



# **MALAYSIAN STANDARD**

**MS ISO 10993-10:2013**

**Biological evaluation of medical devices -  
Part 10: Tests for irritation and skin  
sensitization  
(ISO 10993-10:2010, IDT)**

**ICS: 11.100.20**

Descriptors: medical devices, biological evaluation, tests, irritation, skin sensitization

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# MS ISO 10993-10:2013

## Committee representation

The Industry Standards Committee on Medical Devices and Facilities for Healthcare (ISC R) under whose authority this Malaysian Standard was adopted, comprises representatives from the following organisations:

Association of Malaysia Medical Industries  
Atomic Energy Licensing Board  
Biomedical Engineering Association Malaysia  
Department of Standards Malaysia  
Federation of Malaysian Manufacturers  
Institute for Medical Research  
Malaysia Medical Device Association  
Malaysian Association of Standards Users  
Malaysian Medical Association  
Malaysian Nuclear Agency  
Malaysian Organisation of Pharmaceutical Industries  
Malaysian Rubber Board  
Malaysian Rubber Export Promotion Council  
Medical Device Authority  
Ministry of Health Malaysia  
Ministry of International Trade and Industry  
Pharmaceutical Association of Malaysia  
Radiation Physics, Biophysics and Medical Physics Sub-Group of Institute of Physics Malaysia  
SIRIM Berhad (Secretariat)  
SIRIM QAS International Sdn Bhd  
Universiti Kebangsaan Malaysia  
Universiti Teknologi Malaysia

The Technical Committee on Clinical Laboratory Testing and In Vitro Diagnostic Test Systems which recommended the adoption of the ISO Standard as Malaysian Standard consists of representatives from the following organisations:

Association of Private Hospitals of Malaysia  
Department of Standards Malaysia  
Institute for Medical Research  
Institute of Quality Malaysia  
Malaysia Institute of Medical Laboratory Sciences  
Malaysia Medical Device Association  
Malaysian Association of Clinical Biochemists  
Malaysian Association of Private Medical Laboratories  
Malaysian Society of Infectious Diseases and Chemotherapy  
Medical Device Authority  
SIRIM Berhad (Secretariat)  
The College of Pathologists, Academy of Medicine Malaysia  
Universiti Kebangsaan Malaysia  
Universiti Kebangsaan Malaysia (Makmal Bioserasi)  
Universiti Sains Malaysia

## National foreword

The adoption of the ISO Standard as a Malaysian Standard was recommended by the Technical Committee on Clinical Laboratory Testing and In Vitro Diagnostic Test Systems under the authority of the Industry Standards Committee on Medical Devices and Facilities for Healthcare.

This Malaysian Standard is identical with ISO 10993-10:2010, *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*, published by the International Organization for Standardization (ISO). However, for the purposes of this Malaysian Standard, the following apply:

- a) in the source text, "this International Standard" should read "this Malaysian Standard";
- b) the comma which is used as a decimal sign (if any), to read as a point; and
- c) reference to International Standards should be replaced by corresponding Malaysian Standards as follows:

### Referenced International Standards

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

ISO 10993-2, *Biological evaluation of medical devices - Part 2: Animal welfare requirements*

ISO 10993-9, *Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products*

ISO 10993-12, *Biological evaluation of medical devices - Part 12: Sample preparation and reference materials*

ISO 10993-13, *Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices*

ISO 10993-14 *Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics*

ISO 10993-15, *Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys*

### Corresponding Malaysian Standards

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

MS ISO 10993-2, *Biological evaluation of medical devices - Part 2: Animal welfare requirements*

MS ISO 10993-9, *Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products*

MS ISO 10993-12, *Biological evaluation of medical devices - Part 12: Sample preparation and reference materials*

MS ISO 10993-13, *Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices*

MS ISO 10993-14 *Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics*

MS ISO 10993-15, *Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys*

## MS ISO 10993-10:2013

### National foreword (continued)

#### Referenced International Standards

#### Corresponding Malaysian Standards

ISO 10993-18, *Biological evaluation of medical devices - Part 18: Chemical characterization of materials*

MS ISO 10993-18, *Biological evaluation of medical devices - Part 18: Chemical characterization of materials*

ISO 14155-1\*, *Clinical investigation of medical devices for human subjects - Part 1: General requirements*

MS ISO 14155-1, *Clinical investigation of medical devices for human subjects - Good clinical practice*

ISO 14155-2\*, *Clinical investigation of medical devices for human subjects - Part 2: Clinical investigation plans*

MS ISO 14155-1, *Clinical investigation of medical devices for human subjects - Good clinical practice*

Compliance with a Malaysian Standard does not of itself confer immunity from legal obligations.

NOTE. IDT on the front cover indicates an identical standard i.e. a standard where the technical content, structure, and wording (or is an identical translation) of a Malaysian Standard is exactly the same as in an International Standard or is identical in technical content and structure although it may contain the minimal editorial changes specified in clause 4.2 of ISO/IEC Guide 21-1.

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\* These Standards have been superseded by ISO 1455:2011

## 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 10993-10 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

This third edition cancels and replaces the second edition (ISO 10993-10:2002), which has been technically revised.

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

- *Part 1: Evaluation and testing within a risk management process*
- *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 skin sensitization*
- *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*
- *Part 19: Physico-chemical, morphological and topographical characterization of materials* [Technical Specification]
- *Part 20: Principles and methods for immunotoxicology testing of medical devices* [Technical Specification]

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