

EU Certificate

Quality Management System

REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I,
Section 2 and 3 and Chapter III

Registration No.: HZ 1023833-1

Manufacturer: **MEDICALGORITHMICS S.A.**
Al. Jerozolimskie 81
02-001 Warszawa
Poland

EUDAMED Single
Registration No.: PL-MF-000011413

Products: Products of class IIa:
Z129082 - VARIOUS INSTRUMENTS FOR FUNCTIONAL EXPLORATION
AND THERAPEUTIC INTERVENTIONS - SOFTWARE ACCESSORIES
Z12050403 - ECG HOLTER RECORDERS

Authorised
representative(s): Not applicable

Certificate history

Revision:	Description:	Issue date:
0	Initial Certification	2023-03-29
1	Scope extension	2023-05-05

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 84965710-40

Effective date: 2023-05-05

Expiry date: 2028-03-28

Issue date: 2023-05-05



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.