Product / Project
BioSerenity Link

Document Title
Medical Device File for BioSerenity-Link

DOCUMENT HISTORY TABLE

Rev.	Reason for the change	Author	Change Date
A	Creation for BioSerenity-Link V1.1.1	AGO	10 Dec 2022
B	Update for V1.1.2	AGO	13 JAN 2023
C	Update for V1.1.3 due to : • CC000097 - [WEMU] EEG signals desynchronized with respect to B-link Video linked with ECR-000486 - [B-link] Hotfix - desynchro EEG and B-link video	AGO	02 MAR 2023
D	Update due to B-Link changes during M17 (V1.2.0) • ECR-000453 – [BLINK] Live on demand • ECR-000480 - [BLINK] Continuous improvements 1.2.0	AGO	13 APR 2023
E	Update due to B-Link changes during M18 (V1.3.0): • ECR-000499 – [BLINK] Continuous improvements 1.3.0	AGO	26 JULY 2023
F	Update following: • to change item name to match new PLM naming system ECR-000535 Change of company (Legal Manufacturer) ownership following • ECR-000541 Labelling change implementation after legal manufacturer change - full name Update due to B-Link changes during M20 (V1.5.0): • ECR-000525 [BLINK] Continuous improvements 1.5.0	RMA	6 MAY 2024
G	**V1.6.0 Update according to :** • [SWISS EXPANSION] [WEMU] [CLOUD] CLOUD & B-LINK compatible with Swiss Market	RMA	19 AUG 2023

Table of content

1. Purpose and scope

The aim of this document is to gather all document reference in order to meet ISO 13485 requirements (§4.2.3). The medical device file scope is all products that we manufacture or distribute.

2. Reference Documents & standards

ISO 13485 :2016 Medical Devices – Quality Management Systems- Requirements for regulatory purposes Section 4.2.3

3. Terminology and Acronyms

QRA: Quality and Regulatory Affairs

4. Responsibilities

The QRA Department is responsible to maintain medical devices files up to date according to all product modification.

5. Content of the Medical Device File

All the documents referenced into this document are listed with their versioning into the document BLINK_Product_documentation_and_versioning : **REG6.**

All documents are stored in the PLM Arena System.

Requirements	Proof of conformity
General description of the medical device, intended use/ Purpose and labelling including any instructions for use	General description of medical devices and its intended use are described within ***Label*** Cloud labels: **LAB1** ***Instruction for use*** BLINK: **IFU1**
Specifications for Product	All product specifications are enclosed within the following documents: BLINK PRS: **S1** BLINK SRS: **S2** BLINK SDD: **S3** Version file: **S13**

Requirements	Proof of conformity
Specifications or procedures for manufacturing, packaging, storage, handling and distribution	QP-00034: **QP2** QP-00003: **QP3** QP-00010: **QP4** QP-00011: **QP7** DP-00004: **QP1**
Procedures for measuring and monitoring	Monitoring and measurement of processes are conducted according to the following procedures: - QP-00034: **QP2** - QP-00016: **QP6**
As appropriate, requirement for installation	*Not applicable as there are no installation activities at customer locations (See Quality Manual, clause 7.5.3)*
As appropriate, procedures for servicing	*BLINK Not applicable as there are no servicing*