

ISO/TR 24971 Ed.2  
Medical devices — Guidance on the application of ISO 14971

< Overview >

ISO/TR 24971 Ed.2 is the guidance document for ISO 14971 Ed.3, which contains examples and applications from the annexes of ISO 14971 Ed.2 and adds annexes for new technological fields such as security.

< Technical Committee >

Joint Working Group 1 (JWG1) of ISO/TC 210 and IEC/SC 62A.

< Main Points >

- It follows the same clause structure as ISO 14971 Ed.3 and provides guidance on its application.
- The sections on examples and applications from the annex of ISO 14971 Ed.2 have been moved to and included in ISO/TR 24971 Ed.2.
- A new Annex F has been added to provide guidance on risks related to security.

< Publication History >

- The revision project was approved on August 21, 2017. Following extensive deliberation by JWG1 and after two Committee Drafts (CD), a Draft Technical Report (DTR) was prepared on May 10, 2019 and approved on July 6, 2019.
- Comments on the DTR were reviewed and resolved at the London meeting in 2019. The final draft was compiled in November 2019 and submitted to the ISO Central Office. It was subsequently published on June 16, 2020, after editorial corrections were made in coordination with the ISO Central Office.

< PMDA Involvement >

Attendance at international conferences, teleconferences, and domestic committees.