MALAYSIAN STANDARD

MS ISO 11737-2:2011

Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009, IDT)

ICS: 07.100.10; 11.080.01

Descriptors: medical device, sterilization, requirements, microbiological method, tests, sterility, definition, validation, maintenance

DEPARTMENT OF STANDARDS MALAYSIA

DEVELOPMENT OF MALAYSIAN STANDARDS

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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
Ministry of Health Malaysia
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 Quality Management and Corresponding General Aspects for Medical Devices which recommended the adoption of the ISO Standard as Malaysian Standard consists of representatives from the following organisations:

Association of Private Hospitals of Malaysia

Biomedical Engineering Association Malaysia

Federation of Malaysian Manufacturers

Institute of Quality Malaysia

Malaysia Medical Device Association

Malaysian Medical Association

Malaysian Nuclear Agency

Malaysian Rubber Export Promotion Council

Malaysian Rubber Glove Manufacturers' Association

Ministry of Health Malaysia

Ministry of Health Malaysia (Medical Device Bureau)

SIRIM Berhad (Secretariat)

SIRIM QAS International Sdn Bhd

SterilGamma (M) Sdn Bhd

NATIONAL FOREWORD

The adoption of the ISO Standard as a Malaysian Standard was recommended by the Technical Committee on Quality Management and Corresponding General Aspects for Medical Devices under the authority of the Industry Standards Committee on Medical Devices and Facilities for Healthcare.

This Malaysian Standard is identical with ISO 11737-2:2009, *Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*, 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 10012, *Measurement management systems - Requirements for measurement processes and measuring equipment*	MS ISO 10012, *Measurement management systems - Requirements for measurement processes and measuring equipment*
ISO 11737-1:2006, *Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products*	MS ISO 11737-1:2010, *Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products*
ISO 13485:2003, *Medical devices - Quality management systems - Requirements for regulatory purposes*	ISO 13485:2006, *Medical devices - Quality management systems - Requirements for regulatory purposes*
ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*	ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

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 11737-2 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11737-2:1998) which has been technically revised.

ISO 11737 consists of the following parts, under the general title *Sterilization of medical devices — Microbiological methods*:

— *Part 1: Determination of a population of microorganisms on products*

— *Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*