



New EU Rules to Ensure Safety of Medical Devices

Ranging from simple contact lenses and sticking plasters to sophisticated pacemakers and hip replacements, medical devices and in-vitro diagnostic medical devices are important to our health and quality of life.

People rely on these devices every day and expect them to be safe and incorporate the latest progress in science and innovation. The current rules on the safety and performance of medical devices in the EU were harmonised in the 1990s. To reflect the substantial technological and scientific progress in this sector over the last 20 years, the Commission proposed to update the rules to improve the safety of medical devices for EU citizens, create the conditions to modernise the sector and to consolidate its role as a global leader.

MEDICAL DEVICES CHANGE OF LEGISLATION

What you need to know!



Why do we need new regulations on medical devices?

Problems with diverging interpretation of the existing rules as well as certain incidents –e.g. with breast implants and metal hips – highlighted the weaknesses of the current legal system and damaged the confidence of patients, consumers and health-care professionals in the safety of medical devices.

To address this, the Commission proposed two *Regulations on medical devices and in-vitro diagnostic medical devices in 2012*¹. To ensure harmonised application of the rules throughout the EU, the two new Regulations will replace the three existing Directives on medical devices. The new rules significantly tighten the controls to ensure that medical devices are safe and effective and at the same time foster innovation and improve the competitiveness of the medical device sector. The new rules also better reflect the most recent scientific and technological progress and set the gold standard for medical device regulation globally. The revised rules also provide the conditions needed to consolidate the role of the EU in the long-term as a global leader in the sector.

1. http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/revision_en

What are the main benefits for patients and consumers?

The new Regulations pave the way to a more patient-friendly environment, where transparency and patients' information and choice are a priority; where patients can benefit from innovative, highly performing devices and new therapies become possible. The new rules introduce:

- **better protection of public health and patient safety.** In particular high-risk devices are going to be subject to stricter pre-market control. Certain aesthetic devices (such as coloured contact lenses or equipment for liposuction) presenting high-risk to consumers and practices such as re-processing of single-use devices are included in the scope of the new Regulations and made subject to a stricter and more harmonised regime. Rules on clinical evaluation and clinical investigation (and, for *in-vitro* diagnostic medical devices, performance studies) are generally strengthened and stricter requirements on the use of hazardous substances are introduced.
- a comprehensive **EU database** on medical devices (EUDAMED) that will contain a living picture of the lifecycle of all products being available on the EU market. A large part of the information will be made publicly available, including a newly introduced summary of safety and performance for all Class III and implantable devices. The Commission is required to set up the database by spring 2020 and to maintain it thereafter.
- a new **device identification system based on a unique device identifier (UDI)** that will allow easier traceability of medical devices.
- an **'implant card'** for patients containing information about implanted medical devices that will make information easily available and accessible to the particular patient.
- a **robust financial mechanism to ensure patients are compensated** in case they receive defective products. The Regulations require manufacturers to have measures in place to provide sufficient financial coverage in respect of their potential liability. Such financial coverage shall be proportionate to the risk class, type of device and the size of the enterprise. This should allow patients to be rapidly and effectively compensated, also in case of financial bankruptcy of the relevant company.

Which products are affected by the new Regulations?

In line with the current system, all medical devices, *in-vitro* diagnostic medical devices and their accessories fall under the new Regulations. In addition, certain aesthetic products such as coloured contact lenses or equipment for liposuction, which need to be just as safe as existing medical devices, will also be covered.

Under the new Regulations, both medical devices and *in-vitro* diagnostic medical devices are divided into four risk classes. Depending on the risk class of the product, a different conformity assessment procedure is foreseen before the product can be placed on the EU market. In case of medium or high risk classes, Notified Bodies are involved in the process.

Why did an agreement take so long to reach?

Effective and efficient rules on medical devices are extremely important to ensure high levels of health and safety protection for EU citizens. At the same time, they are very technical and sensitive, and they had to be considered thoroughly.

After three years of discussions at the expert level, the ministers of all EU countries agreed on 5 October 2015 on a general approach to the medical devices package. The European Parliament and the Council agreed on [a final text on 15 June 2016](#)². Based on this agreement and following the legal-linguistic finalisation of the text, the Council voted its first reading position for the two texts on 7 March 2017. The same texts were then adopted without modification by the European Parliament with an early second reading on 5 April 2017, which closed the legislative procedure.

The new rules will now start to apply three years after publication of the Regulation for medical devices and five years after publication for *in-vitro* diagnostic medical devices. New requirements on Notified Bodies and the provisions of the new governance structure will already be applicable six months after the adoption, therefore by the end of 2018.

Will the new rules be able to keep up with the future progress?

The final Regulations contain very important changes to the current system to enable the sector to produce safer and more innovative devices and help address future challenges. The new Regulations contain many provisions to increase security and regulatory certainty (harmonised rules on drug-device combination products, tissue engineering, nanoscience, personalised medicine, substance based devices and genetic tests) and take into account the latest developments in the sector (medical software, apps, cybersecurity).

To help boost innovation in the sector, the EU-wide database on medical devices (EUDAMED), supported by a new device identification system based on a unique device identifier (UDI), will make big sets of data in the field of medical devices available within the EU. By producing more innovative devices, medical device manufacturers will also be able to offer solutions for disease prevention or early diagnosis that will in turn make the healthcare sector more affordable by, for example, helping to prevent or reduce hospitalisation.

Will the transition to the new rules create any disruptions to the availability of medical devices? What are the arrangements?

It is crucial to ensure that the new rules enter into force without any unreasonable delays and they do not create any serious disruption of the medical devices supply. The Commission, Competent Authorities, Notified Bodies and all other stakeholders will work together to ensure that the transition to the new regime is smooth and successful. The Regulations foresee that certificates issued under the current Directives can remain valid for a certain additional period after the general application date of the two Regulations (three years after the entry into force for medical devices and five years for *in-vitro* diagnostic medical devices). Moreover, a set of exemptions from clinical investigation requirements have been introduced for products placed on the market under the current Directives, provided that their clinical evaluation is based on sufficient clinical data and that they are in compliance with relevant common specifications. These regulatory developments will also create new opportunities for qualified staff. The Commission will work with stakeholder organisations and Member State authorities to organise relevant information and training within their constituencies required to carry out these changes.

How will the governance of the new Regulations make medical devices and *in-vitro* diagnostic medical devices safer? How will market surveillance be improved?

The strengthened European governance of the new system is one of the main improvements. The Regulations introduce:

- a new Medical Device Coordination Group (MDCG), composed of Member State experts and chaired by the Commission;
- increased cooperation between Member States in the field of vigilance and market surveillance;
- a mandatory coordinated assessment of multinational clinical investigations.

As a result, a true European mechanism will be put in place for the regulatory management of medical devices. It will allow more frequent exchange of information, so regulatory decisions by either Member States or the Commission can be taken on a more informed basis. Under this new governance, it should be easier to address safety issues and scandals on EU territory and act more quickly whenever required and appropriate.

What will be the role of notified bodies?

Currently, medical devices are not subject to pre-market authorisation by a regulatory authority. Medium and high-risk devices require a conformity assessment procedure, involving an independent third party known as a 'notified body'. Notified Bodies used to be designated and monitored by the Member States and acted under the control of the national authorities. In 2013, joint assessments of Notified Bodies were introduced, with members from other Member States and the Commission involved in the designation procedure. Under the new framework, the successful experience of the joint assessments is reinforced. Under the new Regulations, independent experts could be required to provide an opinion to the Notified Body on certain high-risk products before the final decision on the certification of the product is taken. This will help a Notified Body to make more informed decisions and stimulate a process of continuous learning. It will help drive innovation while preserving a high level of safety and performance of products.

How will the scrutiny mechanism for assessment of high-risk devices work?

For certain high risk devices, the new Regulations require the Notified Bodies to consult with an expert panel before placing the device on the market. According to this procedure, an expert panel could provide a scientific opinion to the Notified Body on its assessment of the manufacturer's clinical file. While the Notified Body would not be bound by the opinion, it would have to provide a justification for not following it. All relevant documents regarding the opinion and the final decision of the Notified Body would be publicly available in EUDAMED.

What will be the impact of the new rules on the industry? Will they result in additional costs for companies and SMEs in particular?

The medical devices sector is a global leader and a major employer in Europe: it employs more than 500,000 people in over 25,000 companies. The sector is driven by small and medium-sized enterprises (SMEs) and the new Regulations will help the EU industry to maintain and further expand its leadership role on a global scale, by making it more competitive and more solid in a complex global environment. This will be the result of three main factors:

- **simplified administrative procedures** - under the new framework, registration of devices and operators will have to be done only once at the EU level. This is a major change compared to today's situation where in many cases manufacturers might be required to register their products in all Member States where those products are placed on the market.

- **increased legal certainty** - growth and competitiveness build on the existence of a stable set of legal requirements. Contrary to a Directive, a Regulation is directly applicable in all Member States: this will help to avoid varying conditions for patients and industry in different countries. The new texts also include precise and detailed clarifications of the scope of the new rules, a list of clear obligations of relevant economic operators as well as an indication of the specific exemption regimes which apply to certain devices or practices such as in-house devices or reprocessing of single-use devices.
- **increased credibility and reputation of the overall system** - industry's reputation is highly sensitive to the credibility of the EU medical device system as a whole. Various incidents as well as public reports regarding an alleged "uneven approach" among the bodies responsible for certification and approval of medical devices have damaged the confidence of patients and healthcare professionals in the safety of the devices they use every day, while confirming some weaknesses in today's legislation. The new Regulations address the shortcomings of the current legislation and aim to increase the overall confidence in the medical device market.

These advantages should counterbalance the extra costs incurred by companies due to compliance with the higher safety standards and new requirements contained in the new Regulations. Specific needs of SMEs have been addressed in the texts particularly in relation to new requirements on financial coverage for manufacturers, person responsible for regulatory compliance and fees charged by Notified Bodies. This gives a potential boost to SMEs active in this sector.

What are the rules on reprocessing single-use medical devices?

Some devices are intended to be discarded after they have been used once. However, under properly controlled conditions some such devices can be safely reused. The Regulation on medical devices contains minimum requirements on reprocessing of single-use medical devices. Reprocessing may only take place when authorised under national law and in accordance with the provisions of the medical devices Regulation. When reprocessing is allowed, the entity that wants to reprocess the device must assume the same obligations as a manufacturer. However, a different regime is applied in the case of reprocessing by health institutions and by third parties at the request of health institutions. Such a regime includes compliance of reprocessing with common specifications or national provisions and harmonised standards to be certified by a Notified Body.

Is the Regulation addressing the issue of risks of use of nanomaterials used for medical devices?

The new Regulation on medical devices lays down a dedicated classification rule for devices incorporating or consisting of nanomaterials. The critical factor is the potential for nanomaterials to be in contact with membranes inside the body. Those devices presenting a high or medium potential for such contact will fall under the highest risk class and thus be subject to the most stringent conformity assessment procedures.