

CERTIFICATE

for the

Quality Assurance System



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

Rudolf Riester GmbH & Co. KG
Bruckstraße 31 • D-72417 Jungingen

Approval is based on the result of the certification audit with report number 50828-Z2-00 and is performed in accordance with the stipulations of

Annex VI, 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 VI, Section 3 of the Directive 93/42/EEC. The listed devices may be affixed with the CE marking indicated below.



Date of the first certification: 21.02.1995

This certificate is valid until: 13.11.2011

Date of the last recertification: 14.11.2006

Certificate-registration No.: 50828-18-02
English version

Thiel

DEKRA Certification GmbH
Stuttgart, den 14.11.2006



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

Annex to the Certificate 50828-18-02 dated 14.11.2006

English version

Revision status: 0

Date: 14.11.2006

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Devices/device categories included in the certificate

Class I devices with measurement function

For the products listed below, the review of the Quality System refers exclusively to the manufacturing steps associated with product conformity and metrological requirements.

Aneroid sphygmomanometers:

- minimus[®]
- exacta[®]
- precisa[®]
- precisa[®] N
- sphygmotensiophone
- oscillometer pachon
- oscillomat
- babyphon[®]
- big ben[®]
- ri-med[®]
- ri-mega[®]
- ri-san[®]
- ri-sana[®]
- sanaphon[®]
- sanaphon[®] N

Mercury sphygmomanometers:

- diplomat-presameter[®]
- nova-presameter[®]
- empire[®] N
- global de luxe[®]
- hospital
- mondial

Lumbal puncture set:

- lumbal-Bouillitte
- lumbal-Claude

Eye tonometer:

- schiotz

Class II a:

Digital sphygmomanometers:

- ri-handy[®]
- ri-comfort[®]

Infrared-thermometer:

- ri-thermo[®]

Digital-thermometer:

- ri-gital[®]

Pulsoxymeter:

- ri-fox



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CERTIFICATE

For Quality Assurance



DEKRA Certification GmbH hereby certifies that for

 **Riester**

Rudolf Riester GmbH & Co. KG
Bruckstraße 31 • D-72417 Jungingen

Scope:

Development, production and distribution
of medical diagnostic instruments

Certified location:

Bruckstraße 31 • D-72417 Jungingen

EN ISO 13485 / 07.2003

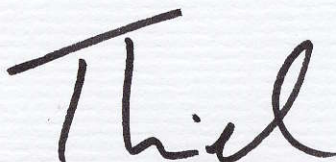
by the means of a certification audit, report no. 50828-Z2-00, proof of the introduction and application of a quality management system in compliance with the above mentioned standards has been attained.

Date of the first certification: 30.10.2002

This certificate is valid until: 13.11.2011

Date of the last recertification: 14.11.2006

Certificate-registration No.: 50828-51-00
English version



DEKRA Certification GmbH
Stuttgart, 14.11.2006



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bei Arzneimitteln
und Medizinprodukten
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