EU DECLARATION OF CONFORMITY according to European medical device regulation 2017/745

DECLARATION UE 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	**BLINK UN Mobile App Android 1.2.0**
PRODUCT REFERENCE REFERENCE PRODUIT	5100-00021-UN
Basic UDI-DI NUMBER NUMERO IUD-ID de base	361522BLINKV088
INTENDED USE INDICATION D'UTILISATION	BioSerenity-Link is a mobile app-based software intended to be configured by qualified healthcare professional to exchange video data with BioSerenity Cloud. Bioserenity-Link may also be used by patients in order to allow some interactions during the record session BioSerenity-Link est un logiciel, basé sur une application mobile, conçu pour être configuré par un professionnel de la santé qualifié pour échanger des données vidéo avec BioSerenity Cloud. Bioserenity-Link peut également être utilisé par les patients afin de permettre certaines interactions pendant la session d'enregistrement
EMDN CODE CODE EMDN	V92 – Medical Device Software – Not included in other classes
CLASSIFICATION	Class I (according to rule 11 and 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	April 14th , 2023 14 avril 2023
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/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
EN 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 réglement**
REG (EU) 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 (EU) 2017/745	C**orrigendum 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 (EU) 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 (EU) 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) 2023/502	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
DÉCISION (EU) 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) 2021/1182	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
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
RGPD 2016/679	RGPD: General Data Protection Regulation (2016/679)

REFERENCE OF APPLIED COMMON SPECIFICATIONS
REFERENCE DES SPECIFICATIONS COMMUNES APPLIQUÉES

No common specification applicable.

Pas de spécifications communes appliquées.