EU DECLARATION OF CONFORMITY according to European Medical Device Regulation 2017/745

DECLARATION EU DE CONFORMITE selon le Règlement Européen 2017/745

DICHIARAZIONE DI CONFORMITÀ UE ai sensi del Regolamento Europeo 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	Neuronaute® IceCap Neonate (M) V1.3.0 Neuronaute® IceCap Neonate (S) V1.3.0 Neuronaute® IceCap Neonate (XS) V1.3.0
PRODUCT REFERENCE REFERENCE PRODUIT RIFERIMENTO PRODOTTO	1001-01018-UN 1001-01019-UN 1001-01020-UN
Basic UDI-DI NUMBER NUMERO IUD-ID de base NUMERO IUD-ID di base	361522IceCapNeonateFM
INTENDED USE INDICATION D'UTILISATION INDICAZIONE DI UTILIZZO	IceCap Neonate is a medical device used as EEG electrodes. It is used by Healthcare Professionals in case of neurological disorders diagnostic with a long-term EEG record. IceCap Neonate shall be placed on the head of babies, newborns and premature babies. L'IceCap Neonate est un dispositif médical utilisé comme des électrodes EEG. Il est utilisé par un professionnel de santé pour le diagnostic de pathologies neurologiques à l'aide d'un enregistrement EEG de longue durée. L'IceCap Neonate est destiné aux bébés, nouveaux-nés et prématurés. L'IceCap Neonate è un dispositivo medico utilizzato come elettrodo EEG. Viene utilizzato da un professionista sanitario per la diagnosi di patologie neurologiche con l'ausilio di una registrazione EEG di lunga durata. IceCap Neonate è destinato a neonati, neonati e neonati prematuri
EMDN CODE CODE EMDN CODICE EMDN	N01010299 – EEG electrodes - other
CLASSIFICATION CLASSIFICAZIONE	Class I - Rule 1

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.
Certifichiamo che i suddetti prodotti sono conformi al regolamento 2017/745/CEE. Le attestazioni di conformità sono conservate presso i locali del fabbricante. La presente dichiarazione di conformità è fornita sotto l'esclusiva responsabilità di BioSerenity.

NOTIFIED BODY ORGANISME NOTIFIE CORPO NOTIFICATO	BSI 2797 - EU certificate n° MDR 802592 BSI 2797 - Certificat UE n° MDR 802592 BSI 2797 - Certificato EU n° MDR 802592
PLACE A	Paris
DATE OF ISSUE DATE DATA	August 19th, 2024 19 Aout 2024 19 agosto 2024
SIGNATURE FIRMA	
NAME / NOM / NOME POSITION / TITRE / TITOLO	Mélanie RENAUD SAMIRI Quality and Regulatory Affairs Director Directeur Qualité et Affaires Réglementaires Direttore Qualità e Affari Regolatori

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 Frankreich
SRN NUMBER SRN-NUMMER	FR-MF-000039391
PRODUCT DESIGNATION PRODUKTBEZEICHNUNG	Neuronaute® IceCap Neonate (M) V1.3.0 Neuronaute® IceCap Neonate (S) V1.3.0 Neuronaute® IceCap Neonate (XS) V1.3.0
PRODUCT REFERENCE PRODUKTREFERENZ	1001-01018-UN 1001-01019-UN 1001-01020-UN
Basic UDI-DI NUMBER Basis-IUD-ID-NUMMER	361522IceCapNeonateFM
INTENDED USE VERWENDUNGSZWECK	IceCap Neonate is a medical device used as EEG electrodes. It is used by Healthcare Professionals in case of neurological disorders diagnostic with a long-term EEG record. IceCap Neonate shall be placed on the head of babies, newborns and premature babies. Die IceCap Neonate ist ein medizinisches Gerät, das ähnlich wie EEG-Elektroden verwendet wird. Sie wird von medizinischen Fachkräften zur Diagnose von neurologischen Erkrankungen mithilfe von Langzeit-EEG-Aufzeichnungen verwendet. Der IceCap Neonate ist für Babys, Neugeborene und Frühgeborene gedacht.
EMDN CODE EMDN-CODE	N01010299 – EEG electrodes – other
CLASSIFICATION KLASSIFIKATION	Class I - Rule 1

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 19. August 2024
FIRMA	
NAME / NAME POSITION / POSITION	Mélanie RENAUD SAMIRI Quality and Regulatory Affairs Director Direktorin für Qualität und regulatorische Angelegenheiten

REFERENCE OF APPLIED REGULATORY STANDARDS
REFERENCE DES NORMES RÉGLEMENTAIRES APPLIQUÉES
RIFERIMENTO ALLE STANDARD NORMATIVI APPLICATI
REFERENZ DER ANGEWENDETEN REGULIERUNGSNORMEN

Standard number Numéro du standard Numero dello standard Nummer der Norm	Standard title Titre du standard Numero dello standard Name der Norm
ISO 10993-1:2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
NF EN ISO 10993-2:2006	Biological evaluation of medical devices — Part 2 : Animal Welfare Requirements
EN ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
EN ISO 10993-12:2021	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
EN ISO 10993-18:2020/ A1 :2022	Biological evaluation of medical devices — Part 18: Chemical characterization of materials
ISO/TS 10993-19:2020	Biological evaluation of medical devices — Part 19: Physico-chemical, morphological and topographical characterization of materials
EN ISO 10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation
EN ISO 13485:2016/A11 :2021	Medical devices — Quality management systems — Requirements for regulatory purposes
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 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
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 IEC 60601-1-2:2014
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
EN 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 IEC 80601-2-26:2020	Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs
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 APPLIQUÉS
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
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
COMMISSION DELEGATED REGULATION (EU) 2023/502	Commission Delegated Regulation (EU) 2023/502 of 1 December 2022 amending Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the frequency of complete re-assessments of notified bodies
REGULATION (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
REG (UE) 1907/2006/CE	C1 REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals **(REACH)**, establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
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) 2012/19/EU	**WEEE -** DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE)
REG (EU) 2011/65/EU	DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
REG (UE) 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
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

REFERENCE OF APPLIED COMMON SPECIFICATIONS
REFERENCE DES SPECIFICATIONS COMMUNES APPLIQUÉES
RIFERIMENTO DELLE 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