

EC CERTIFICATE

for the Quality Assurance System



according to 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 for the medical devices listed in the annex according to the directive 93/42/EEC annex V. The approval is based on the result of the re-certification audit report no. 50020-Z5-xx, the decision dated 27.11.2014 is only valid in connection with the successful performance of the annual surveillance audits.

Date of the first certification: 1996-07-29

Date of the last recertification: 2014-11-30

This certificate is valid until: 2017-11-29

Certificate registration No.: 50020-17-06
duplicate

DEKRA Certification GmbH

Stuttgart, 2014-11-27

Notified Body ID-number: 0124



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
ZLG-BS-295.10.02
www.zlg.de

Lack of fulfilment on conditions as set out in the Certification Agreement may render this certificate invalid.

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

Annex to the Certificate 50020-17-06 dated 27.11.2014

Duplicate

Revision status: 1

Date: 04.12.2014

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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 manufacturing steps associated with product conformity and metrological requirements.

- Sphygmomanometers, Aneroid

Class II a:

- Sphygmomanometers, electronic