COVIDIEN

Declaration of Conformity

USS-120

We hereby declare, under our sole responsibility, that the devices specified below meet the relevant provisions of the Council Directive concerning medical devices- 93/42/EEC and the Essential Principles. This is also a declaration made in accordance with the requirements of Clause 1.8 of schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the stated device.

Issued by Manufacturer:	Covidien llc 15 Hampshire Street Mansfield, MA 02048, USA
Original Date/Place of Issue:	09/26/2007 North Haven, CT
Type of Devices:	Absorbable Fixation Device
Device Name:	AbsorbaTack™ Fixation Device
Product Category(ies) Listed on Current MDD Certificate:	Surgical Staple and Clip Products
MDD Classification/Reorder Codes/GMDN Codes:	See Attached
Conformity Assessment:	Directive 93/42/EEC on Medical Devices (MDD), Annex II
Design Examination Certificate:	G7 077608 0073 Rev. 00 (expires 26-May-2024)
EC Certificate:	G1 077608 0079 Rev 00 (expires 26-May-2024)
Certificate of Conformity Valid Until:	26-May-2024
Standards Associated:	See Attached

Authorized Representative in EU
Covidien Ireland Limited
IDA Business Technology Park
Tullamore, Ireland

Notified Body
TUV SUD Product Service GmbH
Ridlerstrasse 65,
80339 Munich, Germany (0123)

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Regulatory Affairs Director

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Reorder Code	Description	MDD Class	MDD Rule	GMDN Code	Date Added to Declaration MM/DD/YYYY	Reorder Code Status
ABSTACK15	AbsorbaTack™ Fixation Device 15 Violet Absorbable Tacks 5mm	III	8	Endoscopic Manual Linear Stapler [59874]	08/12/2010	Current
ABSTACK20S	AbsorbaTack™ Fixation Device 20 Violet Absorbable Tacks 5mm Short	III	8	Endoscopic Manual Linear Stapler [59874]	08/10/2009	Current
ABSTACK30	AbsorbaTack™ Fixation Device 30 Violet Absorbable Tacks 5mm	III	8	Endoscopic Manual Linear Stapler [59874]	08/12/2010	Current
ABSTACK30X	AbsorbaTack™ Fixation Device 30 Violet Absorbable Tacks 5mm	III	8	Endoscopic Manual Linear Stapler [59874]	05/31/2013	Current

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Standards List

Standard/Directive	Year	Type	Title
EN ISO 10993-1 + AC	2009 + 2010	Biological Evaluation	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3	2014	Biological Evaluation	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-4	2017	Biological Evaluation	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN ISO 10993-5	2009	Biological Evaluation	Biological evaluation of medical devices part 5: Tests for In Vitro Cytotoxicity
EN ISO 10993-6	2016	Biological Evaluation	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation
EN ISO 10993-7 + AC	2008 +2009	Biological Evaluation	Biological evaluation of Medical Devices: Part 7 – Ethylene Oxide Sterilization Residuals
EN ISO 10993-9	2009	Biological Evaluation	Biological evaluation of medical devices – Part 9: Framework for identification and quantification of potential degradation products
EN ISO 10993-10	2013	Biological Evaluation	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11	2018	Biological Evaluation	Biological evaluation of medical devices Part 11: Tests for systemic toxicity
EN ISO 10993-12	2012	Biological Evaluation	Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials
EN ISO 15223-1	2012	Labeling	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN 1041 + AC	2008 + 2013	Manufacturer Information	Information supplied by the manufacturer with medical devices.
EN ISO 14630	2012	Medical Devices	Non-active surgical implants- General Requirements
EN ISO 13485 + AC	2016	Quality Management	Medical devices. Quality management systems. Requirements for regulatory purposes.
IEC 62366-1	2015	Risk Management	Medical devices – Application of usability engineering to medical devices (IEC 62366:2007)
EN ISO 14971	2012	Risk Management	Medical devices. Application of risk management to medical devices.
EN 556-1 + AC	2001 + 2006	Sterility	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices.

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EN ISO 11135	2014	Sterility	Medical Devices – Validation and routine control of ethylene oxide sterilization.
EN ISO 11607-1	2017	Sterility	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2	2017	Sterility	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing, and assembly processes.
EN ISO 11737-1	2018	Sterility	Sterilization of medical devices - Microbiological methods – Part 1: Determination of the population of micro organisms on products.
EN ISO 11737-2	2009	Sterility	Sterilization of medical device – Microbiological methods – Part 2: Test of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14644-1	2015	Sterility	Cleanrooms and Associated Controlled Environments - Part 1: Classification of Air Cleanliness
EN ISO 14644-2	2015	Sterility	Cleanrooms and Associated Controlled Environments - Part 2: Specifications for Testing and Monitoring to Prove Continued Compliance with ISO 14644-1
EN ISO 14644-3	2019	Sterility	Cleanrooms and associated controlled environments Part 3: Test methods

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