European Medical Device Regulation
5 Steps to Prepare for What’s Coming
Since the European Medical Device Regulation (EU MDR) was first announced in 2017, it has undergone several delays. In March 2023, the latest extensions were announced.

While further extensions are always possible, the updated implementation dates are quite realistic now—and it would be a mistake to let yesterday’s delays minimize today’s urgency.

The EU MDR is already impacting both companies and patients, with some medical devices already being removed from the market, awaiting certification.

So as a medical device manufacturer, what do you need to know? What immediate actions are required? And how can you avoid potential bottlenecks and profit-stopping issues?

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European Medical Device Regulation: History and Timeline

The EU MDR was introduced in response to public health scandals like the PIP breast implant scandal and defective vaginal meshes.¹ ² But regulation that was intended to safeguard patients from harm has left many medical device manufacturers scrambling.

In fact, in November 2022, Politico reported, “The new rules have inadvertently triggered a new public health emergency—a looming cliff edge in unavailable devices.”³

Due to the COVID-19 pandemic, medical device companies received a welcome reprieve from EU MDR’s implementation. Most recently, on 15 March 2023, the European Union extended the EU MDR transition periods for devices transitioning to the EU MDR...

...from 26 May 2024 to:⁴

- 26 May 2026
  - for class III implantable custom-made devices

- 31 Dec 2027
  - for class III and implantable class IIb devices

- 31 Dec 2028
  - for non-implantable class IIb and lower-risk devices
  - for class I devices that are a higher class under the MDR

"The new rules have inadvertently triggered a new public health emergency—a looming cliff edge in unavailable devices.”
- Politico, November 2022
While there may be disagreement about further extensions, most experts agree on one thing: there’s a lot to be done to get ready. Although it might be tempting to take a “wait and see” approach, swift action is required by medical device organizations to be prepared.

**Here’s what to do next:**

1. Undertake a readiness review
2. Connect with notified bodies
3. Review your business case
4. Brace for the potential financial impact
5. Understand how EU MDR may affect future clinical research
Undertake a Readiness Review Immediately

As a medical device company, you should immediately undertake a readiness review. Doing so will let you know what changes may be required—and if you want to continue investing in product development.

There are several aspects to consider to prepare for when the EU MDR comes into full effect.

- **Review existing certificates.** Products are already disappearing from the market due to expired certificates. Therefore, it’s paramount to start extending certificates until 2026, if possible.

- **Review device categorization.** Based on the implications of MDR, explore whether a medical device will be reclassified. For example, will your Class II device now be considered Class III? If so, you’ll want to know now to consider the implications.

- **Take stock of the shelf life of current products.** All devices have expiry dates. Find out what’s on your shelf and how long it will last.

- **Get a Quality Management System (QMS) in place.** According to Article 10(9) of the MDR, manufacturers must put a quality management system (QMS) in place to benefit from the extended transition period by 26 May 2024.

- **Consider export.** Find out if your EU certification is valid in non-EU markets since this will greatly impact your business case. Notified bodies, firms licensed to certify devices, are not required to change the date on individual certificates. Be aware that authorities outside the EU may not accept expired certificates.

The takeaway?

Manufacturers should contract with a notified body as soon as possible for a conformity assessment prior to a certificate’s expiry. Doing so means that if a certificate expires prior to the enforcement of the proposed amendment, its validity can be extended.
What to do about existing certificates?

Medical Device and Diagnostic (MDD) notified bodies are not re-issuing MDD certificates with extended expiry dates. Instead, the EU MDR unilaterally extends the validity of current MDD certificates—but only if they meet certain criteria.

**To qualify for an extension, manufacturers must:**

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<th>Manufacturers whose medical device certificates have already expired or manufacturers who fail to contract with a notified body before the certificate expiry</th>
<th>Apply for MDR certification with an MDR-notified body</th>
<th>Apply for MDR certification with an MDR-notified body before their MDD certificate expires</th>
<th>Contract with an MDR-notified body before 26 Sept 2024</th>
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Manufacturers whose medical device certificates have already expired or manufacturers who fail to contract with a notified body before the certificate expiry may apply for an exemption per Article 97 or Article 59 (1) to extend the validity of certificates.
Connect with Notified Bodies

According to an April 2022 MedTech survey, MDR certificates have not been issued yet for more than 85% of the more than 500,000 devices previously certified under the MDD or Active Implantable Medical Devices Directive (AIMDD). With so many devices requiring certification, there is currently an enormous demand for notified bodies.

The lack of capacity amongst notified bodies—the often private firms licensed to certify devices—creates a huge bottleneck. Until more private companies are certified to act as notified bodies, the pressure will simply increase as demand outstrips availability.

MDR certificates have not been issued yet for >85% of the more than 500,000 devices previously certified.

The takeaway?
Resources are very limited. Develop and maintain ongoing relationships with preferred notified bodies and testing houses before the demand gets worse for these limited resources.

- **Seek counsel from accredited notified bodies today.**
  Keeping up contact with notified bodies and testing houses may speed up their response to future requests. With demands on their services at an all-time high, it’s critical to make—and keep—these relationships intact.

- **Seek out specialized notified bodies, if necessary.**
  Specialized medical devices require specialized notified bodies, creating an even tighter squeeze as more applications roll in.
Review Your Business Case

Device makers need to assess the costs involved in achieving conformity and then **take a look at bottom-line numbers to answer these questions.**

The regulation is clear about its conformity requirements, so medical device manufacturers have the information required to reassess their device's business case.

- **Review device components.**
  The EU MDR requires re-assessing not only a device as a whole but also each component within the device to ensure it meets the new standards. Each individual component must meet complex requirements (e.g., proof of biocompatibility of USP Class VI designation, ISO 110993-5:2009 compliance). Some devices have a lot of components, so they may require additional costs if replacement materials are needed.

- **Check your current inventory.**
  The EU MDR removed its 12-month "sell-off" provision, which means non-transitioning MDD-compliant medical devices can be supplied after May 2025 in the EU until the stock is depleted.

**The takeaway?**

Don’t stall out on deciding whether to invest in ongoing device innovation. Review device conformity, crunch the numbers, and decide which devices in your current product line will move forward.
Brace for the Potential Financial Impact

Device companies may face higher costs under the EU MDR.

Take a financial forecast of costs associated with continuing under the EU MDR.

- **Review manufacturing.**
  Due to the increased focus on the biological safety of devices, medical device manufacturers will now need to defend their use of plastics with harmful chemicals like DEHP, the most common phthalate found in medical devices. In some cases, this may require manufacturers to source an acceptable alternative. This change may trigger higher manufacturing costs.

- **Budget for documentation costs.**
  Article 10 (4) of the EU MDR obliges manufacturers to prepare and keep up-to-date technical documentation for their devices. This may require manufacturers to update their documentation so that it is representative of the current device. Compiling and maintaining technical documentation can be a costly budget line item.

The takeaway?

Compliance with the new EU MDR may come with additional costs. If you want to go forward but many changes are required, it may be time to look for more funding.
Understand How EU MDR May Affect Future Clinical Research

The uncertainty around EU MDR may, at least temporarily, curb innovation, as some device companies adopt a “wait and see” approach. But each delay from device companies may pause medical device research initiatives and investments.

Since physician researchers and early startups are drivers of industry innovation, early device development may be suppressed due to increased technical documentation requirements.

“Before the MDR was implemented, the key innovators of medical devices could easily set up an investigator-initiated trial,” said Deborah Ann Schuster at the Outsourcing In Clinical Trials: Medical Devices Europe 2023 meeting.11

“But now the requirements for submitting technical documentation to begin these trials is way more challenging. EU MDR requires the innovators to prepare time-consuming documentation, and they need much more manpower and funding to comply with the regulations.”

The EU MDR may influence how future trials are written and presented.

☐ Conduct post-market surveillance.
   The EU MDR requires manufacturers to actively gather, record, and analyze relevant data on the quality, performance, and safety of a device throughout its lifetime.
The Quandry of Orphan Devices

EU MDR requires more clinical data for CE marking. The two main sources of clinical data—real-world evidence (RWE) and clinical investigation—are more complicated to produce for orphan medical devices. Because the medical conditions that these devices predict, prevent, treat, or diagnose are rare, it’s unlikely medical device companies can find relevant published literature.

Manufacturers may also have few passive post-market surveillance options, translating to costly and time-consuming further clinical investigations and potentially active post-market surveillance.

Unfortunately, all of these factors may unintentionally cause orphan medical devices and the interventions reliant on these devices to be unavailable. For example, two of three infant heart device manufacturers have pulled out of the market amidst all this change, leaving a sole remaining product.\textsuperscript{14}

It may also become harder to bring orphan devices to market, according to an *Orphanet of Rare Diseases* 2023 article: “With the current implementation of this EU MDR, it has become even more difficult to place custom-made devices on the market, including 3-D printed devices.”\textsuperscript{15}

At this time, the European Union lacks an orphan device directive—despite widespread support for such a measure.\textsuperscript{16} According to MDCG 2022-14\textsuperscript{17}, additional short-term and long-term strategies must be implemented for orphan devices.

Therefore, orphan device manufacturers need to:

- **Identify any unexplored clinical research options.** Review alternative ways to collect meaningful data to help establish short-term and long-term safety and efficacy.
- **Set up alerts for literature mentioning their device.** While the chances of finding published, third-party literature on a specific device may not be high, device companies need to stay alert to any literature mentions. Doing so may prevent avoidable research costs.
- **Follow MDCG’s orphan device task force announcements.** Watch out for any potential pathways for these products, such as regulatory guidance or other supportive measures, to satisfy obligations under the law.
Moving Forward with the EU MDR

According to the revised timeline, the next medical devices up in the queue are Class III implantable custom-made devices with a 26 May 2026 deadline. Obviously, manufacturers of these devices will face the most pressure to get ready. But all device manufacturers should be using the extra time to get ready.

Now is the time to assess device inventory, redefine device classifications if required, consider the longevity of existing or proposed devices, and invest or divest.

In order to be ready, device companies need to:

- **Monitor** guidance documents and any potential legislative changes
- **Review** quality processes, compliance plan, and QMS
- **Assess** manufacturing
- **Review** and re-write documentation

During this transitional period, manufacturers and businesses have more time to comply with the MDR and the IVDR—but it’s important to start preparing as soon as possible. Keep track of key dates and account for lead times concerning the expiry of device certificates. Find a key person to own this project and take responsibility for staying abreast of any updates.

The EU MDR has created a sense of uncertainty within the industry. This can create lethargy around research and development. Respond by assessing your readiness today, not tomorrow.
About medrio

Trusted by sponsors, CROs and sites worldwide, Medrio aims to improve 100 million lives through faster, more efficient, and secure clinical trials. With almost two decades of experience, Medrio delivers proven, scalable solutions, unrivaled customer support, and guidance to the industry’s leading innovators, including pharmaceutical, biotech, medical device, diagnostics and more.

The company’s suite of solutions, including CDMS/EDC, eCOA/ePRO, eConsent, and RTSM, enables the capture of quality clinical trial data while optimizing workflows for regulatory readiness. Experience the power of Medrio and realize the full potential of your clinical operations and outcomes.

If you want to learn more about how Medrio powers MDD studies, explore our recent success story or talk with the Medrio team.
References


