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Biological evaluation of medical devices —

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

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Contents

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).

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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.

Introduction

ISO 14971 highlights the importance of taking into account the nature of the materials within a biological risk analysis.

ISO 10993-1 is to serve as a framework in which to plan a biological evaluation which, as scientific knowledge advances human understanding of the basic mechanisms of tissue responses, minimizes the number and exposure of test animals by giving preference to chemical constituent testing and *in vitro* models. In situations where these methods yield equally relevant information to that obtained from *in vivo* models, ISO 10993-1 states that, when selecting the materials to be used for device manufacture, fitness for purpose with regards to characteristics and properties of the material, which include chemical, toxicological, physical, electrical, morphological and mechanical properties, will be the first consideration. The identification and evaluation of the physico-chemical, morphological and topographical properties of materials used in a finished medical device are important in determining the biological evaluation of that device and its materials. Such information can be used in:

— assessing the overall biological evaluation of a medical device according to ISO 10993;

— screening of potential new materials and/or processes for suitability in a medical device for a proposed clinical application.

The compositional characteristics of the materials of manufacture are mainly under the control of the suppliers of these materials. However, other characteristics are chiefly influenced by the requirements to be met by the finished medical device as well as the production processes used by the medical device manufacturer.