

EC Certificate

Full Quality Assurance System MDD Annex II excl. 4

Registration No.: HD 1799860-1

Manufacturer: Medical Measurement Systems B.V.
Colosseum 25
7521 PV Enschede
Netherlands

Products: Products:
- urodynamic measurement systems
- gastrointestinal motility analyzers
- neuromuscular stimulators
- long-term pH recorders

For the following medical devices the activity of the Notified Body is limited to aspects of manufacture concerned with conformity of the products with the metrological requirements:
- uroflowmeters

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.: 3322252-30
Effective date: 2020-08-20
Expiry date: 2023-07-04
Issue date: 2020-08-20



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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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No.	Location	Product groups manufactured
/01	Medical Measurement Systems B.V. Colosseum 25 7521 PV Enschede Netherlands	Products: - urodynamic measurement systems - gastrointestinal motility analyzers - neuromuscular stimulators - long-term pH recorders- uroflowmeters
/02	Medical Measurement Systems B.V. De Cuserstraat 93 1081 CN AMSTERDAM Netherlands	Products: - urodynamic measurement systems - gastrointestinal motility analyzers - neuromuscular stimulators - long-term pH recorders

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