MALAYSIAN STANDARD

MS ISO 18113-2:2010 (CONFIRMED:2015)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009, IDT)

Preview Only

ICS: 11.100.10

Descriptors: medical device, in vitro diagnostic, information supplied by the manufacturer, labelling, reagents

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

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DEPARTMENT OF STANDARDS MALAYSIA

DEVELOPMENT OF MALAYSIAN STANDARDS

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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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Department of Standards Malaysia
Ministry of Science, Technology and Innovation
Level 1 & 2, Block 2300, Century Square
Jalan Usahawan
63000 Cyberjaya
Selangor Darul Ehsan
MALAYSIA

Tel: 60 3 8318 0002
Fax: 60 3 8319 3131
http://www.jsm.gov.my
E-mail: central@jsm.gov.my

OR

SIRIM Berhad
(Company No. 367474 - V)
1, Persiaran Dato' Menteri
Section 2, P. O. Box 7035
40700 Shah Alam
Selangor Darul Ehsan
MALAYSIA

Tel: 60 3 5544 6000
Fax: 60 3 5510 8095
http://www.sirim.my
E-mail: msonline@sirim.my

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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
Ministry of Health Malaysia (Medical Device Bureau)
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
SIRIM Berhad (Secretariat)
The College of Pathologists, Academy of Medicine Malaysia
Universiti Kebangsaan Malaysia
Universiti Sains Malaysia

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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 18113-2:2009, *In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use*, 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 8601, *Data elements and interchange formats - Information interchange - Representation of dates and times*	MS ISO 8601, *Data elements and interchange formats - Information interchange - Representation of dates and times*
ISO 14971, *Medical devices - Application of risk management to medical devices*	MS ISO 14971, *Medical devices - Application of risk management to medical devices*
ISO 15223-1, *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements*	MS ISO 15223-1, *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements*
ISO 18113-1, *In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements*	MS ISO 18113-1, *In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements*

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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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 18113-2 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*.

ISO 18113 consists of the following parts, under the general title In vitro *diagnostic medical devices — Information supplied by the manufacturer (labelling)*:

— *Part 1: Terms, definitions and general requirements*

— *Part 2:* In vitro *diagnostic reagents for professional use*

— *Part 3*: In vitro *diagnostic instruments for professional use*

— *Part 4:* In vitro *diagnostic reagents for self-testing*

— *Part 5:* In vitro *diagnostic instruments for self-testing*

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