CE DECLARATION OF CONFORMITY

according to Directive 93/42/EEC amended by Directive 2007/47/EC

DECLARATION CE DE CONFORMITE

selon la Directive 93/42/CEE amendée par la Directive 2007/47/CE

MANUFACTURER FABRICANT	BioSerenity ICM-iPEPS 47, Boulevard de l'Hôpital 75013 Paris France
DESIGNATION	Cardioskin Application (Android) V 2.10.0 ; Cardioskin Application (iOS)V 2.10.0 Cardioskin Recorder V1.2
PRODUCT REFERENCE REFERENCE PRODUIT	5100-00007; 5100-00008 1005-10003-EU
UDI NUMBER NUMERO IUD	03615220003433; 03615220003440 03615220001651
GMDN CODE CODE GMDN	31733
CLASSIFICATION	IIa rule 10 IIa règle 10
CONFORMITY ASSESSMENT ROUTE EVALUATION DE LA CONFORMITE	Annex II - Full quality assurance system excl. Section 4 Annexe II - Système complet d'assurance qualité excl. Section 4

We hereby declare that the above-mentioned products meet the transposition into national law provisions of council Directive 93/42/EEC for medical devices as amended by Directive 2007/47/EC. All supporting documentation is retained at the premises of the manufacturer.

Nous certifions que les produits mentionnés ci-dessus sont conformes à la Directive européenne 93/42/CEE transposée en droit national relative aux dispositifs médicaux amendée par la Directive 2007/47/CE. Les preuves de conformité sont maintenues dans les locaux du fabricant.

NOTIFIED BODY ORGANISME NOTIFIE	BSI 2797 - EC certificate n° CE 672474 BSI 2797 - Certificat CE n° CE 672474
PLACE A	Paris Paris
DATE OF ISSUE DATE SIGNATURE	January 07rd, 2022 7 Janvier 2022
NAME AND POSITION NOM ET TITRE	Mélanie RENAUD SAMIRI - Quality and Regulatory Affairs Director Mélanie RENAUD SAMIRI - Directeur Qualité et Affaires Réglementaires

CE DECLARATION OF CONFORMITY

according to Directive of the Radio Equipment (2014/53/EU)

DECLARATION CE DE CONFORMITE

selon la Directive sur les équipements radioélectriques (2014/53/EU)

MANUFACTURER FABRICANT	BioSerenity ICM-iPEPS 47, Boulevard de l'Hôpital 75013 Paris France
DESIGNATION	Cardioskin Recorder V1.2
PRODUCT REFERENCE REFERENCE PRODUIT	1005-10003-EU
UDI NUMBER NUMERO IUD	03615220001651
GMDN CODE CODE GMDN	31733

We hereby declare that the above mentioned product is in conformity with the essential requirements of the Radio Equipment Directive (2014/53/EU). All supporting documentation is retained at the premises of the manufacturer.

Nous certifions que le produit mentionné ci-dessus est conforme aux exigences essentielles de la Directive sur les équipements radioélectriques (2014/53/EU). Les preuves de conformité sont maintenues dans les locaux du fabricant.

NOTIFIED BODY ORGANISME NOTIFIE	BSI 2797 - EC certificate n° CE 672474 BSI 2797 - Certificat CE n° CE 672474
PLACE A	Paris Paris
DATE OF ISSUE DATE SIGNATURE	January 7rd, 2022 7 Janvier 2022
NAME AND POSITION NOM ET TITRE	Mélanie RENAUD SAMIRI - Quality and Regulatory Affairs Director per interim Mélanie RENAUD SAMIRI - Directeur Qualité et Affaires Réglementaires parintérim

BIOSERENITY

REFERENCE OF APPLIED REGULATORY STANDARDS
REFERENCE DES NORMES RÉGLEMENTAIRES APPLIQUÉES

Number	Standard Title
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
ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971
EN 60601-1:2006 + A1:2013/AC:2014	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
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 + A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-11: 2015	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
EN 60601-2-47: 2001	Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
IEC 62304+A1: 2018	Medical device software - Software life-cycle processes
EN 62366-1:2015+A1:2020	Medical devices - Application of usability engineering to medical devices
EN 62366-2:2016	Guidance on the application of usability engineering to medical devices
Other regulation Applied	European Medical Device Directive (93/42/CEE amended by 2007/47/EU)
	RED: Radio-equipment Directive (2014/53/EU)
	RGPD: General Data Protection Regulation (2016/679)
	WEEE: Waste Electrical & Electronic Equipment (2012/19/EU)
	RoHS2: Restriction of the use of certain hazardous substances in electrical and electronic equipment (2011/65/EU)
	REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals (1907/2006)
	e-IFU: electronic instructions for use of medical devices (207/2012)

BIOSERENITY

LIST OF ACCESSORIES INCLUDED IN THE CARDIOSKIN
LISTE DES ACCESSOIRES INCLUS DANS LE CARDIOSKIN

Product/Produit	**Accessories/Accessoires**
Cardioskin	Cardioskin Battery - V1.1
	Cardioskin battery Cable – V1.1
	Cardioskin Dock - V1.2