COVIDIEN

Declaration of Conformity

USS-004

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:	**Synthetic Braided and Monofilament Nonabsorbable Suture**
Device Name:	**Monosof™ and Dermalon™ Monofilament Nylon, and Surgilon™ Braided Nylon**
Product Category(ies) listed on Current MDD certificates:	**Non-Active Implants Nonabsorbable Suture, Monosof™, Dermalon™ and Surgilon™**
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 0082 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,
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Revision Date: March 23, 2020

Product Code	Indications	Product Ranges Included/ How Supplied/Specifications	GMDN	Class	Rule
Various codes	Monosof™ sutures are monofilament nylon nonabsorbable sutures, indicated for use in general soft tissue approximation and/or ligation. Monosof™ monofilament nylon sutures are also indicated for microsurgery.	Sutures lengths within the following range 3-96 in. (8-240 cm), including reel lengths of up to 144 in/366 cm	Nylon Suture, Monofilament 38000	III	8
		Suture Diameters within the following range (2 – 11/0 USP) (5 – 0.1 EP)			
		No needle attached or needle attached			
		Uncoated			
		With or without bolster and weight components			
		Undyed and Dyed (Black)			
		EtO or Gamma Sterilized			

Product Code	Indications	Product Ranges Included/ How Supplied/Specifications	GMDN	Class	Rule
Various codes	Dermalon™ sutures are monofilament nylon nonabsorbable sutures, indicated for use in general soft tissue approximation and/or ligation.	Sutures lengths within the following range 3-96 in. (8-240 cm), including reel lengths of up to 144 in/366 cm	Nylon Suture, Monofilament 38000	III	8
		Suture Diameters within the following range (2/0 – 6/0 USP) (3 – 0.7 EP)			
		No needle attached or needle attached			
		Uncoated			
		Dyed (Blue)			
		EtO or Gamma Sterilized			

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Product Code	Indications	Product Ranges Included/ How Supplied/Specifications	GMDN	Class	Rule
Various codes	Surgilon™ sutures are braided nylon nonabsorbable sutures, indicated for use in general soft tissue approximation and/or ligation.	Sutures lengths within the following range 3-96 in (8-240 cm), including reel lengths of up to 144 in/366 cm	Nylon Suture, Multifilament 37977	III	8
		Suture Diameters within the following range (3 – 5/0 USP) (6 – 1 EP)			
		No needle attached or needle attached			
		Coated (Silicone)			
		Undyed and Dyed (Black)			
		EtO or Gamma Sterilized			

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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 10993-10	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	2016	Labeling	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 1041 + A1	2008 + 2013	Manufacturer Information	Information supplied by the manufacturer with medical devices
EN 62366-1	2015	Medical Devices	Medical devices - Application of usability engineering to medical devices
EN ISO 13485 + AC	2016 + 2016	Quality Management	Medical devices - Quality management systems - Requirements for regulatory purposes
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" - Part 1: Requirements for terminally sterilized medical devices
EN ISO 11135	2014	Sterility	Sterilization of healthcare products - Ethylene oxide Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-1	2015	Sterility	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	2015	Sterility	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
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 a population of microorganisms on products

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EN ISO 11737-2	2009	Sterility	Sterilization of medical devices – Microbiological methods. Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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 of Air Cleanliness by Particle Concentration
ISO 14644-2	2015	Sterility	Cleanrooms and Associated Controlled Environments - Part 2: Monitoring to Provide Evidence of Cleanroom Performance Related to Air Cleanliness by Particle Concentration
ISO 14644-3	2005	Sterility	Cleanrooms and associated controlled environments Part 3: Test methods

List of Documents used for Guidance

USP Monograph – Absorbable / Nonabsorbable Surgical Suture	2008	Physical Test <861> Sutures - Diameter Physical Test <871> Sutures - Needle Attachment Physical Test <881> Tensile Strength
European Pharmacopeia (EP)	2008	01/2008:0324 Sutures, Sterile Non-absorbable

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