1. Manufacturer identification

Company : Aktiia SA
Address : Rue du Bassin 8a, 2000 Neuchâtel, Switzerland
SRN : Not available at the time of the declaration

2. Authorized Representative identification

Company : Medidee Services GmbH
Address : Hohnenweg 9, 78098 Triberg im Schwarzwald, Germany
SRN : Not available at the time of the declaration

3. 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 §3.1 have been assessed according to the procedure described in §3.2 and meet all the applicable provisions of the following regulation:

Council Regulation (EU) 2017/745 on medical devices

Date of issue: 22.12.2020

Name, Function: Michael Kisch, CEO

Signature: _____

3.1. Devices identification

Device model	Class[1]	Basic UDI-DI	Intended purpose
Aktiia Bracelet G1	IIa	7649998849AKBraceletYW	Aktiia Bracelet G1 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. Aktiia Bracelet G1 can also calculate heart rate based on the same measurement and analysis technology. Aktiia Bracelet G1 is indicated for monitoring of adult patients in home use.
Aktiia Init I1	IIa	7649998849AKBraceletYW	Aktiia Init I1 is an oscillometric (cuff-based) blood pressure monitor indicated to be used for measuring blood pressure and heart rate in adults with arm circumference ranging from 22cm to 42cm (about 8¾″-16½″). Aktiia Init I1 is indicated for home use.

3.2. Conformity assessment procedure followed

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 : G10 103039 0006

[1] *According to annex VIII of the regulation (EU) 2017/745*