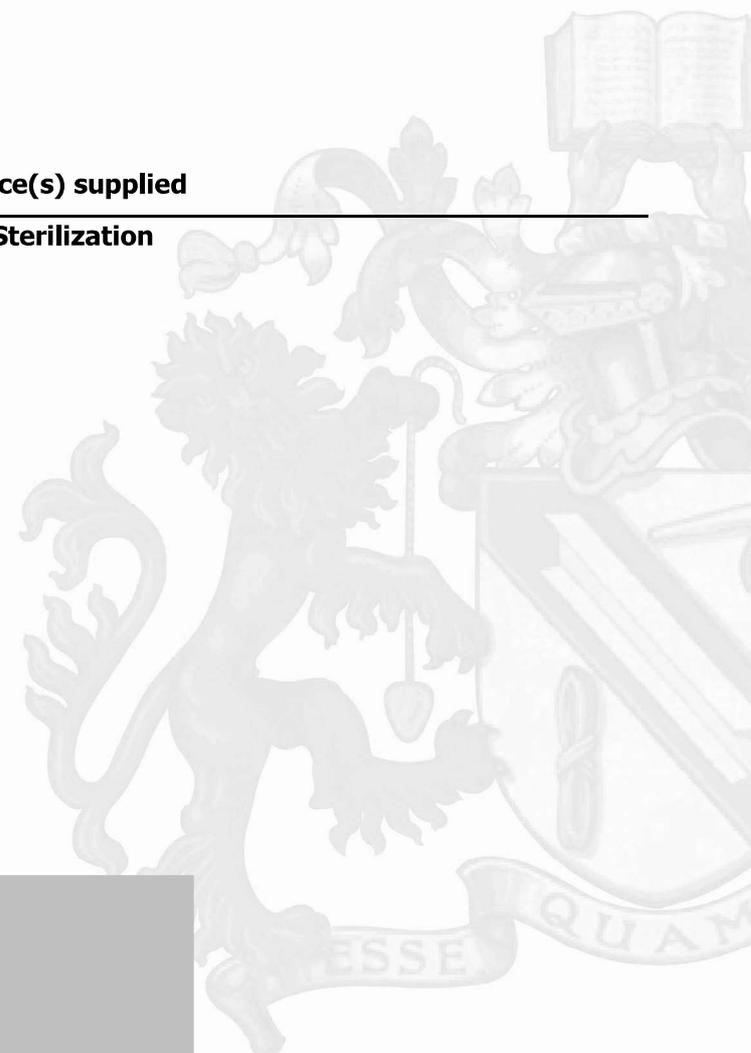
Recognised as being involved in services related to the products covered by:

### MDR 728352 R000

Date: 2021-09-01

Critical Subcontractor/Crucial Supplier	Service(s) supplied
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Sterigenics Shanghai ETO Ltd. No. 333, Shuang Hui Road Yang Shan Free Port Shanghai 201308 China	ETO Sterilization
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