

Impact of changes under the new EU IVD Regulation (EU) 2017/746 to international registrations

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Introduction

Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) introduces a major update of the regulatory framework in the European Union (EU). This modernisation of the European regulatory system brings about several changes to the information provided with IVD devices and their regulatory documentation. It is important to note that not all changes will apply to all IVDs. Therefore, changes to regulatory documentation because of the IVDR are likely to vary from product to product.

Most of these changes will simply mean that additional information is available for existing devices. This in no way changes the use, effectiveness, performance or safety profile of the devices and as such should have no particular impact on registrations since all jurisdictions allow additional information to be provided with an IVD.

The regulatory documentation around a device will be updated – this can include changes to notified body certificates, free sales certificates, and declarations of conformity. The update of the regulatory documentation does not necessarily impact the device characteristics, i.e. changes to the regulatory documentation do not imply changes to the composition of the ingredients or the manufacturing processes unless otherwise indicated.

The European Commission continues to publish useful information communicating changes to the regulatory framework in the European Union (EU). The '[Factsheet for Authorities in non-EU/EEA States on Medical Devices and in vitro Diagnostic Medical Devices](#)' is a useful resource about the changes brought by the EU legislation, that is aimed specifically at regulatory/competent authorities outside of EU/EEA (EEA – European Economic Area). All other factsheets published by the Commission can be found here: https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/spread-word_de

This document analyses the changes to the regulatory documentation due to the IVDR that might be relevant for product registration outside of EU/EEA. It is addressed to economic operators, and to regulators who are based outside of EU/EEA.

This document does not tackle specific issues that may arise at customs due to the transition to the new legislation, however, it is important that customs officers are alerted to the changes to the legislation in the EU to avoid misunderstandings and any unnecessary delays at the point of customs clearance.

Transitional Provisions

Before diving into the relevant IVDR requirements, it is worth taking note of the complex transition process that has been introduced under the regulation (IVDR, article 110). The IVDR provides a gradual transition into the new regulatory framework to avoid market disruption and allow a smooth transition from the directive to the regulation. Some IVDs with certificates issued by notified bodies under the directive may continue to be placed on the market until 27 May 2024.

The Commission "[Factsheet for Authorities in non-EU/EEA States on medical devices and in vitro Diagnostic Medical Devices](#)", highlights explicitly that *"during the transition period, products certified under the directives and products certified under the Regulations will coexist on the market. Both will have equal status under the law, provided that they are accompanied by appropriate certificates, and no discrimination in eligibility criteria in public tenders may take place."*

Additional information on the transitional provisions is [available](#).

Labels

The requirements of the new regulation will trigger changes to the labels of IVDs. These changes will include:

1. The inclusion of UDI (Unique Device Identification)
2. For many IVDs, a new notified body number
3. Single use device (can be a symbol)
4. For near patient tests - an indication of the fact (can be a symbol)
5. For self-tests - contact details for further advice and assistance

The IVDR lays down several new requirements asking various kinds of information to be indicated on the label of the device. To comply with these requirements, the information required to be supplied on the device's label, may take form of symbols (IVDR Annex I, Chapter III, section 20.1).

Instructions for use

The IVDR identifies the information that needs to be included in the instructions for use (IFU) in order to inform the user of a device's intended purpose and proper use, as well as of any precautions. For devices CE-marked under the IVDR, additional information will be provided in the IFU in comparison to devices that have been CE-marked under the IVD directive. For example, changes might concern the description of the intended purpose – the IFU will include information regarding the device's intended purpose and also the intended user (IVDR Annex I, Chapter III, section 20.4.1).

There are several reasons why the new IVD regulation may result in a change to the intended purpose, for example:

1. Clarification of the intended purpose to fit the clinical evidence - purely analytical intended purposes will need to be updated.
2. Restrictions of intended purpose - if the new requirements for clinical evidence cannot be met for all of the established claims there may be limitations to the intended purpose of the device.
3. Consolidation of information due to more explicit requirements under the IVDR

When the intended purpose results in a different set of claims for the device, this would normally result in a need to update existing registrations or request new registrations around the world, as it may even be considered a new device. This is likely to be a challenging exercise and it is important that regulators understand what drives the changes to the description of the intended purpose to ensure that the process for dealing with such changes to the registration runs smoothly and does not lead to unnecessary delays or excessive costs.

When the change to the intended purpose does not in fact change the way in which the device is used the situation will need to be assessed and discussed.

Consult Annex I, Chapter III, section 20 of the IVDR for the full list of information to be provided in the IFU.

It should be noted that none of these changes is considered to impact the functionality or risk profile of the IVD and simply serve to explicitly state additional information (if needed), allow for the traceability of the device (UDI) and reflect the new regulatory oversight (NB number).

Certificates issued by a Notified Body

IVDs that are subject to notified body oversight under the IVDR will require new notified body certificates. These notified body certificates may have an expanded scope (reflecting the new classification for IVDs) and will also contain new information, such as Basic UDI for the devices which they cover. The certificates will also clearly be issued under the regulation. Annex XII, Chapter II of the IVDR specifies the minimum contents of the NB certificates.

Declaration of Conformity

New declarations of conformity (DoC) will be issued under the IVDR. These reflect not only the fact that conformity will be claimed to the regulation but will also include additional information, such as Basic UDI, or where applicable, references to any common specifications (CS).

Given the overall strengthening of requirements under the regulation, a DoC under the regulation should be considered at least equivalent to that under the directives. Annex IV, of the IVDR specifies the information to be included in the DoC.

Classification

The IVDR fundamentally changes the classification system that has been adopted under the IVD directive. This is due to the need to enhance patient safety, take account of the technological progress since the directive has been adopted and to ensure alignment with internationally endorsed principles.

The classification of the product will determine the applicable conformity assessment requirements.

Generally, this will not have an impact on the performance of the devices. Classification will be reflected in the technical documentation.

Certificates of Free Sale

New certificates of free sale (CFS) will apply - these certificates will refer to the new regulation. However, they will be covering essentially the same devices as before. The question of how devices are identified is important in this case - as UDI and even catalogue numbers may change for the IVDs under the regulation. The transition period is also important to note when it comes to CFS. As noted in the Commission '[Factsheet for Authorities in non-EU/EEA States on Medical Devices and in vitro Diagnostic Medical Devices](#)', during the remaining validity of a NB certificate, a device can be covered by both a directive certificate and a regulation certificate.

CFS may therefore be issued with the corresponding certificates under both the IVDD and the IVDR and both types of CFS will be equally valid. To avoid any unintended adverse impact on the supply of products, it will be important that regulatory authorities in non-EU/EEA countries recognise the validity of CFS issued for the IVDs placed on the market under the IVDD after 26 May 2022 (the date of application of the IVDR), until the corresponding certificates issued by notified bodies expire.

Conclusion: Assessment of the changes due to transition to IVDR

It is important to note that not all changes will apply to all IVDs. The table below provides an assessment of the changes due to transition to IVDR. When reading this table, it is important to note that changes to regulatory documentation because of the IVDR are likely to vary from product to product.

Type of information	Type of change	Change in risk / benefit profile of the device	Change in use of the device	Assessment of the impact of the change
Change to ingredients and manufacturing process	None	None	None	No impact on use or patient safety
Labels	Additional information, including UDI, notified body number, new symbols (self-test, near-patient testing, single use) etc.	None	None	No impact on use or patient safety
IFU	Additional information, including notified body number, clarification (intended use, intended user), etc.	None	None, except intended purpose (see below)	No impact on use or patient safety
Notified Body Certificates	Additional information, including UDI, notified body number, product classification, etc. A notified body certificate is a new document for many IVDs.	None	None	No impact on use or patient safety
Declaration of conformity	Additional information, including UDI, notified body number, classification, registration number of manufacturer and European authorised representative (if already issued), etc.	None	None	No impact on use or patient safety

Type of information	Type of change	Change in risk / benefit profile of the device	Change in use of the device	Assessment of the impact of the change
Classification	IVDR adopts new IVD classification (class A, B, C, D) which will be reported on CE Certificates and CE Declarations of Conformity.	None	None	No impact on use or patient safety
Intended Purpose	Intended purpose might be amended for some IVD products, depending on the type of information available to support the claim.	Maybe	Yes	Needs to be assessed for impact on case by case basis
Certificate of Free Sale (CFS)	Additional information, including Basic UDI, notified body certificate number. Possible new layout for the CFS as IVDR foresees the possibility to adopt a model format.	None	None	No impact on use or patient safety

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