

Technical Information Report

AAMI/ISO TIR10993-19: 2020

Biological evaluation of medical devices—
Part 19: Physico-chemical, morphological and
topographical characterization of materials

Biological evaluation of medical devices—Part 19: Physico-chemical, morphological and topographical characterization of materials

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Abstract: This document provides a compilation of parameters and test methods that can be useful for the identification and evaluation of the physical, i.e. physico-chemical, morphological and topographical (PMT) properties of materials in finished medical devices. Such an assessment is limited to those properties that are relevant to biological evaluation and the medical device's intended use (clinical application and duration of use) even if such properties overlap with clinical effectiveness.

Keywords: biological evaluation of medical devices, physico-chemical, morphological, topological

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Committee representation

Association for the Advancement of Medical Instrumentation

Biological Evaluation Working Group 14—Material Characterization

The adoption of ISO/TS 10993-19 as an AAMI Technical Information Report was initiated by the AAMI/BE/WG14, Material Characterization working group. AAMI/BE/WG14 provides input to the AAMI Biological Evaluation committee which is the responsible group for providing the U.S. input to ISO/TC 194. U.S. representatives from AAMI/BE/WG14 and the TAG played an active part in developing the ISO document.

At the time this document was published, the **AAMI/BE/WG14** had the following members:

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Background of AAMI adoption of ISO/TS 10993-19:2020

As indicated in the foreword to the main body of this document (page viii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this technical specification, which was developed by ISO/TC 194/WG14 to provide a compilation of parameters and test methods that can be useful for the identification and evaluation of the physical, i.e. physico-chemical, morphological and topographical (PMT) properties of materials in finished medical devices.

U.S. participation in ISO/TC 194 is organized through the U.S. Technical Advisory Group, AAMI Biological Evaluation committee, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

AAMI/ISO TIR10993-19 was registered by the American National Standards Institute (ANSI) on 4 February 2024.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication. AAMI procedures require that technical information reports are reviewed every three years.

AAMI (and ANSI) have adopted other ISO standards and technical reports.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the recommended practice. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited.

“May” is used to indicate that a course of action is permissible within the limits of the recommended practice. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

NOTE Users of this technical information report are advised that this document is an AAMI identical adoption of an ISO document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

The concepts incorporated in this technical information report should not be considered inflexible or static. This document, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE—Beginning with the ISO foreword on page viii AAMI/ISO TIR10993-19:2020, *Biological evaluation of medical devices—Part 19: Physico-chemical, morphological and topographical characterization of materials* is identical to ISO/TS 10993-19:2020.
