For more than 40 years, Novak M has been manufacturing medical products that are distinguished by top-quality materials, innovation combined with 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.

Operating table Y

Standards

- **MDR 2017/745** The products meet the provision of the Regulation (EU) MDR 2017/745 for medical devices, Class I (Annex VIII, Rule 13).

The products were 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 electrical equipment:

- **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)
- **EN 60601-1-6:2010**: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC/EN 60601-1-6:2010+A1:2013)
- **EN 60601-1:2006**: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC/EN 60601-1:2005 + A1:2012)
- **IEC 60601-2-46:2023**: Medical electrical equipment - Particular requirements for the basic safety and essential performance of operating tables
- **Reduction of Hazardous Substances (RoHS)**: European directive (Directive 2011/65/EU) that restricts the use of hazardous substances in electrical and electronic equipment.

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