



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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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

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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

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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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Attachment 6 of 9

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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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Attachment 7 of 9

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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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Attachment 8 of 9

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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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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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