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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
Certified locations:
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-Z5-00, the decision dated 2019-11-11 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-11-14 to 2024-05-26
Registration No.: 50828-18-06



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-11-11
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



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. 50828-18-06

Valid from 2019-11-14 to 2024-05-26

Revision status of the annex: 0 dated 2019-11-14

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
precisa® N shock-proof
sphygmotensiophone
babyphon®
big ben®
ri-med®
ri-mega®
ri-san®
sanaphon®
R1 shock-proof
e-mega®

Eye tonometer:

schiotz

Class II a:

Digital sphygmomanometers:

ri-champion® N
ri-cardio
ri-medic
RBP-100 / RBP-100 nova

Infrared-thermometer:

ri-thermo® N
ri-thermo® N professional

Digital-thermometer:

ri-gital®
Predictive thermometer RPT-100

Pulsoxymeter:

ri-fox N

Ruth Delbeck-Bayer



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DEKRA Certification GmbH, Stuttgart, 2019-11-11
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CERTIFICATE



EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

Rudolf Riester GmbH

Scope of certification:

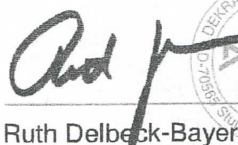
Design and Development, production and distribution of medical diagnostic instruments

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-Z5-00.

Certificate registration no.:	50828-14-01	Certificate valid from:	2019-11-14
Validity of previous certificate:	2019-11-13	Certificate valid to:	2022-11-13



Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-11-11

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



Deutsche
Akkreditierungsstelle
D-ZM-16029-08-00

