



CE DECLARATION OF CONFORMITY according to European medical device regulation 2017/745
DECLARATION CE 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	BioSerenity Emocare® VR App
PRODUCT REFERENCE REFERENCE PRODUIT	1022-20001-EU
Basic UDI-DI NUMBER NUMERO IUD-ID de base	361522EmocareVRApp1.0YY
INTENDED USE INDICATION D'UTILISATION	Emocare is intended for use in hospitals, psychiatrist/psychologist's office or medical centers for patients suffering from post-traumatic stress disorders (PTSD) and Anxiety and Mood disorders using eye movement therapy. It can be used in face to face or in teleconsultation.
EMDN CODE CODE EMDN	V92 – Medical Device Software – Not included in other classes
CLASSIFICATION	Rule 13

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.

PLACE A	Paris
DATE OF ISSUE DATE	January 17 th , 2021 17 Janvier 2021

SIGNATURE

NAME / NOM	Mélanie RENAUD SAMIRI
POSITION / TITRE	Quality and Regulatory Affairs Director Directeur Qualité et Affaires Réglementaires



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 14971:2019	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
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 62366-2:2016	Guidance on the application of usability engineering to medical devices



Applied Regulation Règlement appliqué	Regulation title Titre du règlement
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
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)2012/207	COMMISSION REGULATION (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices

REFERENCE OF APPLIED COMMON SPECIFICATIONS
REFERENCE DES SPECIFICATIONS COMMUNES APPLIQUÉES

No common specification applicable.

Pas de spécifications communes appliquées.

List of accessories included in the Neuronaute IceCap and Neuronaute CareCap
Liste des accessoires inclus dans le Neuronaute IceCap et Neuronaute CareCap

Accessories Accessoires	Reference Référence
Inno Health Platform	1022-21001-EU