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BSI Standards Publication

Biological evaluation of medical devices

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

bsi.

National foreword

This Published Document is the UK implementation of ISO/TS 10993-19:2020. It supersedes DD ISO/TS 10993-19:2006, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/194, Biological evaluation of medical devices.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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.

Biological evaluation of medical devices —

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

1 Scope

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.

This document does neither address the identification or quantification of degradation products nor the evaluation of the physico-chemical properties of the degraded materials, which are covered in ISO 10993-9, ISO 10993-13, ISO 10993-14 and ISO 10993-15.

Chemical characterization of materials is covered by ISO 10993-18.

The ISO 10993 series is not applicable when the material or device is not in contact with the body directly or indirectly.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-18, *Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10993-1, ISO 10993-18 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
physico-chemical
relating to the physical chemistry (of materials)

3.2
morphological
relating to the shape, contours and microstructural organization (of materials)