EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

Rudolf Riester GmbH

Bruckstraße 31, 72417 Jungingen, Germany

Certified location:

Bruckstraße 31, 72417 Jungingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II 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.: 50828-16-06

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

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

84460

Annex to the EC Certificate No. 50828-16-06

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 II b:

Measuring device indicating the oxygen saturation of pulse and non-invasive blood pressure

- ri-vital®

Vital Signs Monitoring

- RVS-100

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

84460

DEKRA

DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

Rudolf Riester GmbH
Mr. Artur Pfister
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72417 Jungingen,

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Date 2024-09-26

Subject: Notified Body Confirmation Letter

Our reference: 50828-CoL-02 Rev.0

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Dear Mr. Pfister

This letter confirms that, DEKRA Certification GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0124 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Rudolf Riester GmbH
Bruckstraße 31
72417 Jungingen
Germany

SRN Number: DE-MF-000006419

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables 1 and 2 below.

Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive MDD. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive MDD.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this

letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Validity of this confirmation letter:

For products included in table 1:

Until the end of applicable transition timelines specified in Article 120.3c of MDR (as amended by (EU) 2023/607)

On behalf of the Notified Body,



i.V. Markus Kopf
2024-09-26

Enclosures:

Confirmation Letter Annex

Annex to Notified Body Confirmation Letter 50828-CoL-02, Rev.0

Table 1

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ri – champion® N	Class IIa	N/A	50828-18-06 0124
RBP-100 /RBP-100 nova	Class IIa	N/A	50828-18-06 0124
ri-thermo® N	Class IIa	N/A	50828-18-06 0124
ri-thermo® N professional	Class IIa	N/A	50828-18-06 0124
ri-gital®	Class IIa	N/A	50828-18-06 0124
Predictive thermometer RPT-100	Class IIa	N/A	50828-18-06 0124
ri-thermo® fastPRObe	Class IIa	N/A	50828-18-06 0124
ri-fox N	Class IIa	N/A	50828-16-06 0124
ri-sonic PCP-1	Class IIa	N/A	50828-18-06 0124
ri-sonic PCP-USB	Class IIa	N/A	50828-18-06 0124
RVS-100	Class IIb	N/A	50828-16-06 0124
minimus	Class I device with a measuring function	N/A	50828-18-06 0124
exacta®	Class I device with a measuring function	N/A	50828-18-06 0124
precisa® N	Class I device with a measuring function	N/A	50828-18-06 0124
precisa® N shock-proof	Class I device with a measuring function	N/A	50828-18-06 0124

sphygmotensiophone	Class I device with a measuring function	N/A	50828-18-06 0124
babyphone®	Class I device with a measuring function	N/A	50828-18-06 0124
big-ben®	Class I device with a measuring function	N/A	50828-18-06 0124
ri-san®	Class I device with a measuring function	N/A	50828-18-06 0124
sanaphon	Class I device with a measuring function	N/A	50828-18-06 0124
R1 shock.proof	Class I device with a measuring function	N/A	50828-18-06 0124
e-mega	Class I device with a measuring function	N/A	50828-18-06 0124
schiötz	Class I device with a measuring function	N/A	50828-18-06 0124