



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.

Blood donor chair N

Standards

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

The products are 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