MEDICAL DEVICES ANNOUNCEMENT

EUROPEAN MEDICAL DEVICES REGULATION PUBLISHED

The MDR was published on May 5, 2017. Economic operators involved in the medical device business will have three years from May 25 to transition.

The European Medical Devices Regulation (MDR), was published in the Official Journal of the European Union on May 5, 2017. Published as Regulation 2017/745, it covers medical devices and active implantable medical devices. Its requirements pertain to the European Commission, as well as manufacturers, Notified Bodies and member state competent authorities. The new regulation is almost three times as long as, and much stricter than the previous Medical Device Directive (MDD).

There will be a transition period of three years, beginning May 25, 2017, for all economic operators involved in the medical devices business in Europe.

Important new requirements for manufacturers and their authorized representatives include:

- New classification rules covering nanomaterials (Rule 19), products composed of substances absorbed or locally dispersed in the human body (Rule 21) and products with no medical purpose [Annex XVI]
- Notified Body intervention for Class I reusable surgical instruments
- Reinforced clinical data with the need to submit clinical evaluation reports for class III and implantable class IIb to an external experts' panel before device certification
- Post-market surveillance plan/report, post-market clinical follow-up reports, and for Class IIa, IIb and IIII a periodic safety update report, and for Class IIb implantable devices and Class III devices a summary of safety and clinical performance
- Designated person responsible for regulatory compliance with demonstrated expertise in the medical devices field
- Unique device identification system for all medical devices marketed in Europe and associated electronic system
- Reinforced role of electronic system (EUDAMED) in market surveillance, vigilance, supply chain traceability

There will be a new designation process for Notified Bodies, which includes reinforced requirements in terms of resources and assessment of manufacturers, as well audits by a Joint Assessment Team delegated by the EU Commission.

SGS is preparing to be designated as a Notified Body under the MDR. This will enable us to provide services to medical device manufacturers, distributors, authorized representatives and importers as soon as possible.

We will keep you informed of future developments and let you know about new training courses and webinars that we are providing to help you implement the new regulations.

ABOUT SGS

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognized as the global benchmark for quality and integrity. With more than 90,000 employees, SGS operates a network of over 2,000 offices and laboratories around the world.

To learn how SGS can help your organisation with Medical Devices contact us at medicaldevices@sgs.com