MALAYSIAN STANDARD

MS ISO 10993-5:2013

Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009, IDT)

ICS: 11.100.20

Descriptors: medical devices, biological evaluation, tests, in vitro, cytotoxicity

DEPARTMENT OF STANDARDS MALAYSIA

DEVELOPMENT OF MALAYSIAN STANDARDS

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Technical corrigendum: A corrected reprint of the current edition which is issued to correct either a technical error or ambiguity in a Malaysian Standard inadvertently introduced either in drafting or in printing and which could lead to incorrect or unsafe application of the publication.

NOTE: Technical corrigenda are not to correct errors which can be assumed to have no consequences in the application of the MS, for example minor printing errors.

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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 10993-5:2009, *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*, 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	Corresponding Malaysian Standards
ISO 10993-1, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system*	MS ISO 10993-1, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system*
ISO 10993-12, *Biological evaluation of medical devices - Part 12: Sample preparation and reference materials*	MS ISO 10993-12, *Biological evaluation of medical devices - Part 12: Sample preparation and reference materials*

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.

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 10993-5 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

This third edition cancels and replaces the second edition (ISO 10993-5:1999) 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]