



MANGO DE BISTURÍ ELECTROQUIRÚRGICO, CONTROL MANUAL

HAND CONTROL ELECTROSURGICAL PENCIL
MANCHE DE BISTOURI ÉLECTROCHIRURGICAL, COMMANDE DIGITALE



CARACTERÍSTICAS

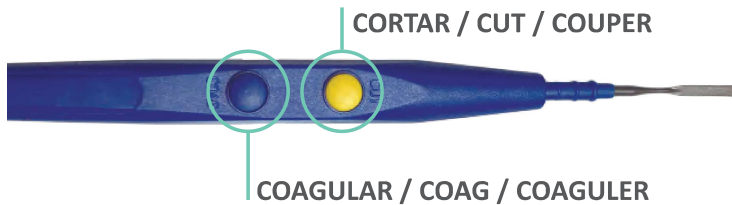
- Fácil manejo
- Ligero
- Cómodo perfil anatómico
- Conector standard de 3 pins

CHARACTERISTICS

- Easy handling
- Light
- Comfortable anatomical shape
- 3-pin standard connector

CARACTÉRISTIQUES

- Facile utilisation
- Léger
- Confortable contour anatomique
- Connecteur standard de 3 pins



MB-100

Mango bisturí electroquirúrgico de control manual de un solo uso, con accesorio AB-80, desmontable.
Single use hand control electrosurgical pencil, with removable AB-80 accessory.
Manche bistouri électrique à usage unique, commande digitale avec accessoire AB-80 amovible.

CLASE IIb estéril
CLASS IIb sterile
CLASE IIb stérile

MB-100/5

Mango bisturí electroquirúrgico de control manual de un solo uso, con accesorio AB-80, desmontable.
Single use hand control electrosurgical pencil, with removable AB-80 accessory.
Manche bistouri électrique à usage unique, commande digitale avec accessoire AB-80 amovible.

CABLE · CABLE · CÂBLE
5m



AL-40

Dispositivo limpiador de electrodo, autoadhesivo.
Adhesive electrode cleaning device.
Dispositif grattoir d'électrode autoadhésive



AL-40

MB-200

Contiene
Contains
Contient

1 MB-100 + 1 AL-40



MBR-600

Mango de bisturí electroquirúrgico reutilizable, con accesorio AB-80 desmontable.
Reusable electrosurgical pencil, with removable AB-80 accessory.
Manche de bistouri électrochirurgical réutilisable, avec accessoire AB-80 amovible.

REUTILIZABLE
REUSABLE
RÉUTILISABLE

VECES · TIMES · FOIS
30



CLASE IIb
CLASS IIb
CLASE IIb

MBR-600

REF	CABLE CABLE CÂBLE	U/BOLSA U/POUCH U/POCHE	U/CAJA U/BOX U/CARTON
MB-100	3 m	1	50
MB-100/5	5 m	1	50
AL-40	-	1	250
MB-200	-	1	50
MBR-600	3 m	1	1

Dispositivo fabricado según Normas · Device
manufactured under Standards · Dispositif fabriqué
suivant Standards: EN 60601-2-2



ACCESORIOS

ACCESSORIES · ACCESSOIRES

CLASE IIb estéril
CLASS IIb sterile
CLASE IIb stérile

Para corte y coagulación, durante la intervención electroquirúrgica con la utilización de un mango de bisturí electroquirúrgico que sea compatible.

Tissue cutting and coagulation, during electrosurgical procedures, in conjunction with a compatible electrosurgical pencil.

Coupe et coagulation des tissus, durant la procédure électrochirurgicale, avec l'utilisation d'un manche bistouri.

ACCESORIOS · ACCESSORIES · ACCESSOIRES

Comunes a todos los modelos de mango BLAYCO® (MB-100, MB-200, MBR-600) · Common to all BLAYCO® pencil models (MB-100, MB-200, MBR-600) · Communs à tous les modèles de manche BLAYCO® (MB-100, MB-200, MBR-600).

Dispositivo fabricado según Normas · Device manufactured under Standards · Dispositif fabriqué suivant Standards: EN 60601-2-2

REF	MEDIDAS MEASUREMENTS DIMENSIONS (mm)	ELECTRODO ELECTRODE ÉLECTRODE		U/BOLSA U/POUCH U/POCHE	U/ESTUCHE U/CASE U/BOÎTE	U/CAJA U/BOX U/CARTON
AB-50	80	BOLA · BALL · BOULE		1	-	50
AB-60	70	AGUJA · NEEDLE · AIGUILLE				
AB-70	150					
AB-80	70	CUCHILLA · BLADE · LAME				
AB-90	160					
ABT-50	80	BOLA · BALL · BOULE	ANTIADHERENTE NON STICK COATED ANTI-ADHÉRENTE	1	-	50
ABT-60	70	AGUJA · NEEDLE · AIGUILLE				
ABT-70	150					
ABT-80	70	CUCHILLA · BLADE · LAME				
ABT-90	160					
ABC-45	45	AGUJA · NEEDLE · AIGUILLE	TUNGSTENO TUNGSTEN TUNGSTÈNE	1	5	30
ABC-55	55					
ABC-65	65					
ABC-55/A30	55 / 30º					
ABC-55/A45	55 / 45º					



STERILE EO

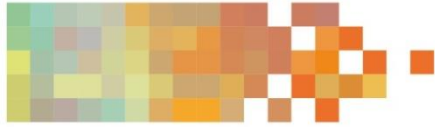


STERILE EO



STERILE EO



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EU DECLARATION OF CONFORMITY

TELIC, S.A.U. with SRN number: ES-MF-000001853 declares under his sole responsibility that the products listed in annexes of the present declaration have been manufactured according to requirements of the **Regulation (EU) 2017/745 on Medical Devices** and meet requirements set in the Essential Requirements of the Annex I of above mentioned Regulation.

Technical documentation, in accordance with the established in the corresponding annexes of the Regulation (UE) 2017/745 on medical devices, is updated and located in our facilities. We are in position to submit these documents in case of Notified Body or Competent Authority requirement.

This declaration applies to design, manufacturing and final control of medical devices. Validity of the present declaration is subject to the expiration of the corresponding EC certificates for different products.

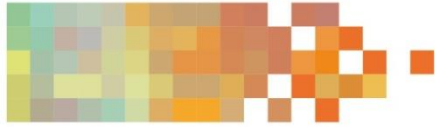
Bigues i Riells, on June 07th 2021



Laura Delgado
Technical Manager



Oscar Lacruz
CEO



EU DECLARATION OF CONFORMITY – ANNEX 1

List of self-certified products

Defibrillation electrodes without cable	
Description	Set of two adhesive pre-gelled pads with conductive hydrogel for defibrillation. To be used for adult patient use.
Commercial brand	DESFI-DORMO
References	ED-1010
Classification	
Product class I - Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734DFELECW/OCABLEADF2
GMDN	11130
EMDN	C020480 (Cardioversion and external defibrillation Devices-accessories)
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // EN ISO 10993-1:2009 // EN ISO 10993-1:2009/AC:2010 // EN ISO 10993-5:2009 // EN ISO 10993-10:2013 // EN 60601-1:2006 // EN 60601-1:2006/AC:2010 // EN 60601-1:2006/A1:2013 // EN 60601-2-4:2003 // EN 60601-2-2:2011 // EN 60601-2-4:2011/A1:2019.	

Defibrillation electrodes with cable for adult patient	
Description	Set of two multi-function electrodes. Adult.
Commercial brand	DESFI-DORMO
References	(REF: EDC-1XXX): EDC-1011, EDC-1015, EDC-1020, EDC-1025, EDC-1030, EDC-1035, EDC-1040, EDC-1045, EDC-1050, EDC-1055, EDC-1060, EDC-1065, EDC-1070
Description	Set of two multi-function electrodes. Adult. Pre-connected.
Commercial brand	DESFI-DORMO
References	(REF: EDC-2XXX): EDC-2015, EDC-2020, EDC-2025, EDC-2030, EDC-2035, EDC-2035L, EDC-2040, EDC-2045, EDC-2050, EDC-2055, EDC-2060, EDC-2065, EDC-2070, EDC-2075, EDC-2080, EDC-2085, EDC-2090.
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734MFELECCABLEAD9X
GMDN	45806
EMDN	C020480 (Cardioversion and external defibrillation Devices-accessories)
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // EN ISO 10993-1:2009 // EN ISO 10993-1:2009/AC:2010 // EN ISO 10993-5:2009 // EN ISO 10993-10:2013 // EN 60601-1:2006 // EN 60601-1:2006/AC:2010 // EN 60601-1:2006/A1:2013 // EN 60601-2-4:2003 // EN 60601-2-2:2011 // EN 60601-2-4:2011/A1:2019.	



Defibrillation electrodes with cable paediatrics	
Description	Set of two defibrillation electrodes. Paediatrics.
Commercial brand	DESFI-DORMO
References	(REF: EDC-P1XX): EDC-P111, EDC-P115, EDC-P120, EDC-P125, EDC-P130, EDC-P135, EDC-P140, EDC-P145, EDC-P150, EDC-P155, EDC-P160, EDC-P170.
Description	Set of two defibrillation electrodes. Paediatrics. Pre-connected.
Commercial brand	DESFI-DORMO
References	(REF: EDC-P2XX): EDC-P215, EDC-P220, EDC-P225, EDC-P230, EDC-P235, EDC-P240, EDC-P245, EDC-P250, EDC-P255, EDC-P260, EDC-P265, EDC-P270, EDC-P275, EDC-P280, EDC-P290.
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734DFELECCABLEPEDVM
GMDN	41587
EMDN	C020480 (Cardioversion and external defibrillation Devices-accessories)
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // EN ISO 10993-1:2009 // EN ISO 10993-1:2009/AC:2010 // EN ISO 10993-5:2009 // EN ISO 10993-10:2013 // EN 60601-1:2006 // EN 60601-1:2006/AC:2010 // EN 60601-1:2006/A1:2013 // EN 60601-2-4:2003 // EN 60601-2-2:2011 // EN 60601-2-4:2011/A1:2019.	

ECG electrodes and accessories	
Description	ECG electrodes Ag/AgCl.
Commercial brand	DORMO
References	-Solid Gel (REF: SX-XX): SX-50, SX-36, SF-36, SX-30, SP-50 -Semiliquid (REF: LX-XX): LF-50, LF-50T LF-36, LP-50, LR-50 -Stress REF: LEH-36
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734ECGELECVL
GMDN	35035
EMDN	C020501 (ECG Electrodes)
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // EN ISO 10993-1:2009 // EN ISO 10993-1:2009/AC:2010 // EN ISO 10993-5:2009 // EN ISO 10993-10:2013 // EN 60601-1:2006 // EN 60601-1:2006/AC:2010 // EN 60601-1:2006/A1:2013 // ANSI/AAMI EC12:2000/(R)2015.	



Neonatal ECG electrodes	
Description	Neonatal ECG electrodes Ag/AgCl.
Commercial brand	DORMO
References	- 1.5 mm connection (REF: KXX-140): K-140, KS-140, KF-140, KFS-140 - 4 mm connection (REF: KXX-150): K-150, KS-150, KF-150, KFS-150 - Stud connection: EKF-22KT
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734NEONATALELECZH
GMDN	17460
EMDN	C020501 (ECG Electrodes)
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // EN ISO 10993-1:2009 // EN ISO 10993-1:2009/AC:2010 // EN ISO 10993-5:2009 // EN ISO 10993-10:2013 // EN 60601-1:2006 // EN 60601-1:2006/AC:2010 // EN 60601-1:2006/A1:2013 // ANSI/AAMI EC12:2000/(R)2015.	

Resting electrodes and accessories	
Description	Resting electrodes.
Commercial brand	DORMO-TAB
References	T-2226
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734TABELEC35
GMDN	35035
EMDN	C020501 (ECG Electrodes)
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // EN ISO 10993-1:2009 // EN ISO 10993-1:2009/AC:2010 // EN ISO 10993-5:2009 // EN ISO 10993-10:2013 // EN 60601-1:2006 // EN 60601-1:2006/AC:2010 // EN 60601-1:2006/A1:2013 // ANSI/AAMI EC12:2000/(R)2015.	

TENS electrodes and spares	
Description	Pre-gelled electrode for electrical stimulation.
Commercial brand	DORMO-TENS
References	- Silicon conductive electrodes female 2mm connection: (REF: DT-XXX) DT-30R, DT-50R, DT-30, DT-50, DT-100



- Replacement hydrogel (REF:RT-XXX) RT-30R, RT-50R, RT-30, RT-50, RT-100 - Paper electrodes with Ag/AgCl and tab connection (REF: T-XXX): T-1005, T-5055, - Non-woven tissue with female wire connection:(REF: SX-XXX): ST-50, ST-100, ST-30R, ST-50R - Non-woven tissue with connection stud (REF:SC-XXX): SC-50, CS-100 - Conductive silicone tape with female 2mm connection (REF: CSC-XX): CSC-1, CSC-25	
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMDN	8427734TENSELECJK
GMN	35995
EMDN	N010201 (Tens System electrodes)
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // EN ISO 10993-1:2009 // EN ISO 10993-1:2009/AC:2010 // EN ISO 10993-5:2009 // EN ISO 10993-10:2013 // ANSI/AAMI NS4:2013.	

Reusable cables for electrosurgery	
Description	Reusable clamp-cables for electrosurgical plates.
Commercial brand	BLAYCO
References	(REF: 42XX-X):4200, 4200-5, 4210, 4210-5, 4212, 4212-5
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734ESUCABLESRE
GMDN	47487
EMDN	V80 (Clinical use accessories not included in other in classes)
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // EN ISO 10993-1:2009 // EN ISO 10993-1:2009/AC:2010. EN ISO 10993-7:2008 // EN ISO 10993-5:2009 // EN ISO 10993-7:2008 // EN ISO 10993-10:2013 // EN 60601-1:2006 // EN 60601-1:2006/AC:2010 // EN 60601-1:2006/A1:2013 // EN 60601-2-2:2009 // EN 60601-2-2:2018	

Bite-blocks	
Description	Bite block for endotracheal tubes and laryngeal masks.
Commercial brand	MORDEDOR-MO
References	Adult:7600 Paediatric: 7650



Classification	
Product class I – Non-sterile. According to Rule 5 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734BITEBLOCKKW
GMDN	10405
EMDN	R0199 (Intubation Devices-other).
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // EN ISO 10993-1:2009 // EN ISO 10993-1:2009/AC:2010 // EN ISO 10993-5:2009 // EN ISO 10993-10:2013.	

Otoscope speculum	
Description	Disposable speculum for otoscope.
Commercial brand	DORMO-SPEC
References	Pediatric: (REF:40XX):4010, 4040, 4060, 4070, 4090 Adult: (REF:40XX): 4020, 4030, 4050, 4080, 4095
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734OTOSCOPE SPECULUMFB
GMDN	35348
EMDN	Z12021085 (Endoscopy instruments- consumables).
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // EN ISO 10993-1:2009 // EN ISO 10993-1:2009/AC:2010 // EN ISO 10993-5:2009 // EN ISO 10993-10:2013.	

Protective pad	
Description	Protective pad for surgical interventions.
Commercial brand	BLAYCO-PAD
References	AC-3020
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734PROTECTIVEPADY2
GMDN	62789
EMDN	T0306 (Patient protection devices during clinical procedures).

**Standards applied**

EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // EN ISO 10993-1:2009 // EN ISO 10993-1:2009/AC:2010 // EN ISO 10993-5:2009 // EN ISO 10993-10:2013.

Nasal holder for gastric catheters

Description Nasal holder for gastric catheters.

Commercial brand DORMO-NAS

References Paediatric: 7550
Adult: 7500

Classification

Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.

GMN 8427734NASALHOLDERY2

GMDN 62581

EMDN A99 (Devices for administration, withdrawal and collection-other).

Standards applied

EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // EN ISO 10993-1:2009 // EN ISO 10993-1:2009/AC:2010 // EN ISO 10993-5:2009 // EN ISO 10993-10:2013.

Cold/hot packs

Description Reusable pack for Cold/Hot.

Commercial brand DORMO

References (REF: FC-XX) FC-01, FC-02

Description Reusable pack for Cold/Hot.

Commercial brand OXD

References (REF: FC-XX) FC-03

Classification

Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.

GMN 8427734HOTCOLDPADCK85

GMDN 37240

EMDN V9099 (Various Devices not included in other classes-other).

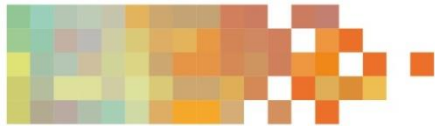
Standards applied

EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // EN ISO 10993-1:2009 // EN ISO 10993-1:2009/AC:2010 // EN ISO 10993-5:2009 // EN ISO 10993-10:2013.



Ultrasound gels	
Description	Ultrasound gel.
Commercial brand	TRANSONIC GEL
References	-Blue. (REF G-15/XXX): G-15, G-15/05, G-15/1, G-15/5, G-15/5RB, G-15A -Clear. (REF: GC-15/XXX): GC-15, GC-15/05, GC-15/1, GC-15/5, GC-15/5RB
Description	Ultrasound gel.
Commercial brand	OXD
References	-Clear. (REF US-CXXX):US-C250, US-C1, US-C5F, US-C5R -Blue (REF:US-BXXX): US-B250, US-B1, US-B5F, US-B5R
Classification	
Product class I – Non-sterile. According to Rule 5 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734USGEL8L
GMDN	15321
EMDN	Z11040185 (Ultrasound scanners-consumables).
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // EN ISO 10993-1:2009 // EN ISO 10993-1:2009/AC:2010 // EN ISO 10993-5:2009 // EN ISO 10993-10:2013.	

ECG Gel	
Description	Conductive gel for electrodes.
Commercial brand	ELECTRO-GEL
References	G-10, G-10A
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734ECGGELVB
GMDN	11425
EMDN	C020599 (Cardiac diagnostic Devices-other).
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // EN ISO 10993-1:2009 // EN ISO 10993-1:2009/AC:2010 // EN ISO 10993-5:2009 // EN ISO 10993-10:2013 // ANSI/AAMI EC12:2000/(R)2015.	



Lubricating gel	
Description	Lubricating water-soluble gel
Commercial brand	DORMO
References	REF: G-20/XXX: G-20, G-20/5RB
Classification	
Product class I – Non-sterile. According to Rule 5 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734LUBRICANTGEL5C
GMDN	33587
EMDN	M9002 (Protective sprays and lubricant sprays gels, fluids and creams).
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // EN ISO 10993-1:2009 // EN ISO 10993-1:2009/AC:2010 // EN ISO 10993-5:2009 // EN ISO 10993-10:2013.	

CERTIFICATE OF REGISTRATION



TELIC, S.A.U.

Polígono Industrial Can Barri
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Bigues i Riells (Barcelona) 08415 SPAIN

UL LLC®(UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2016

EN ISO 13485:2016

Design and manufacture of external defibrillator electrode, paediatric, single-use; multifunction cardiac electrode, adult; external defibrillator electrode pad; electrosurgical return electrode, single-use, non-sterile; vein stripper, single-use, sterile; operating/examination/treatment light handle cover, single-use, sterile; coupling gel, sterile.

Manufacture of sterile surgical vessel loop.



Authorized by

Deborah Jennings-Conner
Global Regulatory Director
Life and Health Sciences, UL LLC



Check Certificate
Status: [here](#)

File Number A17128
Certificate Number 1761.210608
Initial Issue Date July 28, 2018

Cycle Start August 27, 2020
Effective Date June 8, 2021
Expiry Date August 26, 2022

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.



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