ISO 10993-18 Ed.2

Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process

＜Overview＞

ISO 10993-18 Ed.2 provides the concept of evaluation of biological safety by chemical characterization. In addition to introducing specific analysis methods, this revision presents the concept of risk assessment.

＜Technical Committee＞

ISO/TC 194/WG 14

＜Main Points＞

- Enhanced alignment with ISO 10993-1, ISO 10993-12, and ISO 10993-17.
- Inclusion of a flowchart for the chemical characterization process.
- Emphasis on the explanation that analytical testing is not always mandatory.
- Addition of new definitions for terms such as medical device configuration, materials of construction, and material composition.
- Clarification of testing approaches specific to chemical characterization, including digestion and dissolution for hazard identification.
- Addition of considerations regarding the qualification of analytical methods.
- Inclusion of Annexes covering general principles, solvent extraction considerations, and the analytical evaluation threshold (AET), which is the concentration threshold below which identification of extractables or leachables is not required.

＜Publication History＞

- Following the establishment of the New Work Item Proposal (NWIP) for ISO 10993-1 in December 2014, ISO 10993-18 was established as a new project in May 2015 to serve as a supporting document.
- The Committee Draft (CD) document was registered in March 2017. After a second draft was created, the Draft International Standard (DIS) was registered in June 2018.
- The Final Draft International Standard (FDIS) was registered in March 2019 and published in January 2020.

＜PMDA Involvement＞

Attendance at international conferences, teleconferences, and domestic committee meetings.