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

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

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

CERTIFICATE

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the company

ERKA. Kallmeyer Medizintechnik GmbH & Co. KG

Scope of certification:

Manufacturing, final inspection, sales and distribution of medical instruments in the field of non-invasive blood pressure measurement

Certified location:

Im Farchet 15, 83646 Bad Tölz, Germany

CÔNG TY CỔ PHẦN B.H.A

GIÁM ĐỐC

Đặng Minh Hải

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50020-Z6U1-00.

This certificate is valid from 2019-03-26 to 2020-11-29

Registration No.: 50020-14-00

DEKRA

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-03-26

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16029-08-00