

# CERTIFICATE



## EN ISO 13485:2012 + AC:2012

DEKRA Certification GmbH hereby certifies that the company

**Rudolf Riester GmbH**

**Scope of certification:**

Development, production and distribution of medical diagnostic instruments

**Certified location:**

Bruckstraße 31, 72417 Jungingen, Germany

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50828-Z4-00.

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

Registration No.: 50828-11-01



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

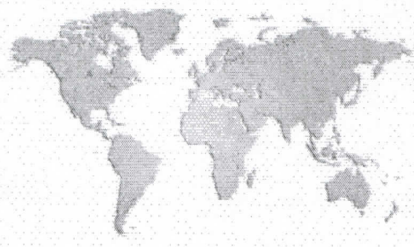


Deutsche  
Akkreditierungsstelle  
D-ZM-16029-08-00



# 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

*Ruth Delbeck-Bayer*



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**

# 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<sup>®</sup>  
  exacta<sup>®</sup>  
  precisa<sup>®</sup> N  
  sphygmotensiophone  
  babyphon<sup>®</sup>  
  big ben<sup>®</sup>  
  ri-med<sup>®</sup>  
  ri-mega<sup>®</sup>  
  ri-san<sup>®</sup>  
  sanaphon<sup>®</sup>  
  R1 shock-proof  
  e-mega<sup>®</sup>

Eye tonometer:                        schiötz


## Class II a:

Digital sphygmomanometers:     ri-champion<sup>®</sup> N  
  ri-cardio  
  ri-medic

Infrared-thermometer:            ri-thermo<sup>®</sup> N

Digital-thermometer:             ri-gital<sup>®</sup>  
  Predictive thermometer RPT-100

Pulsoxymeter:                       ri-fox N





Ruth Delbeck-Bayer  
DEKRA Certification GmbH, Stuttgart, 2016-11-04  
Notified Body ID-number: 0124

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