

Hydraulic examination, massage and therapy tables S

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 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 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 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