

**Declaration of Conformity
DOC # 506**



Legal Manufacturer

Covidien llc
15 Hampshire Street
Mansfield, Massachusetts 02048
USA

European Representative

Covidien Ireland Limited
IDA Business and Technology Park
Tullamore
Ireland

Product Active Monopolar Electrodes

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 RE00254769

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 RE00254769

Place of Issue Boulder, Colorado, USA

Date of Issue December 10, 2020

Named Signatory Authority Juma Hoshino
Title Regulatory Affairs Manager

Approval: Refer to RC248705 in PLM system

Declaration of Conformity

DOC # 506



Revisions:

DOC 506 supersedes DOC 406 under notified body number:0086.

	Approval in PLM System	Description
DOC 406 Rev. A (RE00102991)	RC103888	Initial release
DOC 406 Rev. B (RE00102991)	RC165967	Added product code SEA54506.
DOC 406 Rev. C (RE00102991)	RC187742	Update to reflect the current ISO 13485 Boulder certification for version 2016.
DOC 506 Rev. D (RE00102991)	RC189290	<p>Changed Notified Body address from:</p> <p style="padding-left: 40px;">BSI Group Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP UK Number: 0086</p> <p>to:</p> <p style="padding-left: 40px;">BSI Group The Netherlands B.V. Say Building, John M. Keynesplain 9, 1066 EP Amsterdam Netherlands Number: 2797</p>
DOC 506 Rev. E (RE00102991)	RC247937	New template per RA-020D.
DOC 506 Appendix Rev. F (RE00102991)	RC248705	Addition of E1455G.

Declaration of Conformity DOC # 506



Appendix RE00254769

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
E1000 Valleylab™ Ball Electrode Reusable 3.2 mm	IIb	Rule 9	N/A	Annex II	61876: Open-surgery electro-surgical electrode, monopolar, reusable	Open-surgery electro-surgical electrode, monopolar, reusable	RE00168825
E1002 Valleylab™ Ball Electrode Reusable 5.6 mm	IIb	Rule 9	N/A	Annex II	61876: Open-surgery electro-surgical electrode, monopolar, reusable	Open-surgery electro-surgical electrode, monopolar, reusable	RE00168825
E1003 Valleylab™ Fine Needle Electrode Reusable 2.6" (6.6 cm)	IIb	Rule 9	N/A	Annex II	61876: Open-surgery electro-surgical electrode, monopolar, reusable	Open-surgery electro-surgical electrode, monopolar, reusable	RE00168825
E1005 Valleylab™ Tungsten Loop Electrode Reusable 9.5 mm	IIb	Rule 9	N/A	Annex II	61876: Open-surgery electro-surgical electrode, monopolar, reusable	Open-surgery electro-surgical electrode, monopolar, reusable	RE00168825
E1020 Valleylab™ Hex-locking Blade Electrode Reusable 2.75" (7.0 cm)	IIb	Rule 9	N/A	Annex II	61876: Open-surgery electro-surgical electrode, monopolar, reusable	Open-surgery electro-surgical electrode, monopolar, reusable	RE00168825
E1450-4 Edge™ Blade Electrode 4" (10.16 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825

**Declaration of Conformity
DOC # 506**



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E1450-4NSB Edge™ Blade Electrode 4" (10.16 cm)	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1450-6 Edge™ Blade Electrode 6.5" (16.51 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1450-6NSB Edge™ Blade Electrode 6.5" (16.51 cm)	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1450G Edge™ Blade Electrode 3" (7.62 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1450GNSB Edge™ Blade Electrode 3" (7.62 cm)	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1450X Edge™ Hex-locking Blade Electrode 2.5" (6.35 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1450XNSB Edge™ Hex-locking Blade Electrode 2.5" (6.35 cm)	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825

**Declaration of Conformity
DOC # 506**



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E1452 Edge™ Needle Electrode 2.8" (7.2 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1452-6 Edge™ Needle Electrode 6.5" (16.51 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1452NSB Edge™ Needle Electrode 2.8" (7.2 cm)	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1455 Edge™ Insulated Blade Electrode 2.75" (7.0 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1455-4 Edge™ Insulated Blade Electrode 4" (10.16 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1455-4NSB Edge™ Insulated Blade Electrode 4" (10.16 cm)	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1455-6 Edge™ Insulated Blade Electrode 6.5" (16.51 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825

**Declaration of Conformity
DOC # 506**



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E1455-6NSB Edge™ Insulated Blade Electrode 6.5" (16.51 cm)	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1455B Edge™ Insulated Blade Electrode Safety Sleeve™ 2.75" (7.0 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1455B-4 Edge™ Insulated Blade Electrode Safety Sleeve™ 4" (10.16 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1455B-4NSB Edge™ Insulated Blade Electrode Safety Sleeve™ 4" (10.16 cm)	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1455BNSB Edge™ Insulated Blade Electrode Safety Sleeve™ 2.75" (7.0 cm)	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1455NSB Edge™ Insulated Blade Electrode 2.75" (7.0 cm)	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1455G Edge™ Insulated Blade Electrode 2.75" (7.0 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825

**Declaration of Conformity
DOC # 506**



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E1465 Edge™ Insulated Needle Electrode 2.8" (7.2 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1465NSB Edge™ Insulated Needle Electrode 2.8" (7.2 cm)	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1465-4 Edge™ Insulated Needle Electrode 4" (10.16 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1465-4NSB Edge™ Insulated Needle Electrode 4" (10.16 cm)	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1465-6 Edge™ Insulated Needle Electrode 6.5" (16.51 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1465B Edge™ Insulated Needle Electrode Safety Sleeve™ 2.8" (7.2 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1465B-4 Edge™ Insulated Needle Electrode Safety Sleeve™ 4" (10.16 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825

**Declaration of Conformity
DOC # 506**



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E1465BNSB Edge™ Insulated Needle Electrode Safety Sleeve™ 2.8" (7.2 cm)	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1475X Edge™ Hex-locking Blade Electrode 2.75" (7.0 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1502 Valleylab™ Straight Extension 13 cm	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1504 Valleylab™ Straight Extension 34.3 cm	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1510 Valleylab™ Arthroscopic Hook Electrode 90°	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00131120
E1511 Valleylab™ Arthroscopic Hook Electrode 45°	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00131120
E1512 Valleylab™ Insulated Arthroscopic Blade Electrode	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00131120

**Declaration of Conformity
DOC # 506**



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
E1513 Valleylab™ Arthroscopic Blade Electrode	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00131120
E1550 Valleylab™ Ball Electrode 5 mm	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1551-6 Valleylab™ Blade Electrode 6.5" (16.51 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1551-6NSB Valleylab™ Blade Electrode 6.5" (16.51 cm)	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1551G Valleylab™ Blade Electrode 2.4" (6.2 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1551X Valleylab™ Hex-locking Blade Electrode 2.4" (6.2 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1551XNSB Valleylab™ Hex-locking Blade Electrode 2.4" (6.2 cm)	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825

**Declaration of Conformity
DOC # 506**



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E1552 Valleylab™ Needle Electrode 2.8" (7.2 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1552-6 Valleylab™ Needle Electrode 6.5" (16.51 cm)	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1552NSB Valleylab™ Needle Electrode 2.8" (7.2 cm)	IIb	Rule 9	N/A	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1559 Valleylab™ Tungsten Loop Electrode 10 mm x 10 mm	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1560 Valleylab™ Tungsten Loop Electrode 15 mm x 12 mm	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1561 Valleylab™ Tungsten Loop Electrode 20 mm x 12 mm	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825
E1562 Valleylab™ Tungsten Loop Electrode 20 mm x 15 mm	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electrosurgical electrode, monopolar, single- use	Endoscopic electrosurgical electrode, monopolar, single-use	RE00168825

**Declaration of Conformity
DOC # 506**



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E1563 Valleylab™ Ball Electrode 3 mm	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1564 Valleylab™ Ball Electrode 5 mm	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1565 Valleylab™ Tungsten Square Loop Electrode 5 mm x 5 mm	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1567 Valleylab™ Tungsten Square Loop Electrode 10 mm x 8 mm	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1650 Valleylab™ Straight Micro-Needle Electrode 2 cm	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1651 Valleylab™ Straight Micro-Needle Electrode 3 cm	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1652 Valleylab™ Angled Micro-Needle Electrode 45°, 3 mm from tip 3 cm	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825

**Declaration of Conformity
DOC # 506**



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E1653 Valleylab™ Angled Micro-Needle Electrode 45°, 1 cm from tip 3 cm	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
E1654B Valleylab™ Insulated Micro-Needle Electrode 9 cm	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	RE00168825
SEA54506 Valleylab™ Smoke Evacuation Extension Tube, Edge™ Blade Electrode, 4"	IIb	Rule 9	Sterile	Annex II	61875: Endoscopic electro-surgical electrode, monopolar, single-use	Endoscopic electro-surgical electrode, monopolar, single-use	R0030363

Declaration of Conformity

DOC # 506



Revisions:

	Date of Issue	Description
DOC 506 Appendix Rev. A (RE00254769)	RC248660	Initial Release. Addition of E1455BNSB and removal of duplicate listing E1552NSB and E1455B-4NSB from DOC 506 Rev D (RE00102991).
DOC 506 Appendix Rev. B (RE00254769)	RC247937	Correct entries for reusable electrodes, which are not shipped in sterile form.
DOC 506 Appendix Rev. C (RE00254769)	RC248705	Addition of new product E1455G, inclusion of E1465NSB that was unintentionally left off of the previous revision, updates to correct standard form RE00168825.