Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 077608 0079 Rev. 00

Manufacturer:

Covidien llc
15 Hampshire Street
Mansfield, MA 02048
USA

Product Category(ies):

Medical Instruments, Surgical Products and Hemostatic Materials:
- **Surgical Suture Products, Pledgets and Retention Tapes**
- **Endoscopy Instruments and Accessories including Lubricant**
- **Surgical Staple, Clip Products and Accessories**
- **Manual Surgical Instruments**
- **Implantable Wound Dressing Materials**
- **Ultrasonic Surgical Devices and Accessories**
- **Suction / Irrigation Devices and Accessories**
- **Arthroscopy Implants, Instruments and Accessories**
- **Bone Wax**
- **Temporary Cardiac Pacing Lead**
- **Powered Stapling Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713164286

Valid from: 2019-09-13
Valid until: 2024-05-26

Date, 2019-09-13

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 077608 0079 Rev. 00

Facility(ies):

Covidien llc
15 Hampshire Street,
Mansfield, MA 02048, USA

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV®

COVIDIEN

Declaration of Conformity

USS-033C

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 Class 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:	09/18/2012 North Haven, CT
Type of Devices:	Surgical Staplers and Single Use Loading Units
Device Name:	Endo GIA™ Surgical Stapling Single Use Loading Units, Tri-Staple™ 2.0 Intelligent Reloads and Cartridges
Product Category(ies) Listed on Current MDD Certificate:	Surgical Staple, Clip Products and Accessories
MDD Classification/Reorder Codes/GMDN Codes:	See Attached
Conformity Assessment:	Directive 93/42/EEC on Medical Devices (MDD), Annex II
Design Examination Certificate #: EC Certificate:	G7 077608 0050 Rev. 03 (expires 26-May-2024) G1 077608 0079 Rev. 00 (expires 26-May-2024)
Certificate 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

REGULATORY AFFAIRS COVIDIEN NORTH HAVEN, CONNECTICUT USA

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

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Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration M/D/YYYY*	*Reorder Code Status*
EGIA30AMT	Endo GIA™ Articulating Reload with Tri-Staple™ Technology 30mm Medium/Thick	III	8	Surgical staple, non-biodegradable [35615]	9/27/2011	Current
EGIA30AV	Endo GIA™ Gray Articulating Reload 30mm Extra Thin/Vascular	III	8	Surgical staple, non-biodegradable [35615]	12/22/2015	Current
EGIA30AVM	Endo GIA™ Articulating Reload with Tri-Staple™ Technology 30mm Vascular/Medium	III	8	Surgical staple, non-biodegradable [35615]	9/27/2011	Current
EGIA30CTAV	Endo GIA™ Gray Curved Tip Articulating Reload 30mm Extra Thin/Vascular	III	8	Surgical staple, non-biodegradable [35615]	12/22/2015	Current
EGIA30CTAVM	Endo GIA™ Curved Tip Articulating Reload with Tri-Staple™ Technology 30mm Vascular/Medium	III	8	Surgical staple, non-biodegradable [35615]	9/27/2011	Current
EGIA45AMT	Endo GIA™ Articulating Reload with Tri-Staple™ Technology 45mm Medium/Thick	III	8	Surgical staple, non-biodegradable [35615]	3/15/2010	Current
EGIA45AV	Endo GIA™ Gray Articulating Reload 45mm Extra Thin/Vascular	III	8	Surgical staple, non-biodegradable [35615]	9/27/2011	Current
EGIA45AVM	Endo GIA™ Articulating Reload with Tri-Staple™ Technology 45mm Vascular/Medium	III	8	Surgical staple, non-biodegradable [35615]	3/15/2010	Current
EGIA45AXT	Endo GIA™ Black Articulating Reload with Tri-Staple™ Technology 45mm Extra Thick	III	8	Surgical staple, non-biodegradable [35615]	11/18/2010	Current
EGIA45CTAMT	Endo GIA™ Single Use Curved Tip Articulating Medium/Thick Reload with Tri-Staple™ Technology (45mm Medium/Thick)	III	8	Surgical staple, non-biodegradable [35615]	6/11/2012	Current
EGIA45CTAV	Endo GIA™ Gray Curved Tip Articulating Reload 45mm Extra Thin/Vascular	III	8	Surgical staple, non-biodegradable [35615]	9/27/2011	Current

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Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration M/D/YYYY*	*Reorder Code Status*
EGIA45CTAVM	Endo GIA™ Curved Tip Articulating Reload with Tri-Staple™ Technology 45mm Vascular/Medium	III	8	Surgical staple, non-biodegradable [35615]	11/18/2010	Current
EGIA60AMT	Endo GIA™ Articulating Reload with Tri-Staple™ Technology 60mm Medium/Thick	III	8	Surgical staple, non-biodegradable [35615]	3/15/2010	Current
EGIA60AVM	Endo GIA™ Articulating Reload with Tri-Staple™ Technology 60mm Vascular/Medium	III	8	Surgical staple, non-biodegradable [35615]	3/15/2010	Current
EGIA60AXT	Endo GIA™ Black Articulating Reload with Tri-Staple™ Technology 60mm Extra Thick	III	8	Surgical staple, non-biodegradable [35615]	11/18/2010	Current
EGIA60CTAMT	Endo GIA™ Curved Tip Articulating Reload with Tri-Staple™ Technology 60mm Medium/Thick	III	8	Surgical staple, non-biodegradable [35615]	11/18/2010	Current
EGIA60CTAVM	Endo GIA™ Curved Tip Articulating Reload with Tri-Staple™ Technology 60mm Vascular/Medium	III	8	Surgical staple, non-biodegradable [35615]	11/18/2010	Current
EGIATRS45AMT	Endo GIA™ Reinforced Medium/Thick Reload with Tri-Staple™ Technology, Pre-Loaded with Polyglycolic Acid (PGA) Reinforcement Material (45 mm Medium/Thick)	III	8	Surgical staple, non-biodegradable [35615]	6/3/2014	Current
EGIATRS45AXT	Endo GIA™ Reinforced Extra Thick Reload with Tri-Staple™ Technology, Pre-Loaded with Polyglycolic Acid (PGA) Reinforcement Material (45 mm Extra Thick)	III	8	Surgical staple, non-biodegradable [35615]	6/3/2014	Current
EGIATRS60AMT	Endo GIA™ Reinforced Medium/Thick Reload with Tri-Staple™ Technology, Pre-Loaded with Polyglycolic Acid (PGA) Reinforcement Material (60 mm Medium/Thick)	III	8	Surgical staple, non-biodegradable [35615]	6/3/2014	Current

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Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration M/D/YYYY*	*Reorder Code Status*
EGIATRS60AXT	Endo GIA™ Reinforced Extra Thick Reload with Tri-Staple™ Technology, Pre-Loaded with Polyglycolic Acid (PGA) Reinforcement Material (60 mm Extra Thick)	III	8	Surgical staple, non-biodegradable [35615]	6/3/2014	Current
SIG30AMT	Tri-Staple™ 2.0 Intelligent Reload 30mm Medium/Thick	III	8	Surgical staple, non-biodegradable [35615]	2/28/2017	Current
SIG30AV	Tri-Staple™ 2.0 Gray Intelligent Reload 30mm Extra Thin/Vascular	III	8	Surgical staple, non-biodegradable [35615]	2/28/2017	Current
SIG30AVM	Tri-Staple™ 2.0 Intelligent Reload 30mm Vascular/Medium	III	8	Surgical staple, non-biodegradable [35615]	2/28/2017	Current
SIG30CTAV	Tri-Staple™ 2.0 Gray Curved Tip Intelligent Reload and Introducer 30mm Extra Thin/Vascular	III	8	Surgical staple, non-biodegradable [35615]	2/28/2017	Current
SIG30CTAVM	Tri-Staple™ 2.0 Curved Tip Intelligent Reload and Introducer 30mm Vascular/Medium	III	8	Surgical staple, non-biodegradable [35615]	2/28/2017	Current
SIG45AXT	Tri-Staple™ 2.0 Black Intelligent Reload 45mm Extra Thick	III	8	Surgical staple, non-biodegradable [35615]	2/28/2017	Current
SIG45CTAMT	Tri-Staple™ 2.0 Curved Tip Intelligent Reload and Introducer 45mm Medium/Thick	III	8	Surgical staple, non-biodegradable [35615]	2/28/2017	Current
SIG45CTAV	Tri-Staple™ 2.0 Gray Curved Tip Intelligent Reload and Introducer 45mm Extra Thin/Vascular	III	8	Surgical staple, non-biodegradable [35615]	2/28/2017	Current
SIG45CTAVM	Tri-Staple™ 2.0 Curved Tip Intelligent Reload and Introducer 45mm Vascular/Medium	III	8	Surgical staple, non-biodegradable [35615]	2/28/2017	Current

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Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration M/D/YYYY*	*Reorder Code Status*
SIG60AXT	Tri-Staple™ 2.0 Black Intelligent Reload 60mm Extra Thick	III	8	Surgical staple, non-biodegradable [35615]	2/28/2017	Current
SIG60CTAMT	Tri-Staple™ 2.0 Curved Tip Intelligent Reload and Introducer 60mm Medium/Thick	III	8	Surgical staple, non-biodegradable [35615]	2/28/2017	Current
SIG60CTAVM	Tri-Staple™ 2.0 Curved Tip Intelligent Reload and Introducer 60mm Vascular/Medium	III	8	Surgical staple, non-biodegradable [35615]	2/28/2017	Current
SIGC45MT	Tri-Staple™ 2.0 Intelligent Cartridge 45mm Medium/Thick	III	8	Surgical staple, non-biodegradable [35615]	9/27/2017	Current
SIGC45VM	Tri-Staple™ 2.0 Intelligent Cartridge 45mm Vascular/Medium	III	8	Surgical staple, non-biodegradable [35615]	9/27/2017	Current
SIGC60MT	Tri-Staple™ 2.0 Intelligent Cartridge 60mm Medium/Thick	III	8	Surgical staple, non-biodegradable [35615]	9/27/2017	Current
SIGC60VM	Tri-Staple™ 2.0 Intelligent Cartridge 45mm Vascular/Medium	III	8	Surgical staple, non-biodegradable [35615]	9/27/2017	Current
SIGTRS45AMT	Tri-Staple™ 2.0 Reinforced Intelligent Reload 45mm Medium/Thick	III	8	Surgical staple, non-biodegradable [35615]	2/28/2017	Current
SIGTRS45AXT	Tri-Staple™ 2.0 Black Reinforced Intelligent Reload 45mm Extra Thick	III	8	Surgical staple, non-biodegradable [35615]	2/28/2017	Current
SIGTRS60AMT	Tri-Staple™ 2.0 Reinforced Intelligent Reload 60mm Medium/Thick	III	8	Surgical staple, non-biodegradable [35615]	2/28/2017	Current
SIGTRS60AXT	Tri-Staple™ 2.0 Black Reinforced Intelligent Reload 60mm Extra Thick	III	8	Surgical staple, non-biodegradable [35615]	6/3/2014	Current

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Declaration of Conformity

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Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration M/D/YYYY*	*Reorder Code Status*
SIGTRSB45AMT	Tri-Staple™ 2.0 Reinforced Intelligent Reload 45mm Medium/Thick	III	8	Surgical staple, non-biodegradable [35615]	3/31/2020	Current
SIGTRSB45AXT	Tri-Staple™ 2.0 Black Reinforced Intelligent Reload 45mm Extra Thick	III	8	Surgical staple, non-biodegradable [35615]	3/31/2020	Current
SIGTRSB60AMT	Tri-Staple™ 2.0 Reinforced Intelligent Reload 60mm Medium Thick	III	8	Surgical staple, non-biodegradable [35615]	3/31/2020	Current
SIGTRSB60AXT	Tri-Staple™ 2.0 Black Reinforced Intelligent Reload 60mm Extra Thick	III	8	Surgical staple, non-biodegradable [35615]	3/31/2020	Current
SIGSDS30CTV	Signia™ Small Diameter Curved Tip Intelligent Reload 30 mm Vascular 8 mm - Short	III	8	Surgical staple, non-biodegradable [35615]	9/23/2020	Current
SIGSDS30CTVT	Signia™ Small Diameter Curved Tip Intelligent Reload 30 mm Vascular/Thin 8 mm - Short	III	8	Surgical staple, non-biodegradable [35615]	9/23/2020	Current
SIGSDL45CTVT	Signia™ Small Diameter Curved Tip Intelligent Reload 45 mm Vascular/Thin 8 mm - Long	III	8	Surgical staple, non-biodegradable [35615]	9/23/2020	Current

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Standards List

Standard	Year	Title
EN 556-1 + AC	2001 + 2006	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
EN 1041	2008	Information supplied by the manufacturer with medical devices.
ISO 10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3	2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
ISO 10993-4	2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-6	2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
EN ISO 10993-7 + AC	2008 + 2009	Biological evaluation of Medical Devices: Part 7 - Ethylene Oxide Sterilization Residuals
ISO 10993-10	2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11	2009	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 11135	2014	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11607-1	2019	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2	2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing, and assembly processes.
ISO 11737-1	2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
EN ISO 11737-2	2013	Sterilization of medical devices - Microbiological methods - Part 2: Test of sterility performed in the definition, validation and maintenance of a sterilization process.
EN ISO 13485	2016	Medical devices - Quality management systems. Requirements for regulatory purposes. (ISO 13485:2003)
EN ISO 14630	2012	Non-active surgical implants – General Requirements

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Standard	Year	Title
ISO 14644-1	2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
ISO 14644-2	2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence or cleanroom performance related to air cleanliness by particle concentration
ISO 14644-3	2005	Cleanrooms and associated controlled environments - Part 3: Test methods
EN ISO 14971	2012	Medical devices - Application of risk management to medical devices. (ISO 14971:2007, corrected version 2007-10-01)
ISO 15223-1	2012	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
IEC 62366	2015	Medical devices - Application of usability engineering to medical devices
IEC 60601-1 + A1	2005 + 2012	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	2014	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral standard: Electromagnetic disturbances – Requirements and tests

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SOCIETATE COMERCIALA REPUBLICA MOLDOVA MUN. CHISINAU SRL OXIVIT-MED

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Declaration of Conformity

USS-033A

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:	04/16/1996 North Haven, CT
Type of Devices:	Surgical Staplers and Single Use Loading Units
Device Name:	ILA™/GIA™ Surgical Staplers and Single Use Loading Units
Product Category(ies) Listed on Current MDD Certificate:	Surgical Staple, Clip Products and Accessories
MDD Classification/Reorder Codes/GMDN Codes:	See Attached
Conformity Assessment:	Directive 93/42/EEC on Medical Devices (MDD), Annex II
Design Examination Certificate #: EC Certificate:	G7 077608 0040 Rev. 01 (expires 26-May-2024) G1 077608 0079 Rev 00 (expires 26-May-2024)
Certificate 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)

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1007600044288

Revision Date: July 14, 2020

COVIDIEN

Declaration of Conformity

USS - 033A

Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration M/D/YYYY*	*Reorder Code Status*
030424L	GIA Premium™ Auto Suture™ Loading Unit 50mm - 3.8mm	III	8	Surgical staple, non-biodegradable [35615]	8/9/2004	Current
030735L	GIA™ Premium Auto Suture™ Loading Unit 90mm - 3.8mm	III	8	Surgical staple, non-biodegradable [35615]	8/9/2004	Inactive 4/25/2020
3948L	ILA™ Auto Suture™ Loading Unit 52mm - 3.8mm	III	8	Surgical staple, non-biodegradable [35615]	4/16/1996	Obsolete 2/13/2020
3971	ILA™ Auto Suture™ Loading Unit 100mm - 3.8mm	III	8	Surgical staple, non-biodegradable [35615]	1/24/1997	Obsolete 2/13/2020
3972	ILAN™ Auto Suture™ Knifeless Loading Unit 100mm - 3.8mm	III	8	Surgical staple, non-biodegradable [35615]	1/24/1997	Obsolete 2/13/2020
3973	ILA™ Auto Suture™ Loading Unit 100mm - 4.8mm	III	8	Surgical staple, non-biodegradable [35615]	1/24/1997	Obsolete 2/13/2020
GIA10038L	GIA™ Auto Suture™ Loading Unit with DST Series™ Technology 100mm- 3.8mm	III	8	Surgical staple, non-biodegradable [35615]	6/30/2005	Current
GIA10038S	GIA™ Auto Suture™ Stapler with DST Series™ Technology 100mm - 3.8mm	III	8	Open-surgery manual linear cutting stapler, single-use [59870]	6/30/2005	Current
GIA10048L	GIA™ Auto Suture™ Loading Unit with DST Series™ Technology 100mm - 4.8mm	III	8	Surgical staple, non-biodegradable [35615]	6/30/2005	Current
GIA10048S	GIA™ Auto Suture™ Stapler with DST Series™ Technology 100mm - 4.8mm	III	8	Open-surgery manual linear cutting stapler, single-use [59870]	6/30/2005	Current
GIA6025L	GIA™ Auto Suture™ Loading Unit with DST Series™ Technology 60mm - 2.5mm	III	8	Surgical staple, non-biodegradable [35615]	12/7/2004	Current
GIA6025S	GIA™ Auto Suture™ Stapler with DST Series™ Technology 60mm - 2.5mm	III	8	Open-surgery manual linear cutting stapler, single-use [59870]	12/7/2004	Current

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Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration M/D/YYYY*	*Reorder Code Status*
GIA6038L	GIA™ Auto Suture™ Loading Unit with DST Series™ Technology 60mm - 3.8mm	III	8	Surgical staple, non-biodegradable [35615]	8/9/2004	Current
GIA6038S	GIA™ Auto Suture™ Stapler with DST Series™ Technology 60mm - 3.8mm	III	8	Open-surgery manual linear cutting stapler, single-use [59870]	8/9/2004	Current
GIA6048L	GIA™ Auto Suture™ Loading Unit with DST Series™ Technology 60mm - 4.8mm	III	8	Surgical staple, non-biodegradable [35615]	8/9/2004	Current
GIA6048S	GIA™ Auto Suture™ Stapler with DST Series™ Technology 60mm - 4.8mm	III	8	Open-surgery manual linear cutting stapler, single-use [59870]	8/9/2004	Current
GIA8038L	GIA™ Auto Suture™ Loading Unit with DST Series™ Technology 80mm - 3.8mm	III	8	Surgical staple, non-biodegradable [35615]	8/9/2004	Current
GIA8038S	GIA™ Auto Suture™ Stapler with DST Series™ Technology 80mm - 3.8mm	III	8	Open-surgery manual linear cutting stapler, single-use [59870]	8/9/2004	Current
GIA8048L	GIA™ Auto Suture™ Loading Unit with DST Series™ Technology 80mm - 4.8mm	III	8	Surgical staple, non-biodegradable [35615]	8/9/2004	Current
GIA8048S	GIA™ Auto Suture™ Stapler with DST Series™ Technology 80mm - 4.8mm	III	8	Open-surgery manual linear cutting stapler, single-use [59870]	8/9/2004	Current
SGIA6038S	SGIA™ Auto Suture™ Knifeless Stapler with DST Series™ Technology 60mm - 3.8mm	III	8	Open-surgery manual linear cutting stapler, single-use [59870]	10/26/2005	Inactive 4/25/2020

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Declaration of Conformity
USS-033A

Standards List:

Standard	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 (identical to ISO 10993-11:2017)
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 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 - Requirements for the development, validation and routine control of a sterilization process for medical devices
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 11607-1	2017	Sterility	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems

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MANSFIELD, CONNECTICUT USA

Angela Van Arsdale
Sr. Manager, Regulatory Affairs

S.R.L. OXIVIT-MED 1007600044280

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Declaration of Conformity
USS-033A

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
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
IEC 62366-1	2015	Medical Devices	Medical devices – Application of usability engineering to medical devices

Guidance Document List

Standard	Year	Type	Title
MEDDEV2.7.1 Rev 4	2016	Medical Devices	GUIDELINES ON MEDICAL DEVICES - Clinical Evaluation: A Guide For Manufacturers And Notified Bodies Under Directives 93/42/EEC And 90/385/EEC

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USS-034

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:	04/16/1996 North Haven, CT
Type of Devices:	Surgical Staplers and Single Use Loading Units
Device Name:	PI™ and TA™ Staplers
Product Category(ies) Listed on Current MDD Certificate:	Surgical Staple, Clip Products and Accessories
MDD Classification/Reorder Codes/GMDN Codes:	See Attached
Conformity Assessment:	Directive 93/42/EEC on Medical Devices (MDD), Annex II
Design Examination Certificate #: EC Certificate:	G7 077608 0074 Rev 00 (expires 26-May 2024) G1 077608 0079 Rev 00 (expires 26-May-2024)
Certificate of Conformity Valid Until:	23-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)

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Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration M/D/YYYY*	*Reorder Code Status*
010315	Premium Multifire TA™ Auto Suture™ Single Use Vascular Stapler (30mm - V3)	III	8	Open-surgery manual linear stapler, single-use [59873]	4/1/2004	Inactive Dec 2019
010316L	Premium Multifire TA™ Auto Suture™ Vascular Loading Unit 30mm-V3	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Inactive Dec 2019
015477L	TA Premium™ Auto Suture™ Loading Unit 90mm - 3.5mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Inactive Dec 2019
015888L	TA Premium TM Auto Suture TM Loading Unit 90mm - 4.8mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Inactive May 2020
010911L	Multifire Endo TA™ Auto Suture™ Loading Unit 30mm - 2.5mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Current
015458L	TA Premium™ Auto Suture™ Single Use Loading Unit for use with TA Premium™ Reusable Stapler (55mm - 4.8mm)	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Inactive Dec 2019
015427L	TA Premium™ Auto Suture™ Loading Unit 30mm - 3.5mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Inactive Dec 2019
015433L	TA Premium™ Auto Suture™ Loading Unit 30mm - 4.8mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Inactive Dec 2019
015441L	TA Premium™ Auto Suture™ Vascular Loading Unit 30mm - V3	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Inactive Dec 2019
015451L	TA Premium™ Auto Suture™ Loading Unit 55mm - 3.5mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Inactive Dec 2019
010901	Multifire Endo TA™ Auto Suture™ Loading Unit 30mm - 2.5mm 12mm Stapler	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Inactive Dec 2019

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Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration M/D/YYYY*	*Reorder Code Status*
015485L	TA Premium™ Auto Suture™ Loading Unit 90mm - 4.8mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Inactive Dec 2019
017612	Roticulator™ Auto Suture™ Articulating Stapler 55mm - 3.5mm	III	8	Open surgery manual linear stapler, single use [59873]	4/1/2004	Inactive Dec 2019
017614	Roticulator™ Auto Suture™ Articulating Stapler 55mm - 4.8mm	III	8	Open surgery manual linear stapler, single use [59873]	4/1/2004	Inactive Dec 2019
017615	Roticulator™ Auto Suture™ Articulating Stapler 30mm - 3.5mm	III	8	Open surgery manual linear stapler, single use [59873]	4/1/2004	Inactive Dec 2019
017617	Roticulator™ Auto Suture™ Articulating Stapler 30mm - 4.8mm	III	8	Open surgery manual linear stapler, single use [59873]	4/1/2004	Inactive Dec 2019
017619	Roticulator™ Auto Suture™ Articulating Vascular Stapler 30mm - V3	III	8	Open surgery manual linear stapler, single use [59873]	4/1/2004	Inactive Dec 2019
3922L	PI™ Auto Suture™ Vascular Loading Unit 15mm - V3	III	8	Surgical staple, non-bioabsorbable [35615]	6/1/2005	Inactive Dec 2019
3923L	PI™ Auto Suture™ Loading Unit 30mm - 3.5mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/16/1996	Inactive Dec 2019
3924L	PI™ Auto Suture™ Loading Unit 30mm - 4.8mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/16/1996	Inactive Dec 2019
3925L	PI™ Auto Suture™ Loading Unit 30mm - V3	III	8	Surgical staple, non-bioabsorbable [35615]	4/16/1996	Inactive Dec 2019
3926L	PI™ Auto Suture™ Loading Unit 55mm - 3.5mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/16/1996	Inactive Dec 2019
3927L	PI™ Auto Suture™ Loading Unit 55mm - 4.8mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Inactive Dec 2019

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3929L	PI™ Auto Suture™ Loading Unit 90mm - 3.5mm	III	8	Surgical staple, non-bioabsorbable [35615]	12/30/2003	Inactive Dec 2019
3930A	PI™ Auto Suture™ Loading Unit 90mm - 4.8mm	III	8	Surgical staple, non-bioabsorbable [35615]	1/24/2011	Inactive Dec 2019
4900T	PI™ Stapler 30mm - 3.5mm	III	8	Open surgery manual linear stapler, single use [59873]	4/16/1996	Inactive Dec 2019
4901T	PI™ Stapler 30mm - 4.8mm	III	8	Open surgery manual linear stapler, single use [59873]	4/16/1996	Inactive Dec 2019
4907T	PI™ Auto Suture™ Loading Unit 30mm - 3.5mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/16/1996	Inactive Dec 2019
4908T	PI™ Auto Suture™ Loading Unit 30mm - 4.8mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/16/1996	Inactive Dec 2019
TA3035L	TA™ Auto Suture™ Loading Unit with DST Series™ Technology 30mm - 3.5mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Current
TA3035S	TA™ Auto Suture™ Stapler with DST Series™ Technology 30mm - 3.5mm	III	8	Open surgery manual linear stapler, single use [59873]	4/1/2004	Current
TA3048L	TA™ Auto Suture™ Loading Unit with DST Series™ Technology 30mm - 4.8mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Current
TA3048S	TA™ Auto Suture™ Stapler with DST Series™ Technology 30mm - 4.8mm	III	8	Open surgery manual linear stapler, single use [59873]	4/1/2004	Current
TA30V3L	TA™ Auto Suture™ Vascular Loading Unit with DST Series™ Technology 30mm - V3	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Current
TA30V3S	TA™ Auto Suture™ Vascular Stapler with DST Series™ Technology 30mm - V3	III	8	Open surgery manual linear stapler, single use [59873]	4/1/2004	Current

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Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration M/D/YYYY*	*Reorder Code Status*
TA4535L	TA™ Auto Suture™ Loading Unit with DST Series™ Technology 45mm - 3.5mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Current
TA4535S	TA™ Auto Suture™ Stapler with DST Series™ Technology 45mm - 3.5mm	III	8	Open surgery manual linear stapler, single use [59873]	4/1/2004	Current
TA4548L	TA™ Auto Suture™ Loading Unit with DST Series™ Technology 45mm - 4.8mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Current
TA4548S	TA™ Auto Suture™ Stapler with DST Series™ Technology 45mm - 4.8mm	III	8	Open surgery manual linear stapler, single use [59873]	4/1/2004	Current
TA6035L	TA™ Auto Suture™ Loading Unit with DST Series™ Technology 60mm - 3.5mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Current
TA6035S	TA™ Auto Suture™ Stapler with DST Series™ Technology 60mm - 3.5mm	III	8	Open surgery manual linear stapler, single use [59873]	4/1/2004	Current
TA6048L	TA™ Auto Suture™ Loading Unit with DST Series™ Technology 60mm - 4.8mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Current
TA6048S	TA™ Auto Suture™ Stapler with DST Series™ Technology 60mm - 4.8mm	III	8	Open surgery manual linear stapler, single use [59873]	4/1/2004	Current
TA9035L	TA™ Auto Suture™ Loading Unit with DST Series™ Technology 90mm - 3.5mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Current
TA9035S	TA™ Auto Suture™ Stapler with DST Series™ Technology 90mm - 3.5mm	III	8	Open surgery manual linear stapler, single use [59873]	4/1/2004	Current
TA9048L	TA™ Auto Suture™ Loading Unit with DST Series™ Technology 90mm - 4.8mm	III	8	Surgical staple, non-bioabsorbable [35615]	4/1/2004	Current

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Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration M/D/YYYY*	*Reorder Code Status*
TA9048S	TA™ Auto Suture™ Stapler with DST Series™ Technology 90mm - 4.8mm	III	8	Open surgery manual linear stapler, single use [59873]	4/1/2004	Current

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Standards/Directives List

Standard/Directive	Year	Title
EN 556-1	2001 + 2006	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
EN ISO 11135	2014	Sterilization of health care products — Ethylene oxide — Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11737-1	2006 + 2013	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
EN ISO 11737-2	2009	Sterilization of medical devices - Microbiological methods - Part 2: Test of sterility performed in the definition, validation and maintenance of a sterilization process.
EN ISO 11137-1	2015	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	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
EN ISO 11607-1	2017	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2	2017	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN ISO 13485	2016 + 2016	Medical devices. Quality management systems. Requirements for regulatory purposes.
EN ISO 14630	2012	Non-active surgical implants – General Requirements
EN 1041	2008 + 2013	Information supplied by the manufacturer with medical devices.
EN ISO 14971	2012	Medical devices -- Application of risk management to medical devices.

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EN 62366	2015	Medical devices — Application of usability engineering to medical devices
ISO 14644-1	2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
ISO 14644-2	2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence or cleanroom performance related to air cleanliness by particle concentration
ISO 14644-3	2005	Cleanrooms and associated controlled environments - Part 3: Test methods
EN ISO 10993-1	2009 + 2010	Biological evaluation of medical devices - Part 1: Evaluation and testing.
EN ISO 10993-3	2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-4	2009	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN ISO 10993-5	2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6	2009	Biological evaluation of medical devices Part 6: Tests for local effects after implantation
EN ISO 10993-7	2008 + 2009	Biological evaluation of medical devices. Part 7: Ethylene oxide sterilization residuals
ISO 10993-10	2010	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11	2009	Biological evaluation of medical devices Part 11: Tests for systemic toxicity
EN ISO 10993-12	2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

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