EU Declaration of Conformity

Trade Name: PulseOn Arrhythmia Monitor System
Model: AMS-1
Basic UDI-DI: 643005433AMSD4
Manufacturer: PulseOn Oy, Tekniikantie 12, 02150 Espoo, Finland
SRN: FI-MF-000009325
Certificate number:CR-03-1224-781-22
Notified Body: Eurofins Expert Services Oy (0537), Kivimiehentie 4, 02150 Espoo, Finland

Assessment procedure: Assessment based on the quality management system and on the assessment of technical documentation

System Purpose: The PulseOn Arrhythmia Monitor System is used to assist in the diagnosis, screening and monitoring of cardiac arrhythmias. The system consists of a wrist-worn device and a data management service.

We hereby declare, with our sole responsibility, that the PulseOn Arrhythmia Monitor System conforms with the provisions of the (EU) 2017/745 Regulation of the European Parliament and of the Council on Medical Devices issued on 5 July 2017 concerning medical devices.

Classification: Class IIa

The following standards were used to meet the requirements:

- EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012) Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- EN 60601-1-11:2015 Medical Electrical Equipment – Part 1–11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
- EN 60601-1-2:2015 Medical Electrical Equipment – Part 1–2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
- ECG functions are evaluated using relevant parts of the EN60601-2-47:2015 standard, considering the intended use of the device.
- According to the manufacturer of the Bluetooth modules, the Bluetooth modules meet the requirements of the Electromagnetic Compliance Directive 2014/30/EU and Radio Equipment Directive (RED) 2014/53/EU.
- The CE marking requirement 93/68/EE and RoHS Directive and (EU) 2017/2102 RoHS 2 Directive 2011/65/EU and WEEE Directive 2012/19/EU.
- This declaration is also supported by the Quality Management System in accordance with EN 13485:2016, and EN 14971:2019 Risk Management.

Jari Kaija
CEO
Espoo, 25 February 2022