

Nr. KE-715

**KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY**

Nach Artikel 19 MDR
According to Article 19 MDR



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Wir erklären in alleiniger Verantwortung, dass das Medizinprodukt
We declare under our sole responsibility that the medical device

Sphygmomanometers

Accessories for Aneroid sphygmomanometers

Artikel-Nr. von: / Article No. from:

Artikel-Nr. bis: / Article No. to:

allen Anforderungen der Verordnung (EU) 2017/745 entspricht. Das Verfahren gemäß den Vorgaben in Anhang II und Anhang III derselben Verordnung wurde eingehalten.

meets all the provisions of the regulation (EU) 2017/745. The procedure according to Annex II and Annex III of the above mentioned regulation has been followed.

Zweckbestimmung: Zubehör für Aneroid Blutdruckmessgeräte

Intended purpose: Accessories for Aneroid sphygmomanometer

Verordnungs-Klassifizierung nach Anhang VIII:
Regulation classification according to annex VIII:

**Klasse I
Class I**

Basic-UDI-DI:

40453961310M2

Gemeinsame Spezifikationen:
Common specifications:

Keine gemeinsamen Spezifikationen
No common specifications

SRN- Nr.:


DE-MF-000006419

Diese Erklärung ist gültig für ab dem Ausstellungsdatum in Verkehr gebrachter Produkte.
This declaration is effective for products placed on the market as of the date of issue.

Die festgestellte Konformität bezieht sich auch auf einzelne Komponenten und Bestandteile des Medizinprodukts, soweit diese vom Hersteller als Ersatzteile gesondert in den Verkehr gebracht werden.

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 spare parts or replacement parts.

Jungingen, 08.11.2022


Irina Zhdanova

Geschäftsführerin
Managing Director


Artur Pfister

Für die Einhaltung der Regulierungsvorschriften verantwortliche Person
Person responsible for regulatory compliance (PRRC)

We declare under our sole responsibility that the accessories for

Aneroid sphygmomanometers

meets all the provisions of the regulation (EU) 2017/745 on medical devices.

Regulation classification according Annex VIII: **Accessories Class I**

- 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