



MALAYSIAN STANDARD

MS ISO 11607-2:2009
(CONFIRMED:2015)

Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (First revision) (ISO 11607-2:2006, IDT)

ISO 11607-2:2006 is endorsed as Malaysian Standard with the reference number MS ISO 11607-2:2009.

ICS: 11.080.30

Descriptors: sterilized packaging, sterilization and disinfection, sterilized medical devices, validation requirements

NOTE. This Malaysian Standard has been reviewed and confirmed as being current.

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DEPARTMENT OF STANDARDS MALAYSIA

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Confirmed MS: A Malaysian Standard that has been reviewed by the responsible committee and confirmed that its contents are current.

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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.

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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 Malaysian Medical Industries
Association of Private Hospitals of Malaysia
Biomedical Engineering Association Malaysia
Department of Standards Malaysia
Federation of Malaysian Manufacturers
Institute for Medical Research
Lembaga Perlesenan Tenaga Atom
Malaysia Medical Device Association
Malaysian Association of Standards Users
Malaysian Medical Association
Malaysian Nuclear Agency
Malaysian Organization of Pharmaceutical Industry
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 (Faculty of Allied Health Sciences)
Universiti Teknologi Malaysia (Faculty of Science)

The Technical Committee on Disposable 'Single-use' Devices which recommended the adoption of the ISO Standard consists of representatives from the following organisations:

Academy of Medicine of Malaysia
Association of Malaysian Medical Industries
Clinical Research Centre
Institute for Medical Research
Institute Quality Malaysia
Malaysia Medical Device Association
Malaysian Medical Association
Malaysian Nuclear Agency
Malaysian Rubber Board
Malaysian Sterile Service Association
Ministry of Health Malaysia
Ministry of Health Malaysia (Medical Device Bureau)
SIRIM Berhad (Secretariat)

MS ISO 11607-2:2009

NATIONAL FOREWORD

The adoption of the ISO Standard as a Malaysian Standard was recommended by the Technical Committee on Disposable 'Single-use' Devices under the authority of the Industry Standards Committee on Medical Devices and Facilities for Healthcare.

This Malaysian Standard is the first revision of the following Malaysian Standards:

MS 1927: Part 1, *Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods*;

MS 1927: Part 2, *Packaging materials and systems for medical devices which are to be sterilized - Part 2: Sterilization wrap - Requirements and test methods*;

MS 1927: Part 3, *Packaging materials and systems for medical devices which are to be sterilized - Part 3: Paper for use in the manufacture of paper bags and in the manufacture of pouches and reels - Requirements and test methods*;

MS 1927: Part 4, *Packaging materials and systems for medical devices which are to be sterilized - Part 4: Paper bags - Requirements and test methods*;

MS 1927: Part 5, *Packaging materials and systems for medical devices which are to be sterilized - Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction - Requirements and test methods*;

MS 1927: Part 6, *Packaging materials and systems for medical devices which are to be sterilized - Part 6: Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation - Requirements and test methods*;

MS 1927: Part 7, *Packaging materials and systems for medical devices which are to be sterilized - Part 7: Adhesive coated paper for the manufacture of heat sealable packs for medical use for sterilization by ethylene oxide or irradiation - Requirements and test methods*;

MS 1927: Part 8, *Packaging materials and systems for medical devices which are to be sterilized - Part 8: Re-usable sterilization containers for steam sterilizers - Requirements and test methods*.

This Malaysian Standard is identical with ISO 11607-2:2006, *Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes*, 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 equivalent Malaysian Standards as follows:

NATIONAL FOREWORD *(continued)*

Referenced International Standards

Corresponding Malaysian Standards

ISO 11607-1, *Packing for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*

MS ISO 11607-1, *Packing for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*

This Malaysian Standard cancels and replaces MS 1927: Part 1:2007, MS 1927: Part 2:2007, MS 1927: Part 3:2007, MS 1927: Part 4:2007, MS 1927: Part 5:2007, MS 1927: Part 6:2007, MS 1927: Part 7:2007 and MS 1927: Part 8:2007.

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, 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.