BIOSERENITY

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

DECLARATION CE DE CONFORMITE selon le règlement européen 2017/745

MANUFACTURER FABRICANT	**BioSerenity** ICM-iPEPS 47, Boulevard de l'Hôpital 75013 Paris France
SRN NUMBER NUMERO SRN	FR-MF-000000497
PRODUCT DESIGNATION DÉSIGNATION DU PRODUIT	**Cardioskin Textile V1.3** (**Cardioskin Universal**) **Cardioskin Gel 1.2** **Cardioskin Textile V1.1**
PRODUCT REFERENCE REFERENCE PRODUIT	1005-00031-UN ; 1005-00032-UN; 1005-00033-UN; 1005-00034-UN; 1005-00035-UN. 1005-00028-EU. 1005-00011-EU ; 1005-00012-EU; 1005-00013-EU; 1005-00014-EU; 1005-00015-EU.
INTENDED USE 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. 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 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 A	Paris
DATE OF ISSUE DATE	August 9th 2021 9th Août 2021
SIGNATURE	
NAME / NOM POSITION / TITRE	Julien Dupont Quality and Regulatory Affairs Director Directeur Qualité et Affaires Réglementaires

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REFERENCE OF APPLIED REGULATORY STANDARDS
REFERENCE DES NORMES RÉGLEMENTAIRES APPLIQUÉES

Standard number Numéro du standard	Standard title Titre du standard
EN 1041:2008	Information supplied by the manufacturer of medical devices
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
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

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.