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Medical device regulation

Are you prepared for the changes?

The proposed Medical Device Regulation (MDR) is approaching the final stages of development before becoming law as a regulation. The MDR differs significantly from the outgoing MD Directive that was first introduced in 1993.

The current EU regulatory framework for medical devices consists of the Medical Devices Directive, 93/42/EEC and Active Implantable (AIMD) Medical Devices Directive, 90/385/EEC.

The proposed revision, published by the European Commission on September 26, 2012, will combine the two directives and shall be introduced as a regulation instead of a directive.

The reason for this is because it imposes clear and detailed rules which do not give room for divergent transposition by member states and, as a regulation, it ensures that legal requirements are implemented at the same time throughout the union.

New requirements

The European Commission has changed the requirements with the anticipation of achieving three key objectives:

- to give patients, consumers and healthcare professionals confidence in the devices they might use every day
- to allow industry to bring safe, effective and innovative products to market quickly and efficiently
- to increase the availability of innovative companies to attract investors, estimate costs and anticipate procedures.

Scope of regulated medical device products

The regulation clarifies and expands the scope of regulated medical devices and comprises of:

- the inclusion of active implantable devices combined into a single regulation
- expansion of scope to include products with an aesthetic or non-medical purpose but which are similar to medical devices in terms of function and risk profile
- new classification rules for devices utilizing nanomaterials and devices intended to be ingested or inhaled and medical software
- orally-administered products and requirements for conformity assessment
- expansion of rule 17 to include devices manufactured utilizing non-viable tissues or cells of human origin.

Pre-market scrutiny procedure

The European Commission proposed a 'scrutiny' procedure of a notified body's preliminary assessment report for implantable medical devices classified as class III by the Member State Authorities' Committee prior to the granting of CE marking certification. The aim of this procedure was to improve the overall quality of notified bodies and their review of certain categories of high-risk class medical devices.

This mechanism foresees that the newly formed committee for member state authorities, the Medical Devices Co-ordination Group (MDCG), monitors applications being handled by notified bodies prior to the notified body issuing its certificate. The MDCG will then flag those they would like to check and comment upon the notified body's assessment and the submission dossier of the manufacturer.

The CE marking would be dependent upon both the manufacturer and the notified body addressing any issues identified by the MDCG.

Person responsible for regulatory compliance

Manufacturers will be required to have at least one person available that is responsible for regulatory compliance who possesses expert knowledge in the field of medical devices.

That expert knowledge can be proven by either of the following qualifications:

- Diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or equivalent, in a relevant discipline. Additionally, at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices is required
- Five years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

This person is responsible for ensuring device conformity is appropriately assessed before batches are released. They must also ensure that the technical documentation and declaration of conformity are prepared and kept up-to-date, and that vigilance reporting obligations are fulfilled.

Identification and traceability

The proposed MDR stipulates medical device manufacturers must fit their devices with a unique device identification (UDI) and provides full details of the information that needs to be accessed through the UDI.

The UDI system will be implemented gradually and proportionately according to the risk level (risk class) of the device. There is also a requirement that economic operators shall be able to identify who supplied them and to whom they have supplied medical devices. Additionally, there is an obligation for high-risk device manufacturers to make publicly available a summary of safety and performance, with key elements of the supporting clinical data.

Vigilance and market surveillance
The EU Commission proposes to setup and manage an electronic system to collate and process reports by manufacturers on serious incidents, field safety corrective actions, field safety notices and periodic summary reports.

Notified bodies
The position of notified bodies in relation to manufacturers will be significantly strengthened. They will have a right and duty to carry out unannounced factory inspections and to conduct physical or laboratory tests on devices.

This mandates the current expectations that are within the recommendation, 2013/473/EU, and which most notified bodies are implementing under the controls of their respective competent authorities.

The proposal also requires rotation of the notified body's personnel involved in the assessment of MDs at appropriate intervals to strike a reasonable balance between the knowledge and experience required to carry out thorough assessments.

Timetable for introduction and transition
The new regulation will become applicable three years after its entry into force. The current proposal does allow notified bodies to be designated and manufacturers to be assessed under the new regulation prior to the date of application. This may be one year after its entry into force. The expected date of publication by the European Commission is Q1 2016 onwards.

What you should do next
Before the regulation becomes law, you should be proactive as there are certain measures that you can start putting into place now to ease your transition to the new regulation once it comes into effect.

Plan for significant increases in both personnel and financial resource
Create a customized action plan to address the additional resource requirements, for both personnel and financial, to include securing regulatory affairs resources, such as the 'person responsible for regulatory compliance'.

There is also significant increased workload required under the regulation, such as maintaining a summary safety and clinical performance report, plus keeping clinical evidence updated throughout the product lifecycle.

As well as updating technical files to meet the more stringent requirements of the regulation, time will also be needed to ensure all devices meet the new requirements for performance evaluation and clinical evidence as there is no 'grandfathering' clause in the new regulation.

Training resource (time and cost) also needs consideration, both internal and external, to ensure compliance to the more stringent requirements under the regulation, including those related to material safety.

You need to create standard operating procedures (SOPs) and training on how to handle unannounced notified body inspections of your own organization and your critical suppliers.

Look to transition your current devices to new certificates
As the regulation will not just affect new devices, all of your current certificates will need to be re-issued under the provisions of the new regulation when the existing directive expires.

Maintain an up-to-date quality management system
Prove to your notified body of your manufacturer's ability to provide medical devices that consistently meet both customer and regulatory requirements. This can be demonstrated through an up-to-date certified quality management system (QMS). ISO 13845 is the most common harmonized standard used by medical device manufacturers to prove compliance.

For a comprehensive set of materials that you can download to help you with all of your MDD requirements, please visit lrqausa.com or call 866 971 5772.

"LRQA will update clients once there are clear requirements for what manufacturers should focus on. We do know there will be an increase in workload, so start planning to increase resource and maintain an up-to-date quality management system."

Martin Penver, Head of Notified Body, LRQA

About us

Ever tougher stakeholder demands, changing business conditions and increased competition means you need better operational control, performance and risk management.

To help you, we continue to enhance our services. We don't just verify against the requirements of a standard, but go even further.

Our field-based business development managers tailor our certification, validation, verification and training services to better meet your needs, giving 'added value' beyond the traditional assessment process. We call this enhanced emphasis and approach, 'Business Assurance'.

Our expertise

With more than 20 years' experience as a notified body for the MDD, LRQA has established an in-depth level of knowledge and understanding of certification within the medical devices sector. With our experience of quality management systems and CE marking, we can help ensure that you meet regulatory requirements.

Our involvement in national and European working groups gives us access to a wealth of information, enabling our dedicated product conformity team to keep clients up to date with the latest on current and future developments. This helps you plan for the future and make the most of market opportunities.

Our assessors will provide consistent and constructive audits to help ensure that your system delivers tangible business benefits, while giving you the confidence that your system meets regulatory requirements.

Choosing LRQA means you'll be working with one of the world's most trusted and respected management system bodies providing you, your customers, prospective customers, trading partners and other stakeholders, with business assurance.

Our services

Starting point

Before making an application you need to be able to answer these questions:

- Are you a manufacturer as defined in the directive and responsible for placing products on the market?
- Are your products medical devices?
- What is the classification and your chosen conformity route?

Our team is on hand to offer support and guidance on any of these points.

Application

You will need to complete a simple form letting us know about your company and your products. We will use this information to verify the requirements relating to your products and to work with you to determine the best options for conformity assessment including any other service we can help you with.

Ready for assessment?

Unsure whether you are ready for the formal certification? Choosing our optional gap analysis will give you the confidence to go for certification.

Gap analysis

This assessor-delivered activity offers the opportunity to focus on critical, high risk or weak areas of your system in order to create a certifiable system. It can also look at how existing management systems or procedures can be used within your chosen standard.

Whether you are in the early stages of implementing your management system or looking to go for a 'dry run' before the assessment visit, the scope of the 'gap analysis' can be decided with either your business development manager or assessor and gives you more flexibility in choosing the scope and duration of the visit.

Certification

The formal two-stage certification process for CE marking ensures you have a quality system that meets the requirements of the conformity annex applied and is implemented for manufacture of the medical devices concerned.

In addition, the certification assessment can, if requested, be used to assess the quality system against recognized QMS standards, such as ISO 9001 and ISO 13485.

The assessor will establish that you have correctly identified which essential requirements apply to your products, have fully integrated the requirements into the QMS system and have taken the necessary steps to draw up the technical documentation.

Surveillance visits

Once approved, we will regularly review your system and sample your technical files to ensure its ongoing effectiveness and that you remain compliant with the requirements of the standard and the directive. This gives you, and your top management, the assurance the management systems are on track and continually improving.

LRQA helps you manage your systems and risks to improve and protect the current and future performance of your organization.

To find out more about how LRQA can help you with your requirements, please call us on **866 971 5772** or contact us at **inquiries-usa@lrqa.com**

www.lrqausa.com