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 and Technology Park
Tullamore, Ireland

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

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Revision Date: October 13, 2020

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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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	2016	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

REGULATORY AFFAIRS COVIDIEN NORTH HAVEN, CONNECTICUT USA

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Standards List:

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

Relevant Guidance and Directives:

United States Pharmacopeial (USP) and National Formulary (NF) Monographs	2016	Sutures	Absorbable Surgical Suture <861> Sutures - Diameter <871> Sutures - Needle Attachment <881> Tensile Strength
European Pharmacopoeia (EP) 9.5	2018	Sutures	07/2018:0324 Sutures, Sterile, Non-Absorbable
MEDDEV 2.12/2	2012	Clinical	Post Market Clinical Follow-up Studies: A Guide for Manufacturers and Notified Bodies
MEDDEV 2.7/1 Rev 4	2016	Clinical	European Commission Guidelines for Medical Devices— Evaluation of Clinical Data

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