



COC-00083N

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 2017/745****(EN / FR / IT)**

MANUFACTURER FABRICANT FABBRICANTE	BioSerenity Medical Devices Group 6/8, rue Jean Antoine de Baïf 75013 Paris France
SRN NUMBER NUMERO SRN NUMERO SRN	FR-MF-000039391
PRODUCT DESIGNATION DÉSIGNATION DU PRODUIT DENOMINAZIONE DEL PRODOTTO	Neuronaute® IceCap 2 V1.11.0 Neuronaute® IceCap 2 V1.0.0 Neuronaute® IceCap 2 Small V1.11.0 Neuronaute® IceCap 2 Small V1.0.0 Neuronaute® IceCap Neonate (M) V1.5.0 Neuronaute® IceCap Neonate (S) V1.5.0 Neuronaute® IceCap Neonate (XS) V1.5.0 Accessories (appendix I) Accessoires (annexe I) Accessori (allegato I)
PRODUCT REFERENCE REFERENCE PRODUIT RIFERIMENTO PRODOTTO	1001-01014-UN 1001-01025-UN 1001-01015-UN 1001-01026-UN 1001-01018-UN 1001-01019-UN 1001-01020-UN Accessories (appendix I) Accessoires (annexe I) Accessori (allegato I)
Basic UDI-DI NUMBER NUMERO IUD-ID de base NUMERO IUD-ID di base	361522WEMUelectrodsFY

INTENDED USE
INDICATION D'UTILISATION
INDICAZIONE DI UTILIZZO

The IceCaps are medical devices used as EEG electrodes. They are used by Healthcare Professionals on a patient in case of neurological disorders with a short-term or long-term EEG record (up to 72 hours). IceCap 2 shall be placed on patients weighing at least 10 kg (22.05 lbs) and having a head circumference above 43 cm (16.93 inches). IceCap Neonate shall be placed on the head of babies, newborns and premature babies

Les IceCaps sont des dispositifs médicaux qui s'utilisent comme des électrodes EEG. Ils sont employés par des professionnels de santé sur un patient en cas de troubles neurologiques, pour un enregistrement EEG de courte ou longue durée (jusqu'à 72 heures). L'IceCap 2 est destiné aux patients pesants au moins 10 kg (22.05 lbs) et dont le tour de tête est supérieur à 43cm (16.93 inches). L'IceCap Neonate est destiné aux bébés, nouveaux-nés et prématurés

Gli IceCaps sono dispositivi medici utilizzati come elettrodi EEG. Sono utilizzati dagli operatori sanitari su un paziente in caso di disturbi neurologici con una registrazione EEG a breve o lungo termine (fino a 72 ore). Il dispositivo IceCap 2 è destinato ai pazienti di peso maggiore o uguale a 10 kg (22.05 LBS) e con una circonferenza cranica superiore a 43 cm (16.93 pollici). Il dispositivo IceCap Neonate è destinato a bambini piccoli, neonati e prematuri



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EMDN CODE

CODE EMDN

CODICE EMDN

N01010299 – EEG electrodes - other

CLASSIFICATION

CLASSIFICAZIONE

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.

Certifichiamo che i suddetti prodotti sono conformi al regolamento 2017/745/CEE. Le attestazioni di conformità sono conservate presso i locali del fabbricante. La presente dichiarazione di conformità è fornita sotto l'esclusiva responsabilità di BioSerenity.

NOTIFIED BODY

ORGANISME NOTIFIE

CORPO NOTIFICATO

BSI 2797 - EU certificate n° MDR 802592

BSI 2797 - Certificat UE n° MDR 802592

BSI 2797 - Certificato EU n° MDR 802592

PLACE

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Paris

DATE OF ISSUE

DATE

DATA

February 13th, 2026

13 Février 2026

13 Febbraio 2026

SIGNATURE

FIRMA

Signé par :

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NAME / NOM / NOME

POSITION / TITRE / TITOLO

Pierre EMERICH

Chief Technical and Product Officer (CTPO)

Directeur Technique et Responsable Produit (DTRP)

Direttore Tecnico e Responsabile dei Prodotti (DTRP)



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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
 Frankreich

SRN NUMBER
SRN-NUMMER

FR-MF-000039391

PRODUCT DESIGNATION
PRODUKTBEZEICHNUNG

Neuronaute® IceCap 2 V1.11.0
 Neuronaute® IceCap 2 V1.0.0
 Neuronaute® IceCap 2 Small V1.11.0
 Neuronaute® IceCap 2 Small V1.0.0
 Neuronaute® IceCap Neonate (M) V1.5.0
 Neuronaute® IceCap Neonate (S) V1.5.0
 Neuronaute® IceCap Neonate (XS) V1.5.0
 Accessories (appendix I)
 Zubehör (Anhang I)

PRODUCT REFERENCE
PRODUKTRREFERENZ

1001-01014-UN
 1001-01025-UN
 1001-01015-UN
 1001-01026-UN
 1001-01018-UN
 1001-01019-UN
 1001-01020-UN
 Accessories (appendix I)
 Zubehör (Anhang I)

Basic UDI-DI NUMBER
Basis-IUD-ID-NUMMER

361522WEMUelectrodsFY

INTENDED USE
VERWENDUNGSZWECK

The IceCaps are medical devices used as EEG electrodes. They are used by Healthcare Professionals on a patient in case of neurological disorders with a short-term or long-term EEG record (up to 72 hours). IceCap 2 shall be placed on patients weighing at least 10 kg (22.05 lbs) and having a head circumference above 43 cm (16.93 inches). IceCap Neonate shall be placed on the head of babies, newborns and premature babies
 Die IceCaps sind medizinische Geräte, die als EEG-Elektroden verwendet werden. Sie werden von medizinischem Fachpersonal bei Patienten mit neurologischen Störungen mit Kurzzeit- oder Langzeit-EEG-Aufzeichnung (bis zu 72 Stunden) verwendet. Die IceCap 2 ist für Patienten mit einem Gewicht von mindestens 10 kg (22.05 lbs) und einem Kopfumfang von mehr als 43 cm (16.93 inches) bestimmt. Die IceCap Neonate ist für Babys, Neugeborene und Frühgeborene bestimmt

EMDN CODE
EMDN-CODE

N01010299 – EEG electrodes – other

CLASSIFICATION
KLASSIFIKATION

Class I - Rule 1



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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

February 13th, 2026
13 Februar 2026

SIGNATURE / UNTERSCHRIFT

Signé par :

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NAME / NAME
POSITION / POSITION

Pierre EMERICH
Chief Technical and Product Officer (CTPO)
Technischer Leiter und Produktmanager (TLP)



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REFERENCE OF APPLIED REGULATORY STANDARDS
REFERENCE DES NORMES RÉGLEMENTAIRES APPLIQUÉES
RIFERIMENTO ALLE STANDARD NORMATIVI APPLICATI
REFERENZ DER ANGEWENDETEN REGULIERUNGSNORMEN

Standard number Numéro du standard Numero dello standard Nummer der Norm	Standard title Titre du standard Numero dello standard Name der Norm
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



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REFERENCE OF APPLIED REGULATORY TEXTS
REFERENCE DES TEXTES RÉGLEMENTAIRES APPLIQUÉS
RIFERIMENTO A TESTI NORMATIVI APPLICATI
REFERENZ DER ANGEWENDETEN TEXTE DER REGULIERUNGEN

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
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 (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
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
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



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Applied Regulation Règlement appliqué Regolamentazione applicata Angewendete Regulierung	Regulation title Titre du règlement Titolo del regolamento Titel der Regulierung
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
Regulation (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

REFERENCE OF APPLIED COMMON SPECIFICATIONS
REFERENCE DES SPECIFICATIONS COMMUNES APPLIQUÉES
RIFERIMENTO DELLE 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



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Appendix I**List of accessories included in the IceCap product line****Annexe I****Liste des accessoires inclus dans IceCap product line****Allegato I****Lista di accessori inclusi in IceCap product line****Anhang I****Liste des inbegriffenen Zubehörs der IceCap product line**

Accessories Accessoires Accessori Zubehör	Reference Reference Riferimento Referenz	EMDN codes Codes EMDN Codici EMDN EMDN-Codes	Classification Classification Classificazione Klassifikation
Neuronaute® Touchproof Adapter V1.7.0	1001-15024-UN	N01010299 – EEG electrodes – other	Class I Rule 1 - Accessory of medical device Classe I Règle 1 – Accessoire de dispositif médical Classe I, Regola 1 - Accessorio di dispositivo medico Klasse I Regel 1 – Zubehör für medizinische Geräte
Neuronaute® IceAdapter V1.9.0	1001-15020-UN	N01010299 – EEG electrodes – other	Class I Rule 1 - Accessory of medical device Classe I Règle 1 – Accessoire de dispositif médical Classe I, Regola 1 - Accessorio di dispositivo medico Klasse I Regel 1 – Zubehör für medizinische Geräte



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HISTORY TABLE

Rev.	Reason for the change	Author	Change Date
A	Creation: IceCap 2 & IceCap 2 Small - ECR-000398: [WEMU] - IceCap 2 (PIC) development and inclusion in the WEMU Scope - ECR-000432: [WEMU] – IceCap 2 SMALL - development and inclusion in the WEMU Scope	IMC	AUG 2022
B	Update according to ECR-000458: - Exclusion of IceCap 2 & IceCap 2 Small from WEMU scope to join the “IceCap_Product_Line” - Reformulation of patient condition from “5years old” to “ subject weighing at least 10 kg and having a head circumference above 43 cm”	KHA	NOV 18 th 2022
C	Update according to ECR-000462: - IceCap2 Version 1.2 - Design change of IceCap2 & Small	KHA	MAR 3 rd 2023
D	Update according to ECR-000509: Use of triman logo	KHA	August 3 rd 2023
E	Update according to ECR-000514: Manufacturing update for IceCap2/ 2 Small	KHA	SEPT 15 th 2023
F	Update according to ECR-000513: [WEMU] TPA/IA - Development of a Touchproof Adapter and Compatibility of IceAdapter with Micromed recorder	JPA	Sept 28, 2023
G	Update according to: - ECR-000518 - Registration of IceCap 2 & 2 Small with Adapters in Italy - ECR-000537 - Labelling change implementation after legal manufacturer change	AGO	09 JAN 2024
H	- Update according to ECR-000545 : IceCap 2_Update of label and integration of IceAdapter on technical file - Update template for QF-00062C	JDB	18 April 2024
I	Update according to : ECR-000560 - [SWISS EXPANSION] [WEMU] [WPL] IceCap Product Line compatible with Swiss Market	JDB	16 AUG 2024
J	Update according to : ECR-000572 [M21] Icecap 2 & 2 Small - compatibility extension to third party	JDB	07 OCT 2024
K	Update according to : ECR-000578 : [WPL] [ICECAP2] [JANUARY] Shelf life extension of IceCap2 & IceCap2 SMALL to 24 months and change of manufacturer address Update QF following ECR-000565	JDB	23 DEC 2024
L	Update according to : ECR-000593 [WPL]_IFU-00153 merge for EU,US,CA & print run switched to glued square spine	JDB	08 APR 2025
M	Update according to ECR-000604 : -Merging of technicals files and use eIFU for Icecap product line Update according to ECR-000597 :	JDB	22 SEP 2025



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	-[internalisation] Manufacturing of IceCap2 in Troyes QMS impact		
N	Update according to ECR-000608 : [ICECAP 2] In House manufacturing of IceCap 2 Small reference in Troyes	JDB	11 Feb 2026