In Vitro Diagnostic Regulation (IVDR) Frequently Asked Questions

Thermo Fisher Scientific Microbiology products

What is IVDR?

IVDR stands for '*In Vitro Diagnostic Regulation*'. This is a European regulation that comes into effect 26th May 2022 and sets out requirements for in vitro diagnostic (IVD) medical devices. Manufacturers need to comply with the regulation in order to apply a 'CE' mark and place IVD medical devices on the EU market after May 2022.

IVDR replaces the *In Vitro* Diagnostics Directive (IVDD) which our IVD products currently comply to for CE marking.

What is a CE mark?

A CE mark is required for certain products to be sold within the EU. It is mandatory for products which are covered by the scope of specific European directives or regulations requiring the CE mark, e.g. toys, electronics, personal protection materials, medical devices or *in vitro* diagnostics. In simple terms, for Thermo Fisher Scientific Micriobiology it means that it is required for IVD products intended for a clinical application.

The letters 'CE' will appear on the product label and Instructions for Use (IFU) and indicate that;

- The manufacturer has checked that these products meet EU safety, health or environmental requirements
- The product is compliant with EU legislation
- The product has free movement within the European market

By placing the CE mark on a product, a manufacturer is declaring their sole responsibility and conformity with all the legal requirements to achieve CE marking. The manufacturer is thus ensuring validity for that product to be sold throughout the European free market.

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What important changes does the IVDR bring to the current IVD directive (IVDD)?

The IVDR implements a number of important changes, among which:

- More stringent requirements for documentation e.g. post-market surveillance, technical documentation
- New classification: Class A (low risk) – Class D (highest risk). Class B, C, and D need approval by a Notified Body. Class A products continue to be self-certified.
- More stringent requirements for clinical evidence
- UDI: unique device identification number for every device
- EUDAMED: Europe-wide database of increased transparency and traceability
- Increased surveillance by Notified Body

What is Thermo Fisher Scientific Microbiology's IVDR plan?

Thermo Fisher takes IVDR compliance very seriously, and there is a dedicated project team working to upgrade our documentation and processes at sites that manufacture CE marked IVD products. We are working on the agreed priority lists of clinical products in order to meet the applicable IVDR deadlines.

What products will be IVDR ready?

All IVDs manufactured with a CE mark are affected by IVDR.

When will I know if a product will, or will not be ready for IVDR?

In the existing clinical microbiology portfolio, most products are in scope and you will see no change. If any products will have a change in status or will be removed as part of IVDR, alternative products will be identified where possible. The IVDR team is working to implement any changes and will communicate to affected customers in due course. We will provide notice to ensure you have enough time to validate any changes.

Which is the classification of the Thermo Fisher Scientific Microbiology IVD products under IVDR and which products will need conformity assessment by a Notified Body?

The majority of Thermo Scientific Microbiology IVD products will remain self-classified (Class A) and do not need to be reviewed by a Notified Body. The remaining IVD products will be mostly Class B with some Class C. These Class B/C products require conformity assessment by a Notified Body that is designated in accordance with the IVDR.

Has Thermo Fisher Scientific Microbiology applied to an IVDR-designated notified body?

Yes, we have successfully completed our application with an IVDR-designated notified body. We are in close contact with them and are advancing through the process to obtain IVDR certificates for our products.

Will Thermo Fisher Scientific Microbiology be ready for IVDR?

There is an active, dedicated project team working towards the applicable IVDR deadlines. We have written and submitted many technical files to our Notified Body and are advancing through the process to obtain IVDR certificates.

Who can provide the Declaration of Conformity?

The Declaration of Conformity is the manufacturer's formal declaration that the devices listed on the document are in conformance with the applicable legislation and needs to be completed for all CE marked products.

A declaration of conformity is available for each Thermo Fisher Scientific Microbiology legal manufacturer of CE marked IVD products sold into the EU, including Oxoid Ltd, Oxoid GmbH, Trek Diagnostics, Remel Europe and Remel Inc. If a Declaration of Conformity is required, please contact your local Technical Support.

Will Thermo Fisher Scientific Microbiology label IVDs in accordance with IVDR requirements and where can I get the label?

Yes, as part of our transition activity, labels and IFUs are being updated to include all required information to comply with IVDR. These changes will be implemented once we have received IVDR the IVDR certificate from our notified body, or when we are able to self-declare compliance for Class A products. If a copy of the label is required, please contact your local Technical Support.

Where can I obtain an IVDR-compliant Instructions for Use (IFU)?

As part of our transition activity, labels and IFUs are being updated to include all required information to comply with IVDR. These changes will be implemented once we have received IVDR the IVDR certificate from our notified body, or when we are able to self-declare compliance for Class A's. IFUs will be available on the product webpages on the Thermo Fisher website.

Will IVDR-compliant IFUs be translated?

IFUs for products CE marked under IVDR will be translated into - languages to cover the countries where the product is sold

Do you currently have products that are certified under 98/79/EC Directive that will utilise the grace period afforded by the IVDD certificate?

We have two products currently certified under IVDD; IMAGEN™ Chlamydia kit and its control slide. These devices will be transitioned alongside our other IVD products.

What are your company's timelines for product registration in EUDAMED?

We are already creating plans to gather the required data for EUDAMED. We will work in accordance with EU deadlines on EUDAMED uploads.

What is your plan to be compliant with the post-market surveillance and vigilance processes as defined in IVDR by 26 May 2022?

IVDR-compliant post market surveillance procedures are already in place and upgrades to current reports will begin in 2021. All post market surveillance plans have been updated. The vigilance procedure is being updated to ensure that we will work in accordance with the IVDR requirements.

What is the UKCA mark? Does Thermo Fisher Scientific Microbiology have plans to be compliant by the applicable deadline for Medical Devices including IVDs?

The UKCA (UK Conformity Assessed) marking is a new UK product marking that is used for goods being placed on the market in Great Britain (England, Wales and Scotland). It covers most goods which previously required the CE marking, known as 'new approach' goods.

We plan to comply with UKCA requirements for IVDs in parallel with IVDR implementation, therefore UKCA marking will appear on our clinical IVD products from early 2022.

For more information, visit **thermofisher.com/ivdr-microbiology**