ELECTRODOS PARA E.C.G.

E.C.G. ELECTRODES
ÉLECTRODES POUR E.C.G.

CLASE I
CLASS I
CLASE I

REF		MEDIDAS MEASUREMENTS DIMENSIONS (mm)	SOPORTE BACKING SUPPORT	GEL	ETIQUETA LABEL ÉTIQUETTE	CONEXIÓN CONNECTION CONNEXION	USO PURPOSE USAGE	U/BOLSA U/POUCH U/POCHE	U/CAJA U/BOX U/CARTON
LF-50		Ø 50	ESPUMA FOAM MOUSSE	SEMILÍQUIDO SEMILIQUID SEMI-LIQUIDE	X	CORCHETE · STUD · AGRAFE	A	50	1000
LF-36		36 x 50		SEMILÍQUIDO SEMILIQUID SEMI-LIQUIDE	X		A / P		
SX-50		Ø 50		SÓLIDO SOLID SOLIDE			A		
SX-36		36 x 50		SÓLIDO SOLID SOLIDE			A / P		
SF-36		36 x 42		SÓLIDO SOLID SOLIDE	X		A / P		
SX-30		Ø 30		SÓLIDO SOLID SOLIDE	X		A / P / N		
LEH-36		36 x 50		SEMILÍQUIDO SEMILIQUID SEMI-LIQUIDE	X		STRESS		
SP-50		Ø 50	PAPEL TAPE PAPIER	SÓLIDO SOLID SOLIDE	X		A	50	1000
LP-50		Ø 50		SEMILÍQUIDO SEMILIQUID SEMI-LIQUIDE	X		A		
LR-50		Ø 50	TEXTIL TEXTILE TISSU	SEMILÍQUIDO SEMILIQUID SEMI-LIQUIDE	X		A	50	1000
EKF-22KT		22 x 22	ESPUMA FOAM MOUSSE	SÓLIDO SOLID SOLIDE			A / P / N	6	300

CARDIOLOGÍA · CARDIOLOGY · CARDIOLOGIE

Nomenclatura: A Adultos · P Pediátricos · N Neonatal · PS Polisomnografia · EM Electromiografia
Nomenclature: A Adults · P Pediatric · N Neonates · PS Polisomnography · EM Electromiography
Nomenclature: Adultes · Pédiatrique · Néonatal · Polisomnographie · Électromyographie

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 756915 R000

Manufacturer: Telic, S.A.U.

Address:
Polígono Industrial Can Barri
C/ Molí d'en Barri 7
Bigues i Riells
Barcelona
08415
Spain

Single Registration Number: ES-MF-000001853

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-09-19**

Current Issue Date: **2023-01-16**

Starting Validity Date: **2023-01-16**

Expiry Date: **2027-09-18**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 756915 R000

Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Electrosurgical ground plates	Electrosurgery Pads (Neutral Electrodes) and Cables, Single-Use.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Disposable electrode tip cleaner	Class Is
Cover for surgical light handle	Class Is
Sterile ultrasound gel	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

First Issue Date: **2022-09-19**

Current Issue Date: **2023-01-16**

Starting Validity Date: **2023-01-16**

Expiry Date: **2027-09-18**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 756915 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-09-19	3511303	Issued
Current	3847169	Supplemented: Addition of electrosurgical ground plates. Addition of critical subcontractor.

First Issue Date: **2022-09-19**

Current Issue Date: **2023-01-16**

Starting Validity Date: **2023-01-16**

Expiry Date: **2027-09-18**

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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Telic S.A.U
Polígono Industrial Can Barri
C/ Molí d'en Barri 7
Bigues i Riells
Barcelona
08415
Spain

Holds Certificate Number: **MD 756920**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

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.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-06-02
Effective Date: 2022-08-27
Latest Revision Date: 2022-08-24
Expiry Date: 2025-08-26

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Certificate No: **MD 756920**

Location	Registered Activities
Telic S.A.U Polígono Industrial Can Barri C/ Molí d'en Barri 7 Bigues i Riells Barcelona 08415 Spain	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.
Telic S.A.U Polígono Industrial Can Barri C/ Rieral, 9bis Bigues i Riells Barcelona 08415 Spain	Storage and expeditions 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; sterile surgical vessel loop.

Original Registration Date: 2022-06-02

Effective Date: 2022-08-27

Latest Revision Date: 2022-08-24

Expiry Date: 2025-08-26