

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: <ul style="list-style-type: none">• Automatic recording of heart rate extrapolated from PPG signal;

TELTONIKA TELEMEDIC UAB
Ukmergės st. 120-1, LT-08126
Vilnius, Lithuania

Registration code 305534534
VAT number LT100013091815

Swedbank AB
LT85 7300 0101 6212 7624
S.W.I.F.T. HABALT22

Data on the company is collected and stored in the Register of Legal Entities of the Republic of Lithuania.



ISO 13485 M-222

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



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