MALAYSIAN STANDARD

MS ISO 15189:2022

Medical laboratories – Requirements for quality and competence
(Third revision)
(ISO 15189:2022, IDT)
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ICS: 03.120.10; 11.100.01

Descriptors: medical laboratories, particular requirements, quality, competence

DEPARTMENT OF STANDARDS MALAYSIA

DEVELOPMENT OF MALAYSIAN STANDARDS

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Committee representation

The National Standards Committee on Medical Devices and Facilities for Healthcare (NSC 18) under whose authority this Malaysian Standard was adopted, comprises representatives from the following organisations;

Albukhary International University
Association of Malaysian Medical Industries
Biomedical Engineering Association Malaysia
Department of Atomic Energy
Department of Standards Malaysia (Secretariat)
Federation of Malaysian Manufacturers
Malaysia Nuclear Agency
Malaysia Medical Device Association
Malaysia Medical Device Manufacturers Association
Malaysian Medical Association
Malaysian Investment Development Authority
Malaysian Organisation of Pharmaceutical Industries
Malaysian Rubber Board
Malaysian Rubber Council
Medical Device Authority
Ministry of International Trade and Industry
Universiti Kebangsaan Malaysia
Universiti Teknologi Malaysia
SIRIM QAS International Sdn Bhd

The Technical Committee on Clinical Laboratory Testing and In Vitro Diagnostic Test Systems (NSC 18/TC 7) which supervised this Malaysian Standard consists of representatives from the following organisations:

Academy of Medicine Malaysia (College of Pathologists)
Association of Private Hospitals of Malaysia
Department of Standards Malaysia
Department of Standards Malaysia (Secretariat)
Institution for Medical Research
Malaysia Medical Device Association
Malaysian Association of Clinical Biochemists
Malaysian Association of Private Medical Laboratories
Malaysian Biosafety and Biosecurity Association
Malaysian Institute of Medical Laboratory Sciences
Malaysian Society of Infectious Diseases and Chemotherapy
Medical Device Authority
Universiti Kebangsaan 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 (NSC 18/TC 7) under the authority of the National Standards Committee on Medical Devices and Facilities for Healthcare (NSC 18).

This third edition of MS ISO 15189 cancels and replaces MS ISO 15189:2014, *Medical laboratories - Requirements for quality and competence*.

This document is identical with ISO 15189:2022, *Medical laboratories – Requirements for quality and competence*, published by the International Organization for Standardization (ISO). However, for the purpose of this document, the following by apply:

a) in the source text, “this International Standard” should read “this Malaysian Standard”;

b) the comma which is used as decimal sign (if any), to read as a point;

c) reference to International Standards should be replaced by corresponding Malaysian Standards as follows:

Referenced International Standards	Correponding Malaysian Standards
ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*	MS ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*
ISO 9000:2015, *Quality management systems - Fundamentals and vocabulary*	MS ISO 9000:2015, *Quality management systems - Fundamentals and vocabulary*
ISO 9001:2015, *Quality management systems - Requirements*	MS ISO 9001:2015, *Quality management systems - Requirements*
ISO 15190, *Medical laboratories - Requirements for safety*	MS ISO 15190, *Medical laboratories - Requirements for safety*
ISO 15194, *In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation*	MS ISO 15194, *In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation*
ISO 15198:2004, *Clinical laboratory medicine - In vitro diagnostic medical devices - Validation of user quality control procedures by the manufacturer*	MS ISO 15198:2008, *Clinical laboratory medicine - In vitro diagnostic medical devices - Validation of user quality control procedures by the manufacturer*
ISO/IEC 17011, *Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies*	MS ISO/IEC 17011, *Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies*