CE DECLARATION OF CONFORMITY

according to Directive 93/42/EEC amended by Directive 2007/47/EC

DECLARATION CE DE CONFORMITE

selon la Directive 93/42/CEE amendée par la Directive 2007/47/CE

MANUFACTURER FABRICANT	BioSerenity ICM-iPEPS 47, Boulevard de l'Hôpital 75013 Paris France
DESIGNATION	**Neuronaute® Head Module V1.8.0** **Neuronaute® Mobile Application V2.6.0**
PRODUCT REFERENCE REFERENCE PRODUIT	1001-10004-EU 5100-00009
UDI NUMBER NUMERO IUD	03615220001675 03615220002849
GMDN CODE CODE GMDN	36366
CLASSIFICATION	IIa rule 10 IIa règle 10
CONFORMITY ASSESSMENT ROUTE EVALUATION DE LA CONFORMITE	Annex II - Full quality assurance system excl. Section 4 Annexe II - Système complet d'assurance qualité excl. Section 4

We hereby declare that the above-mentioned products meet the transposition into national law provisions of council Directive 93/42/EEC for medical devices as amended by Directive 2007/47/EC. All supporting documentation is retained at the premises of the manufacturer.

Nous certifions que les produits mentionnés ci-dessus sont conformes à la Directive européenne 93/42/CEE transposée en droit national relative aux dispositifs médicaux amendée par la Directive 2007/47/CE. Les preuves de conformité sont maintenues dans les locaux du fabricant.

NOTIFIED BODY ORGANISME NOTIFIE	BSI 2797 - EC certificate n° CE 672474 BSI 2797 - Certificat CE n° CE 672474
PLACE A	Paris Paris
DATE OF ISSUE DATE	January 7th, 2022 07 Janvier 2022
SIGNATURE	
NAME AND POSITION NOM ET TITRE	Mélanie RENAUD SAMIRI - Quality and Regulatory Affairs Director Mélanie RENAUD SAMIRI - Directeur 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
DESIGNATION	**Neuronaute Head Module V1.8.0**
PRODUCT REFERENCE REFERENCE PRODUIT	1001-10004-EU
UDI NUMBER NUMERO IUD	03615220001675
GMDN CODE CODE GMDN	36366

We hereby declare that the above mentioned 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.

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.

NOTIFIED BODY ORGANISME NOTIFIE	BSI 2797 - EC certificate n° CE 672474 BSI 2797 - Certificat CE n° CE 672474
PLACE A	Paris Paris
DATE OF ISSUE DATE SIGNATURE	January 7th, 2022 07 Janvier 2022
NAME AND POSITION NOM ET TITRE	Mélanie RENAUD SAMIRI - Quality and Regulatory Affairs Director Mélanie RENAUD SAMIRI - Directeur Qualité et Affaires Réglementaires

BIOSERENITY

REFERENCE OF APPLIED REGULATORY STANDARDS
REFERENCE DES NORMES RÉGLEMENTAIRES APPLIQUÉES

Standard number Numéro du standard	Standard title Titre du standard
EN ISO 13485: 2016/AC:2018	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	Medical devices — Application of risk management to medical devices
EN ISO 15223-1: 2016	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
EN 60601-1-2: 2015+AMD1:2020	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromag-netic disturbances — Requirements and tests
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
IEC 80601-2-49:2020	Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
IEC 62304:2006/AMD 1:2015	Medical device software - Software life-cycle processes
EN 62366-1 :2015+A1:2020	Medical device software - Software life-cycle processes
EN 62366-2: 2016	Guidance on the application of usability engineering to medical devices

Applied Regulation Règlement appliqué	Regulation title Titre du réglement
COUNCIL DIRECTIVE 93/42/EEC	**COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices**) 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 (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
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) 2021/610	COMMISSION IMPLEMENTING DECISION (EU) 2021/610 of 14 April 2021 **amending Implementing Decision (EU) 2020/437** as regards **harmonised standards** on medical vehicles and their equipment, anaesthetic and respiratory equipment, biological evaluation of medical devices, packaging for terminally sterilised medical devices, sterilisation of health care products, clinical investigation of medical devices for human subjects, non-active surgical implants, medical devices utilising animal tissues and their derivatives, electroacoustics and medical electrical equipment
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
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 (EU)2012/207	COMMISSION REGULATION (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices

List of accessories included in the Neuronaute®

Liste des accessoires inclus dans le Neuronaute®

Accessories **Accessoires**	**Reference** **Référence**
BioAdapter	1001-15015-EU
Neuronaute - High Capacity Battery module	1001-15016-UN
Neuronaute Battery charger	1001-15017-EU
Neuronaute N-DEO	1905-00003-UN
Neuronaute N-WAY	1906-00001-EU