IVDR Companion Diagnostics (CDx)

Add value.
Inspire trust.

Ensuring an efficient conformity assessment

CDx conformity assessment challenges
The In Vitro Diagnostic Medical Devices Regulation (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.

The IVDR categorises CDx devices as Class C - the second highest risk level. The IVDR certification assessment therefore necessitates the involvement of a Notified Body. In addition, these devices are exempt from technical documentation (TD) sampling. Therefore a technical documentation assessment certificate is required in addition to the quality system certificate.

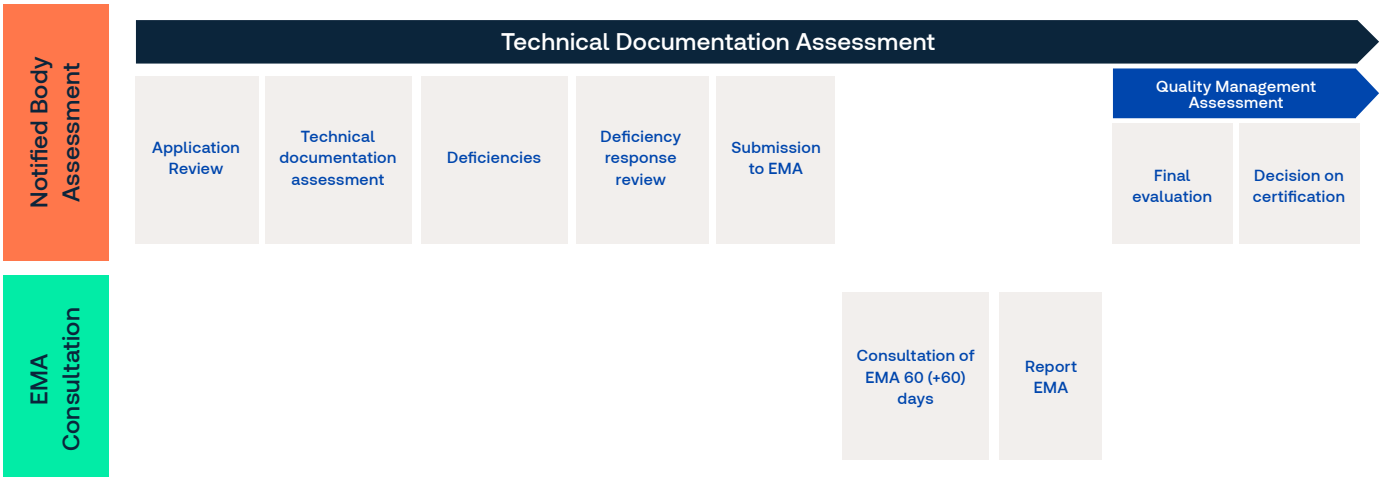
Before the CDx is certified, depending on the medicinal product type, the Notified Body must seek a scientific opinion from either a Competent Authority, designated by a Member State, or the European Medicines Agency (EMA).

This consultation process takes 60 days, which can be extended up to a further 60 days on justified grounds. There are no clock stops permitted within the consultation process, therefore once it commences, it must conclude within a maximum of 120 days.

As per Regulation EU 2024/1860, existing CDx placed on the market under the IVDD have until 31 December 2028 to be certified under the IVDR. However, if a significant change to its design and / or intended purpose is made, the CDx must be certified under the IVDR immediately. Download our infosheet on the extended transition timelines.

It is recommended that CDx manufacturers engage with us early in the product development lifecycle. Our structured dialogue provides the opportunity to clarify the requirements and procedural aspects of the application for conformity assessment. 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
Our CDx IVDR conformity assessment includes:



Key factors influencing the duration of the conformity assessment include:

- Quality of the Technical Documentation
- Number of deficiencies and audit findings identified
- Manufacturer response times

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 Summary of Safety and Performance (SSP) and Instructions for Use (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 the technical and clinical features of CDx devices. TÜV SÜD has the in-depth regulatory and technical expertise to address the needs of customers seeking a successful CDx IVDR certification.

Our IVDR conformity assessment for CDx
TÜV SÜD offers a complete range of certification and auditing services to manufacturers of in vitro diagnostic medical devices. We help you manage risks, protect and promote the health and safety of patients.

- **Technical Documentation 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 Procedures

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 full-scope Notified Body under the IVDR and is one of the world's largest Notified Bodies for all types of medical devices covered by EU 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 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 includes noted scientists, engineers, and physicians recognised as experts 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 your trusted partner of choice for safety, security and sustainability solutions. We specialise in testing, certification, auditing and advisory services. Through close to 28,000 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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