

EN ISO 14971: 2012 Annex - C.2 Questions

C.2.1. What is the intended use and how is the medical device to be used?

It is a special upper extremity orthosis that generates resistance to patient movements. The aim of ExoRehab X is to support the functional treatment of patients with loss of motion in the upper extremity due to neurological, spine or muscular disorders.

C.2.2. Is the medical device intended to be implanted?

NO

C.2.3. Is the medical device intended to be in contact with the patient or other persons?

Yes. The patient is attached to the product via Orthopedic Bandages.

C.2.4. What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?

Steel, aluminium, plastic and Orthopedic Bandages.

C.2.5. Is energy delivered to or extracted from the patient?

NO

C.2.6. Are substances delivered to or extracted from the patient?

NO

C.2.7. Are biological materials processed by the medical device for subsequent re-use transfusion or transplantation?

NO

C.2.8. Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?

NO

C.2.9. Is the medical device intended to be routinely cleaned and disinfected by the user?

NO

C.2.10. Is the medical device intended to modify the patient environment?

NO

C.2.11. Are measurements taken?

Position sensor data are collected to measure patient performance. However, the measurements are not intended for clinical evaluation of the patient, but rather for informatory/advisory purposes

C.2.12. Is the medical device interpretative?

NO

C.2.13. Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?

NO

C.2.14. Are there unwanted outputs of energy or substances?

NO

C.2.15. Is the medical device susceptible to environmental influences?

NO

C.2.16. Does the medical device influence the environment?

NO

C.2.17. Are there essential consumables or accessories associated with the medical device?

NO

C.2.18. Is maintenance or calibration necessary?

A maintenance every 3 months is suggested for longer lifetime of the product.

C.2.19. Does the medical device contain software?

No. Although, the device itself contains the position sensors, the information display is handled via an optional Software on the users' electronic device (medical PC or Laptop) the device itself doesn't contain software and doesn't depend on a software for use.

C.2.20. Does the medical device have a restricted shelf-life?

NO

C.2.21. Are there any delayed or long-term use effects?

NO

C.2.22. To what mechanical forces will the medical device be subjected?

Bending and torsional forces.

C.2.23. What determines the lifetime of the medical device?

Depends on a) how closely the user follows the suggested usage,
b) the frequency of maintenance

C.2.24. Is the medical device intended for single use?

NO

C.2.25. Is safe decommissioning or disposal of the medical device necessary?

NO

C.2.26. Does installation or use of the medical device require special training or special skills?

NO

C.2.27. How will information for safe use be provided?

Through users manuals and informative videos and technical support.

C.2.28. Will new manufacturing processes need to be established or introduced?

NO

C.2.29. Is successful application of the medical device critically dependent on human factors such as the user interface?

NO

C.2.29.1. Can the user interface design features contribute to use mistake?

NO

C.2.29.2. Is the medical device used in an environment where distractions can cause use mistake?

NO

C.2.29.3. Does the medical device have connecting parts or accessories?

YES

C.2.29.4. Does the medical device have a control interface?

No. The device is not controlled via any software. There is an optional software that runs on users' electronic device (medical PC or Laptop), and it only visualizes the collected data

C.2.29.5. Does the medical device display information?

No. Although, the device itself contains the position sensors, the information display is handled via an optional Software on the users' electronic device (medical PC or Laptop).

C.2.29.6. Is the medical device controlled by a menu?

NO

C.2.29.7. Will the medical device be used by persons with special needs?

NO

C.2.29.8. Can the user interface be used to initiate user actions?

NO

C.2.30. Does the medical device use an alarm system?

NO

C.2.31. In what way(s) might the medical device be deliberately misused?

N/A

C.2.32. Does the medical device hold data critical to patient care?

NO

C.2.33. Is the medical device intended to be mobile or portable?

Yes

C.2.34. Does the use of the medical device depend on essential performance?

NO