

**DECLARATION OF CONFORMITY****No. 20191001/9**

**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:	Head Immobilizers such as Head Immobilizer Classic, Head Immobilizer EVA and Head Immobilizer Vacuum Cervical collars such as Adjustable Cervical Collar and Rigid Cervical Collar (sizes S,M,L).
Device Types` Codes:	R-SI-HI-01, R-SI-HI-02, R-SI-HI-03 R-SI-CC-01, R-SI-CC-02, R-SI-CC-03, R-SI-CC-04
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 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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