

Anexa nr.46 Tensiometru electronic automat Adult Cod 260760, Ri-champion smart Pro+, Riester, Germania

<i>Specificarea tehnică deplină solicitată, Standarde de referință</i>	<i>Specificarea tehnică deplină oferită, Standarde de referință</i>
Tensiometru electronic automat Adult Cod 260760 Parametrul Specificația Descriere Tensiometru electronic automat destinat măsurării tensiunii arteriale neinvazive Tip portabil, pacient adult Caracterisitici tehnice pompă electrică integrată manșetă integrală din cauciuc tonometrul și manșeta separate tub aer din cauciuc Parametri tehnici limite de măsurare 0 - 300 mm Hg Eroarea nu mai mare de 3 mm Hg Precizia valorilor afișate sistolic ± 3 mmHg diastolic ± 3 mmHg Conectare la PC USB / RC232 / Sdcard / ethernet Memorie internă Stocarea datelor a minim 100 măsurări Alarma sonora Alimentare baterii alcaline, + 220V Accesorii manșetă pentru adulți - 2 buc	Tensiometru electronic automat Adult Cod 260760 Parametrul Specificația Descriere Tensiometru electronic automat destinat măsurării tensiunii arteriale neinvazive Tip portabil, pacient Adult Caracterisitici tehnice pompă electrică integrată manșetă integrală din cauciuc tonometrul și manșeta separate tub aer din cauciuc Parametri tehnici limite de măsurare 0 - 280 mm Hg Eroarea ± 3 mm Hg Precizia valorilor afișate sistolic ± 3 mmHg diastolic ± 3 mmHg Transmiterea de date prin bluetooth Memorie internă Stocarea datelor a minim 400 măsurări Alarma sonora Alimentare baterii alcaline, + 220V Accesorii manșetă pentru adulți - 2 buc

Anexa nr.47 Tensiometru electronic automat Adult pediatric Cod 260770, Ri-champion smart Pro+, Riester, Germania

<i>Specificarea tehnică deplină solicitată, Standarde de referință</i>	<i>Specificarea tehnică deplină oferită, Standarde de referință</i>
Tensiometru electronic automat Pediatric Cod 260770 Parametrul Specificația Descriere Tensiometru electronic automat destinat măsurării tensiunii arteriale neinvazive Tip portabil, pacient pediatric Caracteristici tehnice pompă electrică integrată manșetă integrală din cauciuc tonometrul și manșeta separate tub aer din cauciuc Parametri tehnici limite de măsurare 0 - 280 mm Hg Eroarea nu mai mare de 3 mm Hg Precizia valorilor afișate sistolic ± 3 mmHg diastolic ± 3 mmHg Conectare la PC USB / RC232 / Sdcard / ethernet Memorie internă Stocarea datelor a minim 100 măsurări Alarma sonora Alimentare baterii alcaline, + 220V Accesorii manșetă pentru pediatrie - 2 buc	Tensiometru electronic automat Pediatric Cod 260770 Parametrul Specificația Descriere Tensiometru electronic automat destinat măsurării tensiunii arteriale neinvazive Tip portabil, pacient pediatric Caracteristici tehnice pompă electrică integrată manșetă integrală din cauciuc tonometrul și manșeta separate tub aer din cauciuc Parametri tehnici limite de măsurare 0 - 280 mm Hg Eroarea ± 3 mm Hg Precizia valorilor afișate sistolic ± 3 mmHg diastolic ± 3 mmHg Transmiterea de date prin bluetooth Memorie internă Stocarea datelor a minim 400 măsurări Alarma sonora Alimentare baterii alcaline, + 220V Accesorii manșetă pentru pediatrie - 2 buc

CERTIFICATE



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


Ruth Delbeck-Bayer

DEKRA Certification GmbH, Stuttgart, 2019-11-11

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



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

Ruth Delbeck-Bayer
DEKRA Certification GmbH
Stuttgart, Handwerkstraße 15

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

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

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



Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-11-11
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ri-champion® smartPRO+

Non-invasive, blood pressure Monitor

- › Clinically validated
- › Fast and low noise measurements
- › Irregular heartbeat detection
- › Average BP measurement function
- › 200 measurements with one set of batteries
- › Optional Bluetooth connectivity
- › Optional mains adapter
- › Automatic off function - if left idle for 3 minutes
- › CE / FDA approved
- › IP21 Water protection



The Riester **ri-champion® smartPRO+** Clinically validated blood pressure monitor, designed for fast and reliable readings. Advanced performance by indicating irregular heartbeat detection and average measurement function.

Power Source:	Four 1.5 V AA alkaline batteries
Battery Life:	200 Readings
Size of Meter w/o Cuff:	141 (L) x 121 (W) x 72 (H)mm, 350 g without batteries
Cuff Size:	S (small): 15 - 24 cm (5.9 - 9.4 inches) with air tube 80 cm W (Wide size): 24 - 43 cm (9.4 - 16.9 inches) with air tube 80 cm
Memory:	Maximum 400 memory records
External Output:	Bluetooth (ri-champion® smartPRO+ only) (Frequency: 2.45 GHz, Bandwidth: 170 MHz, Modulation: GFSK, ERP: 3.54 dBm)
Power Saving:	Automatic power off if system idle for 3 minutes
Operating Conditions:	5°C to 40°C (41°F to 104°F), 15 % to 93 % relative humidity, 700 hPa to 1060 hPa
Storage / Transportation Conditions:	-25°C to 70°C (-13°F to 158°F), 10 % to 95 % relative humidity
Power Supply Input:	DC + 6 V / 1 A (max) via Power Plug
IP Classification:	IP21

Heart Rate Range:	40 - 199 beat per minute	This device has been tested to meet the electrical and safety requirements of: IEC/EN 60601-1, IEC/EN 60601-1-2, EN 301 489-17, EN 301 489-1, EN 300 328. Reference to Standards: EN 1060-3, NIBP-requirements IEC60601-1 General requirement for safety IEC60601-1-2 Requirements for EMC EN1060-4, NIBP clinical investigation AAMI / ANSI / IEC 80601-2-30, ANSI/AAMI/ISO 81060-2, NIBP requirements
Systolic Measurement Range:	60 mmHg - 255 mmHg	
Diastolic Measurement Range:	30 mmHg - 195 mmHg	
Pulse Rate Measurement Range:	40 - 199 beats / minute	
Maximum Inflation Pressure:	280 mmHg	
Accuracy of Pressure:	±3 mmHg or ±2% of reading	
Accuracy of Pulse rate:	±4% of reading	
Measurement Unit:	Either mmHg or kPa	

Art. No. 1735-BT	Blood pressure device ri-champion® smartPRO+ with BT and W-cuff
Art. No. 1735	Blood pressure device ri-champion® smartPRO without BT, with W-cuff
Art. No. 1736-BT	Blood pressure device ri-champion® smartPRO+ with BT and S-cuff
Art. No. 1736	Blood pressure device ri-champion® smartPRO without BT, with S-cuff
Art. No. 12633	Cuff size W (24 - 43 cm)
Art. No. 12632	Cuff size S (15 - 24 cm)
Art. No. 12631	AC adaptor