Declaration of Conformity
DOC # 509

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 Pencils

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 RE00254771

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 RE00254771

Place of Issue Boulder, Colorado, USA
Date of Issue May 23, 2021

Named Signatory Authority Ben Cordileone
Title Principal Regulatory Affairs Associate

Approval: Refer to RC332890 in PLM system

Declaration of Conformity
DOC # 509

COVIDIEN

Revisions:

DOC 509 supersedes DOC 409 under notified body number:0086.

	Approval in PLM System	Description
DOC 409 Rev. A (RE00097556)	RC103888	Initial release.
DOC 409 Rev. B (RE00097556)	RC108450	Updated products E2100, E2100E to include standards EN ISO 11607-1, ISTA 2A, ISO 11135-1, EN 556-1, EN ISO 11737-1, ISO 11737-2, EN ISO 14644-1, ISO 17664.
DOC 409 Rev. C (RE00097556)	RC165967	Added products SEP5000, SEP5000NSB, SEP5015, SEP5012NSB, SEP6000, SEP6000NSB, SEP6015, SEP6015NSB.
DOC 409 Rev. D (RE00097556)	RC187742	Update to reflect the current ISO 13485 Boulder certification for version 2016.
DOC 509 Rev. E (RE00097556)	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 509 Rev. F (RE00097556)	RC247937	New template per RA-020D.
DOC 509 Rev. G (RE00097556	RC332890	Added E3504, E3504H, E3504NSB, E3250H, E3250HNSB