DORMO®

DESFI-DORMO®

ELECTRODOS PARA DESFIBRILACIÓN

DEFIBRILLATION ELECTRODES
ÉLECTRODES POUR DÉFIBRILLATION

CLASE I
CLASS I
CLASE I

ELECTRODOS DE DESFIBRILACIÓN CON CABLE

Electrodos para desfibrilación, para uso en DEA (Desfibrilador Externo Automático). Disponible con cable incorporado desechable, en diversos modelos o bien con conexión de corchete standard para su utilización con cables reutilizables.

⚠ EL USUARIO DEBERÁ VERIFICAR LA IDONEIDAD DEL CONECTOR CON SU EQUIPO.

Las referencias pediátricas etiquetadas con AED no deben ser utilizadas con desfibriladores automáticos o semi-automáticos, excepto si la energía de la descarga de desfibrilación se establece de modo manual por el usuario.

DEFIBRILLATION ELECTRODES WITH CABLE

Defibrillation electrodes AED compatible (Automatic External Defibrillator). Available with pre-attached disposable cable, in different models, or with standard stud connection for use with reusable cables.

⚠ USER MUST CHECK COMPATIBILITY OF CABLE CONNECTION WITH THE EQUIPMENT.

The pediatrics references labeled with AED must not be used with automated or semi-automated external defibrillators, unless the defibrillation energy is set in manual mode by the user.

ÉLECTRODES POUR DÉFIBRILLATION AVEC CÂBLE

Électrodes pour défibrillation usage unique à utiliser avec DEA (Défibrillateur Externe Automatique). Câble jetable incorporé disponible en différents modèles de connecteur ou avec connexion d'agrafe standard pour l'utilisation avec câbles réutilisables.

⚠ L'UTILISATEUR DOIT VÉRIFIER QUEL CONNECTEUR EST L' APPROPRIÉ A SON ÉQUIPEMENT.

Les éléments pédiatriques étiquetés avec AED ne doivent pas être utilisés avec des défibrillateurs automatiques ou semi-automatiques, sauf si l'énergie de défibrillation est réglée en mode manuel par l'utilisateur.

REF	CONECTOR CONECTOR CONNECTEUR		PRECONECTADO PRE-CONNECTED PRECONNECTÉ	MULTIFUNCIÓN MULTIFUNCTION MULTIFONCTION	MARCA BRAND MARQUE	EQUIPO/MODELO EQUIPMENT/MODEL EQUIPE/MODEL	U/CAJA U/BOX U/CARTON
EDC-1015		A	✗	✓	PHYSIO-CONTROL/ MEDTRONIC	Lifepack12 Lifepack15 Lifepack20e Lifepack1000	10
EDC-2015			✓				
EDC-P115		P	✗	✗	MINDRAY	Beneheart D3	
EDC-P215			✓		LECOR	Cor-Res A6S	
EDC-1020		A	✗	✓	AGILENT PHILIPS	Heartstart XL	10
EDC-2020			✓				
EDC-P120		P	✗	✗	AMI ITALIA	Saver One	
EDC-P220			✓				
EDC-1025		A	✗	✓	AGILENT	Heartstream XLT (cable M3507A)	10
EDC-1030		A	✗	✓	PROGETTI	RESCUE RESCUE SAM	10
EDC-P130		P	✗	✗	GENERAL ELECTRIC	Responder AED	
EDC-1035		A	✗	✓	ZOLL	Series E. Series R Series M	10
EDC-2035			✓				
EDC-2035L							
EDC-P135		P	✗	✗	M&B	AED7000/MB7000	
EDC-P235			✓				

DORMO®

DESFI-DORMO®

ELECTRODOS PARA DESFIBRILACIÓN

DEFIBRILLATION ELECTRODES
ÉLECTRODES POUR DÉFIBRILLATION

REF	CONECTOR CONECTOR CONNECTEUR		PRECONECTADO PRE-CONNECTED PRECONNECTÉ	MULTIFUNCIÓN MULTIFUNCTION MULTIFONCTION	MARCA BRAND MARQUE	EQUIPO/MODELO EQUIPMENT/MODEL EQUIPE/MODEL	U/CAJA U/BOX U/CARTON
EDC-1040		A	✗	✓	NIHON KOHDEN	CARDIOLIFE Adapter cable JC-765V CARDIOLIFE Adapter cable JC-865V	10
EDC-2040			✓				
EDC-P140		P	✗	✗			
EDC-P240			✓				
EDC-1045		A	✗	✓	SCHILLER	Defigard 4000 Fred Easy	10
EDC-2045			✓				
EDC-P145		P	✗	✗			
EDC-P245			✓				
EDC-1050		A	✗	✓	CU MEDICAL SYSTEMS	Paramedic CU-ER1	10
EDC-P150		P		✗			
EDC-1055		A	✗	✓	NIHON KOHDEN	CARDIOLIFE, TEC-7731K Adapter cable JC-755V ActiBiphasic CARDIOLIFE TEC-5531K CARDIOLIFE, Adapter cable JC-855V	10
EDC-P155			✓				
EDC-2055		P	✗	✗			
EDC-P255			✓				
EDC-1060		A	✗	✓	HP / PHILIPS	Heartstart XL Heartstart FR2+	10
EDC-P160		P		✗			
EDC-2060		A	✓	✓			
EDC-P260		P		✗			
EDC-2065		A	✓	✓	MEDIANA	D500	10
EDC-P265		P		✗			
EDC-1070		A	✗	✓	CORPULS	CORPULS 3 - 0960 CORPULS 3	10
EDC-P170		P		✗			
EDC-2070		A	✓	✓		CORPULS 3	

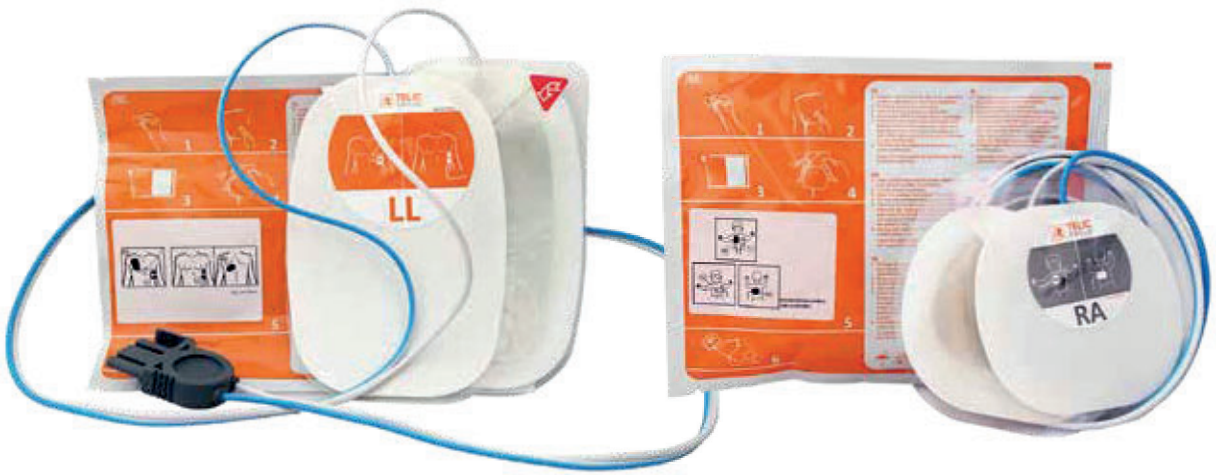
REF	CONECTOR CONECTOR CONNECTEUR		PRECONECTADO PRE-CONNECTED PRECONNECTÉ	MULTIFUNCIÓN MULTIFUNCTION MULTIFONCTION	MARCA BRAND MARQUE	EQUIPO/MODELO EQUIPMENT/MODEL EQUIPE/MODEL	U/CAJA U/BOX U/CARTON
EDC-1075		A	✕	✓	MEDIANA	A10	10
EDC-2075			✓				
EDC-P175		P	✕	✕			
EDC-P275			✓				
EDC-2080		A	✓	✓	SCHILLER	Defigard Touch7 Fred PA-1	10
EDC-P280		P		✕			
EDC-2085		A	✓	✓	TELEFUNKEN HEARTRESET	HR1, FA1	10
EDC-2090		A	✓	✓	ZOLL	X Series	10
EDC-P290		P		✕			

MULTIFUNCTION

Desfibrilación, Cardioversión Sincronizada, Monitorización E.C.G.
Defibrillation, Synchronized Cardioversion, E.C.G. Monitoring.
Défibrillation, Cardioversion Synchronisée, Surveillance E.C.G.

Dispositivo fabricado según Normas EN IEC 60601-2-4
Device manufactured according to EN IEC 60601-2-4 Standard
Dispositif fabriqué suivant Réglementation EN IEC 60601-2-4

En caso de duda en relación a las compatibilidades de los electrodos de desfibrilación, consultar al comercial.
In case of doubt regarding compatibilities of defibrillation electrodes, consult the sales representative
Si vous avez des questions sur la compatibilité des électrodes de défibrillation, consultez votre commercial.



ELECTRODOS PARA DESFIBRILACIÓN
DEFIBRILLATION ELECTRODES
ÉLECTRODES POUR DÉFIBRILLATION

CLASE I
CLASS I
CLASE I

	CONECTOR CONECTOR CONNECTEUR		PRECONECTADO PRE-CONNECTED PRECONNECTÉ	MULTIFUNCIÓN MULTIFUNCTION MULTIFONCTION	U/CAJA U/BOX U/CARTON
ED-1010		A	✕	✕	50

Dispositivo fabricado según Normas EN IEC 60601-2-4 · Device manufactured according to EN IEC 60601-2-4 Standard ·
Dispositif fabriqué suivant Réglementation EN IEC 60601-2-4

By Royal Charter

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
Effective Date: 2022-08-27
Latest Revision Date: 2022-08-24
Expiry Date: 2025-08-26

...making excellence a habit.™

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

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

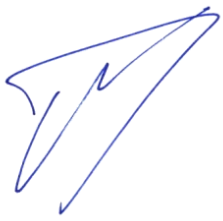
EU DECLARATION OF CONFORMITY

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 June 07th 2021



Laura Delgado
Technical Manager

Oscar Lacruz
CEO

EU DECLARATION OF CONFORMITY – ANNEX 1
List of self-certified products

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 VIII of Regulation (UE) 2017/745.	
GMN	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
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 VIII of Regulation (UE) 2017/745.	
GMN	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-P150, EDC-P155, EDC-P160, EDC-P170.
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-P250, 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 VIII of Regulation (UE) 2017/745.	
GMN	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.	

ECG electrodes and accessories	
Description	ECG electrodes Ag/AgCl.
Commercial brand	DORMO
References	-Solid Gel (REF: SX-XX): SX-50, SX-36, SF-36, SX-30, SP-50 -Semiliquid (REF: LX-XX): LF-50, LF-50T LF-36, LP-50, LR-50 -Stress REF: LEH-36
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734ECGELECVL
GMDN	35035
EMDN	C020501 (ECG Electrodes)
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 // ANSI/AAMI EC12:2000/(R)2015.	

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
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734NEONATALELECZH
GMDN	17460
EMDN	C020501 (ECG Electrodes)
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 // ANSI/AAMI EC12:2000/(R)2015.	

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 VIII of Regulation (UE) 2017/745.	
GMN	8427734TABELEC35
GMDN	35035
EMDN	C020501 (ECG Electrodes)
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 // ANSI/AAMI EC12:2000/(R)2015.	

TENS electrodes and spares	
Description	Pre-gelled electrode for electrical stimulation.
Commercial brand	DORMO-TENS
References	- Silicon conductive electrodes female 2mm connection: (REF: DT-XXX) DT-30R, DT-50R, DT-30, DT-50, DT-100

	- Replacement hydrogel (REF:RT-XXX) RT-30R, RT-50R, 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, CS-100 - Conductive silicone tape with female 2mm connection (REF: CSC-XX): CSC-1, CSC-25
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMDN	8427734TENSELECJK
GMN	35995
EMDN	N010201 (Tens System electrodes)
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 // ANSI/AAMI NS4:2013.	

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
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	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 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 10993-7:2008 // EN ISO 10993-5:2009 // EN ISO 10993-7:2008 // EN ISO 10993-10:2013 // EN 60601-1:2006 // EN 60601-1:2006/AC:2010 // EN 60601-1:2006/A1:2013 // EN 60601-2-2:2009 // EN 60601-2-2:2018	

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

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

Otoscope speculum	
Description	Disposable speculum for otoscope.
Commercial brand	DORMO-SPEC
References	Pediatric: (REF:40XX):4010, 4040, 4060, 4070, 4090 Adult: (REF:40XX): 4020, 4030, 4050, 4080, 4095
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734OTOSCOPESPECULUMFB
GMDN	35348
EMDN	Z12021085 (Endoscopy instruments- consumables).
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.	

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 VIII of Regulation (UE) 2017/745.	
GMN	8427734PROTECTIVEPADY2
GMDN	62789
EMDN	T0306 (Patient protection devices during clinical procedures).

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.

Nasal holder for gastric catheters	
Description	Nasal holder for gastric catheters.
Commercial brand	DORMO-NAS
References	Paediatric: 7550 Adult: 7500
Classification	
Product class I – Non-sterile. According to Rule rule 1 of Annex VIII of Regulation (UE) 2017/745.	
GMN	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 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.	

Cold/hot packs	
Description	Reusable pack for Cold/Hot.
Commercial brand	DORMO
References	(REF: FC-XX) FC-01, FC-02
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	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 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.	

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
Classification	
Product class I – Non-sterile. According to Rule 5 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734USGEL8L
GMDN	15321
EMDN	Z11040185 (Ultrasound scanners-consumables).
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.	

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 VIII of Regulation (UE) 2017/745.	
GMN	8427734ECGGELVB
GMDN	11425
EMDN	C020599 (Cardiac diagnostic Devices-other).
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 // ANSI/AAMI EC12:2000/(R)2015.	

Lubricating gel	
Description	Lubricating water-soluble gel
Commercial brand	DORMO
References	REF: G-20/XXX: G-20, G-20/5RB
Classification	
Product class I – Non-sterile. According to Rule 5 of Annex VIII of Regulation (UE) 2017/745.	
GMN	8427734LUBRICANTGEL5C
GMDN	33587
EMDN	M9002 (Protective sprays and lubricant sprays gels, fluids and creams).
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.	