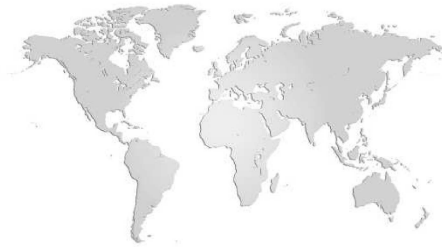


EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex V

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

ERKA. Kallmeyer Medizintechnik GmbH & Co. KG

Im Farchet 15, 83646 Bad Tölz, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex V for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50020-Z7-01, the decision dated 2021-03-01 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2021-03-01 to 2024-05-26

Registration No.: 50020-17-09

A handwritten signature in black ink, appearing to read 'Ruth Delbeck-Bayer'.



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2021-03-01
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra.de/audits



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de

ZLG-BS-295.10.02

Annex to the EC Certificate No. 50020-17-09

Valid from 2021-03-01 to 2024-05-26

Revision status of the annex: 0 dated 2021-03-01

Devices/device categories included in the certificate:

Class I m:

For the products listed below, the review of the Quality System refers exclusively to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

- Sphygmomanometers, aneroid
 - Vario
 - Perfect Aneroid
 - Perfect Aneroid Klinik
 - Profi
 - Profi Klinik
 - Kobold
 - Kobold Klinik
 - Switch Comfort
 - Switch Smart
 - Switch Simplex

Class II a:

- Sphygmomanometers, electronic
 - Erkameter 125
 - Erkameter 125 Pro
 - EN200 BP



Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-03-01
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