

DECLARATION OF CONFORMITY**No. 20210525/2**

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:	Isothermic Blanket, Manual Suction Pump (MVP), Pen Light, Tourniquet, Bandage Scissors, Forceps, Magill Forceps, Scissors, Tongue Clamp, Reflex Hammer, Ring Cutter, Face Mask, Oxygen Tube, Vento Mask, Resuscitator Bag (Ambu bag)
Device Types` Codes:	R-MEI-IB-01, R-MEI-MS-01, R-MEI-PL-01, R-MEI-TQ-01, R-MEI-SC-02, R-MEI-F-01, R-MEI-MF-01, R-MEI-SC-01, R-MEI-TC-01, R-MEI-RH-01, R-MEI-RC-01, R-MEI-FM-01, R-MEI-OT-01, R-MEI-VM-01, R-MEI-RB-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, May 25, 2021

ROYAX s.r.o.

**Royax** Medical
Solution

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