TELIC, SA
MEDICAL SUPPLIES
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EC DECLARATION OF CONFORMITY

MEDICAL DEVICES DIRECTIVE 93/42/EEC

According to ISO/IEC 17050

PRODUCT MANUFACTURER:	TELIC, SA
ADDRESS:	Pol. Ind. Can Barri. C/ Molí d'en Barri, 7-9 E-08415 Bigues BARCELONA – SPAIN

Declaration

The products listed in annex, manufactured by TELIC, SA, conform with the requisites of the Medical Devices Directive 93/42/EEC and its amendments up to 2007/47/EC Directive, and meet the requirements established in the Essential Requirements of the Annex I of above mentioned Directive. Technical documentation in accordance with Annex VII of Directive 93/42/EEC is updated and located in our facilities. We are in position to submit the documentation to a Notified Body or Competent Authority.

This declaration applies to design, manufacturing and final control of medical devices listed in annex.

Quality Management System Certificate:

EN-ISO 13485:2003
Certificate number: 2001 12 0310 EN
Issued: Agencia Española de Medicamentos y Productos Sanitarios
Notified Body nº 0318

Standards applied:

ISO 13485 Medical devices. Quality management systems.
ISO 14971 Medical devices. Application of risk management to medical devices.
ISO 14644-1 Cleanrooms and associated controlled environments. Classification of air cleanliness.
ISO 14644-4 Cleanrooms and associated controlled environments. Design, construction and start-up.
ISO 14644-5 Cleanrooms and associated controlled environments. Operations.
ISO 14644-8 Cleanrooms and associated controlled environments. Classification of airborne molecular contamination.
ISO 10993-1 Biological evaluation of medical devices. Evaluation and testing.
ISO 10993-4 Biological evaluation of medical devices. Selection of tests for interactions with blood.
ISO 10993-5 Biological evaluation of medical devices. Tests for in vitro cytotoxicity.
ISO 10993-7 Biological evaluation of medical devices. Ethylene oxide sterilization residuals.
ISO 10993-9 Biological evaluation of medical devices. Framework for identification and quantification of potential degradation products
ISO 10993-10 Biological evaluation of medical devices. Tests for irritation and delayed-type hypersensitivity.
ISO 10993-11 Biological evaluation of medical devices. Tests for systemic toxicity.
ISO 10993-13 Biological evaluation of medical devices. Identification and quantification of degradation products from polymeric medical devices.

Standards applied:

EN 556 Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices.
ISO 11135-1 Sterilization of health care products. Ethylene oxide. Requirements for development, validation and routine control of a sterilization process for medical devices.
ISO 11135-2 Sterilization of health care products. Ethylene oxide. Guidance on the application of ISO 11135-1.
ISO 11138-1 Sterilization of health care products. Biological indicators. General requirements.
ISO 11138-2 Sterilization of health care products. Biological indicators. Biological indicators for ethylene oxide sterilization processes
ISO 11607-1 Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems.
ISO 11607-2 Packaging for terminally sterilized medical devices. Validation requirements for forming, sealing and assembly processes.
IEC 60601-1 Medical electrical equipment. General requirements for basic safety and essential performance.
IEC 60601-2-2 Medical electrical equipment. Requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.
IEC 60601-2-4 Medical electrical equipment. Particular requirements for the safety of cardiac defibrillators.
ANSI/AAMI EC12 Disposable ECG electrodes.
EN 980 Symbols for use in the labelling of medical devices.
EN 1617 Sterile drainage catheters and accessory devices for single use.
EN 1618 Catheters other than intravascular catheters. Test methods for common properties.
EN 13868 Catheters. Test methods for kinking of single lumen catheters and medical tubing.

Authorised signatory:

Xavier Guerrero
QA Manager

Oscar Lacruz
General Manager

02/May/2012
Date

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Product list annex

EC Full Quality Assurance System Certificate
In accordance with Annex II (except Section 4) of Directive 93/42/EEC
Issued: Agencia Española de Medicamentos y Productos Sanitarios, Notified Body nº 0318
Certificate number 2001 12 0310 CT
Products included:

Device description	Class	Classification Rule	GMDN	Sterile / Non sterile
Dispersive or return electrode for electrosurgery	IIb	A. IX, Rule 9	11500	Non Sterile
Set of two adhesive pregelled pads with conductive hydrogel for defibrillation. Electrodes without leadwire for adult patient use.	IIb	A. IX, Rule 9	15033	Non Sterile

EC Full Quality Assurance System Certificate
In accordance with Annex II (except Section 4) of Directive 93/42/EEC
Issued: Agencia Española de Medicamentos y Productos Sanitarios, Notified Body nº 0318
Certificate number 2006 10 0507 CT
Products included:

Device description	Class	Classification Rule	GMDN	Sterile / Non sterile
Vein strippers	IIa	A. IX, Rule 7	13828	Sterile
Vein strippers ready for invagination	IIa	A. IX, Rule 7	13828	Sterile
Non collapsing capillary drain	IIa	A. IX, Rule 7	14191	Sterile

EC Production Quality Assurance System Certificate
In accordance with Annex V of Directive 93/42/EEC
Issued: Agencia Española de Medicamentos y Productos Sanitarios, Notified Body nº 0318
Certificate number 2011 10 0771 CP
Products included:

Device description	Class	Classification Rule	GMDN	Sterile / Non sterile
Vascular loops for identification, occlusion or retraction	IIa	A. IX, Rule 7	12397	Sterile

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Product list annex (cont.)

EC Full Quality Assurance System Certificate
In accordance with Annex II (except Section 4) of Directive 93/42/EEC
Issued: UL International (UK) Ltd, Notified Body nº 0843
Certificate number 572.120423
Products included:

Device description	Class	Classification Rule	GMDN	Sterile / Non sterile
Defibrillation electrodes with lead wire and electrodes with quick connection and plug connection for adult patient use	IIb	A. IX, Rule 9	18011	Non Sterile
Defibrillation electrodes with lead wire and electrodes with quick connection and plug connection for infant/child patient use	IIb	A. IX, Rule 9	15033	Non Sterile
Sterile Ultrasound Gel	I	A. IX, Rule 5	15321	Sterile

Self-Certified products

Device description	Class	Classification Rule	GMDN	Sterile / Non sterile
ECG electrodes and accessories	I	A. IX, Rule 1	11439	Non Sterile
ECG electrodes and accessories newborn patient use	I	A. IX, Rule 1	17460	Non Sterile
Resting electrodes and accessories	I	A. IX, Rule 1	11439	Non Sterile
Bite-block	I	A. IX, Rule 5	10405	Non Sterile
Nasal holder for gastric catheters	I	A. IX, Rule 1	17514	Non Sterile
Paraffin for rehabilitation and anatomical pathology	I	A. IX, Rule 1	12956	Non Sterile
Lubricating gel	I	A. IX, Rule 5	12401	Non Sterile
Electrosurgical clamp cables for return electrodes	I	A. IX, Rule 1	11500	Non Sterile
Tens electrodes	I	A. IX, Rule 1	17191	Non Sterile
Protective pad	I	A. IX, Rule 1	18411	Non Sterile
Protective/Fixative hydrogel bands	I	A. IX, Rule 1	12705	Non Sterile
ECG gel	I	A. IX, Rule 1	11425	Non Sterile
Ultrasound gel	I	A. IX, Rule 1	15321	Non Sterile
Otoscope speculum	I	A. IX, Rule 5	13662	Non Sterile

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Product list annex (cont.)

Article 12 MDD for Procedure Pack

In accordance with Article 12 of Directive 93/42/EEC for Procedure Pack of articles with their own CE certificate.

Products included:

Device description	Class	Classification Rule	GMDN	Sterile / Non sterile
Electrosurgical pencil, hand control, with 70mm blade electrode and adhesive tip cleaner	IIb	A. IX, Rule 9	11499	Individual components sterile Pack non sterile