

MANGO DE BISTURÍ ELECTROQUIRÚRGICO, CONTROL MANUAL

blayco

HAND CONTROL ELECTROSURGICAL PENCIL
MANCHE DE BISTOURI ELECTROCHIRURGICAL, COMMANDE DIGITALE

CARACTERÍSTICAS

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

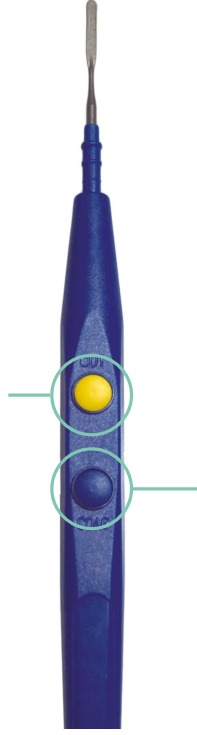
CHARACTERISTICS

- Easy handling
- Light
- Comfortable anatomical shape
- 3-pin standard connector

RENSEIGNEMENTS

- Facile utilisation
- Léger
- Comfortable contour anatomique
- Connecteur standard de 3 pins

CORTAR / CUT / COUPER



COAGULAR / COAG / COAGULER

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.

AL-40

Dispositivo limpiador de electrodo, autoadhesivo. RADIOPAQUE.
Adhesive electrode cleaning device. RADIOPAQUE.
Dispositif autoadhésif nettoyeur d'électrode. RADIO-OPAQUE.

MB-200

Contiene
Contains
Contient

1 MB-100 + 1 AL-40

MBR-600

Mango bisturí, control manual con accesorio AB-80, desmontable.
Hand control electrosurgical pencil, with removable AB-80 accessory.
Manche bistouri, contrôle manuel avec accessoire AB-80 amovible.

REUTILIZABLE
REUSABLE
REUTILISABLE

NECES · TIMES · FOIS
30

NON
STERILE

MB-100



AL-40

MBR-600



ÍNDICE CIRUGÍA · SURGERY INDEX · CHIRURGIE SOMMAIRE



REF	PACIENTE PATIENT	SUPERFICIE TOTAL TOTAL AREA SURFACE TOTAL (cm²)	SUPERFICIE DE CONTACTO CONTACT AREA SURFACE DE CONTACT (cm²)	ESPESOR THICKNESS ESPAISSEUR (mm)	CABLE / CONNECTOR CABLE / CONNECTOR CÂBLE / CONNECTEUR	U/BOLSA U/POUCH U/POCHE	U/CAJA U/BOX U/CARTON
2125	A	215	136,50	1,65	-	1	100
2125-5					-	5	100
2125-C/00					3 m / 4200	1	50
2125-C/10					3 m / 4210	1	50
2125-C/21					3 m / 4221	1	50
2225	P	129	82	1,65	-	1	100
2225-5					-	5	100
2225-C/00					3 m / 4200	1	50
2225-C/10					3 m / 4210	1	50
2425	N	63	32	1,65	-	1	50
2425-C/00					3 m / 4200	1	50
2425-C/10					3 m / 4210	1	50
2925	U	165	114	1,65	-	1	100
2925-5					-	5	100
2925-C/00					3 m / 4200	1	50
2925-C/10					3 m / 4210	1	50
2500	A	215	122	1,65	-	1	100
2500-5					-	5	100
2500-C/00					3 m / 4200	1	50
2500-C/12					3 m / 4212	1	50
2500-C/12/5					5 m / 4212	1	50
2510	A	211	125	1,65	-	1	100
2510-5					-	5	100
2510-C/00					3 m / 4200	1	50
2510-C/12					3 m / 4212	1	50
2600	P	129	73	1,65	-	1	100
2600-C/00					3 m / 4200	1	50
2600-C/12					3 m / 4212	1	50
2700	N	63	29	1,65	-	1	50
2700-C/00					3 m / 4200	1	50
2700-C/12					3 m / 4212	1	50
2900	U	165	108	1,65	-	1	100
2900-5					-	5	100
2900-C/00					3 m / 4200	1	50
2900-C/12					3 m / 4212	1	50
2900-C/12/5					5 m / 4212	1	50





CABLE PINZA REUTILIZABLE · REUSABLE CLAMP-CABLE · CABLE-PINCE REUTILISABLE.



4200



4210



4212

Este listado de correlaciones entre conectores y modelos de unidad electroquirúrgica no supone un compromiso por parte de Telic, SAU, que no puede asumir ninguna responsabilidad al respecto puesto que no existe ningún vínculo legal con el fabricante del equipo. Es responsabilidad del cliente comprobar qué modelo de conector es compatible con el equipo.

The present list correlating connectors with electrosurgical units model does not suppose any commitment by Telic, SAU, who assume no responsibility in that regard as there is not any legal binding with the equipment manufacturer. It is responsibility of the client to check which connector model is compatible with the equipment.

Cette liste des corrélations entre les connecteurs et les modèles d'appareil électro-chirurgical n'implique pas un engagement par Telic, SAU, qui n'assume aucune responsabilité à ce sujet puisqu'il n'est aucun lien juridique avec le fabricant de l'équipement. C'est la responsabilité du client de vérifier quel modèle de connecteur est compatible avec l'équipement.

Rogamos indiquen tipo de conexión al efectuar sus pedidos. (REM es una Marca Registrada de Valleylab Inc.)

You are kindly requested to specify the suitable connection when ordering. (REM is a Registered Trademark of Valleylab Inc.)

On prie d'indiquer le type de connexion à la confirmation de la commande. (REM est une Marque Enregistrée par Valleylab Inc.)

Dispositivo fabricado según Normas · Device manufactured under Standards · Dispositif fabriqué suivant Standards:

ANSI/AAMI/ISO-IEC 60601-2-2



EC CERTIFICATE

TELIC, S.A.U.

Polígono Industrial Can Barri, C/ Molí d'en Barri, 7-9
08415 Bigues, Barcelona, Spain

Full Quality Assurance System Approval Certificate

Annex II (excluding section 4) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

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; Drug-delivery iontophoresis patch; Operating/examination/treatment light handle cover, single-use; coupling gel, sterile.

Device Classification:

Please refer to Attachments

G/UMDN Code:

Please refer to Attachments

Device Descriptions:

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; Drug-delivery iontophoresis patch; Operating/examination/treatment light handle cover, single-use; coupling gel, sterile.

Model Type:

Please refer to Attachments

We hereby declare that an examination of the full quality assurance system has been carried out per report 11801655, following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC, Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with 9 attachments listing model numbers.

File Number A17128
Certificate No. 572.170827

Cycle Start Date 27 August 2017
Effective Date 27 August 2017
Expiry Date 26 August 2022

Authorised by

Deborah Stubbs
Certification Manager

For and on Behalf of UL International (UK) Ltd

Notified Body

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EC CERTIFICATE

TELIC, S.A.U.

Polígono Industrial Can Barri, C/ Molí d'en Barri, 7-9
08415 Bigues, Barcelona, Spain

Attachment 1 of 9

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Multifunction cardiac electrode, adult		EDA-1012	Class IIb	45806
		EDC-1015	Class IIb	45806
		EDC-1020	Class IIb	45806
		EDC-1025	Class IIb	45806
		EDC-1030	Class IIb	45806
		EDC-1035	Class IIb	45806
		EDC-1040	Class IIb	45806
		EDC-1045	Class IIb	45806
		EDC-1050	Class IIb	45806
		EDC-1055	Class IIb	45806
		EDC-1060	Class IIb	45806
		EDC-1065	Class IIb	45806
		EDC-1070	Class IIb	45806
		EDC-1075	Class IIb	45806
		EDC-2015	Class IIb	45806
		EDC-2020	Class IIb	45806
		EDC-2025	Class IIb	45806
		ECD-2030	Class IIb	45806

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Attachment 2 of 9

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Multi-function electrodes. Adult		EDC-2035	Class IIb	45806
		EDC-2040	Class IIb	45806
		EDC-2045	Class IIb	45806
		EDC-2050	Class IIb	45806
		EDC-2055	Class IIb	45806
		EDC-2060	Class IIb	45806
		EDC-2065	Class IIb	45806
		EDC-2070	Class IIb	45806
		EDC-2075	Class IIb	45806

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Attachment 3 of 9

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
External defibrillator electrode, paediatric, single-use		EDC-P115	Class IIb	41587
		EDC-P120	Class IIb	41587
		EDC-P125	Class IIb	41587
		EDC-P130	Class IIb	41587
		EDC-P135	Class IIb	41587
		EDC-P140	Class IIb	41587
		EDC-P145	Class IIb	41587
		EDC-P150	Class IIb	41587
		EDC-P155	Class IIb	41587
		EDC-P160	Class IIb	41587
		EDC-P165	Class IIb	41587
		EDC-P170	Class IIb	41587
		EDC-P175	Class IIb	41587
		EDC-P215	Class IIb	41587
		EDC-P220	Class IIb	41587

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Attachment 4 of 9

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
External defibrillator electrode, paediatric, single-use		EDC-P225	Class IIb	41587
		EDC-P230	Class IIb	41587
		EDC-P235	Class IIb	41587
		EDC-P240	Class IIb	41587
		EDC-P245	Class IIb	41587
		EDC-P250	Class IIb	41587
		EDC-P255	Class IIb	41587
		EDC-P260	Class IIb	41587
		EDC-P265	Class IIb	41587
		EDC-P270	Class IIb	41587
		EDC-P275	Class IIb	41587
External defibrillator electrode pad		ED-1010	Class IIb	11130

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Attachment 5 of 9

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Electrosurgical return electrode, single-use, non-sterile		2125	Class IIb	58494
		2125-5	Class IIb	58494
		2125-C/00	Class IIb	58494
		2125-C/00/5	Class IIb	58494
		2125-C/10	Class IIb	58494
		2125-C/10/5	Class IIb	58494
		2125-C/21	Class IIb	58494
		2225	Class IIb	58494
		2225-5	Class IIb	58494
		2225-C/00	Class IIb	58494
		2225-C/00/5	Class IIb	58494
		2225-C/10	Class IIb	58494
		2225-C/10/5	Class IIb	58494
		2425	Class IIb	58494
		2425-5	Class IIb	58494
		2425-C/00	Class IIb	58494

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Polígono Industrial Can Barri, C/ Molí d'en Barri, 7-9
08415 Bigues, Barcelona, Spain

Attachment 6 of 9

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Electrosurgical return electrode, single-use, non-sterile		2425-C/00/5	Class IIb	58494
		2425-C/10	Class IIb	58494
		2425-C/10	Class IIb	58494
		2425-C/10/5	Class IIb	58494
		2925	Class IIb	58494
		2925-5	Class IIb	58494
		2925-C/00	Class IIb	58494
		2925-C/00/5	Class IIb	58494
		2925-C/10	Class IIb	58494
		2925-C/10/5	Class IIb	58494
		2500	Class IIb	58494
		2500-5	Class IIb	58494
		2500-C/00	Class IIb	58494
		2500-C/00/5	Class IIb	58494
		2500-C/12	Class IIb	58494
		2500-C/12/5	Class IIb	58494

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Polígono Industrial Can Barri, C/ Molí d'en Barri, 7-9
08415 Bigues, Barcelona, Spain

Attachment 7 of 9

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Electrosurgical return electrode, single-use, non-sterile		2510	Class IIb	58494
		2510-5	Class IIb	58494
		2510-C/00	Class IIb	58494
		2510-C/00/5	Class IIb	58494
		2510-C/12	Class IIb	58494
		2510-C/12/5	Class IIb	58494
		2600	Class IIb	58494
		2600-5	Class IIb	58494
		2600-C/00	Class IIb	58494
		2600-C/00/5	Class IIb	58494
		2600-C/12	Class IIb	58494
		2600-C/12/5	Class IIb	58494
		2700	Class IIb	58494
		2700-5	Class IIb	58494
		2700-C/00	Class IIb	58494
		2700-C/00/5	Class IIb	58494

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Polígono Industrial Can Barri, C/ Molí d'en Barri, 7-9
08415 Bigues, Barcelona, Spain

Attachment 8 of 9

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Electrosurgical return electrode, single-use, non-sterile		2700-C/12	Class IIb	58494
		2700-C/12/5	Class IIb	58494
		2900	Class IIb	58494
		2900-5	Class IIb	58494
		2900-C/00	Class IIb	58494
		2900-C/00/5	Class IIb	58494
		2900-C/12	Class IIb	58494
		2900-C/12/5	Class IIb	58494
Vein stripper, single-use		VE-022	Class IIa	32321
		VE-025	Class IIa	32321
		VE-022 OP	Class IIa	32321
		VE-022 BE CO	Class IIa	32321

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Polígono Industrial Can Barri, C/ Molí d'en Barri, 7-9
08415 Bigues, Barcelona, Spain

Attachment 9 of 9

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Drug-delivery iontophoresis patch		IE-SS15	Class IIa	45141
		IE-B20	Class IIa	45141
		IE-MS25	Class IIa	45141
		IE-LS40	Class IIa	45141
Operating/examination/treatment light handle cover, single-use		LHC-01	Class I sterile	44977
		LHC-02	Class I sterile	44977
		LHC-03	Class I sterile	44977
Coupling gel, sterile		G-15E	Class I sterile	58735

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EC CERTIFICATE

TELIC, S.A.U.

Polígono Industrial Can Barri, C/ Molí d'en Barri, 7-9
08415 Bigues, Barcelona, Spain

Production Quality Assurance System Approval Certificate

Annex V, section 3 of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

Manufacture of General and Vascular Surgery Devices

Device Classification:
Class IIa

G/UMDN Code:
61916

Device Descriptions:

A sterile, nonimplantable cord intended to be used during a surgical procedure to assist a surgeon to identify, retract and occlude blood vessels, tendons and nerves. It is constructed of synthetic polymer and is typically coloured to facilitate visualization. This is a single-use device.

Model Type:

Refer to Attachment 1

We hereby declare that an examination of the production quality assurance system has been carried out per report 11801655, following the requirements of the national legislation to which the undersigned is subject, transposing Annex V of Council Directive 93/42/EEC on Medical Devices. We certify that the production quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC, Annex V, Section 4. For Class IIb & III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex III is required. This certificate is issued with 1 attachment listing model numbers covered by this certificate.

File Number A17128
Certificate No. 736.170827

Cycle Start Date 27 August 2017
Effective Date 27 August 2017
Expiry Date 26 August 2022

Authorised by

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EC CERTIFICATE

TELIC, S.A.U.

Polígono Industrial Can Barri, C/ Molí d'en Barri, 7-9
08415 Bigues, Barcelona, Spain

Attachment 1 of 1

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Surgical vessel loop	Surgical vessel loop	405305	Ila	61916
		402509	Ila	61916
		402505	Ila	61916
		402503	Ila	61916
		402501	Ila	61916
		401909	Ila	61916
		401905	Ila	61916
		401903	Ila	61916
		401901	Ila	61916
		400709	Ila	61916

File Number A17128
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