

Nr. KE-2	<p style="text-align: center;">KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY</p> <p style="text-align: center;">Nach Anhang VII in Verbindung mit Anhang VI According to Annex VII in Verbindung mit Anhang VI</p>	
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Rudolf Riester GmbH
Bruckstraße 31, D-72417 Jungingen, Germany
Tel.: (+49) (0)7477-9270-0 Fax: (+49) (0)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

Blutdruckmessgeräte
Sphygmomanometers

Aneroid Blutdruckmessgeräte
Aneroid sphygmomanometers

Artikel-Nr. von: / Article no. from: / **1250-100** Artikel-Nr. bis: / Article no. to / **1527-129**

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.

Richtlinien-Klassifizierung nach Anhang IX: **Klasse I mit Messfunktion**
Directive classification according to annex IX: **Class I with measuring function**

Anhang VI Zertifikat Nr.: / Annex VI Certificate No.: / **50828-18-06**

Benannte Stelle: / Notified Body: / **DEKRA Certification GmbH**
Handwerkstraße 15, D-70565 Stuttgart, Germany

Kennnummer: / Reg. No.: / **CE 0124**

Diese Konformitätserklärung ist gültig bis: **26.05.2024**
This declaration of conformity is valid until:

Die festgestellte Konformität bezieht sich auch auf einzelne Komponenten und Bestandteile des Medizinprodukts, soweit diese vom Hersteller als Zubehör und Ersatzteile (accessories, spare parts bzw. replacement parts) gesondert in den Verkehr gebracht werden.

Zubehörliste siehe Anlage 1 zu dieser Konormitätserklärung.

The established conformity also relates to individual components and parts of the medical device, as far as these are marketed separately by the manufacturer as accessories, spare parts or replacement parts.

List of accessories, see Annex 1 to this Declaration of Conformity.

Jungingen, 20.05.2021



Dr. Dominik Beck
Geschäftsführer
Managing Director
Presidente



Artur Pfister
Leiter Qualitätsmanagement
Quality Manager
Directive de calidad

We declare under our sole responsibility that the Accessories for

Aneroid Blood Pressure Devices

meets all the provisions of the directive 93/42/EEC which apply to it.

Directive classification according Annex IX: **Accessories Class I**
This Annex is valid until: **26.05.2024**

- 101 Bandage cuff adult size 40 x 15 cm, 1 tube, grey
- 102 Bandage cuff adult size 40 x 15 cm, 2 tubes, grey
- 103 Bandage cuff adult size 40 x 15 cm, double tube, grey
- 104 Hook cuff adult size 58 x 16 cm, 1 tube, grey
- 105 Hook cuff adult size 58 x 16 cm, 2 tubes, grey
- 106 Hook cuff adult size 58 x 16 cm, double tube, grey
- 107 Velcro cuff adult size 54.5 x 14.5 cm, 1 tube, black
- 108 Velcro cuff adult size 54.5 x 14.5 cm, 2 tubes, black
- 109 Velcro cuff adult size 54.5 x 14.5 cm, double tube, black
- 120 Velcro cuff small adult size 42 x 13 cm, 1 tube, black
- 121 Velcro cuff small adult size 42 x 13 cm, 2 tubes, black
- 122 Velcro cuff obese size 70 x 15 cm 1 tube, black
- 123 Velcro cuff obese size 70 x 15 cm 2 tubes, black
- 125 Velcro cuff thigh size 70 x 22 cm, 1 tube, black
- 126 Velcro cuff thigh size 70 x 22 cm, 2 tubes, black
- 127 Velcro cuff thigh size 100 x 26 cm, 1 tube, black
- 128 Velcro cuff thigh size XL 100 x 26 cm, 2 tube, black
- 129 Velcro cuff child size 35.5 x 10 cm, 1 tube, blue
- 130 Velcro cuff child size 35.5 x 10 cm, 2 tubes, blue
- 132 Velcro cuff infant size 23 x 7.2 cm, 1 tube, blue
- 133 Velcro cuff infant size, 23 x 7.2 cm, 2 tubes, blue
- 134 Velcro cuff newborn size, 15.5 x 5 cm, 1 tube, blue
- 135 Velcro cuff newborn size, 15.5 x 5 cm, 2 tubes, blue

- 136 Pull through strap velcro cuff adult size 52 x 14.5 cm, 2 tubes, burgundy
- 137 Velcro cuff child size 33 x 10 cm, 2 tubes, burgundy

- 141 Pull through strap velcro cuff adult size 54.5 x 14.5 cm, 1 tube, black
- 142 Pull through strap velcro cuff obese size 70 x 15 cm, 1 tube, black
- 144 Pull through strap velcro cuff child size 35.5 x 10 cm, 1 tube, black

- 150 Disinfectable one-piece cuff, adult size, 54.5 x 14.5 cm, 1-tube, latexfree
- 151 Disinfectable one-piece cuff, adult size, 54.5 x 14.5 cm, 2-tubes, latexfree
- 152 Disinfectable one-piece cuff, obese size, 63x16cm, 1-tube, latexfree
- 153 Disinfectable one-piece cuff, obese size, 63x16cm, 2-tubes, latexfree
- 154 Disinfectable one-piece cuff, child size, 34,5x10cm, 1-tube, latexfree
- 155 Disinfectable one-piece cuff, child size, 34,5x10cm, 2-tubes, latexfree
- 156 Disinfectable one-piece cuff, newborn size, 15x5cm, 1-tube, latex free

157	Disinfectable one-piece cuff, newborn size, 15x5cm, 2-tube, latex free
158	Disinfectable one-piece cuff, infants infant size, 23x7,5cm, 1-tube, latex free
159	Disinfectable one-piece cuff, infant size, 23x7,5cm, 2-tube, latex free
160	Disinfectable one-piece cuff, small adult size, 42x13cm, 1-tube, latex free
161	Disinfectable one-piece cuff, small adult size, 42x13cm, 2-tube, latex free
10363	Air release valve, chrome plated
10357	Bulb latex free, grey for ri-san®
10351	Latex bulb, black
10361	Bulb latex free, black
10358	Bulb latex free, blue
12556	Bulb, black, R1 shock-proof®
10350	Latex bulb with air release valve, Riester
10372	Tube connectors part I short + part II long, chrome plated
10373	Tube connector part II long, chrome plated
10374	Tube connector part I short, chrome plated
10380	Pin connectors part I long+ part II short, grey plastic, for diplomat only
10387	Pin connector part I long, grey plastic for diplomat only
10388	Pin connector part II short, plastic, grey plastic, for diplomat only
12555	Tube connector for R1 shock-proof®
10381	Black latex tube, per meter
10382	Coiled latex tubing, black
10391	Chestpiece, sanaphon, ri-san®, precisa® N
10392	Basket small for mobile stand
10393	Basket big for mobile stand
10385	Mobile stand (base and pipe), Ø 54cm powder coated
10384	Universal metal clamp, for anaesthetic models
11805	Plastic box R1 shock-proof®, e-mega®
10320	Vinyl zipper case, black
10330	Padded nylon zipper case, black