Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 3 din **19.10.2023**

Solicitantul **FCPC „DataControl" S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemitanu 17/6** tel./fax: 022 27 37 12, e-mail: contact@datacontrol.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Telic:

1. SX-50
2. 2600-C/12
3. 2500-C/12
4. LEH-36
5. GC-15
6. MB-100

Se anexează următoarele acte:
1. Declarație de Conformitate
2. Scrisoare de autorizare

Data **19.10.2023** Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Grabazei Alexandru
Date: 2023.10.19 11:39:44 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **FCPC „DataControl" S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemitanu 17/6** tel./fax: 022 27 37 12, e-mail: contact@datacontrol.md,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Telic:

1. SX-50
2. 2600-C/12
3. 2500-C/12
4. LEH-36
5. GC-15
6. MB-100

Sunt autentice și corespund realității.

Grabazei Alexandru, director general *Semnătura* _____

Data **19.10.2023**

TELIC GROUP

Bigues i Riells, October 17, 2023

Dear Sirs,

For the adequate fulfilment of requirements established in Regulation (EU) 2017/745, on Medical Devices, (EU) 1223/2009, for Cosmetic Products, ROYAL DECREE 1599/1997, of 17 October of 1997, on cosmetic products (Second additional provision for personal care products) and (EU) 2016/425 for Personal Protective Equipment (PPE), among other obligations as a manufacturing company, we must keep updated a systematic procedure in order to review experience acquired with our during commercialization. Taking into account product nature and related risks, we must have appropriate means to guarantee, when required, the effectiveness of the corresponding actions in the market.

These regulations also specify, concerning product sales and distribution, the need to keep an appropriate documentation which must include, at least, the following information: commercial name of the product, model, serial and/or lot number, purchase date, shipment or supply date and customer identification.

They also establish that a distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if it does any modification of the product except for a faithful translation of the labeling or reconditioning of the product, whereas product stability is not compromised.

This is the reason why we kindly ask for your cooperation to return a copy of the attached commitment letter, duly stamped and signed, within 7 calendar days of receipt of the same. Otherwise, authorization of representation granted will remain without effect.

We hope that this requirement does not suppose any problems, being sure that the interest in offering the best quality to our common clients is mutual.

Waiting for your news, we remain.

Yours Faithfully,

46624508N
OSCAR LACRUZ
(R: A08733578)

Firmado digitalmente por 46624508N OSCAR LACRUZ (R: A08733578)
Nombre de reconocimiento (DN): 2.5.4.13=RefAEAT/AEAT0259/PUESTO 1/8901A/30082023114302, serialNumber=IDCES-46624508N, givenName=OSCAR, sn=LACRUZ MALET, cn=46624508N OSCAR LACRUZ (R: A08733578), 2.5.4.97=VATES-A08733578, o=TELIC SAU, c=ES
Fecha: 2023.10.18 11:15:40 +02'00'

Signed: Oscar Lacruz Malet
President TELIC, SAU

TELIC, S.A.U. Polígono Industrial Can Barri · C/ Molí d'en Barri, 7-9 E-08415 Bigues · Barcelona (Spain) · TEL +34 938 656 125 · info@telic.es · www.telic.es

TELIC GROUP

Letter of Authorization

Bigues i Riells, October 17, 2023

Dear Sirs,

This letter is to certify that the company F.C.P.C. “DATACONTROL” S.R.L., with registered OFFICE 17/6, N.TESTIMITEANU STREET, MD-2025, CHIȘINAU, REPUBLIC OF MOLDOVA, is one of our authorized distributors to represent the products of TELIC SAU for a period of 5 years counted from the signature of this document, unless you receive communication contrary to this.

F.C.P.C. “DATACONTROL” S.R.L is authorized to import, sell, distribute, register and provide market support for all products manufactured and marketed by TELIC S.A.U., in REPUBLIC OF MOLDOVA.

This authorization was immediately void if the corresponding letter of commitment for traceability and labeling was not signed.

Yours Faithfully,

46624508N
OSCAR
LACRUZ (R:
A08733578)

Firmado digitalmente por 46624508N OSCAR LACRUZ (R: A08733578)
Nombre de reconocimiento (DN): 2.5.4.13=Ref:AEAT/AEAT0259/PUESTO 1/89014/30082023114302, serialNumber=IDCES-46624508N, givenName=OSCAR, sn=LACRUZ MALET, cn=46624508N OSCAR LACRUZ (R: A08733578), 2.5.4.97=VATES-A08733578, o=TELIC SAU, c=ES
Fecha: 2023.10.18 11:17:22 +02'00'

Signed: Oscar Lacruz Malet

President TELIC, SAU

TELIC, S.A.U. Polígono Industrial Can Barri · C/ Molí d'en Barri, 7-9 E-08415 Bigues · Barcelona (Spain) · TEL +34 938 656 125 · info@telic.es · www.telic.es

Telic, S.A.U.
Polígono Industrial Can Barri
C/ Molí d'en Barri, 7,
08415 Bigues i Riells, BARCELONA, Spain
Tel: +34 93 865 61 25
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CE DECLARATION OF CONFORMITY

TELIC, S.A.U. with SRN number: ES-MF-000001853 declares under his sole responsibility that the products listed in annexes of the present declaration have been manufactured according to requirements of the **Directive 93/42/EEC** and meet requirements set in the Essential Requirements of the Annex I of above-mentioned in **Directive 93/42/EEC.** Also, a conformity assessment procedure has been followed in accordance with **Annex VII** of **Directive 93/42/EEC.**

Technical documentation, in accordance with the established in the corresponding annexes of the 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.

Declare, in application of regulation (EU) 2017/745, and considering the transitional periods pursuant including corrigendum and amendments to **article 120** and under reference to the previously valid Directive 93/42/EEC, on our own responsibility, the products of the Annex I.

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 i Riells, on May 25th, 2021

Laura Delgado
Technical Manager

Oscar Lacruz
CEO

EC DECLARATION OF CONFORMITY – ANNEX 1
List of self-certified products legacy devices

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 I - Non-sterile. According to Rule 1 of Annex IX of the Directive 93/42/EEC.	
GMN (BASIC-UDI-DI)	8427734DFELECW/OCABLEADF2
GMDN	11130
EMDN	C020480 (Cardioversion and external defibrillation Devices-accessories)
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // 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/AC:2010 // EN 60601-1:2006/A1:2013 // EN 60601-2-4:2003 // EN 60601-2-2:2011 // EN 60601-2-4:2011/A1:2019.	

Defibrillation electrodes with cable for adult patient	
Description	Set of two multi-function electrodes. Adult.
Commercial brand	DESFI-DORMO
References	(REF: EDC-1XXX): EDC-1011, 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-1090
Description	Set of two multi-function electrodes. Adult. Pre-connected.
Commercial brand	DESFI-DORMO
References	(REF: EDC-2XXX): EDC-2015, EDC-2020, EDC-2025, EDC-2030, EDC-2035, EDC-2035L, EDC-2040, EDC-2045, EDC-2050, EDC-2055, EDC-2060, EDC-2065, EDC-2070, EDC-2075, EDC-2080, EDC-2085, EDC-2090.
Classification	
Product class I - Non-sterile. According to Rule 1 of Annex IX of the Directive 93/42/EEC.	
GMN (BASIC-UDI-DI)	8427734MFELECCABLEAD9X
GMDN	45806
EMDN	C020480 (Cardioversion and external defibrillation Devices-accessories)
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // 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/AC:2010 // EN 60601-1:2006/A1:2013 // EN 60601-2-4:2003 // EN 60601-2-2:2011 // EN 60601-2-4:2011/A1:2019.	

Defibrillation electrodes with cable paediatrics	
Description	Set of two defibrillation electrodes. Paediatrics.
Commercial brand	DESFI-DORMO
References	(REF: EDC-P1XX): EDC-P111, EDC-P115, EDC-P120, EDC-P125, EDC-P130, EDC-P135, EDC-P140, EDC-P145, EDC-P155, EDC-P160, EDC-P170, EDC-P190
Description	Set of two defibrillation electrodes. Paediatrics. Pre-connected.
Commercial brand	DESFI-DORMO
References	(REF: EDC-P2XX): EDC-P215, EDC-P220, EDC-P225, EDC-P230, EDC-P235, EDC-P240, EDC-P245, EDC-P255, EDC-P260, EDC-P265, EDC-P270, EDC-P275, EDC-P280, EDC-P290.
Classification	
Product class I - Non-sterile. According to Rule 1 of Annex IX of the Directive 93/42/EEC.	
GMN (BASIC-UDI-DI)	8427734DFELECCABLEPEDVM
GMDN	41587
EMDN	C020480 (Cardioversion and external defibrillation Devices-accessories)
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018 // EN ISO 14971:2012 // EN ISO 14971:2019 // EN ISO 15223-1:2016 // EN 1041:2008 // EN 1041:2008 + A1 2013 // 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/AC:2010 // EN 60601-1:2006/A1:2013 // EN 60601-2-4:2003 // EN 60601-2-2:2011 // EN 60601-2-4:2011/A1:2019.	

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

DECLARATION OF CONFORMITY

TELIC, S.A.U. with SRN number: ES-MF-000001853 declares under his sole responsibility that the products listed in annexes of the present declaration have been manufactured according to requirements of the **Regulation (EU) 2017/745 on Medical Devices** and meet requirements set in the Essential Requirements of the Annex I of above mentioned Regulation.

Technical documentation, in accordance with the established in the corresponding annexes of the Regulation (UE) 2017/745 on medical devices, 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 i Riells, on ,15th June, 2023

Laura Delgado
Technical Manager

Oscar Lacruz
CEO

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

Return electrodes for electrosurgery	
Description	Pre-gelled electrosurgical plate.
Commercial brand	BLAYCO
References	**Unipolar adult** -2125: Adult unipolar without cable. -2125-5: Adult unipolar without cable 5 units. -2125-C/XX/Y: (2125-C/00, 2125-C/10, 2125-C/10/5): Plate adult unipolar with cable. **Unipolar paediatric** -2225: Unipolar paediatric without cable. -2225-5: Unipolar paediatric without cable 5 units. -2225-C/XX/Y: (2225-C/00, 2225-C/10): Unipolar paediatric with cable. **Unipolar neonatal** -2425: Unipolar neonatal without cable. -2425-C/XX/Y: (2425-C/00, 2425-C/10): Unipolar neonatal with cable. **Dual adult** -2500: Dual adult without cable. -2500-5: dual adult without cable 5 units. -2500-C/XX/Y: (2500-C/00, 2500-C/12): Dual adult with cable. **Dual adult oblong** -2510: Dual adult oblong without cable. -2510-5: Dual adult oblong without cable 5 units. -2510-C/XX/Y: (2510-C/00, 2510-C/00/5, 2510-C/12): Dual adult oblong with cable. **Dual paediatric** -2600: Dual paediatric without cable. -2600-C/XX/Y: (2600-C/00, 2600-C/12): Dual paediatric with cable. **Dual neonatal** -2700: Dual neonatal withou cable. -2700-C/XX/Y: (2700-C/00, 2700-C/12): Dual neonatal with cable. **Dual universal** -2900: Dual universal without cable. -2900-5: Dual universal without cable 5 units. -2900-C/XX/Y: (2900-C/00, 2900-C/12, 2900-C/12/5): Dual universal with cable.
Intended use	
Electrosurgical plates are used as closing element in the circuit constituted together with the active electrode and the electrosurgical unit in electrosurgical interventions. The electrode provides a large contact surface with the patient, compared with the active electrode, that allows reducing the current flow density and minimize the risk of electrosurgical effects or burnings.	
Classification	

Product class IIb - Non-sterile. According to Rule 9 of Annex VIII of Regulation (UE) 2017/745	
GMN (BASIC-UDI-DI)	8427734ESUPLATES3L
GMDN	58494
EMDN	K020102 (Electrosurgery pads (neutral electrodes) and cables, single-use)

EU Quality Assurance System Certificate

In accordance to regulation (EU) 2017/745 Annex IX Chapter I and III

Certificate number: MDR 756915

Issued by: BSI

Notified Body number: 2797

Valid until: 18/09/2027

Standards applied

EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021// EN ISO 20417:2021// EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-10:2013 // EN 60601-1:2006 // EN 60601-1:2006/AC:2010 // EN 60601-1:2006/A1:2013 // EN 60601-1:2006/A12:2014 // EN IEC 60601-2-2:2018

Vein strippers	
Description	Single use vein strippers.
Commercial brand	DORMO-STRIP
References	Conventional stripping: VE-022, VE-022 OP Invagination stripping: VE-025
Intended use	
The vein strippers are a single-use medical device sterilized by ethylene oxide, intended to be used for surgical stripping of varicose veins. This product is not intended to be used in central venous system. Different models are available for use with the two most common stripping techniques: conventional stripping and invagination stripping.	
Classification	
Product class IIa - Sterile. According to Rule 7 to Annex VIII of Regulation (UE) 2017/745	
GMN (BASIC-UDI-DI)	8427734VEINSTRIPPERSZP
GMDN	32321
EMDN	C0699 (Cardiovascular surgery instruments, single-use-other).
EU Quality Assurance System Certificate	
In accordance to regulation (EU) 2017/745 Annex IX Chapter I and III Certificate number: MDR 756915 Issued by: BSI Notified Body number: 2797 Valid until: 18/09/2027	
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021 // EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-7:2008 // EN ISO 10993-7:2008/AC:2009 /EN ISO 10993-7:2008/A1:2022 // EN ISO 10993-9:2021 // // EN ISO 10993-10:2013 // EN ISO 10993-11:2018// EN ISO 10993-13:2010 // EN ISO 10993-18:2020 // EN ISO 10993-23:2021 // EN 556-1:2001 // EN 556-1:2001/AC:2006 EN ISO 11135-1:2007 // EN ISO 11135:2014 // EN 11607-1:2020// EN 11607-2:2020.	

Sterile ultrasound gel	
Description	Ultrasound gel. Sterile.
Commercial brand	TRANSONIC
References	G-15E

Intended use

Sterile ultrasound gel is intended for general use as a transmission media for acoustically coupling a transducer to a human body surface during external therapeutic and diagnostic ultrasound imaging procedures. It is placed on the patient's skin or on the transducer prior to initiating an ultrasound examination.

The sterile product is recommended for diagnostic and therapeutic ultrasound applications when sterility is indicated.

Classification

Product class I - Sterile. According to Rule 5 of Annex VIII of Regulation (UE) 2017/745

GMN (BASIC-UDI-DI)	8427734USGELSTERILEPZ
GMDN	15321
EMDN	Z11040185 (Ultrasound scanners-consumables)

EU Quality Assurance System Certificate

In accordance to regulation (EU) 2017/745 Annex IX Chapter I and III

Certificate number: MDR 756915

Issued by: BSI

Notified Body number: 2797

Valid until: 18/09/2027

Standards applied

EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021 // EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-7:2008 // EN ISO 10993-7:2008/AC:2009 /EN ISO 10993-7:2008/A1:2022 // EN ISO 10993-10:2013 // EN 556-1:2001 / EN 556-1:2001/AC:2006 // EN ISO 11135:2014 / EN ISO 11135:2014/A1:2019 // EN 11607-1:2020 / EN ISO 11607-1:2020/A11:2022 // EN 11607-2:2020 / EN ISO 11607-2:2020/A11:2022.

Cover for surgical light handle	
Description	Cover for surgical light handle.
Commercial brand	BLAYCO
References	LHC-XX: LHC-01, LHC-03
Intended use	
Cover for surgical light handle is intended to prevent the surgeon contacting intended or accidentally with the handle of the lamp during a surgical procedure.	
Classification	
Product class I - Sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745	
GMN (BASIC-UDI-DI)	8427734SURGLIGHTCOVER8F
GMDN	44977
EMDN	V9099 (Various devices not included in other classes – Other).
EU Quality Assurance System Certificate	
In accordance to regulation (EU) 2017/745 Annex IX Chapter I and III Certificate number: MDR 7569515 Issued by: BSI Notified Body number: 2797 Valid until: 18/09/2027	
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021 // EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-7:2008 // EN ISO 10993-7:2008/AC:2009 /EN ISO 10993-7:2008/A1:2022 // EN ISO 10993-10:2013 // EN 556-1:2001 / EN 556-1:2001/AC:2006 // EN ISO 11135:2014 / EN ISO 11135:2014/A1:2019 // EN 11607-1:2020 / EN ISO 11607-1:2020/A11:2022 // EN 11607-2:2020 / EN ISO 11607-2:2020/A11:2022.	

Electrode tip cleaner	
Description	Electrode tip cleaner.
Commercial brand	BLAYCO
References	AL-40

Intended use

During the electrosurgical procedure, carbonized tissue residues can be adhered to the electrode tip, increasing resistance to the current flow and thus, reducing electrode performance. Electrode cleaning pads are used to remove these impurities from the surface of electrodes in disposable or reusable pencils.

Classification

Product class I - Sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745

GMN (BASIC-UDI-DI)	8427734TIPCLEANERJH
GMDN	37483
EMDN	V9099 (Various Devices not included in other classes- Other).

EU Quality Assurance System Certificate

In accordance to regulation (EU) 2017/745 Annex IX Chapter I and III

Certificate number: 756915

Issued by: BSI

Notified Body number: 2797

Valid until: 18/09/2027

Standards applied

EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021 // EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-7:2008 // EN ISO 10993-7:2008/AC:2009 /EN ISO 10993-7:2008/A1:2022 // EN ISO 10993-10:2013 // EN 556-1:2001 / EN 556-1:2001/AC:2006 // EN ISO 11135:2014 / EN ISO 11135:2014/A1:2019 // EN 11607-1:2020 / EN ISO 11607-1:2020/A11:2022 // EN 11607-2:2020 / EN ISO 11607-2:2020/A11:2022.

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

ECG electrodes and accessories	
Description	ECG electrodes Ag/AgCl.
Commercial brand	DORMO
References	-Solid Gel (REF: SX-XX): SX-50, SX-36, SF-36, SF-40, SX-30, SP-50, SM-36 -Semiliquid (REF: LX-XX): LF-40, LF-50, LF-50T LF-36, LP-50, LR-50 -Stress REF: LEH-36
Intended use	
The Dormo® ECG electrodes Ag/AgCl consist of an electrode family designed to detect and amplify the small electric pulses on the skin produced by the heart muscle depolarization during each heartbeat.	
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN (BASIC-UDI-DI)	8427734ECGELECVL
GMDN	35035
EMDN	C020501 (ECG Electrodes)
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021 // EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-10:2013 // EN 60601-1:2006 // EN 60601-1:2006/AC:2010 // EN 60601-1:2006/A1:2013//EN 60601-1:2008//A12:2014// ANSI/AAMI EC12:2000/R2020	

Neonatal ECG electrodes	
Description	Neonatal ECG electrodes Ag/AgCl.
Commercial brand	DORMO
References	- 1.5 mm connection (REF: KXX-140): K-140, KS-140, KF-140, KFS-140 - 4 mm connection (REF: KXX-150): K-150, KS-150, KF-150, KFS-150 - Stud connection: EKF-22KT
Intended use	
The Dormo® Neonatal ECG electrodes Ag/AgCl consist of an electrode family designed to detect and amplify the small electric pulses on the skin produced by the heart muscle depolarization during each heartbeat.	
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN (BASIC-UDI-DI)	8427734NEONATALELECZH
GMDN	17460
EMDN	C020501 (ECG Electrodes)
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021 // EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-10:2013 // EN 60601-1:2006 // EN 60601-1:2006/AC:2010 // EN 60601-1:2006/A1:2013//EN 60601-1:2008//A12:2014// ANSI/AAMI EC12:2000/R2020	

Resting electrodes and accessories	
Description	Resting electrodes.
Commercial brand	DORMO-TAB
References	T-2226
Intended use	
Dormo® -TAB consist of an electrode family designed to detect and amplify the small electric pulses on the skin produced by the heart muscle depolarization during each heartbeat.	
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN (BASIC-UDI-DI)	8427734TABELEC35
GMDN	35035
EMDN	C020501 (ECG Electrodes)
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021 // EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-10:2013 // EN 60601-1:2006 // EN 60601-1:2006/AC:2010 // EN 60601-1:2006/A1:2013//EN 60601-1:2008//A12:2014// ANSI/AAMI EC12:2000/R2020.	

TENS electrodes and spares	
Description	Pre-gelled muscle stimulation electrodes.
Commercial brand	Dormo® -Tens
References	- Silicon conductive electrodes female 2mm connection: (REF: DT-XXX): DT-30, DT-50, DT-100 - Replacement hydrogel (REF:RT-XXX): RT-30, RT-50, RT-100 - Paper electrodes with Ag/AgCl and tab connection (REF: T-XXX): T-1005, T-5055, - Non-woven tissue with female wire connection (REF: SX-XXX): ST-50, ST-100, ST-30R, ST-50R - Non-woven tissue with connection stud (REF:SC-XXX): SC-50, SC-100 - Conductive silicone tape with female 2mm connection (REF: CSC-XX): CSC-1, CSC-25
Intended use	
Dormo® -Tens Pre-gelled muscle stimulation electrodes are adhesive electrodes with conductive gel which have been designed for electro-stimulation use in physiotherapy and beauty-care treatments. Electrodes are indicated for use with transcutaneous electrical stimulation devices. Some common types of transcutaneous stimulation devices include, but are not limited to, Transepithelial Nerve Stimulation (TENS) and electrical muscle stimulation (EMS) devices. Transcutaneous neuro-stimulation electrodes are passive devices serving as an interface between a user's skin and a neuro-stimulation device.	
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN (BASIC-UDI-DI)	8427734TENSELECJK
GMDN	35995
EMDN	N010201 (Tens System Elèctrodes)
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021 // EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-10:2013 // EN 60601-1:2006 // EN 60601-1:2006/AC:2010 // EN 60601-1:2006/A1:2013//EN 60601-1:2008//A12:2014// ANSI/AAMI EC12:2000/R2020 // ANSI/AAMI NS4:2017.	

Reusable cables for electrosurgery	
Description	Reusable clamp-cables for electrosurgical plates.
Commercial brand	BLAYCO
References	(REF: 42XX-X):4200, 4200-5, 4210, 4210-5, 4212, 4212-5
Intended use	
Intended use is to connect the return electrode to the electrosurgical equipment.	
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN (BASIC-UDI-DI)	8427734ESUCABLESRE
GMDN	47487
EMDN	V80 (Clinical use accessories not included in other in classes)
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021// EN ISO 20417:2021// EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-7:2008 // EN ISO 10993-7:2008/AC:2009 /EN ISO 10993-7:2008/A1:2022 // EN ISO 10993-10:2013 // EN 60601-1:2006 // EN 60601-1:2006/AC:2010 // EN 60601-1:2006/A1:2013 // EN 60601-1:2006/A12:2014 // EN IEC 60601-2-2:2018	

Bite-blocks	
Description	Bite block for endotracheal tubes and laryngeal masks.
Commercial brand	MORDEDOR-MO
References	Adult:7600 Paediatric: 7650

Intended use

Accessory to prevent pressure on the endotracheal tube/probe due to biting, in case of oral intubation.

Classification	
Product class I – Non-sterile. According to Rule 5 of Annex VIII of Regulation (UE) 2017/745.	
GMN (BASIC-UDI-DI)	8427734BITEBLOCKKW
GMDN	10405
EMDN	R0199 (Intubation Devices-other).

Standards applied

EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021 // EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-10:2013

Otoscope speculum	
Description	Disposable speculum for otoscope.
Commercial brand	DORMO-SPEC
References	Pediatric: (REF:40XX):4010, 4040, 4060, 4070, 4090, 4100 Adult: (REF:40XX): 4020, 4030, 4050, 4080, 4095
Intended use	
The DORMO®-SPEC product is an ear speculum designed to be inserted into the patient's external ear. It is attached to an otoscope that emits a beam of light through the speculum to explore the ear cavity up to the eardrum.	
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN (BASIC-UDI-DI)	8427734OTOSCOPESPECULUMFB
GMDN	35348
EMDN	Z12021085 (Endoscopy instruments- consumables).
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021 // EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-10:2013	

Protective pad	
Description	Protective pad for surgical interventions.
Commercial brand	BLAYCO-PAD
References	AC-3020
Intended use	
The BLAYCO®-PAD protective pad is principally used to avoid pressure sores in medium to long interventions. Protects bone protrusions in contact with the operating table and prevents post-operative joint discomfort, haematomas, etc. As it relieves the pressure on these areas, it also aids blood flow.	
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN (BASIC-UDI-DI)	8427734PROTECTIVEPADY2
GMDN	62789
EMDN	T0306 (Patient protection 15evices during clinical procedures).
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021 // EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-10:2013	

Nasal holder for gastric catheters	
Description	Nasal holder for gastric catheters.
Commercial brand	DORMO-NAS
References	Paediatric: 7550 Adult: 7500
Intended use	
Nasal holder for gastric catheters Dormo®-Nas, non-sterile, for single use only whose intended use is to act as immobilizer of gastric catheters reducing the risk of gastric decubitus ulcers and nostrils irritation.	
Classification	
Product class I – Non-sterile. According to Rule rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN (BASIC-UDI-DI)	8427734NASALHOLDERY2
GMDN	62581
EMDN	A99 (Devices for administration, withdrawal and collection-other).
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021 // EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-10:2013	

Cold/hot packs	
Description	Reusable pack for Cold/Hot.
Commercial brand	DORMO
References	(REF: FC-XX) FC-01, FC-02
Intended use	
Reusable pack for treatment with cooling or heating effect.	
Description	Reusable pack for Cold/Hot.
Commercial brand	OXD
References	(REF: FC-XX) FC-03
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN (BASIC-UDI-DI)	8427734HOTCOLDPADCK85
GMDN	37240
EMDN	V9099 (Various Devices not included in other classes-other).
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021 // EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-10:2013	

Ultrasound gels	
Description	Ultrasound gel.
Commercial brand	TRANSONIC GEL
References	-Blue. (REF G-15/XXX): G-15, G-15/05, G-15/1, G-15/5, G-15/5RB, G-15A -Clear. (REF: GC-15/XXX): GC-15, GC-15/05, GC-15/1, GC-15/5, GC-15/5RB
Description	Ultrasound gel.
Commercial brand	OXD
References	-Clear. (REF US-CXXX):US-C250, US-C1, US-C5F, US-C5R -Blue (REF:US-BXXX): US-B250, US-B1, US-B5F, US-B5R
Intended use	
Ultrasound gels are intended for general use as a transmission media for acoustically coupling a transducer to a human body surface during external therapeutic and diagnostic ultrasound imaging procedures. It is placed on the patient's skin or on the transducer prior to initiating an ultrasound examination.	
Classification	
Product class I – Non-sterile. According to Rule 5 of Annex VIII of Regulation (UE) 2017/745.	
GMN (BASIC-UDI-DI)	8427734USGEL8L
GMDN	15321
EMDN	Z11040185 (Ultrasound scanners-consumables).
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021 // EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-10:2013	

ECG Gel	
Description	Conductive gel for electrodes.
Commercial brand	ELECTRO-GEL
References	G-10, G-10A
Intended use	
Conductive gel for electromedical procedures (ECG, TENS).	
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN (BASIC-UDI-DI)	8427734ECGGELVB
GMDN	11425
EMDN	C020599 (Cardiac diagnostic Devices-other).
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021 // EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-10:2013// ANSI/AAMI EC12:2000/2020.	

Lubricating gel	
Description	Lubricating water-soluble gel
Commercial brand	DORMO
References	REF: G-20/XXX: G-20, G-20/5RB
Intended use	
Lubricant gel for catheters and general hospital procedures.	
Classification	
Product class I – Non-sterile. According to Rule 5 of Annex VIII of Regulation (UE) 2017/745.	
GMN (BASIC-UDI-DI)	8427734LUBRICANTGEL5C
GMDN	60796
EMDN	M9002 (Protective sprays and lubricant sprays gels, fluids and creams).
Standards applied	
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021 // EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-10:2013.	

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: **2023-03-01**

Starting Validity Date: **2023-03-01**

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
Vein strippers, Sterile, single-use	Class IIa
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.	

First Issue Date: **2022-09-19**

Current Issue Date: **2023-03-01**

Starting Validity Date: **2023-03-01**

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

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
2023-01-16	3847169	Supplemented: Addition of electrosurgical ground plates. Addition of critical subcontractor.
Current	3854636	Supplemented: Addition of vein strippers.

First Issue Date: **2022-09-19**

Current Issue Date: **2023-03-01**

Starting Validity Date: **2023-03-01**

Expiry Date: **2027-09-18**

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