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EC DECLARATION OF CONFORMITY

TELIC, SAU declares that the products listed in annexes of the present declaration have been manufactured according to requirements of the **Medical Devices Directive 93/42/EEC** and meet requirements set in the Essential Requirements of the Annex I of above mentioned Directive.

Technical documentation, in accordance with the established in the corresponding annexes of Directive 93/42/EEC, is updated and located in our facilities. We are in position to submit these documents in case of Notified Body or Competent Authority requirement.

This declaration applies to design, manufacturing and final control of medical devices. Validity of the present declaration is subject to the expiration of the corresponding EC certificates for different products.

Bigues, on 12th January 2017

Cinta Cid
Technical Manager

Oscar Lacruz
CEO

EC DECLARATION OF CONFORMITY – ANNEX 1
List of products with EC mark

Defibrillation electrodes without cable	
Description	Set of two adhesive pre-gelled pads with conductive hydrogel for defibrillation. To be used for adult patient use.
Commercial brand	DESFI-DORMO
References	ED-1010
Classification	
Product class IIb - Non-sterile. According to Rule 9 of Annex IX of the 93/42/EEC Directive	
GMDN	15033
EC Full Quality Assurance System Certificate	
In accordance to Annex II (except Section 4) of Directive 93/42/EEC Certificate number 735.150311 Issued by: UL International (UK) Ltd. Notified Body number 0843 Valid until: 26/08/2017	
Standards applied	
EN-60601-1:2006/A1:2013 Medical electrical equipment. General requirements for basic safety and essential performance. EN-60601-2-4 Medical electrical equipment. Particular requirements for the safety of cardiac defibrillators. 2011/65/EU Directive (RoHS 2)	

Return electrodes for electrosurgery	
Description	Pre-gelled electrosurgical plates.
Commercial brand	BLAYCO, NORMA
References	2125, 2125-5, 2125-C/00, 2125-C/00/5, 2125-C/10, 2125-C/21, 2225, 2225-5, 2225-C/00, 2225-C/10, 2425, 2425-C/00, 2425-C/10, 2925, 2925-5, 2925-C/00, 2925-C/10, 2500, 2500-5, 2500-C/00, 2500-C/12, 2500-C/12/5 2510, 2510-5, 2510-C/00, 2510-C/12, 2600, 2600-C/00, 2600-C/12, 2700, 2700-C/00, 2700-C/12, 2900, 2900-5, 2900-C/00, 2900-C/12, 2900-C/12/5
Classification	
Product class IIb - Non-sterile. According to Rule 9 of Annex IX of the 93/42/EEC Directive	
GMDN	11500
EC Full Quality Assurance System Certificate	
In accordance to Annex II (except Section 4) of Directive 93/42/EEC Certificate number 735.150311 Issued by: UL International (UK) Ltd. Notified Body number 0843 Valid until: 26/08/2017	

Standards applied
EN-60601-1:2006/A1:2013 Medical electrical equipment. General requirements for basic safety and essential performance.
EN-60601-2-2:2009 Medical electrical equipment. Requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.
2011/65/EU Directive (RoHS 2)

Vein strippers	
Description	Single use vein strippers.
Commercial brand	DORMO-STRIP
References	VE-022, VE-025, VE-022 OP, VE-022 BE CO
Classification	
Product class IIa - Sterile. According to Rule 7 of Annex IX of the 93/42/EEC Directive	
GMDN	32321
EC Full Quality Assurance System Certificate	
In accordance to Annex II (except Section 4) of Directive 93/42/EEC Certificate number 737.150311 Issued by: UL International (UK) Ltd. Notified Body number 0843 Valid until: 26/08/2017	

Vascular loops	
Description	Two vascular loops for identification, occlusion, retraction.
Commercial brand	DORMO-LOOP
References	405305, 402509, 402505, 402503, 402501, 401909, 401905, 401903, 401901, 400709
Classification	
Product class IIa - Sterile. According to Rule 7 of Annex IX of the 93/42/EEC Directive	
GMDN	12397
EC Full Quality Assurance System Certificate	
In accordance to Annex V of Directive 93/42/EEC Certificate number 736.150311 Issued by: UL International (UK) Ltd. Notified Body number 0843 Valid until: 26/08/2017	

Defibrillation electrodes with cable for adult patient	
Description	Set of two multi-function electrodes. Adult.
Commercial brand	DESFI-DORMO
References	EDA-1012, EDC-1015, EDC-1020, EDC-1025, EDC-1030, EDC-1035, EDC-1040, EDC-1045, EDC-1050, EDC-1055, EDC-1060, EDC-1065, EDC-1070
Description	Set of two multi-function electrodes. Adult. Pre-connected.
Commercial brand	DESFI-DORMO
References	EDC-2015, EDC-2020, EDC-2030, EDC-2035, EDC-2055, EDC-2060
Classification	
Product class IIb – Non-sterile. According to Rule 9 of Annex IX of the 93/42/EEC Directive	
GMDN	18011
EC Full Quality Assurance System Certificate	
In accordance to Annex II (except Section 4) of Directive 93/42/EEC Certificate number 572.160906 Issued by: UL International (UK) Ltd. Notified Body number 0843 Valid until: 26/08/2017	
Standards applied	
EN-60601-1 Medical electrical equipment. General requirements for basic safety and essential performance. EN-60601-2-4 Medical electrical equipment. Particular requirements for the safety of cardiac defibrillators. 2011/65/EU Directive (RoHS 2)	

Defibrillation electrodes with cable paediatrics	
Description	Set of two defibrillation electrodes. Paediatrics.
Commercial brand	DESFI-DORMO
References	EDC-P115, EDC-P120, EDC-P125, EDC-P130, EDC-P135, EDC-P140, EDC-P145, EDC-P150, EDC-P155, EDC-P165, EDC-P170
Description	Set of two defibrillation electrodes. Paediatrics. Pre-connected.
Commercial brand	DESFI-DORMO
References	EDC-P255
Classification	
Product class IIb – Non-sterile. According to Rule 9 of Annex IX of the 93/42/EEC Directive	
GMDN	15033
EC Full Quality Assurance System Certificate	
In accordance to Annex II (except Section 4) of Directive 93/42/EEC Certificate number 572.160906 Issued by: UL International (UK) Ltd. Notified Body number 0843 Valid until: 26/08/2017	

Standards applied
EN-60601-1 Medical electrical equipment. General requirements for basic safety and essential performance.
EN-60601-2-4 Medical electrical equipment. Particular requirements for the safety of cardiac defibrillators.
2011/65/EU Directive (RoHS 2)

Sterile ultrasound gel	
Description	Ultrasound transmission gel. Sterile.
Commercial brand	TRANSONIC
References	G-15E
Classification	
Product class I - Sterile. According to Rule 5 of Annex IX of the 93/42/EEC Directive	
GMDN	15321
EC Full Quality Assurance System Certificate	
In accordance to Annex II (except Section 4) of Directive 93/42/EEC Certificate number 572.160906 Issued by: UL International (UK) Ltd. Notified Body number 0843 Valid until: 26/08/2017	

Cover for surgical light handle	
Description	Cover for surgical light handle.
Commercial brand	BLAYCO
References	LHC-01, LHC-02, LHC-03
Classification	
Product class I - Sterile. According to Rule 1 of Annex IX of the 93/42/EEC Directive	
GMDN	17977
EC Full Quality Assurance System Certificate	
In accordance to Annex II (except Section 4) of Directive 93/42/EEC Certificate number 572.160906 Issued by: UL International (UK) Ltd. Notified Body number 0843 Valid until: 26/08/2017	

Tungsten electrosurgical accessories	
Description	Disposable sterile electrodes in tungsten
Commercial brand	BLAYCO
References	ABC-45, ABC-55, ABC-65
Classification	
Product class IIb - Sterile. According to Rule 9 of Annex IX of the 93/42/EEC Directive	
GMDN	44684
EC Full Quality Assurance System Certificate	
In accordance to Annex II, section 3 of Directive 93/42/EEC Certificate number 685.130511 Issued by: UL International (UK) Ltd. Notified Body number 0843 Valid until: 10/05/2018	
Standards applied	
EN-60601-1 Medical electrical equipment. General requirements for basic safety and essential performance. EN-60601-2-2 Medical electrical equipment. Requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories. 2011/65/EU Directive (RoHS 2)	

Electrode tip cleaner	
Description	Electrode tip cleaner.
Commercial brand	BLAYCO
References	AL-40
Classification	
Product class I - Sterile. According to Rule 1 of Annex IX of the 93/42/EEC Directive	
GMDN	37483
EC Full Quality Assurance System Certificate	
In accordance to Annex V, section 3 of Directive 93/42/EEC Certificate number 692.130416 Issued by: UL International (UK) Ltd. Notified Body number 0843 Valid until: 02/10/2016	

Buffered iontophoresis electrodes	
Description	Buffered iontophoresis electrode treatment kit
Commercial brand	DORMO-ION
References	IE-SS15, IE-B20, IE-MS25, IE-LS40
Classification	
Product class IIa – Non-sterile. According to Rule 11 of Annex IX of the 93/42/EEC Directive	
GMDN	12185
EC Full Quality Assurance System Certificate	
In accordance to Annex II, section 3 of Directive 93/42/EEC Certificate number 757.150629 Issued by: UL International (UK) Ltd. Notified Body number 0843 Valid until: 26/08/2017	
Standards applied	
EN-60601-1 Medical electrical equipment. General requirements for basic safety and essential performance. 2011/65/EU Directive (RoHS 2)	

EC DECLARATION OF CONFORMITY – ANNEX 2
List of self-certified products

ECG electrodes and accessories	
Description	ECG electrodes Ag/AgCl.
Commercial brand	DORMO
References	LEH-36, LF-50, LF-36, LP-50, LR-50, SX-50, SX-36, SF-36, SX-30, SP-50
Description	Connection adapter to standard stud.
Commercial brand	DORMO
References	4013-5, 4013-B
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex IX of the 93/42/EEC Directive	
GMDN	35035
Standards applied	
ANSI/AAMI EC12 Disposable ECG electrodes. 2011/65/EU Directive (RoHS 2)	

Neonatal ECG electrodes	
Description	Neonatal ECG electrodes Ag/AgCl.
Commercial brand	DORMO
References	K-140, KS-140, K-150, KS-150, KF-140, KFS-140, KF-150, KFS-150, EKF-22KT, P-40/80 (non pre-gelled)
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex IX of the 93/42/EEC Directive	
GMDN	17460
Standards applied	
ANSI/AAMI EC12 Disposable ECG electrodes. 2011/65/EU Directive (RoHS 2)	

Resting electrodes and accessories	
Description	Resting electrodes.
Commercial brand	DORMO-TAB
References	T-2226
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex IX of the 93/42/EEC Directive	
GMDN	35035
Standards applied	
ANSI/AAMI EC12 Disposable ECG electrodes. 2011/65/EU Directive (RoHS 2)	

TENS electrodes and recharges	
Description	Pre-gelled electrode for electrical stimulation.
Commercial brand	DORMO-TENS
References	DT-30R, DT-50R, DT-30, DT-50, DT-100 RT-30R, RT-50R, RT-30, RT-50, RT-100 T-1005, T-5055
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex IX of the 93/42/EEC Directive	
GMDN	17191
Standards applied	
2011/65/EU Directive (RoHS 2)	

Reusable cables for electrosurgery	
Description	Reusable clamp-cables for electrosurgical plates.
Commercial brand	BLAYCO
References	4200, 4200-5, 4210, 4210-5, 4212, 4212-5
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex IX of the 93/42/EEC Directive	
GMDN	35042
Standards applied	
EN-60601-1 Medical electrical equipment. General requirements for basic safety and essential performance.	
EN-60601-2-2 Medical electrical equipment. Requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.	
2011/65/EU Directive (RoHS 2)	

Bite-blocks	
Description	Bite block for endotracheal tubes and laryngeal masks.
Commercial brand	MORDEDOR-MO
References	7600, 7650
Classification	
Product class I – Non-sterile. According to Rule 5 of Annex IX of the 93/42/EEC Directive	
GMDN	10405

Otoscope speculum	
Description	Disposable speculum for otoscope.
Commercial brand	DORMO-SPEC
References	4010, 4020, 4030, 4040, 4050, 4060, 4070, 4080, 4090, 4095
Classification	
Product class I – Non-sterile. According to Rule 5 of Annex IX of the 93/42/EEC Directive	
GMDN	35348

Protective pad	
Description	Protective pad for surgical interventions.
Commercial brand	BLAYCO-PAD
References	AC-3020
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex IX of the 93/42/EEC Directive	
GMDN	35226

Nasal holder for gastric catheters	
Description	Nasal holder for gastric catheters.
Commercial brand	DORMO-NAS
References	7500, 7525, 7550
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex IX of the 93/42/EEC Directive	
GMDN	17514

Cold/hot packs	
Description	Reusable pack for Cold/Hot.
Commercial brand	DORMO, OXD
References	FC-01, FC-02
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex IX of the 93/42/EEC Directive	
GMDN	32975

Ultrasound gels	
Description	Ultrasound transmission gel.
Commercial brand	TRANSONIC GEL, OXD BLUE
References	G-15, G-15/05, G-15/1, G-15/5, G-15/5RB, G-15A US-B250, US-B1, US-B5F, US-B5R
Description	Ultrasound transmission gel.
Commercial brand	TRANSONIC GEL CLEAR, OXD CLEAR
References	GC-15, GC-15/05, GC-15/1, GC-15/5, GC-15/5RB US-C250, US-C1, US-C5F, US-C5R
Classification	
Product class I – Non-sterile. According to Rule 5 of Annex IX of the 93/42/EEC Directive	
GMDN	15321
ECG Gel	
Description	Conductive gel for electrodes.
Commercial brand	ELECTRO-GEL
References	G-10, G-10A
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex IX of the 93/42/EEC Directive	
GMDN	11425

Lubricating gel	
Description	Lubricating water-soluble gel
Commercial brand	DORMO
References	G-20
Classification	
Product class I – Non-sterile. According to Rule 5 of Annex IX of the 93/42/EEC Directive	
GMDN	12401

Paraffin for rehabilitation	
Description	Paraffin 48ºC / 118.4ºF – Rehabilitation.
Commercial brand	DORMO-PARAFFIN
References	5 kg, 2 kg, 1 kg
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex IX of the 93/42/EEC Directive	
GMDN	12956

Paraffin for anatomical pathology	
Description	Paraffin in pearls 58ºC / 136.4ºF – Anatomical Pathology.
Commercial brand	DORMO-PARAFFIN
References	5 kg
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex IX of the 93/42/EEC Directive	
GMDN	33494

Adhesive bandages for kinesiology	
Description	Elastic adhesive bandage (Kinesiologic Tape)
Commercial brand	OXD
References	Blue, Beige, Black, Pink, Green
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex IX of the 93/42/EEC Directive	
GMDN	33521

EC DECLARATION OF CONFORMITY – ANNEX 3
Article 12 Medical Devices Directive 93/42/EEC for Procedure Pack

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

Electrosurgical pencil with electrode tip cleaner	
Description	Electrosurgical pencil, hand control, with 70mm blade electrode and Electrode tip cleaner.
Commercial brand	BLAYCO
References	MB-200
Classification	
• *Electrosurgical pencil:* Product class IIb – Sterile. According to Rule 9 of Annex IX of the 93/42/EEC Directive • *Electrode tip cleaner:* Product class I – Sterile. According to Rule 1 of Annex IX of the 93/42/EEC Directive • Pack MB-200 Non-sterile.	
GMDN	Electrosurgical pencil: 35044 Electrode tip cleaner: 16860
Standards applied	
EN-60601-1 Medical electrical equipment. General requirements for basic safety and essential performance. EN-60601-2-2 Medical electrical equipment. Requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories. 2011/65/EU Directive (RoHS 2)	

CERTIFICATE OF REGISTRATION

TELIC, S.A.U.

Polígono Industrial Can Barri
C/ Molí d'en Barri, 7
Bigues i Riells (Barcelona) 08415 SPAIN

UL LLC®(UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2016
EN ISO 13485:2016

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.

UKAS MANAGEMENT SYSTEMS
4426

Authorized by

Deborah Jennings-Conner
Global Regulatory Director
Life and Health Sciences, UL LLC

Check Certificate Status: here

File Number	A17128	Cycle Start	August 27, 2020
Certificate Number	1761.210215	Effective Date	February 15, 2021
Initial Issue Date	July 28, 2018	Expiry Date	August 26, 2021

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

TRANSONIC

GELES PARA E.C.G. Y ULTRASONIDOS

E.C.G. AND ULTRASOUND GELS
GEL D'E.C.G. ET GEL D'ULTRASONS

CLASE 1
CLASS 1
CLASE 1

pH 7

ELECTRO-GEL

Altamente conductor. Para monitorización de corta y larga duración. No irrita la piel. Hidrosoluble. No corroe terminales ni contactos manteniendo una perfecta higiene de los mismos, posterior a su utilización.

DESCRIPCIÓN
Gel viscoso de base acuosa, sin olor.

DENSIDAD
1,0 g/ml

VISCOSIDAD
300.000 mPa.s (Brookfield LVT)

Highly conductive. For short and long term monitoring. Non skin irritating. Water soluble. Does not damage terminals or contacts providing a perfect hygiene after use.

DESCRIPTION
Water-based Viscous gel, odourless.

DENSITY
1,0 g/ml

VISCOSITY
300.000 mPa.s (Brookfield LVT)

Hautement conducteur. Pour monitoring de courte et longue durée. N'irrite pas la peau. Soluble à l'eau. Non corrosif pour les électrodes, les maintenant parfaitement propres après utilisation.

DESCRIPTION
Gel visqueux, de base aqueuse, inodore.

DENSITÉ
1,0 g/ml

VISCOSITÉ
300.000 mPa.s (Brookfield LVT)

REF	ENVASE PACKAGING RÉCIPIENT	ml	U/CAJA U/BOX U/CARTON
G-10	BOTELLA BOTTLE FLACON	250	**25**

pH 6

TRANSONIC

Gel para diagnóstico y terapia de ultrasonidos. Sin sal. No irrita la piel. No engrasa. Hidrosoluble. No daña el transductor. Se extiende fácil y uniformemente.

DESCRIPCIÓN
Gel viscoso de base acuosa, sin olor.

EFICIENCIA
> 90% desde 0,5 MHz

DENSIDAD
1,0 g/ml

VISCOSIDAD
>800.000 mPa.s (Brookfield LVT)

IMPEDANCIA ACÚSTICA
1,62 (10^6 Rayls)

Gel for ultrasound diagnosis and therapy. Salt free. Does not irritate skin. Non greasy. Hydrosoluble. Does not damage the transducer. It spreads out easily and uniformly.

DESCRIPTION
Odorless water based viscous gel.

EFFICIENCY
> 90%from 0,5 MHz

DENSITY
1,0 g/ml

VISCOSITY
>800.000 mPa.s (Brookfield LVT

ACOUSTIC IMPEDANCE
1,62 (10^6 Rayls)

Gel pour diagnostic et traitement pour ultrason. Ne contient pas de sels. Non irritant pour la peau. Non gras. Soluble dans l'eau. Non corrosif pour la sonde. Se répartit aisément et uniformément.

DESCRIPTION
Gel visqueux, de base aqueuse, inodore.

EFFICACITÉ
> 90% à 0,5 MHz

DENSITÉ
1,0 g/ml

VISCOSITÉ
>800.000 mPa.s (Brookfield LVT)

IMPÉDANCE ACCOUSTIQUE
1,62 (10^6 Rayls)