

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 sui dispositivi medici
2017/745
(EN / FR / IT)

<p>MANUFACTURER FABRICANT FABBRICANTE</p>	<p>BioSerenity Medical Devices Group 20 Rue Berbier du Mets 75013 Paris France</p>
<p>SRN NUMBER NUMERO SRN NUMERO SRN</p>	<p>FR-MF-000039391</p>
<p>PRODUCT DESIGNATION DÉSIGNATION DU PRODUIT DENOMINAZIONE DEL PRODOTTO</p>	<p>Neuronaute® Head Module V2.2.0 Accessories (appendix I) Accessoires (annexe I) Accessori (appendice I) Neuronaute®Plus Core Module V1.6.0 Accessories (appendix II) Accessoires (annexe II) Accessori (appendice II)</p>
<p>PRODUCT REFERENCE REFERENCE PRODUIT RIFERIMENTO DEL PRODOTTO</p>	<p>Neuronaute® Head Module : 1001-10004-EU Accessories (appendix I) Accessoires (annexe I) Accessori (appendice I) Neuronaute®Plus Core Module : 1001-10006-EU Accessories (appendix II) Accessoires (annexe II) Accessori (appendice II)</p>
<p>Basic UDI-DI NUMBER NUMERO IUD-ID de base NUMERO UDI-DI di base</p>	<p>Neuronaute® Head Module & Neuronaute®Plus Core Module : 361522WEMUrecordsVOH7</p>
<p>INTENDED USE INDICATION D'UTILISATION DESTINAZIONE D'USO</p>	<p>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. I dispositivi Neuronaute consentono l'acquisizione, la registrazione, la memorizzazione, la trasmissione e la visualizzazione di segnali elettrofisiologici al fine di analizzare potenziali disturbi neurologici.</p>
<p>EMDN CODE CODE EMDN CODICE EMDN</p>	<p>Neuronaute® Head Module & Neuronaute®Plus Core Module : Z12101003 – EEG HOLTER RECORDERS Accessories (appendix I & II)</p>
<p>CLASSIFICATION CLASSIFICATION CLASSIFICAZIONE</p>	<p>Neuronaute® Head Module & Neuronaute®Plus Core Module : IIa rule 10 IIa règle 10 Norma IIa 10 Accessories (appendix I & II) Accessoires (annexe I & II) Accessori (appendici I e II)</p>
<p>CONFORMITY ASSESSMENT ROUTE</p>	<p>Neuronaute® Head Module & Neuronaute®Plus Core Module : Annex IX - Conformity assessment based on a quality management system and assessment of the technical documentation</p>



BIO SERENITY

COC-00070P

EVALUATION DE LA CONFORMITE

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

ITER DI VALUTAZIONE DELLA CONFORMITÀ

Neuronaute® Head Module & Neuronaute®Plus Core Module :
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

A

LUOGO

Paris

DATE OF ISSUE

DATE

DATA DI RILASCIO

October 22TH 2024

22 octobre 2024

22 Ottobre 2024

SIGNATURE / FIRMA

NAME / NOM / NOME

POSITION / TITRE / TITOLO

Mélanie RENAUD SAMIRI

Quality and Regulatory Affairs Director

Directrice 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)

<p>MANUFACTURER HERSTELLER</p>	<p>BioSerenity Medical Devices Group 20 Rue Barbier du Mets 75013 Paris France</p>
<p>SRN NUMBER SRN-NUMMER</p>	<p>FR-MF-000039391</p> <p>Neuronaute® Kopfmodul V2.2.0 Accessories (appendix I) Zubehör (Anhang I)</p>
<p>PRODUCT DESIGNATION PRODUKTBEZEICHNUNG</p>	<p>Neuronaute®Plus Core-Modul V1.6.0 Accessories (appendix II) Zubehör (Anhang II)</p>
<p>PRODUCT REFERENCE PRODUKTREFERENZ</p>	<p>Neuronaute® Kopfmodul: 1001-10004-EU Accessories (appendix I) Zubehör (Anhang I)</p> <p>Neuronaute®Plus Core-Modul: 1001-10006-EU Accessories (appendix II) Zubehör (Anhang II)</p>
<p>Basic UDI-DI NUMBER Basis-IUD-ID-NUMMER</p>	<p>Neuronaute® Head Module & Neuronaute®Plus Core Module : 361522WEMUrecordsV0H7</p>
<p>INTENDED USE VERWENDUNGSZWECK</p>	<p>Neuronaute devices enable the acquisition, recording, storage, transmission, and display of electrophysiological signals in order to analyze potential neurological disorders. Die Neuronaute-Geräte dienen der Erfassung, Aufzeichnung, Übertragung und Anzeige von elektrophysiologischen Signalen zur Analyse potenzieller neurologischer Pathologien.</p>
<p>EMDN CODE EMDN-CODE</p>	<p>Neuronaute® Head Module & Neuronaute®Plus Core Module : Z12101003 – EEG HOLTER RECORDERS Accessories (appendix I & II)</p>
<p>KLASSIFIKATION</p>	<p>Neuronaute® Head Module & Neuronaute®Plus Core Module :</p> <p>Ila rule 10 Ila Regel 10 Accessories (appendix I & II) Zubehör (Anhang I und II)</p>
<p>CONFORMITY ASSESSMENT ROUTE KONFORMITÄTSBEWERTUNG</p>	<p>Neuronaute® Head Module & Neuronaute®Plus Core Module : Annex IX - Conformity assessment based on a quality management system and assessment of the technical documentation Neuronaute® Kopfmodul und Neuronaute®Plus Core-Modul: Anhang IX – Konformitätsbewertung auf der Grundlage eines Qualitätsmanagementsystems und einer Bewertung der technischen Dokumentation</p>

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
BENANNT STELLE

BSI 2797 - EU certificate n° MDR 802592
BSI 2797 - EU-Zertifikat Nr. MDR 802592

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Paris

DATE OF ISSUE
AUSSTELLUNGSDATUM

October 22TH 2024
22. Oktober 2024

SIGNATURE / UNTERSCHRIFT



NAME / NAME
POSITION / POSITION

Mélanie RENAUD SAMIRI
Quality and Regulatory Affairs Director
Direktorin für Qualität und regulatorische Angelegenheiten

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)
DICHIARAZIONE DI CONFORMITÀ CE ai sensi della Direttiva sulle apparecchiature radio
(2014/53/UE)
(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® Head Module
Neuronaute®Plus Core Module

PRODUCT REFERENCE
REFERENCE PRODUIT
RIFERIMENTO DEL PRODOTTO

Neuronaute® Head Module : 1001-10004-EU
Neuronaute®Plus Core Module : 1001-10006-EU

Basic UDI-DI NUMBER
NUMERO IUD-ID de base
NUMERO UDI-DI di base

Neuronaute® Head Module & Neuronaute®Plus Core Module :
361522WEMUrecordsV0H7

INTENDED USE
INDICATION D'UTILISATION
DESTINAZIONE D'USO

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.
I dispositivi Neuronaute consentono l'acquisizione, la registrazione, la memorizzazione, la trasmissione e la visualizzazione di segnali elettrofisiologici al fine di analizzare potenziali disturbi neurologici.

EMDN CODE
CODE EMDN
CODICE EMDN

Neuronaute® Head Module & Neuronaute®Plus Core Module :
Z12101003 – EEG HOLTER RECORDERS

CLASSIFICATION
CLASSIFICATION
CLASSIFICAZIONE

Neuronaute® Head Module & Neuronaute®Plus Core Module :
Ila rule 10

Ila règle 10

Norma Ila 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.

Dichiariamo con la presente che il suddetto prodotto è conforme ai requisiti fondamentali della Direttiva sulle apparecchiature radio (2014/53/UE). 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.

PLACE

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Mélanie RENAUD SAMIRI

Quality and Regulatory Affairs Director

Directrice Qualité et Affaires Réglementaires

Direttrice qualità e affari regolamentari

CE DECLARATION OF CONFORMITY according to Directive of the Radio Equipment (2014/53/EU)
CE-KONFORMITÄTSERKLÄRUNG gemäß der Funkanlagenrichtlinie (2014/53/EU)
(EN / DE)

<p>MANUFACTURER HERSTELLER</p>	<p>BioSerenity Medical Devices Group 20,Rue Berbier du Mets 75013 Paris FRANCE</p>
<p>SRN NUMBER SRN-NUMMER</p>	<p>FR-MF-000039391</p>
<p>PRODUCT DESIGNATION PRODUKTBEZEICHNUNG</p>	<p>Neuronaute® Head Module Neuronaute®Plus Core Module</p>
<p>PRODUCT REFERENCE PRODUKTREFERENZ</p>	<p>Neuronaute® Head Module : 1001-10004-EU Neuronaute®Plus Core Module : 1001-10006-EU</p>
<p>Basic UDI-DI NUMBER Basis-IUD-ID-NUMMER</p>	<p>Neuronaute® Head Module & Neuronaute®Plus Core Module : 361522WEMUrecordsVOH7</p>
<p>INTENDED USE VERWENDUNGSZWECK</p>	<p>Neuronaute devices enable the acquisition, recording, storage, transmission, and display of electrophysiological signals in order to analyze potential neurological disorders. Die Neuronaute-Geräte dienen der Erfassung, Aufzeichnung, Übertragung und Anzeige von elektrophysiologischen Signalen zur Analyse potenzieller neurologischer Pathologien.</p>
<p>EMDN CODE EMDN-CODE</p>	<p>Neuronaute® Head Module & Neuronaute®Plus Core Module : Z12101003 – EEG HOLTER RECORDERS</p>
<p>CLASSIFICATION KLASSIFIKATION</p>	<p>Neuronaute® Head Module & Neuronaute®Plus Core Module : Ila rule 10 Ila Regel 10</p>

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.

Hiermit bestätigen wir, dass das oben genannte Produkt den grundlegenden Anforderungen der Richtlinie über Funkanlagen (2014/53/EU) entspricht. Der Nachweis der Konformität wird in den Räumlichkeiten des Herstellers aufbewahrt. Diese Konformitätserklärung wird unter der alleinigen Verantwortung von BioSerenity ausgestellt.

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NAME / NAME

Mélanie RENAUD SAMIRI

POSITION / POSITION

Quality and Regulatory Affairs Director

Direktorin für Qualität und regulatorische Angelegenheiten

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

RIFERIMENTO A NORME DI REGOLAMENTAZIONE APPLICATE A NEURONAUTE® HEAD MODULE & NEURONAUTE® PLUS CORE MODULE

REFERENZEN DER ANGEWENDETEN REGULIERUNGSNORMEN NEURONAUTE® HEAD MODULE & NEURONAUTE® PLUS CORE MODULE

Standard number Numéro de la norme Codice della norma Nummer der Norm	Standard title Titre de de la norme 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
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
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 62209-2:2010+A1:2019	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

RIFERIMENTO A TESTI NORMATIVI APPLICATI A NEURONAUTE® HEAD MODULE & NEURONAUTE® PLUS CORE MODULE

REFERENZ DER ANGEWENDETEN TEXTE DER REGULIERUNGEN NEURONAUTE® HEAD MODULE & NEURONAUTE® PLUS CORE MODULE

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	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
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
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)



Applied Regulation Règlement appliqué Regolamentazione applicata Angewendete Regulierung	Regulation title Titre du règlement Titolo del regolamento Titel der Regulierung
REACH 1907/2006	REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals (1907/2006)



BIOSERENITY

COC-00070P

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.

APPENDIX I
LIST OF ACCESSORIES INCLUDED IN THE NEURONAUTE® HEAD MODULE
ANNEXE I
LISTE DES ACCESSOIRES INCLUS DANS LE NEURONAUTE® HEAD MODULE
APPENDICE I
ELENCO DEGLI ACCESSORI IN DOTAZIONE CON NEURONAUTE® HEAD MODULE
ANHANG I
LISTE DES INBEGRIFFENEN ZUBEHÖRS DES NEURONAUTE® HEAD MODULE

Accessories Accessoires Accessori Zubehör	Reference Reference Riferimento Referenz	EMDN codes Codes EMDN Codici EMDN EMDN-Codes	Classification Classification Classificazione Klassifikation
Neuronaute® Mobile Application iOS V3.5.0	5100-00009	Z12101082 – EEG HOLTER SYTEM INSTRUMENTS – SOFTWARE ACCESSORIES	Class IIa Rule 11 – Accessory of medical device Classe IIa Règle 11 – Accessoire de dispositif médical Classe IIa Norma 11 – Accessorio di dispositivo medico Klasse IIa Regel 11 – Zubehör für medizinische Geräte
Neuronaute® BioAdapter V1.10.0	1001-15015-EU	Z12101080 – EEG HOLTER SYTEM INSTRUMENTS – HARDWARE ACCESSORIES	Class I Rule 1 - Accessory of medical device Classe I Règle 1 – Accessoire de dispositif médical Classe I Norma 1 - Accessorio di dispositivo medico Klasse I Regel 1 – Zubehör für medizinische Geräte
Neuronaute® High-Capacity Battery module V1.10.0	1001-15016-UN	Z12101080 – EEG HOLTER SYTEM INSTRUMENTS – HARDWARE ACCESSORIES	Class I Rule 1 - Accessory of medical device Classe I Règle 1 – Accessoire de dispositif médical Classe I Norma 1 - Accessorio di dispositivo medico Klasse I Regel 1 – Zubehör für medizinische Geräte
Neuronaute® IceBox PCB V1.2.0	1001-15019-EU	Z12101080 – EEG HOLTER SYTEM INSTRUMENTS – HARDWARE ACCESSORIES	Class I Rule 1 - Accessory of medical device Classe I Règle 1 – Accessoire de dispositif médical Classe I Norma 1 - Accessorio di dispositivo medico Klasse I Regel 1 – Zubehör für medizinische Geräte
Neuronaute® VEEG PACK V1.8.0	1001-15018- EU	Z12101080 – EEG HOLTER SYTEM INSTRUMENTS – HARDWARE ACCESSORIES	Class I Rule 1 - Accessory of medical device Classe I Règle 1 – Accessoire de dispositif médical Classe I Norma 1 - Accessorio di dispositivo medico Klasse I Regel 1 – Zubehör für medizinische Geräte

APPENDIX II
LIST OF ACCESSORIES INCLUDED IN THE NEURONAUTE® PLUS CORE MODULE
ANNEXE II
LISTE DES ACCESSOIRES INCLUS DANS LE NEURONAUTE® PLUS CORE MODULE
APPENDICE II
ELENCO DEGLI ACCESSORI IN DOTAZIONE CON NEURONAUTE® PLUS CORE MODULE
ANHANG II
LISTE DES INBEGRIFFENEN ZUBEHÖRS DES NEURONAUTE® PLUS CORE MODULE

Accessories Accessoires Accessori Zubehör	Reference Reference Riferimento Referenz	EMDN codes Codes EMDN Codici EMDN EMDN-Codes	Classification Classification Classificazione Klassifikation
Neuronaute® Mobile Application iOS V3.5.0	5100-00009	Z12101082 – EEG HOLTER SYTEM INSTRUMENTS – SOFTWARE ACCESSORIES	Class IIa Rule 11 – Accessory of medical device Classe IIa Règle 11 – Accessoire de dispositif médical Classe IIa Norma 11 – Accessorio di dispositivo medico Klasse IIa Regel 11 – Zubehör für medizinische Geräte
Neuronaute® Mobile App Android V1.4.1	5100-00024	Z12101082 – EEG HOLTER SYTEM INSTRUMENTS – SOFTWARE ACCESSORIES	Class IIa Rule 11 – Accessory of medical device Classe IIa Règle 11 – Accessoire de dispositif médical Classe IIa Norma 11 – Accessorio di dispositivo medico Klasse IIa Regel 11 – Zubehör für medizinische Geräte
Neuronaute® Plus DB25 extender V1.3.0	1001-15021	Z12101080 – EEG HOLTER SYTEM INSTRUMENTS – HARDWARE ACCESSORIES	Class I Rule 1 - Accessory of medical device Classe I Règle 1 – Accessoire de dispositif médical Classe I Norma 1 - Accessorio di dispositivo medico Klasse I Regel 1 – Zubehör für medizinische Geräte
Neuronaute® Plus IceCap extender V1.2.0	1001-15022	Z12101080 – EEG HOLTER SYTEM INSTRUMENTS – HARDWARE ACCESSORIES	Class I Rule 1 - Accessory of medical device Classe I Règle 1 – Accessoire de dispositif médical Classe I Norma 1 - Accessorio di dispositivo medico Klasse I Regel 1 – Zubehör für medizinische Geräte
Neuronaute® Plus Touchproof extender V1.0.0	1001-15023	Z12101080 – EEG HOLTER SYTEM INSTRUMENTS – HARDWARE ACCESSORIES	Class I Rule 1 - Accessory of medical device Classe I Règle 1 – Accessoire de dispositif médical Classe I Norma 1 - Accessorio di dispositivo medico Klasse I Regel 1 – Zubehör für medizinische Geräte
Neuronaute® Plus Holding Band V1.3.0	1001-05001	Z12101085- EEG HOLTER SYTEM INSTRUMENTS- CONSUMABLES	Class I Rule 1 - Accessory of medical device Classe I Règle 1 – Accessoire de dispositif médical Classe I Norma 1 - Accessorio di dispositivo medico Klasse I Regel 1 – Zubehör für medizinische Geräte
Neuronaute® VEEG PACK V1.8.0	1001-15018- EU	Z12101080 – EEG HOLTER SYTEM INSTRUMENTS – HARDWARE ACCESSORIES	Class I Rule 1 - Accessory of medical device



BIOSERENITY

COC-00070P

Accessories Accessoires Accessori Zubehör	Reference Reference Riferimento Referenz	EMDN codes Codes EMDN Codici EMDN EMDN-Codes	Classification Classification Classificazione Klassifikation
			Classe I Règle 1 – Accessoire de dispositif médical Classe I Norma 1 - Accessorio di dispositivo medico Klasse I Regel 1 – Zubehör für medizinische Geräte

DOCUMENT HISTORY TABLE

Rev.	Reason for the change	Author	Change Date
A	Creation according to EU Regulation 2017/745) for MDR submission of WEMU V1.6.0	IMC	SEP 2021
B	Update according to round 2 questions BSI	IMC	MAY 2022
C	Update according to round 3 questions BSI	IMC	SEP 2022
D	Update according to Merge version system MDR V1.6.0 and V1.11.2 MDD → WEMU V2.0.0	KHA	DEC 26 th 2022
E	Update according to ECR-000468: [WEMU] - Head module - Cpt obsolescence -D2 SMLP34RGB1W3	KHA	JAN 30 th 2023
F	<ul style="list-style-type: none"> - Update according ECR-000485 and CC-000096 - Addition of accessories versions in appendix I 	KHA	FEB 28 th 2023
G	Update according to M17 Marathon and inclusion of Neuronaute Plus in WEMU system : <ul style="list-style-type: none"> - ECR-00481 - ECR-00482 - Project -00117 	KHA	April14 th 2023
H	Update according to ANSM feedback: Addition Of Accessories classification	KHA	June 1 st 2023
I	Update according to: ECR-000495: Holding band improvements ECR-000502: Packaging extender Neuronaute Plus ECR-000507 & CC-000110 : Mobile iOS 3.2.0 release according to double Spinner CC.	KHA	June 21 st 2023
J	Update according to ECR-000512: <ul style="list-style-type: none"> - Upgrade of NN+ FW for continuous improvement 	KHA	July 25 th 2023
K	Update according to : <ul style="list-style-type: none"> - ECR-000497 [WEMU] [Mobile App] Neuronaute compatibility with Android 	JPA	September 28, 2023
L	Update according to : <ul style="list-style-type: none"> - ECR-000542 [WEMU] [NN+] Holding band improvement - ECR-000539 [WEMU] [NN+] Replacement of the battery charger - ECR-000541 Labelling change implementation after legal manufacturer change - full name 	AGO	13 MAR 2024
M	Update according to : <ul style="list-style-type: none"> - ECR-000496 - [WEMU] [NN+] Creation of an Extender Touchproof - ECR-000521 - [WEMU] [HBOX] FW improvement for M19 - ECR-000522 - [WEMU] [NN+] FW improvement for M20 - ECR-000524 - [WEMU] [VEEG] Update of the label to remove expiration date 	AGO	17 MAY 2024

Rev.	Reason for the change	Author	Change Date
	<ul style="list-style-type: none"> - ECR-000532 - [WEMU] [M20] Update of Neuronaute label for battery, battery charger and bioadapter - ECR-000540 - [WEMU] [NN+] Upgrade of NN+ motherboard - removal of a capacitor - ECR-000544 - IceCap & CareCap US&EU market withdrawal (<i>implement IceBox PCB in this technical file</i>) - ECR-000547 - [WEMU] [App Android] New version for M20 release integrating offline mode 		
N	Update according to ECR-000556 – hotfix mobile app Android	AGO	14 JUNE 2024
O	Update according to the M20.5 – Swiss export : <ul style="list-style-type: none"> - ECR-000558 – [SWISS EXPANSION] [WEMU] [Android Mobile App] Android Mobile App compatible with Swiss Market - ECR-000559 - [SWISS EXPANSION] [WEMU] [NN+] NN+ compatible with Swiss Market - ECR-000562 - [WEMU][iOS Mobile App] Neuronaute Mobile Application on iOS compatible with iOS 17 	AGO	16 AUG 2024
P	Update according to the M21 marathon : <ul style="list-style-type: none"> - ECR-000573 – [WEMU] [iOS] [M21] Compatibility of Neuronaute Mobile App iOS with BLINK multisession offline - ECR-000570 - [WEMU] [APP AND] [M21] Android Neuronaute Mobile Application update for M21 Marathon - ECR-000569 - [WEMU] [NN+] [M21] FW Update for M21 Marathon - ECO-007927 - Roll back Reg SUB WEMU M21 - ECR-000576 - [WEMU][M21][hotfix] mConf Android 1.4.1 	RMA	17 OCT 2024