BIOSERENITY

# EU DECLARATION OF CONFORMITY according to European medical device regulation 2017/745

## DECLARATION EU DE CONFORMITE selon le règlement européen 2017/745

| | |
|---|---|
| MANUFACTURER<br>FABRICANT | **BioSerenity**<br>ICM-iPEPS<br>47, Boulevard de l'Hôpital<br>75013 Paris<br>France |
| SRN NUMBER<br>NUMERO SRN | FR-MF-000000497 |
| PRODUCT DESIGNATION<br>DÉSIGNATION DU PRODUIT | **Cardioskin Textile V1.3.1 (Cardioskin Universal)**<br>**Cardioskin Gel 1.2**<br>**Cardioskin Textile V1.1** |
| PRODUCT REFERENCE<br>REFERENCE PRODUIT | 1005-00031-UN ; 1005-00032-UN; 1005-00033-UN; 1005-00034-UN; 1005-00035-UN.<br>1005-00028-EU.<br>1005-00011-EU ; 1005-00012-EU; 1005-00013-EU; 1005-00014-EU; 1005-00015-EU. |
| INTENDED USE<br>INDICATION D'UTILISATION | The Cardioskin Textile is intended to be used with the Cardioskin system as a carrier, which is used by Healthcare Professional (HCP) and patients trained by HCP for heart condition diagnosis with a short or long time ECG record.<br>Le textile Cardioskin est destiné à être utilisé avec le système Cardioskin, qui est utilisé par les professionnels de la santé (PS) et les patients formés par les PS pour le diagnostic des maladies cardiaques avec un enregistrement ECG de court ou longue durée |
| EMDN CODE<br>CODE EMDN | C020501 – ECG electrodes |
| CLASSIFICATION | Rule 1 |

We hereby declare that the above-mentioned products meet the requirements of the European medical device regulation 2017/745. All supporting documentation is retained at the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of BioSerenity.
Nous certifions que les produits mentionnés ci-dessus sont conformes au règlement 2017/745/CEE. Les preuves de conformité sont maintenues dans les locaux du fabricant. Cette déclaration de conformité est délivrée sous la seule responsabilité de BioSerenity.

| | |
|---|---|
| PLACE<br>A | Paris |
| DATE OF ISSUE<br>DATE | August 1St, 2022<br>1er Août 2022 |
| SIGNATURE | |
| NAME / NOM<br>POSITION / TITRE | Mélanie RENAUD SAMIRI<br>Quality and Regulatory Affairs Director<br>Directeur Qualité et Affaires Réglementaires |

BIOSERENITY

## REFERENCE OF APPLIED REGULATORY STANDARDS
## REFERENCE DES NORMES RÉGLEMENTAIRES APPLIQUÉES

| Standard number<br>Numéro du standard | Standard title<br>Titre du standard |
|---|---|
| EN ISO 10993-1: 2018 | Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process |
| EN ISO 10993-5: 2009 | Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity |
| EN ISO 10993-10: 2013 | Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization |
| EN ISO 10993-18:2009 | Biological evaluation of medical devices — Part 18: Chemical characterization of materials |
| EN ISO 13485: 2016 | Medical devices — Quality management systems — Requirements for regulatory purposes |
| EN ISO 14155: 2020 | Clinical investigation of medical devices for human subjects — Good clinical practice |
| EN ISO 14971: 2019 | Medical devices — Application of risk management to medical devices |
| EN ISO 15223-1: 2016 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements |
| ISO 20417: 2021 | Medical devices — Information to be supplied by the manufacturer |
| EN 60601-1: 2006/A1:2013 | Medical electrical equipment — Part 1: General requirements for basic safety and essential performance |
| EN 60601-1-1: 2001 | Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems |
| EN 60601-1-2: 2015 | Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests |
| EN 60601-1-6: 2010 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability |
| EN 60601-1-11: 2010 | Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment |
| IEC 62304+A1: 2018 | Medical device software - Software life-cycle processes |
| IEC 62366-1: 2015 | Medical devices - Application of usability engineering to medical devices |

| | |
|---|---|
| **Applied regulatory requirements** | European Medical Device Regulation (2017/745) |
| | European Regulation (2012/207) - Electronic instructions for use of medical devices |
| | WEEE: Waste Electrical & Electronic Equipment (2012/19/EU) |
| | RoHS2 (2011/65/EU) |
| | REACH (EC 1907/2006) |

## REFERENCE OF APPLIED COMMON SPECIFICATIONS
## REFERENCE DES SPECIFICATIONS COMMUNES APPLIQUÉES

No common specification applicable.

Pas de specifications communes appliquées.

## List of accessories included in the Cardioskin Textile
## Liste des accessoires inclus dans le Textile Cardioskin

No accessories applicable.

Pas d'accessoires applicable.