10 steps for the European IVDR CE marking

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01 IS YOUR DEVICE AN IN VITRO DIAGNOSTIC MEDICAL DEVICE?

Define the intended purpose of the in vitro diagnostic medical device. Describe what the device is intended to detect or measure, from which type of specimen, and for what medical purpose—such as screening, diagnosis, or monitoring. Define the target population and intended users and explain the clinical benefits for the individual or public health. Ensure that evidence is provided to demonstrate safety and performance across all relevant patient groups and use environments, unless explicitly excluded. Determine if your device is an in vitro diagnostic medical device, based on the definition of Article 2 of IVDR. Please see the European Commission website for more information.

02 DETERMINE CLASSIFICATION AND AQUIRE SRN

Determine the classification of the device according to the rules set out in Annex VIII of the IVDR: Class A (non-sterile, sterile), Class B, Class C, or Class D.

You may contact your national authority (Competent Authority, CA) at this step to get information of the requirements for national registration. Acquire a Single Registration Number (SRN) for your company from the CA or from the EUDAMED, once it is operational (please see Article 28 and Annex VI)

03 IMPLEMENT A QMS

Implement a Quality Management System (QMS) in accordance with Article 10 of the IVDR. Most companies will apply the EN ISO 13485 standard to meet the key requirements of the IVDR.

04 PREPARE DOCUMENTATION

Prepare Technical Documentation for your device(s) that provides detailed information and evidence for compliance with IVDR Annex I - General Safety and Performance Requirements (GSPR). The structure of documentation is specified in the Annex II - Technical Documentation and Annex III – Technical Documentation on Post-Market Surveillance.

Technical documentation should be presented in a clear, organized, readily searchable, and unambiguous manner. The structure of the technical documentation shall follow Annex II and III requirements.

Wherever possible, compliance should be demonstrated using relevant harmonized standards and common specifications. Please note that if a test report is not issued by a competent and independent conformity assessment body, the notified body may not accept it as valid evidence.

05 APPOINT AN EU AUTHORIZED REP

If your company is located outside of the EU, appoint an Authorized Representative (EC REP) located in the EU with a written agreement.

The Authorized Representative should be qualified to handle regulatory issues. Place EC REP name and address on Technical File, Declaration of Conformity, Instructions for Use and packaging. Additional guidance is available through Article 11 of the IVDR and MDCG document 2022-16.

06 APPLY A NOTIFIED BODY

For all devices except Class A (non-sterile), you must apply a Notified Body to audit and review your QMS and Technical File, depending on the selected conformity route. The appointed Notified Body must have your device category in their designated scope. Please see the Nando database for the designated scopes of all European Notified Bodies.

07 GET EUROPEAN IVDR EC CERTIFICATE

For all devices except Class A (non-sterile), a Notified Body issues a European EC Certificate after successful completion of your Notified Body audit and technical documentation assessment. You may also want to have a voluntary ISO 13485 certificate for your facility that is required by many customers and regulators. ISO 13485 certificate is valid for three years and IVDR CE certificate is valid for 1-5 years, depending upon the certification decision. After initial certification, there will be annual surveillance audits for continuous follow-up of the conformity of the QMS and devices.

08 REGISTER IN THE EUDAMED

All in vitro diagnostic medical devices must be assigned Unique Device Identifier (UDI) and registered in the EUDAMED system, as defined in Parts B and C of Annex VI of the IVDR.
For further information, please see the European Commission website.

09 PREPARE A DECLARATION OF CONFORMITY

Prepare a Declaration of Conformity (DoC), a legally binding document signed by the manufacturer's authorized person. The DoC contains a set of mandatory information and states that the device is following applicable regulations, directives, and other legislation. Please see the Official Journal of the EU 2016/C272/01 and Annex IV of IVDR for detailed requirements of DoC.

10 AFFIX THE CE MARK

When all the previous steps have been completed, you may now affix the CE Marking. For Class A sterile, Class B, Class C, and Class D in vitro diagnostic medical devices, the CE marking must include the notified body number that granted you the EC IVDR Certificate.

Note: The new In Vitro Diagnostic Medical Devices Regulation 2017/746 has entered into force on 26 May 2017 and became fully applicable on 26 May 2022, replacing Directive 98/79/EC. EC certificates issued under Directive 98/79/EC before 26 May 2022 may remain valid under specific translational provisions, according to regulation (EU) 2024/1860.

IVDR (EU) 2017/746 and MDCG Guidance notes.

FOR FURTHER INFORMATION, PLEASE CONTACT:

Mari Levula
Head of IVD Notified Body
Mobile: +358 44 7441308
email: IVD.devices.fimko@sgs.com
SGS Fimko Ltd Takomotie 8 FI-00380 Helsinki, Finland

When you need to be sure

SGS Headquarters
1 Place des Alpes
P.O. Box 2152
1211 Geneva 1
Switzerland

sgs.com