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

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15

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

Digitally signed by Iarovoi Petru
Date: 2021.07.01 10:59:34 EEST
Reason: MoldSign Signature
Location: Moldova

FIRMA DE PRODUCERE ȘI COMERȚ "SOGNO" S.R.L. • REPUBLICA MOLDOVA, MUNICIPIUL CHIȘINĂU • Sogno® S.R.L. IDNO 1004600012854

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:	schiötz

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

DEKRA Certification GmbH, Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
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Nr. KE-328	**KONFORMITÄTSERKLÄRUNG** **DECLARATION OF CONFORMITY** **DECLARACIÓN DE CONFORMIDAD** Nach Anhang VII According to Annex VII Según Anexo VII	Riester The familiar way

Rudolf Riester GmbH
Bruckstraße 31, D-72417 Jungingen, Germany
Tel.: (+49) +7477-9270-0
Fax: (+49) +7477-9270-70
E-mail: info@riester.de
www.riester.de

Wir erklären in alleiniger Verantwortung, dass das Medizinprodukt
We declare under our sole responsibility that the medical device
Declaramos bajo nuestra responsabilidad que el producto médico

Diagnostisches Instrument
Diagnostic instrument with standard-, LED and halogen illumination
Instrumento de diagnóstico

e-scope® Ophthalmoskop

e-scope® Ophthalmoscope

e-scope® Ophthalmoscopio

Artikel-Nr. von: / Article no. from: / Desde no. de artículo: 2120-200

Artikel-Nr. bis: / Article no. to / Al no. de artículo: 2123-203

allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG entspricht, die anwendbar sind.
meets all the provisions of the directive 93/42/EEC which apply to it.
cumple con todas las exigencias de la directiva 93/42/CEE a los cuales se refiere.

Richtlinien-Klasifizierung nach Anhang IX: Klasse I
Directive classification according to annex IX: Class I
Clasificación de la directiva según anexo IX: Clase I

Diese Konformitätserklärung ist gültig bis: **13.11.2021**
This declaration of conformity is valid until:
Esta declaración de conformidad es válida hasta:

Jungingen, 08.11.2020

Gerhard Glufke
Geschäftsführer
Managing Director
Presidente

Artur Pfister
Leiter Qualitätsmanagement
Quality Manager
Directive de calidad

CERTIFICATE

Riester

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

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

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16029-08-00