INFORMATION ONLY

TÜVRheinland®

EC Certificate

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

Registration No.: DD 60143339 0001

Report No.: 21240725 011

Manufacturer:

medis. Medizinische
Messtechnik GmbH
Werner-von-Siemens-Str. 8
98693 Ilmenau
Deutschland

Products:

- Monitoring devices of non-vital physiological parameters
- Monitoring devices of vital physiological parameters

Replaces Certificate, Registration No.: DD 60108354 0001

Expiry Date: 2024-05-26

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: 2019-09-30

Date: 2019-09-30

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. I. Munkler

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.