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EU's In Vitro Diagnostic Medical Device Regulation

A quick guide to the new IVDR

The EU's in vitro diagnostic medical device regulation

Manufacturers of in vitro diagnostic medical devices seeking market access to the European Union (EU) will soon face major changes in the EU's decades-old regulatory framework. The EU's In vitro diagnostic medical device regulation (IVDR) was officially published on 5 May 2017 and came into force on 26 May 2017. The IVDR will replace the EU's current directive on in vitro diagnostic medical devices (98/79/EC).

Background

The origins of the proposed IVDR date back to 2008, when the EU Commission initiated a public consultation on the Community's existing requirements covering medical devices. A separate consultation conducted in 2010 on in vitro diagnostic medical devices generated more than 180 comments and proposals for change from a wide variety of stakeholders. As a result, the

Commission released in 2012 its plan to restructure the EU's medical device regulatory framework, along with a proposed regulation that would replace the existing Directive on in vitro diagnostic medical devices.

Since then, the EU's key legislative institutions have reviewed, commented and amended the proposed IVDR in the first reading. A "trilogue" between the EU Commission, the European Council and the European Parliament to identify common positions took place and achieved a consensus on May 25, 2016. It took almost an additional year for legal and linguistic review, restructure the text, smaller corrections, translations, formal approval and publication.

The expected changes and their impact

The proposed IVDR differs in several important ways from the EU's current directive for in vitro diagnostic medical devices. Specific details of these changes, along with their anticipated impact, include:



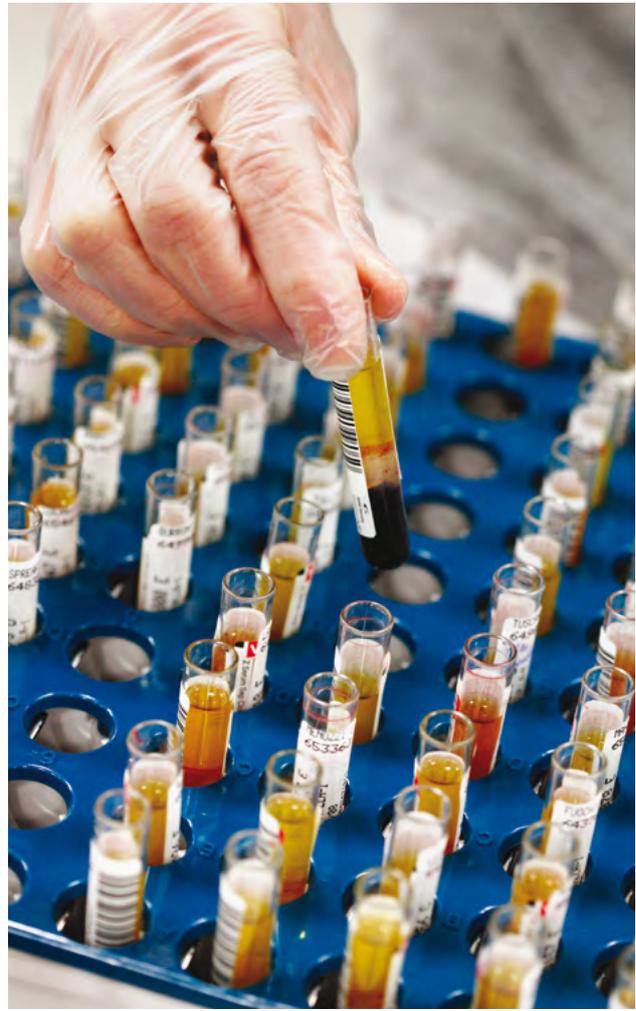
- **Product scope expansion** – The scope of in vitro diagnostic devices covered under the IVDR is expected to be expanded to include diagnostic (including Internet-based) services, genetic testing and other tests that provide information about a patient’s predisposition for a specific disease or for susceptibility for a medical treatment, as well as – by changing of current rules for exemption - devices manufactured for use within a single healthcare institution. This increased product scope will mean that many more manufacturers will be subject to EU requirements for in vitro diagnostic devices.
- **Reclassification of devices according to risk** – The IVDR is expected to impose a classification structure for in vitro diagnostic devices consistent with that of the Global Harmonised Task Force (GHTF). Risk classes will range from Class A for low risk devices to Class D for those devices that pose the greatest risk to patients, healthcare workers and the public. Instead of lists, the regulation will also provide specific rules for properly classifying in vitro diagnostic devices according to their level of risk. Except for Class A (low risk) devices, most in vitro diagnostic devices (> than 70 percent) will require some form of pre-market review and approval by a Notified Body.
- **More rigorous clinical evidence requirements** – The IVDR will likely require device manufacturers to conduct clinical performance studies and provide evidence of safety and performance proportionate with a device’s assigned risk class. In vitro diagnostic device manufacturers will also be required to collect and retain post-market clinical data as part of the ongoing assessment of potential safety risks. For manufacturers, these requirements will require a significant investment of time and resources to conduct the required studies and to maintain required post-market documentation.
- **More stringent documentation** – Technical documentation of devices will be expected to meet more detailed and strict new requirements. In vitro diagnostic device manufacturers will need to review existing documentation, and update or amend that documentation as necessary to meet new content requirements.
- **Identification of “person responsible for regulatory compliance”** – In vitro diagnostic device manufacturers will be required to identify at least one person within their organisation who is ultimately responsible for all aspects of compliance with the requirements of the new IVDR. The organisation must document the specific qualifications of this individual relative to the required tasks. Further, qualifications of responsible persons will be subject to review by Notified Bodies to ensure requisite knowledge and skill.

- **Implementation of unique device identification**
 - The proposed IVDR mandates the use of unique device identification (UDI) mechanisms. This requirement is expected to increase the ability of manufacturers and authorities to trace specific devices through the supply chain, and to facilitate the prompt and efficient recall of in vitro diagnostic medical devices that have been found to present a safety risk. To support this effort, the European Databank on Medical Devices (Eudamed) is expected to be expanded to provide more efficient access to information on approved devices.
- **More rigorous surveillance by Notified Bodies** – The IVDR will increase surveillance of manufacturers by Notified Bodies. Unannounced audits, along with product sample checks and product testing will strengthen the EU’s enforcement regime and help to reduce risks from unsafe devices. Annual safety and performance reporting by device manufacturers will also be required for class C and D devices.
- **Greater Scrutiny of Notified Bodies** – Competent authorities and Reference Laboratories may have to be involved in conformity assessment of high risk devices which will result in elongated conformity assessment procedures. Tighter designation rules for Notified Bodies may lead to a reduced number of Notified Bodies available.
- **No “grandfathering” provisions** – Under the IVDR, all currently approved in vitro diagnostic devices must be recertified in accordance with the new requirements. Manufacturers with currently approved devices will have five years to demonstrate compliance with the IVDR’s new requirements.

The IVDR timeline

The IVDR was officially published on 5 May 2017 and entered into force on 26 May 2017. Manufacturers of currently approved medical devices will have a transition time of five years until 26 May 2022 to meet the requirements of the IVDR. Products already certified by a Notified Body may be placed on the market for further 2 years provided further conditions are met.

It is important to note that, as an EU regulation, the IVDR will have the force of law throughout the EU when it comes into effect. This approach will eliminate country-by-country interpretations of the requirements permitted under current directives.



How you can prepare?

The new requirements in the IVDR, combined with the complex development process for in vitro diagnostic medical devices, is likely to make the transition a complicated and time-consuming process for most device manufacturers.

Because of these complexities, manufacturers of in vitro diagnostic medical devices are well-advised to stay current on the progress of the IVDR through the legislative process, as well as additional changes that may impact them. In addition, since a larger number of medical devices, including in vitro diagnostic medical devices, are expected to require Notified Body review and approval, delays in the review and approval process by Notified Body should be expected. Manufacturers of currently approved devices are therefore advised to consult with their respective Notified Body to evaluate potential compliance issues and to develop a plan to address them promptly. Advanced preparation and early action will be key to ensuring a smooth transition to the new requirements.



How we can help?

TÜV SÜD is closely following developments related to the IVDR, and will provide a number of helpful resources for medical devices manufacturers covering webinars, white papers and information factsheets. These and other resources are designed to help medical device manufacturers stay fully informed about the anticipated changes, and to provide assistance in achieving compliance with the new requirements.

TÜV SÜD is the world's largest EU Notified Body for all types of medical devices covered by EU directives and regulations. We are also a leading global management certification body for quality management systems, including management systems applicable in the manufacture of medical devices. This unique combination of experience makes TÜV SÜD ideally suited to address the needs of medical device manufacturers seeking to achieve or maintain compliance with medical device requirements in the EU and other major markets around the world.

Why choose TÜV SÜD?

TÜV SÜD offers a complete range of testing, certification and auditing services to manufacturers of medical devices, helping them to manage risks and to protect and promote the health and safety of patients. Our global network of more than 500 dedicated medical health and services professionals include noted

scientists and physicians recognised as authorities in their respective fields. These capabilities make TÜV SÜD the preferred single source for worldwide compliance with medical device regulations.

Choose certainty. Add value.

TÜV SÜD is a premium quality, safety and sustainability company that specialises in testing, inspection, auditing and certifications. Represented in over 1,000 locations worldwide, we hold accreditations in Europe, the Americas, the Middle East, Asia and Africa. By delivering services to our customers, we add tangible value to businesses, consumers and the environment.

Related services

TÜV SÜD provides the following related services:

- Global approval of medical devices (foreign affairs)
- ISO 9001 – Quality management system certification
- ISO 13485 – Quality management system certification for medical devices
- Medical device market assessment and certification
- Medical device testing