Telic, S.A.U.

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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 **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 I** 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 April 23rd, 2025

Laura Delgado	**Òscar Lacruz**
Technical Direction	**CEO**

DECLARATION OF CONFORMITY
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
Intended use	
ELECTRODES FOR EXTERNAL DEFIBRILLATOR are used as interface with the patient for the transfer of the corresponding energy for different functions performed by the defibrillation equipment: defibrillation pulses, synchronized cardioversion or E.C.G. monitoring (last intended use only applicable to Ref #EDC-10XX, EDC-20XX, EDC-P1XX and EDC-P2XX).	
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex IX of the Directive 93/42/EEC.	
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 13485:2016/A11:2021 // EN ISO 14971:2019 // EN ISO 14971:2019/A11:2021 // EN ISO 15223-1:2021 / ISO 15223-1/AMD1:2015// EN ISO 10993-1:2020 // EN ISO 10993-5:2009 // EN ISO 10993-10:2023 // EN 60601-1:2006 // EN 60601-1:2006/CORR:2010 // EN 60601-1:2006/A1:2013 // EN 60601-1:2006/A12:2014 // EN 60601-1:2006/A2:2021 // EN 60601-1:2006/A13:2024 // EN 60601-2-4:2011 // EN 60601-2-4:2011/A1:2019 // EN 60601-2-2:2018 // EN IEC 60601-2-2:2018/A1:2024.	

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-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-2035, EDC-2040, EDC-2045, EDC-2055, EDC-2060, EDC-2065, EDC-2070, EDC-2075, EDC-2080, EDC-2090.
Intended use	
ELECTRODES FOR EXTERNAL DEFIBRILLATOR are used as interface with the patient for the transfer of the corresponding energy for different functions performed by the defibrillation equipment: defibrillation pulses, synchronized cardioversion or E.C.G. monitoring (last intended use only applicable to Ref #EDC-10XX, EDC-20XX, EDC-P1XX and EDC-P2XX).	
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex IX of the Directive 93/42/EEC.	
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 13485:2016/A11:2021 // EN ISO 14971:2019 // EN ISO 14971:2019/A11:2021 // EN ISO 15223-1:2021 / ISO 15223-1/AMD1:2015// EN ISO 10993-1:2020 // EN ISO 10993-5:2009 // EN ISO 10993-10:2023 // EN 60601-1:2006 // EN 60601-1:2006/CORR:2010 // EN 60601-1:2006/A1:2013 // EN 60601-1:2006/A12:2014 // EN 60601-1:2006/A2:2021 // EN 60601-1:2006/A13:2024 // EN 60601-2-4:2011 // EN 60601-2-4:2011/A1:2019 // EN 60601-2-2:2018 // EN IEC 60601-2-2:2018/A1:2024.	

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.
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.
Intended use	
ELECTRODES FOR EXTERNAL DEFIBRILLATOR are used as interface with the patient for the transfer of the corresponding energy for different functions performed by the defibrillation equipment: defibrillation pulses, synchronized cardioversion or E.C.G. monitoring (last intended use only applicable to Ref #EDC-10XX, EDC-20XX, EDC-P1XX and EDC-P2XX).	
Classification	
Product class I – Non-sterile. According to Rule 1 of Annex IX of the Directive 93/42/EEC.	
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 13485:2016/A11:2021 // EN ISO 14971:2019 // EN ISO 14971:2019/A11:2021 // EN ISO 15223-1:2021 / ISO 15223-1/AMD1:2015// EN ISO 10993-1:2020 // EN ISO 10993-5:2009 // EN ISO 10993-10:2023 // EN 60601-1:2006 // EN 60601-1:2006/CORR:2010 // EN 60601-1:2006/A1:2013 // EN 60601-1:2006/A12:2014 // EN 60601-1:2006/A2:2021 // EN 60601-1:2006/A13:2024 // EN 60601-2-4:2011 // EN 60601-2-4:2011/A1:2019 // EN 60601-2-2:2018 // EN IEC 60601-2-2:2018/A1:2024.	