Declaration of Conformity
DOC # 514

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	Patient Return 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 RE00254777

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 RE00254777
Place of Issue	Boulder, Colorado, USA
Date of Issue	July 13, 2020
Named Signatory Authority	Nancy Sauer
Title	Regulatory Affairs Director

OXIVIT-MED 1007600044280

Approval: Refer to RC247937 in PLM system

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Revisions:

DOC 514 supersedes DOC 414 under notified body number:0086.

	Approval in PLM system	Description
DOC 514 Rev. A (RE00055885)	RC067654	Initial release.
DOC 514 Rev. B (RE00055885)	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 514 Rev. C (RE00055885)	RC247937	New template per RA-020D.

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Appendix RE00254777

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
E7506 Valleylab™ Non-REM Polyhesive™ Patient Return Electrode 9' (2.7 m)	IIb	Rule 9	N/A	Annex II	58494: Electrosurgical diathermy system return electrode, single-use, non-sterile	Electrosurgical diathermy system return electrode, single-use, non-sterile	RE00057404
E7507 Valleylab™ REM Polyhesive™ Adult Patient Return Electrode 9' (2.7 m)	IIb	Rule 9	N/A	Annex II	58494: Electrosurgical diathermy system return electrode, single-use, non-sterile	Electrosurgical diathermy system return electrode, single-use, non-sterile	RE00057404
E7507-DB Valleylab™ REM Polyhesive™ Adult Patient Return Electrode 15' (4.6 m)	IIb	Rule 9	N/A	Annex II	58494: Electrosurgical diathermy system return electrode, single-use, non-sterile	Electrosurgical diathermy system return electrode, single-use, non-sterile	RE00057404
E7508 Valleylab™ REM Polyhesive™ Adult Cordless Patient Return Electrode	IIb	Rule 9	N/A	Annex II	58494: Electrosurgical diathermy system return electrode, single-use, non-sterile	Electrosurgical diathermy system return electrode, single-use, non-sterile	RE00057404
E7509 Valleylab™ REM Polyhesive™ Adult Cordless Patient Return Electrode	IIb	Rule 9	N/A	Annex II	58494: Electrosurgical diathermy system return electrode, single-use, non-sterile	Electrosurgical diathermy system return electrode, single-use, non-sterile	RE00057404

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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
E7509B Valleylab™ REM Polyhesive™ Adult Cordless Patient Return Electrode	IIb	Rule 9	N/A	Annex II	58494: Electrosurgical diathermy system return electrode, single-use, non-sterile	Electrosurgical diathermy system return electrode, single-use, non-sterile	RE00057404
E7510-25 Valleylab™ REM Polyhesive™ Infant Patient Return Electrode 9' (2.7 m)	IIb	Rule 9	N/A	Annex II	58494: Electrosurgical diathermy system return electrode, single-use, non-sterile	Electrosurgical diathermy system return electrode, single-use, non-sterile	RE00057404
E7510-25DB Valleylab™ REM Polyhesive™ Infant Patient Return Electrode 15' (4.6 m)	IIb	Rule 9	N/A	Annex II	58494: Electrosurgical diathermy system return electrode, single-use, non-sterile	Electrosurgical diathermy system return electrode, single-use, non-sterile	RE00057404
E7512 Valleylab™ REM Polyhesive™ Neonatal Patient Return Electrode 9' (2.7 m)	IIb	Rule 9	N/A	Annex II	58494: Electrosurgical diathermy system return electrode, single-use, non-sterile	Electrosurgical diathermy system return electrode, single-use, non-sterile	RE00057404

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Revisions:

	Date of Issue	Description
DOC 514 Rev. A (RE00254777)	RC248707	Initial Release.
DOC 514 Rev. B (RE00254777)	RC351384	Correction to E7510-25DB to state 15' (4.6 m) cord length.