

New EU medical device regulations: Impact on the MedTech sector



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Abstract

Regulation plays a fundamental role in the translation of innovative medical devices from concept to clinical application and ensures that only devices that exhibit the highest standards of safety and quality are released onto the EU Single Market for sale and clinical use. The impending introduction of a revised Medical Device Regulatory Framework in the EU will require an assessment of how stakeholders in the MedTech sector will be affected. Understanding the impact will be essential for maintaining compliance in the changing regulatory environment as well as for promoting commercial competitiveness and facilitating early access to innovative medical device technologies. In Ireland, a national initiative has been launched to centralise expertise on the regulatory requirements for medical devices in the EU and to analyse how the new medical device regulations will affect requirements for medical device clinical investigations and commercialisation of medical device technologies.

Background

Health is considered a key determinant of economic growth by the EU. This is reflected in the substantial contribution that the medical technology (MedTech) sector makes to the balance of trade within the EU: MedTech employs over 575,000 people across 25,000 companies, and medical devices ranging from plasters to dialysis machines are designed, manufactured, sold, and distributed on the European Single Market generating annual revenues in excess of 100 billion euro per annum.¹

Device profile and EU regulatory framework

Approximately 500,000 medical devices are available for sale on the EU Single Market.² The variation in complexity, risk profile, and applications of these devices has complicated efforts to create a harmonised regulatory process across EU member states.

New approach to regulation

Medical device regulation in the EU is based on the “New Approach” to regulation, which was

established in the mid-1980s to harmonise regulation of the technical aspects of industrial products in the EU.³ This approach is based on the concept of a minimum set of mandatory “essential requirements” for safety and performance for a product to be sold in the EU. This approach does not prescribe detailed technical specifications or solutions but promotes the use of voluntary standards (“harmonised standards”) that are developed by recognised European Standards Organisations and are referenced in the *Official Journal of the European Union*. Compliance with such standards can be used to demonstrate conformance with essential requirements as appropriate.

EU medical device directives

The current regulatory framework for medical devices in the EU centres on Council Directives 90/385/EEC,⁴ 93/42/EEC,⁵ and 98/79/EC,⁶ which are collectively known as the Medical Device Directives (MDD). These directives each define one of the three categories of medical device: active implantable medical devices, general category medical devices, and in vitro diagnostic medical devices. In addition, each directive outlines the scope and intent of the regulation for each device category with the associated obligations for the manufacture of medical devices for commercial, research, or clinical purposes.

Transposition into national law

The provisions of the directives must be written into national law by each member state and are then enforced through the appointment of a national “competent authority” that takes legal responsibility for regulation in that member state. Using directives as the legal instrument for regulating medical devices gives each EU member state some flexibility in how the regulatory obligations are written into law, allowing for specific national circumstances to be taken into consideration.

CE marking

Medical devices sold on the EU Single Market must be CE marked to certify that the device complies with the essential requirements of the relevant Medical Device Directive and any additional EU legislation (where applicable). This is achieved through a process (Figure 1) that takes into consideration the category of device, along with pertinent device

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characteristics and the device risk profile.

A manufacturer must first determine if the device is within the scope of regulation of the MDD. If applicable, the manufacturer applies to an organisation known as a “notified body” to demonstrate that the relevant obligations for CE marking have been met. Each EU member state’s competent authority may designate one or more notified bodies to assess conformity for specified types of medical devices. However, a manufacturer is free to choose any notified body that has been designated⁷ to assess conformity for their respective type of device. Examples of device types include: non-active functional implants (MD 0204), devices for wound care (MD 0300), and medical devices incorporating medicinal substances (MDS 7001).

In fulfilment of the requirements for CE marking, a manufacturer must identify and comply with the applicable essential requirements. This can be achieved through the use of harmonised standards. The manufacturer may be required to establish a quality management system covering some or all aspects of device design and production. Furthermore, the manufacturer must prepare technical documentation that captures the evidence required to demonstrate conformance. Depending on the risk profile of the device the manufacturer may self-certify that the device meets the essential requirements or may require an independent audit and certification by the notified body. The manufacturer draws up a written declaration of conformance and affixes the CE mark to the device as per the regulatory requirements.

Table 1. Medical device classification examples

Class	Risk	Examples
I	Low	Plasters, wheelchairs, corrective glasses, stethoscopes
IIa	Medium Risk	Infusion pump syringes, devices intended for storage and transport of organs for transplant, fridges specifically intended for storing blood, surgical gloves, hearing aids, diagnostic ultrasound machines
IIb	Higher Risk	Long term corrective contact lenses, dressings for severe burns or ulcerated wounds, surgical lasers, incubators for babies
III	Highest Risk	Cardiovascular catheters, prosthetic heart valves, aneurysm clips, breast implants, hip replacement systems

Risk classification

Given the heterogeneity of medical devices on the EU Single Market, subjecting all devices to the same level of scrutiny during a conformity assessment is not considered practical or cost-effective. Consequently, medical devices are stratified using a risk-based classification system that considers the vulnerability of the human body and the potential risks associated with the medical device. The classification system⁸ for general and active implantable medical devices is shown in Table 1.

Class I represents the lowest perceived risk and Class III represents the highest perceived risk. Devices are classified using a rule-based system that considers criteria such as the duration of contact, invasiveness, local vs. systemic effects, and the part of the body affected by the device.

Essential requirements and conformity assessment routes

A device’s characteristics, such as the device’s state of sterility (sterile or nonsterile), presence of a measurement function, incorporation of a medicinal product or software, along with the associated risk classification will determine the applicable essential requirements and available conformity assessment routes.

For example, a nonsterile Class I device without a measurement function only requires the manufacturer to self-certify conformance to the essential requirements. However, Class II-Class III devices require an independent conformity assessment to be conducted by a notified body. This may include an audit of the manufacturer’s technical documentation, quality system or a product inspection and may focus on some or all aspects of the device design and production.

Define scope of regulation	Is the device a medical device and, if so, what are the applicable directives?
Classification	Is the device a Class I, Class IIa, Class IIb, Class III medical device?
Identify essential requirements & conformity assessment route	What are the applicable essential requirements that must be met and what conformity assessment routes are available?
Compliance with essential requirements	What harmonised standards can be applied to demonstrate conformance to the essential requirements?
Conformity assessment	Review of device documentation, assessment of quality systems, and device examination by notified body (as appropriate)
CE mark	Draw up Declaration of Conformity and affix CE mark

Figure 1. CE marking steps

The role of regulation and the need for change

The EU Medical Device Regulatory Framework plays a fundamental role in facilitating the work of the MedTech Sector. It also ensures that only devices that exhibit the highest standards of safety and quality are released onto the EU Single Market for sale and clinical use. This is critical for maintaining commercial competitiveness as well as for facilitating early access to innovative medical device technologies for patients and healthcare providers.

However, changes to the regulatory framework are needed because of advances in medical science and technology, expansion of the EU, and changing socio-economic conditions.⁹ Furthermore, confidence in the system has been undermined by high-profile medical device problems, such as the misuse of industrial-grade silicone in breast implants manufactured by the company Poly Implant Prothèse.¹⁰ This has precipitated a revision of the Medical Device Regulatory Framework^{11, 12} that is scheduled for legal adoption in the EU in 2017.

Impact of scientific and technological advancements

Since the introduction of the MDD in the early 1990s, medical device science and technology has advanced significantly. Innovations in areas including information and communications technologies, minimally invasive surgical procedures, nanoscience, tissue engineering and personalised medicine are transforming healthcare delivery models and improving patient

outcomes. These advances, however, are challenging the legally defined concepts of a medical device and the associated boundaries of regulation.

Impact of changing socioeconomic conditions

Due to the ageing population, the increasing prevalence of chronic diseases, and financial pressures on healthcare institutions, the mandate has increased for early access to high-quality, cost-effective, and safe innovative medical device technologies. This has placed competing demands on the regulatory system to adapt to technological and scientific developments while facilitating innovation and upholding the highest standards of quality and safety.

Impact of the EU political landscape, device scandals, and notified body oversight

The smooth and proper functioning of the EU Single Market is central to promoting internal trade and economic growth and for facilitating timely access to innovative medical devices in the EU. However, with the expansion of the EU and growth of the EU Single Market to 32 participating countries, important differences have emerged in how the provisions of the directives are interpreted. This has resulted in variation of how the EU Medical Device Regulatory Framework is applied across member states. Furthermore, in recent years, high-profile adverse incidents have badly damaged the confidence of key stakeholders in the EU Medical Devices Regulatory Framework and have highlighted shortcomings in the oversight of notified bodies.¹⁰

New medical device regulations

In 2012 the EU Commission published its proposals for the revision of the EU Medical Device Regulatory Framework with the replacement of the MDD by two medical device regulations: The Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR).^{11,12} In 2014, the EU parliament responded with a list of amendments for the proposed regulations and in 2015 the EU Council stated its informal position on the proposals. A discussion was then initiated between the EU Commission, EU Council, and the EU Parliament to reach an agreement on the proposed regulations. The agreed texts were published in June 2016.^{13, 14} After translation into the official EU languages and associated legal-linguistic checks the regulations were formally adopted by the EU Parliament in April 2017.¹⁵ The regulations were published in the *Official Journal of the European Union* in May 2017 and became legally binding on the 20th day after publication.

Key changes in the regulatory framework

The new regulations aim to make key changes in several areas to account for technological and scientific progress and to improve the clarity, robustness, transparency, and traceability of the regulatory system (Table 2).¹⁶

Entry into force, transition period, and date of application

After the new regulations are legally binding (Entry into Force) there will be a transition period of 3 years for the MDR and 5 years for the IVDR before they are fully applicable in EU law (Date of Application). This transition period is meant to allow all major stakeholders including the EU Commission, competent authorities, notified bodies, and manufacturers to meet their respective obligations from the date of application.

Aims of regulatory reform

Replacing the MDD with the MDR and IVDR is expected to improve the clarity of the regulatory requirements and to harmonise how the regulations are applied across EU member states. Furthermore, the increased scrutiny during conformity assessments and enhanced clinical evidence requirements throughout the medical device lifecycle are expected to translate into a

Table 2. EU Medical Device Regulation – Key changes

Change	Details
Legal Framework	Replacement of directives with regulations as the legal instruments for the regulatory framework
Scope	Extension of the scope of regulation to account for technological and scientific progress but also to include nonmedical devices with a similar risk profile such as cosmetic implants and medical devices sold as a distance sale or information service over the internet
Economic Operator Obligations	Clarification of the obligations of key stakeholders in the medical device supply chain and health care institutions involved in the manufacture of medical devices
Clinical Evidence	Re-enforcement of clinical evidence requirements throughout the medical device life cycle
Device Classification	Update of existing classification rules and the addition of new classification rules
Conformity Assessment	Increased scrutiny during conformity assessments
Notified Body Oversight	More stringent criteria for the designation and oversight of notified bodies by competent authorities and the EU Commission
Transparency	Increased reporting obligations for manufacturers and economic operators throughout the medical device life cycle
Traceability	Introduction of a Unique Device Identification system to improve traceability through the supply chain

more robust CE marking process. This should improve standards for safety and quality of medical device products released onto the EU Single Market.

Enhanced reporting requirements in the MDR and IVDR will also require that information about the approval and regulation of medical devices in the EU be publicly available. This should allow healthcare providers and patients to make more informed decisions.

The revised regulations also include introduction of a Unique Device Identification system. This is meant to improve traceability throughout the supply chain and thereby help authorities and manufacturers take prompt and appropriate actions in response to concerns about device safety.

Prospective impact on the MedTech sector

Compliance with the MDR/IVDR from the date of application will require that manufacturers assess the impact of, and plan for, changes in the regulatory framework. This might require manufacturers to gather additional clinical evidence, re-negotiate supply chain agreements, and alter documentation, quality management systems, and product labelling. The associated changes may affect operational costs, time to market, and staff competency requirements and therefore may also affect medical device product lines.

Analysing the impact

Ireland has launched a national initiative to centralise expertise on the regulatory requirements and pathways for conducting medical device investigations and commercialising medical device technologies. CÚRAM, the Science Foundation Ireland-funded Centre for Research in Medical Devices, is building on the strengths of the Irish MedTech sector to develop innovative medical device technologies. Based in the National University of Ireland, Galway, the centre comprises of six academic partnerships and 24 industrial collaborations with a strong focus on biomaterials, device design, tissue engineering, drug delivery, and regenerative medicine.

Molecular Medicine Ireland, as a funded partner in CÚRAM, is analysing how the introduction of the new medical device regulations is affecting the clinical research and commercialisation activities of CÚRAM and its industrial partners. The expertise they build will place CÚRAM in a position to influence the on-going development of the EU Medical Device Regulatory Framework through active engagement with key stakeholders at national and EU levels.

Concurrently, a variety of web-based information, training, and interactive tools are being developed by Molecular Medicine Ireland to ensure that CÚRAM and its partners are kept abreast of key developments.¹⁷ This will ensure that CÚRAM's clinical research and

commercialisation activities are adequately supported as the medical device regulatory environment changes in the EU. ■

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Acknowledgments

The authors would like to thank colleagues in CÚRAM and the Health Products Regulatory Authority (HPRA) along with Science Foundation Ireland and the European Regional Development Fund (Grant Number 13/RC/2073).

Conflicts of Interest and Disclaimers

No conflicts of interest to declare.

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