EU Regulation 2017/746 on In Vitro Diagnostic Medical Devices

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A quick guide to the IVDR

Introduction
On 26 May 2017 a new European regulation related to in vitro diagnostic medical devices entered into force. The Date of Application (DoA) of the In Vitro Diagnostic Medical Devices Regulation (IVDR) was 26 May 2022. Following the publication of Regulation 2022/112 and Regulation 2023/607, the transitional provisions of the IVDR have been modified and 'sell off' dates in article 110(4) of the IVDR are removed (refer to IVDR Implementation Timeline below for further details). 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.

- **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 device**s – 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 non-sterile (low risk) devices, most in vitro diagnostic devices (> than 80 percent) require some form of pre-market review and approval by a Notified Body.

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.

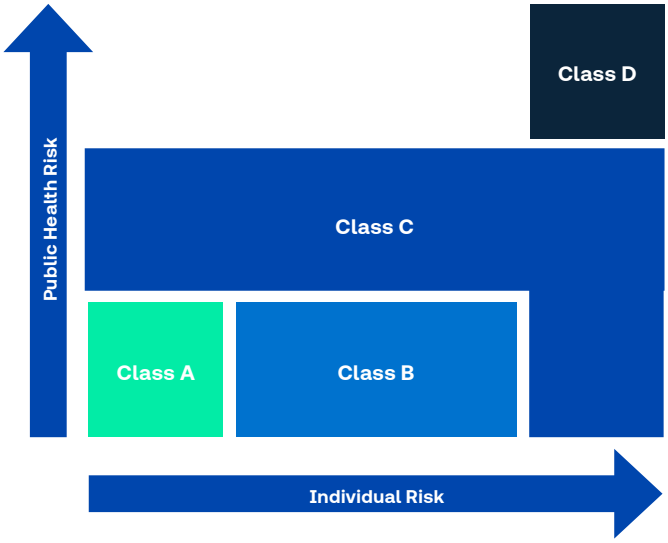

Fig. A Classification based on risks

- **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 postmarket 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 organisation 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 organisation, 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 panel, reference laboratories (if designated) 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** – All currently approved in vitro diagnostic devices must be recertified in accordance with IVDR requirements. From 26 may 2022 all class A self declared and all new devices placed on the EU market need to comply with IVDR requirements. For more details on the IVDR transition, refer to the IVDR implementation timeline section below.

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.

Class D

Annex IX – Chapter I Quality Management System	**Annex XI** Production Quality Assurance
Annex IX – Chapter II Assessment of Technical Documentation (including testing by EU reference labs if designated)	**Annex X** Type-examination (including testing by EU reference labs if designated)

For novel IVD: Expert Consultation

Verification of manufactured devices under Annex IX 4.12 or Annex XI 5

CE 0123

Class C

Annex IX – Chapter I Quality Management System	**Annex XI** Production Quality Assurance
Annex IX – Chapter II Assessment Technical Documentation (sampling except for self-tests, nearpatient tests and companion diagnostics)	**Annex X** Type-examination

For companion diagnostic: Consultation with EMA/Medicinal product CA

CE 0123

Class B

Annex IX – Chapter I
Quality Management System

Annex IX – Chapter II
Assessment Technical Documentation (sampling except for self-tests, near-patient tests)

CE 0123

Class A (sterile)

Annex IX (limited to the aspects relating to establishing, securing and maintaining sterile conditions)	**Annex XI** (limited to the aspects relating to establishing, securing and maintaining sterile conditions)

CE 0123

Class A

Article 48.10
Manufacturer's self declaration

CE

Conditions to benefit from extended transition period
Following the publication of regulation 2022/112, devices of all other classes covered by a valid NB certificate or with a Declaration of Conformity issued prior to 26 May 2022, may be placed on the market for additional time 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.

Refer to the next section for the detailed implementation timing.

IVDR implementation timeline
Under Regulation EU 2023/607 , the 'sell off' dates in article 110(4) of the IVDR are removed. This allows in vitro diagnostic medical devices which are already placed on the market, to remain on the market without having to be disposed of. This can only be done if the devices were originally compliant to previous legal requirements under In Vitro Diagnostic Directive (IVDD).

The transition period depends on the class of the IVD device under the current Directive and Regulation 2017/746 as well as additional conditions available below in the next section:

- Devices placed on the EU market prior to 26 May 2022 as self-declared (i.e. with no notified body involvement) and that require the involvement of a notified body under the Regulation, may be placed on the market or put into service under the Directive until the following dates:
  - 26 May 2026, for class D devices;
  - 26 May 2027, for class C devices;
  - 26 May 2028, for class B devices and class A devices placed on the market in sterile condition.
- Devices placed on the EU market prior to 26 May 2022 with notified body certificate, may be placed on the market or put into service under the Directive until 25 May 2026.

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 timeconsuming 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 IVDR requirements, and ensure a timely review and approval of their devices ahead of the IVDR Date of Application.

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

Visit TÜV SÜD's IVDR Service Registration page to request for services for IVDR certification or reach out to us at medicaldevice@tuvsud.com for medical devices requests.

Add value. Inspire trust
TÜV SÜD is a trusted partner of choice for safety, security and sustainability solutions. It specialises in testing, certification, auditing and advisory services. Through more than 25,000 employees across over 1,000 locations, it adds value to its customers, inspiring trust in a physical and digital world.

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
- Testing services including EMC and NRTL testing

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