



MS ISO GUIDE 35:2008

MALAYSIAN STANDARD

REFERENCE MATERIALS - GENERAL AND STATISTICAL PRINCIPLES FOR CERTIFICATION (ISO GUIDE 35:2006, IDT)

ISO GUIDE 35:2006 is endorsed as Malaysian Standard with the reference number MS ISO GUIDE 35:2008.

ICS: 71.040.30

Descriptors: reference materials, general, statistical principles, certification

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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
Atomic Energy Licensing Board
Biomedical Engineering Association Malaysia
Department of Standards Malaysia
Federation of Malaysian Manufacturers
Institute for Medical Research
Malaysian Association of Standards Users
Malaysian Medical Association
Malaysian Medical Devices Association
Malaysian Nuclear Agency
Malaysian Organization of Pharmaceutical Industry
Malaysian Rubber Board
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Universiti Kebangsaan Malaysia (Faculty of Allied Health Sciences)
Universiti Teknologi Malaysia (Faculty of Science)

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

Academy of Medicine of Malaysia (The College of Pathologists)

Association of Private Hospitals of Malaysia

Institute for Medical Research

Institute of Quality Malaysia

Malaysia Institute of Medical Laboratory Sciences

Malaysian Association of Clinical Biochemists

Malaysian Association of Private Medical Laboratories

Malaysian Medical Devices Association

Malaysian Society of Infectious Diseases and Chemotherapy

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Universiti Sains Malaysia (School of Health Sciences)

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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 GUIDE 35:2006, *Reference materials - General and statistical principles for certification*, 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:

<u>Referenced International Standards</u>	<u>Corresponding Malaysian Standards</u>
ISO 3534-1, <i>Statistics - Vocabulary and symbols - Part 1: Probability and general statistical terms</i>	MS ISO 3534-1, <i>Statistics - Vocabulary and symbols - Part 1: Probability and general statistical terms</i>

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.