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)

MANUFACTURER FABRICANT FABBRICANTE	**BioSerenity Medical Devices Group** 20, Rue Berbier du Mets 75013 Paris France
SRN NUMBER NUMERO SRN NUMERO SRN	FR-MF-000039391
PRODUCT DESIGNATION DÉSIGNATION DU PRODUIT DENOMINAZIONE DEL PRODOTTO	Bioserenity Cloud V5.3.0
PRODUCT REFERENCE REFERENCE PRODUIT RIFERIMENTO DEL PRODOTTO	1012-21001-UN
Basic UDI-DI NUMBER NUMERO IUD-ID de base NUMERO IDI-ID di base	361522BiosCloudV09X
INTENDED USE INDICATION D'UTILISATION DESTINAZIONE D'USO	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.
EMDN CODES CODES EMDN CODICI EMDN	Z12040182: Strumenti diagnostici e di monitoraggio per la medicina generale – Accessori software Z12050382: Elettrocardiografi – Accessori software Z12100882: Strumenti per telemetria EEG – Accessori software Z12101082: Strumenti per sistemi holter EEG – Accessori software
CLASSIFICATION CLASSIFICAZIONE	IIa (rule 11) IIa (norma 11)
CONFORMITY ASSESSMENT ROUTE EVALUATION DE LA CONFORMITE ITER DI VALUTAZIONE DELLA CONFORMITÀ	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 Allegato IX - Valutazione della conformità sulla base di un sistema di gestione della qualità e valutazione della documentazione tecnica

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	August 19th, 2024 19 aout 2024 19 agosto 2024
SIGNATURE FIRMA	
NAME / NOM / NOME	Mélanie RENAUD SAMIRI
POSITION / TITRE / TITOLO	Quality and Regulatory Affairs Director Directeur Qualité et Affaires Réglementaires Direttrice qualità e affari regolamentari

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

MANUFACTURER HERSTELLER	**BioSerenity Medical Devices Group** 20, Rue Berbier du Mets 75013 Paris France
SRN NUMBER SRN-NUMMER	FR-MF-000039391
PRODUCT DESIGNATION PRODUKTBEZEICHNUNG	Bioserenity Cloud V5.3.0
PRODUCT REFERENCE PRODUKTREFERENZ	1012-21001-UN
Basic UDI-DI NUMBER Basis-IUD-ID-NUMMER	361522BiosCloudV09X
INTENDED USE VERWENDUNGSZWECK	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 elektrophysiologischen Signaldaten aus Aufzeichnungen zur Unterstützung der Diagnose von physiologischen Beschwerden.
EMDN CODES EMDN-CODES	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
KLASSIFIKATION	IIa (rule 11) IIa (Regel 11)
CONFORMITY ASSESSMENT ROUTE KONFORMITÄTSBEWERTUNG	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

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 BENANNTE STELLE	BSI 2797 – EU certificate n° MDR 802592 BSI 2797 – EU-Zertifikat Nr. MDR 802592
PLACE ORT	Paris
DATE OF ISSUE AUSSTELLUNGSDATUM	August 19th, 2024 24. August 2024
UNTERSCHRIFT	
NAME	Mélanie RENAUD SAMIRI
POSITION	Quality and Regulatory Affairs Director Direktorin für Qualität und regulatorische Angelegenheiten

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
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
RIFERIMENTO A TESTI NORMATIVI APPLICATI
REFERENZ DER ANGEWENDETEN TEXTE DER REGULIERUNGEN

Applied Regulation Règlement appliqué Regolamentazione applicata Angewendete Regulierung	Regulation title Titre du réglement Titolo del regolamento Titel der Regulierung
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
REG (EU) 2024/1860	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
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
DECISION (EU) 2023/1410	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
DECISION (EU) 2024/815	Commission Implementing Decision (EU) 2024/815 of 6 March 2024 amending Implementing Decision (EU) 2021/1182 as regards **harmonised standards** 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
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
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 Spezifikationen