In Vitro Diagnostic Regulation (IVDR)
Regulation (EU) 2017/746

Version 2, May 2017

Frequently asked questions

This FAQ document aims to answer some key questions on the new IVDR and the changes that it brings for the IVD industry. Questions are grouped by key theme. This document will be updated over time, to reflect any further changes that occur. For more information, please see our IVDR transition webpage.

Transition period

What is the transition period for the IVDR?

The new European In Vitro Diagnostic Regulation was published in the Official Journal of the European Union on 5th May 2017. The Regulations will enter into force on May 25th 2017, marking the start of the transition period for manufacturers selling IVD devices into Europe.

The IVDR, which replaces IVD Directive (98/79/EC), has a transition period of five years, after which the Regulation will apply, and no new applications against the Directives will be accepted. Manufacturers have the duration of the transition period to update their technical documentation and processes to meet the new, more stringent requirements.

Note: *BSI encourages you to begin preparing for transition now, to ensure you can apply for certification as soon as possible on your Notified Body's designation to the IVDR. This will help to ensure certification before the end of the transition period.*

How long do I have to achieve certification to the IVDR?

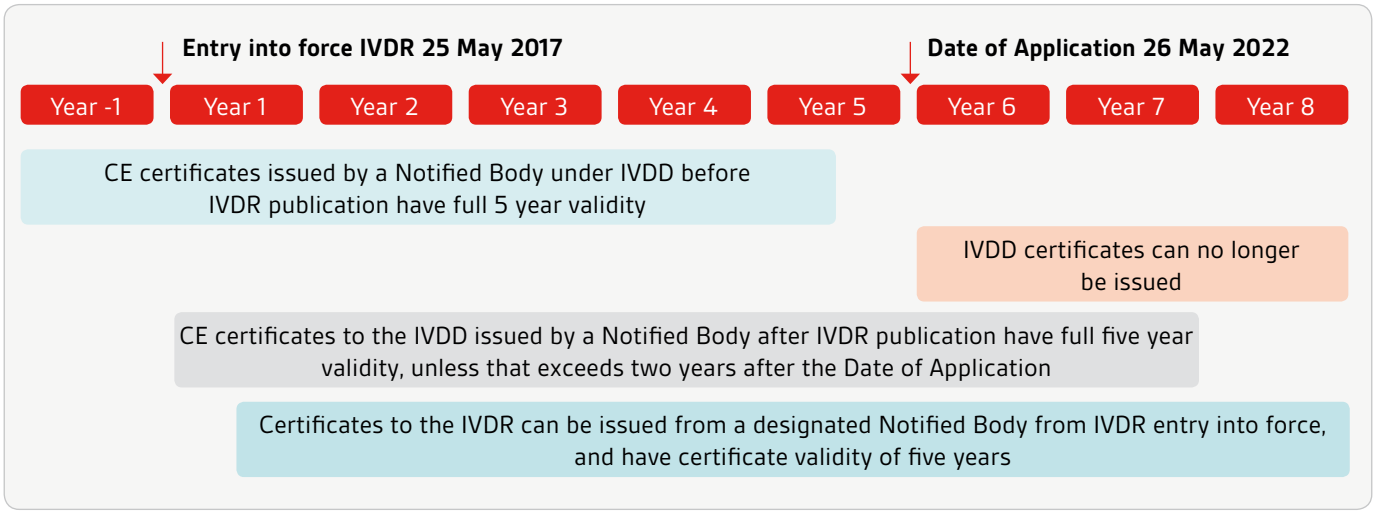
The IVDR has a five year transition period, beginning on May 25th 2017. Current certificates to the In Vitro Diagnostic Directive (IVDD) have their full five year validity.

During the transition period, Notified Bodies designated to the IVDD can continue to issue IVDD certificates until the Date of Application (i.e. the end of the transition period). These IVDD certificates will have a full five year validity, unless that exceeds two years after the Date of Application of the IVDR. The validity of the IVDD certificates after the Date of Application is conditional on compliance with the provisions described in Article 110 clause 3.

Notified Bodies can begin to issue certificates to the IVDR once they have been designated.

After the Date of Application, Notified Bodies will only be able to issue certificates to new IVDR.

What is the plan for implementation of the IVDR?



Note: *the blocks above display the time period within which a certificate type can be valid, not the period of validity for a single certificate.*

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Notified Body activity

When will BSI begin conformity assessment against the new Regulation?

All Notified Bodies can begin auditing to the new Regulation once they have been designated as a Notified Body under the IVDR by their Competent Authority.

Can I apply for an IVDD certificate once my Notified Body is designated under the IVDR?

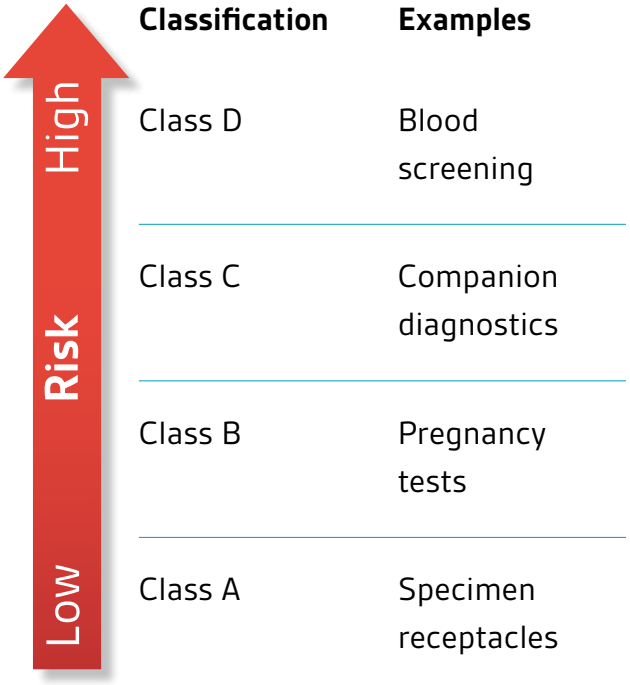
Yes, as long as your Notified Body maintains designation to the IVDD. Notified Bodies will be able to maintain their IVDD designation during the transition period. However, these certificates will have limited validity.

Classification under the IVDR

How are devices classified under the IVDR?

The classification of IVDs has changed from a list-based approach in the Directive, to a rule-based approach in the Regulation. The rule-based approach comprises of four risk categories, from Class A (lowest risk) to Class D (highest risk). The rule-based classification system is less exclusive than the list-based system; instead of naming specific devices, the risk classification of the device is determined by its intended use and the analytes being measured.

If more than one rule applies, the rule resulting in the highest classification should be followed.



Am I able to self-certify devices under the IVDR?

In most cases, Class A devices can be self-certified unless they are sold sterile, while Class B, C and D devices will require conformity assessment by a Notified Body designated under the IVDR.

Who decides the Class of my device?

The classification of the device is decided by the legal manufacturer. If your Notified Body disagrees with your classification, they may consult their Competent Authority. The Notified Body's and manufacturer's Competent Authorities may consult, if they are different.

The Medical Device Coordination Group (MDCG) will be involved in decisions of classification for borderline products.

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Activities under the IVDR

Will the assessment of Technical Documentation be carried out on-site or via submission to the Notified Body?

While it is preferable to conduct on-site assessments where possible, BSI conducts both on-site and desktop reviews of Technical Documentation. Any changes to activity under the IVDR will be dependent on further guidance that Notified Bodies receive from the EU Commission, which is yet to be issued.

Note: *For BSI clients undergoing an ISO 13485 only audit, the assessor will only conduct an in depth review of your QMS files. BSI does not combine CE mark and ISO 13485 audits.*

Will the frequency of Unannounced Audit Visits (UAVs) change under the IVDR?

The 2013 EU Commission Recommendation - "Commission Recommendation of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices" – requires Notified Bodies to conduct UAVs. The Recommendation has now been incorporated into the new IVDR, and states the frequency of UAVs under the IVDR will now be at least every five years for all IVD devices.

Impact of the IVDR on Quality Management Systems (QMS)

Is there a deadline for my QMS to be compliant with the IVDR?

All IVD devices, whether currently certified to the European IVD Directive or yet to be certified, will need to comply with the requirements of the IVDR to continue being sold in the EU market once the transition period has ended. The IVDR requires manufacturers to demonstrate an effective QMS. Therefore, to receive certification to the IVDR, you must have a compliant QMS.

Note: *ISO 13485:2016 was published in March 2016, with a transition period of three years. We are awaiting the harmonization of this standard to allow the presumption of conformity to the current Directives. It is also important to consider whether ISO 13485:2016 is harmonized to the Regulation in the future.*

How will the new IVDR impact contract manufacturers?

If a contract manufacturer intends to take legal manufacturer responsibility for the devices that they provide to market, they must comply with the Regulation in its entirety.

If a contract manufacturer does not take legal manufacturer responsibility, the only implication is that they may be subject to audits on behalf of the legal manufacturers they provide services to. This includes unannounced audits.

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How can BSI support me through the transition?

BSI has a range of materials designed to provide information about the new requirements related to the IVD Regulation, and the transition period.

How can I keep up to date with the changes in industry?

BSI has a dedicated IVD Regulation Transition webpage, where we post any new information, including guidance documents, webinars and other useful pieces of information designed to support you. Bookmark the IVDR Transitions webpage and remain informed with the most recent updates.

You can also sign up to BSI's monthly newsletter and join our LinkedIn group to ensure you receive information and access to the newest guidance on a regular basis.

Where can I find more information to expand my knowledge?

BSI offers a wide range of free webinars and white papers, to keep you informed on the current thinking and latest changes in the regulatory space. Take advantage of our expertise and learn more about key topics including legislation, risk and regulatory changes.

BSI's suite of training courses can provide more support, from introductory courses through to more specialised programmes aimed at those with regulatory experience. Call us for more information: **0345 086 9000**.

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