EG ZERTIFIKAT

zum Qualitätssicherungssystem



gemäß Richtlinie 93/42/EWG, Anhang VI

DEKRA Certification GmbH bescheinigt hiermit als Benannte Stelle der Europäischen Union, dass das Unternehmen

Rudolf Riester GmbH

Bruckstraße 31, 72417 Jungingen, Deutschland

Zertifizierter Standort:

Bruckstraße 31, 72417 Jungingen, Deutschland

ein Qualitätssicherungssystem für die in der Anlage genannten Medizinprodukte gemäß Anhang VI der Richtlinie 93/42/EWG anwendet. Diese Genehmigung beruht auf dem Ergebnis des Re-Zertifizierungsaudits Bericht Nr. 50828-Z5-00, dem Entscheid von 2019-11-11 und ist nur in Verbindung mit der erfolgreichen Durchführung der jährlichen Überwachungsaudits gültig.

Dieses Zertifikat ist gültig von 2019-11-14 bis 2024-05-26

Registrier-Nr.: 50828-18-06

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-11-11
Benannte Stelle ID-Nummer: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

84460

Anlage zum Zertifikat Nr. 50828-18-06

gültig von 2019-11-14 bis 2024-05-26

Revisionsstand der Anlage: 4 vom 2021-05-25

In die Genehmigung eingeschlossene Medizinprodukte / Produktkategorien:

Klasse I m:

Für nachfolgend aufgeführte Produkte bezieht sich die Überprüfung des Qualitätssicherungssystems ausschließlich auf die Herstellungsschritte im Zusammenhang mit der Konformität der Produkte mit den messtechnischen Anforderungen.

- Aneroid Blutdruckmessgeräte:
  - minimus®
  - exacta®
  - precisa® N
  - precisa® N shock-proof
  - sphygmotensiophone
  - babyphon®
  - big ben®
  - ri-med®
  - ri-mega®
  - ri-san®
  - sanaphon
  - R1 shock-proof
  - e-mega®

- Augentonometer:
  - schiötz

Anlage zum Zertifikat Nr. 50828-18-06

gültig von 2019-11-14 bis 2024-05-26

Revisionsstand der Anlage: 4 vom 2021-05-25

In die Genehmigung eingeschlossene Medizinprodukte / Produktkategorien:

Klasse II a:

- Digitale Blutdruckmessgeräte:
  - ri-champion® N
  - ri-cardio
  - ri-medic
  - RBP-100 / RBP-100 nova
- Infrarot-Thermometer:
  - ri-thermo® N
  - ri-thermo® N professional
- Digital-Thermometer:
  - ri-gital®
  - Predictive thermometer RPT-100
  - ri-thermo® fastPRObe
- Pulsoximeter:
  - ri-fox N
- Elektronisches Stethoskop:
  - ri-sonic PCP-1
  - ri-sonic PCP-USB

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-05-25
Benannte Stelle ID-Nummer: 0124

DEKRA

DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

Rudolf Riester GmbH
Mr. Artur Pfister
Bruckstraße 31
72417 Jungingen,

Germany

DEKRA Certification GmbH
Handwerkstraße 15
D-70565 Stuttgart

Contact Hagji Gjelaj
Phone -
Fax +49.711.7861-2615
Email hagji.gjelaj

Headquarters
Phone +49.711.7861-2566
Fax +49.711.7861-2615

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