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ISO 10993-12:2021, IDT
(ICS 11.100.20)

SINGAPORE STANDARD

Biological evaluation of medical devices

– Part 12 : Sample preparation and reference materials

Singapore Standards Council

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The content of this Singapore Standard was approved on 1 April 2021 by the Biomedical and Health Standards Committee (BHSC) under the purview of the Singapore Standards Council.

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The Technical Committee set up the National Mirror Working Group for ISO/TC 194 to prepare this standard. The Working Group consists of the following experts who contribute in their *individual capacity*:

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Denova Sciences Pte Ltd
Edwards Lifesciences (Singapore) Pte Ltd
Emcero Pte Ltd
Health Sciences Authority

Nanyang Technological University
National University of Singapore
Osteopore International Pte Ltd
*Wise Consultants and Services Pte Lt*d

Contents Page

National Foreword

This Singapore Standard was prepared by the National Mirror Working Group for ISO/TC 194 set up by the Technical Committee on Medical Devices under the purview of BHSC.

It is a revision of SS ISO 10993-12 : 2017 "Biological evaluation of medical devices – Sample preparation and reference materials".

This standard is an identical adoption of ISO 10993-12:2021, "Biological evaluation of medical devices – Part 12: Sample preparation and reference materials", including its Amendment, published by the International Organization for Standardization.

NOTE – Where numerical values are expressed as decimals, the comma is read as a full point.

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

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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 206, *Biological and clinical evaluation of medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fifth edition cancels and replaces the fourth edition (ISO 10993-12:2012), which has been technically revised.

The main changes compared to the previous edition are as follows:

— change of scope to cover extractions only for biological evaluation tests;

— harmonization of definitions with ISO 10993-18;

— revision of 10.3.1 extraction condition table and Annex D regarding exhaustive extraction.

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

It is important that sample preparation methods be appropriate for both the biological evaluation methods and the materials being evaluated. Each biological test method requires the selection of materials, extraction solvents and conditions.

This document is based on existing national and international standards and regulations, wherever possible.

Biological evaluation of medical devices — Part 12: Sample preparation and reference materials

1 Scope

This document specifies requirements and gives guidance on the procedures in the preparation of samples and the selection of reference materials for medical device testing primarily in biological test systems primarily in accordance with one or more parts of the ISO 10993 series.

Specifically, this document addresses the following:

— test sample selection;

— selection of representative portions from a medical device;

— test sample preparation;

— experimental controls;

— selection of, and requirements for, reference materials;

— preparation of extracts.

This document is not applicable to live cells but can be relevant to the material or medical device components of combination products containing live cells.

Extractions for chemical characterization are covered in ISO 10993-18. Clause 7, 8, 9, 10 [with the exception of 10.3.5 and 10.3.11 b)], and 11 can apply to extractions for chemical characterization. Information given in C.1 to C.4 can also be relevant.

2 Normative references

There are no normative references in this document.