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

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

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| MANUFACTURER<br>FABRICANT | **BioSerenity Medical Devices Group**<br>20 Rue Berbier du Mets<br>75013 Paris<br>FRANCE |
| SRN NUMBER<br>NUMERO SRN | FR-MF-000039391 |
| PRODUCT DESIGNATION<br>DÉSIGNATION DU PRODUIT | Bioserenity Cloud V5.2.1 |
| PRODUCT REFERENCE<br>REFERENCE PRODUIT | 1012-21001-UN |
| Basic UDI-DI NUMBER<br>NUMERO IUD-ID de base | 361522BiosCloudV09X |
| INTENDED USE<br>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.<br>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<br>CODES EMDN | Z12040182: General medicine diagnosis and monitoring instruments – software accessories<br>Z12050382: Electrocardiographs – software accessories<br>Z12100882: EEG telemetry instruments – software accessories<br>Z12101082: EEG holter systems instruments – software accessories |
| CLASSIFICATION | IIa (rule 11)<br>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.

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| NOTIFIED BODY<br>ORGANISME NOTIFIE | BSI 2797 – EU certificate n° MDR 802592<br>BSI 2797 - Certificat UE n° MDR 802592 |
| PLACE<br>A | Paris |
| DATE OF ISSUE<br>DATE | May 26th, 2024<br>26 mai 2024 |
| SIGNATURE |  |
| NAME / NOM | Mélanie RENAUD SAMIRI |
| POSITION / TITRE | Quality and Regulatory Affairs Director<br>Directeur Qualité et Affaires Réglementaires |

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

| Standard number<br>Numéro du standard | Standard title<br>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**<br>**Règlement appliqué** | **Regulation title**<br>**Titre du réglement** |
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| **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.