

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4 Full Quality Assurance System Medical Devices

Registration No.: HD 60149004 0001

Report No.: 21182491 034

Manufacturer: Geratherm Medical AG

Fahrenheitstr. 1 99331 Geratal Deutschland

Products: Medical devices for diagnosis and monitoring

(see attachment for products and sites included)

Replaces Certificate, Registration No.: HD 60146884 0001

Expiry Date: 2024-05-26

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 GAP.

Effective Date:

2020-04-27

Date:

2020-04-27

Dipl.-Ing. I. Munkler

Notified Body

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

Registration No.: Report No.:

HD 60149004 0001 21182491 034

Manufacturer:

Geratherm Medical AG

Fahrenheitstr. 1 99331 Geratal Deutschland

Products included:

- medical thermometers
- temperature monitors
- medical infrared thermometers
- non-invasive sphygmomanometers
- puls oximeters

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

- clinical liquid-in-glass thermometers

Notified Body

Dipl.-Ing. I. Munkler

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Date: 2020-04-27



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg Doc. 2/2, Rev.0

Attachment to Certificate

Registration No.: Report No.:

HD 60149004 0001 21182491 034

Manufacturer:

Geratherm Medical AG

Fahrenheitstr. 1 99331 Geratal Deutschland

Site included:

Geratherm Medical AG Ohrdrufer Straße 44 99331 Geratal Germany

Date: 2020-04-27

Notified Body

Dipl.-Ing. I. Munkler

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