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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.

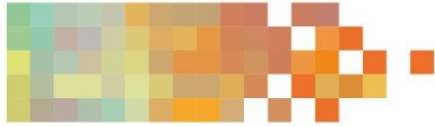
Technical documentation, in accordance with the established in the corresponding annexes of the Regulation (UE) 2017/745 on medical devices, is updated and located in our facilities. We are in position to submit these documents in case of Notified Body or Competent Authority requirement.

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 ,1th March, 2023

Laura Delgado
Technical Manager

Oscar Lacruz
CEO



DECLARATION OF CONFORMITY – ANNEX 1

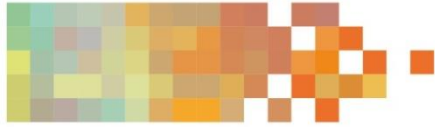
List of products with EC mark

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/00/5, 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, 2500-C/12/5): 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 without 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

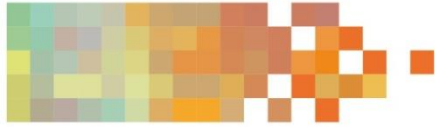
Issued by: BSI

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

Uso previsto

Los extractores de venas son un producto sanitario de un solo uso, estéril por óxido de etileno, cuyo uso previsto es la extracción quirúrgica de venas varicosas. Este producto no está indicado para su uso en el sistema venoso central. Se dispone de distintos modelos compatibles con las dos técnicas de extracción más comunes: extracción convencional y por invaginación.

Classification

Product class IIa - Sterile. According to Rule 7 to Annex VIII del Reglamento (UE) 2017/745

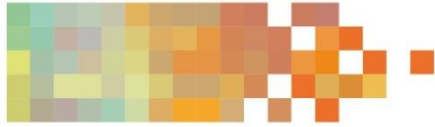
GMN (BASIC-UDI-DI)	8427734VEINSTRIPPERSZP
GMDN	32321
EMDN	C0699 (Cardiovascular surgery instruments, single-use-other).

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

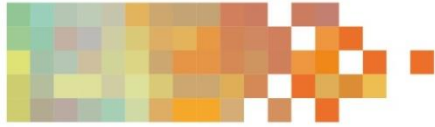
Issued by: BSI

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

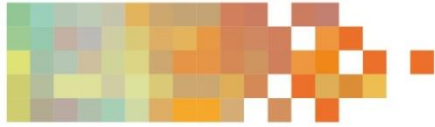
GMN (BASIC-UDI-DI)	8427734SURGLIGHTCOVER8F
GMDN	44977
EMDN	V9099 (Various devices not included in other classes – Other).

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

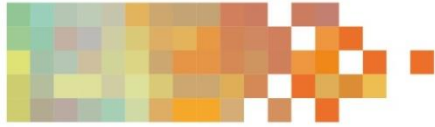
Product class I - Sterile. According to Rule 1 of Annex VIII of Regulation (UE) 2017/745	
GMN (BASIC-UDI-DI)	8427734TIPCLEANERJH
GMDN	37483
EMDN	V9099 (Various Devices not included in other classes- Other).

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

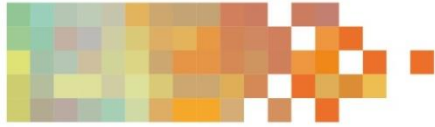
EN ISO 13485:2016 // EN ISO 13485:2016/AC2018/EN ISO 13485:2016/A11:2021 // EN ISO 14971:2019/EN ISO 14971:2019/A11:2021// EN ISO 15223-1:2021 // EN ISO 10993-1:2020// EN ISO 10993-5:2009 // EN ISO 10993-7:2008 // EN ISO 10993-7:2008/AC:2009 /EN ISO 10993-7:2008/A1:2022 // EN ISO 10993-10:2013 // EN 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, SX-30, SP-50, SM-36 -Semiliquid (REF: LX-XX): 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.

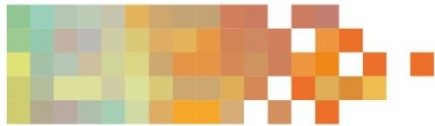
GMN (BASIC-UDI-DI) 8427734NEONATALELECZH

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.

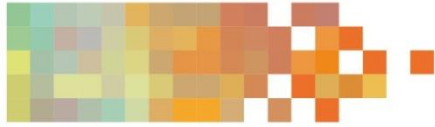
Classification

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

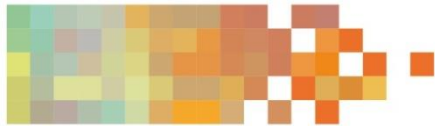
GMN (BASIC-UDI-DI)	8427734TABELEC35
GMDN	35035
EMDN	C020501 (ECG Electrodes)

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.

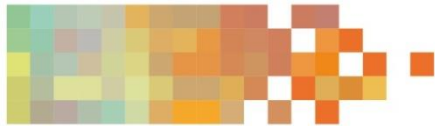
Classification

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.

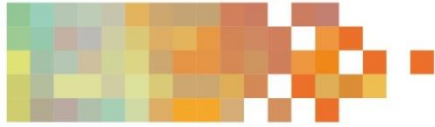
Classification

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.

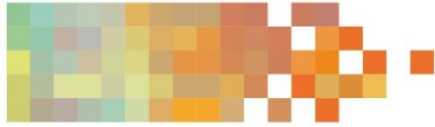
Classification

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.

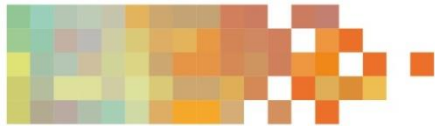
Classification

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.

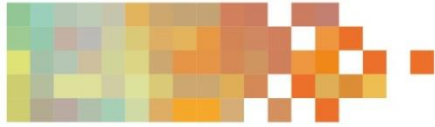
Classification

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

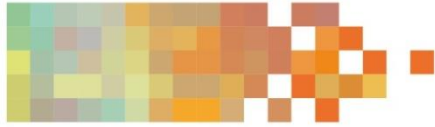
Classification

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

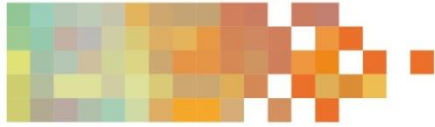
GMN (BASIC-UDI-DI)	8427734HOTCOLDPADCK85
GMDN	37240
EMDN	V9099 (Various Devices not included in other classes-other).

Standards applied

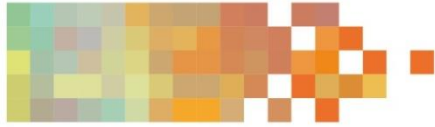
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Ultrasound gels	
Description	Ultrasound gel.
Commercial brand	TRANSONIC GEL
References	-Blue. (REF G-15/XXX): G-15, G-15/05, G-15/1, G-15/5, G-15/5RB, G-15A -Clear. (REF: GC-15/XXX): GC-15, GC-15/05, GC-15/1, GC-15/5, GC-15/5RB
Description	Ultrasound 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.	