DECLARATION OF CONFORMITY
No. 20191001/8

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:	Splints such as Traction Splints (Adult and pediatric) and Fixin Splint and Vacuum Splints such as Vacuum Splint Arm Multi Chamber, Vacuum Splint Arm Single Chamber, Vacuum Splint Leg Multi Chamber, and Vacuum Splint Leg Single Chamber, Vacuum Splint Ankle Single Chamber
Device Types` Codes:	R-SI-TS-01, R-SI-TS-02, R-SI-FS-01 R-SI-ARMCH-01, R-SI-AROCH-01, R-SI-LMCH-01, R-SI-LOCH-01, R-SI-AOCH
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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