

ISO 10993-1 Ed.6

Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process

< Overview >

ISO 10993-1 Ed.6 provides the basic principles that are important for evaluating the biological safety of medical devices in non-clinical test. The recent revision includes significant changes to the document titles, document structure, and the correspondence table for contact categories and biological effects to be evaluated.

< Technical Committee >

ISO/TC 194/WG 1

< Main Points >

- This document has been completely reorganised and the title has been aligned with the risk management framework described in ISO 14971.
- Additional content has been added to provide more guidance and clarification of calculation of exposure duration.
- Additional content has been added to provide more guidance on characterization of the device and identification of biological hazards.
- The identification of biological effects (previously referred to as biological end points) has been modified.
- The term "externally communicating" has been replaced by language which reflects the specific tissue contact of device components.
- The term "effects after implantation" has been changed to "local effects after tissue contact" as some nonimplanted devices also will need this type of assessment.
- Annex A has been revised to only provide guidance on materials characterization, the rest of its former content has been incorporated into the main text.
- Annex B has been added to explain the rationale for the changes to biological effects to be evaluated.

< Publication History >

- A New Work Item Proposal (NWIP) was established, kicking off the review of the 2018 version in August 2021.
- A Committee Draft (CD) was prepared in July 2023.
- A Draft International Standard (DIS) was developed in April 2024.

- A Final Draft International Standard (FDIS) was prepared in February 2025, with publication anticipated within fiscal year 2025.

<PMDA Involvement>

Attendance at international conferences, teleconferences, and domestic committees.