

ISO 10993-10 Ed.4

Biological evaluation of medical devices — Tests for skin sensitization

< Overview >

ISO 10993-10 Ed.4 is a specification for skin sensitization testing of biological safety. It includes the exaggerated extraction method using organic solvents proposed by Japan. In the process of the revision from Ed.3 to Ed.4, the description of the irritation test was transferred from ISO 10993-10 to ISO 10993-23.

< Technical Committee >

ISO/TC 194/ WG 8

< Main Points >

- In ISO 10993-10 Ed.4, the irritation testing portion was moved from ISO 10993-10 Ed.3 to ISO 10993-23, making this standard specific to sensitization testing.
- For future adoption of alternative sensitization test methods, multiple alternative test methods have been included as Annex C (informative).
- The "exaggerated extraction method using organic solvents" proposed by Japan is included.

< Publication History >

- ISO 10993-10 Ed.1 published in 1995.
- ISO 10993-10 Ed.2 published in 2002, with Amendment 1 in 2006.
- ISO 10993-10 Ed.3 published in August 2010.
- ISO 10993-10 Ed.4 published in July 2021.

< PMDA Involvement >

Attendance at international and domestic committee meetings.