Telic, S.A.U.
Polígono Industrial Can Barri
C/ Molí d'en Barri, 7-9,
08415 Bigues i Riells, BARCELONA, Spain
Tel: +34 93 865 61 25
Fax: +34 93 865 62 46

EC DECLARATION OF CONFORMITY

TELIC, S.A.U. 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 Septembre 28th 2017

Digitally signed by Grabazei Alexandru
Date: 2019.02.18 15:41:51 EET
Reason: MoldSign Signature
Location: Moldova

Laura Delgado
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	11130
UMDNS	-26915
EC Full Quality Assurance System Certificate	
In accordance to Annex II (except Section 4) of Directive 93/42/EEC Certificate number 572.170827 Issued by: UL International (UK) Ltd. Notified Body number 0843 Valid until: 26/08/2022	
Standards applied	
EN ISO 14971:2012// EN 60601-2-4:2011// EN ISO 10993-1:2009//EN ISO 10993-1:2009/AC:2010//EN ISO 10993-4:2009//EN-ISO 10993-5:2009// EN ISO 10993-7:2008// EN ISO 10993-7:2008/AC:2009// EN ISO 10993-10:2013// EN ISO 10993-11:2009// EN ISO 15223-1:2012 Directiva 2011/65/EU (RoHS 2).	

Return electrodes for electrosurgery	
Description	Pre-gelled electrosurgical plates.
Commercial brand	BLAYCO
References	2125, 2125-5, 2125-C/00, 2125-C/00/5, 2125-C/10, 2125-C/10/5, 2125-C/21 2225, 2225-5, 2225-C/00,2225-C/00/5, 2225-C/10, 2225-C/10/5 2425, 2425-5, 2425-C/00, 2425-C/00/5, 2425-C/10,2425-C/10/5 2925, 2925-5, 2925-C/00, 2925-C/00/5, 2925-C/10, 2925-C/10/5 2500, 2500-5, 2500-C/00,2500-C/00/5, 2500-C/12, 2500-C/12/5 2510, 2510-5, 2510-C/00,2510-C/00/5, 2510-C/12, 2510-C/12/5 2600, 2600-5, 2600-C/00,2600-C/00/5, 2600-C/12, 2600-C/12/5 2700, 2700-5, 2700-C/00,2700-C/00/5, 2700-C/12, 2700-C/12/5 2900, 2900-5, 2900-C/00, 2900-C/00/5, 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	58494
UMDNS	11500
EC Full Quality Assurance System Certificate	
In accordance to Annex II (except Section 4) of Directive 93/42/EEC Certificate number 572.170827 Issued by: UL International (UK) Ltd. Notified Body number 0843	

Valid until: 26/08/2022
Standards applied
EN ISO 14971:2012// EN 60601-2-2:2009//EN 60601-2-2:2009/A11:2011//EN ISO 15223-1:2012// EN ISO 10993-1:2009//EN ISO 10993-1:2009/AC:2010//EN ISO 10993-5:2009//EN-ISO 10993-10:2013// EN 60601-1:2006/EN 60601-1:2006/A1:2013 // EN 60601-2-2:2009// EN 60601-2-2:2009/A11:2011. 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
UMDNS	13828
EC Full Quality Assurance System Certificate	
In accordance to Annex II (except Section 4) of Directive 93/42/EEC Certificate number 572.170827 Issued by: UL International (UK) Ltd. Notified Body number 0843 Valid until: 26/08/2022	
Standards applied	
EN ISO 14971:2012// EN 62366:2008/ EN 62366:2008/A1:2015// EN ISO 11607-1:2009/ EN ISO 11607-1:2009/A1:2014// EN ISO 11607-2:2006/ EN ISO 11607-2:2006/A1:2014// EN ISO 10993-1:2009/EN ISO 10993-1:2009/AC:2010// EN ISO 10993-4:2009// EN ISO 10993-5:2009// EN ISO 10993-7:2008/ EN ISO 10993-7:2008/AC:2009//EN ISO 10993-10:2013// EN ISO 10993-11:2009// EN 556-1:2001/ EN 556-1:2001/AC:2006// EN ISO 11135-1:2007// CEN ISO/TS 11135-2:2008// EN ISO 14644-1:2015// EN ISO 14644-3:2005// EN ISO 14644-4:2001// EN ISO 14644-5:2004// EN ISO 14644-8:2013// EN ISO 15223-1:2012// EN 1041:2008+A1:2013.	

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	61916
UMDNS	-12240
EC Full Quality Assurance System Certificate	
In accordance to Annex V of Directive 93/42/EEC Certificate number 736.170827	

Issued by: UL International (UK) Ltd. Notified Body number 0843 Valid until: 26/08/2022
Standards applied
EN ISO 14971:2012// EN ISO 10993-1:2009/EN ISO 10993-1:2009/AC:2010//EN ISO 10993-4:2009//EN ISO 10993-5:2009// EN ISO 10993-7:2008/EN ISO 10993-7:2008/AC:2009//EN ISO 10993-10:2013//EN ISO 10993-11:2009//// EN ISO 11135-1:2007// EN ISO 14644-1:2015//EN ISO 14644-2:2015//EN ISO 14644-4:2001//EN ISO 14644-5:2004// EN ISO 15223-1:2012.

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, EDC-1075.
Description	Set of two multi-function electrodes. Adult. Pre-connected.
Commercial brand	DESFI-DORMO
References	EDC-2015, EDC-2020, EDC-2025, EDC-2030, EDC-2035, EDC-2040, EDC-2045, EDC-2050, EDC-2055, EDC-2060, EDC-2065, EDC-2070, EDC-2075.
Classification	
Product class IIb – Non-sterile. According to Rule 9 of Annex IX of the 93/42/EEC Directive	
GMDN	45806
UMDNS	-3698
EC Full Quality Assurance System Certificate	
In accordance to Annex II (except Section 4) of Directive 93/42/EEC Certificate number 572.170827 Issued by: UL International (UK) Ltd. Notified Body number 0843 Valid until: 26/08/2022	
Standards applied	
EN ISO 14971:2012// EN 60601-2-4:2011// EN ISO 10993-1:2009//EN ISO 10993-1:2009/AC:2010//EN ISO 10993-4:2009//EN ISO 10993-5:2009// EN ISO 10993-7:2008// EN ISO 10993-7:2008/AC:2009// EN ISO 10993-10:2013// EN ISO 10993-11:2009// EN ISO 15223-1:2012 Directiva 2011/65/EU (RoHS 2).	

Defibrillation electrodes with cable pediatrics	
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-P160, EDC-P165, EDC-P170, EDC-P175.
Description	Set of two defibrillation electrodes. Paediatrics. Pre-connected.
Commercial brand	DESFI-DORMO

References	EDC-P215, EDC-P220, EDC-P225, EDC-P230, EDC-P235, EDC-P240, EDC-P245, EDC-P250, EDC-P255, EDC-P260, EDC-P265, EDC-P270, EDC-P275.

Classification

Product class IIb – Non-sterile. According to Rule 9 of Annex IX of the 93/42/EEC Directive

GMDN	41587
UMDNS	-26914

EC Full Quality Assurance System Certificate

In accordance to Annex II (except Section 4) of Directive 93/42/EEC

Certificate number 572.170827

Issued by: UL International (UK) Ltd.

Notified Body number 0843

Valid until: 26/08/2022

Standards applied

EN ISO 14971:2012// EN 60601-2-4:2011// EN ISO 10993-1:2009/EN ISO 10993-1:2009/AC:2010//EN ISO 10993-4:2009//EN ISO 10993-5:2009// EN ISO 10993-7:2008// EN ISO 10993-7:2008/AC:2009//EN ISO 10993-10:2013//EN ISO 10993-11:2009// EN ISO 15223-1:2012.

ANSI/AAMI DF80:2003

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	58735
UMDNS	-1519

EC Full Quality Assurance System Certificate

In accordance to Annex II (except Section 4) of Directive 93/42/EEC

Certificate number 572.170827

Issued by: UL International (UK) Ltd.

Notified Body number 0843

Valid until: 26/08/2022

Standards applied

EN ISO 14971:2012// EN ISO 10993-1:2009//EN ISO 10993-1:2009/AC:2010// EN ISO 10993-4:2009//EN ISO 10993-5:2009//EN ISO 10993-10:2013//EN ISO 10993-11:2009// EN ISO 15223-1:2012// EN ISO 11607-1:2009//EN ISO 11607-1:2009/A1:2014//EN ISO 11607-2:2006//EN ISO 11607-2:2006/A1:20//EN ISO 14644-1:2015//EN ISO 14644-3:2005//EN ISO 14644-4:2001//EN ISO 14644-5:2004//EN ISO 14644-8:2013 14// EN 556-1:2001//EN 556-1:2001/AC:2006//EN ISO 11137-1:2015//EN ISO 11137-2:2015// EN ISO 14644-1:2015//EN ISO 14644-3:2005//EN ISO 14644-4:2001//EN-ISO 14644-5:2004//EN ISO 14644-8:2013.

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	44977
UMDNS	17977
EC Full Quality Assurance System Certificate	
In accordance to Annex II (except Section 4) of Directive 93/42/EEC Certificate number 572.170827 Issued by: UL International (UK) Ltd. Notified Body number 0843 Valid until: 26/08/2022	
Standards applied	
EN ISO 14971:2012// EN 556-1:2001// EN 556-1:2001/AC: 2006// EN ISO 11135-1:2007// EN ISO 14644-1:2015// EN ISO 14644-3:2005// EN ISO 14644-4:2001// EN ISO 14644-5:2004// EN ISO 15223-1:2012.	

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	61869
UMDNS	16860
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	
ISO 13485:2003// EN 60601-1:2006// EN 60601-2-2:2009// EN ISO 14971:2012// EN ISO 10993-1:2009// EN 1041:2008// EN ISO 15223-1:2012// EN ISO 11135-1:2007// EN 556-1:2001/AC: 2006// EN ISO 11607-1:2009//EN ISO 11607-2:2006. 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
UMDNS	15013
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	
Standards applied	
EN ISO 14971:2012//EN 556-1:2001/ EN 556-1:2001/AC: 2006// EN ISO 11135-1:2007//EN 868-5:2009//ISO-2859-1:1999// EN ISO 15223-1:2012.	

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	45141
UMDNS	-4494 ó 4495
EC Full Quality Assurance System Certificate	
In accordance to Annex II, section 3 of Directive 93/42/EEC Certificate number 572.170827 Issued by: UL International (UK) Ltd. Notified Body number 0843 Valid until: 26/08/2022	
Standards applied	
EN ISO 14971:2012// EN ISO 10993-1:2009/EN ISO 10993-1:2009/AC: 2010// EN ISO 10993-5:2009// EN ISO 10993-10:2013// EN ISO 15223-1:2012// EN 1041:2008+A1:2013. 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
UMDNS	-26935
Standards applied	
EN ISO 14971:2012// EN ISO 15223-1:2012// EN ISO 10993-1:2009/EN ISO 10993-1:2009/AC : 2010// EN ISO 10993-5:2009// EN ISO 10993-7:2008/EN ISO 10993-7:2008/AC : 2009// EN ISO 10993-10:2013. 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
UMDNS	-26935
Standards applied	
EN ISO 14971:2012// EN ISO 15223-1:2012// EN ISO 10993-1:2009/EN ISO 10993-1:2009/AC : 2010// EN ISO 10993-5:2009// EN ISO 10993-7:2008/EN ISO 10993-7:2008/AC : 2009// EN ISO 10993-10:2013. 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
UMDNS	17191
Standards applied	
EN ISO 14971:2012// EN ISO 15223-1:2012// EN ISO 10993-1:2009/EN ISO 10993-1:2009/AC: 2010// EN ISO 10993-5:2009// EN ISO 10993-7:2008/EN ISO 10993-7:2008/AC: 2009// EN ISO 10993-10:2013// EN ISO 15223-1:2012. 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	35995
UMDNS	-4558 ó 17191
Standards applied	
EN ISO 14971:2012// EN ISO 15223-1:2012// EN ISO 10993-1:2009/EN ISO 10993-1:2009/AC: 2010// EN ISO 10993-5:2009// EN ISO 10993-7:2008/EN ISO 10993-7:2008/AC: 2009// EN ISO 10993-10:2013// EN ISO 15223-1:2012. ANSI/AAMI EC12:2000 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	47487
UMDNS	11496
Standards applied	

EN ISO 14971:2012// EN 60601-2-2:2009/ EN 60601-2-2:2009/A11:2011// EN ISO 15223-1:2012. 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
UMDNS	10405
Standards applied	
EN ISO 9001:2015//	EN 46002:1996.

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
UMDNS	12849
Standards applied	
EN ISO 14971:2012// EN ISO 15223-1:2012.	

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	62789
UMDNS	-27909
Standards applied	
EN ISO 14971:2012// EN 556-1:2001/ EN 556-1:2001/AC: 2006// EN ISO 11135-1:2007// EN ISO 14644-1:2015// EN ISO 14644-3:2005// EN ISO 14644-4:2001// EN ISO 14644-5:2004// EN ISO 15223-1:2012.	

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	62581
UMDNS	-28865
Standards applied	
EN ISO 14971:2012// EN ISO 15223-1:2012.	

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	37240
UMDNS	-17863
Standards applied	
EN-ISO 14971:2012// EN ISO 15223-1:2012.	

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
UMDNS	-17912
Standards applied	
EN ISO 14971:2012// EN ISO 10993-1:2009/EN ISO 10993-1:2009/AC: 2010// EN ISO 10993-4:2009// EN ISO 10993-5:2009// EN ISO 10993-10:2013// EN ISO 10993-11:2009// EN ISO 15223-1:2012.	

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
UMDNS	-480
Standards applied	
EN ISO 14971:2012// EN ISO 10993-1:2009/EN ISO 10993-1:2009/AC: 2010// EN ISO 10993-4:2009// EN ISO 10993-5:2009// EN ISO 10993-7:2008/EN ISO 10993-7:2008/AC: 2009// EN ISO 10993-10:2013// EN ISO 10993-11:2009// EN ISO 15223-1:2012. ANSI/AAMI EC12:2000.	

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	33587
UMDNS	-21069
Standards applied	
EN ISO 14971:2012// EN ISO 10993-1:2009/EN ISO 10993-1:2009/AC: 2010// EN ISO 10993-5:2009// EN ISO 10993-10:2013// EN ISO 15223-1:2012.	

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	35232
UMDNS	-25297
Standards applied	
EN ISO 14971:2012// EN ISO 15223-1:2012.	

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	57738
UMDNS	-22669
Standards applied	
EN ISO 14971:2012// EN ISO 15223-1:2012.	

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
UMDNS	25609
Standards applied	
EN ISO 14971:2012// EN ISO 15223-1:2012.	

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: 61869 Electrode tip cleaner: 37483
UMDNS	Electrosurgical pencil: 16860 Electrode tip cleaner: 15013
Standards applied	
EN ISO 14971:2012// EN 60601-1:2006/EN 60601-1:2006/A1:2013// EN 60601-2-2:2009//EN 60601-2-2:2009/A11:2011//EN ISO 15223-1:2012. 2011/65/EU Directive (RoHS 2).	