CE MDR

The CE logo indicates compliance with the Medical Devices Regulation (MDR), which ensures a unified regulatory framework for medical devices within the European Union.

Description

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.

Attachments

CE MDR Declaration of conformity, TeltoHeart page 1

CE MDR Declaration of conformity, TeltoHeart page 2

CE MDR Declaration of conformity, TeltoHeart page 3

You can find PDF version of the declaration **here**.