

EC Certificate



Production Quality Assurance Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1036863-1

Manufacturer: Diagnosis S.A.
ul. Gen. Władysława Andersa 38 A
15-113 Białystok
Poland

Products:

- Blood Pressure Meters
- Digital Thermometers
- Infrared Thermometers
- Lancets
- Ultrasonic Nebulizers
- Compressor Nebulizers
- Mesh Nebulizers
- Accessories for nebulizers
- ECG Monitors
- ECG signal acquisition devices
- ECG viewing application - software
- Fingertip Pulse Oximeters

For the following devices, the scope only covers the aspects of manufacture concerned with the conformity of the products with metrological requirements:

- Aneroid sphygmomanometers
- Mercury free clinical thermometers

Replaces EC Certificate number DD 1036863-1 dated 2021-05-05

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 84952934-20

Effective date: 2021-05-24

Expiry date: 2024-05-26

Issue date: 2021-05-24


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The seal of TÜV Rheinland LGA Products GmbH, featuring a blue triangle with a horizontal line through it, and the text "TÜV Rheinland LGA Products GmbH" and "Zertifizierungsstelle".

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 manufacturing sites:

No.	Location	Product groups manufactured
/01	Diagnosis S.A. ul. Gen. Władysława Andersa 38 A 15-113 Białystok Poland	Activity: Administration.
/02	Diagnosis S.A. ul. Przemysłowa 8 16-010 Wasilków Poland	Activity: Production of ECG signal acquisition devices and final inspection of Blood Pressure Meters, Digital Thermometers, Infrared Thermometers, Lancets, Ultrasonic Nebulizers, Compressor Nebulizers, Mesh Nebulizers, Accessories for nebulizers, Fingertip Pulse Oximeters, ECG Monitors, ECG signal acquisition devices, Aneroid sphygmomanometers, Mercury free clinical thermometers.

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