

The new Medical Device Regulation

Impacts, Challenges and Room for Manoeuvre

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Summary

The European Union adopted the Medical Device Regulation (MDR) in 2017 with the aim of improving patient safety. The MDR is a key pillar of modern medicine and plays an essential part in the healthcare provision of millions of people throughout Europe. It entered into force on 25 May 2017, with a three-year transition period. This lengthy transition period for the recertification of medical devices is now coming to an end – the Medical Device Regulation will become fully applicable from 26 May 2021.

The new Regulation amalgamates and replaces the previous Medical Devices Directive 93/42/EEC (MDD) and Active Implantable Medical Device Directive 90/385/EEC (AIMDD). As well as introducing new regulations for the certification of medical devices, the MDR also aims to improve post-market surveillance.

The Regulation contains a number of new measures designed to improve patient safety, such as the introduction of a mandatory implant card. Compulsory labelling of medical devices using the globally harmonised UDI (Unique Device Identification) system promises greater transparency and enhanced traceability, while stricter requirements for the certification process and tougher demands on the Notified Bodies responsible for certification are intended to guarantee medical devices' safety, performance and clinical benefits.

However, the Medical Device Regulation also introduces changes that contradict its own goals and could jeopardise patient safety and care. The new rules will result in innovative devices and procedures being withheld from patients or only becoming available later than is appropriate and necessary, and will even prevent some devices from being developed in the first place. Moreover, some well-established but unprofitable orphan devices will disappear from the market and no longer be available to the patients who rely on them.

In spite of its good intentions with regard to patient safety, the new Regulation poses a major challenge for innovations and for medical technology in general. All medical devices that were certified under the previous Directives will lose their conformity under the new legislation. Certificates issued under the Medical Devices Directive 93/42/EEC (MDD) and Active Implantable Medical Device Directive 90/385/EEC (AIMDD) will expire either on or before 27 May 2024, depending on the device type and certificate expiry date. The relevant devices may only be put into service for one further year after this date. Despite calls from many manufacturers, there is no stock protection beyond this deadline.

In addition, the new Medical Device Regulation requires the Notified Bodies to submit an application for re-designation in time for them to be audited and designated before the transition period ends on 26 May 2021. The more stringent requirements have led to a drastic reduction in the number of Notified Bodies. In Germany, for example, their number has fallen from eleven under the Medical Devices Directive 93/42/EEC (MDD) and Active Implantable Medical Device Directive 90/385/EEC (AIMDD) to just four under the Medical Device Regulation, at the time of writing (04/2020). Moreover, there are new restrictions regarding their range of services, and only a handful of full-service providers remain on the market. The resulting capacity bottlenecks are delaying market access for many existing and new devices.

Furthermore, the few remaining Notified Bodies will now have an even higher workload. Devices that did not previously fall under the relevant Directives are now classified as medical devices under the Medical Device Regulation. In addition, many devices have had their previous classification upgraded, while clinical trials are now mandatory for more devices. This will significantly increase the (financial) resources required to develop and certify new devices.



Implementing the regulatory requirements poses a heavy burden particularly for small and medium-sized enterprises, many of which have fewer than twenty employees. In many cases, they are forced to reassign resources from R&D to documentation and certification duties. Moreover, for many small businesses it is difficult or even impossible to cover the additional costs (see Infobox).

There are also implications for biomedical engineering R&D. University and non-university research institutions are important links in the overall innovation process and play an especially significant role in basic and translational research. Their close cooperation with the medical technology industry is key to enabling innovation and to funding research. Moreover, these institutions are responsible for most of the training and continuing professional development of young medical technology professionals and are a key pillar of Germany's globally renowned expertise in the field of medical technology.

Against this backdrop, this acatech IMPULSE seeks to provide an unbiased evaluation of the new Regulation. It focuses on the following aims:

- To present an overview of the changes introduced by the Medical Device Regulation.
- To analyse the impacts of the Medical Device Regulation on different actors in the field of medical technology.
- To evaluate the new aspects of the Medical Device Regulation.
- To identify and describe possible courses of action and aspects of the MDR where there is some leeway.

The project group believes that action is required in order to mitigate the negative impacts of the Medical Device Regulation and ensure a safe and stable pipeline of innovative devices. Accordingly, it recommends the following measures:

- Stock protection for medical devices that are already certified and well-established: In order to ensure that patients receive the care they need, a simplified recertification procedure should apply to devices whose safety and clinical benefits are clearly substantiated by user experience.
- Trial regulations for new devices: Gradual market access should be enabled for new devices, under strict surveillance. Safety, performance and clinical benefits should be tested during a trial phase encompassing a surveillance group with a single-centre study, multi-centre studies and a controlled market rollout.
- Clear rules and device-specific criteria for certification.

Infobox: Small and medium-sized medical device companies: industry data

The medical technology landscape in Germany is dominated by small and medium-sized enterprises (SMEs). 93% of companies in this sector have fewer than 250 employees, while 11,000 have fewer than 20. Compared to this figure of over 11,000 small businesses, there are fewer than 80 companies with over 500 employees.

The medical technology landscape in other countries covered by the Medical Device Regulation is also characterised by large numbers of small businesses. For example, half of the 1,400 or so medical device companies in Switzerland have fewer than 10 employees. The Medical Device Regulation poses a particularly serious challenge for the numerous SMEs in the medical technology sector.

Germany's medical technology industry employs over 200,000 people. It has an annual turnover of around €32 billion, with a value added figure of approximately €15 billion. 65% of medical devices made in Germany are exported.

The medical technology sector is a fast-moving, innovative industry. Products that are less than three years old account for one third of German medical device manufacturers' sales, while 9% of sales is invested directly in R&D.

- Pragmatic implementation of the new classification rules for medical devices: The schematic approach to applying the new classification rules in the Medical Device Regulation should be replaced with a needs-based approach informed by clinical experience.
- Prompt designation of Notified Bodies: It is important to avoid delays in certification and ensure that innovation is not held back. This will require transparency in terms of whether the Notified Bodies have adequate resources for particular groups of devices.
- While independence is an important factor when appointing expert panel members, their technical expertise should also be taken into account.
- A financial and structural support programme for small and medium-sized enterprises, clinical trials, trial sites and orphan devices.



At a glance

This acatech IMPULSE discusses the improvements to patient safety promised by the Medical Device Regulation. For example, patient benefits should come about through stricter certification requirements, tougher demands on certification bodies and the introduction of implant registers. The IMPULSE publication also addresses some of the Medical Device Regulation's problematic impacts on (university) research, as well as for manufacturers and indirectly also for patients, not least in the context of the coronavirus pandemic.

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