Biomedical Alliance in Europe

26 April 2024

# Urgent! Imminent deadline to avoid medical devices from disappearing

Europe is approaching a key deadline for implementing the Medical Devices Regulation (MDR), in only a few weeks. Healthcare professionals across Europe represented within the BioMed Alliance are concerned that the sector may not be ready for requirements that become applicable on 26 May 2024, and that as a result some essential medical devices will disappear from the market.

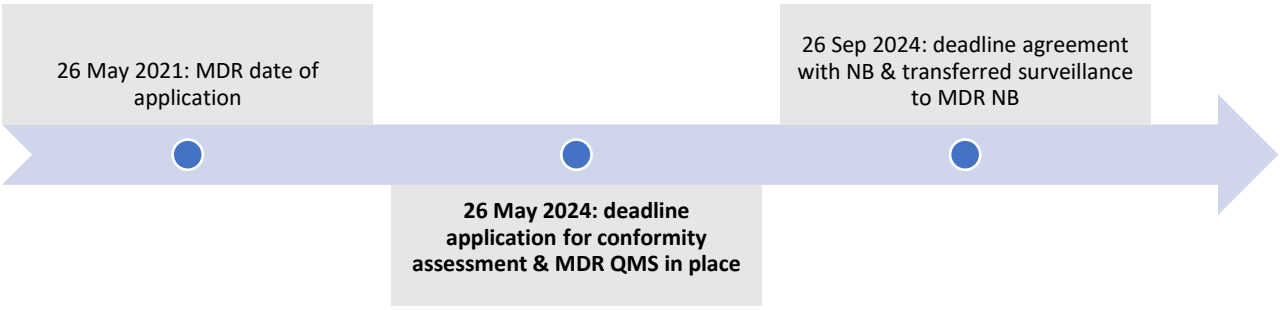
The transition towards the MDR has been progressing, but its full implementation has been delayed and accompanied by numerous issues that have led to concerns among clinicians. The clinical community represented within BioMed Alliance has raised awareness about problems including limited capacity of Notified Bodies, absence of EUDAMED, high costs of certification, issues with the evaluation of paediatric and orphan devices, research and development leaving Europe, limited transparency and predictability, and general issues with the certification of both legacy and innovative new devices. Now urgent action is needed as a major deadline in the MDR implementation is approaching next month.

## Upcoming deadlines

On the 26th of May 2024, there is a new deadline that manufacturers have to comply with, in order for legacy devices (placed on the market under the previous directives) to benefit from extended transition periods up to 2028. After that date they must have lodged an application for conformity assessment under MDR with a Notified Body, and have an MDR Quality Management System (QMS) in place. Otherwise, the certificates of these devices will not be valid under MDR, and they will not benefit from the extended transition times up to 2028.

Manufacturers must also have a signed agreement with a Notified Body and have transferred their surveillance to a Notified Body designated under the MDR, by 26 September. This year will be an important year in the transition to MDR and manufacturers must act now to ensure they can continue to sell their devices in Europe.

Many large companies have already met these requirements but particularly small and medium enterprises, and manufacturers of devices used in small numbers of patients, may not have done so in time.



| Extended transition periods | |
|---|---|
| 26 May 2026 | End of derogation for class III custom-made implantable devices |
| 31 December 2027 | End of transition period for class III & class IIb implantable devices |
| 31 December 2028 | End of transition period for other class IIb IIA, class I sterile/measuring devices, devices requiring NB involvement for the first time |

## Key issues

Legacy devices that have been certified under the previous medical devices directives, and that have often been on the market for numerous years without issues, will thus disappear from the market if manufacturers do not submit their application under MDR before 26 May 2024.

Many manufacturers may decide not to apply for recertification and withdraw their devices from the European market, partially due to the high costs of conformity assessment under the new system[1]. The BioMed Alliance is concerned that this could lead to reduced availability of essential devices used in patient care, and particularly of devices intended for small patient groups, such as paediatric devices or orphan devices, due to the limited potential return on investment for industry. From discussions with clinicians, manufacturers, and regulators it seems highly likely that there will be shortages. This may lead to a degradation or interruption of care, and a reduced or delayed access to devices among European patients compared to those in other jurisdictions in other parts of the world.

The proposal for a regulation 2024/0021 (COD) may offer a way to address shortages in the future, as the proposed article 10a refers to a mechanism requiring manufacturers to provide prior notice 6 months before the supply of essential medical devices and in vitro diagnostics is stopped. This provision could help anticipate shortages of devices and IVDs and allow time for competent authorities, the European Commission and the healthcare system to mitigate the shortages or find alternatives. We very much welcome the proposal but unfortunately it is yet to be adopted and will not come into effect until the end of the year at the earliest. The EU must therefore take immediate measures in the interim period to prevent shortages of essential medical devices.

## Ways forward

**Short term**

- Manufacturers should **submit their applications for conformity assessment** under MDR as soon as possible.
- Once regulation 2024/0021 (COD) is adopted, the mechanism through which manufacturers can **report interruptions of supply** of essential devices must be implemented as soon as possible – and preferably through a single, central, transparent reporting system.
- There is a need for an **interim solution** helping to anticipate shortages while the reporting mechanism is not yet functional. Manufacturers need to inform their competent authorities in advance in case they intend to withdraw a device from the market, so that regulators and

[1] See e.g. our press release of 27 June 2023: https://www.biomedeurope.org/images/news/2023/Letter_Kyriakides_Med_Devices_signed_270627.pdf

clinical specialists have time to adapt and find alternatives, or else solutions to keep the device on the market.

- It is important to **improve communication** between manufacturers, notified bodies, competent authorities, the Commission and healthcare professionals to rapidly detect and prevent upcoming shortages.
- Facilitate the implementation of national and EU-wide **derogations** for devices that are about to disappear from the market and play a critical role in EU healthcare, as an interim emergency measure (article 59 MDR).
- The new incoming Commission must make issues related to the MDR and IVDR implementation a **political priority**, and support the evaluation of the two regulations and any follow-up legislative actions.
- The **evaluation process of MDR and IVDR** should include extensive input from the different stakeholder groups and the main issues in the system and potential solutions must be carefully examined. The evaluation should not be rushed through, allowing for sufficient time to address major shortcomings in our regulatory system and prevent future issues that could hinder patient access to medical devices.

**Long term:**

- We must establish special **regulatory pathways for orphan devices**, providing affordable routes to conformity assessment.
- N**otified body** oversight, transparency and communication need to be improved.
- The pilot with **early advice** provided by Expert Panels should be expanded, to support more manufacturers in the early stages of their route to conformity assessment.
- Promote the use of **registries** as a source of clinical evidence, including for the post-market surveillance of e.g. orphan devices. Public financial support should be available.
- Explore providing **certificates with conditions**, for essential legacy devices that have been on the market without issues for a significant period of time.
- Need for broader efforts to retain **research and innovation** in Europe. Including through support for breakthrough innovation, SMEs and start-ups. A wide range of approaches can be beneficial including providing early advice, enhancing legal clarity, support for research and innovation, facilitating the conduct trials, supporting early feasibility studies, etc.