Reach the European market with MDR certification

SGS MEDICAL DEVICE SOLUTIONS

Introducing the MDR

As of May 26, 2021, the European Union's (EU) Medical Device Regulation (MDR) came into force. The aim is to enhance European patient safety and device traceability and transparency.

The MDR is a new law that repeals the Medical Device Directive (MDD) and Active Implantable Medical Devices (AIMD) Directive. It applies to all manufacturers and distributors that want to sell medical devices in the EU.

MDR places more emphasis on unifying the market and includes tightened and new requirements. It also introduces principal and supportive responsibilities for the European Medicines Agency (EMA) and national competent authorities in assessing certain product categories.

Key areas

- Broader scope and up-classification rules
- Tougher clinical evaluation
- Improved EUDAMED database to improve traceability and transparency
- New unique device identifiers (UDIs)
- Stronger post-market surveillance
- Reinforced regulatory requirements

Some new areas

- At least one person in your organization must be formally responsible for regulatory compliance.
- Extended scope on products with no medical purpose but are analogous to devices with a medical purpose. This is aimed at medical devices like those with cosmetic purposes.

An MDR Notified Body

Although the regulation has changed, our ability to provide high-quality support and manage the marking process remains the same.

Our Notified Bodies team has worked hard to prepare for the MDR designation. SGS Belgium NV has been designated an MDR Notified Body by the European Commission (EC) and Federal Agency for Medicines and Health Products (FAMHP), the Belgian competent authority.

With our existing approvals under the UK Conformity Assessed (UKCA) scheme, we are one of the few regulatory bodies that can provide medical device certification services across all of Europe, including the UK and Northern Ireland.

Whatever your product or market, we also have an experienced global network of local teams to cater to your specific country and language needs.

Any medical device

The medical device type can dictate the tailored service we provide. Our expert teams can provide training and full technical documentation assessment, as part of our MDR conformity services.

Our expert auditors and product assessors can support you to bring any medical device to the European market, including:

- Non-active medical devices (e.g. orthopedic implants, surgical instruments and other sterile single-use items)
- Electrical and electronic medical devices, including embedded and standalone software
- Devices containing an ancillary medicinal substance to support its function (e.g. drug-eluting stents, metered-dose inhalers and bone cement that includes antibiotics)
- Devices containing animal tissues (e.g. wound dressings with collagen)

Medical device training courses

Stay up to date on the latest medical device standards and regulations with SGS Academy's series of training courses.

SGS Academy's training solutions help organizations to improve personal competence and skills, enable sustainable business development and gain a competitive advantage.

With expert trainers, training moves beyond theory to provide valuable real-world insights.

Medical device training courses

- Introduction to the new MDR – online
- MDR – implementing the changes
- MDR internal auditor
- MDR medical devices auditor/lead auditor training course
- MDR technical documentation training course
- ISO 14971 and ISO 31000 – adopting a product and process risk-based approach
- Medical devices clinical evaluation implementation
- Introduction to the new IVDR – online

SGS medical device solutions

In addition to our MDR service, we offer a range of solutions to act as the one-stop shop for all your medical device certification and testing needs.

Certifications

ISO 13485
Medical Devices – Quality Management Systems

MDSAP
Medical Device Single Audit Program

3P510k
510(k) Third-Party Review

JPAL
Japanese Pharmaceutical Affairs Law

UKCA
UK Conformity Assessed

Training with SGS Academy

ISO 13485 Medical Devices QMS Lead Auditor Training

Build your knowledge, skills and practical toolkit to effectively lead medical device quality management system audit teams to perform audits of ISO 13485, in accordance with ISO 19011 auditing guidance.

Duration: 4 days

ISO 13485 Medical Devices QMS Internal Auditor Training

Build your knowledge, skills, and practical toolkit to perform internal audits of an ISO 13485 medical device quality management system.

Duration: 3 days

ISO 13485 Documenting and Implementation

This course provides knowledge and skills to create and maintain quality management system documentation that meets ISO 13485 requirements.

Duration: 2 days

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WHEN YOU NEED TO BE SURE