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CE DECLARATION OF CONFORMITY

AS PER MEDICAL DEVICE REGULATION (EU) 2017/745 (MDR) ANNEX IV

2024-03-20

V2.0

Vilnius

1. This EU declaration of conformity is issued under the sole responsibility of TELTONIKA TELEMEDIC, UAB, the manufacturer of the below listed CE marked medical device. The requirements specified in EU Medical Device Regulation 2017/745 (MDR) have been fulfilled in relation to the listed device group.

2. We, Manufacturer

Name:	TELTONIKA TELEMEDIC UAB
Address:	Ukmergės g. 120-1, LT-08126, Vilnius
E-mail address:	info@teltonika.lt

3. DECLARE THAT THE DOC IS ISSUED UNDER OUR SOLE RESPONSIBILITY AND BELONGS TO THE FOLLOWING PRODUCT:

Product Name:	MyHealth app
SRN:	LT-MF-000007642
B-UDI:	477905185MHAppQH
Product Classification:	IIa
Intended use:	Software as a Medical Device: The MyHealth app, in conjunction with the TeltoHeart smart wearable, is intended for use in patients suspected of having arrhythmias. An advanced PPG-based atrial fibrillation detection and Heart rate monitor algorithms alerts the patient and advises them to perform a 6-lead electrocardiogram either at home or in a hospital environment. Heart monitoring functionality consists of: • Automatic recording of heart rate extrapolated from PPG signal;

• Detection of suspected atrial fibrillation from PPG-based AF algorithm;
• Manual 6-lead ECG recording using physical electrodes.
Heart rate and rhythm data is interpreted by an algorithm which detects atrial fibrillation and alerts patient if any are detected by way of notifications on the device.
Electrocardiogram (ECG) is recorded manually by the patient and can be sent to their medical practitioner (e.g. cardiologist or other qualified medical staff) for further interpretation and help in diagnosis. The device does not diagnose any medical conditions.
For more precise diagnosis it is recommended to use standalone electrocardiographs or use smart wearable data only in conjunction with additional medical examination data. The diagnosis is determined only by medical practitioner. MyHealth app is intended for use by adults aged 22 and above.

4. The conformity with the essential requirements has been demonstrated against the following harmonized standards and other technical specifications:

Quality Management System

EN ISO 13485:2016 + A11:2021
EN ISO 14971: 2019 + A11:2021

Medical Software

EN 62304: 2006 + Cor.:2008 + A1:2015
EN 62366-1: 2015 + AC:2015 + A1:2020
EN ISO 20417: 2021
EN ISO 15223-1: 2021
ISO/HL7 27931: 2009
ISO TR 24971: 2009

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IEC TR 62366-2: 2016
IEC TR 80002-1: 2009
IEC TR 80002-3: 2014
ISO 81001-1: 2021
IEC 81001-5-1: 2021

5. Notified Body

Name:	SIQ LJUBLJANA
Notified Body Number:	1304
Notified Body Assessment Performed:	2024-03-20
EC Certificate Number:	MDR-009

Signed for and on behalf of: Martynas Osauskas, Director