



For more than 40 years, Novak M has been manufacturing medical products that are distinguished by top-quality materials, innovation combined with expert knowledge and up-to-date technology and industrial design. Medical products are designed in close contact with end-user, making the work of medical staff easier and ensuring comfort and safety to their patients. Novak M products meet all safety requirements and comply with the strict standards.

Stretcher X2 - hydraulic

Standards

- **MDR 2017/745** The product meets the provision of the Regulation (EU) MDR 2017/745 for medical devices, Class I (Annex VIII, Rule 1).

The product was tested by Slovenian Institute of Quality and Metrology and proved to be in compliance with the following standards regarding general and electric safety of medical equipment:

- **EN 60601-1:2006**: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC/EN 60601-1:2006 + A1:2013 + A12:2014, Clause 9)

The product is harmonized with the following standards:

- **EN 1041:2008+A1:2013**: Information supplied by the manufacturer of medical devices
- **EN ISO 9001:2015**: Quality management systems - Requirements (ISO 9001:2015)
- **EN ISO 13485:2016**: Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016)
- **EN ISO 14971:2019**: Medical devices - Application of risk management to medical devices (ISO 14971:2019)
- **EN ISO 15223-1:2017**: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO/DIS 15223-1:2020)
- **EN 62366:2008 + A1:2015**: Medical devices – Application of usability engineering to medical devices

Patents

- **EU patent Nr. EP3496694** Connecting element for a medical bedrail, assembly comprising it and procedure for assembling said assembly: In 2020, safety rails are granted the EU patent (standard equipment on products: Stretcher X, Stretcher X2, Stretcher SL, Day hospital chair ZeroG)
- **US patent Nr. 11110019** Connecting element for a medical bedrail, assembly comprising it and procedure for assembling said assembly: In 2021, safety rails are granted the EU patent (standard equipment on products: Stretcher X, Stretcher X2, Stretcher SL, Day hospital chair ZeroG).

Awards

- **Red Dot**: Stretcher X2 receives Red Dot Design Award in 2022.