

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




Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2021-03-01
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. 50020-17-09

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
Notified Body ID-number: 0124

I hereby certify that this is a true copy of the original.

Bad Tölz, the 23rd day of March 2021



Michael Leitenstorfer

Notary

Die Echtheit vorstehender Unterschrift des Notars Michael Leitenstorfer in Bad Tölz und die Echtheit des begedrückten Dienstsiegels werden hiermit bestätigt. Zugleich wird bescheinigt, dass der Vorgenannte zur Vornahme der Amtshandlung befugt war.

München, 28. Dezember 2021
Der Präsident des Landgerichts München II
Im Auftrag



Bettina Günther
Justizangestellte





TỔNG LÃNH SỰ QUÁN NƯỚC CHXHCN VIỆT NAM
tại Frankfurt am Main, CHLB Đức

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Country:
- Giấy tờ, tài liệu này**
This public document
2. do Ông (Bà): **Bettina Günther** ký
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acting in the capacity of:
4. và con dấu của: **Tòa án phúc thẩm Tp. München II**
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7. Cơ quan cấp: **Tổng lãnh sự quán Việt Nam tại Frankfurt/Main**
by
8. Số: **174/2022/CN-HPHLS**
No.:
- Lãnh sự/ Consul**



Nguyễn Hà Linh