



**EU DECLARATION OF CONFORMITY according to European medical device regulation 2017/745**  
**DECLARATION UE DE CONFORMITE selon le règlement européen 2017/745**  
**DICHIARAZIONE DI CONFORMITÀ UE ai sensi del Regolamento europeo sui dispositivi medici**  
**2017/745**  
**(EN / FR / IT)**

<p>MANUFACTURER FABRICANT FABBRICANTE</p>	<p><b>BioSerenity Medical Devices Group</b> 6/8 Rue Jean Antoine de Baïf 75013 Paris France</p>
<p>SRN NUMBER NUMERO SRN NUMERO SRN</p>	<p>FR-MF-000039391</p>
<p>PRODUCT DESIGNATION DÉSIGNATION DU PRODUIT DENOMINAZIONE DEL PRODOTTO</p>	<p>Bioserenity Cloud V7.1.0</p>
<p>PRODUCT REFERENCE REFERENCE PRODUIT RIFERIMENTO DEL PRODOTTO</p>	<p>1012-21001-UN</p>
<p>Basic UDI-DI NUMBER NUMERO IUD-ID de base NUMERO IDI-ID di base</p>	<p>361522BiosCloudV09X</p>
<p>INTENDED USE INDICATION D'UTILISATION DESTINAZIONE D'USO</p>	<p>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. BioSerenity Cloud è progettato per l'utilizzo da parte di professionisti sanitari qualificati per consentire l'elaborazione dei dati di segnali elettrofisiologici fornendo una registrazione elettrofisiologica per facilitare la diagnosi di disturbi fisiologici.</p>
<p>EMDN CODES CODES EMDN CODICI EMDN</p>	<p>Z12040182: Strumenti diagnostici e di monitoraggio per la medicina generale – Accessori software Z12100882: Strumenti per telemetria EEG – Accessori software Z12101082: Strumenti per sistemi holter EEG – Accessori software</p>
<p>CLASSIFICATION CLASSIFICAZIONE</p>	<p>Ila (rule 11) Ila (norma 11)</p>
<p>CONFORMITY ASSESSMENT ROUTE</p>	<p>Annex IX - Conformity assessment based on a quality management system and assessment of the technical documentation</p>
<p>EVALUATION DE LA CONFORMITE</p>	<p>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</p>
<p>ITER DI VALUTAZIONE DELLA CONFORMITÀ</p>	<p>Allegato IX - Valutazione della conformità sulla base di un sistema di gestione della qualità e valutazione della documentazione tecnica</p>



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.

Dichiariamo con la presente che i suddetti prodotti sono conformi ai requisiti del Regolamento europeo sui dispositivi medici 2017/745. Tutta la documentazione di supporto è conservata presso la sede del fabbricante. La presente dichiarazione di conformità è emessa sotto la responsabilità esclusiva di BioSerenity.

NOTIFIED BODY

ORGANISME NOTIFIE

ORGANISMO NOTIFICATO

BSI 2797 – EU certificate n° MDR 802592

BSI 2797 - Certificat UE n° MDR 802592

BSI 2797 – Certificato UE n° MDR 802592

PLACE

LUOGO

Paris

Parigi

DATE OF ISSUE

DATE

DATA DI RILASCIO

March 3rd, 2026

3 Mars 2026

3 Marzo 2026

SIGNATURE / FIRMA

Signé par :

*Pierre Emerich*

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NAME / NOM / NOME

Pierre Emerich

POSITION / TITRE / TITOLO

Chief Technology Officer (CTO)

Responsable de la stratégie technologique (CTO)

Direttore responsabile della strategia tecnologica (CTO)



**EU DECLARATION OF CONFORMITY** according to European medical device regulation 2017/745  
**EU-KONFORMITÄTSERKLÄRUNG** gemäß der EU-Verordnung 2017/745  
 (EN / DE)

<p>MANUFACTURER HERSTELLER</p>	<p><b>BioSerenity Medical Devices Group</b> 6/8 Rue Jean Antoine de Baïf 75013 Paris France</p>
<p>SRN NUMBER SRN-NUMMER</p>	<p>FR-MF-000039391</p>
<p>PRODUCT DESIGNATION PRODUKTBEZEICHNUNG</p>	<p>Bioserenity Cloud V7.1.0</p>
<p>PRODUCT REFERENCE PRODUKTREFERENZ</p>	<p>1012-21001-UN</p>
<p>Basic UDI-DI NUMBER Basis-IUD-ID-NUMMER</p>	<p>361522BiosCloudV09X</p>
<p>INTENDED USE VERWENDUNGSZWECK</p>	<p>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.          Die BioSerenity Cloud ist für die Verwendung durch qualifizierte medizinische Fachkräfte in Verbindung mit den Produkten von BioSerenity vorgesehen. Sie ermöglicht die Verarbeitung von electrophysiologischen Signaldaten aus Aufzeichnungen zur Unterstützung der Diagnose von physiologischen Beschwerden.</p>
<p>EMDN CODES EMDN-CODES</p>	<p>Z12040182 General medicine diagnosis and monitoring instruments – software accessories          Z12100882 EEG telemetry instruments – software accessories          Z12101082 EEG holter systems instruments – software accessories</p>
<p>CLASSIFICATION KLASSIFIKATION</p>	<p>Ila (rule 11) Ila (Regel 11)</p>
<p>CONFORMITY ASSESSMENT ROUTE KONFORMITÄTSBEWERTUNG</p>	<p>Annex IX - Conformity assessment based on a quality management system and assessment of the technical documentation          Anhang IX – Konformitätsbewertung auf der Grundlage eines Qualitätsmanagementsystems und einer Bewertung der technischen Dokumentation</p>



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.

Hiermit bestätigen wir, dass die oben genannten Produkte der Verordnung 2017/745/EWG entsprechen. Der Nachweis der Konformität wird in den Räumlichkeiten des Herstellers aufbewahrt. Diese Konformitätserklärung wird unter der alleinigen Verantwortung von BioSerenity ausgestellt.

NOTIFIED BODY  
BENANNT STELLE

BSI 2797 – EU certificate n° MDR 802592  
BSI 2797 – EU-Zertifikat Nr. MDR 802592

PLACE  
ORT

Paris

DATE OF ISSUE  
AUSSTELLUNGSDATUM

March 3rd, 2026  
3. März 2026

SIGNATURE  
UNTERSCHRIFT

Signé par :  
  
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NAME

Pierre Emerich

POSITION

Chief Technology Officer (CTO)  
Technischer Leiter (CTO)

**REFERENCE OF APPLIED REGULATORY STANDARDS**  
**REFERENCE DES NORMES RÉGLEMENTAIRES APPLIQUÉES**  
**RIFERIMENTO A NORME DI REGOLAMENTAZIONE APPLICATE**  
**REFERENZEN DER ANGEWENDETEN REGULIERUNGSNORMEN**

Standard number Numéro du standard Codice della norma Nummer der Norm	Standard title Titre du standard Titolo della norma Name der Norm
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
IEC 62304:2006/AMD 1:2015	Medical device software - Software life-cycle processes
IEC 82304-1:2016	Health software - Part 1: General requirements for product safety
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**  
**RIFERIMENTO A TESTI NORMATIVI APPLICATI**  
**REFERENZ DER ANGEWENDETEN TEXTE DER REGULIERUNGEN**

Applied Regulation Règlement appliqué Regolamentazione applicata Angewendete Regulierung	Regulation title Titre du règlement Titolo del regolamento Titel der Regulierung
<b>REG (UE) 2017/745</b>	<b>REGULATION (EU) 2017/745</b> 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
<b>Rect REG (UE) 2017/745</b>	<b>Corrigendum to Regulation (EU) 2017/745</b> 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
<b>Rect REG (UE) 2017/745 (2)</b>	<b>Corrigendum to Regulation (EU) 2017/745</b> 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
<b>REG (UE) 2020/561</b>	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
<b>REG (EU) 2023/607</b>	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
<b>REG (EU) 2024/1860</b>	Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices
<b>DECISION (EU) 2021/1182</b>	COMMISSION IMPLEMENTING DECISION (EU) 2021/1182 of 16 July 2021 on the <b>harmonised standards</b> for medical devices drafted in support of Regulation (EU) 2017/745 of the European Parliament and of the Council
<b>DECISION (EU) 2022/6</b>	COMMISSION IMPLEMENTING DECISION (EU) 2022/6 of 4 January 2022 amending Implementing Decision (EU) 2021/1182 as regards <b>harmonised standards</b> 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
<b>DECISION (EU) 2022/757</b>	Commission Implementing Decision (EU) 2022/757 of 11 May 2022 amending Implementing Decision (EU) 2021/1182 as regards <b>harmonised standards</b> for quality management systems, sterilisation and application of risk management to medical devices
<b>DECISION (EU) 2023/1410</b>	Commission Implementing Decision (EU) 2023/1410 of 4 July 2023 amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for sterilization of health care products and biological evaluation of medical devices
<b>DECISION (EU) 2024/815</b>	Commission Implementing Decision (EU) 2024/815 of 6 March 2024 amending Implementing Decision (EU) 2021/1182 as regards <b>harmonised standards</b> for medical gloves for single use, biological evaluation of medical devices, sterilization of health care products, packaging for terminally sterilized medical devices and processing of health care products
<b>REC 2013/172/UE</b>	COMMISSION RECOMMENDATION of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union
<b>REG (EU) 2021/2226</b>	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
<b>RGPD 2016/679</b>	RGPD: General Data Protection Regulation (2016/679)



**REFERENCE OF APPLIED COMMON SPECIFICATIONS**  
**REFERENCE DES SPECIFICATIONS COMMUNES APPLIQUÉES**  
**RIFERIMENTO A SPECIFICHE COMUNI APPLICATE**  
**REFERENZ DER GEMEINSAMEN ANWENDBAREN SPEZIFIKATIONEN**

No common specification applicable.  
Pas de spécifications communes appliquées.  
Nessuna specifica comune applicabile.  
Keine Anwendung gemeinsamer