

Mango de bisturí electroquirúrgico reutilizable Reusable electrosurgical pencil

Manches de bistouri électrochirurgical réutilisable Blayco

Blayco MBR600 reusable electrosurgical pencil easy to use, lightweight, with corriortable anatomical profile, fingertip control, with 3 m cable and standard 3-pin connector. Mango de bisturí electroquirúrgico reutilizable Blayco MBR600 de fácil manejo, ligero, con comodo perifi anatómico, control de bolón, con cable de 3 m y conector estándar de 3 pins. Se sirve con electrodo activo de cuchilla de 70 mm de longitud, desmontable.

Served with 70 mm blade active electrode, removable.

Manche bistouri électrochtrugical réutilisable Blayon MBR600 tarté à utiliser, réutilisable avec profit anatomique confortable, commande à buton-pression, avec câble de 3 m et connecteur standard à 3 broches.

Livré avec électrode active de lame de 70 mm de longueur, amovible.

	South States	ABLE
Presentación Presentation Présentation	Mango de bisturi electroquirúrgico MBR600 Blayco + Electrodo activo de cuchilla da 70 mm Blayco MBR600 reusable electrosurgical pencil + 70 mm blade active electrode Manche de bistouri électrochururgical Blayco MBR600 + Électrode active de lame de 70 mm	UTU3A
Control Control Contrôle	Botón Fingertip Bouton	
Cable Cable Câble	E co	
Código Code Code	TCR06F	Clase IIb
Referencia Reference <i>Réference</i>	MBR600F	THE AND A DESCRIPTION OF A DESCRIPTION O



Blayco AL-40 active electrode cleaning device, self-adhesive, sterle, radiopaque.

Dispositivo limpiador de electrodos activos Blayco AL-40, autoadhesivo, estéril, radiopaco.

Dispositif de nettoyage d'électrode

Blayco

Cleaning device for electrode

Limpiador de electrodo

AL-40,	Unidades / Caja Units / Box Unité / Carton
ctrode active Blayco ɔaque.	Unidades / Bolsa Units / Pouch Unité / Poche
Dispositif de nettoyage d'électrode active Blayco AL-40, auto-adhésif, stérile, radio-opaque.	Grosor Thickness Epaisseur
	Medida Dimensions <i>Mesure</i>
	Código Code Code

250

-

6 mm

50 x 50 mm

TCG01

AL-40

Referencia Reference *Réference*

Clase l estéril S X STERILE EO RADIOPAQUE





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** ...making excellence a habit."

Page 1 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80 Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK. A Member of the BSI Group of Companies.





EU Quality Management System Certificate

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

MDR 756915 R000

maintaining sterile conditions.

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	13 12 17 12
Disposable electrode tip cleaner	Class Is	
Cover for surgical light handle	Class Is	
Sterile ultrasound gel	Class Is	- A BAR STORE
For Class Is devices, the Notified Body conformity	assessment is limited to the aspects relating	to establishing, securing and

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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

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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 Latest Revision Date: 2022-08-24 Effective Date: 2022-08-27 Expiry Date: 2025-08-26

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Certificate No: MD 756920

Location

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

Telic S.A.U Polígono Industrial Can Barri C/ Rieral, 9bis Bigues i Riells Barcelona 08415 Spain **Registered Activities**

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.

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.

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