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MEDICAL DEVICE GUIDANCE DOCUMENT

IN-VITRO DIAGNOSTIC (IVD) MEDICAL DEVICE CLASSIFICATION SYSTEM

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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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 incident 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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IN-VITRO DIAGNOSTIC (IVD) MEDICAL DEVICE CLASSIFICATION SYSTEM

1 Introduction

In Vitro Diagnostic Classification system 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.

2 Scope and application

This document provides guidance on the risk classification system for IVD medical devices.

It applies to all devices or products that fall within the definition of IVD medical devices in the Guidance Document: The Definition of Medical Device (MDA/GD/0006).

3 Normative references

The following normative references are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the normative reference (including any amendments) applies.

a) Medical Device Act 2012 (Act 737)

b) Medical Device Regulations 2012

4 Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations under it and the following terms and definitions apply.

4.1 accessories (IVD)

For the purposes of this guidance document, an accessory is an article that is intended specifically by its manufacturer to:

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; or

b) augment or extend the capabilities of that device in fulfilment of its intended use as an IVD medical device;

and therefore should be considered an IVD medical device demonstration of the analytical performance characteristics supporting the intended use of the IVD medical device.

4.2 examination

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

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.

4.3 harm

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

4.4 hazard

Potential source of harm.

4.5 IVD medical device

In vitro diagnostic tests are used for in vitro examination of specimens derived from the human body to provide information for screening, diagnosis, or treatment monitoring purposes.

Includes any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination with any other reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, that is intended by its manufacturer to be used in vitro for the examination of any specimen, including any blood or tissue donation, derived from the human body, solely or principally for the purpose of providing information:-

a) concerning a physiological or pathological state or a congenital abnormality

b) to determine the safety and compatibility of any blood or tissue donation with a potential recipient thereof; or

c) to monitor therapeutic measures; and includes a specimen receptacle.

4.6 intended use/ purpose

As defined in Medical Device Regulations 2012.

4.7 instrument

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

4.8 IVD analyser

IVD analysers are equipment intended to be used with IVD reagents so as to allow the IVD reagents to achieve their intended use.

Note. Devices which produce an analytical result from an applied sample by performing functions beyond the mere analytical reading of a generated signal, such as performed by a simple spectrophotometer, gamma counter, luminometer, fluorometer, etc. The analysers can be further divided into the following three types:

a) Closed-System Analyzer

An analyser that is intended by its manufacturer to be used only in combination with the reagents that it also provides. Closed-system analysers may be batch analysers, random-access analysers or the newer multichannel batch analysers. In many cases, closed-system analysers give the user no programming capabilities other than data management and no access to the assay protocol(s).

b) Open- System Analyzer

An analyser that is manufactured with general purpose features for use only with secondary reagents. Secondary reagents are reagents produced for use with specific analysers by other suppliers. Secondary reagents may be marketed and labelled for one specific analyser or may claim multiple analysers. Most open-system analysers give the user programming capabilities for inputting preferred assay protocols. An example would be an automated microplate analyser that can be adapted by the user to commercially available microplate test kits.

c) Partially-Closed-System Analyzer

An analyser that is intended by its manufacturer to be used both in combination with the reagents that it provides, or with secondary reagents for the analysis of analytes for which the manufacturer does or does not provide reagents. In the latter case, the analyser serves as a general-purpose analyser in an open system.

4.9 IVD Examination

In-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. Examples are reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

4.10 IVD medical device for self-testing

A medical device intended by the manufacturer to be able to be used by lay persons in a non-clinical environment.

4.11 lay person

Any individual who does not have formal training in a relevant field or discipline.

4.12 manufacturer

As defined in Section 2 of Act 737.

4.13 near patient testing/ point of care testing (POCT)

Any testing performed outside a laboratory environment by a health care professional not necessarily a laboratory professional, generally near to, or at the side of, the patient.

4.14 reagent

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

4.15 risk

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

4.16 specimen

A discrete portion of a body fluid or tissue, or of any other sample associated with a human body, which is taken for:-

a) examination;

b) study; or

c) analysis of one or more quantities or characteristics, in order to determine the character of the whole.

4.17 specimen receptacle

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

Specimen containers intended for use in self-testing, evacuated or non-evacuated blood collection tubes and specimen containers intended for the collection of urine, faeces, cells or tissue specimens for subsequent in vitro examination.

4.18 test kit

An IVD that consist of a reagents or articles or any combination of these, and that is intended to be used to conduct a specific test or assay.

4.19 test or an assay

Test or an assay refers to an analysis to determine the presence, absence or quantity of a specific chemical or substance.

4.20 transmissible agent

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

4.21 transmission

The conveyance of disease to a person.

5 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.

5.1 Classification for IVD medical device

5.1.1 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; and

d) the impact of the result (true or false) to the individual and/ or to public health.

6 General classification system for IVD medical devices

6.1 There are four classes of IVD medical devices namely CLASS A, B, C and D. Table 1 below indicates the four risk classes of IVD medical devices.

The examples given are for illustration only and the manufacturer shall 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 (non-exhaustive list)
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.

6.2 **Figure 1** below 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;

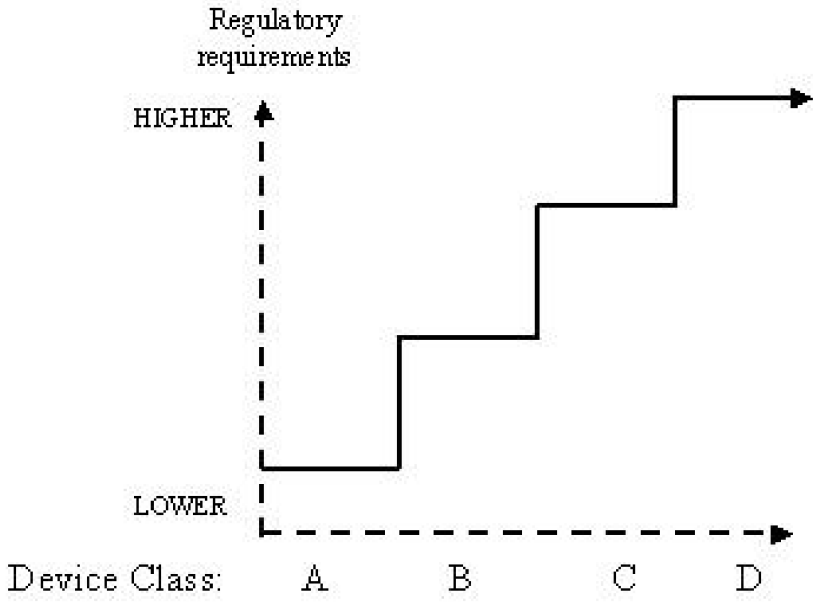
c) the need for technical data;

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



7 Determination of device class using rules-based system

7.1 The manufacturer shall-

a) decide if the product concerned is an IVD Medical Device based on the intended use and 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.

8 Classification rules

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

8.1 RULE 1 - Detection of transmissible agents that cause life-threatening disease and pose a high public health risk

8.1.1 Rule 1 IVD Medical Devices intended for the following purposes are classified as Class D:

a) IVD medical devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, tissues or organs to assess their suitability for transfusion or transplantation.

b) IVD medical devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or suspected high risk of propagation.

8.1.2 Rationale: Rule 1 is presented in two parts:

Rule 1 (a) This rule applies to all assays intended to be used to ensure the safety of blood, blood components, blood products, cells, tissues and organs intended for transfusion or transplantation with regard to transmissible agents.

In most cases, the result of the test is the major determinant as to whether the donation/product will be used.

The IVD medical devices may be used to detect the presence of structural components of the infectious agent, or nucleic acids, or to detect exposure to surrogate markers such as antibodies to the agent.

Rule 1 (b) This rule applies to IVDs that are intended to detect infectious agents capable of causing serious disease with a high risk of transmission which: -

i. could result in death or long-term disability;

ii. are often incurable or require major therapeutic interventions; and

iii. where accurate diagnosis is vital to mitigate the public health impact of the disease.

8.1.3 Example of medical devices classification applies under Rule 1 is as per **Table 2** below.

Table 2. Example according to classes for Rule 1

Class	Intended use	Example (non-exhaustive list)
Class D	Intended to be used for blood, organ and tissue donor screening	Human immunodeficiency virus (HIV)
		Hepatitis C virus (HCV)
		Hepatitis B virus (HBV)
		HTLV I/II
	Intended for the diagnosis of infection with, or exposure to	Human immunodeficiency virus (HIV)
		Hepatitis B virus (HBV)
		Hepatitis C virus (HCV)
		HTLV I/II
		This includes near-patient and self-testing IVD medical devices for any of the concerned transmissible agents

8.1.4 This rule applies to all types of assays such as first-line or screening assays, confirmatory assays and supplemental assays. Refer Rule 1 or Rule 1a or Rule 1b.

8.2 RULE 2 - Detection of red blood cell antigens and antibodies and non-red cell typing.

8.2.1 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 [A(ABO1) B(ABO2), AB(ABO3), rhesus (C,c,D,E,e)[RH1(D), RH2 (C), RH3(E), RH4 (c),RH5(e), Kell system [(Kell (K)], Kidd system [JK1(JKa), JK2 (Jkb)] and Duffy system [FYI (Fya),FY2 (Fyb)] determination which are classified as Class D.

8.2.2 Rationale: Rule 2 divides blood grouping IVDs into two subsets depending on:

a) the nature of the blood group marker the IVD medical device is design to detect; and

b) its importance in a transfusion or transplantation setting.

8.2.3 This rule applies to all IVD medical devices, including single reagents, kits or automated systems, used to ensure the immunological compatibility of donated blood, cells, tissues or organs.

8.2.4 It applies to all reagents and reagent products used in blood grouping systems, as well as for blood typing and tissue typing. It also included reagent products for determining irregular and anti-erythrocyte antibodies and unusual antibodies (antibody screening and identification test).

8.2.5 A high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation places the device into Class D.

8.2.6 Example of IVD medical devices that are applies under Rule 2 is as per **Table 3** below.

Table 3. Example according to classes for Rule 2

Class	Intended	Example (non-exhaustive list)
Class C	intended for: a. to be used in tissue typing; b. to test for human leukocyte antigens, and antibodies; c. or platelet markers.	human leukocyte antigen (HLA) typing
		Genotyping of Human Neutrophil antigen (HNA)
		Human Platelet Antigens
Class D	intended for detecting a. red blood cell antigens, antibodies; b. or genetic markers specific to the following high-risk blood groups: c. or ABO blood group system.	ABO system [ABO1 (A), ABO2 (B), ABO3 (AB)]
		rhesus system [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)]
		Kell system [Kel1 (K)]
		Kidd system [JK1 (Jka), JK2 (Jkb)]
		Duffy system [FY1 (Fya), FY2 (Fyb)]

8.3 RULE 3 - Detection of transmissible agent or biological characteristic

8.3.1 **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 for Rule 3 (a) are in Table 4.

Table 4. Example according to classes for Rule 3 (a)

Class	Intended use	Example (non-exhaustive list)
Class C	Sexually transmitted diseases	Chlamydia trachomatis
		Neisseria gonorrhoeae
		Syphilis (Treponema pallidum)
		Donovanosis (Klebsiella (Calymmatobacterium) granulomatis)
		Herpes simplex virus 1 & 2
		Lymphogranuloma venereum (C. trachomatis L-1, L-2, L-3)

Class	Intended use	Example (non-exhaustive list)
		Human papillomavirus, Trichomoniasis (Trichomonas vaginalis), Haemophilus ducreyi

b) in detecting the presence in cerebrospinal fluid (CSF) or blood of an infectious agent without a high or suspected high risk of propagation. Examples for Rule 3(b) are in Table 5.

Table 5. Example according to classes for Rule 3 (b)

Class	Intended	Example (non-exhaustive list)
Class C	detecting the presence in CSF or blood of an infectious agent	Direct detection of Cryptococcus neoformans antigens
		detection of Neisseria meningitidis in CSF or blood
		detection of Haemophilus influenzae type B (Hib) antigen,
		detection of IgM antibodies to malaria parasites.
		Detection of Streptococcus pneumoniae
		Streptococcus B
		Enterovirus in CSF or blood
		Detection of Dengue fever
		Zika or Chikungunya in blood

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 fetus or embryo being tested, or to the individual's offspring. Examples for Rule 3(c) are in Table 6.

Table 6. Example according to classes for Rule 3 (c)

Class	Intended	Example (non-exhaustive list)
Class C	Diagnostic assay in detecting the presence of an infectious agent where there is a significant risk that an erroneous result	Cytomegalovirus (CMV)
		Chlamydia pneumoniae
		Methycillin Resistant Staphylococcus aureus

Class	Intended	Example (non-exhaustive list)
	would cause death or severe disability	Influenza
		typhoid fever
		pertussis
		Salmonella typhi
		Shiga toxin-producing E. coli or Verotoxin-producing E. coli (e.g., 0157 and H7 antisera)
		Mycobacterium sp
		Legionella
		Anthrax

d) in pre-natal screening of women in order to determine their immune status towards transmissible agents. Examples for Rule 3(d) are in Table 7.

Table 7. Example according to classes for Rule 3 (d)

Class	Intended	Example (non-exhaustive list)
Class C	pre-natal screening of women in order to determine their immune status towards transmissible agents	Immune status tests for Rubella
		Toxoplasmosis
		Cytomegalovirus
		Measles virus
		Treponema pallidum
		Herpes simplex virus

e) in determining infectious 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 for Rule 3(e) are in Table 8.

Table 8. Example according to classes for Rule 3 (e)

Class	Intended	Example (non-exhaustive list)
Class C	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	Enteroviruses
		Cytomegalovirus (CMV) and Herpes Simplex HSV in transplant patients (note: The herpes simplex virus, or herpes, is categorized into 2 types: herpes simplex virus type 1 (HSV-1)

	life-threatening situation for the patient	and herpes simplex virus type 2 (HSV-2) HSV-1 is mainly transmitted by oral-to-oral contact to cause oral herpes (which can include symptoms known as “cold sores”), but can also cause genital herpes HSV-2 is a sexually transmitted infection that causes genital herpes

f) in screening for selection of patients for selective therapy and management, or for disease staging, or in the diagnosis of cancer. Examples for Rule 3(f) are in Table 9.

Table 9. Example according to classes for Rule 3 (f)

Class	Intended	Example (non-exhaustive list)
Class C	selective therapy and management, or for disease staging, or in the diagnosis of cancer	Viral genotyping assays to establish a suitable course of therapy
		Her2/neu testing to select patients with breast cancer for treatment using the drug Herceptin
		carcinoembryonic antigen (CEA) Colorectal Cancer
		carbohydrate antigen (CA15-3), carbohydrate antigen (CA19-9)
		cancer antigen (CA125) in Lung cancer

g) in human genetic testing. Examples for Rule 3(g) are in Table 10.

Table 10. Example according to classes for Rule 3 (g)

Class	Intended	Example (non-exhaustive list)
Class C	human genetic testing	Prenatal genetic screening
		tests for detecting the Philadelphia chromosome
		FISH probe to detect the BCR-ABL translocation
		Testing for disease or disorders such as cystic fibrosis, sickle cell disorder, breast cancer, Huntington’s disease, and Alzheimer disease

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 for Rule 3(h) are in Table 11.

Table 11. Example according to classes for Rule 3 (h)

Class	Intended	Example (non-exhaustive list)
Class C	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	Test for monitoring biological components including **cardiac markers** such as, Troponin, CK-MB, Hs-CRP, Myoglobin
		Test intended for therapeutic monitoring of immunosuppressive medicines such as, cyclosporine, digoxin, vancomycin, tacrolimus.
		partial thromboplastin and prothrombin time test (PTT) that intended to be used as general or primary screening procedures for the detection of coagulation abnormalities.

i) In the management of patients suffering from a life-threatening infectious disease or condition. Examples for Rule 3(i) are in Table 12.

Table 12. Example according to classes for Rule 3 (i)

Class	Intended	Example (non-exhaustive list)
Class C	management of patients suffering from a life-threatening infectious disease.	HCV viral load
		HIV viral load
		HCV geno and subtyping

j) In screening for congenital disorders in fetus or new-born babies where failure to detect and treat such disorders could lead to life threatening situations or severe disabilities. Examples for Rule 3(j) are in Table 13.

Table 13 Example according to classes for Rule 3 (j)

Class	Intended	Example (non-exhaustive list)
Class C	screening for congenital disorders in the fetus	Spina Bifida
		Down syndrome

8.3.2 Rationale: This rule applies to IVDs that are intended to be used for the detection of transmissible agents or biological characteristics:

a) which cause diseases that, although often treatable, may result in death or long-term disability if not treated in a timely manner.

b) where an incorrect result could lead to a patient management decision which has a significant impact on patient outcomes (e.g. result in death or severe disability).

c) where an accurate diagnosis offers an opportunity to mitigate the public health impact of the condition..

d) Where they provide information that is critical for patient treatment.

The application of this rule as defined above should be in accordance with the rationale for this rule which as follows

Devices in this class presents 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 major negative impact on outcome. The devices provide 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.

8.4 RULE 4 - IVDs for self-testing

8.4.1 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.

8.4.2 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 labelling and instructions for use are critical to the proper outcome of the test.

8.4.3 Example of medical device applies under Rule 4 for self-testing devices is as per in **Table 14**.

Table 14. Example according to classes for Rule 4 for Self-testing devices

Class	Intended use	Example (non-exhaustive list)
Class B	Self-testing device	Urine test strip menopause testing (Through detection of follicle stimulating hormone (FSH) in urine) Fertility testing (ovulation test system that works by the detection of luteinising hormone (LH) in urine) Pregnancy self-test
Class C	Self-testing device	Blood glucose monitoring (e.g prick)

8.4.4 Point-of-care testing (POCT) is defined as medical testing at or near the site of patient care by specially trained healthcare professionals. These are tests which can be performed at the bedside and typically involve blood and urine testing. The goal of POCT is to collect the specimen and obtain accurate results in a very short period of time at or near the location of the patient.

8.4.5 POCT is often accomplished through the use of transportable, portable, and handheld instruments (e.g., blood glucose meter, INR meter). Bench analysers are also available for blood gas, pH, electrolyte, metabolite and haemoglobin measurement. Urinalysis analysers are also available for rapid and accurate urine testing.

8.4.6 POCT is carried out in a wide range of settings, in primary care, the community and secondary care, supporting the delivery of the right care in the right place at the right time.

8.4.7 Example of medical device applies under Rule 4 for Point of Care testing (POCT) devices is as per in **Table 15**.

Table 15. Example according to classes for Rule 4 for Point of Care testing (POCT)

Class	Intended	Example (non-exhaustive list)
Class B	Point-of-care	cholesterol test
Class C	Point-of-care	Prothrombin time test
		blood glucose monitors (portable)
		blood gas analysers

8.5 RULE 5 - Reagents, Instruments

8.5.1 The following IVD medical devices are classified as Class A:

a) reagents or other articles which possess no 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; instruments to be use with assays are not to be classified Class A as mentioned here, unless the IVD assay is Class A; and

c) specimen receptacles.

8.5.2 **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.

8.5.3 Example of medical device applies under Rule 5 are as per in **Table 16**.

Table 16. Example according to classes for Rule 5

Class	Intended	Example (non-exhaustive list)
Class A	Instruments	analyzer without reagent
	Intended for the microscopic examinations	Microscope
	Manual automated or semi automated open analyser	Plate reader
	General Laboratory instrument for IVD	BSC, Incubator, centrifuge, water bath
	Microbiological growth media	nutrient agar
		blood agar
		mac conkey
		manitol salt agar
	General laboratory use /consumables	plain urine cup
		micro centrifuge tube
		pipette tips
		96 well plate
		slides
		Tubes without anticoagulant

8.5.4 Class A IVD medical devices are for products that are intended for general laboratory use, accessories which possess no critical characteristics, such as buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for in vitro diagnostic procedures relating to a specific examination.

8.5.5 All instruments, software, calibrators, controls and quality controls reagents, etc. associated with a specific assay are classified in the same risk class as that assay. It follows that each individual component of a test kit (e.g. sample buffers, dilution buffers, controls, coated microplates) is classified to the same risk class as that test kit.

8.5.6 Primary plating media plated directly from an original swab that is intended to produce colonies of a specific colour/morphology for a specific organism falls under rule 6 or rule 3 and would be either Class B (e.g. Candida, Salmonella) or Class C (e.g. Methicillin-resistant Staphylococcus aureus (MRSA), Vancomycin-Resistant Enterococci (VRE), Clostridium difficile (C. difficile). The intended use for these media is often for screening and/or direct identification and or direct detection.

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

8.5.8 The interdependence of the instruments and the test methodology prevents the instruments from being assessed separately, even though the instrument itself classified as Class A.

8.5.9 Software that is supplied separately to an IVD Class A medical device. E.g. instrument or analyser, with intended to operate IVD.

8.6 RULE 6 – Others IVDs

8.6.1 **Rule 6** IVD medical devices not covered in Rules 1 through 5 are classified as Class B.

8.6.2 **Rationale:** The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows:

a) 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 .

b) 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.

c) 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.

8.6.3 Example of medical device applies under Rule 6 are as per in **Table 17**.

Table 17. Example according to classes for Rule 6

Class	Intended use	Example (non-exhaustive list)
Class B	IVD medical devices not covered in other rules	d dimer
		Albumin
		creatinine

Class	Intended use	Example (non-exhaustive list)
		Acid phosphatase
		chloride
		alpha-amylase
		C-peptide
		vitamin B12
		non-assay specific bacterial or viral RNA nucleic acid extraction kit
		enzymes
		metabolic markers
		specific IgE assays
		celiac disease
		Hepatitis A

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

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

8.7.2 Example of medical device applies under Rule 7 are as per in **Table 18.**

Table 18. Example according to classes for Rule 7

Class	Intended use	Example (non-exhaustive list)
Class B	Control for IVD	Chemistry analytes control (level1, level2, level3)
		Serological assay (positive/negative)
		Independent control materials i.e. AFB control slides

MEDICAL DEVICE AUTHORITY
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