1. Manufacturer identification

Company : Aktiia SA
Address : Rue du Bassin 8a, 2000 Neuchâtel, Switzerland
SRN : CH-MF-000015833

2. Product Identification

Product Name: Hilo
Model/Version: Hilo Band, Hilo Cuff
Classification: IIa, Rule 10
Basic UDI-DI: 7649998849AKBraceletYW
EMDN Code(s): Z12030205 – Non-invasive Blood Pressure Gauges
Z12030282 – Vital Signs Monitoring Instruments – Software Accessories

3. Authorized Representative identification

Company : Veranex Germany GmbH
Address : Landsberger Strasse 302, 80687 Munich, Germany
SRN : DE-AR-000005578

4. Intended Purpose

Hilo Band
Hilo Band is a non-invasive blood pressure (BP) monitor intended to measure optical Photoplethysmography (PPG) signals on the user's wrist and to calculate blood pressure values using a Pulse Wave Analysis (PWA) technique, following a calibration process using an oscillometric blood pressure monitor. Hilo Band can also calculate heart rate based on the same measurement and analysis technology.

Hilo Cuff
Hilo Cuff is an oscillometric blood pressure monitor intended to initialize the Hilo Band which is a component of the Hilo Blood Pressure Monitoring System. The Hilo Cuff helps with measurement of baseline blood pressure and heart rate of a user to initialize the Hilo Band.

5. Compliance with Common Specifications

There is no Common Specification, and harmonized standards regarding design or clinical use for this device.

6. Conformity Assessment

MDR 2017/745 Annex IX, Conformity assessment based on a quality management system and assessment of the technical documentation.

Conformity assessment procedure realized under the supervision of the notified body «TüV Süd Product Service GmbH» with identification number 0123.

Certificate number : G15 103039 0009 Rev. 00

7. Declaration of conformity

The present declaration is written according to the requirements of MDR (EU) 2017/745 Article 19 and Annex IV.

We declare under our sole responsibility that the medical devices listed in §2 have been assessed according to the procedure described in §6 and meet all the applicable provisions of Regulation (EU) 2017/745 on medical devices.

Where these devices are placed on the market in a system or procedure pack, this Declaration also attests compliance with the requirements of Article 22 of Regulation (EU) 2017/745, including verification of mutual compatibility, conformity with intended purposes, proper packaging and instructions.

Council Regulation (EU) 2017/745 on medical devices

This Declaration of Conformity is issued at San Diego, California on 17th December 2025.

Name, Function: Neil Puri, VP of Quality and Regulatory Affairs

Signature: Neil Puri _____