

MEDICAL DEVICE GUIDANCE DOCUMENT

IN-VITRO DIAGNOSTIC (IVD) MEDICAL DEVICE CLASSIFICATION SYSTEM



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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

- a) Medical Device Act 2012 (Act 737); and
- b) Medical Device Regulations 2012.

In this Guidance Document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission; and
- “can” indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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Introduction

In Vitro Diagnostic Classification system for product or device has been developed to encourage and support global convergence of regulatory systems. It is intended for use by Medical Device Authority (MDA), Conformity Assessment Bodies and manufacturers. The IVD classification system also will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health. This document is prepared based on GHTF harmonized document on IVD medical device classification system.

IN-VITRO DIAGNOSTIC (IVD) MEDICAL DEVICE CLASSIFICATION SYSTEM

1 Purpose

This guidance document may assist a manufacturer to allocate its IVD medical devices into appropriate risk class according to GHTF classification system, based on IVD medical device intended use and classification principles.

2 Scope

Guidance document on classification applies to all devices or products that fall in the definition of IVD medical device.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 Accessories (IVD)

- a) be used together with an IVD medical device to enable that device to be used in accordance with its intended use as an IVD medical device;
- b) or to augment or extend the capabilities of that device in fulfilment of its intended use as an IVD medical device;
- c) and therefore should be considered an IVD medical device demonstration of the analytical performance characteristics supporting the intended use of the IVD medical device.

3.2 IVD medical device for self-testing

Any IVD medical device intended by the manufacturer for use by lay persons.

3.3 Examination

Set of operations having the object of determining the value of a property.

Note: In the IVD medical device industry and in many laboratories that use IVD medical devices, examination of an analyte in a biological sample is commonly referred to as a test, assay or analysis.

3.4 Harm

Physical injury or damage to the health of people or damage to property or the environment.

3.5 Hazard

Potential source of harm.

3.6 Risk

Combination of the probability of occurrence of harm and the severity of that harm.

3.7 Intended use / purpose

The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

3.8 Instrument

Equipment or apparatus intended by the manufacturer to be used as an IVD medical device.

3.9 IVD medical device

Refer to MDA/GD/0006: Definition of Medical Device.

3.10 Reagent

Chemical, biological or immunological components, solutions or preparations intended by the manufacturer to be used as IVD medical devices.

3.11 Lay person

Individual that does not have formal training in a relevant field or discipline.

3.12 Near patient / point of care testing (testing)

Testing performed outside a laboratory environment by a healthcare professional not necessarily a laboratory professional, generally near to, or at the side of, the patient.

3.13 Self-testing

Testing performed by lay persons.

3.14 Specimen receptacle

A device, whether vacuum-type or not, specifically intended by its manufacturer for the primary containment of specimens derived from the human body.

3.15 Transmissible agent

An agent capable of being transmitted to a person, as a communicable, infectious or contagious disease.

3.16 Transmission

The spread of disease to a person.

3.17 Manufacturers

a) person who is responsible for-

- i) the design, production, fabrication, assembly, processing, packaging and labelling of a medical device whether or not it is the person, or subcontractor acting on the person's behalf, who carries out these operations; and
- ii) assigning to the finished medical device under his own name, its intended purpose and ensuring the finished product meets the regulatory requirements; or

b) any other person who-

- i) assembles, packages, processes, fully refurbishes, reprocesses or labels one or more ready-made medical device; and
- ii) assigning to the ready-made medical device under his own name, its intended purpose and ensuring the finished product meets the regulatory requirement,

but shall not include the following person-

- (A) any person who assembles or adapts medical devices in the market that are intended for individual patients; and
- (B) any person who assembles, packages or adapts medical devices in relation to which assembling, packaging or adaptation does not change the purpose intended for the medical devices.

4 General principles

Regulatory controls are intended to safeguard the health and safety of patients, users and other persons by ensuring that manufacturers of IVD devices follow specified procedures during design, manufacture and marketing. The risk presented by a particular device depends substantially on its intended use. The Essential Principles of Safety and Performance of medical devices also applies to IVD devices.

Regulatory controls shall be proportional to the level of risk associated with a medical device. The level of regulatory control shall increase with increasing degree of risk, taking account of the benefits offered by use of the device. The imposition of regulatory controls should not place an unnecessary burden on regulators or manufacturers.

4.1 Classification for IVD medical device

4.1.1 The IVD medical device classification system is based on the following criteria-

- a) the intended use and indications for use as specified by the manufacturer (including but not limited to specific disorder, populations, condition or risk factor for which the test is intended);
- b) the technical / scientific / medical expertise of the intended user (lay person or healthcare professional);
- c) the importance of the information to the diagnosis (sole determinant or one of several), taking into consideration the natural history of the disease or disorder including presenting signs and symptoms which may guide a physician;
- d) the impact of the result (true or false) to the individual and / or to public health.

5 General classification system for IVD medical devices

5.1 A four class system is adopted. There are four classes of IVD medical devices namely CLASS A, B, C and D.

Table 1: indicates the four risk classes of IVD medical devices.

The examples given are for illustration only and the manufacturer must apply the classification rules to each IVD medical device according to its intended use.

Table 1. General classification system for IVD medical devices

CLASS	RISK LEVEL	DEVICE EXAMPLES
A	Low Individual Risk and Low Public Health Risk	Clinical Chemistry Analyser, Prepared Selective Culture Media
B	Moderate Individual Risk and/or Low Public Health Risk	Vitamin B12, Pregnancy Self-Testing, Anti-Nuclear Antibody, Urine Test Strips
C	High Individual Risk and/or Moderate Public Health Risk	Blood Glucose Self-Testing, HLA Typing. PSA Screening, Rubella
D	High Individual Risk and High Public Health Risk	HIV Blood Donor Screening, HIV Blood Diagnostic

5.2 Figure 1: shows a conceptual illustration of increasing levels of regulatory requirements as the device class increases.

These may include, for example-

- a) operation of a quality system, for all devices;
- b) documentation of clinical evidence to support the manufacturer's specified intended use;
- c) the need for technical data;
- d) product testing using in-house or independent resources;
- e) the need for and frequency of independent external audit of the manufacturer's quality system; and
- f) independent external review of the manufacturer's technical data.

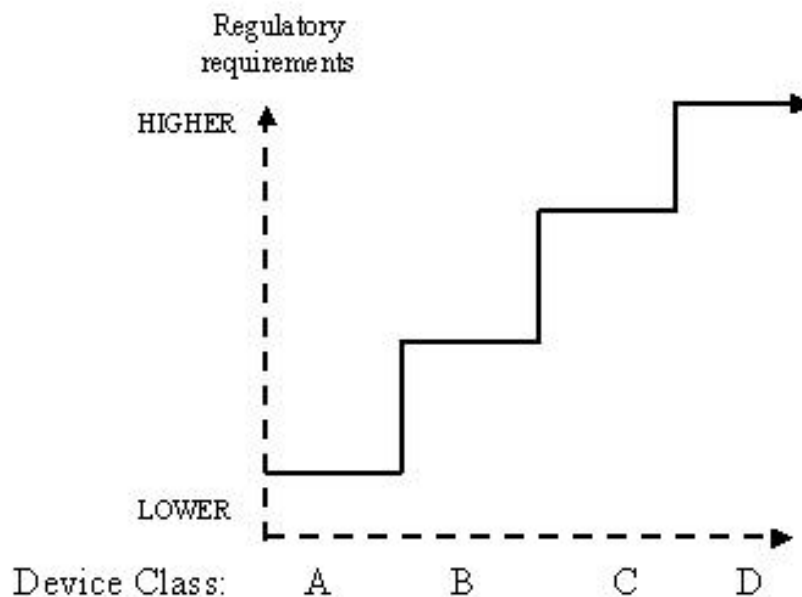


Figure 1. Conceptual illustration of regulatory requirements increasing with device risk class

6 Determination of device class using rules-based system

6.1 The manufacturer shall-

- a) decide if the product concerned is an IVD Medical Device based on the intended use and the indications for use using the definition in this document;

- b) take into consideration all the rules as listed in the Classification Rules in order to establish the proper classification for the device. Where an IVD Medical Device has multiple intended uses as specified by the manufacturer, which places the device into more than one class, it will be classified in the higher class;
- c) where more than one of the classification rules applies to the IVD medical device, it should be allocated to the highest class indicated, e.g. a self-testing for HIV would be a class D under rule 1 and not a class C under rule 4;
- d) apply any special rules that may be imposed by MDA resulting in a device class other than that suggested by the present rules, then a different conformity assessment procedure may be indicated. This may have an effect on the acceptability of such devices for free movement in a global context unless other, or additional, conformity assessment procedures are carried out. For example, where such special rules result in the lower classification of a particular IVD medical device than that indicated in the rules indicated below, and as a consequence, a less vigorous conformity assessment procedure is carried out, this may be unacceptable to other jurisdictions.

7 Classification rules

7.1 There are seven classification's rules of IVD medical device-

RULE 1 - IVD Medical Devices intended for the following purposes are classified as Class D:

- a) Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, cells, tissues or organs in order to assess their suitability for transfusion or transplantation; or
- b) Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening often incurable disease with a high risk of propagation.

Rationale: Devices in this Class are intended to be used to ensure the safety of blood and blood components for transfusion and / or cells, tissues and organs for transplantation. In most cases, the result of the test is the major determinant as to whether the donation/product will be used. Serious diseases are those that result in death or long-term disability, that are often incurable or require major therapeutic interventions and where an accurate diagnosis is vital to mitigate the public health impact of the condition.

Examples: Tests to detect infection by HIV, HCV, HBV, HTLV. Pyrogenicity tests (Endotoxin Activity Assay) marketed for detection of bacterial contamination of blood components. This Rule applies to all types of assays, such as first-line assays, confirmatory assays and supplemental assays.

RULE 2 - IVD medical devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation, are classified as Class C, except for ABO system [A (ABO1), B (ABO2), AB (ABO3)], rhesus system [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)], Kell system [Kel1 (K)], Kidd system [JK1 (Jka), JK2 (Jkb)] and Duffy system [FY1 (Fya), FY2 (Fyb)] determinations which are classified as Class D.

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: A high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation places the device into Class D. The rule divides blood grouping devices into two subsets, Class C or D, depending on the nature of the blood group antigen the IVD medical device is designed to detect, and its importance in a transfusion setting.

Examples: HLA, Duffy System (other Duffy systems except those listed in the rule as Class D are in Class C).

RULE 3 - IVD medical devices are classified as Class C if they are intended for use:

- a) in detecting the presence of, or exposure to, a sexually transmitted agent. Examples: Sexually transmitted diseases, such as *Chlamydia trachomatis*, *Neisseria gonorrhoeae*;
- b) in detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation. Examples: *Neisseria meningitidis* or *Cryptococcus neoformans*;
- c) in detecting the presence of an infectious agent where there is a significant risk that an erroneous result would cause death or severe disability to the individual or fetus being tested. Examples: diagnostic assay for CMV, *Chlamydia pneumoniae*, Methicillin Resistant *Staphylococcus aureus*;
- d) in pre-natal screening of women in order to determine their immune status towards transmissible agents. Examples: Immune status tests for Rubella or Toxoplasmosis;
- e) in determining infective disease status or immune status, and where there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient. Examples: Enteroviruses, CMV and HSV in transplant patients;
- f) in screening for selection of patients for selective therapy and management, or for or for disease staging, or in the diagnosis of cancer. Example: personalized medicine;

NOTE: those IVD medical devices where the therapy decision would usually be made only after further investigation and those used for monitoring would fall into class B under rule 6.

- g) in human genetic testing. Examples: Huntington's Disease, Cystic Fibrosis;
- h) to monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient. Examples: Cardiac markers, Cyclosporin, Prothrombin time testing;
- i) In the management of patients suffering from a life-threatening infectious disease. Examples: HCV viral load, HIV Viral Load and HIV and HCV geno- and subtyping;
- j) In screening for congenital disorders in the fetus. Examples: Spina Bifida or Down Syndrome.

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: Devices in this Class present a moderate public health risk, or a high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation,

or would have a major negative impact on outcome. The devices provide the critical, or sole, determinant for the correct diagnosis. They may also present a high individual risk because of the stress and anxiety resulting from the information and the nature of the possible follow-up measures.

RULE 4 - IVD medical devices intended for self-testing are classified as Class C, except those devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test in which case they are Class B.

IVD medical devices intended for blood gases and blood glucose determinations for near-patient testing would be Class C. Other IVD medical devices that are intended for near-patient should be classified in their own right using the classification rules.

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: In general, these devices are used by individuals with no technical expertise and thus the labeling and instructions for use are critical to the proper outcome of the test.

Example for self-testing class C: Blood glucose monitoring;

Example for self-testing class B: Pregnancy self-test, Fertility testing, Urine test-strips.

RULE 5 - The following IVD medical devices are classified as Class A

- a) reagents or other articles which possess specific characteristics, intended by the manufacturer to make them suitable for in vitro diagnostic procedures related to a specific examination;
- b) instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures;
- c) specimen receptacles.

Note: Any product for general laboratory use not manufactured, sold or represented for use in specified in vitro diagnostic applications are not deemed to be IVD medical devices, as defined in this document. However, in certain jurisdictions products for general laboratory use are considered to be IVD medical devices.

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: These devices present a low individual risk and no or minimal public health risk.

Examples: Selective / differential microbiological media (excluding the dehydrated powders which are considered not to be a finished IVD medical device), identification kits for cultured microorganisms, wash solutions, instruments and plain urine cup.

Note 1: In certain jurisdictions there may be differences as to whether a device classified in this rule is considered an IVD medical device.

Note 2: The performance of software or an instrument that is specifically required to perform a particular test will be assessed at the same time as the test kit.

Note 3: The interdependence of the instrument and the test methodology prevents the instrument from being assessed separately, even though the instrument itself is still classified as Class A.

RULE 6 - IVD medical devices not covered in Rules 1 through 5 are classified as Class B.

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: These devices present a moderate individual risk as they are not likely to lead to an erroneous result that would cause death or severe disability, have a major negative impact on patient outcome or put the individual in immediate danger. The devices give results that are usually one of several determinants. If the test result is the sole determinant however other information is available, such as presenting signs and symptoms or other clinical information which may guide a physician, such that classification into Class B may be justified. Other appropriate controls may also be in place to validate the results. This Class also includes those devices that present a low public health risk because they detect infectious agents that are not easily propagated in a population.

Examples: Blood gases, *H. pylori* and physiological markers such as hormones, vitamins, enzymes, metabolic markers, specific IgE assays and celiac disease markers.

RULE 7 - IVD medical devices that are controls without a quantitative or qualitative assigned value will be classified as Class B.

Rationale: For such controls, the qualitative or quantitative value is assigned by the user and not the manufacturer.

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