

Declaration of Conformity DOC # 516



Legal Manufacturer

Covidien Ilc
15 Hampshire Street
Mansfield, Massachusetts 02048
USA

European Representative

Covidien Ireland Limited
IDA Business and Technology Park
Tullamore
Ireland

Product Electrosurgical Vessel Sealing Devices

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 RE00255136

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 RE00255136

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

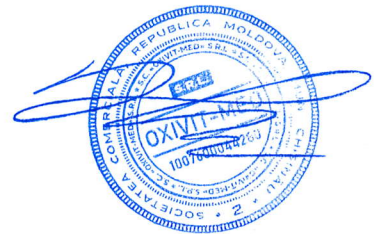
Declaration of Conformity DOC # 516



Revisions:

DOC 516 supersedes DOC 416 under notified body number:0086.

	Approval in PLM system	Description
DOC 416 Rev. A (RE00024785)	RC084059	Initial release.
DOC 416 Rev. B (RE00024785)	RC085076	Added products LF5637 and LF5644.
DOC 416 Rev. C (RE00024785)	RC085586	Added products LF5637 and LF5644; incorrect attachment in Rev B.
DOC 416 Rev. D (RE00024785)	RC092670	Corrected device name for products LF5637 and LF5644.
DOC 416 Rev. E (RE00024785)	RC099369	Added product BZ4212.
DOC 416 Rev. F (RE00024785)	RC109481	Added products LF1923, LF1937, and LF1944.
DOC 416 Rev. G (RE00024785)	RC115903	Added product LF2019.
DOC 416 Rev. H (RE00024785)	RC153262	Added product LF1930T.
DOC 516 Rev. I (RE00024785)	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
DOC 516 Rev. J (RE00024785)	RC210546	Removed products SURG II-8, SURG II-20, VLSURGEN. Update of BZ4112 and BZ4212 to current standards list per RE00001840 in PLM system.
DOC 516 Rev. K (RE00024785)	RC247937	New template per RA-020D.



Declaration of Conformity DOC # 516



Appendix RE00255136

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
BZ4112 BiZact™ Open/Sealer Divider	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece /electrode, bipolar, single- use	Open-surgery electrosurgical handpiece /electrode, bipolar, single- use	RE00001840
BZ4212 BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer Divider	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece /electrode, bipolar, single- use	Open-surgery electrosurgical handpiece /electrode, bipolar, single- use	RE00001840
LF1212 LigaSure™ Curved, Small Jaw, Open Sealer/Divider	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use.	R0043534
LF1212A LigaSure™ Curved, Small Jaw, Open Sealer/Divider	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use.	R0043534
LF1520 LigaSure™ Blunt Tip Open Sealer/Divider	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use.	R0043534
LF1537 LigaSure™ Blunt Tip Laparoscopic Sealer/Divider	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single- use.	Endoscopic electrosurgical handpiece/ electrode, bipolar, single- use	RE00253948
LF1544 LigaSure™ Blunt Tip Laparoscopic Sealer/Divider	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single- use.	Endoscopic electrosurgical handpiece/ electrode, bipolar, single- use	R0043534



Declaration of Conformity DOC # 516



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LF1623 LigaSure™ Blunt Tip Open Sealer/Divider	IIB	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	R0038384
LF1637 LigaSure™ Blunt Tip Laparoscopic Sealer/Divider	IIB	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	R0005665
LF1644 LigaSure™ Blunt Tip Laparoscopic Sealer/Divider	IIB	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	R0038384
LF1723 LigaSure™ Maryland Jaw Open Sealer/Divider One-step Sealing	IIB	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	R0043534
LF1737 LigaSure™ Maryland Jaw Laparoscopic Sealer/Divider One-step Sealing	IIB	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	R0043534
LF1744 LigaSure™ Maryland Jaw Laparoscopic Sealer/Divider One-step Sealing	IIB	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	R0043534
LF1823 LigaSure™ Blunt Tip Open Sealer/Divider, Nano-coated	IIB	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	RE00001849
LF1837 LigaSure™ Blunt Tip Laparoscopic Sealer/Divider, Nano-coated	IIB	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	RE00001849



Declaration of Conformity DOC # 516



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LF1844 LigaSure™ Blunt Tip Laparoscopic Sealer/Divider, Nano-coated	IIB	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single- use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single- use	RE00001849
LF1923 LigaSure™ Maryland Jaw Open Sealer/Divider One-step Sealing, Nano- coated	IIB	Rule 9	Sterile	Annex II	56296: Open- surgery electrosurgical handpiece/ electrode, bipolar, single- use.	Open-surgery electrosurgical handpiece/elect rode, bipolar, single-use.	RE00128946
LF1937 LigaSure™ Maryland Jaw Laparoscopic Sealer/Divider One-step Sealing, Nano- coated	IIB	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single- use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single- use	RE00128946
LF1944 LigaSure™ Maryland Jaw Laparoscopic Sealer/Divider One-step Sealing, Nano- coated	IIB	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single- use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single- use	RE00128946
LF1930T LigaSure™ Maryland Jaw Thoracic Sealer/Divider One-step Sealing, Nano- coated	IIB	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single- use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single- use	RE00128946
LF2019 LigaSure™ Exact Dissector, Nano-coated	IIB	Rule 9	Sterile	Annex II	56296: Open- surgery electrosurgical handpiece/ electrode, bipolar, single- use	Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use.	R0038324
LF4318 LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider	IIB	Rule 9	Sterile	Annex II	56296: Open- surgery electrosurgical handpiece/ electrode, bipolar, single- use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use.	R0043534



Declaration of Conformity DOC # 516



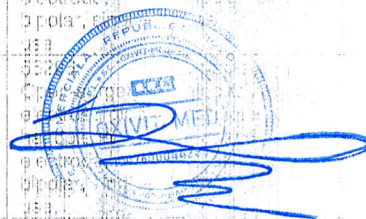
Catalog Number and Description	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)	External Standards List
LF4418 LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider, Nano-Coated	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	RE00001849
LF5637 LigaSure™ Retractable L-Hook Laparoscopic Sealer/Divider	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	R0013063
LF5644 LigaSure™ Retractable L-Hook Laparoscopic Sealer/Divider	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	R0013063
LigaSure 8 LigaSure™ Vessel Sealing System	IIb	Rule 9	N/A	Annex II	11490: General-purpose Electrosurgical Diathermy System Generator	General-purpose electrosurgical diathermy system generator	RE00253948
LS1020 LigaSure Atlas™ Tissue Fusion Open Instrument	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	R0043534
LS1037 LigaSure Atlas™ Tissue Fusion Laparoscopic Instrument	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	R0043534
LS1200 LigaSure Precise™ Tissue Fusion Open Instrument	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	RE00253948
LS1500 LigaSure™ Dolphin Tip Laparoscopic Sealer/Divider	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	RE00253948



Declaration of Conformity DOC # 516



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LS1520 LigaSure™ Dolphin Tip Open Sealer/Divider	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use.	RE00253948
LS2111 LigaSure™ Tissue Fusion Electrode Angled Jaw	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use	Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use	RE00253948
LS2071 LigaSure™ Tissue Fusion Electrode	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use	RE00253948
LS3092 LigaSure™ Tissue Fusion Electrode Curved Jaw	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use	Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use	RE00253948
LS3112 LigaSure™ Tissue Fusion Electrode Curved Jaw	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use	Open-surgery electrosurgical handpiece/ electrode, bipolar, single- use	RE00253948



Declaration of Conformity DOC # 516



Revisions:

	Date of Issue	Description
DOC 516 Appendix Rev. A (RE00255136)	RC248718	Initial Release.
DOC 516 Appendix Rev. B (RE00255136)	RC247937	Corrected entry for LigaSure 8 generator. The product is not sterile.



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