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**

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)

Revision Date: December 4, 2020

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Product Code	Description	Description – Part 2	GMDN	Class / Rule	Status
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)	60480; Barbed polyester suture, non-antimicrobial	Class III / Rule 8	Current
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)	60480; Barbed polyester suture, non-antimicrobial	Class III / Rule 8	Current
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)	17245; Polybutester Suture	Class IIb / Rule 8	Current
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-3, 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	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

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Standards List

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
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

List of Documents/Guidance Used for Guidance

Standard/Directive Year Title	Year	Title
MEDDEV 2.7.1	2016	European Commission Guidelines for Medical Devices – Evaluation of Clinical Data
European Pharmacopeia	2017	1/2008; 0324 Sutures, Sterile Non-Absorbable

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Addendum to Declaration of Conformity

Covidien llc declares that the Medical Device(s) specified in Appendix A comply with Article 120 of the Regulation (EU) 2017/745 (MDR) as amended by Regulation (EU) 2023/607 and 93/42/EEC (MDD).

This addendum to the Declaration(s) of Conformity is supported by the EC Certificate according to the provisions of the relevant Annex(es) of 93/42/EEC (MDD), and the evidence of compliance to the conditions presented under Article 1 Paragraph 3c of the amended Regulation (EU) 2023/607.

The Medical Device(s) specified in Appendix A:

- o Continue to comply with 93/42/EEC (MDD);
- o Do not have any significant changes in design or intended purpose since 26 May 2021; and
- o Do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health
- • Covidien has a quality management system compliant with Article 10(9) of Regulation (EU) 2017/745 (MDR).
- • Covidien has submitted a formal application in accordance with Section 4.3, first subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) for conformity assessment and a signed agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) before the expiry date of the listed certificate for the Medical Device(s) specified under Appendix A.
- • Post market surveillance, market surveillance, vigilance, registration of economic operators and of devices in accordance with Regulation (EU) 2017/745 (MDR) is in place for the device (s) listed Medical Device(s) specified under Appendix A.

Signature, Date of Issue:

Name: Wing Ng Title: Sr Director Regulatory Affairs, AST

Signature: Date: Sep 21, 2023

Name: Nancy Sauer Title: Sr Director Regulatory Affairs, GST

Signature Date: Sep 21, 2023