

ISO 10993-23 Ed.1

Biological evaluation of medical devices — Tests for irritation

< Overview >

ISO 10993-23 Ed.1 is a specification for irritation testing of biological safety. It includes *in vitro* irritation tests using three-dimensional skin models. ISO 10993-23 Ed.1 was prepared by separating sections on irritation testing from ISO 10993-10 Ed.3.

< Technical Committee >

ISO/TC 194/WG 8.

< Main Points >

- ISO 10993-23 Ed.1 was created by separating the irritation testing section from ISO 10993-10 Ed.3.
- An *in vitro* irritation test using a three-dimensional skin model has been included, based on the results of an Inter-laboratory Test (ILT) by members of ISO/TC194/WG8.

< Publication History >

- ISO 10993-23 Ed.1 was published in January 2021.

< PMDA Involvement >

Attendance at international and domestic committee meetings.