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	Bioserenity Cloud V5.0.0
PRODUCT REFERENCE REFERENCE PRODUIT	1012-21001-UN
Basic UDI-DI NUMBER NUMERO IUD-ID de base	361522BiosCloudV09X
INTENDED USE INDICATION D'UTILISATION	BioSerenity Cloud is intended to be used by qualified healthcare professional in order to allow data processing of electrophysiological signals by providing electrophysiological recording to help diagnosis of physiological disorders. Le BioSerenity Cloud est destiné à être utilisé par un professionnel de santé qualifié avec les produits BioSerenity. Il permet le traitement des données des signaux électrophysiologiques à partir d'enregistrements pour aider au diagnostic des troubles physiologiques.
EMDN CODES CODES EMDN	Z12040182: General medicine diagnosis and monitoring instruments – software accessories Z12050382: Electrocardiographs – software accessories Z12100882: EEG telemetry instruments – software accessories Z12101082: EEG holter systems instruments – software accessories
CLASSIFICATION	IIa (rule 11) IIa (règle 11)
CONFORMITY ASSESSMENT ROUTE	Annex IX - Conformity assessment based on a quality management system and assessment of the technical documentation
EVALUATION DE LA CONFORMITE	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	July 31th, 2023 31 juillet 2023
SIGNATURE	
NAME / NOM	Mélanie RENAUD SAMIRI
POSITION / TITRE	Quality and Regulatory Affairs Director Directeur Qualité et Affaires Réglementaires

REFERENCE OF APPLIED REGULATORY STANDARDS
REFERENCE DES NORMES RÉGLEMENTAIRES APPLIQUÉES

Standard number Numéro du standard	Standard title Titre du standard
EN ISO 13485:2016/A11: 2021	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects — Good clinical practice (ISO 14155:2011)
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 15223-1:2016, Corrected version 2017-03)
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 60601-2-25 :2016	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
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

REFERENCE OF APPLIED REGULATORY TEXTS
REFERENCE DES TEXTES RÉGLEMENTAIRES APPLIQUÉES

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
REG (EU) 2023/607	Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices
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
RGPD 2016/679	RGPD: General Data Protection Regulation (2016/679)

REFERENCE OF APPLIED COMMON SPECIFICATIONS
REFERENCE DES SPECIFICATIONS COMMUNES APPLIQUÉES

No common specification is applicable to BioSerenity Cloud.