Declaration of Conformity
DOC # 507

COVIDIEN

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

European Representative
Covidien Ireland Limited
IDA Business and Technology Park
Tullamore
Ireland

Product	Electrosurgical Generators
Classification (MDD)	Class IIb
Conformity Assessment Route	European Medical Device Directive 93/42/EEC amended by 2007/47/EC, Annex II
Reorder Codes / GMDN Codes	Refer to Appendix RE00254770

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacture. Covidien is exclusively responsible for the Declaration of Conformity.

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principals, the classification rules and the full quality assurance procedures at each stage, from the design of the device until its final inspection before being supplied, in accordance with Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods Regulations.

Notified Body	**BSI Group The Netherlands B.V.** Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands **Number: 2797**
EC Certificate	**CE 00500**
Standards to which Conformity is Declared	Refer to Appendix RE00254770
Place of Issue	Boulder, Colorado, USA
Date of Issue	July 13, 2020
Named Signatory Authority	Nancy Sauer
Title	Regulatory Affairs Director

Approval: Refer to RC247937 in PLM system

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Revisions:

DOC 507 supersedes DOC 407 under notified body number:0086.

	Approval in PLM System	Description
DOC 407 Rev. A (RE00055001)	RC055150	Initial release.
DOC 407 Rev. B (RE00055001)	RC093433	Added product ForceTriad ZE.
DOC 407 Rev. C (RE00055001)	RC106695	Added product VLFX8GEN.
DOC 407 Rev. D (RE00055001)	RC158813	Updated VLFT10GEN and VLFX8Gen to reflect the current version of standard ISO 15223-1:2016
DOC 507 Rev. E (RE00055001)	RC189290	Changed Notified Body address from: BSI Group Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP UK Number: 0086 to: BSI Group The Netherlands B.V. Say Building, John M. Keynesplain 9, 1066 EP Amsterdam Netherlands Number: 2797 ForceTriad removed.
DOC 507 Rev. F (RE00055001)	RC198822	Added product ForceTriad per CE00500 MDD recertification Sample Plan.
DOC 507 Rev. G (RE00055001)	RC210546	Removal of Surg II-8, SurgII-20, and VLSURGGEN.
DOC 507 Rev. H (RE00055001)	RC212837	VLLS10GEN standards updated to reflect R0053174.
DOC 507 Rev. I (RE00055001)	RC237598	VLLS10GEN standards list corrected from previous revision and VLFT10GEN standards updated to reflect R0053174. VLFX8GEN to reflect the current version of standard ISO 13485:2016
DOC 507 Rev. J (RE00055001)	RC247937	New template per RA-020D.

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Appendix RE00254770

This appendix declares the products included in the above referenced Declaration of Conformity. Refer to the external standards list in PLM system.

Catalog Number and Description	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)	External Standards List
Force FX-8C Force FX™ Electrosurgical Generator 8C 240 V	IIb	Rule 9	N/A	Annex II	11490: General-purpose Electrosurgical Diathermy System Generator	General-purpose Electrosurgical Diathermy System Generator	RE00061244
Force FX-8CA Force FX™ Electrosurgical Generator 8CA Autobipolar 240 V	IIb	Rule 9	N/A	Annex II	11490: General-purpose Electrosurgical Diathermy System Generator	General-purpose Electrosurgical Diathermy System Generator	RE00061244
Force FX-C Force FX™ Electrosurgical Generator C 120 V	IIb	Rule 9	N/A	Annex II	11490: General-purpose Electrosurgical Diathermy System Generator	General-purpose Electrosurgical Diathermy System Generator	RE00061244
Force FX-CS Force FX™ Electrosurgical Generator CS 120 V	IIb	Rule 9	N/A	Annex II	11490: General-purpose Electrosurgical Diathermy System Generator	General-purpose Electrosurgical Diathermy System Generator	RE00061244
Force FX-8CS Force FX™ Electrosurgical Generator 8CS 240 V	IIb	Rule 9	N/A	Annex II	11490: General-purpose Electrosurgical Diathermy System Generator	General-purpose Electrosurgical Diathermy System Generator	RE00061244
Force FX-8CAS Force FX™ Electrosurgical Generator 8CA Autobipolar 240 V	IIb	Rule 9	N/A	Annex II	11490: General-purpose Electrosurgical Diathermy System Generator	General-purpose Electrosurgical Diathermy System Generator	RE00061244
ForceTriad ForceTriad™ Energy Platform	IIb	Rule 9	N/A	Annex II	11490: General-purpose Electrosurgical Diathermy System Generator	General-purpose Electrosurgical Diathermy System Generator	RE00174176

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Catalog Number and Description	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)	External Standards List
FTBRKIT ForceTriad™ Bipolar Resection Activation Kit	IIb	Rule 9	N/A	Annex II	11490: General-purpose Electrosurgical Diathermy System Generator	General-purpose Electrosurgical Diathermy System Generator	RE00174176
FTRCKIT ForceTriad™ Remote Control Activation Kit	IIb	Rule 9	N/A	Annex II	11490: General-purpose Electrosurgical Diathermy System Generator	General-purpose Electrosurgical Diathermy System Generator	RE00174176
VLFT10GEN Valleylab™ FT10 FT Series Energy Platform	IIb	Rule 9	N/A	Annex II	11490: General-purpose Electrosurgical Diathermy System Generator	General-purpose Electrosurgical Diathermy System Generator	R0053174
VLLS10GEN Valleylab™ LS10, LS Single Channel Vessel Sealing Generator	IIb	Rule 9	N/A	Annex II	11490: General-purpose Electrosurgical Diathermy System Generator	General-purpose Electrosurgical Diathermy System Generator	R0046040
VLFX8GEN Valleylab™ FX8 FX Series Energy Platform	IIb	Rule 9	N/A	Annex II	11490: General-purpose Electrosurgical Diathermy System Generator	General-purpose Electrosurgical Diathermy System Generator	RE00019992

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Revisions:

	Date of Issue	Description
DOC 507 Appendix Rev. A (RE00254770)	RC248666	Initial Release.