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

Certified location:

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-Z6-00, the decision dated 2017-11-30 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2017-11-30 to 2020-11-29

Registration No.: 50020-17-07

DEKRA Certification GmbH • Stuttgart, Handwerkstraße 15 • D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2017-10-25
Notified Body ID-number: 0124

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. 50020-17-07

Revision status: 0

Valid from 2017-11-30 to 2020-11-29

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
  - 16-156

Class II a:

- Sphygmomanometers, electronic
  - 16-157

DEKRA Certification GmbH Stuttgart Handwerkstraße 15 D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2017-10-25
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