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

DECLARATION EU DE CONFORMITE selon le Règlement Européen 2017/745

MANUFACTURER FABRICANT	**BioSerenity** 20 Rue Berbier du Mets 75013 Paris France
SRN NUMBER NUMERO SRN	FR-MF-000039391
PRODUCT DESIGNATION DÉSIGNATION DU PRODUIT	Neuronaute® IceCap Neonate (M) V1.1.0 Neuronaute® IceCap Neonate (S) V1.1.0 Neuronaute® IceCap Neonate (XS) V1.1.0
PRODUCT REFERENCE REFERENCE PRODUIT	1001-01018-UN 1001-01019-UN 1001-01020-UN
Basic UDI-DI NUMBER NUMERO IUD-ID de base	361522IceCapNeonateFM
INTENDED USE INDICATION D'UTILISATION	IceCap Neonate is a medical device used as EEG electrodes. It is used by Healthcare Professionals on a patient in case of neurological disorders diagnostic with a short or long-term EEG record (up to 72 hours). IceCap Neonate shall be placed on the head of babies, newborns and premature babies. L'IceCap Neonate est un dispositif médical destiné aux patients. Il s'utilise 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 courte ou longue durée (jusqu'à 72h). L'IceCap Neonate est destiné aux bébés, nouveaux-nés et prématurés.
EMDN CODE CODE EMDN	N01010299 – EEG electrodes - other
CLASSIFICATION	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.

PLACE A	Paris
DATE OF ISSUE DATE	February 19, 2024 19 fevrier 2024
SIGNATURE	
NAME / NOM POSITION / TITRE	Mélanie RENAUD SAMIRI 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
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

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
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 (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

REFERENCE OF APPLIED COMMON SPECIFICATIONS
REFERENCE DES SPECIFICATIONS COMMUNES APPLIQUÉES

No common specification applicable.

Pas de spécifications communes appliquées.