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**Biological evaluation of medical  
devices —**

Part 19:  
**Physico-chemical, morphological and  
topographical characterization of  
materials**

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## Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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This document was prepared by Technical Committee ISO/TC 194, *Biological and clinical evaluation of medical devices*.

This second edition cancels and replaces the first edition (ISO 10993-19:2006), which has been technically revised. The main changes compared to the previous edition are as follows:

- errors identified in the revision and commenting processes have been corrected;
- Table 1 (on methodology abbreviations) has been updated and moved to [Annex A](#);
- Table 2 (on examples of relevant methodologies and parameters) has been updated, moved to [Annex A](#) and split into two tables: one listing typical methods, and one listing other methods (i.e. those that are rarely used);
- pointers to ISO 10993-18:2020, Annex C have been added to [5.3](#) and [Annex A](#), where material equivalence is discussed.
- pointers to ISO/TR 10993-22 for information on nanomaterials have been added to [5.3](#) and Table A.3.

A list of all parts in the ISO 10993 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).