

Nr. KE-714

**KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY**
Nach Artikel 19 MDR
According to Article 19 MDR



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

Vital Signs Monitor

Accessories for RVS-100

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 RVS-100

Intended purpose: Accessories for RVS-100

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

**Klasse I
Class I**

Basic-UDI-DI:

40453961960-RMBPAX8

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

RVS-100

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

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

1961-RRXXE	RVS-200 NIBP (Riester) + SpO2 (Riester)
1961-RRXXA	RVS-200 NIBP (Riester) + SpO2 (Riester), Australian plug
1961-RRXXG	RVS-200 NIBP (Riester) + SpO2 (Riester), British plug
1961-RRXXU	RVS-200 NIBP (Riester) + SpO2 (Riester), US plug
1961-RRXPE	RVS-200 NIBP (Riester) + SpO2 (Riester) + Printer
1961-RRXPA	RVS-200 NIBP (Riester) + SpO2 (Riester) + Printer, Australian plug
1961-RRXPG	RVS-200 NIBP (Riester) + SpO2 (Riester) + Printer, British plug
1961-RRXPU	RVS-200 NIBP (Riester) + SpO2 (Riester)+ Printer, US plug
1961-RRBXE	RVS-200 NIBP (Riester) + SpO2 (Riester) + Predictive Temperature oral/axillary
1961-RRBXA	RVS-200 NIBP (Riester) + SpO2 (Riester) + Predictive Temperature oral/axillary, Australian plug
1961-RRBXG	RVS-200 NIBP (Riester) + SpO2 (Riester) + Predictive Temperature oral/axillary, British plug
1961-RRBXU	RVS-200 NIBP (Riester) + SpO2 (Riester) + Predictive Temperature oral/axillary, US plug
1961-RRBPE	RVS-200, NIBP (Riester) + SpO2 (Riester) + Predictive Temperature oral/axillary + Printer
1961-RRBPA	RVS-200, NIBP (Riester) + SpO2 (Riester) + Predictive Temperature oral/axillary + Printer, Australian plug
1961-RRBPG	RVS-200, NIBP (Riester) + SpO2 (Riester) + Predictive Temperature oral/axillary + Printer, British plug
1961-RRBPU	RVS-200, NIBP (Riester) + SpO2 (Riester) + Predictive Temperature oral/axillary + Printer, US plug
1961-RNXXE	RVS-200 NIBP (Riester) + SpO2 (Nellcor)
1961-RNXXA	RVS-200 NIBP (Riester) + SpO2 (Nellcor), Australian plug
1961-RNXXG	RVS-200 NIBP (Riester) + SpO2 (Nellcor), British plug
1961-RNXXU	RVS-200 NIBP (Riester) + SpO2 (Nellcor), US plug
1961-RNXPE	RVS-200 NIBP (Riester) + SpO2 (Nellcor) + Printer
1961-RNXPA	RVS-200 NIBP (Riester) + SpO2 (Nellcor) + Printer, Australian plug
1961-RNXPG	RVS-200 NIBP (Riester) + SpO2 (Nellcor) + Printer, British plug
1961-RNXPU	RVS-200 NIBP (Riester) + SpO2 (Nellcor) + Printer, US plug
1961-RNBXE	RVS-200, NIBP (Riester) + SpO2 (Nellcor) + Predictive Temperature oral/axillary
1961-RNBXA	RVS-200, NIBP (Riester) + SpO2 (Nellcor) + Predictive Temperature oral/axillary, Australian plug
1961-RNBXG	RVS-200, NIBP (Riester) + SpO2 (Nellcor) + Predictive Temperature oral/axillary, British plug
1961-RNBXU	RVS-200, NIBP (Riester) + SpO2 (Nellcor) + Predictive Temperature oral/axillary, US plug
1961-RNBPE	RVS-200, NIBP (Riester) + SpO2 (Nellcor) + Predictive Temperature oral/axillary + Printer
1961-RNBPA	RVS-200, NIBP (Riester) + SpO2 (Nellcor) + Predictive Temperature oral/axillary + Printer, Australian plug
1961-RNBPG	RVS-200, NIBP (Riester) + SpO2 (Nellcor) + Predictive Temperature oral/axillary + Printer, Australian plug
1961-RNBPU	RVS-200, NIBP (Riester) + SpO2 (Nellcor) + Predictive Temperature oral/axillary + Printer, US plug
13300	Sensor SpO2 Riester Neonatal for RVS-100
13301	Sensor SpO2 Riester Children for RVS-100
13302	Sensor SpO2 Riester Adults for RVS-100
13303	Sensor SpO2 Nellcor Neonatal for RVS-100
13304	Sensor SpO2 Nellcor Children for RVS-100
13305	Sensor SpO2 Nellcor Adults for RVS-100
13315	Barcode reader
13316	WiFi for RVS-100
13317	Mobile stand with basket for RVS-100
13324	Wall mount basket for RVS-100/200
13333	NIBP extension tube incl. connector
12668	Rectal Probe Filac 3000, length 2,7m
12669	Oral/Axillary Probe Filac 3000, length 2,7m
12688	Single probe covers predictive thermometer (Pack of 500 pcs)
129.006	Velcro cuff 1 tube, children, with NIBP connector for RVS-100/200
13321	Paper roll for printer RVS (pack with 20 pcs.)