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** ICM-iPEPS 47, Boulevard de l'Hôpital 75013 Paris France
SRN NUMBER NUMERO SRN	FR-MF-000000497
PRODUCT DESIGNATION DÉSIGNATION DU PRODUIT	**Neuronaute® Head Module V2.1.0** Accessories (appendix I) Accessoires (annexe I) **Neuronaute®Plus Core Module V1.0.0** Accessories (appendix II) Accessoires (annexe II)
PRODUCT REFERENCE REFERENCE PRODUIT	**Neuronaute® Head Module :** 1001-10004-EU Accessories (appendix I) Accessoires (annexe I) **Neuronaute®Plus Core Module :** 1001-10006-UN Accessories (appendix II) Accessoires (annexe II)
Basic UDI-DI NUMBER NUMERO IUD-ID de base	**Neuronaute® Head Module & Neuronaute®Plus Core Module :** 361522WEMUrecordsV0H7
INTENDED USE INDICATION D'UTILISATION	Neuronaute devices enable the acquisition, recording, storage, transmission, and display of electrophysiological signals in order to analyze potential neurological disorders. Les dispositifs Neuronaute permettent l'acquisition, l'enregistrement, la transmission et l'affichage de signaux électrophysiologiques afin d'analyser des pathologies neurologiques potentielles.
EMDN CODE CODE EMDN	**Neuronaute® Head Module & Neuronaute®Plus Core Module :** Z12101003 – EEG HOLTER RECORDERS Accessories (appendix I & II)
CLASSIFICATION	**Neuronaute® Head Module & Neuronaute®Plus Core Module :** IIa rule 10 IIa règle 10 Accessories (appendix I & II) Accessoires (annexe I & II)
CONFORMITY ASSESSMENT ROUTE EVALUATION DE LA CONFORMITE	**Neuronaute® Head Module & Neuronaute®Plus Core Module :** Annex IX - Conformity assessment based on a quality management system and assessment of the technical documentation **Neuronaute® Head Module & Neuronaute®Plus Core Module :** 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.

NOTIFIED BODY ORGANISME NOTIFIE	BSI 2797 - EU certificate n° MDR 729450 BSI 2797 - Certificat UE n° MDR 729450
PLACE A	Paris
DATE OF ISSUE DATE	April 18th 2023 18 Avril 2023
SIGNATURE	
NAME / NOM POSITION / TITRE	Mélanie RENAUD SAMIRI Quality and Regulatory Affairs Director Directrice Qualité et Affaires Réglementaires

CE DECLARATION OF CONFORMITY according to Directive of the Radio Equipment (2014/53/EU)
DECLARATION CE DE CONFORMITE selon la Directive sur les équipements radioélectriques (2014/53/EU)

MANUFACTURER FABRICANT	**BioSerenity** ICM-iPEPS 47, Boulevard de l'Hôpital 75013 Paris France
SRN NUMBER NUMERO SRN	FR-MF-000000497
PRODUCT DESIGNATION DÉSIGNATION DU PRODUIT	**Neuronaute® Head Module** **Neuronaute®Plus Core Module**
PRODUCT REFERENCE REFERENCE PRODUIT	**Neuronaute® Head Module :** 1001-10004-EU **Neuronaute®Plus Core Module :** 1001-10006-UN
Basic UDI-DI NUMBER NUMERO IUD-ID de base	**Neuronaute® Head Module & Neuronaute®Plus Core Module :** 361522WEMUrecordsV0H7
INTENDED USE INDICATION D'UTILISATION	Neuronaute devices enable the acquisition, recording, storage, transmission, and display of electrophysiological signals in order to analyze potential neurological disorders. Les dispositifs Neuronaute permettent l'acquisition, l'enregistrement, la transmission et l'affichage de signaux électrophysiologiques afin d'analyser des pathologies neurologiques potentielles.
EMDN CODE CODE EMDN	**Neuronaute® Head Module & Neuronaute®Plus Core Module :** Z12101003 – EEG HOLTER RECORDERS
CLASSIFICATION	**Neuronaute® Head Module & Neuronaute®Plus Core Module :** IIa rule 10 IIa règle 10

We hereby declare that the abovementioned product is in conformity with the essential requirements of the Radio Equipment Directive (2014/53/EU). 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 le produit mentionné ci-dessus est conforme aux exigences essentielles de la Directive sur les équipements radioélectriques (2014/53/EU). 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	April 18th 2023 Le 18 Avril 2023
SIGNATURE	
NAME / NOM	Mélanie RENAUD SAMIRI
POSITION / TITRE	Quality and Regulatory Affairs Director Directrice Qualité et Affaires Réglementaires

REFERENCE OF APPLIED REGULATORY STANDARDS TO NEURONAUTE® HEAD MODULE & NEURONAUTE® PLUS CORE MODULE

REFERENCE DES NORMES RÉGLEMENTAIRES APPLIQUÉES AU NEURONAUTE®HEAD MODULE & NEURONAUTE®PLUS CORE MODULE

Standard number Numéro de la norme	Standard title Titre de de la norme
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
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: General requirements for basic safety and essential performance
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
EN 60601-1:2006 + A1:2013/AC:2014	Medical electrical equipment — Part 1-4: General requirements for safety — Collateral standard: Programmable electrical medical systems
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
IEC 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
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 62209-2 :10	Human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices - Human models, instrumentation, and procedures - Part 2: Procedure to determine the specific absorption rate (SAR) for wireless communication devices used in close proximity to the human body (frequency range of 30 MHz to 6 GHz)
EN 62311 :2020 (Specific to Neuronaute Plus Core Module)	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz to 300 GHz)
EN 50566: 2017 (Specific to Neuronaute Plus Core Module)	Product standard to demonstrate the compliance of wireless communication devices with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 30 MHz to 6 GHz: hand-held and body mounted devices in close proximity to the human body
ETSI EN 300 328 V2.2.2 (Specific to Neuronaute Plus Core Module)	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum
ETSI EN 301 893 V2.1.1 (Specific to Neuronaute Plus Core Module)	5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 62366-2:2016	Guidance on the application of usability engineering to medical devices

REFERENCE OF APPLIED REGULATORY TEXTS TO NEURONAUTE® HEAD MODULE & NEURONAUTE® PLUS CORE MODULE

REFERENCE DES TEXTES RÉGLEMENTAIRES APPLIQUÉS AU NEURONAUTE®HEAD MODULE & NEURONAUTE®PLUS CORE MODULE

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
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
RED 2014/53/EU	RED: Radio-equipment Directive (2014/53/EU)
RGPD 2016/679	RGPD: General Data Protection Regulation (2016/679)
WEEE 2012/19/EU	WEEE: Waste Electrical & Electronic Equipment (2012/19/EU)
RoHS2 2011/65/EU	RoHS2: Restriction of the use of certain hazardous substances in electrical and electronic equipment (2011/65/EU)
REACH 1907/2006	REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals (1907/2006)
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

REFERENCE OF APPLIED COMMON SPECIFICATIONS
REFERENCE DES SPECIFICATIONS COMMUNES APPLIQUÉES

No common specification applicable.
Pas de spécifications communes appliquées.

Appendix I
List of accessories included in the Neuronaute® Head Module
Annexe I
Liste des accessoires inclus dans le Neuronaute® Head Module

Accessories Accessoires	Reference Reference	EMDN codes Codes EMDN	Classification Classification
Neuronaute ® Mobile Application V3.1.0	5100-00009	Z12101082 – EEG HOLTER SYTEM INSTRUMENTS – SOFTWARE ACCESSORIES	Rule 11 – Accessory of medical device Règle 11 – Accessoire de dispositif médical
Neuronaute® BioAdapter V1.9.0	1001-15015-EU	Z12101080 – EEG HOLTER SYTEM INSTRUMENTS – HARDWARE ACCESSORIES	Rule 1 - Accessory of medical device Règle 1 – Accessoire de dispositif médical
Neuronaute® High-Capacity Battery module V1.9.0	1001-15016-UN	Z12101080 – EEG HOLTER SYTEM INSTRUMENTS – HARDWARE ACCESSORIES	Rule 1 - Accessory of medical device Règle 1 – Accessoire de dispositif médical
Neuronaute® VEEG PACK V1.7.0	1001-15018- EU	Z12101080 – EEG HOLTER SYTEM INSTRUMENTS – HARDWARE ACCESSORIES	Rule 1 - Accessory of medical device Règle 1 – Accessoire de dispositif médical

Appendix II
List of accessories included in the Neuronaute® Plus Core Module
Annexe II
Liste des accessoires inclus dans le Neuronaute® Plus Core Module

Accessories Accessoires	Reference Reference	EMDN codes Codes EMDN	Classification Classification
Neuronaute ® Mobile Application V3.1.0	5100-00009	Z12101082 – EEG HOLTER SYTEM INSTRUMENTS – SOFTWARE ACCESSORIES	Rule 11 – Accessory of medical device Règle 11 – Accessoire de dispositif médical
Neuronaute Plus DB25 extender V1.0.0	1001-15021	Z12101080 – EEG HOLTER SYTEM INSTRUMENTS – HARDWARE ACCESSORIES	Rule 1 - Accessory of medical device Règle 1 – Accessoire de dispositif médical
Neuronaute Plus IceCap extender V1.0.0	1001-15022	Z12101080 – EEG HOLTER SYTEM INSTRUMENTS – HARDWARE ACCESSORIES	Rule 1 - Accessory of medical device Règle 1 – Accessoire de dispositif médical
Neuronaute Plus Holding Band	1001-05001	Z12101085- EEG HOLTER SYTEM INSTRUMENTS- CONSUMABLES	Rule 1 - Accessory of medical device Règle 1 – Accessoire de dispositif médical
Neuronaute® VEEG PACK V1.7.0	1001-15018- EU	Z12101080 – EEG HOLTER SYTEM INSTRUMENTS – HARDWARE ACCESSORIES	Rule 1 - Accessory of medical device Règle 1 – Accessoire de dispositif médical