INTERNATIONAL STANDARD

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Biological evaluation of medical devices —

Part 18: Chemical characterization of materials

Évaluation biologique des dispositifs médicaux —

Partie 18: Caractérisation chimique des matériaux

Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10993-18 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

ISO 10993 consists of the following parts, under the general title *Biological evaluation of medical devices*:

— *Part 1: Evaluation and testing*

— *Part 2: Animal welfare requirements*

— *Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

— *Part 4: Selection of tests for interactions with blood*

— *Part 5: Tests for in vitro cytotoxicity*

— *Part 6: Tests for local effects after implantation*

— *Part 7: Ethylene oxide sterilization residuals*

— *Part 9: Framework for identification and quantification of potential degradation products*

— *Part 10: Tests for irritation and delayed-type hypersensitivity*

— *Part 11: Tests for systemic toxicity*

— *Part 12: Sample preparation and reference materials*

— *Part 13: Identification and quantification of degradation products from polymeric medical devices*

— *Part 14: Identification and quantification of degradation products from ceramics*

— *Part 15: Identification and quantification of degradation products from metals and alloys*

— *Part 16: Toxicokinetic study design for degradation products and leachables*

— *Part 17: Establishment of allowable limits for leachable substances*

— *Part 18: Chemical characterization of materials*

The following parts are under preparation:

— *Part 19: Physico-chemical, mechanical and morphological characterization*

— *Part 20: Principles and methods for immunotoxicology testing of medical devices*

Future parts will deal with other relevant aspects of biological testing.

For the purposes of this part of ISO 10993, the CEN annex regarding fulfilment of European Council Directives has been removed.

Introduction

ISO 10993-1 provides a framework for a structured programme of assessment for the evaluation of biological safety. Clause 3 of ISO 10993-1:2003 states that in the selection of materials to be used for device manufacture the first consideration should be fitness for purpose. This should have regard to the characteristics and properties of the material, which include chemical, toxicological, physical, electrical, morphological and mechanical properties. This information is necessary prior to any biological evaluation. Subclause 7.2 of ISO 10993-1:2003 notes that the continuing acceptability of a biological evaluation is an aspect of a quality management system.

Also ISO 14971 points out that a toxicological risk analysis should take account of the chemical nature of the materials.

The requirements specified in this document are intended to yield the following information, which will be of value in predicting the biological response of the materials:

— The chemical composition of the materials used in the manufacturing process including processing additives and residues e.g. trace chemicals, cleaning, disinfection and testing agents, acids and caustic substances.

— The characterization of materials to be used in the production of medical devices, as well as in devices in their final form.

— Identification of the materials of construction of the medical device.

— The potential of medical device materials to release substances or breakdown products due to the manufacturing process.

— Changes in the materials of construction, which result from changes in the manufacturing process or insufficient control of the manufacturing process.

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 processes used by the medical device manufacturer.

Biological evaluation of medical devices —

Part 18:
Chemical characterization of materials

1 Scope

This part of ISO 10993 describes a framework for the identification of a material and the identification and quantification of its chemical constituents. The chemical characterization information generated can be used for a range of important applications, for example:

— As part of an assessment of the overall biological safety of a medical device (ISO 10993-1 and 14971).

— Measurement of the level of a leachable substance in a medical device in order to allow the assessment of compliance with the allowable limit derived for that substance from health based risk assessment (ISO 10993-17).

— Judging equivalence of a proposed material to a clinically established material.

— Judging equivalence of a final device to a prototype device to check the relevance of data on the latter to be used to support the assessment of the former.

— Screening of potential new materials for suitability in a medical device for a proposed clinical application.

This part of ISO 10993 does not address the identification or quantification of degradation products, which is covered in ISO 10993-9, ISO 10993-13, ISO 10993-14 and ISO 10993-15.

The ISO 10993 series of standards is applicable when the material or device comes into contact with the body directly or indirectly (see 4.2.1 of ISO 10993-1:2003).

This part of ISO 10993 is intended for suppliers of materials and manufacturers of medical devices, when carrying out a biological safety assessment.

2 Normative references

The following referenced documents are indispensable for the application 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 10993-1:2003, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

ISO 10993-17, *Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances*

ISO 14971:2000, *Medical devices — Application of risk management to medical devices*