Add value.
Inspire trust.

IVDR Companion Diagnostics (CDx)

Ensuring an efficient conformity assessment

CDx conformity assessment challenges

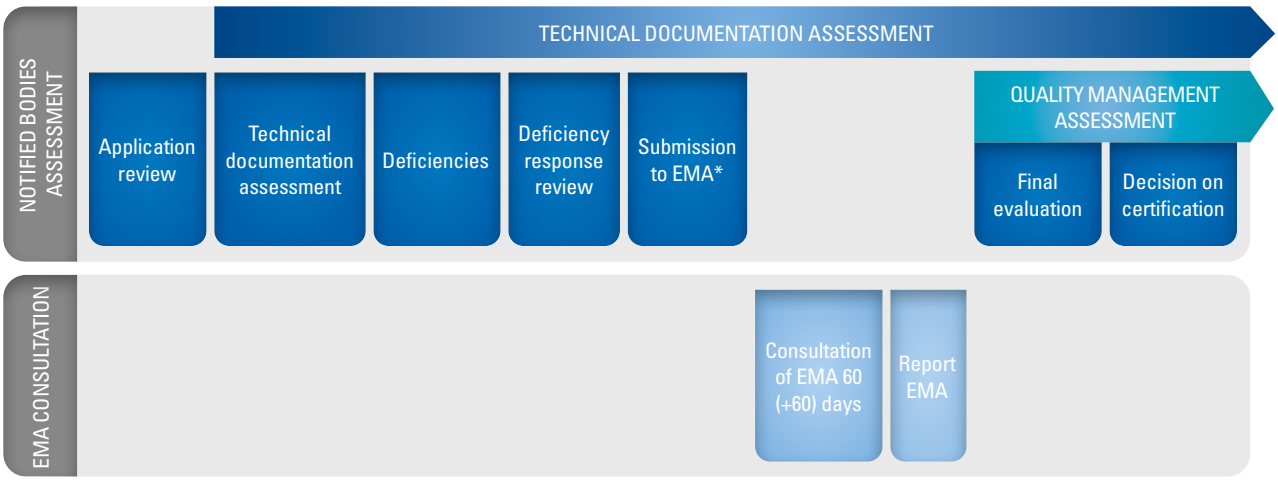
The In-vitro Diagnostic Medical Devices Regulation (IVDR) replaces the old In Vitro Diagnostic Medical Device Directive (IVDD) and introduces significant implications for the regulation of CDx. The IVDR defines a CDx as a device which is essential for the safe and effective use of a corresponding medicinal product to identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product or patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product.

Previously, CDx were classified as general in vitro diagnostic medical devices and self-declared by the manufacturer. The IVDR introduced a new rules-based classification system, which categorises CDx devices as Class C - the second highest risk level. In addition, it exempts these devices from technical documentation (TD) sampling. The IVDR certification assessment therefore necessitates the involvement of a Notified Body.

Before the CDx is certified, depending on the medicinal product type, the Notified Body must seek a scientific opinion from either a Competent Authority, designated by a Member State, or European Medicines Agency (EMA). This consultation process shall take 60 days, which can be extended by a further 60 days on justified grounds. As per Regulation EU 2022/112, existing CDx certified under the IVDD have until 26 May 2026 to be certified under the IVDR. However, if a significant change to its design and/or intended purpose is required, the CDx must be certified under the IVDR immediately.

It is recommended that CDx manufacturers liaise with the relevant Notified Body early in the product development lifecycle. As the Notified Body is only permitted to review the completed TD, following successful application management, early communication and well-prepared documents are the most effective ways for device manufacturers to positively influence the efficiency of a Notified Body's review.

IVDR CONFORMITY ASSESSMENT FOR CDX



The process can vary significantly depending on various factors such as

- Quality of TD
- Number of deficiencies identified
- Manufacturer response times
- Audit findings
- EMA Submission*

*To facilitate the EMA assessment, the EMA submission for consultation will be started once the notified body has performed their review as part of the conformity assessment of the device and the draft SSP and IFU have been updated accordingly.

How can we help you?

CDx devices are complex and require the involvement of multiple stakeholders before they can be brought to market. The key to minimising time to market is a thorough understanding of the relevant regulations, and TÜV SÜD has in-depth knowledge and experience of medical equipment certification standards around the globe. This unique combination of experience makes TÜV SÜD ideally suited to address the needs of customers seeking completion of a successful CDx IVDR certification.

Our IVDR conformity assessment for CDx

TÜV SÜD offers a complete range of testing, certification and auditing services to manufacturers of medical devices. We help them to manage risks, as well as protect and promote the health and safety of patients.

Our CDx IVDR conformity assessment include:

TD assessment

- Assessment of technical documentation to ensure applicable IVDR requirements are fulfilled
- Consultation of EMA for scientific opinion on CDx and follow-up of request for additional information

- **Quality management system assessment**
  - Assessment of quality management system to ensure applicable IVDR requirements are fulfilled
- **Applicable Conformity Assessment Prodecures**
  We work with you to ensure that you meet the necessary ADR requirements, and that all necessary documents are provided to gain access to Australia's automotive market. In addition, we support you with the communication with local authorities.
- **Multi regulation management**

TYPE OF DEVICES	APPLICABLE CONFORMITY ASSESSMENT ROUTE	TYPE OF NB´S CERTIFICATE
Companion diagnostics [Class C]	■ Technical documentation assessment – IVDR Annex IX Ch. II **and** ■ Quality Management System – IVDR Annex IX, Ch. I & III	■ EU technical documentation certificate **and** ■ EU quality management system certificate
	■ Type Examination – IVDR Annex X **and** ■ Production quality assurance – IVDR Annex XI	■ EU type examination certificate **and** ■ EU production quality assurance certificate

Why choose TÜV SÜD?

TÜV SÜD is designated as a Notified Body under the IVDR and is the world's largest Notified Body for all types of medical devices covered by EU directives and regulations. We have actively participated in the development of the EMA consultation process from the beginning, and we were the first Notified Body to apply this process and issue a certificate for CDx under the IVDR. Our dedicated CDx specialists also have a wealth of hands-on experience with CDx conformity assessments across the globe, giving you a unique insight into both the certification process and best practice to ensure an efficient market launch for your CDx products.

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.

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, the company 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:

- In Vitro Device Regulation (IVDR) conformity assessments
- Testing services including EMC testing, NRTL testing
- Medical Device Single Audit Program (MDSAP)

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