# EC CERTIFICATE

## for the Quality Assurance System

## according the Directive 93/42/EEC, Annex VI

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

**Rudolf Riester GmbH**

Bruckstraße 31, 72417 Jungingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex VI for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50828-Z4-00, the decision dated 2016-11-04 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2016-11-14 to 2019-11-13

Registration No.: 50828-18-05

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2016-11-04
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



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# Annex to the EC Certificate No. 50828-18-05

Revision status: 0

Valid from 2016-11-14 to 2019-11-13

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.

| | |
|---|---|
| Aneroid sphygmomanometers: | minimus® |
| | exacta® |
| | precisa® N |
| | sphygmotensiophone |
| | babyphon® |
| | big ben® |
| | ri-med® |
| | ri-mega® |
| | ri-san® |
| | sanaphon® |
| | R1 shock-proof |
| | e-mega® |
| Eye tonometer: | schiötz |

Class II a:

| | |
|---|---|
| Digital sphygmomanometers: | ri-champion® N |
| | ri-cardio |
| | ri-medic |
| Infrared-thermometer: | ri-thermo® N |
| Digital-thermometer: | ri-gital® |
| | Predictive thermometer RPT-100 |
| Pulsoxymeter: | ri-fox N |

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