

DECLARATION OF CONFORMITY**No. 20191001/1**

According to Directive 93/42/EEC, Annex VII and Annex IV of the Medical Device Regulation 2017/745 of EU Parliament and the Council

Manufacturer:	ROYAX, s.r.o.
Address:	Obchodní 107, Cestlice, 251 01, Czech Republic
Name of Device:	Main Stretcher such as Power Assisted Stretcher Valens RX6, Power Assisted Stretcher Valens RX3, Compact Stretcher, Sarir Stretcher, FERIA Stretcher, Stretcher Tactix, POWER ASSISTED ROLL-IN TROLLEY VALENS RX6 for INCUBATOR PLATFORM, COMPACT ROLL-IN TROLLEY for TACTIX STRETCHER or INCUBATOR PLATFORM
Device Types` Codes:	R-S-RS-VRX-02, R-S-RS-VRX-03, R-S-RS-CMPT-02, R-S-RS-SA-01, R-S-RS-FE-01, R-S-BAS-01, R-S-RS-VRI-01, R-S-RS-CMPT-01
Class of Device:	Class I According to Rule 1 of the Part III (Classification) namely non-invasive device of Annex IX of the EU Community Council Directive 93/42 EEC.

ROYAX, s.r.o. hereby declares that the above specified medical device has been determined as a Class I device according to the requirements of Annex IX of the European Community Council Directive 93/42/EEC and Annex IX of the Medical Device Regulation 2017/745 of EU Parliament and the Council.

ROYAX, s.r.o. further declares that the product complies with the relevant provisions of Directive 93/42/EEC and Annexes of the Medical Device Regulation 2017/745 of EU Parliament and the Council concerning medical devices and as well as the product's conformity with the Essential Requirements in Annex I of the Directive 93/42/EEC.

The product has been designed, developed, manufactured and tested in accordance with all applicable standards mentioned below and by using a quality management system according to DIN EN ISO 13485:2016 for medical devices.

The above mentioned products have met the requirements of the medical device for placing CE marking and ISO 13485:2016 for medical devices.

The current declaration of conformity has been drafted in accordance with the requirements of the Annexes IV and V of the Medical Device Regulation 2017/745 of EU Parliament and the Council.

Standards Applied:

- ISO 13485:2016 Quality management system for medical device
- EN 1789:2007+A1:2010 Medical vehicles and their equipment - Road ambulances
- EN 1865-1:2010-12 Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment (for all kinds of stretchers)
- EN 1865-2:2010-12 Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher (for power assisted stretchers: Valens RX36 and Valens RX3)

ROYAX, s.r.o.

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- EN 1041:2008 information supplied by manufacturer
- EN ISO 15223:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
- EN 14971:2012 Medical devices - Application of risk management to medical devices

In Cestlice, Czech Republic, March 10, 2020

ROYAX s.r.o.

**Royax** Medical
Solution

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