Medical Device Classification under the IVDR (EU) 2017/746

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Risk-based classification of in vitro diagnostic medical devices

IVDR (EU) 2017/746 :
Regulation (EU) 2017/746 of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices (IVDR) entered into force as of May 25, 2017, with a date of application of May 26, 2022.

Principles of risk-based classification:
The IVDR imposes a classification structure for in vitro diagnostic medical devices. Risk classes range from Class A for low-risk devices to Class D for the highest-risk devices.

Devices with a high individual health risk and a high risk to public health are classified as Class D, while devices with a high individual health risk and/or moderate public health risk are classified as Class C. Devices with moderate individual health risk are in Class B and those with a low health risk are classified as Class A.

The regulation provides specific rules for properly classifying in vitro diagnostic medical devices according to their level of risk. Except for Class A non-sterile devices, all in vitro diagnostic medical devices require certification by a Notified Body.

Classification according to Annex VIII
Annex VIII of the IVDR outlines the specific rules for classification of devices. Refer to Annex VIII for the full classification rules.

Fig. A Classification based on risks

Section 1 describes the implementing rules that provide a set of general rules to be considered when classifying devices.

Brief Summary of Implementing Rules	
1	The intended purpose of the devices determines their classification
2	Devices used in combination are classified separately
3	Accessories are classified separately from the device with which they are used
4	Software, which drives a device or influences the use of a device, falls within the same class as the device Independent software that is an IVD is classified in its own right
5	Calibrators used with a device are classified in the same class as the device
6	Controls with quantitative or qualitative assigned values intended for one or more specific analytes are in the same class as the device
7	All classification and implementing rules must be considered to establish the proper classification for the device
8	Devices with multiple intended purposes that fall into more than one class are classified in the higher class
9	If several classification rules apply to the same device, the rule resulting in the higher classification applies
10	Each of the classification rules applies to first line assays, confirmatory assays and supplemental assays

The classification rules are defined in Section 2.

Class D devices include products used in the diagnosis or monitoring of infectious diseases causing a high public safety risk, and devices to determine the safety of blood and blood products through their use in the screening for transfusion-transmissible infections and determination of blood compatibility parameters. Annex VIII rule 1 & 2 of the IVDR defines Class D devices as those intended to be used for:

- Detection of the presence of or exposure to a transmissible agent in blood, blood components, cells, organs, tissues or their derivatives, to assess their suitability for transfusion, transplantation or cell administration
- Detection of the presence of, or exposure to a transmissible agent that causes life-threatening disease that is suspected to have or has a high risk of propagation
- Determining the infectious load of a life-threatening disease where monitoring is critical to patient management
- Blood grouping or determining feto-maternal blood group to ensure the immunological compatibility of blood, blood components, cells, tissue, organs that are intended for transfusion or transplantation or cell administration, for example: blood and blood components.
- The following markers are classified as Class D:
    - ABO system [A (ABO1), B (ABO2), AB (ABO3)]
    - Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]
    - Kell system [KEL1 (K)]
    - Kidd system [JK1 (Jka), JK2 (Jkb)]
    - Duffy system [FY1 (Fya), FY2 (Fyb)

Class C comprises the largest and most diverse group of devices.

Devices for blood grouping or determining feto-maternal blood group to ensure the immunological compatibility of blood, blood components, cells, tissue, organs that are intended for transfusion or transplantation or cell administration that are not included in the above list are classified as Class C under rule 2.

Rule 3 assigns Class C to devices intended:

- for detecting the presence of, or exposure to, a sexually transmitted agent
- for detecting the presence in cerebrospinal fluid or blood of an infectious agent without a high or suspected high risk of propagation
- for detecting the presence of an infectious agent, if 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
- for pre-natal screening of women to determine their immune status towards transmissible agents
- for determining infective disease status or immune status, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient‘s offspring
- to be used as companion diagnostics
- to be used for disease staging, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient‘s offspring
- to be used in screening, diagnosis, or staging of cancer
- for human genetic testing
- for monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient‘s offspring
- for management of patients suffering from a life-threatening disease or condition
- for screening for congenital disorders in the embryo or fetus
- for screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities.

Rule 4(b) specifies that devices for Near Patient Testing should be classified based on their intended purpose.

Class A includes products for general laboratory use, accessories without critical characteristics, 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; instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures; and specimen receptacles, as defined in Rule 5.

Class B devices are defined by Rule 6 as devices not covered by the preceding rules. In addition, controls without a qualitative or quantitative assigned value are also classified as Class B per Rule 7.

According to Implementing Rules 1.8 and 1.9, devices for which multiple rules apply are classified in the highest applicable risk class.

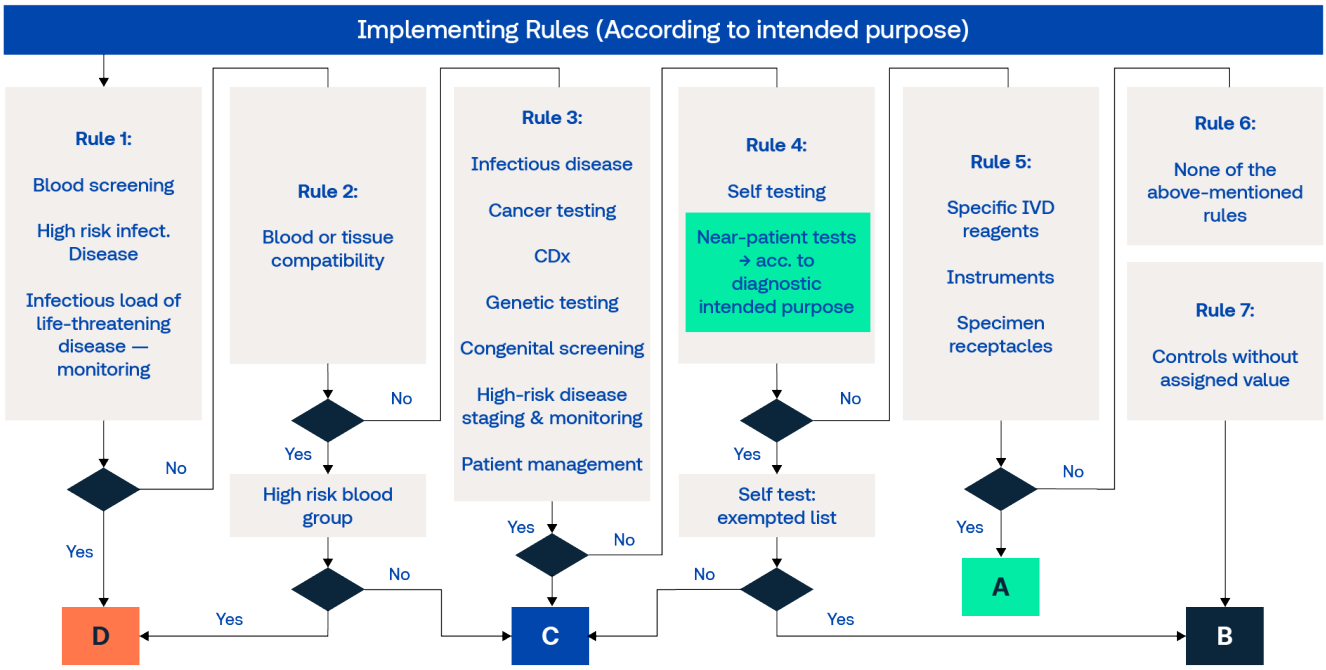

Fig. B Application of classification rules

Additional Information on Classification
The guidance document MDCG 2020-16 provides additional information including explanation of the classification rules, and examples of devices falling under each rule.

Classification Dispute
The determination of device classification is the responsibility of the manufacturer. The notified body reviews the device classification during the review of pre-application information. According to article 47 of the IVDR, in the event of a dispute between the manufacturer and the notified body, the case is referred for a decision to the competent authority of the Member State in which the manufacturer or their authorized representative has its registered place of business. Where the notified body concerned is established in a Member State other than that of the manufacturer, the competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body.

How TÜV SÜD can help
TÜV SÜD is the first Notified Body to issue a certificate under the IVDR. As one of the world's largest EU Notified Bodies for all types of medical devices covered by EU directives and regulations, TÜV SÜD is designated as a full-scope Notified Body under the IVDR.

Our experts' experience and expertise make TÜV SÜD your partner of choice to bring your innovative in vitro diagnostic medical devices to the EU market, providing a full range of certification and testing services to ensure global market access.

We work collaboratively with our partners to ensure access to critical innovative diagnostic technologies for patients and providers.

Contact us to discuss your needs for IVDR certification.

Related services

TÜV SÜD provides the following related services
- EN ISO 13485 certification
- Testing services including EMC and NRTL testing
- Medical Device Single Audit Program (MDSAP)

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