COC-00076B

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

DECLARATION UE 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™ Recorder V2.0.0** **Accessories (appendix I)** **Cardioskin ™ Recorder V2.0.0** **Accessoires (annexe I)**
PRODUCT REFERENCE REFERENCE PRODUIT	1005-10003-EU
Basic UDI-DI NUMBER NUMERO IUD-ID de base	361522CCWrecordsV0QD
INTENDED USE INDICATION D'UTILISATION	Cardioskin™ enables acquisition, recording, storage, transmission, and display of 15-lead electrocardiogram (ECG) in order to analyse potential cardiac pathological abnormalities. Le Cardioskin™ permet l'acquisition, l'enregistrement, la transmission et l'affichage d'un électrocardiogramme (ECG) à 15 dérivations afin d'analyser les pathologies cardiaques potentielles.
EMDN CODE CODE EMDN	Recorder: Z12050403 – ECG Holter Recorders **Accessories (appendix I)** / **Accessoires (annexe I)**
CLASSIFICATION	**Cardioskin ™ Recorder:** IIa rule 10 IIa règle 10 **Accessories (appendix I)** /**Accessoires (annexe I)**
CONFORMITY ASSESSMENT ROUTE EVALUATION DE LA CONFORMITE	Annex IX - Conformity assessment based on a quality management system and assessment of the technical documentation Annexe IX - Evaluation de la conformité sur la base d'un système de gestion de la qualité et de l'évaluation de la documentation technique

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.

NOTIFIED BODY ORGANISME NOTIFIE	BSI 2797 – EU certificate n° MDR 729450 BSI 2797 - Certificat UE n° MDR 729450
PLACE A	Paris
DATE OF ISSUE DATE	December 21th, 2022 21 décembre 2022
SIGNATURE	
NAME / NOM POSITION / TITRE	Mélanie RENAUD SAMIRI Quality and Regulatory Affairs Director Directrice 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
SRN NUMBER NUMERO SRN	FR-MF-000000497
PRODUCT DESIGNATION DÉSIGNATION DU PRODUIT	**Cardioskin ™ Recorder V2.0.0**
PRODUCT REFERENCE REFERENCE PRODUIT	1005-10003-EU
Basic UDI-DI NUMBER NUMERO IUD-ID de base	361522CCWrecordsV0QD
INTENDED USE INDICATION D'UTILISATION	Cardioskin™ enables acquisition, recording, storage, transmission, and display of 15-lead electrocardiogram (ECG) in order to analyse potential cardiac pathological abnormalities. Le Cardioskin™ permet l'acquisition, l'enregistrement, la transmission et l'affichage d'un électrocardiogramme (ECG) à 15 dérivations afin d'analyser les pathologies cardiaques potentielles.
EMDN CODE CODE EMDN	Recorder: Z12050403 – ECG Holter Recorders
CLASSIFICATION	IIa rule 10 IIa règle 10

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. This declaration of conformity is issued under the sole responsibility of BioSerenity.

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. Cette déclaration de conformité est délivrée sous la seule responsabilité de BioSerenity.

PLACE A	Paris
DATE OF ISSUE DATE	December 21th, 2022 21 décembre 2022
SIGNATURE	
NAME / NOM POSITION / TITRE	Mélanie RENAUD SAMIRI Quality and Regulatory Affairs Director Directrice Qualité et Affaires Réglementaires

REFERENCE OF APPLIED REGULATORY STANDARDS
REFERENCE DES NORMES RÉGLEMENTAIRES APPLIQUÉES

Standard number Numéro de la norme	Standard title Titre de de la norme
EN ISO 13485:2016/A11: 2021	Medical devices — Quality management sys¬tems — Requirements for regulatory purposes
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects — Good clinical practice
EN ISO 14971:2019/A11:2021	Medical devices — Application of risk management to medical devices
EN ISO 15223-1:2021	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
IEC 60601-1-2:2014+AMD1:2020	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
EN 60601-1:2006 + A1:2013/AC:2014	Medical electrical equipment — Part 1-4: General requirements for safety — Collateral standard: Programmable electrical medical systems
IEC 60601-1-6:2010 +AMD1:2013 +AMD2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-11:2015/AMD 1:2020	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 60601-2-47:2015	Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
IEC 62304:2006/AMD 1:2015	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

Applied Regulation Règlement appliqué	Regulation title Titre du réglement
REG (UE) 2017/745	**REGULATION (EU) 2017/745** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
Rect REG (UE) 2017/745	C**orrigendum to Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
Rect REG (UE) 2017/745 (2)	**Corrigendum to Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
REG (UE) 2020/561	REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions
DÉCISION (UE) 2020/437	COMMISSION IMPLEMENTING DECISION (EU) 2020/437 of 24 March 2020 on **the harmonised standards** for medical devices drafted in support of Council Directive 93/42/EEC
DECISION (EU) 2021/1182	COMMISSION IMPLEMENTING DECISION (EU) 2021/1182 of 16 July 2021 on the **harmonised standards** for medical devices drafted in support of Regulation (EU) 2017/745 of the European Parliament and of the Council
DECISION (EU) 2022/6	COMMISSION IMPLEMENTING DECISION (EU) 2022/6 of 4 January 2022 amending Implementing Decision (EU) 2021/1182 as regards **harmonised standards** for biological evaluation of medical devices, sterilisation of health care products, aseptic processing of health care products, quality management systems, symbols to be used with information to be supplied by the manufacturer, processing of health care products and home light therapy equipment
DECISION (EU) 2022/757	Commission Implementing Decision (EU) 2022/757 of 11 May 2022 amending Implementing Decision (EU) 2021/1182 as regards **harmonised standards** for quality management systems, sterilisation and application of risk management to medical devices
REC 2013/172/UE	COMMISSION RECOMMENDATION of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union
REG (EU) 2021/2226	COMMISSION IMPLEMENTING REGULATION (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices
RED 2014/53/EU	RED: Radio-equipment Directive (2014/53/EU)
RGPD 2016/679	RGPD: General Data Protection Regulation (2016/679)
WEEE 2012/19/EU	WEEE: Waste Electrical & Electronic Equipment (2012/19/EU)
RoHS2 2011/65/EU	RoHS2: Restriction of the use of certain hazardous substances in electrical and electronic equipment (2011/65/EU)
REACH 1907/2006	REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals (1907/2006)
REC 2013/172/UE	COMMISSION RECOMMENDATION of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union
DECISION (EU) 2021/610	COMMISSION IMPLEMENTING DECISION (EU) 2021/610 of 14 April 2021 amending Implementing Decision (EU) 2020/437 as regards harmonised standards on medical vehicles and their equipment, anaesthetic and respiratory equipment, biological evaluation of medical devices, packaging for terminally sterilised medical devices, sterilisation of health care products, clinical investigation of medical devices for human subjects, non-active surgical implants, medical devices utilising animal tissues and their derivatives, electroacoustics and medical electrical equipment
REG (UE) 2020/561	REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions

REFERENCE OF APPLIED COMMON SPECIFICATIONS
REFERENCE DES SPECIFICATIONS COMMUNES APPLIQUÉES

No common specification applicable.
Pas de spécifications communes appliquées.

List of accessories included in the Cardioskin™ Recorder and Cardioskin™ Mobile Application
Liste des accessoires inclus dans le Cardioskin™ Recorder et Cardioskin™ Mobile Application

Accessories Accessoires	Reference Reference	EMDN codes Codes EMDN	Classification Classification
Cardioskin battery V1.1	1005-15004-UN	Z12050480 – Holter system instruments for cardiovascular parameters – hardware accessories	Class I Rule 1 - Accessory of medical device Règle 1 – Accessoire de dispositif médical
Cardioskin battery Cable V1.1	1005-15009-UN	Z12050480 – Holter system instruments for cardiovascular parameters – hardware accessories	Class I Rule 1 - Accessory of medical device Règle 1 – Accessoire de dispositif médical
Cardioskin Dock V1.2	1005-15010-EU	Z12050480 – Holter system instruments for cardiovascular parameters – hardware accessories	Class I Rule 13 - Accessory of medical device Règle 13 – Accessoire de dispositif médical
Cardioskin adapter V1.11.0	1005-15014-UN	Z12050480 – Holter system instruments for cardiovascular parameters – hardware accessories	Class I Rule 13 - Accessory of medical device Règle 13 – Accessoire de dispositif médical
Cardioskin Mobile application-Android V3.0.0	5100-00007	Z12101082 – EEG HOLTER SYTEM INSTRUMENTS – SOFTWARE ACCESSORIES	Class IIa Rule 11 – Accessory of medical device Règle 11 – Accessoire de dispositif médical
Cardioskin Mobile application -iOS V3.0.0	5100-00008	Z12101082 – EEG HOLTER SYTEM INSTRUMENTS – SOFTWARE ACCESSORIES	Class IIa Rule 11 – Accessory of medical device Règle 11 – Accessoire de dispositif médical