



America

Add value.
Inspire trust.

EU Regulation 2017/746 on In Vitro Diagnostic Medical Devices

A quick guide to the new IVDR

Introduction

On May 26, 2017 a new European regulation related to in vitro diagnostic medical devices entered into force. From May 26, 2022 both manufacturers of in vitro diagnostic devices and diagnostic providers will be subject to the In Vitro Diagnostic Medical Devices Regulation (IVDR), if they wish to access the European market. It is important to note that as an EU regulation, the IVDR has the force of law throughout the EU and eliminates country-by-country interpretations of the requirements permitted under directives.

Which devices or services are covered by the European Regulation?

The regulation applies to reagents, reagent products, calibrators, control materials, kits, instruments, apparatus, pieces of equipment, software or systems, whether used alone or in combination, and intended to be used for the examination of specimens derived from the human body (blood, urine, tissue, etc.) to diagnose diseases, to monitor

a person's state of health, to monitor therapeutic measures, to determine predisposition to a medical condition or a disease, or to provide information about susceptibility for a medical treatment. The IVDR is also applicable to devices not placed on the market but used for provision of diagnostic services and devices manufactured for use within a single healthcare institution.

IVD devices include:

- **Devices for self-testing** – Devices intended by the manufacturer to be used by lay persons, including devices used for testing services offered to lay persons by means of information society services. For example, pregnancy tests or DNA genetic testing.
- **Devices for near-patient testing** – Devices not intended for self-testing but intended to perform testing outside a laboratory environment, generally near to or at the side of the patient by a health professional (i.e. doctor's office or ambulance).



- **Companion diagnostic devices** – Devices essential for the safe and effective use of a corresponding medicinal product to identify, before and/or during treatment, patients who are most likely to benefit or be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product.
- **Accessories** – Accessories are items that are not in vitro diagnostic medical devices but which are intended by the manufacturer to be used together, particularly in vitro diagnostic medical device(s) in accordance with its/their intended purpose(s).

Risk based classification

The IVDR imposes a classification structure for in vitro diagnostic devices. Risk classes 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 provides 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 90 per cent) require some form of pre-market review and approval by a Notified Body.

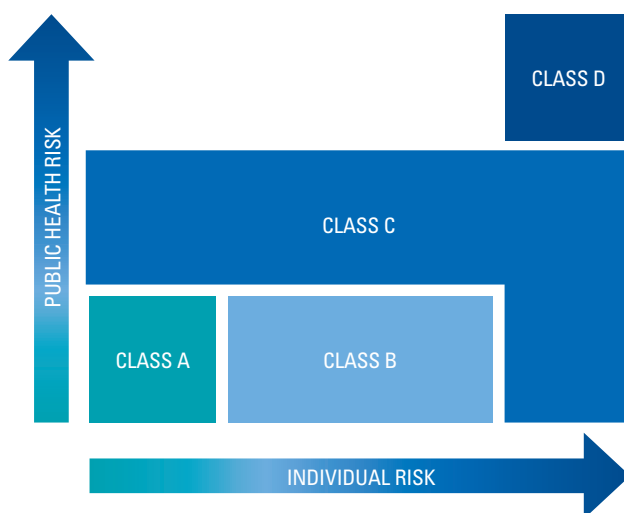


Figure 1: Classification based on risks

New requirements and provisions

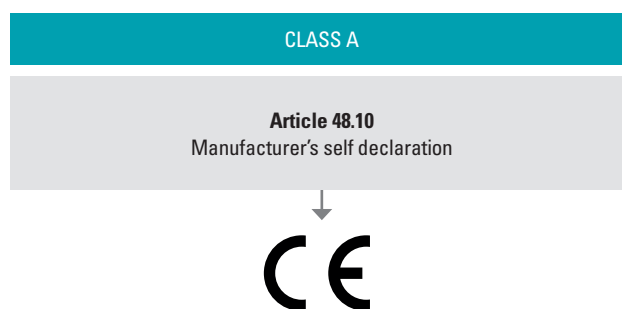
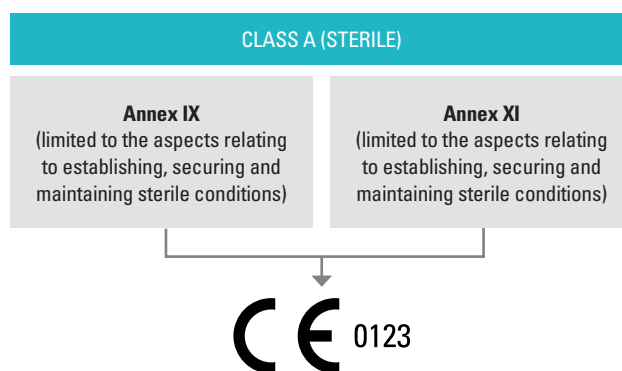
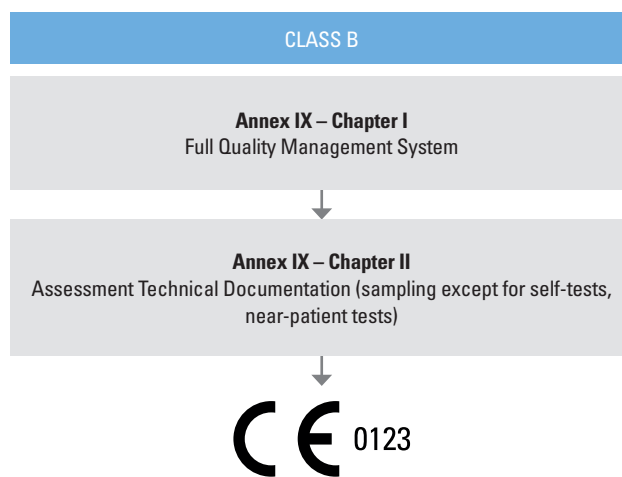
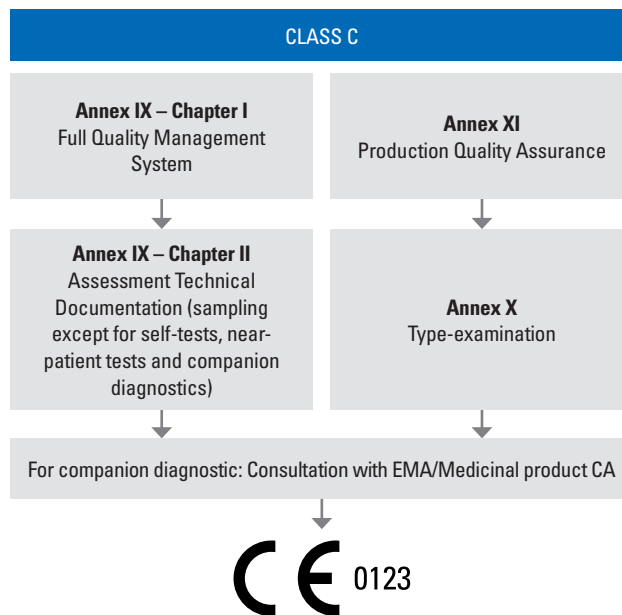
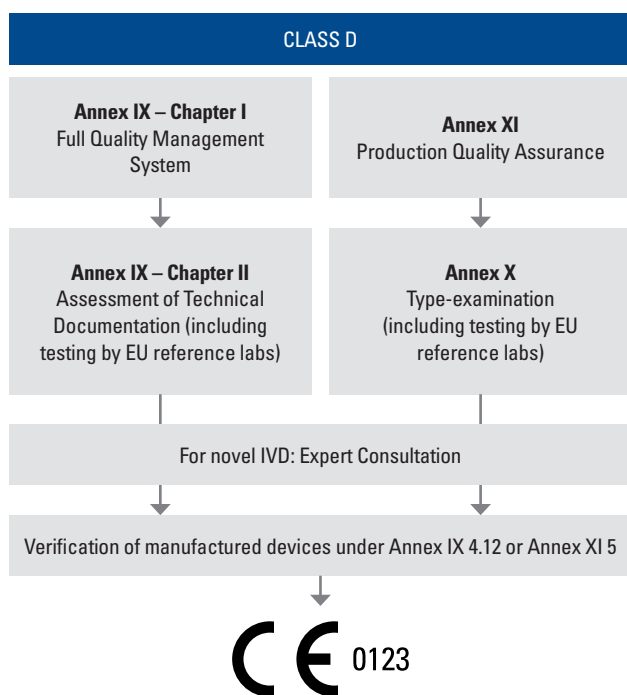
In addition to a wider scope of certification and a new system of classification of in vitro diagnostic devices, the IVDR introduces major changes to the demonstration of device compliance. This document provides a summary of the most important aspects and requirements of the regulation and the potential impacts.

- **Detailed and prescriptive safety and performance requirements** – Annex I of the IVDR, General Safety and Performance Requirements, introduces more prescriptive requirements for in vitro diagnostic devices, with a strong emphasis on risk management. The regulation also introduces new performance study requirements for devices used for near-patient testing.
- **Clinical evidence requirements** – The IVDR requires manufacturers to provide evidence of safety and performance proportionate with a device's assigned risk class. Those data shall be collected through clinical performance studies, unless other sources of clinical performance data are deemed sufficient. In addition, manufacturers are requested to collect and retain post-market clinical data as part of the ongoing assessment of potential safety risks. This represents a significant investment of time and resources to conduct studies and maintain required post-market documentation.
- **Stringent documentation** – Technical documentation of devices is subject to more detailed and strict requirements (Annex II and Annex III). In vitro diagnostic device manufacturers are expected to review, update or amend that documentation as necessary to meet IVDR requirements.
- **Identification of "person responsible for regulatory compliance"** – The IVDR requires manufacturers to identify at least one person within their organization who is ultimately responsible for all aspects of compliance with the requirements of the regulation. The specific qualifications of this individual, related to the required tasks that must be documented by the organization, are subject to review by Notified Bodies to ensure requisite knowledge and skill.
- **Increased traceability** – The 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. The UDI and access to associated information on approved devices will be stored in the European Databank on Medical Devices (Eudamed).

- Rigorous surveillance by Notified Bodies** – The IVDR increases the surveillance of manufacturers by Notified Bodies, using unannounced audits, product sample checks and product testing in order to help reduce risks from unsafe devices. In addition, manufacturers of Class C and D devices are required to make available, respectively submit at least annually a Periodic Safety Update Report for each device or, where relevant, group of devices.
- Greater scrutiny of Notified Bodies** – Expert panels, reference laboratories and competent authorities shall be involved in conformity assessments as indicated in the diagram for class D and C devices, which will result in elongated conformity assessment procedures. In addition, tighter designation rules for Notified Bodies will have an impact on the number of available Notified Bodies.
- No “grandfathering” provisions** – Under the IVDR, all currently approved in vitro diagnostic devices must be recertified in accordance with the new requirements. From May 26, 2022 all devices placed on the EU market need to demonstrate compliance with the IVDR’s new requirements. Manufacturers can however take advantage of an additional grace period until May 26, 2024 for those in vitro diagnostic devices that are covered a valid EC certificate under the IVDD.

Conformity assessment procedures

Manufacturers may select the route of conformity assessment if there are different options. The different procedures are described in the Annexes of the IVDR.



IVDR implementation timeline

Manufacturers of devices currently placed on the market have time until May 26, 2022 to meet the requirements of the IVDR. Devices covered by a valid certificate issued under IVDD by a Notified Body may be placed on the market for further two years if the following conditions are met:

- Continued compliance to Directive 98/79/EC.
- No significant change in the design and intended purpose.
- Compliance with the requirements of the IVDR relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices.

How can you prepare?

The requirements of the IVDR, combined with the complex development process for in vitro diagnostic medical devices, makes the transition a challenging and time-consuming process for most device manufacturers. In addition, since a large number of in vitro diagnostic medical devices are expected to require Notified Body involvement in conformity assessments, delays in the certification process by a Notified Body should be expected.

Advanced preparation, resource preparation, early action, and communication with the Notified Body will be key to ensuring a smooth transition to the new requirements.

How can TÜV SÜD help you?

TÜV SÜD is closely following developments related to the IVDR and will provide a number of helpful resources for medical devices manufacturers, including webinars, technical meetings and information factsheets. These and other resources are designed to help medical device manufacturers stay fully informed about the anticipated changes.

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. We are also a global service provider of electrical safety, software, cybersecurity, and functional testing. 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 750 dedicated medical health and services professionals include noted scientists, engineers, and physicians recognized as authorities in their respective fields. These capabilities make TÜV SÜD the preferred single source for worldwide compliance with medical device regulations.

Add value. Inspire trust

TÜV SÜD is a trusted partner of choice for safety, security and sustainability solutions. It specializes in testing, certification, auditing and advisory services. Since 1866, the company has remained committed to its purpose of enabling progress by protecting people, the environment and assets from technology-related risks. Through more than 24,000 employees across over 1,000 locations, it adds value to customers and partners by enabling market access and managing risks. By anticipating technological developments and facilitating change, TÜV SÜD inspires trust in a physical and digital world to create a safer and more sustainable future.

Related services

TÜV SÜD provides the following related services:

- Certification of devices under Japanese PAL
- MDSAP certification
- IEC 60601 – Medical electrical equipment
- IEC 61010 – Laboratory electrical equipment safety
- IEC 62443 – Cybersecurity Management
- EMC testing
- NRTL testing