



For more than 45 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

The products are classified as Class I medical devices in accordance with Regulation (EU) 2017/745 on medical devices, Annex VIII, Rule 1.

Legislation and applied standards

- **Regulation (EU) 2017/745, MDR:** Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices
- **ZMedPri-1:** Zakon o medicinskih pripomočkih, Uradni list RS, št. 40/25; national legislation laying down the implementation and supervision of requirements for medical devices in the Republic of Slovenia.
- **EN ISO 13485:2016:** Medical devices – Quality management systems –Requirements for regulatory purposes
- **EN ISO 20417:2021:** Information supplied by the manufacturer of medical devices
- **EN ISO 14971:2019:** Medical devices - Application of risk management to medical devices
- **EN ISO 15223-1:2021:** Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- **EN 62366:2008 + A1:2015:** Medical devices - Application of usability engineering to medical devices
- **IEC 60601-1:2005 + A1:2012 + A2:2020:** Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

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.