

ÜVRheinland

Dipl.-Ing. D. Meierungs

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

Registration No.: DD 60108354 0001

Report No.: 21240725 001

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 60040098 0001

Expiry Date: 2021-07-27

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: 2016-07-28

Date: 2016-06-15

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.