COVIDIEN

Declaration of Conformity

USS-048

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, U.S.A.
Original Date/Place of Issue:	08/04/1995 North Haven, CT
Type of Devices:	Skin/Fascia Staplers
Device Name:	See Attached
Product Category(ies) Listed on Current MDD Certificate:	Surgical Staple, Clip Products and Accessories
MDD Classification/Reorder Codes/GMDN Codes:	See Attached
Conformity Assessment:	Directive 93/42/EEC on Medical Devices (MDD), For Class IIa/IIb: Annex II excluding (4) For Class I sterile: Annex V All Class I, non-sterile, non-measurement devices listed on Declarations of Conformance are not regulated by TÜV SÜD P.S. and follow conformity assessment procedures set out in Annex VII.
EC Certificate:	G1 077608 0079 Rev 00 (expires 26-May-2024) G2S 077608 0072 Rev. 00 (expires 23-May-2024)
Certificate of Conformity Valid Until:	23-May-2024
Standards Associated:	See Attached

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

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

Mary Mellows
Manager, Regulatory Affairs

Revision Date: October 3, 2019

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USS-048

Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration MM/DD/YYYY*	*Reorder Code Status*
050258	SM™ Auto Suture™ Skin Stapler Reload 35	IIb	8	Surgical Staple, non-bioabsorbable [35615]	8/4/1995	Current
050284	SM™ Auto Suture™ Skin Stapler Reload 35W	IIb	8	Surgical Staple, non-bioabsorbable [35615]	8/4/1995	Current
054006	Signet™ Auto Suture™ Skin Stapler 35W	IIa	7	Skin Stapler/staple, non-bioabsorbable [35884]	8/4/1995	Current
054887	Royal™ Auto Suture™ Skin Stapler 35W	IIa	7	Skin Stapler/staple, non-bioabsorbable [35884]	8/4/1995	Current
059035	Multifire Premium™ Auto Suture™ Pistol Grip Skin Stapler 35	IIa	7	Skin Stapler/staple, non-bioabsorbable [35884]	8/4/1995	Current
059036	Multifire Premium™ Auto Suture™ Pistol Grip Skin Stapler Reload 35	IIa	7	Skin Stapler/staple, non-bioabsorbable [35884]	8/4/1995	Current
059037	Multifire Premium™ Auto Suture™ Pistol Grip Skin Stapler 35W	IIa	7	Skin Stapler/staple, non-bioabsorbable [35884]	8/4/1995	Current
059038	Multifire Premium™ Auto Suture™ Pistol Grip Skin Stapler Reload 35W	IIa	7	Skin Stapler/staple, non-bioabsorbable	8/4/1995	Current

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USS-048

				[35884]		
060210	SFS™ Auto Suture™ Fascia Stapler 20W	I non-sterile	1	Surgical stapler, reusable [32369]	8/4/1995	Current
070614	DFS™ Auto Suture™ Fascia Stapler 20W	IIb	8	Open-surgery manual linear stapler, single use [59873	5/23/2019	Current
150462	Auto Suture™ Premium Extractor	I sterile	1	Surgical staple remover, single-use [47192	8/4/1995	Current
8886803512	Appose™ ULC Auto Suture™ Slim Body Skin Stapler 35	IIa	7	Skin Stapler/staple, non-bioabsorbable [35884]	2/16/2000	Current
886803712	Appose™ ULC Auto Suture™ Slim Body Skin Stapler 35W	IIa	7	Skin Stapler/staple, non-bioabsorbable [35884]	2/16/2000	Current

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Mary Mellows
Manager, Regulatory Affairs

Standards/Directives List

Standard/Directive	Year	Title
EN 556-1 + AC	2001 + 2006	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
EN ISO 11135-1	2007	Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11737-1 + AC	2006 + 2013	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
EN ISO 11137-1 + AC	2006 + 2013	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
EN ISO 11137-2	2013	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
EN ISO 11607-1 + A1	2010 + 2014	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2 + A1	2006 + 2014	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
ISO 15223-1	2012	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN ISO 13485 + AC	2012 + 2012	Medical devices. Quality management systems. Requirements for regulatory purposes.
EN ISO 14630	2012	Non-active surgical implants – General Requirements
EN 1041	2008	Information supplied by the manufacturer with medical devices.
EN ISO 14971	2012	Medical devices -- Application of risk management to medical devices.
EN ISO 17664	2004	Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices.
EN 62366	2014	Medical devices — Application of usability engineering to medical devices
ISO 14644-1	2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
ISO 14644-2	2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence or cleanroom performance related to air cleanliness by particle concentration

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Mary Mellows
Manager, Regulatory Affairs

ISO 14644-3	2005	Cleanrooms and associated controlled environments - Part 3: Test methods
EN ISO 10993-1 + AC	2009 + 2010	Biological evaluation of medical devices - Part 1: Evaluation and testing.
EN ISO 10993-3	2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-4	2009	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN ISO 10993-5	2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6	2009	Biological evaluation of medical devices Part 6: Tests for local effects after implantation
EN ISO 10993-7 + AC	2008 + 2009	Biological evaluation of medical devices. Part 7: Ethylene oxide sterilization residuals
ISO 10993-10 '	2010	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11	2009	Biological evaluation of medical devices Part 11: Tests for systemic toxicity

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Mary Mellows
Manager, Regulatory Affairs