CERTIFICATE

Riester

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

Digitally signed by Iarovoi Petru
Date: 2019.02.06 16:48:01 EET
Reason: MoldSign Signature
Location: Moldova

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

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

DEKRA

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

DAkkS
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

DEKRA Certification GmbH Stuttgart Handwerkstraße 15 D-70565 Stuttgart

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

B4460

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

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

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