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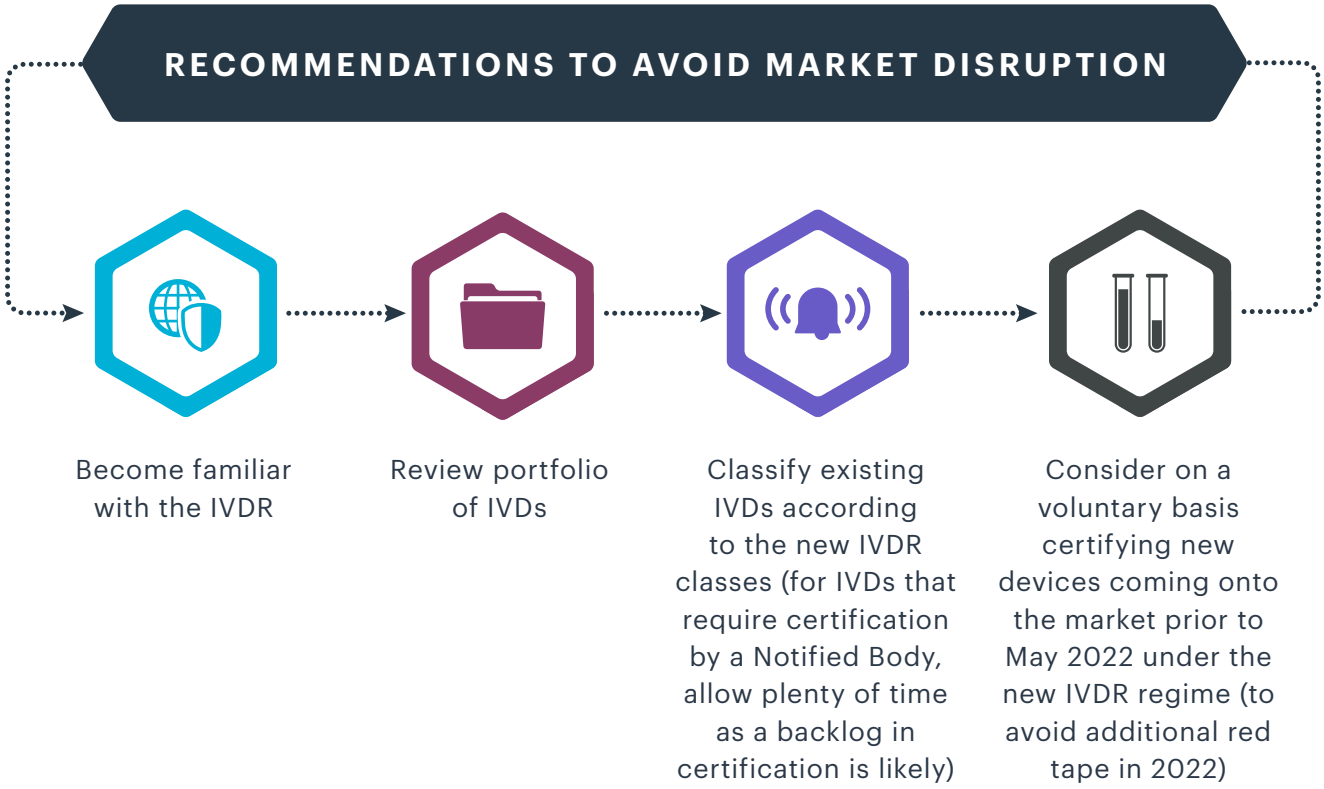
Act Now to be Ready on Time – Guide to New Classification Rules for In Vitro Diagnostic Medical Devices

July 2020

In advance of the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (the **IVDR**) becoming fully applicable on 26 May 2022, we outline the key changes to the classification of in vitro diagnostic medical devices (**IVD**s).



KEY CHANGES

New Classes of IVDs

Under the IVDR, IVDs will now be graded into four categories in accordance to the risk they pose to health and safety, starting with the lowest risk category at Class A, up to the highest at Class D. This is in dramatic contrast to the list-based approach (List A and List B) under the IVDD.

List A of the IVDD covers IVDs considered to be "high risk", for example products or materials used to determine blood groups, or for the detection of HIV or Hepatitis B, C and D. Such IVDs are now most likely to be categorised in Class D under the new IVDR.

List B of the IVDD covers IVDs considered to be a "moderate risk" such as self-testing blood glucose measuring devices. Such IVDs are now most likely to be categorised in Class C under the new IVDR.

CLASSIFICATION UNDER THE IVDR

Classification under "OLD" **IVDD** Regime

Classification under "NEW" **IVDR** Regime

Definition of an IVD

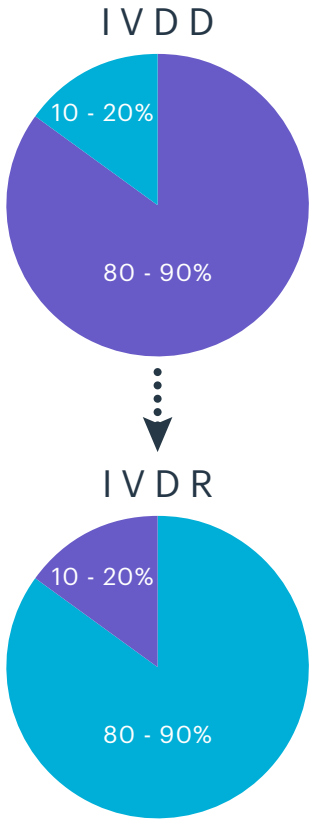
The IVDR expands the definition of an IVD. With ever-evolving technologies, the definition now encompasses software which is specifically intended to be used for a purpose set out in the definition of an IVD. However, it should be noted that software used merely for general purpose, even if in a healthcare setting or for well-being purposes will not meet the definition of an IVD.

The IVDR also introduces some new definitions, for example-

- ‘companion diagnostic’ - a device which is essential for the safe and effective use of a corresponding medicinal product
- ‘devices for near-patient testing’ - devices designed for use by health professionals outside a laboratory environment.

The impact of changes in classification

- IVDs that require assessment by a Notified Body
- IVDs that can be tested and declared by its manufacturer



Under the old IVDD regime just 10-20% of IVDs fell into List A or B and were subjected to an assessment by a Notified Body (In Ireland, the National Standards Authority of Ireland (NSAI) has been designated by the Health Products Regulatory Authority (HPRA) as competent to assess the conformity of in vitro medical devices).

The new IVDR classification regime flips these figures on their head. Under the IVDR’s 4 class system, 80-90% of IVDs will require assessment by a Notified Body.

The IVDR provides that all IVDs classified within categories B, C and D require conformity assessment by a Notified Body.

The conformity assessment of Class D devices will require the involvement of an EU Reference Laboratory to verify the performance claimed by the manufacturer and compliance with the applicable Common Specifications.

Class A devices will be self-certified by their manufacturers unless sold as sterile.

Certain IVDs, for example genetic and pregnancy testing devices, which previously fell outside the scope of Notified Body assessments, will require conformity assessment under the IVDR regime, as they will fall under Class B of the IVDR.

CLASSIFICATION RULES UNDER THE IVDR

The IVDR provides seven rules which are used to classify an IVD and are set out in Annex VIII of the Regulation. The application of these classification rules is based on intended purpose and inherent risks posed by the IVD. These rules and their corresponding applicable classes* are as follows:

	INTENTION OF DEVICE:	POTENTIAL APPLICABLE CLASSES*
RULE 1	to detect transmissible agents of a life-threatening disease where it is critical for patient management or where the disease has a high risk or suspected high risk of propagation.	**Class D**
RULE 2	to be used for blood grouping or tissue typing for the purposes of transfusion or transplantation.	**Class C (some Class D)**
RULE 3	to detect, screen and manage various infectious diseases including for example; detecting the presence of a sexually transmitted agent, pre-natal screening and management of patients suffering from a life-threatening condition.	**Class C**
RULE 4	for self-testing.	**Class C / Class B**
RULE 5	Products for general laboratory use.	**Class A**
RULE 6	Devices not covered in rules 1 – 5.	**Class B**
RULE 7	Devices which are controls without a quantitative or qualitative assigned value.	**Class B**

*For general guidance only.

OTHER CHANGES

Online Sales of IVDs

IVDs and testing services offered online that are accessible to European citizens must comply with the IVDR the moment they are offered for use in the EU.

Transition phase

Until 26 May 2022, IVDs CE marked in accordance with the IVDD can continue to be placed on the market. There are however some limitations, including:

- IVD certificates issued **prior to 25 May 2017** remain valid until the end of the period indicated on the certificate (except for certificates issued under Annex VI of the IVDD which become void on 27 May 2024). IVDs subject to these certificates, which are placed on the market prior to 26 May 2022, may continue to be made available once in the supply chain until 27 May 2025.
- IVD certificates issued **after 25 May 2017** will become void on 27 May 2024. Similarly, IVDs subject to these certificates, which are placed on the market prior to 26 May 2022, may continue to be made available once in the supply chain until 27 May 2025.
- IVDs falling under either of the aforesaid points may only be placed on the market or put into service provided that from 26 May 2022:
  a) the IVD continues to comply with the IVDD;
  b) there are no significant changes in the IVD's design or intended purpose; and
  c) the requirements of the IVDR relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices are applicable in lieu of the corresponding provisions in the IVDD.
- Manufacturers can, and we recommend should, on a voluntary basis, certify their IVDs under the IVDR before 26 May 2022.
- The first step for manufacturers is to classify their devices according to their new risk classes. For those that need certification by a Notified Body, make sure you plan this in good time.

Certification Dispute

If a dispute arises between a manufacturer and the Notified Body as to the classification of an IVD, it is for the HPRA to determine. It is crucial that companies fully document the justification for their decision on classification, should it be disputed.

Device identification

The introduction of a unique device identifier (UDI) for every IVD device will significantly enhance traceability and support post-market safety activities. Each IVD will have a UDI composed of two parts:

- a device identifier (UDI-DI) specific to the model and packaging of the device and
- a production identifier (UDI-PI) to identify the point of manufacture

Manufacturers are responsible for entering the necessary data on the European database (Eudamed), which includes the UDI database, and for keeping it up to date.

GUIDANCE

The HPRA is currently drafting a detailed implementation plan for the IVDR. It is closely monitoring the Commission's Implementation Rolling Plan (which is revised quarterly) to ensure it has identified all essential implementing acts and other relevant initiatives adopted.

An essential part of the HPRA's implementation plan is engagement with stakeholders. Therefore, we encourage companies likely to be affected by the IVDR to engage with the HPRA via their designated mailbox devices@hpra.ie.

If you require any further information on the classification of in vitro diagnostic devices or any other aspect of the MDR or IVDR, please contact Charleen O'Keeffe or Laura Scott.

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