

EC Certificate



Full Quality Assurance System Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

Registration No.: HD 1023833-1

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

Products: - Telemetry system, electrocardiograph
- Cardiac rehabilitation monitoring systems
- Holter analyzer, software

Replaces EC certificate, Registration No.: HD 60110960 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 84947413-20
Effective date: 2021-03-09
Expiry date: 2024-05-26
Issue date: 2021-03-09



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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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The scope of certification includes the following additional sites:

No.	Location	Product groups manufactured
/01	MEDICALGORITHMICS S.A. Al. Jerozolimskie 81 02-001 Warszawa Poland	Activity: Design and development.
/02	MEDICALGORITHMICS S.A. ul. Marynarki Polskiej 100 80-557 Gdańsk Poland	Activity: Design, development and production of Telemetry system, electrocardiograph, Cardiac rehabilitation monitoring systems, Holter analyzer, software.

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