COVIDIEN

Declaration of Conformity

USS-005

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:	**8/4/95 North Haven, CT U.S.A.**
Type of Devices:	**Nonabsorbable Suture**
Device Name:	**Surgipro™ and Surgipro™ II Monofilament Polypropylene**
Product Category(ies) listed on Current MDD certificates:	**Non-Active Implants, Nonabsorbable Polypropylene Suture, Surgipro™ and Surgipro™ II**
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 0081 Rev. 00 (expires 26-May-2024)**
EC Certificate #:	**G1 077608 0079 Rev 00 (expires 26-May-2024)**
Declaration 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)

REGULATORY AFFAIRS COVIDIEN NORTH HAVEN, CONNECTICUT U.S.A.

Mary Mellows
Manager, Regulatory Affairs

Revision Date: October 9, 2019

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Product Code	Description	Product Ranges Included/ How Supplied	GMDN	Class	Rule	Manufacturing Site
Various codes	Surgipro™ and Surgipro II™ are monofilament, nonabsorbable, polypropylene and polyethylene sutures, indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic and neurological surgery.	Suture Lengths within the following range 3-96 in. (8-240 cm), including reel lengths of up to 144 in./ 366 cm.	Polyolefin suture, monofilament 13909	III	8	North Haven, Dominican Republic
		Suture Diameters within the following range Surgipro™ (2 – 2/0, 6-0, 10-0 USP)(5-3, 0.7, 0.2 EP) Surgipro II™ (3/0 - 8/0 USP) (2 – 0.4 EP)				
		No needle attached or if needle attached see Needle Types below				
		Uncoated				
		With or without pledgets and with or without beads and collar components				
		Un-dyed and Dyed (Blue)				
		EtO Sterilized				
		Absorption: Permanent				
		Tensile Strength: Permanent				
		Packaging: Paper Retainer or NuPack Retainer				

Needle Types: 1.75, 3.10, 3.16, 3.20, 3.25, 3.35, 4.16, 4.19, 4.20, 4.21, 4.25, 4.30, 4.31,4.35, 4.41, 4.45, 4.50, 4.51, 5.65, 5.99, BGS-21, BGS-24, BGS-25, BGS-26, BGS-28, BGS-29, BGST-29, BP-9, BP-27, BPST-27, BTP-1, BTP-X, BTV-20, C-1, C-12, C-13, C-14, C-15, C-16, C-17, C-18, C-21, C-22, C-23, C-25, C-26, C-27, C-50, CS-5, CV, CV-1, CV-11, CV-13, CV-14, CV-15, CV-16, CV-17, CV-18, CV-19, CV-20, CV-22, CV-23, CV-25, CV-26, CV-47, CV-300,CV-301, CV-305, CV-307, CV-310, CV-316, CV-327, CV-330, CV-331, CV-337, CV-345, CV-351, CV-358, CV-370, CV-395, CVF, CVF-1, CVF-11, CVF-15, CVF- 21, CVF-22, CVF-23, CVH-1, CVH-11, CVL, CVL-1, CVL-11, DGE-6, DGE-10, DO-3, DTO-2, DX-11, DX-13, DX-16, DX-19, DXH-16, EGS-22, EKS, EST, GCC-90, GS-10, GS-11, GS-12, GS-13, GS-18, GS-20, GS- 21, GS-22, GS-23, GS-24, GS-25, GS-26, GS-27, GS-30, GS-34, GU-44, GU-45, GU-46, HBGS-21, HE-1, HE-2, HE-3, HE-5, HE-6, HE-7, HE-10, HGS-20, HGS-21, HGS-22, HGS-23, HGS-24, HGU-46, HOS-10, HOS-11, HOS-12, HOS-14, HOS-16, KS, KV-1, KV-5, KV-7, KV-8, KV-9, KV-11, KV-15, KV-16, KV-20, KV-25, KV-26, KV-30, KV-34, KV-37, KV-40, KV-56, KVF-1, KVF-5, KVF-11, KVF-15, MV-50-3, MV-70-3, MV-70-4, MV-100-3, MV-100-4, MV-135-3, MV- 135-4, MV-135-5, MV-175-6, MV-175-8, MV-175-9, MVF-135-5, MVF-175-8, MVF-175-9, MVK-100-4, MVK-70-3, P-10, P-11, P-12, P-13, P-14, P-15, P-16, P-17, P-18, P-21, P-22, P-24, PC-10, PC-11, PC-12, PC-13, PCS-11, SBE-1, SBE-2, SBE-3, SBE-4, SBE-6, SC, SC-1, SC-2, SC-4, SC-6, SC-10, SC-11, SC-250, SCC, SCC-1, SCC-5, SCE-4, SD-1, SE-22, SE-90-6, SE-100-8, SE-110-11, SE-140-6, SE-140-8, SE-140-9, SE-140-11, SE-160-4, SE-160-6, SE-160-8, SE-160-9, SE-175-6, SE-175-8, SE-CC-6, SK, SLO-110-11, SS-1, SS-2, SS-14, SS-22, SS-24, SS-28, SS-29, ST, ST-1, ST-2, ST-3, ST-4, T-37, TJ-32, TJ-40, V-20, V-26, V-30, VF-20, Y-5, Y-16, Y-31, YE-7, YV-95

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NORTH HAVEN, CONNECTICUT

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Manager, Regulatory Affairs

Standards List

Standard/Directive	Year	Type	Title
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
EN ISO 11135	2014	Sterility	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 11607-1 + A1	2009 + 2014	Sterility	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2 + A1	2006 + 2014	Sterility	Packaging for terminally sterilized medical devices- Part 2: Validation requirements for forming, sealing, and assembly processes.
EN ISO 11737-1 +AC	2006 + 2009	Sterility	Sterilization of Medical Devices- microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2	2009	Sterility	Sterilization of Medical Devices- Microbiological methods-- part 2: tests of sterility performed in definition, validation and maintenance of a sterilization process
EN ISO 15223-1	2016	Labeling	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
EN ISO 13485 + AC	2003 +2012	Quality Management	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 1041	2008	Manufacturer Information	Information supplied by the manufacturer of medical devices
IEC 62366	2015	Medical Devices	Medical Devices – Application of usability engineering to medical devices
EN ISO 14971	2012	Risk Management	Medical devices – Application of risk management to medical devices
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

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Standard/Directive	Year	Type	Title
EN ISO 10993-10	2013	Biological Evaluation	Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization
EN ISO 10993-11	2017	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 10993-17	2009	Biological Evaluation	Biological evaluation of medical devices -Part 17: Establishment of allowable limits for leachable substances
EN ISO 10993-18	2009	Biological Evaluation	Biological evaluation of medical devices -Part 18: Chemical characterization of materials
EN ISO 14630	2012	Medical Devices	Non-active surgical implants – General requirements
ISO 14644-1	2015	Sterility	Cleanrooms and associated controlled environments – Part 1: Classification or air elements
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
ISO 14644-3	2005	Sterility	Cleanrooms and associated controlled environments Part 3: Test methods

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