

EU MDR Declaration of Conformity (DoC)

Manufacturer: Covidien llc
15 Hampshire Street
Mansfield, Massachusetts 02048
USA

Manufacturer SRN: TBD

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

Authorized Representative SRN: TBD

Notified Body: BSI Group The Netherlands B.V
Say Building,
John M. Keynesplein 9,
1066 EP Amsterdam
Netherlands
Number: 2797

Conformity Assessment Certificate(s): RE00360498 MDR 728352, Covidien llc EU QMS Certificate Regulation (EU) 2017/745 Annex IX Chapter 1 and III

Conformity Assessment Route: European Medical Device Regulation 2017/745, Annex IX

Risk Class and Classification Rules:

Product Description	Product Code	Classification	MDR Rule
Emprint™ Ablation Generator	CAGEN1	Class IIb	MDR Rule 9
Emprint™ HP Ablation Generator	CAGENHP	Class IIb	
Emprint™ Reinforced Percutaneous Antenna	CAXXL2	Class IIb	
Emprint™ Ablation Pump	CAPUMP1	Class IIa	MDR Rule 9

EU MDR Declaration of Conformity

Form

RE00362158

Revision [B]

Page 2 of 3

Medtronic

Software in Emprint™ HP Ablation Generator	CAGENHP	Class IIb	MDR Implementing Rule 3.3 of Annex VIII
--	---------	-----------	---

Intended purpose:

The Covidien Emprint™ Ablation System is 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.

Statement:

We hereby declare under our sole responsibility that the product(s) specified herein conform to EU Medical Device Regulation 2017/745 and relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Union Legislation	Declaration of Conformity Document Number
RoHS 2011/65/EU	RE00219196 and LEFT-349 Issue 7 LEFT Generator CoFC for 1 x CAGEN1_25-JUN-20_RoHS
REACH Regulation (EC) No 1907/2006	RE00212086, RE00212083, RE00279583

Place: Boulder, Colorado USA

Name:



Title: Senior Manager – Regulatory Affairs

Signature:



Date:

02 Jun 2022

EU MDR Declaration of Conformity

Form

RE00362158

Revision [B]

Page 3 of 3

Medtronic

Products Covered:

Product Name	Product Identifier	Class	Basic UDI-DI	GMDN Codes
	CFN			
EMPRINT ABLATION GENERATOR	CAGEN1	IIb	0763 000B00000997T	61286
EMPRINT HP ABLATION GENERATOR and Software	CAGENHP	IIb	0763 000B00000997T	61286
CA15L2 15CM REIN PERCUTANEOUS ANTENNA X1	CA15L2	IIb	0763 000B00001006K	61286
CA20L2 20CM REIN PERCUTANEOUS ANTENNA X1	CA20L2	IIb	0763 000B00001006K	61286
CA30L2 30CM REIN PERCUTANEOUS ANTENNA X1	CA30L2	IIb	0763 000B00001006K	61286
CAPUMP1 ABLATION PUMP	CAPUMP1	IIa	0763 000B00001026P	36664

Common Specification(s)

The following common specifications were used to demonstrate conformity:

Number	Date of Issue	Title
Not Applicable	Not Applicable	Not Applicable

Revision History

[Revision History may be captured in document management systems (DMS). Complete this section when revision history is not captured in a DMS. This section may be removed when revision history is captured in a DMS.]

Revision	Date Effective	Description of Change
[1.0]	[12-NOV-2017]	[Initial release of document]

