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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.

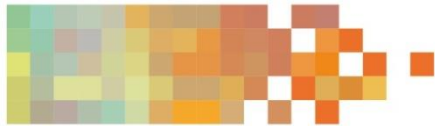
Technical documentation, in accordance with the established in the corresponding annexes of the Regulation (UE) 2017/745 on medical devices, is updated and located in our facilities. We are in position to submit these documents in case of Notified Body or Competent Authority requirement.

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 ,16 Januaryth, 2023

Laura Delgado
Technical Manager

Oscar Lacruz
CEO



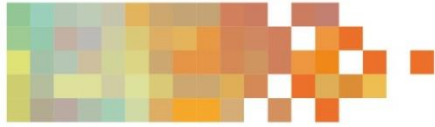
DECLARATION OF CONFORMITY – ANNEX 1
List of products with EC mark

Return electrodes for electrosurgery

Description	Pre-gelled electrosurgical plate.
Commercial brand	BLAYCO
References	<p>Unipolar adult</p> <p>-2125: Adult unipolar without cable.</p> <p>-2125-5: Adult unipolar without cable 5 units.</p> <p>-2125-C/XX/Y: (2125-C/00, 2125-C/00/5, 2125-C/10, 2125-C/10/5): Plate adult unipolar with cable.</p> <p>Unipolar paediatric</p> <p>-2225: Unipolar paediatric without cable.</p> <p>-2225-5: Unipolar paediatric without cable 5 units.</p> <p>-2225-C/XX/Y: (2225-C/00, 2225-C/10): Unipolar paediatric with cable.</p> <p>Unipolar neonatal</p> <p>-2425: Unipolar neonatal without cable.</p> <p>-2425-C/XX/Y: (2425-C/00, 2425-C/10): Unipolar neonatal with cable.</p> <p>Dual adult</p> <p>-2500: Dual adult without cable.</p> <p>-2500-5: dual adult without cable 5 units.</p> <p>-2500-C/XX/Y: (2500-C/00, 2500-C/12, 2500-C/12/5): Dual adult with cable.</p> <p>Dual adult oblong</p> <p>-2510: Dual adult oblong without cable.</p> <p>-2510-5: Dual adult oblong without cable 5 units.</p> <p>-2510-C/XX/Y: (2510-C/00, 2510-C/00/5, 2510-C/12): Dual adult oblong with cable.</p> <p>Dual paediatric</p> <p>-2600: Dual paediatric without cable.</p> <p>-2600-C/XX/Y: (2600-C/00, 2600-C/12): Dual paediatric with cable.</p> <p>Dual neonatal</p> <p>-2700: Dual neonatal without cable.</p> <p>-2700-C/XX/Y: (2700-C/00, 2700-C/12): Dual neonatal with cable.</p> <p>Dual universal</p> <p>-2900: Dual universal without cable.</p> <p>-2900-5: Dual universal without cable 5 units.</p> <p>-2900-C/XX/Y: (2900-C/00, 2900-C/12, 2900-C/12/5): Dual universal with cable.</p>

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