

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60117866 0001

Report No.: 26300376 001

Manufacturer: Diagnosis S.A.
ul. Gen. Wladyslawa Andersa 38 A
15-113 Bialystok
Poland

Products: (see attachments for products and sites included)
Replaces EC Certificate, Registration No.: DD 60110986 0001

Expiry Date: 2022-03-11

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.

Effective Date: 2017-04-18

Date: 2017-04-18

Notified Body

Maciej Sciera



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Doc. 1/2, Rev. 0

**Attachment to
Certificate**

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Manufacturer: **Diagnosis S.A.**
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Product included:

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

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

- Aneroid sphygmomanometers

Date: 2017-04-18

Notified Body


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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

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Manufacturer: **Diagnosis S.A.**
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15-113 Bialystok
Poland

Sites included:

Diagnosis S.A.
ul. Przemyslowa 8
16-010 Wasilkow, Poland

Manufacture

Date: 2017-04-18

Notified Body



Maciej Sciera

