

Declaration of Conformity

Company: **ALVO Spółka z ograniczoną odpowiedzialnością Spółka komandytowa**

64-030 Śmigiel, Południowa 21A, Polska,

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We declare under our sole responsibility that:

The medical device: **Operating table**
model: Electromechanical
of class: I, rule 12 according to Annex IX of 93/42/EEC directive

meets all provisions of the directive 93/42/EEC which apply to it, meets all applicable harmonised standards required by the directive 93/42/EEC and meets all additional standards applicable to the product, in particular:

1. **PN-EN 60601-1-2:2007** Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests
2. **EN 60601-1:2006** Medical electrical equipment. General requirements for basic safety and essential performance
3. **EN 61000-4-2:2009** Electromagnetic compatibility (EMC) - Part 4.2: Testing and measurement techniques - Electrostatic discharge immunity test
4. **EN 61000-4-3:2006 + A1:2008+A2:2010** Electromagnetic compatibility (EMC). Testing and measurement techniques. Radiated, radio-frequency, electromagnetic field immunity test
5. **EN 61000-4-4:2012** Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrical fast transient/burst immunity test
6. **EN 61000-4-5:2006** Electromagnetic compatibility (EMC). Testing and measurement techniques. Surge immunity test
7. **EN 61000-4-6:2009** Electromagnetic compatibility (EMC). Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields
8. **EN 61000-4-8:2010** Electromagnetic compatibility (EMC). Testing and measurement techniques. Power frequency magnetic field immunity test

9. **EN 61000-4-11:2004** Electromagnetic compatibility (EMC). Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests
10. **EN 55011:2009** Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement
11. **EN 61000-3-2:2006+A1:2009+A2:2009** Electromagnetic compatibility (EMC). Limits. Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
12. **EN 61000-3-3:2013** Electromagnetic compatibility (EMC). Limits. Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
13. **EN 1041:2008** Information supplied by the manufacturer of medical devices
14. **EN 60601-2-46:1998** Medical electrical equipment -- Part 2-46: Particular requirements for the safety of operating tables
15. **EN ISO 14971:2012** Medical devices - Application of risk management to medical devices
16. **EN ISO 13485:2012**
EN ISO 13485:2012/AC:2012 Medical devices - Quality management systems - Requirements for regulatory purposes
17. **EN 980:2008** Symbols for use in the labelling of medical devices
18. **EN 62366:2008** Medical devices - Application of usability engineering to medical devices

Place and date: Śmigiel 29.03.2016r.

Agata Olszewska

Member of the Board


ALVO®
Spółka z ograniczoną odpowiedzialnością Sp.k.
Agata Olszewska
Członek Zarządu