

# ISO/TR 24971:2020 (E)

## Medical devices — Guidance on the application of ISO 14971

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**Annex A (informative) Identification of hazards and characteristics related to safety**

- A.1 General
- A.2 Questions
  - A.2.1 What is the intended use and how is the medical device to be used?
  - A.2.2 Is the medical device intended to be implanted?
  - A.2.3 Is the medical device intended to be in contact with the patient or other persons?
  - A.2.4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?
  - A.2.5 Is energy delivered to or extracted from the patient?
  - A.2.6 Are substances delivered to or extracted from the patient?
  - A.2.7 Are biological materials processed by the medical device for subsequent reuse, transfusion or transplantation?
  - A.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?
  - A.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user?
  - A.2.10 Does the medical device modify the patient environment?
  - A.2.11 Are measurements taken?
  - A.2.12 Is the medical device interpretative?
  - A.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?
  - A.2.14 Are there unwanted outputs of energy or substances?
  - A.2.15 Is the medical device susceptible to environmental influences?
  - A.2.16 Does the medical device influence the environment?
  - A.2.17 Does the medical device require consumables or accessories?
  - A.2.18 Is maintenance or calibration necessary?
  - A.2.19 Does the medical device contain software?
  - A.2.20 Does the medical device allow access to information?
  - A.2.21 Does the medical device store data critical to patient care?
  - A.2.22 Does the medical device have a restricted shelf life?
  - A.2.23 Are there any delayed or long-term use effects?
  - A.2.24 To what mechanical forces will the medical device be subjected?
  - A.2.25 What determines the lifetime of the medical device?
  - A.2.26 Is the medical device intended for single use?
  - A.2.27 Is safe decommissioning or disposal of the medical device necessary?
  - A.2.28 Does installation or use of the medical device require special training or special skills?
  - A.2.29 How will information for safety be provided?
  - A.2.30 Are new manufacturing processes established or introduced?
  - A.2.31 Is successful application of the medical device dependent on the usability of the user interface?

- A.2.31.1 Can the user interface design features contribute to use error?
- A.2.31.2 Is the medical device used in an environment where distractions can cause use error?
- A.2.31.3 Does the medical device have connecting parts or accessories?
- A.2.31.4 Does the medical device have a control interface?
- A.2.31.5 Does the medical device display information?
- A.2.31.6 Is the medical device controlled by a menu?
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