Manufacturer	*Authorized European Representative*	*Notified Body*
Covidien llc 15 Hampshire Street Mansfield, MA 02048 USA	Covidien Ireland Limited IDA Business & Technology Park Tullamore, Ireland	BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands 2797

Declaration of Conformity

Document #/Revision #: Emprint Microwave Ablation System_DOC_B

Product/Family Name: Emprint Microwave Ablation System

Classification Rationale: Please refer to the table in schedule 1 for device classification in accordance with Annex IX

EU Conformity Assessment Route: Annex II, Annex VII

Start of CE Marking: 2014

Covidien llc declares under our sole responsibility that the above product(s) to which this declaration relates, and which bear(s) the CE Marking, is (are) in conformity with the Essential Requirements of EC Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EC of the European Parliament and of the Council, concerning medical devices, which allows their free distribution, sale and circulation in the European Union (EU); they comply with the provisions of the defined regulatory requirements and which comply with the referenced standards, as stated above.

This declaration is made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (TGA) Medical Device Regulations 2002, relating to the devices stated in Schedule I of this document.

- All supporting documentation is retained by the manufacturer
- As required by the above Directive, this Declaration is supported by
    - EC Certificate: MDD Annex II, CE 00500, issued by BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands, on 2020-01-24
    - Quality System Certificate: FM 71825, issued by BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herdon, VA 20170-6007 USA, on 2018-10-26
- This Declaration of Conformity is applicable to all of the medical devices referenced in Schedule I, manufactured by Covidien llc and/or produced under its certified Quality System control. Products referenced in Schedule I can be traced by means of the related product identification referenced in the relevant labeling (i.e.: lot number, serial number, etc.).
- Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential requirements/principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

This Declaration shall be retained for a period of the lifetime of the medical device (LMD) + 1 year or minimum of 15 years once the record is obsoleted or superseded.

Date of Issue: 19 May 2020

Place of Issue: Boulder, Colorado, USA

Medical Device Part Number	Description	Class/ Rule	Conformity Assessment Route	GMDN Code and Term
CAGEN1	Microwave Ablation Generator with Thermosphere™ Technology	IIb/Rule 9	Annex II	61287, Microwave ablation system generator
CAGENHP	Microwave Ablation Generator with Thermosphere™ Technology	IIb/Rule 9	Annex II	61287, Microwave ablation system generator
CA15L1	Emprint Short Percutaneous Ablation Antenna	IIb/Rule 9	Annex II	61286, Microwave ablation probe
CA20L1	Emprint Standard Percutaneous Ablation Antenna	IIb/Rule 9	Annex II	61286, Microwave ablation probe
CA30L1	Emprint Long Percutaneous Ablation Antenna	IIb/Rule 9	Annex II	61286, Microwave ablation probe
CA15L2	Emprint Reinforced Short Percutaneous Ablation Antenna	IIb/Rule 9	Annex II	61286, Microwave ablation probe
CA20L2	Emprint Reinforced Standard Percutaneous Ablation Antenna	IIb/Rule 9	Annex II	61286, Microwave ablation probe
CA30L2	Emprint Reinforced Long Percutaneous Ablation Antenna	IIb/Rule 9	Annex II	61286, Microwave ablation probe
CA108L1	Emprint Ablation Catheter/Antenna Kit	IIb/Rule 9	Annex II	61286, Microwave ablation probe
CAPUMP1	Emprint™ Ablation Pump	I/Rule 12	Annex VII	36664, Pump, powered
CA190RC1	Emprint Reusable Ablation Cable	I/Rule 1	Annex VII	47487, Medical device electrical cable, reusable
RTP20	Cool-tip™ RF Ablation Remote Temperature Probe E Series	IIa/Rule 10	Annex II	35254, Thermometer probe, electronic, single use
RTP20B	Cool-tip™ RF Ablation Remote Temperature Probe E Series	IIa/Rule 10	Annex II	35254, Thermometer probe, electronic, single use

Accessory Part Number	Description	Class/ Rule	Conformity Assessment Route	GMDN Code and Term
CART1	Emprint Ablation Cart	N/A	N/A	N/A
CARTHP	Emprint HP Ablation Cart	N/A	N/A	N/A

Revision	Description	Performed by	Date
A	Consolidated Emprint Microwave Ablation System CFN's and format update. Supersedes DOC's 503, 523, and 525	S. Pavlik	2020-03-18
B	Added CAGENHP and CARTHP to the DOC	R. Duggineni	2020-05-19