



# 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<br>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<br>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<br>electrode, paediatric,<br>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,<br>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

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,<br>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,<br>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,<br>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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### Attachment 9 of 9

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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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