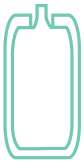
REF			PACIENTE PATIENT	SUPERFICIE TOTAL TOTAL AREA SURFACE TOTAL (cm²)	SUPERFICIE DE CONTACTO CONTACT AREA SURFACE DE CONTACT (cm²)	ESPESOR HIDROGEL THICKNESS HYDROGEL ÉPAISSEUR HYDROGEL (mm)	CABLE / CONECTOR CABLE / CONNECTOR CÂBLE / CONNECTEUR		U/BOLSA U/POUCH U/POCHE	U/CAJA U/BOX U/CARTON
2125	UNIPOLAR		A	217	136	0,69	-		1	100
2125-5							-		5	100
2125-C/00							3 m / 4200		1	50
2125-C/00/5							5 m / 4200		1	50
2125-C/10							3 m / 4210		1	50
2125-C/10/5							5 m / 4210		1	50
2125-C/21							3 m / 4221		1	50
2225			P	145	83	0,69	-		1	100
2225-5							-		5	100
2225-C/00							3 m / 4200		1	50
2225-C/00/5							5 m / 4200		1	50
2225-C/10							3 m /4210		1	50
2225-C/10/5							5 m / 4210		1	50
2425			N	83	32	0,69	-		1	100
2425-5							-		5	100
2425-C/00							3 m / 4200		1	50
2425-C/00/5							5 m / 4200		1	50
2425-C/10							3 m / 4210		1	50
2425-C/10/5							5 m / 4210		1	50
2925			U	168	109	0,69	-		1	100
2925-5							-		5	100
2925-C/00							3 m / 4200		1	50
2925-C/00/5							5 m / 4200		1	50
2925-C/10							3 m / 4210		1	50
2925-C/10/5							5 m / 4210		1	50

2500	DUAL		A	217	128	0,69	-	COMPATIBLE REM	1	100
2500-5							-		5	100
2500-C/00							3 m / 4200		1	50
2500-C/00/5							5 m / 4200		1	50
2500-C/12							3 m / 4212		1	50
2500-C/12/5							5 m / 4212		1	50
2510			A	221	128	0,69	-		1	100
2510-5							-		5	100
2510-C/00							3 m / 4200		1	50
2510-C/00/5							5 m / 4200		1	50
2510-C/12							3 m / 4212		1	50
2510-C/12/5							5 m / 4212		1	50
2600			P	145	73	0,69	-		1	100
2600-5							-		5	100
2600-C/00							3 m / 4200		1	50
2600-C/00/5							5 m / 4200		1	50
2600-C/12							3 m / 4212		1	50
2600-C/12/5							5 m / 4212		1	50

ELECTRODOS PARA E.C.G.

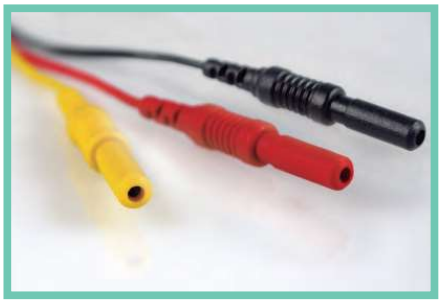
E.C.G. ELECTRODES
ÉLECTRODES POUR E.C.G.

CLASE I
CLASS I
CLASE I

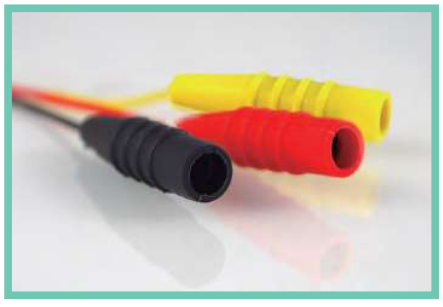
REF		MEDIDAS MEASUREMENTS DIMENSIONS (mm)	SOPORTE BACKING SUPPORT	GEL	ETIQUETA LABEL ÉTIQUETTE	CONEXIÓN CONNECTION CONNEXION	USO PURPOSE USAGE	U/BOLSA U/POUCH U/POCHE	U/CAJA U/BOX U/CARTON
LF-50		Ø 50	ESPUMA FOAM MOUSSE	SEMILÍQUIDO SEMILIQUID SEMI-LIQUIDE	X	CORCHETE · STUD · AGRAFE	A	50	1000
LF-36		36 x 50		SEMILÍQUIDO SEMILIQUID SEMI-LIQUIDE	X		A / P		
SX-50		Ø 50		SÓLIDO SOLID SOLIDE			A		
SX-36		36 x 50		SÓLIDO SOLID SOLIDE			A / P		
SF-36		36 x 42		SÓLIDO SOLID SOLIDE	X		A / P		
SX-30		Ø 30		SÓLIDO SOLID SOLIDE	X		A / P / N		
LEH-36		36 x 50		SEMILÍQUIDO SEMILIQUID SEMI-LIQUIDE	X		STRESS		
SP-50		Ø 50	PAPEL TAPE PAPIER	SÓLIDO SOLID SOLIDE	X		A	50	1000
LP-50		Ø 50		SEMILÍQUIDO SEMILIQUID SEMI-LIQUIDE	X		A		
LR-50		Ø 50	TEXTIL TEXTILE TISSU	SEMILÍQUIDO SEMILIQUID SEMI-LIQUIDE	X		A	50	1000
EKF-22KT		22 x 22	ESPUMA FOAM MOUSSE	SÓLIDO SOLID SOLIDE			A / P / N	6	300

Nomenclatura: A Adultos · P Pediátricos · N Neonatal · PS Polisomnografia · EM Electromiografia
Nomenclature: A Adults · P Pediatric · N Neonates · PS Polisomnography · EM Electromiography
Nomenclature: A Adultes · P Pédiatrique · N Néonatal · PS Polisomnographie · EM Électromyographie

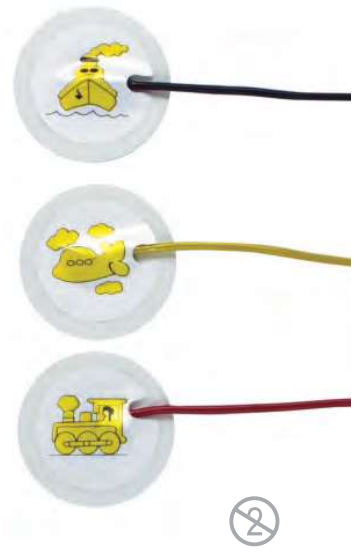
REF	MEDIDAS MEASUREMENTS DIMENSIONS (mm)	SOPORTE BACKING SUPPORT	GEL	ETIQUETA LABEL ÉTIQUETTE	CONEXIÓN CONNECTION CONNEXION	USO PURPOSE USAGE	U/BOLSA U/POUCH U/POCHE	U/CAJA U/BOX U/CARTON
K-140	Ø 30	PE (CLEAR TAPE)	SÓLIDO SOLID SOLIDE	X	Ø1,5 mm CONECTOR SEGURIDAD HEMBRA SAFETY PLUG FEMALE CONNECTEUR DE SURETÉ FEMELLE	P / N	3	99
KS-140	Ø 25			X				
K-150	Ø 30			X	Ø4 mm HEMBRA FEMALE FEMELLE			
KS-150	Ø 25			X				
KF-140	Ø 30	ESPUMA FOAM MOUSSE	SÓLIDO SOLID SOLIDE	X	Ø1,5 mm CONECTOR SEGURIDAD HEMBRA SAFETY PLUG FEMALE CONNECTEUR DE SURETÉ FEMELLE	P / N	3	99
KFS-140	Ø 25			X				
KF-150	Ø 30			X	Ø4 mm HEMBRA FEMALE FEMELLE			
KFS-150	Ø 25			X				



K-140, KS-140, KF-140, KFS -140



K-150, KS-150, KF-150, KFS-150



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	1761.210608	Effective Date	June 8, 2021
Initial Issue Date	July 28, 2018	Expiry Date	August 26, 2022

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

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

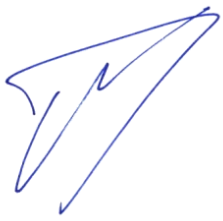
EU DECLARATION OF CONFORMITY

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.	