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Declaration of Conformity

Name and address of the manufacturer	MEDICALGORITHMICS S. A. Aleje Jerozolimskie 81 02-001 Warsaw, Poland Telephone: +48 22 825 1249 E-mail: technical@medicalgorithmics.com
SRN (Single Registration Number)	PL-MF-000011413
Basic UDI-DI	590302156PECGT-IVMG

Intended use

The PocketECG IV transmitter is intended to acquire, analyze, visualize, record or/and transmit the ECG and acceleration data. The results of arrhythmia are displayed, stored or/and transmitted along with the ECG signals. The acceleration signals are analyzed in order to determine the physical activity of the patient. It is assumed that the device can further transmit the ECG and acceleration signals along with analysis results using available wireless technologies.

Name of the device	Product name: Unified Arrhythmia Diagnostic System PocketECG IV Type: P4TR-CE-ADS Batch no: Please refer to attached Packing List; the Declaration of Conformity is considered valid only in conjunction with Packing List.

EU

Classification	Class IIa: Annex VIII, Rule 10 indent 3 of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
Name and identification of the Notified Body	TÜV Rheinland LGA Products GmbH (0197)
Conformity assessment procedure	MDR: Annex IX Chapter I, Section 2 and 3
EU Certificate Registration No.	HZ 1023833-1

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Harmonized standards applied

art 3.1 (Safety standard)	Safety of the PocketECG IV device as a medical device is covered by IEC 60601 standard series	Report number: CBTR 28230491 and its amendments
art 3.1.b (EMC)	ETSI EN 301 489-1 v2.1.1 (2017-02) ETSI EN 301 489-3 v2.1.1 (2019-03)	Report number: 104993844LEX-001 (Intertek, date: 9/13/2022)
art 3.2 (Efficient use of the radio frequency spectrum)	ETSI EN 301 908-1 V13.1. (2019-11) ETSI EN 301 511 v12.5.1 (2017-03)	Report number: 104993844LEX-002 (Intertek, date: 9/13/2022)
Health standard (EMF Exposure Evaluation)	EN 50566:2017 EN 62209-1528:2020 EN 62479:2010 EN 62311:2008	Report number: SAR.20221006 (RF Exposure Lab, dates of test: October 6-7 & December 9, 2022)

Conformity assessment procedure Annex II of the Directive 2014/53/UE

This declaration of conformity is issued under the sole responsibility of Medicalgorithmics S.A.
We hereby declare that the medical device specified above meets the provision of:

- the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by TÜV Rheinland LGA Products GmbH;
- the European Parliament and of the Council 2014/53/UE of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.
- Directive 2011/65/EU on Restriction of the use of certain hazardous substances in electrical and electronic equipment as amended by Commission Delegated Directive 2015/863 (RoHS).

All supporting documentation is retained at the premises of the manufacturer.

Karolina Rudzka
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Name

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Signature

Regulatory Affairs and Quality Assurance Manager (PRRC)
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Function

Warsaw, 2023-06-28
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Place, Issue date