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Medical Device Administrative Control System (MDACS)

Classification of In Vitro Diagnostic (IVD) Medical Devices

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中華人民共和國
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Revision History

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0	1 Dec 2009	• First issue of TR-006	TR-006:2006(E)
1	30 Sep 2021	• Update document name and format; and • Rename of Medical Device Control Office to Medical Device Division.	TR-006:2021(E)

Table of Contents

1. Introduction

1.1 This document describes the principles of IVD medical devices classification in accordance with the requirements of the Medical Device Administrative Control System.

2. Rationale, Purpose and Scope

2.1 Rationale

2.1.1 This guidance document provides guidance on the principles of classification of IVD medical devices.

2.2 Purpose

2.2.1 The purpose of this document is to

(a) assist a manufacturer to allocate its *IVD* medical device to an appropriate risk class using a set of harmonized classification principles;

(b) base such classification principles on an IVD medical device's intended use;

(c) allow MDD to rule upon matters of interpretation for a particular IVD medical device, when appropriate.

2.3 Scope

2.3.1 This document applies to all products that fall within the definition of an IVD medical device. An IVD medical device is defined as a device which, whether used alone or in combination, is intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles,

software, and related instruments or apparatus or other articles. Note: International reference materials (e.g. WHO) and materials used for external quality assessment schemes are excluded.

3. Definitions and Abbreviations

3.1 Please refer to Guidance Notes GN-00 (Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System) for the definitions and abbreviations of the terms that appear in this document.

4. General Principles

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

The Classification of an IVD medical device is based on the following criteria:

4.1.1 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)

4.1.2 the technical/scientific/medical expertise of the intended user (lay person or healthcare professional)

4.1.3 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

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

5. Recommendations in IVD Medical Device Classification

5.1 The manufacturer should document its justification for placing its product into a

particular risk class, including the resolution of any matters of interpretation where it has asked a Conformity Assessment Body and/or MDD for a ruling.

5.2 Where more than one of the classification rules applies to the IVD medical device, the device should be allocated to the highest class indicated.

5.3 Accessories should be classified separately using this guidance document.

5.4 Calibrators intended to be used with an IVD reagent should be placed in the same class as the IVD reagent.

5.5 Stand alone control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes should be placed in the same class as the IVD reagent(s).

5.6 Stand alone control materials with no assigned values intended for use with multiple or single analytes should not be placed in the same class as the IVD reagent(s).

5.7 While most software is incorporated into the IVD medical device itself, some is not. Provided such standalone software falls within the scope of the definition for an 'IVD medical device', it should be classified as follows:

5.7.1 Where it controls or influences the intended output of a separate IVD medical device, it will have the same class as the device itself.

5.7.2 Where it is not incorporated in an IVD medical device, it is classified in its own right using the rules in Clause 8 of this document.

Note 1: 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 2: 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.

6. General Classification System for IVD Medical Devices

6.1 **Figure 1** indicates the four risk classes of devices. The examples given are for illustration only; the manufacturer must apply the classification rules to each IVD medical device according to its intended use.

Figure 1: Proposed general classification system for IVD medical devices.

CLASS	RISK LEVEL	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

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

6.2.1 operation of a quality system (recommended for all devices);

6.2.2 documentation of clinical evidence to support the manufacturer's specified intended use;

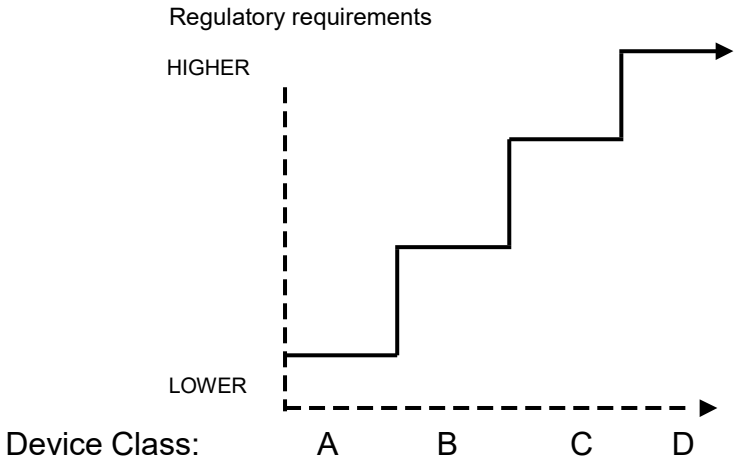
6.2.3 the need for technical data;

6.2.4 product testing using in-house or independent resources;

6.2.5 the need for and frequency of independent external audit of the manufacturer's quality system; and

6.2.6 independent external review of the manufacturer's technical data.

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



7. The Determination of Device Class

7.1 The manufacturer should:

7.1.1 Decide if the product concerned is an IVD medical device based on the intended use and the indications for use using the definition in Guidance Notes GN-00.

7.1.2 Take into consideration all the rules as listed in Clause 8 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 place the device into more than one class, it will be classified in the higher class.

7.1.3 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.

7.1.4 Determine that the device is not subject to special rules used by MDD.

8. Classification Rules

8.1 **Rule 1:** IVD medical devices intended for the following purposes are classified as Class D:

8.1.1 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

8.1.2 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: The application of this rule as defined above should be in accordance with

the rationale that follows: 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. This Rule applies to first-line assays, confirmatory assays and supplemental assays.

8.2 **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)] determination 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).

8.3 **Rule 3:** IVD medical devices are classified as Class C if they are intended for use:

8.3.1 in detecting the presence of, or exposure to, a sexually transmitted agent. Examples: Sexually transmitted diseases, such as *Chlamydia trachomatis*, *Neisseria gonorrhoeae*.

8.3.2 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.*

8.3.3 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,* Methycillin Resistant *Staphylococcus aureus*.

8.3.4 in pre-natal screening of women in order to determine their immune status towards transmissible agents. Examples: Immune status tests for Rubella or Toxoplasmosis.

8.3.5 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.

8.3.6 in screening for selection of patients for selective therapy and management, or for disease staging, or in the diagnosis of cancer. Examples: 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.

8.3.7 in human genetic testing. Examples: Huntington’s Disease, Cystic Fibrosis.

8.3.8 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.

8.3.9 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.

8.3.10 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.

8.4 **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 labelling 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.

8.5 **Rule 5: The following IVD medical devices are classified as Class A:**

8.5.1 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.

8.5.2 Instruments intended by the manufacturer specifically to be used for in vitro

diagnostic procedures

8.5.3 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.

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.

8.6 **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.

8.7 **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.

9. Enquiries

9.1 Enquiries concerning this document and the MDACS should be directed to:

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9.2 All latest versions of published documents and application forms for MDACS are available at MDD website.

10. References

10.1 Global Harmonization Task Force. Principles of In Vitro Diagnostic (IVD) Medical Devices Classifications. Final Document GHTF/SG1/N045:2008. http://www.imdrf.org accessed on 23 June 2020.

10.2 Department of Health. Guidance Notes for Definitions and Abbreviations for the Medical Device Administrative Control System. Guidance Note GN-00.

10.3 Department of Health. Overview of the Medical Device Administrative Control System. Guidance Notes GN-01.