

# Orthopaedic device manufacturers' perspective on MDR compliance

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Dear Editor,

The Medical Devices Regulation (MDR 2017/745) will finally go into effect on May 26, 2021. We anticipated this event and shared our perspective in a recent article published in AboutOpen | HTA & Market Access (1).

All stakeholders (manufacturers of medical devices, notified bodies, competent authorities, medical device coordination group, etc.) have been working towards this for years! What's known for certain is that there's a bumpy road ahead. Eudamed, a central element within the MDR, is not fully functional yet. Many guidance documents (MDCG) are still in preparation. The notified bodies have insufficient capacity, and many of them have not (yet) been designated to certify products under MDR. We hold our breath for 2024, the year that all medical devices under the MDR must be certified.

Listening to the market, we note that there is still much uncertainty among manufacturers. One problem is that the interpretation of the MDR still differs between the notified bodies on essential points. This may lead to an uneven playing field that could eventually create unfair competition if these differences and alignment are not addressed.

We still think there's a possibility that the MDR will ultimately lead to more bureaucracy, paperwork, and regulatory activity for its own sake. In particular, post-market clinical studies with limited patient population and participating investigators will have a marginal impact on patient safety. Alternative methods to traditional clinical studies such as independent registries should be strongly considered. Consequences, if not considered, include removal of devices and therapies from the European marketplace, denying patients and healthcare professionals access to safe and performing legacy devices.

The stakes are high. Needless to say, we hope that the ultimate goal of the MDR – to market products that meet the highest safety standards – will be achieved. Time will tell ....

## Reference

1. Fennema P, Achakri H. Getting your devices ready for MDR compliance – a clinical approach and orthopaedic device manufacturers' perspective. AboutOpen. 2019;5(1):70-75. [CrossRef](#)

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