Annex I

CLASSIFICATION RULES FOR IN VITRO DIAGNOSTIC DEVICES

Rule 1

IVDDs intended for the following purposes are classified as Class D: 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 IVDD 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 2

IVDDs 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 IVDDs intended for the following purposes are classified as Class D:

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 IVDD 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

IVDDs are classified as Class C if they are intended for use:

- In detecting the presence of, or exposure to, a sexually transmitted agent. Examples: Sexually transmitted diseases, such as Chlamydia trachomatis, Neisseria gonorrhoeae. ⁞SEP⁞
- in detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation. Examples: Neisseria meningitis or Cryptococcus neoformans. ⁞SEP⁞
- 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. ⁞SEP⁞
- in pre-natal screening of women in order to determine their immune status towards transmissible agents. Examples: Immune status tests for Rubella or Toxoplasmosis. ⁞SEP⁞
- 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. ⁞SEP⁞
- 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. ⁞SEP⁞

NOTE: those IVDDs 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.

in human genetic testing. Examples: 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. Examples: Cardiac markers, Cyclosporin, Prothrombin time testing.

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 sub-typing.

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

IVDDs 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.

IVDDs intended for blood gases and blood glucose determinations for near-patient testing would be Class C. Other IVDDs 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, addition data required Guidelines on Submission of Documentation for Registration of In Vitro Diagnostic Devices

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

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Rule 5

The following IVDDs are classified as Class 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.

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 IVDDs, as defined in this document. However, in certain jurisdictions products for general laboratory use are considered to be IVDDs.

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 IVDD), identification kits for cultured microorganisms, wash solutions, instruments and plain urine cup.

Note 1: Note 2: Note 3:

In certain jurisdictions there may be differences as to whether a device classified in this rule is considered an IVDD.

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.

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

IVDDs 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

IVDDs 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.