COVIDIEN

Declaration of Conformity

USS-144

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:	**7/10/2014 North Haven, CT U.S.A.**
Type of Devices:	**Synthetic Absorbable Knotless Suture**
Device Name:	**V-Loc 180™ and V-Loc™ 90 Absorbable Wound Closure Device, V-LOC™ PBT Nonabsorbable Wound Closure Device**
Product Category(ies) listed on Current MDD certificates:	**Non-Active Implants, Absorbable & NonAbsorbable Knotless Suture, V-Loc 180™ and V-Loc™ 90, V-LOC™ PBT**
MDD Classification/ Reorder Codes/GMDN Codes:	**See Attached**
Conformity Assessment:	**Directive 93/42/EEC on Medical Devices (MDD) For Class III: Annex II For Class IIb: Annex II excluding (4)**
Design Examination Certificate #:	**G7 077608 0063 Rev. 00 (expires 02-May-2024)**
EC Certificate #:	**G1 077608 0079 Rev 00 (expires 26-May-2024)**
Declaration of Conformity Valid Until:	**02-May-2024**
Standards Associated:	**See Attached**

REGULATORY AFFAIRS COVIDIEN NORTH HAVEN CONNECTICUT USA

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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Product Code	Description	Description part 2	GMDN	Class	Rule
VLOCMXXBC	V-Loc™ 90 absorbable wound closure device	XX – Needle Type (See below) B - Suture Length (15,23,30,45,60 cm) C -Suture Size(0,2-0,3-0,4-0)	Polyglyconate Suture; 17246	III	8
VLOCLXXBC	V-Loc™ 180 absorbable wound closure device	XX – Needle Type (See below) B - Suture Length (15,23,30,45,60 cm) C -Suture Size(0, 2-0,3-0,4-0)	Polydioxanone suture; 16584	III	8
VLOCNXXBC	V-Loc ™ PBT Non-Absorbable Wound Closure Device	XX – Needle Type (See below) B -Suture Length (15,23,30,45,60 cm) C -Suture Size(1,0,2-0,3-0)	Polybutester Suture; 17245	IIb	8

Needle Types: BTP-1, BTP- X, CV-15, CV-23, CV-25, GS-11, GS-21, GS-22, GS-25, GS-26, GU-46, HOS-11, HOS-12, P-11, P-12, P-13, P-14, P-17, SC, SC-1, SC-2, SK, TS-s, V-20, V-30

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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
ISO 10993-9	2009	Biological Evaluation	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products
ISO 10993-10	2013	Biological Evaluation	Biological evaluation of medical devices - Part 10: Tests 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
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	2008	Manufacturer Information	Information supplied by the manufacturer with medical devices
EN 62366	2015	Medical Devices	Medical devices - Application of usability engineering to medical devices
EN ISO 13485 + AC	2012 + 2012	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 11607-1 + AC	2009 + 2014	Sterility	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2 + AC	2006 + 2-14	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 the definition, validation and maintenance of a sterilization process

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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
USP Monograph-Absorbable/Nonabsorbable Surgical Suture	Current	Device Specific	<861> Diameter <871> Needle Attachment <881> Tensile Strength
European Pharmacopeia	2017	Device Specific	01/2008:0666 Suture, Sterile, Synthetic, Absorbable, Monofilament

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