DECLARATION OF CONFORMITY
No. 20191001/11

CE

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:	Obchodni 107, Cestlice, 251 01, Czech Republic
Name of Device:	CPR Case Class I, CPR Case Class II, CPR Case Class III, Trolley Bag, CPR Case Explorer, Trauma Bag Class I, Trauma Bag Class II, Back Bag, Ampularium, Pouch/Waist Bag
Device Types` Codes:	**R-MB-CPR-01, R-MB-CPR-02, R-MB-CPR-03, R-MB-TB-01, R-MB-E-01, R-MB-T-01, R-MB-T-02, R-MB-BB-01, R-MB-A-01, R-MB-WB-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 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 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.

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