



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 6/8, rue Jean Antoine de Baïf 75013 Paris France</p>
<p>SRN NUMBER NUMERO SRN NUMERO SRN</p>	<p>FR-MF-000039391</p> <p>Neuronaute®Plus Core Module V2.2.0 Accessories (appendix I) Accessoires (annexe I) Accessori (appendice I)</p>
<p>PRODUCT DESIGNATION DÉSIGNATION DU PRODUIT DENOMINAZIONE DEL PRODOTTO</p>	<p>Neuronaute®Plus Core Module : 1001-10006-EU Accessories (appendix I) Accessoires (annexe I) Accessori (appendice I)</p>
<p>PRODUCT REFERENCE REFERENCE PRODUIT RIFERIMENTO DEL PRODOTTO</p>	<p>Neuronaute®Plus Core Module : 361522WEMUrecordsV0H7 Accessories (appendix I) Accessoires (annexe I) Accessori (appendice I)</p>
<p>Basic UDI-DI NUMBER NUMERO IUD-ID de base NUMERO UDI-DI di base</p>	<p>Neuronaute®Plus Core Module : 361522WEMUrecordsV0H7</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>INTENDED USE INDICATION D'UTILISATION DESTINAZIONE D'USO</p>	<p>Neuronaute®Plus Core Module : Z12101003 – EEG HOLTER RECORDERS Accessories (appendix I)</p> <p>Neuronaute®Plus Core Module :</p> <p>IIa rule 10 IIa règle 10 Norma IIa 10 Accessories (appendix I) Accessoires (annexe I) Accessori (appendici I)</p>
<p>EMDN CODE CODE EMDN CODICE EMDN</p>	<p>Neuronaute®Plus Core Module :</p> <p>IIa rule 10 IIa règle 10 Norma IIa 10 Accessories (appendix I) Accessoires (annexe I) Accessori (appendici I)</p>
<p>CLASSIFICATION CLASSIFICATION CLASSIFICAZIONE</p>	<p>Neuronaute®Plus Core Module : Annex IX - Conformity assessment based on a quality management system and assessment of the technical documentation 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</p>
<p>CONFORMITY ASSESSMENT ROUTE</p>	<p>Neuronaute®Plus Core Module : Annex IX - Conformity assessment based on a quality management system and assessment of the technical documentation 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</p>
<p>EVALUATION DE LA CONFORMITE</p>	<p>Neuronaute®Plus Core Module : Annex IX - Conformity assessment based on a quality management system and assessment of the technical documentation 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</p>
<p>ITER DI VALUTAZIONE DELLA CONFORMITÀ</p>	<p>Neuronaute®Plus Core Module : Annex IX - Conformity assessment based on a quality management system and assessment of the technical documentation 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</p>
<p>ITER DI VALUTAZIONE DELLA CONFORMITÀ</p>	<p>Neuronaute®Plus Core Module : Annex IX - Conformity assessment based on a quality management system and assessment of the technical documentation 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</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.

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

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LUOGO

Paris

DATE OF ISSUE

DATE

DATA DI RILASCIO

May 19th , 2026

19 mai 2026

19 maggio 2026

SIGNATURE / FIRMA

Signé par :

0CD9CCF3F5B043B...

NAME / NOM / NOME

POSITION / TITRE / TITOLO

Pierre Emerich

Chief Technology Officer (CTO)

Directeur technique

Direttore tecnico



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 6/8, rue Jean Antoine de Baïf 75013 Paris France
SRN NUMBER SRN-NUMMER	FR-MF-000039391
PRODUCT DESIGNATION PRODUKTBEZEICHNUNG	Neuronaute®Plus Core-Module V2.2.0 Accessories (appendix II) Zubehör (Anhang II)
PRODUCT REFERENCE PRODUKTREFERENZ	Neuronaute®Plus Core-Module: 1001-10006-EU Accessories (appendix I) Zubehör (Anhang I)
Basic UDI-DI NUMBER Basis-IUD-ID-NUMMER	Neuronaute®Plus Core Module : 361522WEMUrecordsV0H7
INTENDED USE VERWENDUNGSZWECK	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.
EMDN CODE EMDN-CODE	Neuronaute®Plus Core Module : Z12101003 – EEG HOLTER RECORDERS Accessories (appendix I)
KLASSIFIKATION	Neuronaute®Plus Core Module : Ila rule 10 Ila Regel 10 Accessories (appendix I) Zubehör (Anhang I)
CONFORMITY ASSESSMENT ROUTE	Neuronaute®Plus Core Module : Annex IX - Conformity assessment based on a quality management system and assessment of the technical documentation
KONFORMITÄTBEWERTUNG	Neuronaute®Plus Core-Modul: Anhang IX – Konformitätsbewertung auf der Grundlage eines Qualitätsmanagementsystems und einer Bewertung der technischen Dokumentation



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

PLACE
ORT

Paris

DATE OF ISSUE
AUSSTELLUNGSDATUM

May 19th, 2026
19 Mai 2026

SIGNATURE / UNTERSCHRIFT

Signé par :

0CD9CCF3F5B043B...

NAME / NAME
POSITION / POSITION

Pierre Emerich
Chief Technology Officer (CTO)
Technischer Direktor (TD)



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)

<p>MANUFACTURER FABRICANT FABBRICANTE</p>	<p>BioSerenity Medical Devices Group 6/8, rue Jean Antoine de Baïf 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®Plus Core Module V2.1.1</p>
<p>PRODUCT REFERENCE REFERENCE PRODUIT RIFERIMENTO DEL PRODOTTO</p>	<p>Neuronaute®Plus Core Module : 1001-10006-EU</p>
<p>Basic UDI-DI NUMBER NUMERO IUD-ID de base NUMERO UDI-DI di base</p>	<p>Neuronaute®Plus Core Module : 361522WEMUrecordsV0H7</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®Plus Core Module : Z12101003 – EEG HOLTER RECORDERS</p>
<p>CLASSIFICATION CLASSIFICATION CLASSIFICAZIONE</p>	<p>Neuronaute®Plus Core Module : Ila rule 10 Ila règle 10 Norma Ila 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.

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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Signé par :

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NAME / NOM / NOME

POSITION / TITRE / TITOLO

Pierre Emerich

Chief Technology Officer (CTO)

Directeur technique

Direttore tecnico



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

MANUFACTURER HERSTELLER	BioSerenity Medical Devices Group 6/8, rue Jean Antoine de Baïf 75013 Paris FRANCE
SRN NUMBER SRN-NUMMER	FR-MF-000039391
PRODUCT DESIGNATION PRODUKTBEZEICHNUNG	Neuronaute®Plus Core Module V2.2.0
PRODUCT REFERENCE PRODUKTREFERENZ	Neuronaute®Plus Core Module : 1001-10006-EU
Basic UDI-DI NUMBER Basis-IUD-ID-NUMMER	Neuronaute®Plus Core Module : 361522WEMUrecordsV0H7
INTENDED USE VERWENDUNGSZWECK	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.
EMDN CODE EMDN-CODE	Neuronaute®Plus Core Module : Z12101003 – EEG HOLTER RECORDERS
CLASSIFICATION KLASSIFIKATION	Neuronaute®Plus Core Module : IIa rule 10 IIa Regel 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.

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.

PLACE

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AUSSTELLUNGSDATUM

19 Mai 2026

SIGNATURE / UNTERSCHRIFT

Signé par :

0CD9CCF3F5B043B...

NAME / NAME

Pierre Emerich

POSITION / POSITION

Chief Technology Officer (CTO)

Technischer Direktor

REFERENCE OF APPLIED REGULATORY STANDARDS TO NEURONAUTE® PLUS CORE MODULE
REFERENCE DES NORMES RÉGLEMENTAIRES APPLIQUÉES AU NEURONAUTE®PLUS CORE MODULE
RIFERIMENTO A NORME DI REGOLAMENTAZIONE APPLICATE A NEURONAUTE®PLUS CORE MODULE
REFERENZEN DER ANGEWENDETEN REGULIERUNGSNORMEN 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/Amd 1:2024	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
EN 82304-1:2016	Health softwarePart 1: General requirements for product safety
IEC 62354:2014	General testing procedures for medical electrical equipment
EN IEC 62353 : 2014	Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment

REFERENCE OF APPLIED REGULATORY TEXTS TO NEURONAUTE® PLUS CORE MODULE
REFERENCE DES TEXTES RÉGLEMENTAIRES APPLIQUÉS AU NEURONAUTE® PLUS CORE MODULE
RIFERIMENTO A TESTI NORMATIVI APPLICATI A NEURONAUTE® PLUS CORE MODULE
REFERENZ DER ANGEWENDETEN TEXTE DER REGULIERUNGEN 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
Regulation (EU) 2024/568	Regulation (EU) 2024/568 of the European Parliament and of the Council of 7 February 2024 on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95
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
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
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
REG (EU) 2025/1234	Commission Implementing Regulation (EU) 2025/1234 of 25 June 2025 amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for which the instructions for use may be provided in electronic form
RED 2014/53/EU	RED : Radio-equipment Directive (2014/53/EU)



Applied Regulation Règlement appliqué Regolamentazione applicata Angewendete Regulierung	Regulation title Titre du règlement Titolo del regolamento Titel der Regulierung
RGPD 2016/679	RGPD: General Data Protection Regulation (2016/679)
WEEE 2012/19/EU	WEEE: Waste Electrical & Electronic Equipment (2012/19/EU)
Regulation (EU) 2023/1542	WEEE - Regulation of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (Text with EEA relevance)
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)



BIO SERENITY

COC-00070Z

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 PLUS CORE MODULE
ANNEXE I
LISTE DES ACCESSOIRES INCLUS DANS LE NEURONAUTE® PLUS CORE MODULE
APPENDICE I
ELENCO DEGLI ACCESSORI IN DOTAZIONE CON NEURONAUTE® PLUS CORE MODULE
ANHANG I
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 App Android V2.0.0	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 V1.4.0	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 V1.3.0	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 V1.1.0	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 V1.5.0	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® Plus Low Noise extender V1.0.0	1001-15026	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



BIO SERENITY

COC-00070Z

Accessories Accessoires Accessori Zubehör	Reference Reference Riferimento Referenz	EMDN codes Codes EMDN Codici EMDN EMDN-Codes	Classification Classification Classificazione Klassifikation
Neuronaute® Plus Holding Band Mini V1.0.0	1001-05002	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