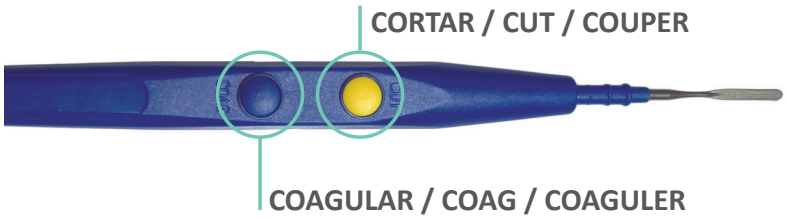
MANGO DE BISTURÍ ELECTROQUIRÚRGICO, CONTROL MANUAL

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.

CABLE · CABLE · CÂBLE **3m**

STERILE EO · LATEX

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**

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

STERILE EO · LATEX · RADIOPAQUE

CLASE I estéril
CLASS I sterile
CLASE I stérile

MB-200

Contiene
Contains
Contient
— **1 MB-100 + 1 AL-40**

LATEX

CLASE IIb
CLASS IIb
CLASE IIb
+
CLASE I estéril
CLASS I sterile
CLASE I stérile

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

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) · Common to all BLAYCO® pencil models (MB-100, MB-200) · Communs à tous les modèles de manche BLAYCO® (MB-100, MB-200).

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					

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