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

DECLARATION UE 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)

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	**BLINK UN Mobile App Android 1.6.0**
PRODUCT REFERENCE REFERENCE PRODUIT RIFERIMENTO DEL PRODOTTO	5100-00021-UN
Basic UDI-DI NUMBER NUMERO IUD-ID de base NUMERO UDI-DI di base	361522BLINKV088
INTENDED USE INDICATION D'UTILISATION DESTINAZIONE D'USO	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 BioSerenity-Link è un software basato su app mobile destinato a essere configurato da professionisti sanitari qualificati per scambiare dati video con BioSerenity Cloud. Bioserenity-Link può anche essere utilizzato da pazienti per consentire alcune interazioni durante la sessione di registrazione
EMDN CODE CODE EMDN CODICE EMDN	V92 – Medical Device Software – Not included in other classes V92 – Software per dispositivi medici – Non incluso in altre classi
CLASSIFICAZIONE CLASSIFICATION	Classe I (in conformità alla norma 11 e 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 Medical Devices Group.
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 Medical Devices Group.
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 Medical Devices Group.

PLACE A LUOGO	PARIS
DATE OF ISSUE DATE DATA DI RILASCIO	August 19th, 2024 19 aout 2024 19 agosto 2024
SIGNATURE FIRMA	
NAME / NOM / NOME	Mélanie RENAUD SAMIRI
POSITION / TITRE / TITOLO	Quality and Regulatory Affairs Director Directeur 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)

MANUFACTURER HERSTELLER	**BioSerenity Medical Devices Group** 20 Rue Berbier du Mets 75013 Paris FRANCE
SRN NUMBER SRN-NUMMER	FR-MF-000039391
PRODUCT DESIGNATION PRODUKTBEZEICHNUNG	**BLINK UN Mobile App Android 1.6.0**
PRODUCT REFERENCE PRODUKTREFERENZ	5100-00021-UN
Basic UDI-DI NUMBER Basis-IUD-ID-NUMMER	361522BLINKV088
INTENDED USE VERWENDUNGSZWECK	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 ist eine auf einer mobilen Anwendung basierende Software, die von qualifizierten medizinischen Fachkräften für den Austausch von Videodaten mit BioSerenity Cloud konfiguriert werden kann. Bioserenity-Link kann auch von Patienten für bestimmte Interaktionen während der Aufzeichnung genutzt werden.
EMDN CODE EMDN-CODE	V92 – Medical Device Software – Not included in other classes
KLASSIFIKATION	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 Medical Devices Group.
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 der BioSerenity Medical Devices Group ausgestellt.

PLACE ORT	Paris
DATE OF ISSUE AUSSTELLUNGSDATUM	August 19th, 2024 19. August 2024
SIGNATURE / UNTERSCHRIFT	
NAME	Mélanie RENAUD SAMIRI
POSITION	Quality and Regulatory Affairs Director Direktorin für Qualität und regulatorische Angelegenheiten

REFERENCE OF APPLIED REGULATORY STANDARDS
REFERENCE DES NORMES RÉGLEMENTAIRES APPLIQUÉES
RIFERIMENTO A NORME DI REGOLAMENTAZIONE APPLICATE
REFERENZEN DER ANGEWENDETEN REGULIERUNGSNORMEN

Standard number **Numéro du standard** **Codice della norma** **Nummer der Norm**	**Standard title** **Titre du standard** **Titolo della norma** **Name der Norm**
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

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

Applied Regulation Règlement appliqué Regolamentazione applicata Angewendete Regulierung	Regulation title Titre du réglement Titolo del regolamento Titel der Regulierung
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 (Text with EEA relevance)
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
RGPD 2016/679	RGPD: General Data Protection Regulation (2016/679)

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 Spezifikatio