In Vitro Diagnostic Medical Device Regulation (IVDR) Certification Services

PLACE YOUR IN VITRO DIAGNOSTIC MEDICAL DEVICES ON THE EU MARKET

WHAT IS THE IVDR?

The EU In Vitro Diagnostic Medical Device Regulation (IVDR) 2017/746 entered into force on May 26, 2017, replacing the EU In Vitro Diagnostic Medical Devices Directive (IVDD). In vitro diagnostic medical devices (IVDs) placed on the EU market must be certified against the new requirements.

The IVDR regulates in vitro diagnostic medical devices placed on the EU market. It aims to improve the safety and efficacy of IVDs, ensuring patient clinical safety and creating a transparent and robust framework for manufacturers and healthcare professionals.

Key changes from the IVDD include:

- Expanded scope of products to be considered IVDs
- Changes in device classification (from Class A devices with the lowest risk to Class D devices with the highest risk)
- Stricter oversight of manufacturers by Notified Bodies
- Enhanced requirements for post-market surveillance
- Increased transparency through the Unique Device Identification (UDI) system and the European Database on Medical Devices (EUDAMED)

IVDR certification is a compliance requirement set by the EU to ensure the safety and performance of IVDs.

HOW TO GET YOUR IVDR CERTIFICATION AND CE MARK?

SGS is a designated IVDR Notified Body. We can perform conformity assessments against IVDR in your country. Our expert auditors and product assessors can support you in bringing a wide range of IVDs to the EU market, including:

- Immunogenetics, genetics of cancer and inherited conditions
- Cancer markers
- Infectious disease markers
- Clinical biochemistry and other general analytes
- Sterile IVDs
- In vitro diagnostic medical device software (IVD MDSW)
- Self-tests and near-patient tests

We will issue you a certificate for your in vitro medical device following a successful conformity assessment. This enables you to affix the CE mark to your device and legally place it on the EU market. The certificate must be renewed every five years and is subject to annual surveillance, post-market follow-up, sampling and/or testing.

WHAT ARE THE KEY REQUIREMENTS FOR IVDR CERTIFICATION?

- Classifying the device based on risk, following the IVDR classification rules
- Implementing a compliant quality management system (QMS), such as an ISO 13485 QMS
- Preparing technical documentation and a performance evaluation report
- Compiling sufficient clinical evidence to demonstrate device safety and efficacy. This is likely to include conducting clinical performance studies
- Engaging a Notified Body for a conformity assessment

WHO IS IT FOR?

Manufacturers of in vitro diagnostic medical devices who intend to place their products within the EU. This includes companies of all sizes, from large multinationals to small startups.

HOW DO WE SUPPORT YOUR CERTIFICATION JOURNEY?

We offer various services to help you achieve certification efficiently, allowing you to save time and reduce costs:

- Online or face-to-face training courses
- Integrated audit solutions
- Assessment and certification services under Annex IX and Annex XI of the IVDR
- Support from our account management team
- Additional resources to meet your specific needs

WHY SGS?

With decades of experience and expertise in medical devices regulatory compliance, we are:

- A Notified Body in Belgium (1639) for the IVDR and Medical Device Regulation (MDR)
- A Notified Body in Finland (0598) for Software as a Medical Device (SaMD) certification
- An Approved Body (0120) for the UKCA mark
- An Approved Auditing Organization (AO) for the Medical Device Single Audit Program (MDSAP)

For more information on our IVDR Certification Services, email: certification@sgs.com.