DORMO®

DESFI-DORMO®

ELECTRODOS PARA DESFIBRILACIÓN

DEFIBRILLATION ELECTRODES
ÉLECTRODES POUR DÉFIBRILLATION

CLASE I
CLASS I
CLASE I

ELECTRODOS DE DESFIBRILACIÓN CON CABLE

Electrodos para desfibrilación, para uso en DEA (Desfibrilador Externo Automático). Disponible con cable incorporado desechable, en diversos modelos o bien con conexión de corchete standard para su utilización con cables reutilizables.

⚠ EL USUARIO DEBERÁ VERIFICAR LA IDONEIDAD DEL CONECTOR CON SU EQUIPO.

Las referencias pediátricas etiquetadas con AED no deben ser utilizadas con desfibriladores automáticos o semi-automáticos, excepto si la energía de la descarga de desfibrilación se establece de modo manual por el usuario.

DEFIBRILLATION ELECTRODES WITH CABLE

Defibrillation electrodes AED compatible (Automatic External Defibrillator). Available with pre-attached disposable cable, in different models, or with standard stud connection for use with reusable cables.

⚠ USER MUST CHECK COMPATIBILITY OF CABLE CONNECTION WITH THE EQUIPMENT.

The pediatrics references labeled with AED must not be used with automated or semi-automated external defibrillators, unless the defibrillation energy is set in manual mode by the user.

ÉLECTRODES POUR DÉFIBRILLATION AVEC CÂBLE

Électrodes pour défibrillation usage unique à utiliser avec DEA (Défibrillateur Externe Automatique). Câble jetable incorporé disponible en différents modèles de connecteur ou avec connexion d'agrafe standard pour l'utilisation avec câbles réutilisables.

⚠ L'UTILISATEUR DOIT VÉRIFIER QUEL CONNECTEUR EST L' APPROPRIÉ A SON ÉQUIPEMENT.

Les éléments pédiatriques étiquetés avec AED ne doivent pas être utilisés avec des défibrillateurs automatiques ou semi-automatiques, sauf si l'énergie de défibrillation est réglée en mode manuel par l'utilisateur.

REF	CONECTOR CONECTOR CONNECTEUR		PRECONECTADO PRE-CONNECTED PRECONNECTÉ	MULTIFUNCIÓN MULTIFUNCTION MULTIFONCTION	MARCA BRAND MARQUE	EQUIPO/MODELO EQUIPMENT/MODEL EQUIPE/MODEL	U/CAJA U/BOX U/CARTON
EDC-1015		A	✗	✓	PHYSIO-CONTROL/ MEDTRONIC	Lifepack12 Lifepack15 Lifepack20e Lifepack1000	10
EDC-2015			✓				
EDC-P115		P	✗	✗	MINDRAY	Beneheart D3	
EDC-P215			✓		LECOR	Cor-Res A6S	
EDC-1020		A	✗	✓	AGILENT PHILIPS	Heartstart XL	10
EDC-2020			✓				
EDC-P120		P	✗	✗	AMI ITALIA	Saver One	
EDC-P220			✓				
EDC-1025		A	✗	✓	AGILENT	Heartstream XLT (cable M3507A)	10
EDC-1030		A	✗	✓	PROGETTI	RESCUE RESCUE SAM	10
EDC-P130		P	✗	✗	GENERAL ELECTRIC	Responder AED	
EDC-1035		A	✗	✓	ZOLL	Series E. Series R Series M	10
EDC-2035			✓				
EDC-2035L							
EDC-P135		P	✗	✗	M&B	AED7000/MB7000	
EDC-P235			✓				

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REF	CONECTOR CONECTOR CONNECTEUR		PRECONECTADO PRE-CONNECTED PRECONNECTÉ	MULTIFUNCIÓN MULTIFUNCTION MULTIFONCTION	MARCA BRAND MARQUE	EQUIPO/MODELO EQUIPMENT/MODEL EQUIPE/MODEL	U/CAJA U/BOX U/CARTON
EDC-1040		A	✗	✓	NIHON KOHDEN	CARDIOLIFE Adapter cable JC-765V CARDIOLIFE Adapter cable JC-865V	10
EDC-2040			✓				
EDC-P140		P	✗	✗			
EDC-P240			✓				
EDC-1045		A	✗	✓	SCHILLER	Defigard 4000 Fred Easy	10
EDC-2045			✓				
EDC-P145		P	✗	✗			
EDC-P245			✓				
EDC-1050		A	✗	✓	CU MEDICAL SYSTEMS	Paramedic CU-ER1	10
EDC-P150		P	✗	✗			
EDC-1055		A	✗	✓	NIHON KOHDEN	CARDIOLIFE, TEC-7731K Adapter cable JC-755V ActiBiphasic CARDIOLIFE TEC-5531K CARDIOLIFE, Adapter cable JC-855V	10
EDC-P155			✓				
EDC-2055		P	✗	✗			
EDC-P255			✓				
EDC-1060		A	✗	✓	HP / PHILIPS	Heartstart XL	10
EDC-P160		P	✗	✗			
EDC-2060		A	✓	✓	HP / PHILIPS	Heartstart XL Heartstart FR2+	
EDC-P260		P	✓	✗	HP / PHILIPS	Heartstart XL	
EDC-2065		A	✓	✓	MEDIANA	D500	10
EDC-P265		P	✓	✗			
EDC-1070		A	✗	✓	CORPULS	CORPULS 3 - 0960 CORPULS 3	10
EDC-P170		P	✗	✗			
EDC-2070		A	✓	✓		CORPULS 3	

REF	CONECTOR CONECTOR CONNECTEUR		PRECONECTADO PRE-CONNECTED PRECONNECTÉ	MULTIFUNCIÓN MULTIFUNCTION MULTIFONCTION	MARCA BRAND MARQUE	EQUIPO/MODELO EQUIPMENT/MODEL EQUIPE/MODEL	U/CAJA U/BOX U/CARTON
EDC-1075		A	✕	✓	MEDIANA	A10	10
EDC-2075			✓				
EDC-P175		P	✕	✕			
EDC-P275			✓				
EDC-2080		A	✓	✓	SCHILLER	Defigard Touch7 Fred PA-1	10
EDC-2085		A	✓	✓	TELEFUNKEN HEARTRESET	HR1, FA1	10
EDC-2090		A	✓	✓	ZOLL	X Series	10
EDC-P290		P	✓	✕			

MULTIFUNCTION

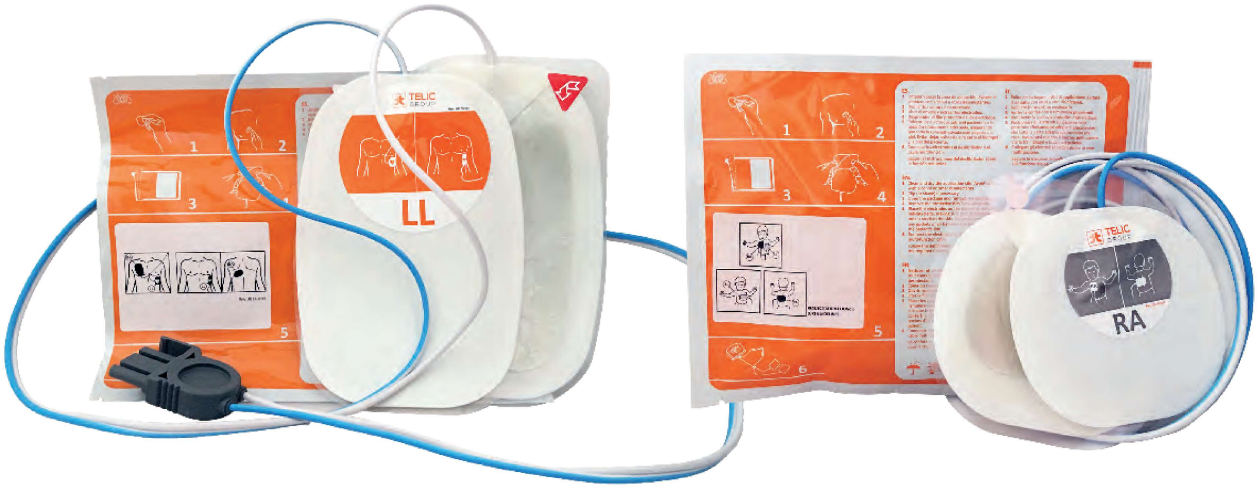
Desfibrilación, Cardioversión Sincronizada, Monitorización E.C.G.
Defibrillation, Synchronized Cardioversion, E.C.G. Monitoring.
Défibrillation, Cardioversion Synchronisée, Surveillance E.C.G.

Dispositivo fabricado según Normas EN IEC 60601-2-4
Device manufactured according to EN IEC 60601-2-4 Standard
Dispositif fabriqué suivant Réglementation EN IEC 60601-2-4

En caso de duda en relación a las compatibilidades de los electrodos de desfibrilación, consultar al comercial.

In case of doubt regarding compatibilities of defibrillation electrodes, consult the sales representative

Si vous avez des questions sur la compatibilité des électrodes de défibrillation, consultez votre commercial.



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	CONECTOR CONECTOR CONNECTEUR		PRECONECTADO PRE-CONNECTED PRECONNECTÉ	MULTIFUNCIÓN MULTIFUNCTION MULTIFONCTION	U/CAJA U/BOX U/CARTON
ED-1010		A	✕	✕	50

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Dispositivo fabricado según Normas EN IEC 60601-2-4 · Device manufactured according to EN IEC 60601-2-4 Standard · Dispositif fabriqué suivant Réglementation EN IEC 60601-2-4

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