











CARDIOLOGÍA · CARDIOLOGY · CARDIOLOGIE

| REF | MEDIDAS MEASUREMENTS DIMENSIONS (mm) | SOPORTE BACKING SUPPORT | GEL | ETIQUETA LABEL ÉTIQUETTE | CONEXIÓN CONNECTION CONNEXION | USO PURPOSE USAGE | U/BOLSA U/POUCH U/POCHE | U/CAJA U/BOX U/CARTON |
|----------|---|-------------------------------|---|--------------------------------|-------------------------------------|-------------------------|-------------------------------|-----------------------------|
| LF-50 |  Ø 50 | ESPUMA FOAM MOUSSE | SEMILÍQUIDO SEMILIQUID SEMI-LIQUIDE | X | CORCHETE · STUD · AGRAFE | A | 50 | 1000 |
| LF-36 |  36 x 50 | | SEMILÍQUIDO SEMILIQUID SEMI-LIQUIDE | X | | A / P | | |
| SX-50 |  Ø 50 | | SÓLIDO SOLID SOLIDE | | | A | | |
| SX-36 |  36 x 50 | | SÓLIDO SOLID SOLIDE | | | A / P | | |
| SF-36 |  36 x 42 | | SÓLIDO SOLID SOLIDE | X | | A / P | | |
| SX-30 |  Ø 30 | | SÓLIDO SOLID SOLIDE | X | | A / P / N | | |
| LEH-36 |  36 x 50 | | SEMILÍQUIDO SEMILIQUID SEMI-LIQUIDE | X | | STRESS | | |
| SP-50 |  Ø 50 | PAPEL TAPE PAPIER | SÓLIDO SOLID SOLIDE | X | A | 50 | 1000 | |
| LP-50 |  Ø 50 | | SEMILÍQUIDO SEMILIQUID SEMI-LIQUIDE | X | A | | | |
| LR-50 |  Ø 50 | TEXTIL TEXTILE TISSU | SEMILÍQUIDO SEMILIQUID SEMI-LIQUIDE | X | A | 50 | 1000 | |
| EKF-22KT |  22 x 22 | ESPUMA FOAM MOUSSE | SÓLIDO SOLID SOLIDE | | A / P / N | 6 | 300 | |

Nomenclatura: Adultos A Pediátricos P Neonatal N Polisomnografía PS Electromiografía EM
 Nomenclature: Adults A Pediatric P Neonates N Polisomnography PS Electromiography EM
 Nomenclature: Adultes A Pédiatrique P Néonatal N Polisomnographie PS Électromyographie EM

EU Quality Management System Certificate

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

MDR 756915 R000

Manufacturer: Telic, S.A.U.

Address:

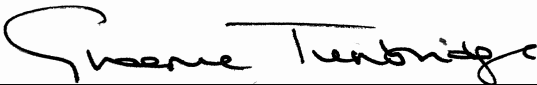
Polígono Industrial Can Barri
C/ Molí d'en Barri 7
Bigues i Riells
Barcelona
08415
Spain

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

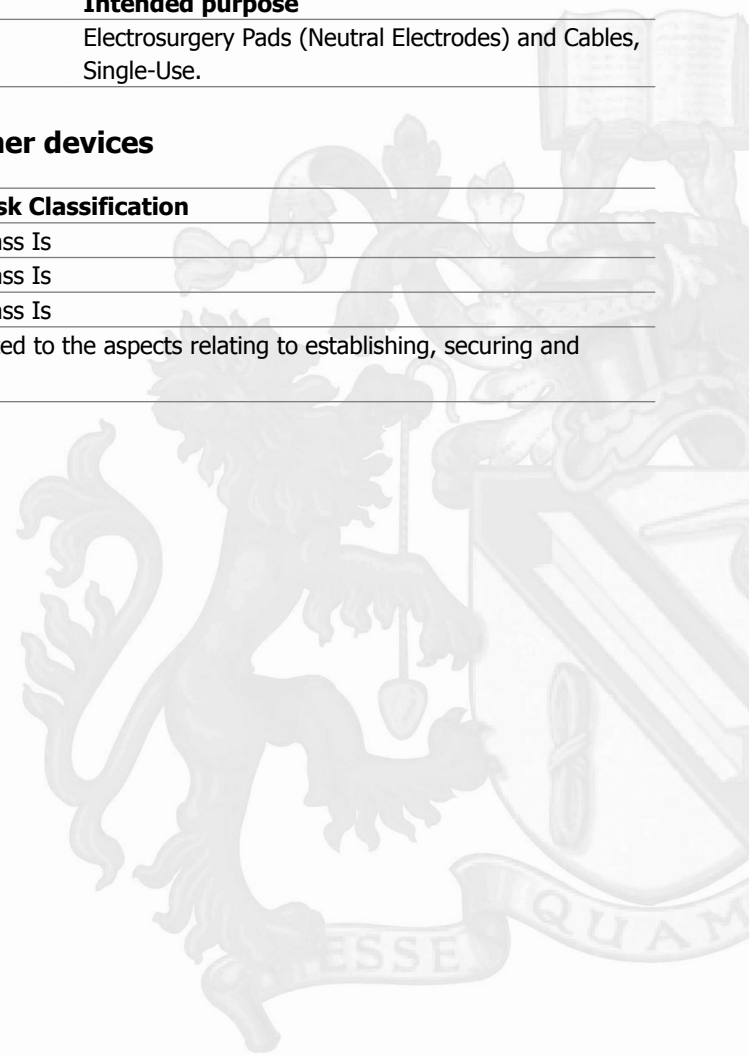
Device Schedule: Class III and Class IIb devices

| 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.



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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. |



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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.

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

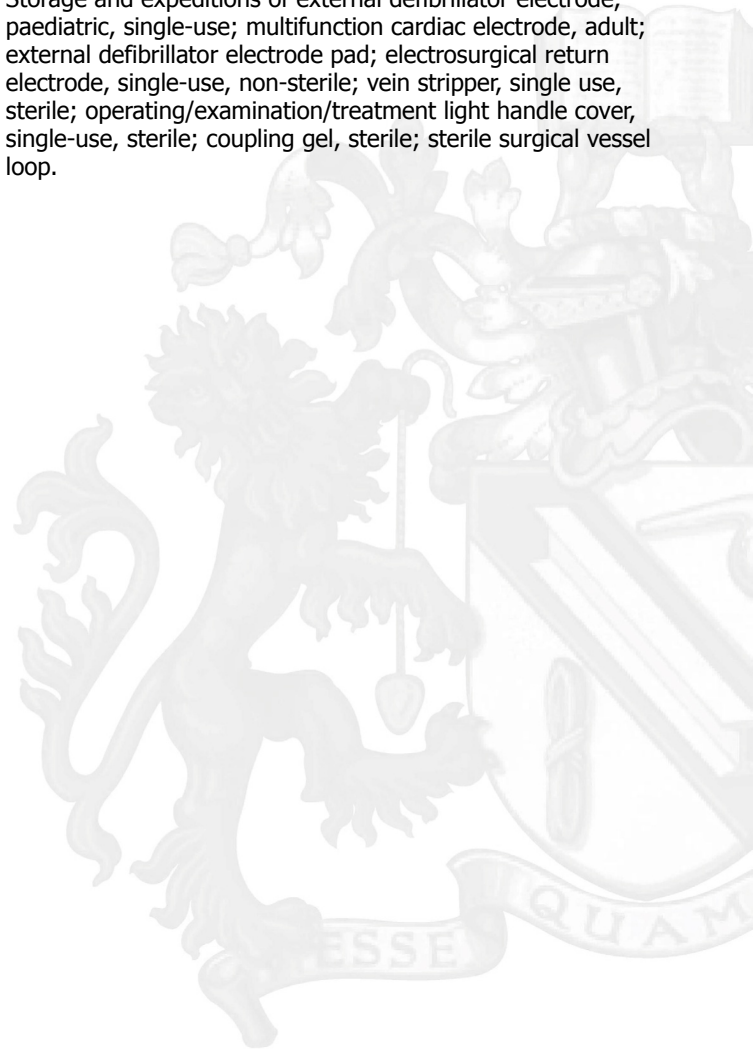
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Certificate No: **MD 756920**

| Location | 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

Page: 2 of 2

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

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact:

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780

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