

General Classification System for IVD Medical Devices

General Principles

Regulatory controls are intended to safeguard the health and safety of patients, users and other persons by ensuring that manufacturers of IVD Medical Devices follow specified procedures during design, manufacture and marketing.

The risk presented by a particular device depends substantially on its intended use.

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

The Classification of an IVD Medical Device is based on the following criteria:

- the intended use and indications for use as specified by the manufacturer (specific disorder, condition or risk factor for which the test is intended)
- the technical/scientific/medical expertise of the intended user (lay person or professional)
- 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
- the impact of the result (true or false) to the individual and/or to public health

Certain jurisdictions may lower the classification of IVD Medical Devices for which traceability is established through the use of reference measurement procedures and/or available reference materials.

General Classification System for IVD Medical Devices

A four class system is adopted, the use of an alphabetical system in this document is chosen as a distinctive format.

Figure 1 indicates the four risk classes of 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.

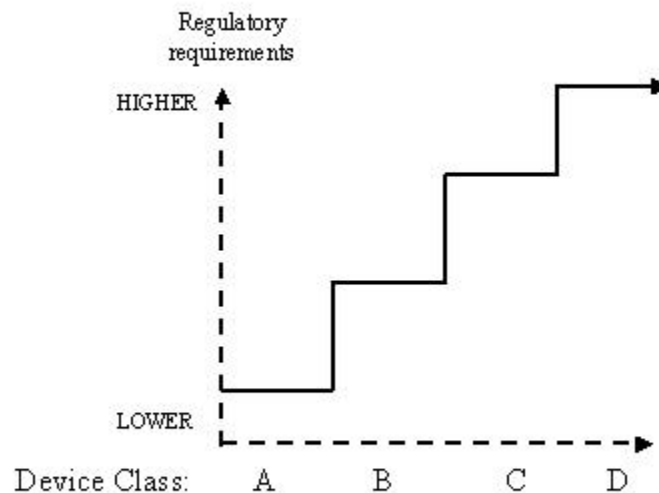
Figure 1 : General Classification System for IVD Medical Devices

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

Figure 2 shows a conceptual illustration of increasing levels of regulatory requirements as the device class increases. These may include, for example:

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

Figure 2 Conceptual illustration of regulatory requirements increasing with device risk class



Determination of Device Class

The manufacturer should:

1. 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.
2. 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.

3. Determine that the device is not subject to special national rules that apply within a particular jurisdiction.

NOTE: Where special rules are applied, 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.

Classification Rules

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

- 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
- 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, rhesus (C,c,D,E, e) and anti-Kell determination which are classified as Class D.

Rationale: A high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation. The rule divides blood grouping into two subsets 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, Anti-Duffy, Anti-Kidd

Rule 3: IVD Medical Devices are classified as Class C if they are intended for use:

- in detecting the presence of, or exposure to, a serious sexually transmitted agent. Examples: Sexually transmitted diseases, such as Chlamydia trachomatis, Neisseria gonorrhoeae.
- 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.
- 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: CMV, Chlamydia pneumoniae.
- in screening pre-natal women in order to determine their immune status towards transmissible agents. Examples: Rubella or Toxoplasma gondii.
- 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. Example: Legionella pneumophila.
- in screening for selection of patients for selective therapy, or in the diagnosis of, cancer,

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

- in predictive genetic screening, when the outcome of the test would ordinarily result in a substantial impact on the life of the individual.

Examples: Guthrie test for phenylketonuria, Huntington's Disease, Cystic Fibrosis.

- 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. Example: Cardiac markers, Cyclosporin, Prothrombin time testing.

- In the management of patients suffering from a life-threatening infectious disease. Example: HIV Viral Load

Rationale: 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 near-patient testing and 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.

Rationale: 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.

Examples for class C: Blood glucose monitoring, near-patient test for Streptococcus B, occult blood test, near-patient devices for blood gases.

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

Rule 5: The following IVD Medical Devices are classified as Class A:

- Reagents which possess specific characteristics, intended by the manufacturer to make them suitable for in vitro diagnostic procedures related to a specific examination.
- Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures
- 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 . However, in certain jurisdictions products for general laboratory use are considered to be IVD Medical Devices.

Rationale: These devices present a low individual risk and no or minimal public health risk.

Examples: Selective/differential microbiological media, identification kits for cultured microorganisms, wash solutions, instruments and plain urine cup.

Note 1: In certain jurisdictions there might be differences to whether a device classified in this rule is considered an IVD Medical Device.

Note 2: Performance of software or 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 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: 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 the outcome or put the individual in immediate danger. The devices are usually one of several determinants. If it is the sole determinant however other information is available, such as presenting signs and symptoms or other clinical

information which may guide a physician, the risk classification 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.

(Source : Adapted from GHTF documents)