



# MANGO DE BISTURÍ ELECTROQUIRÚRGICO, CONTROL MANUAL

HAND CONTROL ELECTROSURGICAL PENCIL  
MANCHE DE BISTOURI ÉLECTROCHIRURGICAL, COMMANDE DIGITALE



## CARACTERÍSTICAS

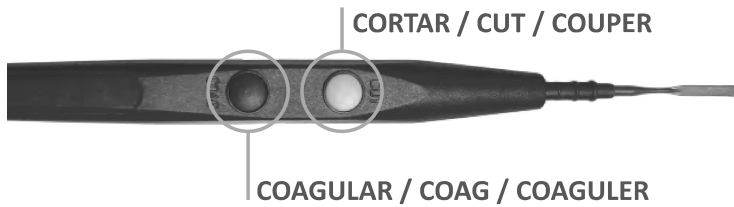
- Fácil manejo
- Ligero
- Cómodo perfil anatómico
- Conector standard de 3 pins

## 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

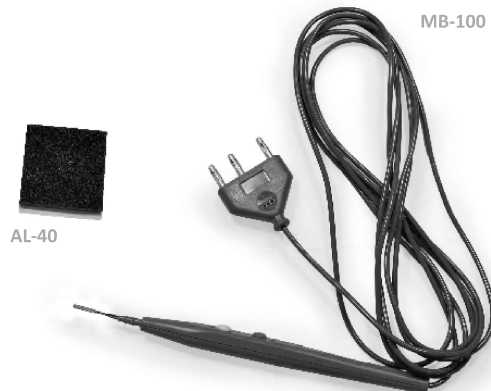
② STERILE EO ~~LATEX~~ CLASE IIb estéril  
CLASS IIb sterile  
CLASE IIb stérile

## AL-40

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



② STERILE EO ~~LATEX~~ RADIOPAQUE CLASE I estéril  
CLASS I sterile  
CLASE I stérile



## MB-200

Contiene  
Contains  
Contient

1 MB-100 + 1 AL-40



② ~~LATEX~~ CLASE IIb estéril  
CLASS IIb sterile  
CLASE IIb stérile + CLASE I estéril  
CLASS I sterile  
CLASE I stérile

## 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.

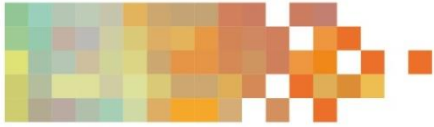


REUTILIZABLE  
REUSABLE  
RÉUTILISABLE

VECES · TIMES · FOIS  
30



CLASE IIb  
CLASS IIb  
CLASE IIb



## Telic, S.A.U.

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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.

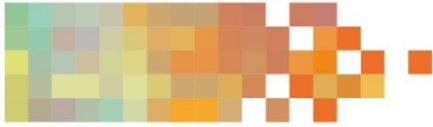
Bigues i Riells, on June 07<sup>th</sup> 2021

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**Laura Delgado**  
Technical Manager

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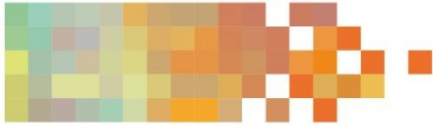
**Oscar Lacruz**  
CEO



**EU DECLARATION OF CONFORMITY – ANNEX 1**  
**List of self-certified products**

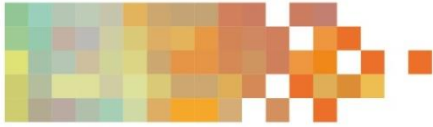
<b>Defibrillation electrodes without cable</b>	
Description	Set of two adhesive pre-gelled pads with conductive hydrogel for defibrillation. To be used for adult patient use.
Commercial brand	DESFI-DORMO
References	ED-1010
<b>Classification</b>	
Product class I - Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734DFELECW/OCABLEADF2
GMDN	11130
EMDN	C020480 (Cardioversion and external defibrillation Devices-accessories)
<b>Standards applied</b>	
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.	

<b>Defibrillation electrodes with cable for adult patient</b>	
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.
<b>Classification</b>	
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)
<b>Standards applied</b>	
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.	



<b>Defibrillation electrodes with cable paediatrics</b>	
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.
<b>Classification</b>	
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)
<b>Standards applied</b>	
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.	

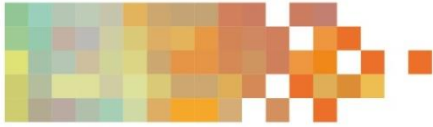
<b>ECG electrodes and accessories</b>	
Description	ECG electrodes Ag/AgCl.
Commercial brand	DORMO
References	-Solid Gel (REF: SX-XX): SX-50, SX-36, SF-36, SX-30, SP-50 -Semiliquid (REF: LX-XX): LF-50, LF-50T LF-36, LP-50, LR-50 -Stress REF: LEH-36
<b>Classification</b>	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734ECGELECVL
GMDN	35035
EMDN	C020501 (ECG Electrodes)
<b>Standards applied</b>	
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.	



<b>Neonatal ECG electrodes</b>	
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
<b>Classification</b>	
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)
<b>Standards applied</b>	
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.	

<b>Resting electrodes and accessories</b>	
Description	Resting electrodes.
Commercial brand	DORMO-TAB
References	T-2226
<b>Classification</b>	
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)
<b>Standards applied</b>	
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.	

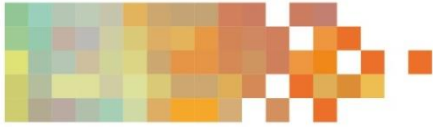
<b>TENS electrodes and spares</b>	
Description	Pre-gelled electrode for electrical stimulation.
Commercial brand	DORMO-TENS
References	- Silicon conductive electrodes female 2mm connection: (REF: DT-XXX) DT-30R, DT-50R, DT-30, DT-50, DT-100



<ul style="list-style-type: none"> <li>- Replacement hydrogel (REF:RT-XXX) RT-30R, RT-50R, RT-30, RT-50, RT-100</li> <li>- Paper electrodes with Ag/AgCl and tab connection (REF: T-XXX): T-1005, T-5055,</li> <li>- Non-woven tissue with female wire connection:(REF: SX-XXX): ST-50, ST-100, ST-30R, ST-50R</li> <li>- Non-woven tissue with connection stud (REF:SC-XXX): SC-50, CS-100</li> <li>- Conductive silicone tape with female 2mm connection (REF: CSC-XX): CSC-1, CSC-25</li> </ul>	
<b>Classification</b>	
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)
<b>Standards applied</b>	
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.	

<b>Reusable cables for electrosurgery</b>	
Description	Reusable clamp-cables for electrosurgical plates.
Commercial brand	BLAYCO
References	(REF: 42XX-X):4200, 4200-5, 4210, 4210-5, 4212, 4212-5
<b>Classification</b>	
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)
<b>Standards applied</b>	
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	

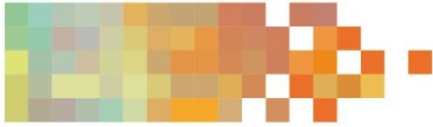
<b>Bite-blocks</b>	
Description	Bite block for endotracheal tubes and laryngeal masks.
Commercial brand	MORDEDOR-MO
References	Adult:7600 Paediatric: 7650



<b>Classification</b>	
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).
<b>Standards applied</b>	
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.	

<b>Otoscope speculum</b>	
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
<b>Classification</b>	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734OTOSCOPESPECULUMFB
GMDN	35348
EMDN	Z12021085 ( Endoscopy instruments- consumables).
<b>Standards applied</b>	
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.	

<b>Protective pad</b>	
Description	Protective pad for surgical interventions.
Commercial brand	BLAYCO-PAD
References	AC-3020
<b>Classification</b>	
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**

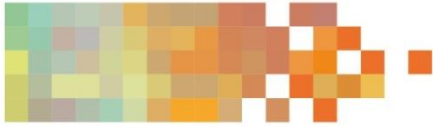
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.

GMN	8427734HOTCOLDPADCK85
GMDN	37240
EMDN	V9099 (Various Devices not included in other classes-other).

**Standards applied**

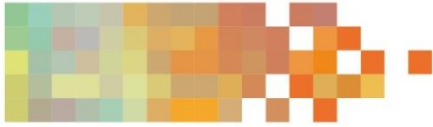
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // EN ISO 10993-1:2009 // EN ISO 10993-1:2009/AC:2010 // EN ISO 10993-5:2009 // EN ISO 10993-10:2013.





<b>Ultrasound gels</b>	
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
<b>Classification</b>	
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).
<b>Standards applied</b>	
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.	

<b>ECG Gel</b>	
Description	Conductive gel for electrodes.
Commercial brand	ELECTRO-GEL
References	G-10, G-10A
<b>Classification</b>	
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).
<b>Standards applied</b>	
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.	



<b>Lubricating gel</b>	
Description	Lubricating water-soluble gel
Commercial brand	DORMO
References	REF: G-20/XXX: G-20, G-20/5RB
<b>Classification</b>	
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).
<b>Standards applied</b>	
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  
C/ Molí d'en Barri, 7  
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.



UL LLC  
333 Pfingsten Road  
Northbrook, IL 60062-2096 USA