ORDIN DE PLATA NR.: 183 TIP.DOC. 1

DATA EMITERII:miercuri, 27 decem

PLATITI: 20000-00 LEI: Douazeci Mii lei 00 bani

PLATITOR: (R) S.C. "OXIVIT-MED" S.R.L.
CONTUL DE PLATI/CODUL IBAN
MD44ML000000002251729503
CODUL FISCAL :1007600044280 /

PRESTATORUL PLATITOR
BC"Moldindconbank"S.A. fil."Invest" Chisinau
CODUL BANCII:
:MOLDMD2X329:

BENEFICIAR (R) I.M.S.P. "Spitalul Clinic Republican Timofei Mosneaga"
CONTUL DE PLATI/CODUL IBAN
MD57MO2251ASV96476607100
CODUL FISCAL :1003600150783 /

PRESTATORUL BENEFICIAR
Mobiasbanca-OTP Group S.A.
CODUL BANCII:
:MOBBMD22 :

DESTINATIA PLATII:Pentru garantia pentru oferta la procedura de achizi?ie publica nr. ocds-b3wdp1-MD-1700575543949 din 27.12.2023

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:
DATA PRIMIRII:27/12/2023
DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Kojevnikov Dmitrii

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(semnatura electronica)

CONTABIL-SEF:Web Kojevnikov Dmitrii

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L.S. (semnatura electronica)

CONDUCATOR: _____ (semnatura manuala)

CONTABIL-SEF: _____ (semnatura manuala)

SEMNATURA PRESTATORUL L.S.

MOTIVUL REFUZULUI L.S.

Digitally signed by Kojevnikov Dmitrii
Date: 2023.12.26 17:13:06 EET
Reason: MoldSign Signature
Location: Moldova

MOBIAS BANCA

Nr. 12101-304

18.03.2016

CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **BC „Mobiasbancă – Groupe Societe Generale" S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **OXIVIT-MED SRL**, cod fiscal (IDNO) **1007600044280,** deține următoarele conturi curente la BC "Mobiasbancă-Groupe Societe Generale" S.A., Filiala. 1 Stejaur :

1. **MDL - 2224710SV23488147100; IBAN- MD09MO2224ASV23488147100**
2. **EUR - 2224710SV22227957100; IBAN- MD17MO2224ASV22227957100**
3. **USD - 2224710SV22214937100; IBAN- MD86MO2224ASV22214937100**

Certificatul este emis în baza cererii întreprinderii: Oxivit-Med SRL.

L.Ș.

Dumitru Popa
Director filială „Stejaur"

Executor : Mariana Guzun
Tel: 022 812 614

Filiala Nr. 1 „Stejaur"
Bd. Ştefan cel Mare şi Sfânt 196
MD-2004, Chişinău, Moldova
Cod MOBBMD22
Cont de corespondenţă 35213892
la Centrul de Decontări al BNM

Tel. +373 22 81 26 15
Fax. +373 22 81 26 15
www.mobiasbanca.md

BC „Mobiasbancă – Groupe Société Générale" SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 1002600006089
Sediul Central:
bd. Ştefan cel Mare şi Sfânt 81a
MD-2012, Chişinău, Moldova

GROUPE SOCIETE GENERALE

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea Comercială "OXIVIT-MED" S.R.L.

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal

1007600044280

Data înregistrării **30.07.2007**

Data eliberării **30.07.2007**

Bordeianu Tatiana, registrator de stat

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT A REPUBLICII MOLDOVA L.Ș.

MD 0067985

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. **531861** data **19.09.2023**

Denumirea completă: **Societatea Comercială "OXIVIT-MED" S.R.L.**
Denumirea prescurtată: **S.C. "OXIVIT-MED" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată,**
Numărul de identificare de stat şi codul fiscal (IDNO): **1007600044280**
Data înregistrării de stat: **30.07.2007**
Sediul: **MD-2032, bd . Decebal, 82, ap.(of.) 90, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
2. Comerţul cu ridicata al parfumurilor şi produselor cosmetice
3. Comerţul cu amănuntul al produselor cosmetice şi de parfumerie, articolelor de toaletă
4. Intermedieri pentru vînzarea unui asortiment larg de mărfuri
5. Alte tipuri de comerţ cu amănuntul în magazine nespecializate
6. Alte tipuri de comerţ cu ridicata
7. Închirierea altor maşini şi echipamente

Capitalul social: **5400** lei,

Administrator: **KOJEVNIKOV DMITRII, IDNP 0972305012362,**

Asociaţii:
1. KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 5400 lei, ce constituie 100%
Beneficiar efectiv:
1.1. KOJEVNIKOV DMITRII, IDNP 0972305012362

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: **19.09.2023**.

Registrator în domeniul înregistrării de stat **Rusu Diana**

Digitally signed by Rusu Diana
Date: 2023.09.19 11:22:47 EEST
Reason: MoldSign Signature
Location: Moldova

EB 0461498

Date cu caracter personal

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chișinău, Republica Moldova
telefon: + 373 22 808002; fax: + 373 22 808003
web: www.oxivit-med.com; e-mail:info@oxivit-med.com

Lista fondatorilor companiei SRL „Oxivit-Med”

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	0972305012362

STAPLING SOLUTIONS FOR CHALLENGING APPLICATIONS

Stapling Product Catalogue 2016

Medtronic
Further, Together

Stapling solutions for challenging tissue and applications

Surgical stapling products from Medtronic enable surgeons to handle the broadest range of tissues and applications with outstanding clinical performance.

Table of Contents

Table of Contents

Staplers for Open Surgery

Endo GIA™ reloads with Tri-Staple™ technology and Endo GIA™ Ultra universal staplers

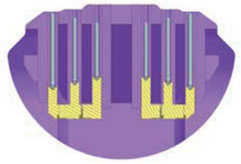
Endo GIA™ Ultra universal handle

45° of articulation, approved for 25 firings. Compatible with Tri-Staple™ technology and Endo GIA™ Ultra universal single use loading units (SULUs).

Order Code	Description	Box Qty
EGIAUSHORT	**Endo GIA™ Ultra universal short stapler** 6 cm shaft length	3
EGIAUSTND	**Endo GIA™ Ultra universal standard stapler** 16 cm shaft length	3
EGIAUXL	**Endo GIA™ Ultra universal XL stapler** 26 cm shaft length	3

Endo GIA™ loading units

The reload design with Tri-Staple™ technology, intended to be used over a wider range of tissue thicknesses. They are compatible with the Endo GIA™ Ultra and the standard Endo GIA™ stapling system.



Order Code	Color Code	Description	Box Qty
EGIA30AV		**Endo GIA™ 30 mm articulating vascular reload**	6
EGIA30AVM		**Endo GIA™ 30 mm articulating vascular/medium reloads** With Tri-Staple™ technology	6
EGIA30AMT		**Endo GIA™ 30 mm articulating medium/thick reloads** With Tri-Staple™ technology	6
EGIA45AV		**Endo GIA™ 45 mm articulating vascular reloads***	6
EGIA45AVM		**Endo GIA™ 45 mm articulating vascular/medium reloads** With Tri-Staple™ technology	6
EGIA45AMT		**Endo GIA™ 45 mm articulating medium/thick reloads** With Tri-Staple™ technology	6
EGIA45AXT		**Endo GIA™ 45 mm articulating x-tra thick reloads** With Tri-Staple™ technology	6
EGIA60AVM		**Endo GIA™ 60 mm articulating vascular medium reloads** With Tri-Staple™ technology	6
EGIA60AMT		**Endo GIA™ 60 mm articulating medium/thick reloads** With Tri-Staple™ technology	6

*Code EGIA30AV and EGIA45AV do not come with Tri-Staple™ technology, have a slimmer fixed anvil

Endo GIA™ reloads with Tri-Staple™ technology

Endo GIA™ curved tip reload with Tri-Staple™ technology

Order Code	Color Code	Description	Box Qty
EGIA30CTAV		**Endo GIA™ curved tip 30mm reload articulating vascular reload***	6
EGIA30CTAVM		**Endo GIA™ curved tip 30 mm articulating vascular/medium reloads** With Tri-Staple™ technology	6
EGIA45CTAV		**Endo GIA™ curved tip 45 mm articulating vascular reload***	6
EGIA45CTAVM		**Endo GIA™ curved tip 45 mm articulating vascular/medium reloads** With Tri-Staple™ technology	6
EGIA60CTAVM		**Endo GIA™ curved tip 60 mm articulating vascular/medium reloads** With Tri-Staple™ technology	6
EGIA60CTAMT		**Endo GIA™ curved tip 60 mm articulating medium/thick reloads** With Tri-Staple™ technology	6

* Code EGIA30CTAV and EGIA45CTAV vascular reloads do not come with Tri-Staple™ technology, have a slimmer fixed anvil

Endo GIA™ radial reload with Tri-Staple™ technology

Order Code	Color Code	Description	Box Qty
EGIARADVM		**Endo GIA™ radial reload – medium tissue** With Tri-Staple™ technology	6
EGIARADMT		**Endo GIA™ radial reload – thick tissue** With Tri-Staple™ technology	6
EGIARADXT		**Endo GIA™ radial reload – extra-thick tissue** With Tri-Staple™ technology	6

iDrive™ Ultra powered stapling system

iDrive™ Ultra powered stapling system

The iDrive™ Ultra powered stapling system provides surgeons with improved precision,[1] enabling them to position and keep the stapler exactly where they intend, completely one-handed and at a push of a button.

Order Code	Description	Box Qty
IDRVULTRA1	iDrive™ Ultra powered handle	1
EGIAADAPT	Endo GIA™ adapter	1
EGIAADAPTXL	Endo GIA™ extra long adapter	1
IDRVBIG	iDrive™ battery insertion guide	1
INTB100	iDrive™ battery pack	1
INTBIC1NC	iDrive™ battery charger and power supply	1
IDRVTRAY	iDrive™ sterilization tray	1
IDRVRET	iDrive™ Ultra manual adapter tool	1

1. Average 61% reduction in reload tip travel during firing when compared to Ethicon Endo-Surgery Echelon Flex™ in indicated media, n=10 surgeons, 172 total trials, p<0.0005. Seils D, Tantawy T, Peterson D. Final report on results, University of Connecticut Biodynamics study. 2012; p.7, table 3. Internally funded study.

Endo GIA™ universal stapling system

Endo GIA™ universal stapling system

It accommodates straight and articulating loading units, approved for 25 firings.

Order Code	Description	Box Qty
030403	**GIA™ universal 12 mm** Single use instrument for open surgery, 6 cm shaft length	3
030449	**Endo GIA™ universal 12 mm** Single use instrument, 16 cm shaft length	3
EGIAUNIVXL	**Endo GIA™ universal XL 12 mm** Single use instrument for bariatric surgery, 26 cm shaft length	3

Endo GIA™ universal Roticulator™ loading units

Single use loading units (SULUs) with titanium staples for use with the Endo GIA™ universal (030449), GIA™ universal (030403), and Endo GIA™ universal XL (EGIAUNIVXL) articulation up to 45°. Also compatible with the Endo GIA™ Ultra stapling system.

Order Code	Color Code	Description	Box Qty
030450		Endo GIA™ universal Roticulator™ 30 – 2.0 mm	6
030451		Endo GIA™ universal Roticulator™ 30 – 2.5 mm	6
030452		Endo GIA™ universal Roticulator™ 30 – 3.5 mm	6
030453		Endo GIA™ universal Roticulator™ 45 – 4.8 mm Requires 15 mm trocar	6
030454		Endo GIA™ universal Roticulator™ 45 – 2.5 mm	6
030455		Endo GIA™ universal Roticulator™ 45 – 3.5 mm	6
030456		Endo GIA™ universal Roticulator™ 45 – 4.8 mm Requires 15 mm trocar	6
030457		Endo GIA™ universal Roticulator™ 60 – 2.5 mm	6
030458		Endo GIA™ universal Roticulator™ 60 – 3.5 mm	6
030459		Endo GIA™ universal Roticulator™ 60 – 4.8 mm Requires 15 mm trocar	6

Endo GIA™ universal stapling system

Endo GIA™ universal straight loading units

Single use loading units (SULUs) with titanium staples for use with Endo GIA™ universal (030449), GIA™ Universal (030403) and Endo GIA™ universal XL (EGIAUNIVXL) single use instruments. Also compatible with the Endo GIA™ Ultra stapling system.

Order Code	Color Code	Description	Box Qty
030416		Endo GIA™ universal straight 30 – 2.0 mm	6
030418		Endo GIA™ universal straight 30 – 2.5 mm	6
030419		Endo GIA™ universal straight 30 – 3.5 mm	6
030426		Endo GIA™ universal straight 45 – 2.0 mm	6
030425		Endo GIA™ universal straight 45 – 2.5 mm	6
030422		Endo GIA™ universal straight 45 – 3.5 mm	6
030423		Endo GIA™ universal straight 45 – 4.8 mm Requires 15 mm trocar	6
030412		Endo GIA™ universal straight 60 – 2.5 mm	6
030414		Endo GIA™ universal straight 60 – 3.5 mm	6
030415		Endo GIA™ universal straight 60 – 4.8 mm Requires 15 mm trocar	6

Multifire Endo GIA™ 30 staplers and reloads

Multifire Endo GIA™ 30 staplers

Single use staplers with titanium staples, approved for 8 firings.

Order Code	Color Code	Description	Box Qty
030811	☐	**MultiFire Endo GIA™ 30 – 2.5 mm** 12 mm stapler	3
030813	■	**MultiFire Endo GIA™ 30 – 3.5 mm** 12 mm stapler	3

Multifire Endo GIA™ 30 reloads

Single use loading units (SULU's) with titanium staples for use with Multifire Endo GIA™ 30 – 12mm stapler.

Order Code	Color code	Description	Box Qty
030805L	☐	**MultiFire Endo GIA™ 30 – 2.5 mm**	6
030807L	■	**MultiFire Endo GIA™ 30 – 3.5 mm**	6

MultiFire Endo TA™ 30 staplers and reloads

KNIFELESS

Endo TA™ 30 multifire stapling system

Single use staplers with titanium staples, approved for 8 firings.

Order Code	Color Code	Description	Box Qty
010901	☐	**MultiFire Endo TA™ 30 – 2.5 mm** 12 mm single use stapler	3

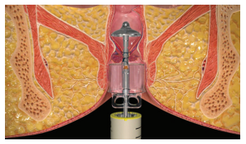
KNIFELESS

Endo TA™ 30 multiFire loading units

Single use loading units (SULU's) with titanium staples for use with MultiFire Endo TA™ 30 staplers.

Order Code	Color Code	Description	Box Qty
010911L	☐	**MultiFire Endo TA™ 30 – 2.5 mm**	6

Circular Staplers



EEA™ haemorrhoid and prolapse stapler with DST Series™ technology

Shaft length 12 cm, 33 mm diameter, 32 DST Series™ titanium staples, 3.5 and 4.8 mm size.
Shell volume 20 cc. Comes with a transparent anoscope, a detachable anvil and a conical dilator.

Order Code	Color Code	Description	Box Qty
HEM3335		**EEA™ haemorrhoid and prolapse stapler set 33 mm** with DST Series™ technology. 3.5 mm staples	3
HEM3348		**EEA™ haemorrhoid and prolapse stapler set 33 mm** with DST Series™ technology. 4.8 mm staples	3

EEA™ staplers with DST Series™ technology

Circular staplers, available in 22 and 35 cm shaft length and in 3.5 and 4.8 mm staple heights.

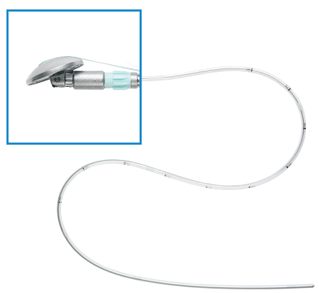
Order Code	Color Code	Description	Box Qty
EEA21		**EEA™ 21mm stapler with DST Series™ technology** Single use stapler with 4.8 mm staples	3
EEA2135		**EEA™ 21 mm stapler with DST Series™ technology** Single use stapler with 3.5 mm staples	3
EEA25		**EEA™ 25 mm stapler with DST Series™ technology** Single use stapler with 4.8 mm staples	3
EEA2535		**EEA™ 25 mm stapler with DST Series™ technology** Single use stapler with 3.5 mm staples	3
EEA28		**EEA™ 28 mm stapler with DST Series™ technology** Single use stapler with 4.8 mm staples	3
EEA2835		**EEA™ 28 mm stapler with DST Series™ technology** Single use stapler with 3.5 mm staples	3
EEA31		**EEA™ 31 mm stapler with DST Series™ technology** Single use stapler with 4.8 mm staples	3
EEA33		**EEA™ 33 mm stapler with DST Series™ technology** Single use stapler with 4.8 mm staples	3

Directional stapling technology

Circular Staplers

EEA™ XL staplers with DST Series™ technology

Order Code	Color Code	Description	Box Qty
EEAXL21		**EEA™ XL 21 mm stapler with DST Series™ technology** Single use stapler with 4.8 mm staples	3
EEAXL2135		**EEA™ XL 21 mm stapler with DST Series™ technology** Single use stapler with 3.5 mm staples	3
EEAXL25		**EEA™ XL 25 mm stapler with DST Series™ technology** Single use stapler with 4.8 mm staples	3
EEAXL2535		**EEA™ XL 25 mm stapler with DST Series™ technology** Single use stapler with 3.5 mm staples	3
EEAXL28		**EEA™ XL 28 mm stapler with DST Series™ technology** Single use stapler with 4.8 mm staples	3
EEAXL2835		**EEA™ XL 28 mm stapler with DST Series™ technology** Single use stapler with 3.5 mm staples	3
EEAXL31		**EEA™ XL 31 mm stapler with DST Series™ technology** Single use stapler with 4.8 mm staples	3
EEAXL33		**EEA™ XL 33 mm stapler with DST Series™ technology** Single use stapler with 4.8 mm staples	3



OrVil™ device

Pre-tilted anvil trans-oral delivery device, mounted on a 90 cm long PVC nasogastric tube
Attention: Only compatible with XL staplers 21 and 25.

Order Code	Color Code	Description	Box Qty
EEAORVIL21		**EEA™ OrVil™ 21 mm device with DST Series™ technology** Compatible with XL stapler 21 only	3
EEAORVIL25		**EEA™ OrVil™ 21 mm device with DST Series™ technology** Compatible with XL stapler 25 only	3

Circular Staplers

EEA™ introducer device with DST Series™ technology

Facilitate the smooth insertion of the EEA™ circular stapler during bariatric and colorectal procedures.

Order Code	Color Code	Description	Box Qty
EEATAID21D		EEA™ 21 mm introducer	6
Endoscopic		EEA™ 25 mm introducer	6
EEATAID28D		EEA28 disposable trans-anal/abdominal introducer	6
EEATAID31D		EEA31 disposable trans-anal/abdominal introducer	6
EEATAID33D		EEA33 disposable trans-anal/abdominal introducer	6

Purstring™ device

Single use instruments with stainless steel staples.

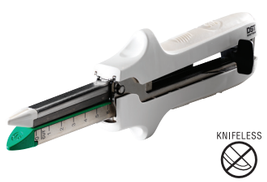
Order Code	Description	Box Qty
020242	**Purstring™ 65** Single use instrument with Monosof™ 2 – 0 mm non absorbable monofilament nylon suture	3
020730	**Purstring™ 45** Single use instrument with Surgidac™ 2 – 0 mm non absorbable braided polyester surgical suture	3

EEA™ sizers

Order Code	Description	Box Qty
020250	**EEA™ reusable sizer set** (25, 28, 31 mm)	1

Staplers for Open Surgery

Directional stapling technology



GIA™ staplers with DST Series™ technology

Single use reloadable stapler with titanium staples, approved for 8 firings.

Order Code	Color code	Description	Box Qty
GIA6025S		GIA™ 60 mm – 2.5 mm	3
GIA6038S		GIA™ 60 mm – 3.8 mm	3
GIA6048S		GIA™ 60 mm – 4.8 mm	3
GIA8038S		GIA™ 80 mm – 3.8 mm	3
GIA8048S		GIA™ 80 mm – 4.8 mm	3
GIA10038S		GIA™ 100 mm – 3.8 mm	3
GIA10048S		GIA™ 100 mm – 4.8 mm	3
SGIA6038S		SGIA™ 60 – 3.8 mm Knifeless	3

GIA™ loading units

Single use loading units (SULUs) with titanium staples for use with GIA™ DST Series™ reloadable staplers.

Order Code	Color code	Description	Box Qty
GIA6025L		GIA™ 60 – 2.5 mm	6
GIA6038L		GIA™ 60 – 3.8 mm	6
GIA6048L		GIA™ 60 – 4.8 mm	6
GIA8038L		GIA™ 80 – 3.8 mm	6
GIA8048L		GIA™ 80 – 4.8 mm	6
GIA10038L		GIA™ 100 – 3.8 mm	6
GIA10048L		GIA™ 100 – 4.8 mm	6

Poly GIA™ 75 stapler – 0.060 mm

Single use stapler with Lactomer™ absorbable staples.

Order Code	Color code	Description	Box Qty
030775		**Poly GIA™ 75 – 0.060 mm** Closure gap 1.5 mm	6

Staplers for Open Surgery

Directional stapling technology

TA™ stapler with DST Series™ technology

Single use reloadable stapler with titanium staples, approved for 8 firings.

Order Code	Color Code	Description	Box Qty
TA30V3S		TA™ 30 mm – V3 (Vascular)	3
TA3035S		TA™ 30 – 3.5 mm	3
TA3048S		TA™ 30 – 4.8 mm	3
TA4535S		TA™ 45 – 3.5 mm	3
TA4548S		TA™ 45 – 4.8 mm	3
TA6035S		TA™ 60 – 3.5 mm	3
TA6048S		TA™ 60 – 4.8 mm	3
TA9035S		TA™ 90 – 3.5 mm	3
TA9048S		TA™ 90 – 4.8 mm	3

TA™ loading units

Single use loading units (SULUs) with titanium staples for use with TA™ staplers with DST Series™ technology reloadable staplers.

Order Code	Color Code	Description	Box Qty
TA30V3L		TA™ 30 mm – V3 (Vascular)	6
TA3035L		TA™ 30 – 3.5 mm	6
TA3048L		TA™ 30 – 4.8 mm	6
TA4535L		TA™ 45 – 3.5 mm	6
TA4548L		TA™ 45 – 4.8 mm	6
TA6035L		TA™ 60 – 3.5 mm	6
TA6048L		TA™ 60 – 4.8 mm	6
TA9035L		TA™ 90 – 3.5 mm	6
TA9048L		TA™ 90 – 4.8 mm	6

Staplers for Open Surgery

Premium MultiFire TA™ stapler

Single use reloadable stapler with titanium staples, approved for 8 firings.

Order Code	Color Code	Description	Box Qty
010315		**Premium MultiFire TA™ 30 mm – V3 (Vascular)** Single use reloadable stapler	3

Premium MultiFire TA™ loading units

Single use loading units (SULUs) with titanium staples for use with Premium MultiFire TA™ single use reloadable stapler.

Order Code	Color Code	Description	Box Qty
010316L		**Premium MultiFire TA™ 30 mm – V3** (Vascular) single use loading unit	6

Roticulator™ staplers

Single use staplers with titanium staples.

Order Code	Color Code	Description	Box Qty
017619		Roticulator™ 30 – V3 (Vascular)	3
017615		TA™ Roticulator™ 30 – 3.5 mm	3
017617		TA™ Roticulator™ 30 – 4.8 mm	3
017612		TA™ Roticulator™ 55 – 3.5 mm	3
017614		TA™ Roticulator™ 55 – 4.8 mm	3

Roticulator 55 Poly™ staplers

Single use staplers with absorbable Lactomer™ staples.

Order Code	Color Code	Description	Box Qty
013602		Roticulator 55 Poly™ – 0.170 mm	3
013601		Roticulator 55 Poly™ – 0.200 mm	3

Staplers for Open Surgery

Premium Poly™ CS 57 staplers

Single use staplers with absorbable Lactomer™ staples (2 instruments per kit).

Order Code	Color Code	Description	Box Qty
015140		Premium Poly™ CS 57 – 0.140 mm	3
015170		Premium Poly™ CS 57 – 0.170 mm	3

Reusable Stapling Instruments

GIA 50 Premium™ stapler

Reusable instrument.

Order Code	Description	Box Qty
030470	GIA 50 Premium™ Reusable instrument	1

GIA 50 Premium™ loading units

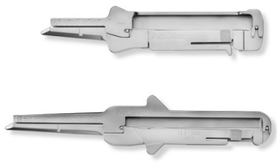
Single use loading units (SULUs) with stainless steel staples for use with GIA 50 Premium™ stainless steel instruments.

Order Code	Color code	Description	Box Qty
030424L 030472L		GIA 50 Premium™ 3.8 mm Single use loading unit	6

GIA 90 Premium™ loading units

Single use loading units SULUs with stainless steel staples for use with GIA 90 Premium™ stainless steel instruments.

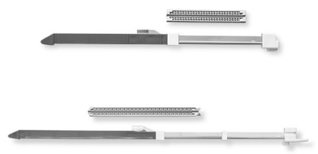
Order Code	Color code	Description	Box Qty
030735L		GIA 90 Premium™ 3.8 mm Single use loading unit	6



ILA™ stapler

Order Code	Description	Box Qty
3957	ILA™ 52 Two-piece reusable anastomotic stapler	1
3975	ILA™ 100 Reusable stapler	1

Reusable Stapling Instruments



ILA™ loading units

Single use loading units (SULU's) with titanium staples for use with ILA™ 52 and ILA™ 100 stainless steel instruments.

Order Code	Color code	Description	Box Qty
3948L		ILA™ 52 – 3.8 mm anastomotic Single use loading unit	6
3972		ILA™ 100 – 3.8 mm anastomotic Single use loading unit	6

TA Premium™ stapler

Reusable Instruments.

Order Code	Description	Box Qty
010450	TA Premium™ 30 mm	1
010460	TA Premium™ 55 mm	1
010470	TA Premium™ 90 mm	1

Reusable Stapling Instruments

TA Premium™ loading units

Single use loading units (SULUs) with titanium staples for use with TA Premium™ stainless steel instruments.

Order Code	Color code	Description	Box Qty
015441L		TA Premium™ 30 mm – V3 mm (Vascular)	6
015427L		TA Premium™ 30 – 3.5 mm	6
015433L		TA Premium™ 30 – 4.8 mm	6
015451L		TA Premium™ 55 – 3.5 mm	6
015458L		TA Premium™ 55 – 4.8 mm	6
015477L		TA Premium™ 90 – 3.5 mm	6
015485L		TA Premium™ 90 – 4.8 mm	6

Premium Polysorb™ 55 loading units

Single use loading units (SULUs) with absorbable Lactomer™ staples for use with TA Premium™ stainless steel instruments.

Order Code	Color code	Description	Box Qty
013501L		Premium Polysorb™ 55 – 0.060 mm	6
013507L		Premium Polysorb™ 55 – 0.200 mm	6

TA™ 90 B loading units

Single use loading units (SULUs) with titanium staples for use with TA™ 90 B and TA™ 90 BN stainless steel instruments.

Order Code	Color code	Description	Box Qty
015888L		TA™ 90 B – 4.8 mm	6

Skin Staplers

MultiFire Premium™ skin staplers

Single use skin staplers with stainless steel staples.

Order Code	Description	Box Qty
059035	**MultiFire Premium™** With 35 regular staples	6
059037	**MultiFire Premium™** With 35 wide staples	6

MultiFire Premium™ loading units

Single use loading units (SULUs) with stainless steel staples for use with MultiFire Premium™ single use skin staplers.

Order Code	Description	Box Qty
059036	**MultiFire Premium™** With 35 regular staples	12
059038	**MultiFire Premium™** With 35 wide staples	12

Appose™ ULC 35 staplers

Single use skin staplers with stainless steel staples.

Order Code	Description	Box Qty
8886803512	**Skin Stapler** With 35 regular staples	12
8886803712	**Skin Stapler** With 35 wide staples	12

Skin Staplers

Premium™ skin staple remover

Single use skin staple remover.

Order Code	Description	Box Qty
150462	**Premium™ skin staple remover** Plastic with metal tips	12

DFS™ staplers

Single use fascia stapler with stainless steel staples.

Order Code	Description	Box Qty
070614	**DFS™ – 20 W** Single use fascia stapler, 20 wide staples	6

IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

15-emea-stapling-product-catalogue-602410

Medtronic

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To contact us, please visit
medtronic.com/covidien/support/emea-customer-service

COVIDIEN

Declaration of Conformity

USS-041

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:	08/04/1995 North Haven, CT
Type of Devices:	Surgical Staplers and Single Use Loading Units
Device Name:	EEA™ Staplers – See Attached
Product Category(ies) Listed on Current MDD Certificate:	Surgical Staple, Clip Products and Accessories, Manual Surgical Instruments
MDD Classification/Reorder Codes/GMDN Codes:	See Attached
Conformity Assessment:	Directive 93/42/EEC on Medical Devices (MDD), For Class IIa/IIb: Annex II excluding (4) All Class I, non-sterile, non-measurement devices listed on Declarations of Conformance are not regulated by TÜV SÜD P.S. and follow conformity assessment procedures set out in Annex VII.
EC Certificate: **Certificate of Conformity Valid Until:**	G1 077608 0079 Rev 00 (expires 26-May-2024) 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)

Angela Van Arsdale
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Sr. Manager, Regulatory Affairs

Revision Date: September 24, 2020

COVIDIEN

Declaration of Conformity

USS - 041

Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration M/D/YYYY*	*Reorder Code Status*
020250	EEA™ Auto Suture™ Reusable Sizer 25mm / 28mm / 31mm	I non-sterile	6	Colorectal sizer [58016]	8/4/1995	Current
020251	EEA™ Auto Suture™ Reusable Sizer 34mm	I non-sterile	6	Colorectal sizer [58016]	8/4/1995	Current
110214L	EEA™ Auto Suture™ Loading Unit 25mm	IIb	8	Surgical staple, non-bioabsorbable [35615]	8/4/1995	Current
110238L	EEA™ Auto Suture™ Loading Unit 28mm	IIb	8	Surgical staple, non-bioabsorbable [35615]	6/17/1997	Current
110276L	EEA™ Auto Suture™ Loading Unit 31mm	IIb	8	Surgical staple, non-bioabsorbable [35615]	8/4/1995	Current
111981	Premium Plus CEEA™ Auto Suture™ Circular Stapler 34mm	IIb	8	Intraluminal circular stapler [59875]	11/22/1996	Current
111983	Premium Plus CEEA™ Auto Suture™ Circular Stapler 21mm	IIb	8	Intraluminal circular stapler [59875]	9/9/1996	Current
111985	Premium Plus CEEA™ Auto Suture™ Circular Stapler 25mm	IIb	8	Intraluminal circular stapler [59875]	8/4/1995	Current
111987	Premium Plus CEEA™ Auto Suture™ Circular Stapler 28mm	IIb	8	Intraluminal circular stapler [59875]	8/4/1995	Current
111989	Premium Plus CEEA™ Auto Suture™ Circular Stapler 31mm	IIb	8	Intraluminal circular stapler [59875]	8/4/1995	Current
EEA21	EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology 21mm - 4.8mm	IIb	8	Intraluminal circular stapler [59875]	2/21/2007	Current
EEA2135	EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology 21mm - 3.5mm	IIb	8	Intraluminal circular stapler [59875]	3/22/2007	Current
EEA25	EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology 25mm - 4.8mm	IIb	8	Intraluminal circular stapler [59875]	12/20/2005	Current

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Angela Van Arsdale

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Declaration of Conformity

USS - 041

Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration M/D/YYYY*	*Reorder Code Status*
EEA2535	EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology 25mm - 3.5mm	IIb	8	Intraluminal circular stapler [59875]	2/21/2007	Current
EEA28	EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology 28mm - 4.8mm	IIb	8	Intraluminal circular stapler [59875]	5/9/2006	Current
EEA2835	EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology 28mm - 3.5mm	IIb	8	Intraluminal circular stapler [59875]	2/21/2007	Current
EEA31	EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology 31mm - 4.8mm	IIb	8	Intraluminal circular stapler [59875]	5/9/2006	Current
EEA33	EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology 33mm - 4.8mm	IIb	8	Intraluminal circular stapler [59875]	3/22/2007	Current
EEAORVIL21	EEA™ OrVil™ Auto Suture™ Transoral Circular Stapler Anvil 21mm	IIa	6	Intraluminal circular stapler [59875]	1/23/2007	Current
EEAORVIL21A	EEA™ OrVil™ Auto Suture™ Transoral Circular Stapler Anvil with Advancing Proximal Guide Suture 21mm	IIa	6	Intraluminal circular stapler [59875]	3/13/2013	Current
EEAORVIL25	EEA™ OrVil™ Auto Suture™ Transoral Circular Stapler Anvil 25mm	IIa	6	Intraluminal circular stapler [59875]	1/23/2007	Current
EEAORVIL25A	EEA™ OrVil™ Auto Suture™ Transoral Circular Stapler Anvil with Advancing Proximal Guide Suture 25mm	IIa	6	Intraluminal circular stapler [59875]	3/13/2013	Current
EEATAID21D	EEA™ Auto Suture™ Introducer Device 21mm	IIa	6	Dilator, rectal [11262]	1/27/2010	Current
EEATAID21R	EEA™ Auto Suture™ Introducer Device 21mm	I non-sterile	6	Guide [37150]	1/27/2010	Current
EEATAID25D	EEA™ Auto Suture™ Introducer Device 25mm	IIa	6	Dilator, rectal [11262]	1/27/2010	Current
EEATAID25R	EEA™ Auto Suture™ Introducer Device 25mm	I non-sterile	6	Guide [37150]	1/27/2010	Current

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Angela Van Arsdale

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Sr. Manager, Regulatory Affairs

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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*
EEATAID28D	EEA™ Auto Suture™ Introducer Device 28mm	IIa	6	Dilator, rectal [11262]	1/27/2010	Current
EEATAID28R	EEA™ Auto Suture™ Introducer Device 28mm	I non-sterile	6	Guide [37150]	1/27/2010	Current
EEATAID31D	EEA™ Auto Suture™ Introducer Device 31mm	IIa	6	Dilator, rectal [11262]	1/27/2010	Current
EEATAID31R	EEA™ Auto Suture™ Introducer Device 31mm	I non-sterile	6	Guide [37150]	1/27/2010	Current
EEATAID33D	EEA™ Auto Suture™ Introducer Device 33mm	IIa	6	Dilator, rectal [11262]	1/27/2010	Current
EEATAID33R	EEA™ Auto Suture™ Introducer Device 33mm	I non-sterile	6	Guide [37150]	1/27/2010	Current
EEAXL21	EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology 21mm - 4.8mm XL	IIb	8	Intraluminal circular stapler [59875]	5/9/2006	Current
EEAXL2135	EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology 21mm - 3.5mm XL	IIb	8	Intraluminal circular stapler [59875]	1/23/2007	Current
EEAXL25	EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology 25mm - 4.8mm XL	IIb	8	Intraluminal circular stapler [59875]	9/9/2005	Current
EEAXL2535	EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology 25mm - 3.5mm XL	IIb	8	Intraluminal circular stapler [59875]	9/9/2005	Current
EEAXL28	EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology 28mm - 4.8mm XL	IIb	8	Intraluminal circular stapler [59875]	3/22/2007	Current
EEAXL2835	EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology 28mm - 3.5mm XL	IIb	8	Intraluminal circular stapler [59875]	2/21/2007	Current
EEAXL31	EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology 31mm - 4.8mm XL	IIb	8	Intraluminal circular stapler [59875]	3/22/2007	Current
EEAXL33	EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology 33mm - 4.8mm XL	IIb	8	Intraluminal circular stapler [59875]	3/22/2007	Current

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Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration M/D/YYYY*	*Reorder Code Status*
HEM3335	EEA™ Auto Suture™ Hemorrhoid and Prolapse Stapler with DST Series™ Technology 33mm - 3.5mm	IIb	8	Haemorrhoidal surgical stapler [46737]	6/15/2009	Current
HEM3348	EEA™ Auto Suture™ Hemorrhoid and Prolapse Stapler with DST Series™ Technology 33mm - 4.8mm	IIb	8	Haemorrhoidal surgical stapler [46737]	6/15/2009	Current

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Declaration of Conformity
USS-041

Standards/Directives List

Standard/Directive	Year	Title
EN 556-1 + AC	2001 + AC: 2006	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
EN ISO 11135-1 + A1	2014, A1:2019	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 11737-1 + AC	2006 + 2009	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
EN ISO 11137-1 + AC	2006 + 2013	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	2013	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
EN ISO 11607-1	2009	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2	2006	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
ISO 15223-1	2012	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN ISO 13485	2016	Medical devices. Quality management systems. Requirements for regulatory purposes.
EN ISO 14630	2012	Non-active surgical implants – General Requirements
EN 1041	2008	Information supplied by the manufacturer with medical devices.
EN ISO 14971	2012	Medical devices -- Application of risk management to medical devices.
EN ISO 17664	2004	Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices.

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EN 62366	2008	Medical devices — Application of usability engineering to medical devices
ISO 14644-1	1999	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
ISO 14644-2	2000	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 + AC	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 + 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

List of Relevant Documents/Guidances Used for Guidance:

Standard/Directive/Guidance	Year	Title
MEDDEV 2.7.1 Rev. 4	2016	European Commission Guidelines for Medical Devices – Evaluation of Clinical Data

REGULATORY AFFAIRS COVIDIEN NORTH HAVEN, CONNECTICUT USA

Angela Van Arsdale
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Sr. Manager Regulatory

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Declaration of Conformity

USS-033B-TF-01

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:	09/18/2012 North Haven, CT
Type of Devices:	Surgical Staplers
Device Name:	GIA™ and Endo GIA™ Surgical Staplers
Product Category(ies) Listed on Current MDD Certificate:	Manual Surgical Instruments / Endoscopy Instruments and Accessories including Lubricant
MDD Classification/Reorder Codes/GMDN Codes:	See Attached
Conformity Assessment:	Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
EC Certificate: **Certificate of Conformity Valid Until:**	G1 077608 0079 Rev 00 (expires 26-May-2024) 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)

Mary Mellows
Manager, Regulatory Affairs

Revision Date: October 3, 2019

COVIDIEN

Declaration of Conformity

USS - 033B-TF-01

Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration M/D/YYYY*	*Reorder Code Status*
030403	GIA™ Auto Suture™ Universal Stapler	IIa	6	Open-surgery manual linear cutting stapler, single-use [59870]	8/9/2004	Current
030449	Endo GIA™ Auto Suture™ Universal Stapler 12mm	IIa	6	Endoscopic manual linear cutting stapler, single-use [59871]	8/9/2004	Current
EGIAUNIVXL	Endo GIA™ Auto Suture™ Universal Stapler 12mm XL	IIa	6	Endoscopic manual linear cutting stapler, single-use [59871]	8/9/2004	Current

Mary Mellows
Manager, Regulatory Affairs

Revision Date: October 3, 2019

COVIDIEN

Declaration of Conformity
USS-033B-TF-01

Standards List

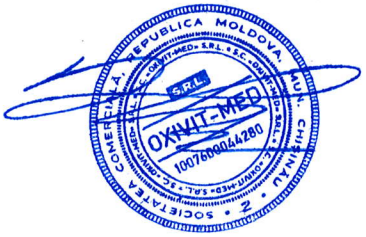
Standard	Year	Title
EN 556-1 + AC	2001 + 2006	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
EN 1041	2008	Information supplied by the manufacturer with medical devices.
EN ISO 10993-1 + AC	2009 + 2010	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.
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 + 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 11135-1	2007	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	2009	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2	2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing, and assembly processes.
EN ISO 11737-1 + AC	2006 + 2013	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 + AC	2012 + 2012	Medical devices - Quality management systems. Requirements for regulatory purposes.
EN ISO 14630	2009	Non-active surgical implants – General Requirements
ISO 14644-1	1999	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration

Mary Mellows
Manager, Regulatory Affairs

COVIDIEN

Declaration of Conformity
USS-033B-TF-01

Standard	Year	Title
ISO 14644-2	2000	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 15223-1	2012	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN 62366	2008	Medical devices - Application of usability engineering to medical devices



Mary Mellows
Manager, Regulatory Affairs

COVIDIEN

Declaration of Conformity

USS-033C-TF-01

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:	09/18/2012 North Haven, CT
Type of Devices:	Surgical Staplers
Device Name:	Endo GIA™ Ultra Universal Staplers and Signia™ Intelligent Loading Units
Product Category(ies) Listed on Current MDD Certificate:	Endoscopy Instruments and Accessories including Lubricant; 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 excluding (4)
EC Certificate: **Certificate of Conformity Valid Until:**	G1 077608 0079 Rev 00 (expires 26-May-2024) 26-May-2024
Standards Associated:	See Attached

REGULATORY AFFAIRS COVIDIEN NORTH HAVEN, CONNECTICUT, USA

Authorized Representative in EU
Covidien Ireland Limited
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80339 Munich, Germany (0123)

Revision Date: October 3, 2019

Mary Mellows
Manager, Regulatory Affairs

REPUBLICA MOLDOVA OXIVIT-MEDIC 1007600

COVIDIEN

Declaration of Conformity

USS - 033C-TF-01

Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration M/D/YYYY*	*Reorder Code Status*
EGIAUSHORT	Endo GIA™ Ultra Universal Stapler 12mm Short	IIa	6	Endoscopic manual linear cutting stapler, single-use [59871]	3/15/2010	Current
EGIAUSTND	Endo GIA™ Ultra Universal Stapler 12mm	IIa	6	Endoscopic manual linear cutting stapler, single-use [59871]	3/15/2010	Current
EGIAUXL	Endo GIA™ Ultra Universal Stapler 12mm XL	IIa	6	Endoscopic manual linear cutting stapler, single-use [59871]	3/15/2010	Current
SIGLU45A	Signia™ Intelligent Loading Unit 45mm	IIa	6	Endoscopic manual linear cutting stapler, single-use [59871]	9/27/2017	Current
SIGLU60A	Signia™ Intelligent Loading Unit 60mm	IIa	6	Endoscopic manual linear cutting stapler, single-use [59871]	9/27/2017	Current

REGULATORY AFFAIRS COVIDIEN NORTH HAVEN, CONNECTICUT USA

Mary Mellows

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Manager, Regulatory Affairs

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Declaration of Conformity
USS-033C-TF-01

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.
EN ISO 10993-1 + AC	2009 + 2010	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.
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 + 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
EN ISO 11607-1 + A1	2010 + 2014	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2 + A1	2006 + 2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing, and assembly processes.
EN ISO 11737-1 + AC	2006 + 2013	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
EN ISO 13485	2012	Medical devices - Quality management systems. Requirements for regulatory purposes. (ISO 13485:2003)
EN ISO 14630	2012	Non-active surgical implants – General Requirements
ISO 14644-1	2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration

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Manager, Regulatory Affairs

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Standard	Year	Title
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
EN 62366	2015	Medical devices - Application of usability engineering to medical devices (IEC 62366:2007)
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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Declaration of Conformity

USS-141

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:	03/13/2013 North Haven, CT
Type of Devices:	Wound Protection Ring
Device Name:	SurgiSleeve™
Product Category(ies) Listed on Current MDD Certificate:	Endoscopy Instruments and Accessories
MDD Classification/Reorder Codes/GMDN Codes:	See Attached
Conformity Assessment:	Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
EC Certificate:	G1 077608 0079 Rev 00 (exp 26-May-2024)
Certificate of Conformity Valid Until:	24-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)

Angela Van Arsdale
Angela Van Arsdale
Sr. Manager, Regulatory Affairs

Revision Date: September 30, 2020

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Declaration of Conformity

USS - 141

Reorder Code	*Description*	*MDD Class*	*MDD Rule*	*GMDN Code*	*Date Added to Declaration M/D/YYYY*	*Reorder Code Status*
WPLG914	SurgiSleeve™ Large Wound Protector 9cm-14cm	IIa	6	Abdominal radial retractor [47431]	3/13/2013	Current
WPLGR914	SurgiSleeve™ Large Wound Protector with Retraction Ring 9cm-14cm	IIa	6	Abdominal radial retractor [47431]	11/21/2014	Current
WPMD509	SurgiSleeve™ Medium Wound Protector 5cm-9cm	IIa	6	Abdominal radial retractor [47431]	3/13/2013	Current
WPSM256	SurgiSleeve™ Small Wound Protector 2.5cm-6cm	IIa	6	Abdominal radial retractor [47431]	3/13/2013	Current
WPXLGR1117	SurgiSleeve™ Large Wound Protector with Retraction Ring 11cm-17cm	IIa	6	Abdominal radial retractor [47431]	11/21/2014	Current
WPXSM24	SurgiSleeve™ Extra Small Wound Protector 2cm - 4cm	IIa	6	Abdominal radial retractor [47431]	11/21/2014	Current

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Declaration of Conformity
USS-141

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" - Part 1: Requirements for terminally sterilized medical devices.
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 ISO 11135-1	2007	Sterility	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 14644-1	1999	Sterility	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
ISO 14644-2	2000	Sterility	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	Sterility	Cleanrooms and associated controlled environments - Part 3: Test methods
EN ISO 11607-1	2009	Packaging	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2	2006	Packaging	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 13485	2016	Quality Management	Medical devices - Quality management systems - Requirements for regulatory purposes
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 10993-5	2009	Biological Evaluation	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6	2009	Biological Evaluation	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation

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SOCIETATEA COMERCIALA REPUBLICA MOLDOVA S.R.L. OXIVIT-MED 1007600044280

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Declaration of Conformity
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Standards List:

Standard/Directive	Year	Type	Title
EN ISO 10993-7 + AC	2008 + 2009	Biological Evaluation	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
ISO 10993-10	2010	Biological Evaluation	Biological evaluation of medical devices - Part 10: Tests for and skin sensitization
EN 1041	2008	Manufacturer Information	Information supplied by the manufacturer with medical devices.
EN ISO 14971	2012	Risk Management	Medical devices – Application of risk management to medical devices.
EN 62366	2008	Medical Devices	Medical devices – Application of usability engineering to medical devices.

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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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Facility(ies):

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

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

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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)

Angela Van Arsdale
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Sr. Manager, Regulatory Affairs

COVIDIEN

Declaration of Conformity

USS-033C

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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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*
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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Declaration of Conformity

USS-033C

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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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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1007600044280

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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REPUBLICA MOLDOVA OXIVIT-MED

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

REGULATORY AFFAIRS COVIDIEN NORTH HAVEN, CONNECTICUT USA

Angela Van Arsdale
Angela Van Arsdale
Sr. Manager, Regulatory

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)

REGULATORY AFFAIRS
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REPUBLICA MOLDOVA
OXIVIT-MED
1007600044288

Revision Date: July 14, 2020

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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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COVIDIEN
NORTH HAVEN, CONNECTICUT USA

Angela Van Arsdale
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Declaration of Conformity

USS - 033A

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

REGULATORY AFFAIRS COVIDIEN NORTH HAVEN CONNECTICUT USA

Angela Van Arsdale
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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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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

REGULATORY AFFAIRS
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Declaration of Conformity

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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Declaration of Conformity

USS - 034

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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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*
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

REGULATORY AFFAIRS COVIDIEN NORTH HAVEN, CONNECTICUT USA

Angela Van Arsdale
Sr. Manager, Regulatory Affairs

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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*
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

REGULATORY AFFAIRS COVIDIEN NORTH HAVEN, CONNECTICUT USA

Angela Van Arsdale
Sr. Manager, Regulatory Affairs

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Declaration of Conformity
USS-034

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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Angela Van Arsdale
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Declaration of Conformity
USS-034

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

REGULATORY AFFAIRS
COVIDIEN
NORTH HAVEN, CONNECTICUT USA

Angela Van Arsdale
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OXIVIT-MED

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

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www.zlg.de
ZLG-BS-244.10.08

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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Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 077608 0040 Rev. 01

Manufacturer:

Covidien llc
15 Hampshire Street
Mansfield, MA 02048
USA

Product:

Non-Active Implants
Non-absorbable staple products

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713138923

Valid from: 2019-11-29
Valid until: 2024-05-26

Date, 2019-11-29

Christoph Dicks
Head of Certification/Notified Body

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 077608 0040 Rev. 01

Facility(ies):

Covidien
60 Middletown Avenue, North Haven CT 06473, USA

Covidien (U.S.S.C. Puerto Rico, Inc.)
Building 911-67, Sabanetas Industrial Park, Ponce PR 00731, USA

Model(s): **Non-absorbable staple products**

Parameters:

GIA™ Auto Suture™ 60, 80 and 100 Single Use Staplers with 2.5, 3.8 and 4.8mm Metal Staples

- GIA6025S
- GIA6038S
- GIA6048S
- GIA8038S
- GIA8048S
- GIA10038S
- GIA10048S

GIA™ Auto Suture™ 60, 80 and 100 Single Use Loading Units with 2.5, 3.8 and 4.8mm Metal Staples

- GIA6025L
- GIA6038L
- GIA6048L
- GIA8038L
- GIA8048L
- GIA10038L
- GIA10048L

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Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 077608 0074 Rev. 00

Manufacturer:

Covidien llc
15 Hampshire Street
Mansfield, MA 02048
USA

EC-Representative:

Covidien Ireland Limited
IDA Business and Technology Park, Tullamore, IRELAND

Product:

Non-Active Implants
Nonabsorbable staple products

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713099714

Valid from: 2019-05-31
Valid until: 2024-05-26

Date, 2019-05-31

Stefan Preiß
Head of Certification/Notified Body

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

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 077608 0074 Rev. 00

Facility(ies):

Covidien
60 Middletown Avenue, North Haven CT 06473, USA

Covidien (U.S.S.C. Puerto Rico, Inc.)
Building 911-67, Sabanetas Industrial Park, Ponce PR 00731, USA

Model(s):

Nonabsorbable staple products as specified in the attachment to this certificate

Parameter:

PI™ 30 Auto Suture™ Single Use Staplers with 3.5 or 4.8mm Metal Staples, and PI™ Auto Suture™ 30 Single Use Loading Units with 3.5 or 4.8mm Metal Staples.

- 4900T
- 4901T
- 4907T
- 4908T

PI™ Auto Suture™ Single Use Loading Units in 15, 30, 55, and 90 with 2.5, 3.5, or 4.8mm Metal Staples for use with PI™ Auto Suture™ 15, 30, 55, and 90 Reusable Staplers.

- 3922L
- 3923L
- 3924L
- 3925L
- 3926L
- 3927L
- 3929L
- 3930A

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 077608 0074 Rev. 00

TA™ Auto Suture™ 30, 45, 60, and 90 Single Use Staplers with 2.5, 3.5, or 4.8mm Metal Staples, and TA™ Auto Suture™ 30, 45, 60, and 90 Single Use Loading Units with 2.5, 3.5, or 4.8mm Metal Staples.

- TA9048S
- TA9035S
- TA6048S
- TA6035S
- TA4548S
- TA4535S
- TA3048S
- TA3035S
- TA30V3S
- TA9048L
- TA9035L
- TA6048L
- TA6035L
- TA4548L
- TA4535L
- TA3048L
- TA3035L
- TA30V3L

TA™ Auto Suture™ 30, 55, and 90 Single Use Loading Units with 2.5, 3.5, or 4.8mm Metal Staples for use with TA™ Auto Suture™ 30, 55, and 90 Reusable Staplers.

- 015427L
- 015433L
- 015441L
- 015451L
- 015458L
- 015477L
- 015485L

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Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 077608 0074 Rev. 00

PREMIUM MULTIFIRE TA™ Auto Suture™ Vascular Single Use Stapler with 2.5mm Metal Staples and PREMIUM MULTIFIRE TA™ Auto Suture™ 30mm Vascular Single Use Loading Unit with 2.5mm Metal Staples.

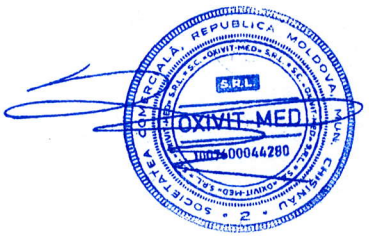
- 010315
- 010316L

ROTICULATOR™ Auto Suture™ 30V-3, 30 and 55 Single Use Staplers with 2.5, 3.5, or 4.8mm Metal Staples.

- 017612
- 017614
- 017615
- 017617
- 017619

MULTIFIRE ENDO TA™ Auto Suture™ 30 Single Use Staplers with 2.5 or 3.5mm Metal Staples, and MULTIFIRE ENDO TA™ Auto Suture™ 30 Single Use Loading Units with 2.5 or 3.5mm Metal Staples.

- 010901
- 010903
- 010911L
- 010913L



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Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 077608 0050 Rev. 03

Manufacturer:

Covidien llc
15 Hampshire Street
Mansfield, MA 02048
USA

Product:

Non-Active Implants
Non-Absorbable staple products

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G7 077608 0050 Rev. 03

Report no.: 713161282

Valid from: 2020-09-03
Valid until: 2024-05-26

Date, 2020-09-03

Christoph Dicks
Head of Certification/Notified Body

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Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 077608 0050 Rev. 03

Model(s): **Non-Absorbable staple products**

Parameters:

Endo GIA™ 30, 45 and 60mm Single Use Loading Units (articulating) with Tri-Staple™ Technology with standard or curved tip anvils and Metal Staples in the range of 2.0 to 3.0mm (Vascular/Medium (Tan)), 3.0 to 4.0mm (Medium/Thick (Purple)) and 4.0 to 5.0mm (Extra Thick (Black) – in 45 and 60mm):

- EGIA30AVM
- EGIA30CTAVM
- EGIA30AMT
- EGIA45AVM
- EGIA45CTAVM
- EGIA45CTAMT
- EGIA45AMT
- EGIA45AXT
- EGIA60AVM
- EGIA60CTAVM
- EGIA60AMT
- EGIA60CTAMT
- EGIA60AXT

Endo GIA™ 30 and 45mm Single Use Reloads (articulating) with 2.0mm Metal Staples and standard or curved tip anvils:

- EGIA45AV
- EGIA45CTAV
- EGIA30AV
- EGIA30CTAV

Endo GIA™ 45 and 60mm Single Use Reinforced Reloads (articulating) with Tri-Staple™ Technology with Metal Staples in the range of 3.0 to 4.0mm (Medium/Thick (Purple)) and 4.0 to 5.0mm (Extra Thick (Black)) and Preloaded with Polyglycolic Acid (PGA) Reinforcement Material.

- EGIATRS45AMT
- EGIATRS45AXT

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EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 077608 0050 Rev. 03

- EGIATRS60AMT
- EGIATRS60AXT

Endo GIA™ 30, 45 and 60mm Single Use Reloads (articulating) with Tri-Staple™ 2.0 Technology with standard or curved tip anvils and Metal Staples in the range of 2.0 to 3.0mm (Vascular/Medium (Tan)), 3.0 to 4.0mm (Medium/Thick (Purple)) and 4.0 to 5.0mm (Extra Thick (Black) - in 45 and 60mm) and 2.0mm (Extra Thin/Vascular (Gray) - in 30 and 45mm):

- SIG45AXT
- SIG60AXT
- SIG30AMT
- SIG30AV
- SIG30AVM
- SIG30CTAV
- SIG30CTAVM
- SIG45CTAMT
- SIG45CTAV
- SIG45CTAVM
- SIG60CTAVM
- SIG60CTAMT

Endo GIA™ 45 and 60mm Single Use Reinforced Reloads (articulating) with Tri-Staple™ 2.0 Technology with Metal Staples in the range of 3.0 to 4.0mm (Medium/Thick (Purple)) and 4.0 to 5.0mm (Extra Thick (Black)) and Preloaded with Polyglycolic Acid (PGA) Reinforcement Material:

- SIGTRS45AMT
- SIGTRS45AXT
- SIGTRS60AMT
- SIGTRS60AXT
- SIGTRSB45AMT
- SIGTRSB45AXT
- SIGTRSB60AMT
- SIGTRSB60AXT

Tri-Staple™ 2.0 45 and 60mm Single Use Intelligent Cartridges with Metal Staples in the range of 2.0 to 3.0mm [Vascular/Medium (Tan)] and 3.0 to 4.0mm [Medium/Thick (Purple)]:

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EC Certificate

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Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 077608 0050 Rev. 03

- SIGC45VM
- SIGC60VM
- SIGC45MT
- SIGC60MT

Signia™ Small Diameter (8mm) Short and Long 30 and 45mm Single Use Intelligent Reloads (articulating) with Curved Tip Anvils and Metal Staples in the range of 2.0mm (Vascular (Gray)) and 2.5mm (Vascular/Thin (White))

- SIGSDS30CTV
- SIGSDL30CTVT
- SIGSDL45CTVT

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Declaration of Conformity
DOC # 516

COVIDIEN

Legal Manufacturer
Covidien llc
15 Hampshire Street
Mansfield, Massachusetts 02048
USA

European Representative
Covidien Ireland Limited
IDA Business and Technology Park
Tullamore
Ireland

Product	Electrosurgical Vessel Sealing Devices
Classification (MDD)	Class IIb
Conformity Assessment Route	European Medical Device Directive 93/42/EEC amended by 2007/47/EC, Annex II
Reorder Codes / GMDN Codes	Refer to Appendix RE00255136

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacture. Covidien is exclusively responsible for the Declaration of Conformity.

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principals, the classification rules and the full quality assurance procedures at each stage, from the design of the device until its final inspection before being supplied, in accordance with Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods Regulations.

Notified Body	**BSI Group The Netherlands B.V.** Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands **Number: 2797**
EC Certificate	**CE 00500**
Standards to which Conformity is Declared	Refer to Appendix RE00255136
Place of Issue	Boulder, Colorado, USA
Date of Issue	July 13, 2020
Named Signatory Authority	Nancy Sauer
Title	Regulatory Affairs Director

Approval: Refer to RC247937 in PLM system

Declaration of Conformity
DOC # 516

COVIDIEN

Revisions:

DOC 516 supersedes DOC 416 under notified body number:0086.

	Approval in PLM system	Description
DOC 416 Rev. A (RE00024785)	RC084059	Initial release.
DOC 416 Rev. B (RE00024785)	RC085076	Added products LF5637 and LF5644.
DOC 416 Rev. C (RE00024785)	RC085586	Added products LF5637 and LF5644; incorrect attachment in Rev B.
DOC 416 Rev. D (RE00024785)	RC092670	Corrected device name for products LF5637 and LF5644.
DOC 416 Rev. E (RE00024785)	RC099369	Added product BZ4212.
DOC 416 Rev. F (RE00024785)	RC109481	Added products LF1923, LF1937, and LF1944.
DOC 416 Rev. G (RE00024785)	RC115903	Added product LF2019.
DOC 416 Rev. H (RE00024785)	RC153262	Added product LF1930T.
DOC 516 Rev. I (RE00024785)	RC189290	Changed Notified Body address from: BSI Group Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP UK Number: 0086 to: BSI Group The Netherlands B.V. Say Building, John M. Keynesplain 9, 1066 EP Amsterdam Netherlands Number: 2797
DOC 516 Rev. J (RE00024785)	RC210546	Removed products SURG II-8, SURG II-20, VLSURGGEN. Update of BZ4112 and BZ4212 to current standards list per RE00001840 in PLM system.
DOC 516 Rev. K (RE00024785)	RC247937	New template per RA-020D.

Declaration of Conformity
DOC # 516

COVIDIEN

Appendix RE00255136

This appendix declares the products included in the above referenced Declaration of Conformity. Refer to the external standards list in PLM system.

Catalog Number and Description	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)	External Standards List
BZ4112 BiZact™ Open/Sealer Divider	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece /electrode, bipolar, single-use	Open-surgery electrosurgical handpiece /electrode, bipolar, single-use	RE00001840
BZ4212 BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer Divider	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece /electrode, bipolar, single-use	Open-surgery electrosurgical handpiece /electrode, bipolar, single-use	RE00001840
LF1212 LigaSure™ Curved, Small Jaw, Open Sealer/Divider	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	R0043534
LF1212A LigaSure™ Curved, Small Jaw, Open Sealer/Divider	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	R0043534
LF1520 LigaSure™ Blunt Tip Open Sealer/Divider	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	R0043534
LF1537 LigaSure™ Blunt Tip Laparoscopic Sealer/Divider	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	RE00253948
LF1544 LigaSure™ Blunt Tip Laparoscopic Sealer/Divider	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	R0043534

OXIVIT-MED
10076000044280

Declaration of Conformity
DOC # 516

COVIDIEN

Catalog Number and Description	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)	External Standards List
LF1623 LigaSure™ Blunt Tip Open Sealer/Divider	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	R0038384
LF1637 LigaSure™ Blunt Tip Laparoscopic Sealer/Divider	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	R0005665
LF1644 LigaSure™ Blunt Tip Laparoscopic Sealer/Divider	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	R0038384
LF1723 LigaSure™ Maryland Jaw Open Sealer/Divider One-step Sealing	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	R0043534
LF1737 LigaSure™ Maryland Jaw Laparoscopic Sealer/Divider One-step Sealing	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	R0043534
LF1744 LigaSure™ Maryland Jaw Laparoscopic Sealer/Divider One-step Sealing	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	R0043534
LF1823 LigaSure™ Blunt Tip Open Sealer/Divider, Nano-coated	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	RE00001849
LF1837 LigaSure™ Blunt Tip Laparoscopic Sealer/Divider, Nano-coated	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	RE00001849

Declaration of Conformity
DOC # 516

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Catalog Number and Description	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)	External Standards List
LF1844 LigaSure™ Blunt Tip Laparoscopic Sealer/Divider, Nano-coated	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	RE00001849
LF1923 LigaSure™ Maryland Jaw Open Sealer/Divider One-step Sealing, Nano-coated	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/electrode, bipolar, single-use.	RE00128946
LF1937 LigaSure™ Maryland Jaw Laparoscopic Sealer/Divider One-step Sealing, Nano-coated	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	RE00128946
LF1944 LigaSure™ Maryland Jaw Laparoscopic Sealer/Divider One-step Sealing, Nano-coated	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	RE00128946
LF1930T LigaSure™ Maryland Jaw Thoracic Sealer/Divider One-step Sealing, Nano-coated	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	RE00128946
LF2019 LigaSure™ Exact Dissector, Nano-coated	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	R0038324
LF4318 LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	R0043534

Declaration of Conformity
DOC # 516

COVIDIEN

Catalog Number and Description	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)	External Standards List
LF4418 LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider, Nano-Coated	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	RE00001849
LF5637 LigaSure™ Retractable L-Hook Laparoscopic Sealer/Divider	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	R0013063
LF5644 LigaSure™ Retractable L-Hook Laparoscopic Sealer/Divider	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	R0013063
LigaSure 8 LigaSure™ Vessel Sealing System	IIb	Rule 9	N/A	Annex II	11490: General-purpose Electrosurgical Diathermy System Generator	General-purpose electrosurgical diathermy system generator	RE00253948
LS1020 LigaSure Atlas™ Tissue Fusion Open Instrument	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	R0043534
LS1037 LigaSure Atlas™ Tissue Fusion Laparoscopic Instrument	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	R0043534
LS1200 LigaSure Precise™ Tissue Fusion Open Instrument	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	RE00253948
LS1500 LigaSure™ Dolphin Tip Laparoscopic Sealer/Divider	IIb	Rule 9	Sterile	Annex II	57944: Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/ electrode, bipolar, single-use	RE00253948

Declaration of Conformity
DOC # 516

COVIDIEN

Catalog Number and Description	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)	External Standards List
LS1520 LigaSure™ Dolphin Tip Open Sealer/Divider	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	RE00253948
LS2111 LigaSure™ Tissue Fusion Electrode Angled Jaw	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use	RE00253948
LS2071 LigaSure™ Tissue Fusion Electrode	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use	RE00253948
LS3092 LigaSure™ Tissue Fusion Electrode Curved Jaw	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use	RE00253948
LS3112 LigaSure™ Tissue Fusion Electrode Curved Jaw	IIb	Rule 9	Sterile	Annex II	56296: Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use	Open-surgery electrosurgical handpiece/ electrode, bipolar, single-use	RE00253948

Declaration of Conformity
DOC # 516

COVIDIEN

Revisions:

	Date of Issue	Description
DOC 516 Appendix Rev. A (RE00255136)	RC248718	Initial Release.
DOC 516 Appendix Rev. B (RE00255136)	RC247937	Corrected entry for LigaSure 8 generator. The product is not sterile.

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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 00500**

Issued To: **Covidien llc**
15 Hampshire Street
Mansfield
Massachusetts
02048
USA

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1995-02-01** Date: **2020-09-18** Expiry Date: **2024-05-26**

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Certificate No: CE 00500

Certificate Scope:

The design, development and manufacture of electrosurgical generators and associated sterile and non-sterile accessories; sterile surgical smoke evacuation accessories; electrosurgical vessel sealing systems and associated sterile and non-sterile accessories; RF ablation generators and associated sterile and non-sterile accessories; microwave ablation generators and associated sterile and non-sterile accessories; sterile and non-sterile electromagnetic navigation accessories; ultrasonic surgical systems and associated sterile and non-sterile accessories.

Spanish:

Diseño, desarrollo y manufactura de generadores electroquirúrgicos y accesorios estériles y no estériles relacionados; accesorios estériles de evacuación de humo quirúrgico; sistemas electroquirúrgicos de sellado de vasos sanguíneos y accesorios estériles y no estériles relacionados; generadores de RF de ablación y accesorios estériles y no estériles relacionados; generadores de ablación por microondas y accesorios estériles y no estériles relacionados; accesorios de navegación electromagnética estériles y no estériles; sistemas quirúrgicos ultrasónicos y accesorios estériles y no estériles relacionados.

Portuguese:

Concepção, desenvolvimento e fabricação de geradores eletro-cirúrgicos e acessórios estéreis e não estéreis associados, acessórios estéreis de evacuação de fumaça cirúrgica, sistemas eletro-cirúrgicos de selagem de vasos e acessórios estéreis e não estéreis associados, geradores de ablação por RF e acessórios estéreis e não estéreis associados, geradores de ablação por microondas e acessórios estéreis e não estéreis associados, acessórios de navegação eletromagnética estéreis e não estéreis, sistemas cirúrgicos ultrassônicos e acessórios estéreis e não estéreis associados.

First Issued: **1995-02-01** Date: **2020-09-18** Expiry Date: **2024-05-26**

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Supplementary Information to CE 00500

Issued To:

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NBOG code	Device description	Intended purpose per IFU
Class IIb		
MD 1104	Electrosurgical electrodes	Intended to be used to remove tissue and control bleeding by use of high-frequency electrical current.
MD 1104	Electrosurgical and vessel sealing RF generators	Intended for use with monopolar and bipolar accessories for cutting, coagulating, desiccating, and fulgurating tissue and sealing (fusing) vessels.
MD 1104	Electrosurgical smoke evacuation system accessories and electrodes	Intended for use with standard monopolar electrosurgical generators, standard monopolar electrodes, and smoke evacuators
MD 1104 MD 1301 MD 0102	RF ablation generators and accessories	Intended for use in percutaneous, laparoscopic, and intraoperative coagulation and ablation of tissue, including partial or complete ablation of non-resectable liver tumors and osteoid osteoma tumors within bone

First Issued: **1995-02-01** Date: **2020-09-18** Expiry Date: **2024-05-26**

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Supplementary Information to CE 00500

Issued To:

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NBOG code	Device description	Intended purpose per IFU
MD 1402	Microwave ablation generators and accessories.	Intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors. It is not for use in cardiac procedures.
MD 1104	Cordless ultrasonic generator and accessories	Indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The device can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open and endoscopic procedures. Can be used to coagulate isolated vessels up to 5 mm in diameter.

First Issued: **1995-02-01** Date: **2020-09-18** Expiry Date: **2024-05-26**

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Supplementary Information to CE 00500

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NBOG code	Device description	Intended purpose per IFU
Class IIa		
MD 0102	Smoke evacuation accessories	N/A
MD 1301	Temperature probes for ablation systems	N/A
MD 1402	Electromagnetic navigation accessories	N/A

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00500**

Date: **2020-09-18**

Issued To: **Covidien llc**
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Date	Reference Number	Action
01 February 1995		First Issued.
13 December 1996		Addition of Sub-contractors.
22 June 1998		Addition of Sub-contractors.
25 January 1999		Addition of Sub-contractors.
19 April 1999		Addition of Sub-contractors.
28 February 2000		Addition of sterilisation Sub-Contractor.
20 April 2000		Addition of Sub-Contractor.
24 July 2000		Extension to the scope, bipolar monitoring devices added.
12 July 2001		Addition of Sub-Contractors and Certificate renewal.
03 April 2003	4356583	Addition of Sub-Contractors and removal of Sub-Contractors.
5 October 2003	4356583	Extension of scope to include lesion generators and the addition of sub-contractor Ion Beam Applications in Queensbury New York for Ethylene Oxide Sterilisation.
24 February 2005	4647875	Certificate renewal and issue in new format.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00500**

Date: **2020-09-18**

Issued To: **Covidien llc**
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Date	Reference Number	Action
21 March 2006	4799198	Change of address format. Addition of sub-contractors: Gambro BCT (Lakewood), Sterigenics (Willowbrook), Sterigenics (Gurnee) and Linemaster (Woodstock). Change of sub-contractor address: Beam One (Lima). Removal of subcontractors: Steris Isomedix (Sandy), Delphi Medical Systems (Longmont) and Sterigenics (Santa Teresa).
07 February 2008	7068083	Extension to scope for Microwave generator. Addition of significant subcontractors 'Thermo Fisher Scientific', 'HEI Inc' in relation to the manufacture of microwave generators and accessories. Addition of 'Covidien Medical Products (Shanghai) Manufacturing' and 'Buffalo Filters, Buffalo' as a significant subcontractor for manufacturing activities Maintenance of addresses for other significant subcontractors.

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Certificate No: **CE 00500**

Date: **2020-09-18**

Issued To: **Covidien llc**
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Date	Reference Number	Action
18 February 2009	7316357	Certificate re-issue due to: change of company name, removal of subcontractor 'Nellcor Puritan Bennett Mexico', change of subcontractor company name 'Aaron Medical Industries, Inc.' to 'Bovie Medical Corp', change of subcontractor company name 'Gambro BCT, Inc.' to 'Caridian BCT Sterilization Services, Inc.' and addition of "Covidien Ireland Limited" as EU Rep.
27 January 2010	7464667	Certificate renewal – scope amended "ultrasonic surgical aspirators and associated accessories" deleted "Lesion" amended to "ablation". Subcontractors removed: Kendall, a division of Tyco Healthcare Group LP, Norfolk UK– Gamma Sterilization, United States Surgical (USS) North Haven US – Manufacture & Design, HEI Inc, Boulder, US – Manufacture. Address amendment for Bovie Medical Corp and name correction for Cardian BCT. Address change for Design Standards Corporation from 182 Ceda Road to 957 Clarement Road.
16 April 2010	7510978	Change company name from Covidien LP (formerly known as Valleylab a division of Tyco Healthcare Group LP) to Valleylab, a division of Tyco Healthcare Group LP.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00500**

Date: **2020-09-18**

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Date	Reference Number	Action
10 November 2010	7603788	Company name change from Valleylab, a division of Tyco Healthcare Group LP to Covidien Energy-based Devices . The addition of Covidien Energy-based Devices as a significant sub contractor for Design and Manufacture. Changes to the format of the address on the certificate and to Covidien Energy-based Devices address.
13 April 2012	7817940	Extension of scope to include "ultrasonic surgical systems and associated accessories."
12 June 2012	7841245	Subcontractor name change from 'Caridian BCT Inc' to 'Terumo BCT'. The addition of Synergy Health (Suzhou) as a significant subcontractor for Sterilisation. Subcontractor name change from 'BeamOne, LLC' to Synergy Health Applied Sterilization Technologies, LLC' in 2 places.
07 January 2013	7930922	Addition of subcontractors Accellent Inc, El Paso, Texas and Venusa de Mexico S.A. de C.V., Chihuahua, Mexico both for manufacturing services.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00500**

Date: **2020-09-18**

Issued To: **Covidien llc**
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Date	Reference Number	Action
26 January 2015	8258195	Correction of subcontractor address for, 'Buffalo Filter and New Deantronics Taiwan Ltd.'. Addition of subcontractor, 'Buffalo Filter, CEA Medical Manufacturing, DeRoyal Industries, Inc., Modern Medical Equipment Manufacturing Ltd., SEI MEDICAL S.A. DE C.V. and Vanguard AG', for Sterile manufacture. Addition of subcontractor, 'Electrochem Solutions Inc, Contract Medical Manufacturing, LLC, New Deantronics Taiwan Ltd. for Design and manufacture.
26 January 2015	8258496	Certificate renewal.
05 October 2015	8318433	Addition of subcontractor, 'Covidien llc., 161 Cheshire Lane Suite 100, Plymouth, Minnesota, 55441-5433, USA', for manufacture and 'Emblation Microwave, Forrester Lodge, Inglewood, Alloa, FK10 2HU, Scotland, UK', for manufacture, design. Change of subcontractor name from Venusa de Mexico S.A. de C.V. an Accellent Company to Lake Region Medical. Amendment to scope.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00500**

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Date	Reference Number	Action
30 March 2016	8470731	Removal of subcontractor, 'Electrochem Solutions Inc, 13955 SW Milikan Way, Beaverton, Oregon 97005, USA'. Change of subcontractor name from, 'Covidien Energy-based Devices (Formerly Valleylab, a division of Tyco Healthcare Group LP)', to 'Covidien', for manufacture, design. Addition of subcontractor, 'Greatbatch Medical S. de R.L. de C.V., Calle 5 Norte No. 511, Ciudad Industrial, Tijuana, Baja California, 22444, Mexico', for manufacture. Amendment to scope.
06 May 2016	8524761	Remove duplicate EU representative.
01 March 2019	7794476	Administrative Subcontractor Service wording update for '*Sterile Manufacture*' to '*Gamma Sterilization, Manufacture*' for Buffalo Filter, division of MEDTEK, 5900 Genesee Street, New York. '*Sterile Manufacture*' to '*Gamma Sterilization, ETO Sterilization, Dry Heat Sterilization, Moist Heat Sterilization, Manufacture*' for CEA Medical Manufacturing, 1735 Merchants Court, Colorado.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00500**

Date: **2020-09-18**

Issued To: **Covidien llc**
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Date	Reference Number	Action
		'*Sterile Manufacture*' to '*ETO Sterilization, Manufacture*' for DeRoyal Industries, Inc, 200 DeBusk Lane, Tennessee '*Sterile Manufacture*' to '*Manufacture*' for Modern Medical Equipment, Gold King Ind. Bldg., Hong Kong '*Sterile Manufacture*' to '*Manufacture*' for SEI MEDICAL S.A. DE C.V., Roberto Fierro y Francisco Sarabia, Juarez '*Sterilization*' to '*ETO Sterilization*' for Sterigenics US, LLC, 7775 South Quincy, Illinois '*Sterilization*' to '*ETO Sterilization*' for Synergy Health (Suzhou), 26 Xinchang Road, Jiangsu '*Sterilization*' to '*Gamma Sterilization*' for Synergy Health Americas, 500 West 4th Street, Ohio '*Sterile Manufacture*' to '*Gas Plasma Sterilization, Manufacture*' for Vanguard AG, Landsberger Str. 266, Berlin Traceable to NB 0086.

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Date	Reference Number	Action
17 October 2019	8747987	Addition of the subcontractors: Covidien (Plainfield); Medtronic Engineering and Innovation Center Private Ltd; NextPhase Medical Devices, LLC; Covidien (Tijuana); Royal Sterilization Systems; Cadex Electronics Inc.; Bovie Medical Corporation; New Deantronics Taiwan Ltd.; Sterigenics Shanghei ETO Ltd.; Sterigenics US, LLC.; Isomedix Operations, Inc.; Covidien llc, GI Solution; Sotera Health LLC; Trelleborg Sealing Solutions Tustin, Inc. Removal of the subcontractors: SEI MEDICAL S.S. DE C.V.; Accellent, Inc.; BOWA-Electronic GmbH & Co. KG; Linemaster Switch Corporation; United States Surgical (USS) A Div of Tyco Healthcare Group LP; CEA Medical Manufacturing; Synergy Health – Applied Sterilization Technologies, LLC (Denver, Co); Synergy Health Americas; Cole-Parmer Instrument Company; Design Standards Corporation; HEI, Inc.; Kendall, a division of Tyco, Nicolay GmbH; Sterigenics US, LLC (Gurnee, IL); Sterigenics (Queensbury, NY); Sutter Medizintechnik GmbH. Clarified scope wording adding to system granularity and an extension to scope to include surgical navigation.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00500**

Date: **2020-09-18**

Issued To: **Covidien llc**
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Date	Reference Number	Action
		Corrected names or addresses of subcontractors to align with ISO certificates: Covidien LLC; Buffalo Filter, LLC.; DeRoyal Industries, Inc.; Emblation Ltd.; Vanguard AG. Maintenance of subcontractor activities to align with BSI subcontractor activities for: Buffalo Filter, division of MEDTEK; DeRoyal Industries, Inc.; Emblation Ltd; Sterigenics US, LLC; Vanguard AG; Covidien LLC; "Finished device supplier" activity added to Emblation Ltd.; "ETO Sterilization" removed from DeRoyal Industries, Inc. activities.
24 January 2020	3061488	Certificate renewal. Amended scope to remove "procedure planning software", "software de planificacion de procedimientos" and "software de planeamento de processos". Removed subcontractors: Contract Medical Manufacturing, LLC, Oxford, USA; DeRoyal Industries, Inc., Powell, USA; Royal Sterilization Systems, New Tazewell, USA; Sterigenics US, LLC, Willowbrook, USA. Changed subcontractors: Covidien, LLC, Tijuana, Mexico to add Control of Sterilization and make a spelling correction to the name; Modern Medical Equipment Manufacturing Ltd to update address;

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00500**

Date: **2020-09-18**

Issued To: **Covidien llc**
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Date	Reference Number	Action
		Buffalo Filter, LLC, Lancasters, USA to change "Control of Manufacture" to "Manufacture". Spelling corrections to the names of: Covidien llc, Mansfield, USA; Covidien llc, Plainfield, USA; Covidien llc, Plymouth, USA Added subcontractors: Isomedix Operations, Inc., San Diego, USA for ETO Sterilization; Medtronic B.V., Heerlen, The Netherlands as EU Representative; Midwest Sterilization Corporation, Jackson, USA for ETO Sterilization. Added Product Table.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00500**

Date: **2020-09-18**

Issued To: **Covidien llc**
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Date	Reference Number	Action
18 September 2020	3175231	Removed subcontractor Buffalo Filter, LLC. Added subcontractor ConMed Corporation for Design, Control of Manufacture, Finished Device Supplier and Control of Sterilization. Added subcontractor Consolidated Medical Equipment Company for Manufacture. Correction to subcontractor services supplied: •"Finished Device Supplier" added to Bovie Medical Corporation, New Deantronics Taiwan Ltd. •"Finished Device Supplier" removed from Covidien llc, Plainfield, Covidien llc, Tijuana, Covidien llc, Plymouth, Covidien llc, GI Solutions. •"Assembly" changed to "Manufacture" for Trelleborg Sealing Solutions Tustin, Inc. •"Control of Sterilzation" added to Covidien llc, Plymouth and Kirwan Surgical Products LLC Correction to address of Emblation Ltd from FK10 2HU, Scotland to Scotland, FK10 2HU, UK. Correction to address of Medtronic Engineering and Innovation Center Private Ltd, correcting Hyderadad to Hyderabad Removed subcontractor NextPhase Medical Devices. Added subcontractor International Sterilization Laboratory, LLC for ETO Sterilization Added Isomedix Operations, Inc(Chester) for E Beam Sterilization

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00500**

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Issued To: **Covidien llc**
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Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
20 July 2021	3479846	Addition of significant subcontractor Sterigenics Radiation Technologies, LLC

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Inspiring trust for a more resilient world.

20th July 2021

Covidien llc
15 Hampshire Street
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 00500	93/42/EEC Annex II excluding Section 4	3479846	Addition of significant subcontractor Sterigenics Radiation Technologies, LLC

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack

Gary Slack
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
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SUSTAINABLE DEVELOPMENT GOALS

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 00500**

Date: **2020-09-18**

Issued To: **Covidien llc**
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Subcontractor:	**Service(s) supplied**
Bovie Medical Corporation 5115 Ulmerton Road Clearwater Florida 33760 USA	**Design** **Finished Device Supplier** **Manufacture**
Cadex Electronics, Inc. 22000 Fraserwood Way Richmond British Columbia V6W 1J6 Canada	**Manufacture**
ConMed Corporation 6455 S Yosemite Street Greenwood Village Colorado 80111 USA	**Control of Manufacture** **Control of Sterilization** **Design** **Finished Device Supplier**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 00500**
Date:	**2020-09-18**
Issued To:	**Covidien llc** **15 Hampshire Street** **Mansfield** **Massachusetts** **02048** **USA**

Subcontractor:	**Service(s) supplied**
Consolidated Medical Equipment Company Ave. Alejandro Dumas No. 11321 Complejo Industrial Chihuahua Chihuahua Chihuahua 31136 Mexico	**Manufacture**
Covidien Ireland Limited IDA Business and Technology Park Tullamore Ireland	**EU Representative**
Covidien llc 2824 Airwest Boulevard Plainfield IN 46168 USA	**Labelling** **Packaging**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 00500**
Date:	**2020-09-18**
Issued To:	**Covidien llc** **15 Hampshire Street** **Mansfield** **Massachusetts** **02048** **USA**

Subcontractor:	**Service(s) supplied**
Covidien llc Boulevard Insurgentes 19030 Libramiento Tijuana B.C. 22225 Mexico	**Control of Sterilization** **Manufacture**
Covidien llc 5920 Longbow Drive Boulder Colorado 80301 USA	**Design** **Finished Device Supplier** **Labelling** **Manufacture** **Packaging**
Covidien llc 161 Cheshire Lane Suite 100 Plymouth Minnesota 55441-5433 USA	**Control of Sterilization** **Manufacture**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 00500**
Date:	**2020-09-18**
Issued To:	**Covidien llc** **15 Hampshire Street** **Mansfield** **Massachusetts** **02048** **USA**

Subcontractor:	**Service(s) supplied**
Covidien llc, GI Solutions 540 Oakmead Parkway Sunnyvale CA 94085 USA	**Manufacture**
Covidien Medical Products (Shanghai) Manufacturing, LLC Building #10 789 Puxing Road Shanghai 201114 People's Republic of China	**Manufacture**
Emblation Ltd. 3 Forrester Lodge Inglewood, Alloa Scotland FK10 2HU United Kingdom	**Design** **Finished Device Supplier** **Manufacture**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 00500**

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Subcontractor:	**Service(s) supplied**
Greatbatch Medical S. de R.L. de C.V. Calle 5 Norte No. 511 Ciudad Industrial Tijuana BC CP 22444 Mexico	**Manufacture**
International Sterilization Laboratory, LLC 217 Sampey Road Groveland Florida 34736 USA	**ETO Sterilization**
Isomedix Operations, Inc 2 Nucifora Boulevard Chester New York 10918 USA	**Radiation (E Beam Sterilization)**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 00500**
Date:	**2020-09-18**
Issued To:	**Covidien llc** **15 Hampshire Street** **Mansfield** **Massachusetts** **02048** **USA**

Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 1000 S. Sarah Place Ontario California 91761 USA	**Radiation (E Beam Sterilization)**
Isomedix Operations, Inc. 7685 Saint Andrews Avenue San Diego California 92154 USA	**ETO Sterilization**
Kirwan Surgical Products LLC 180 Enterprise Drive Marshfield Massachusetts 02050 USA	**Control of Sterilization** **Manufacture**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 00500**
Date:	**2020-09-18**
Issued To:	**Covidien llc** **15 Hampshire Street** **Mansfield** **Massachusetts** **02048** **USA**

Subcontractor:	**Service(s) supplied**
Lake Region Medical Venusa de Mexico S.A. de C.V. 1525-6 Hertz Street Cuidad Juarez Chihuahua 32470 Mexico	**Manufacture**
Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands	**EU Representative**
Medtronic Engineering and Innovation Center Private Ltd DLF Cyber City, Block No. 3 APHB Colony, Gachibowli, Telangana Ground Floor, Plot No. 129-132, APHB Hyderabad 500019 India	**Design**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 00500**

Date: **2020-09-18**

Issued To: **Covidien llc**
15 Hampshire Street
Mansfield
Massachusetts
02048
USA

Subcontractor:	**Service(s) supplied**
Midwest Sterilization Corporation P.O. Box 411 1204 Lenco Avenue Jackson Missouri 63755 USA	**ETO Sterilization**
Modern Medical Equipment Manufacturing Ltd Flat A, 11/F Mai Wah Ind. Bldg. 1- 7 Wah Sing Street Kwai Chung, New Territories Hong Kong	**Manufacture**
New Deantronics Taiwan Ltd. 12F, No. 51, Sec. 4, ChongYang Rd. Tu Cheng Dist. New Taipei City 23675 Taiwan	**Design** **Finished Device Supplier** **Manufacture**

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Subcontractor:	**Service(s) supplied**
Sterigenics Radiation Technologies, LLC 7695 Formula Place San Diego California 92121 USA	**Radiation (E Beam Sterilization)**
Sterigenics Shanghai ETO, Ltd. No. 333 Shuang Hui Road Yang Shan Free Port Shanghai 201308 China	**ETO Sterilization**
Sterigenics US, LLC 4900 Gifford Avenue Los Angeles California 90058 USA	**ETO Sterilization**

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USA

Subcontractor:	**Service(s) supplied**
Synergy Health (Suzhou) Sterilization Technologies Ltd No. 26 Xinchang Road Suzhou Industrial Park Jiangsu 215125 China	**ETO Sterilization**
Synergy Health AST, LLC 9020 Activity Road, Suite D San Diego California 92126 USA	**Radiation (E Beam Sterilization)**
Terumo BCT, Inc. 10811 W. Collins Avenue Lakewood Colorado 80215 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Trelleborg Sealing Solutions Tustin, Inc. 222 Industrial Park Drive Elk Rapids MI 49629 USA	**Manufacture**
Vanguard AG Landsberger Str. 266 Berlin 12623 Germany	**Gas Plasma Sterilization** **Manufacture**

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