

Runibeda

EU DECLARATION OF CONFORMITY

Manufacturer:	JC „Runibeda“
Code:	305573341
VAT Code	LT100013424612
Address of manufacturer:	Europos pr. 96, LT-46351 Kaunas, Lithuania
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Phone no:	+370 673 54050
Eudamed SRN:	LT-MF-000004853
Basic UDI-ID:	477905279LECTICAX4

Declares on its own responsibility that medical device:

TRANSPORT STRETCHER, LECTICA

Classification 1 class (By Regulation (EU) 2017/745 of the European Parliament and of the Council, Annex VIII rule No.1)

Complies with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices

Complies with the requirements of the common standards of the European Union:

- LST EN 60601-1-6:2010+A1:2015 Medical electrical equipment -- Part 2-52: Particular requirements for basic safety and essential performance of medical beds (EN 60601-2-52:2010+A1:2015)
- LST EN 60601-1-6:2010 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)
- LST EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014)
- LST EN ISO 10993-1:2010 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process — Technical Corrigendum 1(ISO 10993-1:2009)
- LST EN ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
- LST EN ISO 10993-10:2013 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity (ISO 10993-10:2010)
- LST EN 1041:2008+A1:2014 Information supplied by the manufacturer of medical devices
- LST EN ISO 14971:2020 Medical devices. Application of risk management to medical devices (ISO 14971:2020)
- LST EN ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied General requirements (ISO 15223-1:2016)

Also, producer declare, that declaration of conformity and all technical documents of this medical device complies with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices.

On behalf of JC “Runibeda” director Nida Dailidone
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