

ORDIN DE PLATĂ		Nr.	1204	DATA EMITERII	7 iulie 2026	TIP.DOC.1
PLĂTIȚI:	21 500-00	LEI	Douazeci si unu mii cinci sute lei 00 bani			
PLĂTITOR: (R) BIOSISTEM MLD SRL		CODUL IBAN		MD95ML000000002251429243		
		CODUL FISCAL		1010600028048		
		CODUL LEI				
PRESTATORUL PLĂTITOR: BC'Moldindconbank'S.A.						
BENEFICIAR: (R) Agentia Asigurare Resurse si Administrare Patrimoniu a Ministerului Apararii		CODUL IBAN		MD28TRPCAA518410A00572AA		
		CODUL FISCAL		1006601001229		
		CODUL LEI				
PRESTATORUL BENEFICIAR: Ministerul Finantelor - Trezoreria de Stat						
DESTINAȚIA PLĂȚII: /P/21500,00/M//1010600028048/BIOSISTEM MLD SRL//Pentru garantia pentru oferta la procedura de achiziție publica nr. ocds-b3wdp1-MD-1781683906715 din 08.07.2026/				TIPUL TRANSFERULUI NORMAL/URGENT/INSTANT N L.Ș.		
CODUL TRANZACȚIEI	DATA PRIMIRII	DATA EXECUTĂRII		LAZAR ANNA		
101				LAZAR ANNA		
Document transmis prin instrument de plată electronic cu acces la la distanță de tip internet-banking				SEMNĂTURILE EMITENTULUI		
				L.Ș.		
MOTIVUL REFUZULUI						
Nota: Responsabilitatea privind veridicitatea și corectitudinea informației indicate în ordinul de plată îi revine emitentului*						
*Regulamentul cu privire la transferul de credit, debitarea directă și atribuirea codurilor IBAN, aprobat prin HCE al BNM nr. 108 din 08.06.2023						

Digitally signed by Poiata Vitalie
Date: 2026.07.07 17:02:48 EEST
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ





GUVERNUL
REPUBLICII
MOLDOVA



SERVICIUL FISCAL DE STAT



CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№

1315048

Din
От

07.07.2026 13:15



DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare

Фискальный код / Идентификационный номер

1010600028048

Denumirea

Наименование

Societatea cu Răspundere Limitată "BIOSISTEM MLD"



ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI

INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСТВИЯ ИЛИ НАЛИЧИЯ

ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie

На дату выдачи данной справки задолженность перед национальным публичным бюджетом составляет

0 MDL



VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО

22.07.2026 13:15



Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul guvernamental integrat EVO / Справка выдана в соответствии со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предоставленных Государственной налоговой службой на Интегрированный правительственный портал EVO.

Generat și semnat de Portalul guvernamental integrat EVO la 07.07.2026 13:15

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022

Сертификат подписан электронной подписью в соответствии с Законом № 124 от 19.05.2022



Certificatul este descărcat din Portalul guvernamental integrat EVO (evo.gov.md) și este semnat electronic de către posesorul acestui portal și are aceiași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică (msign.gov.md)

Сертификат скачен с Интегрированный правительственный портал EVO (evo.gov.md) и подписан электронной подписью владельца портала и имеет такую же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлинности электронной подписи можно осуществить с помощью Интегрированный правительственный портал EVO (msign.gov.md)

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "BIOSISTEM MLD"
— ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT —

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării

12.08.2010

Data eliberării

12.08.2010

Svirepova Ludmila, registrator

*Funcția, numele, prenumele persoanei
care a eliberat certificatul*

L. Svirepova
semnătura

MD 0101250





AGENȚIA SERVICII PUBLICE

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. 531522 data 15.09.2023

Denumirea completă: **Societatea cu Răspundere Limitată "BIOSISTEM MLD"**

Denumirea prescurtată: **"BIOSISTEM MLD" S.R.L.**

Forma juridică de organizare: **Societate cu răspundere limitată,**

Numărul de identificare de stat și codul fiscal (IDNO): **1010600028048**

Data înregistrării de stat: **12.08.2010**

Sediul: **MD-2001, str. Albișoara, 16/1, ap. 7, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1. Activitatea farmaceutică; importul și (sau) producerea articolelor de parfumerie și cosmetică**
- 2. Fabricarea, comercializarea, asistența tehnică, repararea și verificarea articolelor de tehnică și optică medicală**
- 3. Acordarea asistenței medicale de către instituțiile medico-sanitare private**
- 4. Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului**
- 5. Întreținerea și repararea mașinilor de birou și a tehnicii de calcul**
- 6. Consultații în domeniul sistemelor de calcul**

Capitalul social: **5400 lei,**

Administrator: **POIATA VITALIE, IDNP 0983103892591,**

Asociații:

1. **POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%**

Beneficiar efectiv:

- 1.1. **POIATA VITALIE, IDNP 0983103892591,**

2. **NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

- 2.1. **NASEDCHIN ALEXANDR, IDNP 2002001070747,**

3. **KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

- 3.1. **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 și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: **15.09.2023.**

**Registrator în domeniul
înregistrării de stat**

Digitally signed by Rusu Diana
Date: 2023.09.15 16:44:17 EEST
Reason: MoldSign Signature
Location: Moldova



Rusu Diana



EB 0461494



BC "MOLDINDCONBANK" S.A.

Filiala "Invest"

Republica Moldova, MD-2068
mun. Chișinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 - 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московской, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent în moneda națională al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML000000002251429243**.

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza
Tel. 43-45-96

Lista fondatorilor Biosistem-mld SRL

Nr.	Nume, Prenume	IDNP
1.	Vitalie Poiata	0983103892591
2.	Alexandr Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362



MD-2005 mun.Chișinău, str. Albișoara, 38
Tel. (022) 820-770, Email: am@am.gov.md

CONFIRMARE

privind înregistrarea în „Lista producătorilor” de produse
supuse reglementărilor de responsabilitate extinsă a producătorului
(echipamente electrice și electronice)

În scopul plasării pe piață a produselor de echipamente electrice și electronice, în conformitate cu prevederile art. 12 alin. (5) și alin. (14) lit. b) din Legea nr. 209 din 29.07.2016 privind deșeurile, și punctele 46 – 50 din Regulamentul privind deșeurile de echipamente electrice și electronice, aprobat prin Hotărârea Guvernului nr. 212 din 07.03.2018, se emite numărul de înregistrare

MD2024-10-EEE-049

pentru BIOSISTEM MLD, IDNO: 1010600028048, cu adresa juridică: mun. Chișinău, str. Albișoara 16/1, ap. 1.

Numărul de înregistrare este valabil începînd cu data de 30.10.2024 pînă la data de 30.10.2027.

Director adjunct
Nicolae STRULEA

To,
Biosistem-mld SRL
Albisoara 16/1 ap.7
Chisinau, R. Moldova

26.02.2019

MANUFACTURERS AUTHORIZATION

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, ("Mindray") manufacturer of Hematology analyzers, hereby authorize: **Biosistem-mld SRL**, with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, to submit bids and subsequently negotiate and sign Contracts.

The authorization period is valid one year from issue date and automatically renewable if no termination letter is issued by either part.

Neither this Letter of Authorization nor any further extension, will impose any obligation or grant any rights regarding further distribution of Product, nor allow any party to seek compensation for goodwill developed during the term of Letter of Authorization or any further extension.

Best regards,



Luan Haijiao

Deputy Manager of International Sales and Marketing System,
Commonwealth of Independent States
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

**SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.**

Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan,
Shenzhen 518057, P.R. China
Tel: +86 755 81888998
Fax: +86 755 26582680
Website: www.mindray.com

Declaration of Conformity DOC # 507

**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 Generators

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 RE00254770

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 RE00254770

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 # 507



Revisions:

DOC 507 supersedes DOC 407 under notified body number:0086.

	Approval in PLM System	Description
DOC 407 Rev. A (RE00055001)	RC055150	Initial release.
DOC 407 Rev. B (RE00055001)	RC093433	Added product ForceTriad ZE.
DOC 407 Rev. C (RE00055001)	RC106695	Added product VLFX8GEN.
DOC 407 Rev. D (RE00055001)	RC158813	Updated VLFT10GEN and VLFX8Gen to reflect the current version of standard ISO 15223-1:2016
DOC 507 Rev. E (RE00055001)	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 ForceTriad removed.
DOC 507 Rev. F (RE00055001)	RC198822	Added product ForceTriad per CE00500 MDD recertification Sample Plan.
DOC 507 Rev. G (RE00055001)	RC210546	Removal of Surg II-8, SurgII-20, and VLSURGGEN.
DOC 507 Rev. H (RE00055001)	RC212837	VLLS10GEN standards updated to reflect R0053174.
DOC 507 Rev. I (RE00055001)	RC237598	VLLS10GEN standards list corrected from previous revision and VLFT10GEN standards updated to reflect R0053174. VLFX8GEN to reflect the current version of standard ISO 13485:2016
DOC 507 Rev. J (RE00055001)	RC247937	New template per RA-020D.



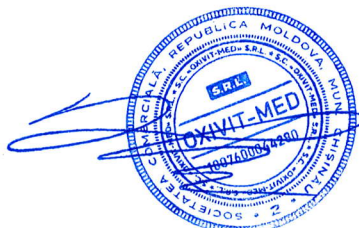
Declaration of Conformity DOC # 507



Appendix RE00254770

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

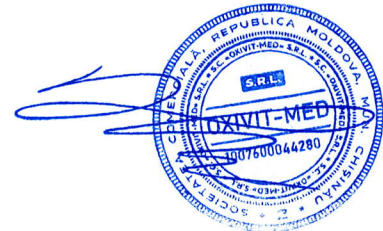
Catalog Number and Description	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)	External Standards List
Force FX-8C Force FX™ Electrosurgical Generator 8C 240 V	IIb	Rule 9	N/A	Annex II	11490: General- purpose Electrosurgical Diathermy System Generator	General- purpose Electrosurgical Diathermy System Generator	RE00061244
Force FX-8CA Force FX™ Electrosurgical Generator 8CA Autobipolar 240 V	IIb	Rule 9	N/A	Annex II	11490: General- purpose Electrosurgical Diathermy System Generator	General- purpose Electrosurgical Diathermy System Generator	RE00061244
Force FX-C Force FX™ Electrosurgical Generator C 120 V	IIb	Rule 9	N/A	Annex II	11490: General- purpose Electrosurgical Diathermy System Generator	General- purpose Electrosurgical Diathermy System Generator	RE00061244
Force FX-CS Force FX™ Electrosurgical Generator CS 120 V	IIb	Rule 9	N/A	Annex II	11490: General- purpose Electrosurgical Diathermy System Generator	General- purpose Electrosurgical Diathermy System Generator	RE00061244
Force FX-8CS Force FX™ Electrosurgical Generator 8CS 240 V	IIb	Rule 9	N/A	Annex II	11490: General- purpose Electrosurgical Diathermy System Generator	General- purpose Electrosurgical Diathermy System Generator	RE00061244
Force FX-8CAS Force FX™ Electrosurgical Generator 8CA Autobipolar 240 V	IIb	Rule 9	N/A	Annex II	11490: General- purpose Electrosurgical Diathermy System Generator	General- purpose Electrosurgical Diathermy System Generator	RE00061244
ForceTriad ForceTriad™ Energy Platform	IIb	Rule 9	N/A	Annex II	11490: General- purpose Electrosurgical Diathermy System Generator	General- purpose Electrosurgical Diathermy System Generator	RE00174176



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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
FTBRKIT ForceTriad™ Bipolar Resection Activation Kit	IIb	Rule 9	N/A	Annex II	11490: General- purpose Electrosurgical Diathermy System Generator	General- purpose Electrosurgical Diathermy System Generator	RE00174176
FTRCKIT ForceTriad™ Remote Control Activation Kit	IIb	Rule 9	N/A	Annex II	11490: General- purpose Electrosurgical Diathermy System Generator	General- purpose Electrosurgical Diathermy System Generator	RE00174176
VLFT10GEN Valleylab™ FT10 FT Series Energy Platform	IIb	Rule 9	N/A	Annex II	11490: General- purpose Electrosurgical Diathermy System Generator	General- purpose Electrosurgical Diathermy System Generator	R0053174
VLLS10GEN Valleylab™ LS10, LS Single Channel Vessel Sealing Generator	IIb	Rule 9	N/A	Annex II	11490: General- purpose Electrosurgical Diathermy System Generator	General- purpose Electrosurgical Diathermy System Generator	R0046040
VLFX8GEN Valleylab™ FX8 FX Series Energy Platform	IIb	Rule 9	N/A	Annex II	11490: General- purpose Electrosurgical Diathermy System Generator	General- purpose Electrosurgical Diathermy System Generator	RE00019992



Declaration of Conformity DOC # 507



Revisions:

	Date of Issue	Description
DOC 507 Appendix Rev. A (RE00254770)	RC248666	Initial Release.



EU MDR Declaration of Conformity

RE00302885

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EU MDR Declaration of Conformity (DoC) # 603

Manufacturer:

Covidien Inc
15 Hampshire Street
Mansfield, Massachusetts 02048
USA

Manufacturer SRN:

To be determined

Authorized Representative:

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

Authorized Representative SRN:

NL-AR-000006050

Notified Body:

Not Applicable

Conformity Assessment Certificate(s):

Annex IX: Conformity Assessment Based on a Quality Management System and on Assessment of Technical Documentation

Conformity Assessment Procedure:

Not Applicable for Class I (non-measuring, non-sterile, non-reusable) products, only DoC in accordance with Annex IV.

Risk Class:

Refer to the Products Covered table below

Classification Rule:

Refer to the Products Covered table below

Intended Purpose:

Refer to the Products Covered table below



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Statement:

We, Covidien llc, hereby declare under our sole responsibility that the product(s) specified herein conform to EU Medical Device Regulation 2017/745 and relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Other Union Legislation(s):

Union Legislation	Applicable Declaration of Conformity Document Number
SCBIGA, SCSTA	
RoHS 3 DIRECTIVE 2015/863	RE00288844
REGULATION (EU) 2017/745	RE00197250
SCSTA	
REACH (EC) No 1907/2006 and Directive 2006/121/EC	RE00276478
E0005-3C, E0017, E0502-1, E0507-B	
REACH (EC) No 1907/2006 and Directive 2006/121/EC	RE00295055
RoHS DIRECTIVE 2015/863	RE00295120
REGULATION (EU) 2017/745	RE00183046
E0560, E0560E	
RoHS DIRECTIVE 2015/863	RE00292613
REACH (EC) No 1907/2006 and Directive 2019/1194	RE00267106
REGULATION (EU) 2017/745	RE00181385
E0020V, E0021S, E0022W	
RoHS DIRECTIVE 2015/863	RE00312498
REACH (EC) No 1907/2006 and Directive 2019/1194	RE00306266
REGULATION (EU) 2017/745	RE00183046
FT0021S, FT0022W	
RoHS DIRECTIVE 2015/863	RE00291385
REACH (EC) No 1907/2006 and Directive 2019/1194	RE00294089
REGULATION (EU) 2017/745	RE00194763
SE3695, SEA3700, SEA3745	
RoHS 3 DIRECTIVE 2015/863	RE00297912
REACH (EC) No 1907/2006 and Directive 2006/121/EC	RE00297339
REGULATION (EU) 2017/745	RE00183749
SEA3730, SEA3741	
RoHS 3 DIRECTIVE 2015/863	RE00316499
REACH (EC) No 1907/2006 and Directive 2006/121/EC	RE00297407

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**Medtronic Controlled Information
CONFIDENTIAL**

00009859 Revision C



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Union Legislation	Applicable Declaration of Conformity Document Number
REGULATION (EU) 2017/745	RE00183749



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Medtronic

Place: Boulder, Colorado, USA
Name: Ben Cordileone
Title: Sr. Regulatory Affairs Manager

Signature:



Date: 12-Apr-2022



EU MDR Declaration of Conformity

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Medtronic

Products Covered

Product Name	Medtronic Product Identifier CFN	Risk Class	Classification Rule	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Intended Purpose	Quality Certificates
Sonicision™ Reusable Battery Insertion Guide	SCBIGA	Class I	Rule 1	0763000B0000 4457Q	60486, Surgical instrument battery insertion guide	K020280, Electrosurgical ultrasonic devices - accessories	RE00280978	The Sonicision Reusable Battery Insertion Guide is intended to facilitate the aseptic transfer of the non-sterile Sonicision Reusable Battery Pack into the Sonicision Curved Jaw Cordless Ultrasonic Dissection Device.	Not Applicable
Sonicision™ Sterilization Tray	SCSTA	Class I	Rule 1	0763000B0000 4467S	13730, Sterilization container	K020280, Electrosurgical ultrasonic devices - accessories	RE00280981	The Sonicision Reusable Sterilization Tray is intended to store the generator (SCGAA), battery (SCBA), and battery insertion guide (SCBIGA) during sterilization.	Not Applicable



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D00009859 Revision C

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Medtronic

Product Name	Medtronic Product Identifier	Risk Class	Classification Rule	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Intended Purpose	Quality Certificates
	CFN								
Valleylab™ Active Adapter, 4 mm	E0005-3C	Class I	Rule 1	0763000B0000 21575	35041, Electrosurgical cable adapter	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00219572	The E0005-3C, Valleylab™ Active Adapter, 4mm, is intended to be inserted into a single-pin monopolar instrument receptacle of an electrosurgical hardware unit and the 4mm plug of an active accessory is plugged into the adapter.	Not Applicable
Valleylab™ Universal Monopolar Adapter	E0017	Class I	Rule 1	0763000B0000 21575	35041, Electrosurgical cable adapter	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00219572	The Universal Monopolar Adapter, E0017, is intended to be plugged into the active accessory jack on all Covidien electrosurgical generators and designed to accept most standard active accessory plugs. Most standard foot switching active electrosurgical accessories have a connection plug which will fit into the plug receptacle of the E0017 adapter.	Not Applicable

EU MDR Declaration of Conformity

RE00302885

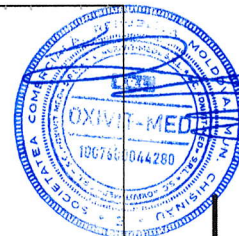
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Product Name	Medtronic Product Identifier CFN	Risk Class	Classification Rule	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Intended Purpose	Quality Certificates
Valleylab™ Monopolar Adapter	E0502-1	Class I	Rule 1	0763000B0000 21575	35041, Electrosurgical cable adapter	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00219572	The Valleylab™ Monopolar Adapter, E0502-1, is intended to allow the use of Covidien electrosurgical disposable active accessories with most electrosurgical generators. These adapters are made to accept the 1/8 inch diameter pin tip cable connector used on the power cord of these active accessories	Not Applicable
Valleylab™ Multiple Return/S Cord Adapter	E0507-B	Class I	Rule 1	0763000B0000 9698X	35041, Electrosurgical cable adapter	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00219572	The adapter is intended to monitor the continuity of the return electrode cable.	Not Applicable



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Medtronic

Product Name	Medtronic Product Identifier CFN	Risk Class	Classification Rule	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Intended Purpose	Quality Certificates
Valleylab™ REM™ Patient Return Electrode Cord	E0560	Class I	Rule 1	0763000B0000 1236X	47487, Medical device electrical cable, reusable	K020102, Electrosurgical Pads and Cables	RE00057404	The E0560 and E0560E Cords for Patient Return Electrodes are reusable cord/clamp assemblies that are intended to be used with compatible REM Polyhesive Adult Cordless Patient Return Electrodes.	Not Applicable
Valleylab™ Cord Clamp	E0560E	Class I	Rule 1	0763000B0000 1236X	47487, Medical device electrical cable, reusable	K020102, Electrosurgical Pads and Cables	RE00057404	The E0560 and E0560E Cords for Patient Return Electrodes are reusable cord/clamp assemblies that are intended to be used with compatible REM Polyhesive Adult Cordless Patient Return Electrodes.	Not Applicable
Valleylab™ Bipolar Forceps Cord, Reusable	E0020V	Class I	Rule 1	0763000B0000 1246Z	47487, Medical device electrical cable, reusable	K020102, Electrosurgical Pads and Cables	RE00133312	Cords are to electrically connect bipolar electrosurgical instruments to Covidien electrosurgical generators	Not Applicable
Valleylab™ Bipolar Forceps Cord, StorZ™*	E0021S	Class I	Rule 1	0763000B0000 1246Z	47487, Medical device electrical cable, reusable	K020102, Electrosurgical Pads and Cables	RE00133312	Cords are to electrically connect bipolar electrosurgical instruments to Covidien electrosurgical generators	Not Applicable



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Product Name	Medtronic Product Identifier CFN	Risk Class	Classification Rule	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Intended Purpose	Quality Certificates
Valleylab™ Bipolar Forceps Cord, Wolf™*	E0022W	Class I	Rule 1	0763000B0000 1246Z	47487, Medical device electrical cable, reusable	K020102, Electrosurgical Pads and Cables	RE00133312	Cords are to electrically connect bipolar electrosurgical instruments to Covidien electrosurgical generators	Not Applicable
ForceTriad™ Bipolar Resection Cord, Storz™*	FT0021S	Class I	Rule 1	0763000B0000 1246Z	47487, Medical device electrical cable, reusable	K020102, Electrosurgical Pads and Cables	RE00174174	The Bipolar Resection Cords are intended to electrically connect bipolar resectoscope electrosurgical instruments to compatible energy platforms for endoscopically controlled removal (resection) or coagulation of tissue using 0.9% NaCl solution (saline) as the irrigation medium.	Not Applicable



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Product Name	Medtronic Product Identifier	Risk Class	Classification Rule	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Intended Purpose	Quality Certificates
	CFN								
ForceTriad™ Bipolar Resection Cord, Wolf™*	FT0022W	Class I	Rule 1	0763000B000001 246Z	47487, Medical device electrical cable, reusable	K020102, Electrosurgical Pads and Cables	RE00174174	The Bipolar Resection Cords are intended to electrically connect bipolar resectoscope electrosurgical instruments to compatible energy platforms for endoscopically controlled removal (resection) or coagulation of tissue using 0.9% NaCl solution (saline) as the irrigation medium.	Not Applicable



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Product Name	Medtronic Product Identifier CFN	Risk Class	Classification Rule	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Intended Purpose	Quality Certificates
RAPIDVAC SMOKE EVACUATOR 220V	SE3695	Class I	Rule 1	0763000B0000033 77L	37861, Surgical plume evacuation system	K02010107, SMOKE EVACUATION DEVICES	RE00230798	The RapidVac™ Smoke Evacuator captures particulates and adsorbs gases from surgical smoke. The smoke evacuator is specifically designed to improve visibility and reduce potential health hazards associated with surgical smoke. It can be used in both open and laparoscopic procedures.	Not Applicable
RAPIDVAC 3 PORT FILTER RFID	SEA3700	Class I	Rule 1	0763000B0000033 77L	44979, Surgical plume evacuation system filter	K02010107, SMOKE EVACUATION DEVICES	RE00230798	The RapidVac™ ULPA Filter is intended to capture the smoke plume.	Not Applicable



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Product Name	Medtronic Product Identifier CFN	Risk Class	Classification Rule	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Intended Purpose	Quality Certificates
RAPIDVAC INTERLINK CABLE	SEA3730	Class I	Rule 1	0763000B0000033 77L	47487, Electrical- only medical device connection cable, reusable	K02010107, SMOKE EVACUATION DEVICES	RE00230798	The RapidVac™ Interlink Cable is intended to attach to a generator's RF activation port and to the smoke evacuator's Remote Activator jack.	Not Applicable
REMOTE SWITCH ACTIVATOR	SEA3741	Class I	Rule 1	0763000B0000033 77L	47487, Electrical- only medical device connection cable, reusable	K02010107, SMOKE EVACUATION DEVICES	RE00230798	The Remote Switch Activator (RSA) is intended to activate and deactivate the flow of the smoke evacuator when the device is in RapidVac+ mode.	Not Applicable
RAPIDVAC FOOTSWITCH	SEA3745	Class I	Rule 1	0763000B0000033 77L	36336, Footswitch, electrical	K02010107, SMOKE EVACUATION DEVICES	RE00230798	The RapidVac™ Footswitch is intended for footswitching operation with the smoke evacuator by simply plugging it into the footswitch jack on the front panel.	Not Applicable



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Common Specification(s)



The following common specifications were used to demonstrate conformity. Refer to Products Covered section for Standards list:

Number	Date of Issue	Title

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EU MDR Declaration of Conformity (DoC) # 603A

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

Manufacturer SRN: To be determined

Authorized Representative: Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

Authorized Representative SRN: NL-AR-000006050

Notified Body: Not Applicable

Contract Manufacturer: Linemaster Switch Corp.
29 Plaine Hill Road
Woodstock, CT 06281
USA

Conformity Assessment Certificate(s): Annex IX: Conformity Assessment Based on a Quality Management System and on Assessment of Technical Documentation

Conformity Assessment Procedure: Not Applicable for Class I (non-measuring, non-sterile, non-reusable) products, only DoC in accordance with Annex IV.

Risk Class: Class I

Classification Rule: Rule 1

Intended Purpose: This product is intended to activate monopolar electrosurgical energy from the generator to an instrument to be used with Covidien's line of electrosurgical generators.



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Statement:

We, Covidien, llc, hereby declare under our sole responsibility that the product(s) specified herein conform to EU Medical Device Regulation 2017/745 and relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Other Union Legislation(s):

Union Legislation	Applicable Declaration of Conformity Document Number
E6008, E6008L, E6009, E6009L, E6019, FT6003, FT6009, LF0500, LS0300	
RoHS DIRECTIVE 2015/863	RE00267600
REACH (EC) No 1907/2006 and Directive 2019/1194	RE00236973
REGULATION (EU) 2017/745	RE00194763



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Place: Boulder, Colorado, USA
Name: Ben Cordileone
Title: Sr. Regulatory Affairs Manager

Signature:



Date: 12-Apr-2022



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Products Covered



Product Name	Medtronic Product Identifier	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Quality Certificates
Valleylab™ Monopolar Footswitch	E6008	0763000B000016075	36336, Footswitch, electrical	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00208898	Not Applicable
Valleylab™ Bipolar Standard Footswitch	E6009	0763000B000016177	36336, Footswitch, electrical	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00208898	Not Applicable
Valleylab™ Bipolar Dome Footswitch	E6019	0763000B000016177	36336, Footswitch, electrical	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00208898	Not Applicable
Valleylab™ Three-Pedal Footswitch	FT6003	0763000B000016075	36336, Footswitch, electrical	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00208898	Not Applicable
ForceTriad™ FT Series Bipolar Resection Footswitch	FT6009	0763000B000016177	36336, Footswitch, electrical	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00208898	Not Applicable
LigaSure™ Tissue Fusion Footswitch, Orange	LF0500	0763000B000016177	36336, Footswitch, electrical	K020180, Electrosurgical Devices, Mono - and	RE00208898	Not Applicable

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				Bipolar - Accessories		
LigaSure™ Tissue Fusion Footswitch, Purple	LS0300	0763000B0000 16177	36336, Footswitch, electrical	K020180, Electrosurgic al Devices, Mono - and Bipolar - Accessories	RE00208898	Not Applicable
Valleylab™ Monopolar Footswitch	E6008L	0763000B0000 16075	36336, Footswitch, electrical	K020180, Electrosurgic al Devices, Mono - and Bipolar - Accessories	RE00208898	Not Applicable
Valleylab™ Bipolar Footswitch	E6009L	0763000B0000 16177	36336, Footswitch, electrical	K020180, Electrosurgic al Devices, Mono - and Bipolar - Accessories	RE00208898	Not Applicable



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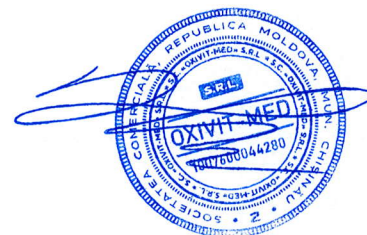
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Common Specification(s)

The following common specifications were used to demonstrate conformity:

Number	Date of Issue	Title
Certificate No.: C2019-02785	30-Sep- 2019	RE00181210: Linemaster ISO 13485 Certificate



**Declaration of Conformity
DOC # 509**



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 Pencils

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 RE00254771

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 RE00254771

Place of Issue Boulder, Colorado, USA
Date of Issue May 23, 2021

Named Signatory Authority Ben Cordileone
Title Principal Regulatory Affairs Associate

Approval: Refer to RC332890 in PLM system

Declaration of Conformity DOC # 509



Revisions:

DOC 509 supersedes DOC 409 under notified body number:0086.

	Approval in PLM System	Description
DOC 409 Rev. A (RE00097556)	RC103888	Initial release.
DOC 409 Rev. B (RE00097556)	RC108450	Updated products E2100, E2100E to include standards EN ISO 11607-1, ISTA 2A, ISO 11135-1, EN 556-1, EN ISO 11737-1, ISO 11737-2, EN ISO 14644-1, ISO 17664.
DOC 409 Rev. C (RE00097556)	RC165967	Added products SEP5000, SEP5000NSB, SEP5015, SEP5012NSB, SEP6000, SEP6000NSB, SEP6015, SEP6015NSB.
DOC 409 Rev. D (RE00097556)	RC187742	Update to reflect the current ISO 13485 Boulder certification for version 2016.
DOC 509 Rev. E (RE00097556)	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 509 Rev. F (RE00097556)	RC247937	New template per RA-020D.
DOC 509 Rev. G (RE00097556)	RC332890	Added E3504, E3504H, E3504NSB, E3250H, E3250HNSB



Declaration of Conformity DOC # 516



Legal Manufacturer

Covidien Inc
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

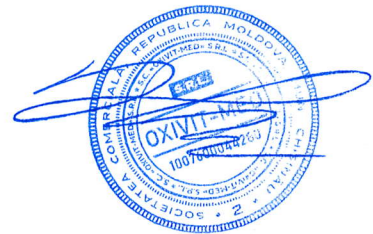
Declaration of Conformity DOC # 516



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, VLSURGEN. 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.



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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



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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
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



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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/elect rode, 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



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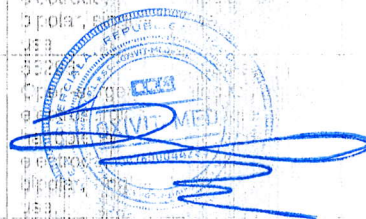
Catalog Number and Description	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)	External Standards List
LF4418 LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider, Nano-Coated	IIb	Rule 9	Sterile	Annex II	56296: 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



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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
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



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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.



Declaration of Conformity DOC # 516

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.

Declaration of Conformity DOC # 514



Legal Manufacturer

Covidien llc
15 Hampshire Street
Mansfield, Massachusetts 02048
USA

European Representative

Covidien Ireland Limited
IDA Business and Technology Park
Tullamore
Ireland

Product Patient Return Electrodes

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 RE00254777

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 RE00254777

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 # 514



Revisions:

DOC 514 supersedes DOC 414 under notified body number:0086.

	Approval in PLM system	Description
DOC 514 Rev. A (RE00055885)	RC067654	Initial release.
DOC 514 Rev. B (RE00055885)	RC189290	Changed Notified Body address from: BSI Group Kitemark Court, Davy Avenue, Knowhill, 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 514 Rev. C (RE00055885)	RC247937	New template per RA-020D.

	Approval in PLM system	Description
DOC 514 Rev. A (RE00055885)	RC067654	Initial release.
DOC 514 Rev. B (RE00055885)	RC189290	Changed Notified Body address from: BSI Group Kitemark Court, Davy Avenue, Knowhill, 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 514 Rev. C (RE00055885)	RC247937	New template per RA-020D.



Declaration of Conformity DOC # 514



Appendix RE00254777

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
E7506 Valleylab™ Non-REM Polyhesive™ Patient Return Electrode 9' (2.7 m)	IIb	Rule 9	N/A	Annex II	58494: Electrosurgical diathermy system return electrode, single-use, non- sterile	Electrosurgical diathermy system return electrode, single-use, non- sterile	RE00057404
E7507 Valleylab™ REM Polyhesive™ Adult Patient Return Electrode 9' (2.7 m)	IIb	Rule 9	N/A	Annex II	58494: Electrosurgical diathermy system return electrode, single-use, non- sterile	Electrosurgical diathermy system return electrode, single-use, non- sterile	RE00057404
E7507-DB Valleylab™ REM Polyhesive™ Adult Patient Return Electrode 15' (4.6 m)	IIb	Rule 9	N/A	Annex II	58494: Electrosurgical diathermy system return electrode, single-use, non- sterile	Electrosurgical diathermy system return electrode, single-use, non- sterile	RE00057404
E7508 Valleylab™ REM Polyhesive™ Adult Cordless Patient Return Electrode	IIb	Rule 9	N/A	Annex II	58494: Electrosurgical diathermy system return electrode, single-use, non- sterile	Electrosurgical diathermy system return electrode, single-use, non- sterile	RE00057404
E7509 Valleylab™ REM Polyhesive™ Adult Cordless Patient Return Electrode	IIb	Rule 9	N/A	Annex II	58494: Electrosurgical diathermy system return electrode, single-use, non- sterile	Electrosurgical diathermy system return electrode, single-use, non- sterile	RE00057404



 COVIDIEN

Declaration of Conformity DOC # 514



Revisions:

	Date of Issue	Description
DOC 514 Rev. A (RE00254777)	RC248707	Initial Release.
DOC 514 Rev. B (RE00254777)	RC351384	Correction to E7510-25DB to state 15' (4.6 m) cord length.



Declaration of Conformity
DOC # 514

Revisions:

	Date of Issue	Description
DOC 514 Rev. A (RE00254777)	RC248707	Initial Release.
DOC 514 Rev. B (RE00254777)	RC351384	Correction to E7510-25DB to state 15' (4.6 m) cord length.

DoC-SURGERY-201908-001(V4.0)



EC Declaration of Conformity

Manufacturer: Nanjing Mindray Bio-Medical Electronics Co., Ltd.
666# Middle Zhengfang Road, Jiangning, 211111 Nanjing, Jiangsu,
P.R.China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
(DIMDI No.: DE/0000040627)

Product Name: Insufflator

Model: HS-50F, HS-50V, HS-50H, HS-50S, HS-30S

UMDNS Code: 12144 **GMDN Code:** 16849

Classification: IIa (According to Annex IX, Rule 11 of Directive 93/42/EEC)

Compliance of the designated product(s) with the directives has been assessed following the procedure relating to the EC Declaration of Conformity set out in Annex II, Article 3 of Directive 93/42/EEC and has been certified by the Notified Body.

TÜV SÜD Product Service GmbH

Ridlerstraße 65, 80339 MÜNCHEN, Germany

Certificate No.: G1 070744 0016

Issue date: 2020-03-04

Expiry date: 2024-05-26

We, declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Device, as amended by 2007/42/EC. All supporting documentations are retained under the premises of the manufacturer. This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Standards Applied:

EN ISO 13485:2016/ISO 13485:2016

EN ISO 14971:2012/ISO 14971:2007

EN 60601-1:2006+A1:2013/IEC 60601-1:2005+A1:2012

IEC 60601-2-18:2009/ EN 60601-2-18:2015

EN 60601-1-2:2015/IEC 60601-1-2:2014

IEC 60601-1-6:2010+AMD1:2013/EN 60601-1-6:2010/A1:2015

IEC 62366-1:2015/EN 62366-1:2015

IEC 62304:2006+A1:2015/EN 62304:2006/A1:2015

EN 1041:2008

ISO 15223-1:2016

EN ISO 10993-1:2009+AC:2010

EN ISO 10993-5:2009

EN ISO 10993-10:2013

ISO 17664:2017

Start of CE-Marking:

2019-8-28

Signature:

Zhai Pei

Place, Date of Issue:

Nanjing, 2020.12.30

Name of Authorized Signatory: Mr. Zhai pei

Position Held in Company:

Manager, Technical Regulation



DoC-SURGERY-201803-001(V4.0)



EC Declaration of Conformity

Manufacturer: Nanjing Mindray Bio-Medical Electronics Co., Ltd.
666# Middle Zhengfang Road, Jiangning, 211111 Nanjing, Jiangsu,
P.R.China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
(DIMDI No.: DE/0000040627)

Product Name: Rigid Endoscope
Model: M 01000A/M 01030A/M 01000/M 01030
G 01000A/G 01030A/G 01000/G 01030
UMDNS Code: 20475 **GMDN code:** 12291

Classification: IIa (According to Annex IX, Rule 6 of Directive 93/42/EEC)

Compliance of the designated product(s) with the directives has been assessed following the procedure relating to the EC Declaration of Conformity set out in Annex II, Article 3 of Directive 93/42/EEC and has been certified by the Notified Body.

TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 MÜNCHEN, Germany

Certificate No.: G1 070744 0016

Issue date: 2019-08-27

Expiry date: 2024-05-26

We, declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Device, as amended by 2007/42/EC. All supporting documentations are retained under the premises of the manufacturer. This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Standards Applied:

EN ISO 13485:2016/ISO 13485:2016

EN ISO 14971:2012/ISO 14971:2007

IEC 60601-1-6:2010+AMD1:2013/EN 60601-1-6:2010/A1:2015

IEC 62366-1:2015/EN 62366-1:2015

EN 60601-1:2006+A1:2013/IEC 60601-1:2005+A1:2012

IEC 60601-2-18:2009

EN 1041:2008

EN ISO 10993-1:2009+AC:2010

EN ISO 10993-5:2009 EN ISO 10993-10:2013

ISO 15223-1:2016

ISO 8600-1:2015

ISO 8600-3:1997+A1:2003

ISO 8600-4:2014

ISO 8600-5:2005

ISO 8600-7:2012

ISO 17664:2004

Start of CE-Marking: 2018-3-13

Signature:

Li Xiaoqiao

Place, Date of Issue:

Nanjing, 2019-9-27

Name of Authorized Signatory: Mr. Li Xiaoqiao

Position Held in Company: Management Representative



DoC-SURGERY-201908-001(V4.0)



EC Declaration of Conformity

Manufacturer: Nanjing Mindray Bio-Medical Electronics Co., Ltd.
666# Middle Zhengfang Road, Jiangning, 211111 Nanjing, Jiangsu,
P.R.China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
(DIMDI No.: DE/0000040627)

Product Name: Insufflator

Model: HS-50F, HS-50V, HS-50H, HS-50S, HS-30S

UMDNS Code: 12144 **GMDN Code:** 16849

Classification: IIa (According to Annex IX, Rule 11 of Directive 93/42/EEC)

Compliance of the designated product(s) with the directives has been assessed following the procedure relating to the EC Declaration of Conformity set out in Annex II, Article 3 of Directive 93/42/EEC and has been certified by the Notified Body.

TÜV SÜD Product Service GmbH

Ridlerstraße 65, 80339 MÜNCHEN, Germany

Certificate No.: G1 070744 0016

Issue date: 2020-03-04

Expiry date: 2024-05-26

We, declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Device, as amended by 2007/42/EC. All supporting documentations are retained under the premises of the manufacturer. This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Standards Applied:

EN ISO 13485:2016/ISO 13485:2016

EN ISO 14971:2012/ISO 14971:2007

EN 60601-1:2006+A1:2013/IEC 60601-1:2005+A1:2012

IEC 60601-2-18:2009/ EN 60601-2-18:2015

EN 60601-1-2:2015/IEC 60601-1-2:2014

IEC 60601-1-6:2010+AMD1:2013/EN 60601-1-6:2010/A1:2015

IEC 62366-1:2015/EN 62366-1:2015

IEC 62304:2006+A1:2015/EN 62304:2006/A1:2015

EN 1041:2008

ISO 15223-1:2016

EN ISO 10993-1:2009+AC:2010

EN ISO 10993-5:2009

EN ISO 10993-10:2013

ISO 17664:2017

Start of CE-Marking:

2019-8-28

Signature:

Zhai Pei

Place, Date of Issue:

Nanjing, 2020.12.30

Name of Authorized Signatory: Mr. Zhai pei

Position Held in Company:

Manager, Technical Regulation



DoC-SURGERY-201803-001(V4.0)



EC Declaration of Conformity

Manufacturer: Nanjing Mindray Bio-Medical Electronics Co., Ltd.
666# Middle Zhengfang Road, Jiangning, 211111 Nanjing, Jiangsu,
P.R.China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
(DIMDI No.: DE/0000040627)

Product Name: Rigid Endoscope
Model: M 01000A/M 01030A/M 01000/M 01030
G 01000A/G 01030A/G 01000/G 01030
UMDNS Code: 20475 **GMDN code:** 12291

Classification: IIa (According to Annex IX, Rule 6 of Directive 93/42/EEC)

Compliance of the designated product(s) with the directives has been assessed following the procedure relating to the EC Declaration of Conformity set out in Annex II, Article 3 of Directive 93/42/EEC and has been certified by the Notified Body.

TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 MÜNCHEN, Germany

Certificate No.: G1 070744 0016

Issue date: 2019-08-27

Expiry date: 2024-05-26

We, declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Device, as amended by 2007/42/EC. All supporting documentations are retained under the premises of the manufacturer. This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Standards Applied:

EN ISO 13485:2016/ISO 13485:2016

EN ISO 14971:2012/ISO 14971:2007

IEC 60601-1-6:2010+AMD1:2013/EN 60601-1-6:2010/A1:2015

IEC 62366-1:2015/EN 62366-1:2015

EN 60601-1:2006+A1:2013/IEC 60601-1:2005+A1:2012

IEC 60601-2-18:2009

EN 1041:2008

EN ISO 10993-1:2009+AC:2010

EN ISO 10993-5:2009 EN ISO 10993-10:2013

ISO 15223-1:2016

ISO 8600-1:2015

ISO 8600-3:1997+A1:2003

ISO 8600-4:2014

ISO 8600-5:2005

ISO 8600-7:2012

ISO 17664:2004

Start of CE-Marking: 2018-3-13

Signature:

Li Xiaoqiao

Place, Date of Issue:

Nanjing, 2019-9-27

Name of Authorized Signatory: Mr. Li Xiaoqiao

Position Held in Company: Management Representative



Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-tech Industrial
Park, Nanshan, Shenzhen, 518057, P. R. China

Manufacturer SRN: CN-MF-000014156

EC-Representative Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80 20537 Hamburg, Germany

Product: Endoscope Light Source

Model: HB500R, HB500R-TEC

Basic UDI-DI: 69449040AB065100088F

Classification: IIa (According to Rule 10 of MDR Annex VIII)

Conformity Assessment Route: Annex IX excluding CHAPTER II

EMDN code Z120204

GMDN code: 35158

Supplementary information /

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: TÜV SÜD Product Service GmbH Ridlerstraße 65
80339 München, Germany.

Notified Body No. : 0123

EC Certificate No.: G10 044751 0176

Start of CE-Marking: 2023-6-29

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2024-4-10

Signature:

Name of Authorized Signatory:

Mr. Wang Xinbing

Position Held in Company:

Deputy Director, Technical Regulation

Applied Standards List

Product: Endoscope Light Source

Model: HB500R, HB500R-TEC-

Standards Applied:

EN ISO 14971:2012/A11:2021	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN 60601-1:2006/A2:2021	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015/A1:2021	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010/A2:2021	Medical electrical equipment - Part 1-6: General Requirements for basic safety and essential performance -Collateral standard: usability
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 62366-1:2015/A1:2020	Medical devices -- Application of usability engineering to medical devices
EN 60601-2-18: 2015	Medical electrical equipment-Part 2-18:Particular requirements for the basic safety and essential performance of endoscopic equipment
EN 62471:2008	Photobiological safety of lamps and lamp systems.
EN 60825-1:2014/A11:2021	Safety of laser products – Part 1: Equipment classification and requirements.



Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Manufacturer SRN: CN-MF-000014156

EC-Representative Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80 20537 Hamburg, Germany

Product: Endoscope Camera System

Model: UX5/UX5-TEC/UX5-NOR/UX5-SIM/UX3/UX3-TEC/
UX3-NOR/UX3-SIM/UX1/UX1-TEC/UX1-NOR/UX1-SIM/
UX4/UX410/UX420/UX430/UX450/UX460/UX470/UX5/
UX510/UX520/UX530/UX550/UX560/UX570/UX5-SIM/
UX5-NOR/UX5-TEC/UX7/UX7-TEC/UX7-NOR/ UX7-SIM

Basic UDI-DI: 69449040AB065100078D

Classification: I(According to Rule 13 of MDR Annex VIII)

Conformity Assessment Route: Article 52.7

EMDN code: Z120204

GMDN code: 35958

Supplementary information TV-300/TV-300T(220V)/TV-300T(110V)/TV-500/
TV-500T(220V)/TV-500T(110V)/TP-MFS Mobile Trolley;
CH5-SW100/CH5-SW110/CH5-SR100/CH5-SR110/
CH3-SW100/CH3-SW110 camera head

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Start of CE-Marking: 2023-6-29

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2024-12-31

Signature:

Name of Authorized Signatory:

Position Held in Company:

Mr. Wang Xinbing

Deputy Director, Technical Regulation

Applied Standards List

Product: Endoscope Camera System

Model:

UX5/UX5-TEC/UX5-NOR/UX5-SIM/UX3/UX3-TEC/
UX3-NOR/UX3-SIM/UX1/UX1-TEC/UX1-NOR/UX1-SIM/
UX4/UX410/UX420/UX430/UX450/UX460/UX470/UX5/
UX510/UX520/UX530/UX550/UX560/UX570/UX5-SIM/
UX5-NOR/UX5-TEC/UX7/UX7-TEC/UX7-NOR/ UX7-SIM

Standards Applied:

EN ISO 14971:2012/A11:2021	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN 60601-1:2006/A2:2021	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015/A1:2021	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010/A2:2021	Medical electrical equipment - Part 1-6: General Requirements for basic safety and essential performance -Collateral standard: usability
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 62366-1:2015/A1:2020	Medical devices -- Application of usability engineering to medical devices
EN ISO 17664-1:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
EN 60601-2-18: 2015	Medical electrical equipment-Part 2-18:Particular requirements for the basic safety and essential performance of endoscopic equipment

To whom it may concern:

I hereby confirm that the following product without notified body involvement is reasonable.

The product **Endoscope Camera System (UX1, UX3, UX5, etc.)** belong to Class I according to the Rule 13 of MDR Annex VIII.

According to MDR-Regulation (EU) 2017/745, Article 52 (1-7), only manufacturers of Class IIa-Class III are subjects to conformity assessment procedures performed by notified body. For Class I devices, the involvement of the notified body is not required.

Manufacturers of Class I medical devices can self-declare compliance with MDR and affix the CE Mark without requiring certification from a notified body.

Thus, UX series without EU notified body No. is considered acceptable.

Name: Amber Wang

Amber Wang

Position: International RA of Technical Regulation Department

Date: February 07, 2025



Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Manufacturer SRN: CN-MF-000014156

EC-Representative Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80 20537 Hamburg, Germany

Product: Endoscope Camera System

Model: UX5/UX5-TEC/UX5-NOR/UX5-SIM/UX3/UX3-TEC/
UX3-NOR/UX3-SIM/UX1/UX1-TEC/UX1-NOR/UX1-SIM/
UX4/UX410/UX420/UX430/UX450/UX460/UX470/UX5/
UX510/UX520/UX530/UX550/UX560/UX570/UX5-SIM/
UX5-NOR/UX5-TEC/UX7/UX7-TEC/UX7-NOR/ UX7-SIM

Basic UDI-DI: 69449040AB065100078D

Classification: I(According to Rule 13 of MDR Annex VIII)

Conformity Assessment Route: Article 52.7

EMDN code: Z120204

GMDN code: 35958

Supplementary information TV-300/TV-300T(220V)/TV-300T(110V)/TV-500/
TV-500T(220V)/TV-500T(110V)/TP-MFS Mobile Trolley;
CH5-SW100/CH5-SW110/CH5-SR100/CH5-SR110/
CH3-SW100/CH3-SW110 camera head

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Start of CE-Marking: 2023-6-29

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2024-12-31

Signature:

Name of Authorized Signatory:

Position Held in Company:

Mr. Wang Xinbing

Deputy Director, Technical Regulation

Applied Standards List

Product: Endoscope Camera System

Model:

UX5/UX5-TEC/UX5-NOR/UX5-SIM/UX3/UX3-TEC/
UX3-NOR/UX3-SIM/UX1/UX1-TEC/UX1-NOR/UX1-SIM/
UX4/UX410/UX420/UX430/UX450/UX460/UX470/UX5/
UX510/UX520/UX530/UX550/UX560/UX570/UX5-SIM/
UX5-NOR/UX5-TEC/UX7/UX7-TEC/UX7-NOR/ UX7-SIM

Standards Applied:

EN ISO 14971:2012/A11:2021	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN 60601-1:2006/A2:2021	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015/A1:2021	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010/A2:2021	Medical electrical equipment - Part 1-6: General Requirements for basic safety and essential performance -Collateral standard: usability
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 62366-1:2015/A1:2020	Medical devices -- Application of usability engineering to medical devices
EN ISO 17664-1:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
EN 60601-2-18: 2015	Medical electrical equipment-Part 2-18:Particular requirements for the basic safety and essential performance of endoscopic equipment

To whom it may concern:

I hereby confirm that the following product without notified body involvement is reasonable.

The product **Endoscope Camera System (UX1, UX3, UX5, etc.)** belong to Class I according to the Rule 13 of MDR Annex VIII.

According to MDR-Regulation (EU) 2017/745, Article 52 (1-7), only manufacturers of Class IIa-Class III are subjects to conformity assessment procedures performed by notified body. For Class I devices, the involvement of the notified body is not required.

Manufacturers of Class I medical devices can self-declare compliance with MDR and affix the CE Mark without requiring certification from a notified body.

Thus, UX series without EU notified body No. is considered acceptable.

Name: Amber Wang

Amber Wang

Position: International RA of Technical Regulation Department

Date: February 07, 2025





DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417: 2021
EN 60601-1-2:2015
EN 60601-1:2006+A12:2014

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Z119008-01.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: Shenzhen Beacon Display Technology Co., Ltd.

Address: 15F, Building 6, Hengda Shishang Huigu(East), Fulong Road,Dalang Subdistrict, Longhua, Shenzhen, 518109 , P.R. China

SRN: CN-MF-000008774

Product Information

Name: LCD Monitor

Model: See annex

EMDN: Z119008

Basic UDI-DI: 697002782001FH

Classification: Class I, According to Rule 13, Annex VIII, Regulation (EU) 2017/745

Intended Use: The monitor is intended to be used in displaying and viewing digital images, for review and analysis by trained medical practitioners.

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:  Date: 2021.10.11

Position: GM

Place: Guangdong/China



Annex

Product Name	Model	EMDN	Basic UDI-DI
LCD Monitor	C22S+、C22SP+、C24S+、G22S+、G22SP+、G23S+、G23SP+、 C32S+、C32SP+、G32S+、G32SP+、C53S+、C53SP+、G52S+、 G52SP+、G53S+、G53SP+、C43W+、C44W+、C61W+、 C81W+、C82W+、C83W+、C85W+、C86W+、C145T、C14S、 G11S、C22W、C22WT、C23W、C23WT、C24W、C24WT、 M553T、M652T、M862T、M982T、E150、E190、E2421、 E2422、E2721、S2421P、S271P、S272P、S273P、S2785P、 S3281P、S3285P、S3180P、S421、S551、S5583P、S5580P、 PV26、PV27、S3221P、S3181P、U2221、S1001T、 M8681T、C411W、HL2316SHA、HL2316SHTB、 HL2416SH、HL2416SHT S556、S556P、SP2421T、SP5581T、SP5581P、S3285P-3D、 S3221P-3D、C1216W、C610W、C616W、C811W、C810RT、 C810WT、C811RT、C811WT、HL2316SL、HL2416SL、C310S、 C510S、G510S、C316S、C516S、G516S、G310S、G316S、 C821W E2420、S2720P、S2780P、S3282P、S3286P、S4385P、 S5586P、S3286P-3D、SP6582P、SP6582T、SP3222T、 SP3222P、P2740、P2780、P3280、C821WT、C822W、 C822WT	Z119008	697002782001FH

Signature: 

Date: 2020.10.11

Position: GM

Place: Guangdong/China





Declaration of Conformity

Manufacturer:

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

CN-MF-000014156

**Manufacturer SRN:
EC-Representative**

Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80 20537 Hamburg, Germany

Product:

Light Cable

Model:

LC0005S, LC0003S, LC0005L

Basic UDI-DI:

69449040AB0651000487

Classification:

I (According to Rule 13 of MDR Annex VIII)

Conformity Assessment Route:

Article 52.7

GMDN code:

35158

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS:

/

Start of CE-Marking:

2021-6-4

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue:

Shenzhen, 2022.4.12

Signature:

Name of Authorized Signatory:

Mr. Wang Xinbing

Position Held in Company:

Deputy Director, Technical Regulation

Applied Standards List

Product: Light Cable
Model: LC0005S, LC0003S, LC0005L

Standards Applied:

EN ISO 14971:2012 Medical devices – Application of risk management to medical devices

EN 1041:2008/A1:2013 Information supplied by the manufacturer of medical devices

EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part1: General requirements

EN60601-1:2006/A1:2013 Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance

EN60601-1-2:2015 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

EN 60601-1-6: 2010/A1:2015 Medical electrical equipment - Part 1-6: General Requirements for basic safety and essential performance -Collateral standard: usability

EN 62366-1:2015 Medical devices -- Application of usability engineering to medical devices

EN ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

EN 60601-2-18:2015 Medical electrical equipment-Part 2-18:Particular requirements for the basic safety and essential performance of endoscopic equipment

EN 62471:2008 Photobiological safety of lamps and lamp systems.

EN 60825-1:2014 Safety of laser products – Part 1: Equipment classification and requirements.

Declaration of Conformity V1.0

Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan,
Shenzhen, 518057, P. R. China

Manufacturer SRN: CN-MF-000014156

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

Product: Fluid Management System

Model: HP100G, HP200G, HP200L, HP200D

Basic UDI-DI: 69449040AB0651000589

Classification: IIa (According to Rule 12 of MDR Annex VIII)

Conformity Assessment Route: Annex IX excluding CHAPTER II

EMDN code: Z120190

Intended Purpose: The product is intended for irrigation and/or suction during endoscopic examination and surgery.

Supplementary information: Included are following reusable irrigation tubing set: IR100R, following reusable suction tubing set: SU100R and following Two-Pedal Footswitch-Fluid Management System: FS200.

We declare that the above-mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: SGS Belgium NV

Notified Body No. : 1639

Identification of the Certificate: /

Start of CE-Marking: 2023-9-13

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2023.9.13

Signature:

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Deputy Director, Technical Regulation

Attachment of Declaration of Conformity: Applied Standards List-V1.0

Applied Standards List

Product: Fluid Management System

Model: HP100G, HP200G, HP200L, HP200D

Standards Applied:

EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-8:2007/A1:2013	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN 60601-1-6:2010 /A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 17664-1:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021)
EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

EU DECLARATION OF CONFORMITY - MDR 2017/745/UE -

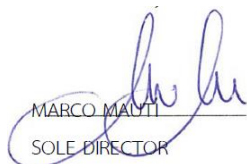
REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017

It is declared the conformity with Regulation (EU) 2017/745 and the following Directives: Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (RoHS 2) and Commission Delegated Directive (EU) 2015/863 of 31 March 2015.

This declaration of conformity is issued under the sole responsibility of LED SpA in compliance to Article 19 of EU MDR 2017/745. We hereby declare that the medical device specified under meet the provision of the Annex I of Regulation EU MDR 2017/745 for medical devices.

The declaration is based on:

Manufacturers Name:	LED SpA
Manufacturers Address:	Via Selciatella 40 04011 Aprilia (LT) Italy
SRN (Single Registration Number):	IT-MF-000012232
Basic UDI-DI:	803363832 ESA0013E
Product Category:	Electrosurgical Accessories
Name of the Device(s):	See TABLE attached column #
Product code:	See TABLE attached column REF
Classification with rule number:	Class II b (Rule 9)
Conformity with assessment route:	Annex IX Chapters I and III of Regulation (EU) 2017/745.
Intended use:	Devices destined to be connected, for temporary use, to high frequency electrosurgical units for surgical operations in which cutting and / or coagulation of soft tissues is required, with a monopolar and / or bipolar technique, for minor surgery and / or major in open and / or intra-operative percutaneous and / or endoscopic and / or laparoscopic. See attached table.
Notified Body Name and address (code):	<u>IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.,</u> Via Quintiliano 43 20138 Milano – ITALY, NB: 0051
Common Specification (CS):	-
Identification of certificates issued:	EU certificate, 052 / MDR expiring 2027-09-21


MARCO MAUTI
SOLE DIRECTOR
LED SpA

LED SpA
Marco Mauti
Sole Director

Aprilia (LT), 25.09.2025

EN - LIST OF DEVICES

Trade mark **LED**

#	REF					
PENCIL	00201.02 00206.00 00206.40					
PENCIL S	00205.00 00420.00 00205.40 00420.05					
CONNECTION	00402.00 00402.01 00402.02 00402.03 00402.04 00402.05	00404.02 00404.04 00404.08 00404.09 00404.10 00404.11	00411.00 00412.00 00413.00 00414.00 00415.00 00416.00 00417.00 00418.00			
NEUTRAL	00400.00 00401.00 00401.01 00401.02 00401.03 00401.10 00401.11 00401.12	00401.20 00401.21 00401.22 00403.01 00403.02	5365A 6429A			
ELECTRODE	00500.00 00500.00/L 00500.03 00500.D1 00500.D12 00500.D1/S 00500.D12/S	00500.L1 00500.L1/L 00500.L2 00500.L2/L 00500.L3 00500.L3/L 00500.L4 00500.L4/L 00500.L5 00500.L5/L 00500.L6 00500.L6/L 00500.L7 00500.L7/L 00500.L8 00500.L8/L 00500.L9 00500.L9/L 00500.L10 00500.L10/L 00500.S05 00500.S10 00500.S15	500500.D1/S 500500.D12/S 500500.L1 500500.L1/L 500500.L2 500500.L2/L 500500.L3 500500.L3/L 500500.L4 500500.L4/L 500500.L5 500500.L5/L 500500.L6 500500.L6/L 500500.L7 500500.L7/L 500500.L8 500500.L8/L 500500.L9 500500.L9/L 500500.L10 500500.L10/L 500500.S05 500500.L10/L	152-110 152-112 152-115 152-120 152-122 152-125 152-130 152-132 152-140 152-142 152-145 152-150 152-152 152-160 152-162 152-165	152-175-10 152-190-13 152-190-20 152-195	00420.10 00420.12 00420.14
BIPOLAR	110-700 110-750NS 110-755NS 110-760NS	310-110-05 310-112-05 310-140-10 310-140-20 310-142-10 310-142-20 310-180-10 310-180-20 310-182-10 310-185-10	310-510 310-550 310-590	410-100-15 410-100-19 410-200-18 410-200-21 410-200-23	500-300-00 510-000-00 510-000-00_L 510-300J01 510-300J02 510-300J03 510-300J04 510-300J05 510-300J06 510-300J07 510-300-10 510-300-20 510-300-30 510-300-40 510-300-50 510-300-10_L 510-300-20_L 510-300-30_L 510-300-40_L 510-300-50_L	
MONOPOLAR	330-134-20 330-160					



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