ISO/TR 24971:2020 (E)

Medical devices — Guidance on the application of ISO 14971

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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?
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A.2.22 Does the medical device have a restricted shelf life?
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