

The European Commission's proposed amendments—overview and assessment

Medical Device Regulation 2.0

The European Commission is pulling—at least by the standards of Brussels bureaucracy—something of an emergency brake on the Medical Device Regulation, commonly abbreviated to MDR.

The MDR is a regulation of the European Parliament and of the Council dated 5 April 2017 and is designated Regulation (EU) 2017/745. It replaced the Medical Devices Directive of 14 June 1993 (Directive 93/42/EEC—internationally abbreviated as MDD). Following several delays, the MDR came into force on 26 May 2021.

It was clear to all stakeholders outside the Brussels bubble that the MDR would cause a great deal of frustration. Now that the negative effects have become increasingly apparent, this realisation has evidently finally reached Brussels as well. Since 16 December 2025, there has been a 170-page commission proposal (2025/0404 [COD]) to revise the MDR and the IVDR (In-vitro-diagnostic Medical Devices Regulation), which is not particularly relevant to the dental sector. We will focus here solely on the MDR.

The primary aim of the new proposal is to simplify the regulations for medical devices and reduce the administrative burden on manufacturers, whilst continuing to ensure a high level of protection for public health and patient safety.

Anyone hoping that there will be less bureaucracy for medical device manufacturers will be disappointed after reading the draft. As is so often the case when a reduction in bureaucracy is promised, the administrative burden is reduced at best in isolated instances but is usually merely shifted elsewhere.

In the field of medical device law, so-called SMEs play an important role. They were defined by the European Commission in a recommendation of 6 May 2003 (2003/361/EC). The definitions are reproduced here as an extract from Article 2 of the recommendation:

(1) "The size classes of micro, small and medium-sized enterprises (SMEs) comprise enterprises which employ fewer than 250 persons, and which have an annual turnover not exceeding EUR 50 million or an annual balance sheet total not exceeding EUR 43 million.

(2) Within the SME category, a small enterprise is defined as an enterprise which employs fewer than 50 persons, and whose annual turnover or annual balance sheet total does not exceed EUR 10 million.

(3) Within the SME category, a microenterprise is defined as an enterprise which employs fewer than ten persons, and whose annual turnover or annual balance sheet total does not exceed EUR 2 million."

If we consider the German manufacturing market, 93% of it consists of SMEs, of which 12,000 are microenterprises within the meaning of this recommendation. The number of employees stands at around 210,000. There are currently around 500,000 different medical devices on the German market. 68% of German production is exported (source: BVMed industry report, as of October 2025). The MDR is of particular importance to Germany, which is now the world's second-largest manufacturer of medical devices. If the MDR weakens medical device manufacturers, it will primarily weaken German manufacturers.

Overview of the proposal

Objectives of the proposal

- Simplification of regulations and reduction of the administrative burden.
- Improvement of the predictability and cost-effectiveness of the certification process.
- Promotion of innovation and competitiveness in the EU medical device industry.
- Ensuring the availability of safe and innovative products.

Key proposed changes

- Introduction of more flexible requirements for clinical data and evidence.
- Adjustment of classification rules to lower the risk classes of certain products.
- Introduction of "regulatory sandboxes" (real-world laboratories) for innovative technologies.
- Strengthening the role of the European Medicines Agency (EMA) in coordinating and supporting expert panels.
- Promoting digitalisation, e.g. through the electronic submission of declarations of conformity and technical documentation.

Stakeholders affected

- **Manufacturers:** simplified procedures, reduced costs and support from the EMA, particularly for SMEs.
- **Notified bodies:** improved legal clarity and more efficient procedures.
- **Patients and healthcare systems:** ensuring the availability of safe and innovative products.

Digitalisation

- Expansion and adaptation of the EUDAMED database to incorporate new requirements.
- Introduction of an IT system to monitor supply disruptions and shortages.
- Electronic submission of documents and data, including declarations of conformity and implant cards.

International cooperation

- Promotion of global regulatory convergence and participation in international forums such as the International Medical Device Regulators Forum (IMDRF).

Budget and resources

- Estimated financial impact on the EU budget and the European Medicines Agency (EMA).
- Additional human resources for the EMA and the European Commission to implement the new tasks.

Timetable

- The regulation is set to enter into force from the second quarter of 2027, with transition periods for the implementation of the new requirements.

The document emphasises the need for EU-wide coordination to resolve the structural problems of the existing MDR (and IVDR, which we will not discuss further here) and to create a future-proof and innovation-friendly system. But for the time being, this is merely wishful thinking on the part of the European Commission. Similar arguments were previously put forward to justify why the MDD was insufficient and why the MDR was needed.

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The EU Commission's perspective

The Commission recognises that the much stricter requirements introduced by the MDR, which were also extended to medical devices already on the market, left the risk of supply bottlenecks and the discontinuation of medical devices, given the limited capacities of the notified bodies responsible for CE certification and the inadequate preparation of manufacturers, despite transition periods having been extended several times. It is acknowledged that the structural problems associated with the implementation of the MDR were underestimated and have not yet been resolved. An analysis commissioned by the commission has revealed that the MDR's regulations are negatively impacting both the availability of products and the competitiveness of EU manufacturers, with the European Commission now acknowledging for the first time the "many micro, small and medium-sized manufacturers" (SMEs).

One of the key criticisms of the MDR is its extreme bureaucratic burden, which transfers ideas from the regulation of pharmaceutical law—with its multinational corporations as the big players—to medical device law, without recognising that in this sector the big players are the so-called SMEs, not the international corporations. What large corporations can afford in terms of bureaucratic and testing costs, SMEs simply cannot. Medical devices are developed to meet specific healthcare needs, initially usually only in small batches, often enough in microenterprises. 52% of ideas for developing new or improving existing products come from users (BVMed, ibid.). One need only think of the development of dental implants since the 1950s, which, given the predominantly negative attitude of so-called school dentistry at the time under the aegis of the MDR, would hardly have been able to achieve CE marking, as many regarded implantology as the "red-light district of dentistry".

The commission notes the lack of a timeframe for product testing by notified bodies that manufacturers can reliably estimate, as well as the varying practices in this regard from country to country. Several of the certification requirements contained in the MDR are disproportionate to the actual risks posed by the products, leading to unnecessarily high costs and burdens. Overly ambitious requirements could lead small manufacturers to withdraw medical devices from the market or delay their market entry, with potentially negative consequences for patient care and public health.

This criticism can already be found in the comprehensive article on the MDR published in *BDIZ EDI konkret*, specifically in issues 2/2019 to 1/2020. At any rate, it has now also reached the commission.

The commission describes the need for change as urgent ("urgent need to take action"). One must agree with it on this point.

Results of the MDR evaluation

The commission reports on the results of the evaluation it ordered, which—unsurprisingly—has confirmed the warnings that were already being raised before the MDR came into force and have continued since then.

Most of the respondents who took part in the MDR evaluation came from Germany (23.42%), followed by Belgium (11.24%) and France (9.13%).

The commission's key finding from the evaluation is that, whilst the MDR has increased product safety and market transparency, this has come at the cost of high and often disproportionate compliance costs caused by the high regulatory complexity of the MDR requirements.

The Commission states: "The evaluation found that the regulations have strengthened the regulatory framework through stricter requirements for the designation and supervision of notified bodies, the conduct of conformity assessments and the collection of clinical data. However, these three dimensions are closely interlinked, and weaknesses in one area affect the entire system. A fragmented and protracted notification procedure reduces available capacity and leads to inconsistencies in supervision, which in turn contributes to divergent conformity assessment procedures. At the same time, incomplete or inconsistently assessed clinical data prolongs assessments and undermines predictability, whilst limiting the ability to demonstrate that the safety objectives of the regulations have been met. Although progress is evident, the combined effect of capacity bottlenecks, fragmented supervision and inconsistent data requirements means that efficiency, harmonisation and effectiveness fall short of expectations. This has led to a perceived unpredictability and disproportionate nature of the regulatory framework and has undermined stakeholders' confidence in the system. More specifically, the evaluation shows that this leads to a reduction in the availability of certain devices (e.g. innovative and niche devices), which has a negative impact on patient safety and the competitiveness of the industry.

The evaluation highlights several shortcomings and inefficiencies in the current regulatory framework, particularly regarding the simplification and optimisation of procedures. A fragmented and non-harmonised regulatory framework has led to numerous inefficiencies and unnecessary burdens for stakeholders, who are calling for a more centralised administrative structure. An unexpectedly high administrative burden appears to stem from redundant reporting and unnecessary duplication of work, posing significant challenges for stakeholders. The unpredictability and disproportionate nature of the system further exacerbate these concerns, particularly for economic operators who seek clarity and consistency in requirements to foster innovation without compromising safety. Digital solutions are frequently cited as potential ways to alleviate some of these burdens, increase efficiency and reduce resource bottlenecks. The fragmentation of administrative structures, overlapping reporting obligations and insufficient digitalisation contribute to increased administrative and compliance costs for public authorities and economic operators.

In summary, the targeted evaluation reveals the following:

- Certain requirements, particularly regarding conformity assessment procedures, are excessively complex, burdensome, time-consuming and costly.
- The application of the legislation by national authorities and notified bodies is not sufficiently harmonised.
- The existing coordination mechanisms are not sufficiently efficient or effective.
- There is a lack of adequate technical and regulatory advisory services at EU level.
- Adaptive pathways for breakthrough innovations and niche products do not exist.
- The regulations have unintended negative impacts on innovation, competitiveness and patient care.
- There is a need for improved coherence with other EU legislation, such as the Clinical Trials Regulation (CTR).

The evaluation has shown that the implementation of both regulations can be simplified and the administrative burden reduced without jeopardising their main objectives."

Proposed amendments

The commission is proposing numerous amendments to the MDR. A few provisions are to be repealed entirely, many are to be partially or completely reworded, and many new ones are to be added.

However, the commission is not guided by the principle of "less is more". Its primary concern is always patient safety. Yet the coronavirus crisis has shown that the clash between patient safety and regulatory depth in medical devices can lead to absurd results if the Gordian knot is not cut without regard for the printed standards. One need only think of the chaos surrounding face masks. At least the MDR is now to be explicitly granted exit options for general health emergencies and crises.

1. There are to be relaxations for micro and small enterprises regarding the person responsible for compliance with regulatory requirements. They will no longer be required to have constant and unrestricted access to such a person, but only to be able to access one (Art. 15[2] of the new MDR).
2. The validity period of the CE marking, previously set at five years, and thus the requirement for recertification, is to be abolished. Instead, notified bodies are to carry out periodic reviews, but only at intervals that are proportionate to the risk posed by a specific medical device (Art. 56[2] of the new MDR).
3. More data than previously should be available for clinical evaluation. This should apply to performance and safety tests. The use of new testing methods, such as computer simulation, should be encouraged. Manufacturers of class IIb and III medical devices should be allowed to seek advice from a panel of experts prior to conducting clinical investigations (Art. 61 of the new MDR).
4. Clinical investigations for "other" (non-commercial) purposes are no longer to fall under the MDR, and Article 83 of the new MDR is therefore to be deleted without replacement.
5. In order to put an end, at least in part, to the absurdity surrounding the certification of medical devices that have long been established on the market, a definition of a "well-established technology device" is to be introduced, which is intended to replace the existing list in Article 18(3), 52(4) and 61(6)(b) of the MDR. One need only think of all the surgical instruments that are still manufactured and ground by small craft workshops today. Had these businesses been forced to obtain certification under the rules currently still in force, these products would certainly have disappeared from the market as

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"made in Germany". The amendment will also be relevant to the information requirements under Article 18 of the MDR (keyword: implant passport). In future, this will generally no longer be required (new Article 18[3] of the MDR).

6. In future, there should no longer be an obligation to involve notified bodies if the product is repackaged or given a different name. The provision in Article 16(4) of the MDR is to be repealed.
7. Anyone who assembles or adapts a medical device that is already on the market for an individual patient within the scope of its intended purpose should no longer be required to fulfil manufacturer obligations (Article 16[1], second subparagraph, of the new MDR).
8. The classification rules for medical device classes in Annex VIII to the MDR are to be revised so that, in future, reusable surgical instruments, for example, are classified in a low-risk class. This, too, was one of the MDR's missteps: favouring single-use products in this area rather than products that have proven their worth for decades, particularly in the case of surgical instruments, from a sustainability perspective. Many hospitals have switched to single-use instruments in the wake of the MDR, some further driven by the COVID-19 crisis, resulting in a huge mountain of waste and corresponding costs.
9. The summary reports on safety and clinical performance required under Article 32 of the MDR should no longer be subject to separate review by notified bodies.
10. The time interval within which manufacturers must submit the safety reports required under Article 86 of the MDR is also to be extended.
11. For the reporting of serious incidents, the deadline is to be extended from the current 15 days (Article 87[3] of the new MDR) to 30 days.
12. Changes are to be made regarding notified bodies in Annex VII of the MDR.
13. Under certain circumstances, the transfer of so-called in-house devices to third parties is to be facilitated (previously excluded by Article 5[5][a] of the MDR).
14. The rules on the provision of information in the event of discontinuation or interruption of supply are also to be amended (new Article 10a MDR).
15. There will be new and simplified rules for medical devices of particular importance and for medical devices for rare applications (so-called orphan devices; new Article 52a MDR).
16. The commission wishes to be granted the power to adopt derogations from the MDR in the event of public health emergencies or crises, with the aim of rapidly placing products back on the market (Articles 59 and 59a of the new MDR).
17. To facilitate the development and testing of innovative products or new regulatory approaches, it should be possible to establish so-called regulatory sandboxes (real-world laboratories; Art. 59b and 59c of the new MDR).
18. The MDR is to shift focus from the preference for single-use devices to the production of reusable medical devices. In future, manufacturers will have to justify why a device is offered only as a single-use device (Art. 17[1] of the new MDR). All medical devices unjustifiably declared as single-use devices are deemed to be reusable.
19. Anyone who makes a single-use device reusable becomes its manufacturer within the meaning of the MDR (Art. 17[3], second sentence, MDR new). This is a hurdle that will hopefully be mitigated during the consultation process on the implementation of the commission's proposal.
20. Medical devices that have been granted a CE marking under the MDD remain marketable under the MDR if they are granted orphan product status (Art. 120[14] of the new MDR).
21. The definition of nanomaterials contained in Annex I, Chapter III, No. 10.6 of the MDR is to be replaced as it is outdated.
22. A new provision is to be introduced allowing for cooperation between manufacturers and notified bodies (Annex VII MDR).
23. The tasks of notified bodies in relation to medical devices classified as low and medium risk are to be reduced (Art. 52 and Annexes IX, X and XI MDR).
24. The additional consultation procedure in connection with the clinical evaluation is to be required only for class III implantable medical devices. However, national legislators are to be able to enact more extensive regulations in this regard (Article 54 of the MDR).
25. The fees charged by notified bodies are to be reduced for micro and small manufacturers as well as for orphan products, with the commission being granted the right to set the fees for notified bodies (Art. 50 MDR).
26. Cooperation between the authorities responsible for the MDR in the Member States is to be regulated (Art. 4, 4a, 51a and 51b MDR).
27. Joint asset teams are to be formed for this purpose (Articles 36–44 MDR).

28. The national authority responsible for the notified bodies is to be assigned the role of an ombudsman for the resolution of conflicts between manufacturers and notified bodies (Article 35 MDR).
29. Notified bodies are to be required to cooperate within the Notified Bodies Coordination Group (NBCG-Med) in future. The NBCG-Med is to be required to report to the MDCG (Art. 49 MDR).
30. The role of external expert panels is to be strengthened (Art. 106, 106a MDR).
31. In future, the EMA (European Medicines Agency) is to provide scientific, technical and administrative support in further areas, including for small and medium-sized manufacturers (Article 106b of the MDR).
32. Digitalisation is to be incorporated into the MDR, for example for the CE declaration (Art. 19, 110a, Annexes I and VI MDR).
33. In future, the technical documentation, reports and similar documents to be produced by manufacturers are also to be able to be provided in digital form (new Art. 52b MDR).
34. The online sale of medical devices is subject to new regulations (Art. 6 MDR).
35. The requirements for UDI and EUDAMED are clarified. Not everything should be required to go through EUDAMED (Art. 27–33, Annex VII MDR).
36. A new section on international cooperation is introduced (Art. 108a and 108b MDR new).
37. Unlike previously, it should be possible to conduct performance studies as part of combined studies in a single procedure, provided that this option is chosen in accordance with Art. 14c of regulation (EU) No 536/2014 (CTR; Art. 79a MDR new).
38. There are to be new provisions on cybersecurity (Art. 87a and Annex I MDR new).

Assessment

On a positive note, the European Commission is acting. The manufacturers who participated in the consultations on the reform of the MDR have therefore not done so in vain. The reform proposal thus stands as a typical example of the strategy that the European Commission has been pursuing in other areas since this legislative term of the European Parliament: simplification and deregulation.

On the negative side, the European Commission has not sufficiently considered SMEs.

However, it should become easier to place medical devices on the market if, as we hope, the EU legislator implements the commission's proposals.

Nor should the German Federal Government and the Bundestag be absolved of their responsibilities. In the Medical Devices Act Implementation Act (MPDG), which replaced the Medical Devices Act (MPG) as a result of the MDR, there is a need to streamline certain aspects, primarily to make life easier for SMEs. Germany was once the "pharmacy of the world" in the pharmaceutical sector. That was a long time ago. In the medical devices sector, Germany has now risen to become the world's number two. With little effort, significant support could be provided to domestic industrial SMEs. In dentistry, medical devices are far more important than medicines, particularly in implantology. Innovation and high quality improve patient protection in the long term.

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