

EC Certificate

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

Registration No.: HD 60124378 0001

Report No.: 21182491 017

Manufacturer: Geratherm Medical AG

Fahrenheitstr. 1 98716 Geschwenda

Deutschland

Products: Medical Devices

(see attachment for products and sites included)

Replaces Certificate, Registration No.: HD 60078684 0001

Expiry Date: 2022-10-15

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.

Effective Date: 2017-11-09

Date: 2017-11-09

10/020 h 04.00 @ TUY, TUEY and TUV are registered trademarks. Utilisation and application requires prior approval.

Dipl.-Ing. I. Munkler

TÜVRheinlan

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 60124378 0001

21182491 017

Manufacturer:

Geratherm Medical AG

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98716 Geschwenda

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Products included:

- medical thermometers
- temperature monitors
- medical infrared thermometers
- non-invasive sphygmomanometers
- nebulizers
- 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 Journass

10/020 h 04.08 @ TUY, TUEV and TUY are registered trademarks. Utilisation and application requires prior approval.

Date: 2017-11-09



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

Attachment to Certificate

Registration No.: Report No.:

HD 60124378 0001

21182491 017

Manufacturer:

Geratherm Medical AG

Fahrenheitstr. 1 98716 Geschwenda

Deutschland

Site included:

Geratherm Medical AG Ohrdrufer Straße 44 98716 Geraberg Germany

Date: 2017-11-09

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Notified Body

Dipl.-Ing. I. Munkler-rungs

DÜVRheinland