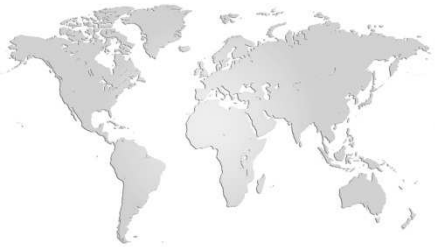
EC CERTIFICATE

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

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

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

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

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DEKRA Certification GmbH, Stuttgart, 2021-03-01
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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	ERKA. Kallmeyer Medizintechnik GmbH & Co. KG
Manufacturer address and contact details	Farchet 15, 83646 Bad Tölz, Germany
Single Registration Number (SRN) (if available)	DE-MF-000009663

Authorised Representative name (if applicable)	
Authorised Representative address and contact details	
Single Registration Number (SRN) (if available)	

Notified body name (if applicable)	DERKA Certification GmbH Stuttgart
Notified body number (if applicable)	0124
Directive Certificate number(s) to which this confirmation is made (if applicable)	50020-17-09
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26
End date of extended validity/transition period	2028-12-31

We, as the manufacturer declare under our sole responsibility:

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

ERKA. Kallmeyer Medizintechnik GmbH & Co. KG Im Farchet 15 D - 83646 Bad Tölz

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

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GmbH & Co. KG

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☑Expired/expires *after* 20 March 2023:

☑Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

☐A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☑A QMS in accordance with Article 10(9) MDR is in place.

☐A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: ERKA. Kallmeyer Medizintechnik GmbH & Co. KG

Location & Date: Bad Tölz, 10.7.2024

Signature, Print Name, Title: Björn Kallmeyer, General Manager

Contact Details (at least email): b.kallmeyer@erka.org

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Vario	50020-17-09	2024-05-26	DEKRA, 0124	DEKRA, 0124	2028-12-31	
Perfect Aneroid	50020-17-09	2024-05-26	DEKRA, 0124	DEKRA, 0124	2028-12-31	
Perfect Aneroid Klinik	50020-17-09	2024-05-26	DEKRA, 0124	DEKRA, 0124	2028-12-31	
Profi	50020-17-09	2024-05-26	DEKRA, 0124	DEKRA, 0124	2028-12-31	
Profi Klinik	50020-17-09	2024-05-26	DEKRA, 0124	DEKRA, 0124	2028-12-31	
Kobold	50020-17-09	2024-05-26	DEKRA, 0124	DEKRA, 0124	2028-12-31	
Kobold Klinik	50020-17-09	2024-05-26	DEKRA, 0124	DEKRA, 0124	2028-12-31	
Switch Comfort	50020-17-09	2024-05-26	DEKRA, 0124	DEKRA, 0124	2028-12-31	

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Switch Smart	50020-17-09	2024-05-26	DEKRA, 0124	DEKRA, 0124	2028-12-31	
Switch Simplex	50020-17-09	2024-05-26	DEKRA, 0124	DEKRA, 0124	2028-12-31	
Erkameter 125	50020-17-09	2024-05-26	DEKRA, 0124	DEKRA, 0124	2028-12-31	
Erkameter 125 Pro	50020-17-09	2024-05-26	DEKRA, 0124	DEKRA, 0124	2028-12-31