CERTIFICATE

for the
Quality Assurance System

DEKRA Certification

As a notified body of the European Union (Reg. No. 0124) DEKRA Certification GmbH hereby approves the Quality Assurance System applied for manufacture and final inspection by the company

ERKA. Kallmeyer Medizintechnik GmbH & Co. KG

Im Farchet 15 • 83646 Bad Tölz, Germany

Approval is based on the decision dated 16.11.2009 and the result of the report no. 50020-Z4-00 and is performed in accordance with the stipulations of

Annex V, Section 3 of the Directive 93/42/EEC

of the Council dated June 14, 1993 governing medical devices. The certification is applicable to the devices specified in the Annex. The devices in question are subjected to testing and examination in accordance with Annex V, Section 3 of the Directive 93/42/EEC. The listed devices may be affixed with the CE marking indicated below.

CE 0124

Date of the first certification:	29.07.1996	Date of the last recertification:	30.11.2009
This certificate is valid until:	29.11.2014	Certificate-registration No.:	50020-17-05
			English version

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

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-992.94.16

DEKRA Certification GmbH
Stuttgart, 16.11.2009

Annex to the Certificate 50020-17-05 dated 16.11.2009

English version

Revision status: 0 Date: 30.11.2009 Page 1 of 1

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.

Non-invasive sphygmomanometers and equipment

version	art. no.
Aneroid sphygmomanometer	200. ... – 294. ..
Mercury sphygmomanometer	100. ... – 112. ... 116. ... – 194. ...

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