



## Major construction site MDR - forecasts and potentials

The European Medical Device Regulation (EU) 745/2017 (MDR) came into force in 2017 and must be applied by manufacturers on a mandatory basis from May 26, 2021. However, the MDR system is still not fully implemented and poses enormous challenges for producers of medical devices. Is the industry and the healthcare system now threatened by a massive decline in inventory and innovation products?

### Acute problem within the EU



Manufacturers are unable to transition existing products to MDR due to excessive requirements & expenses. Many products have already been withdrawn from the market or will disappear by 2024.



Inventory products are lost to patients in daily use. In many cases, there are no alternatives.



The innovative strength of the medical technology industry in the EU is suffering enormously as a result of the MDR Regulation. In addition, the MDR results in a drastic reduction in the availability of innovative medical devices for institutions and end users



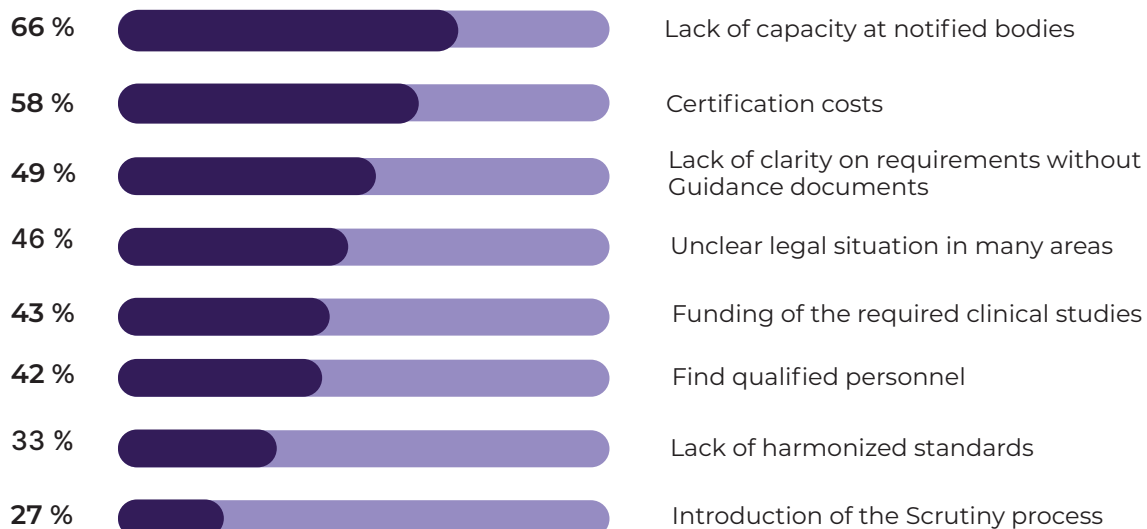
Structural problems (e.g., in the cooperation with notified bodies or due to legal uncertainties) make it difficult for manufacturers to implement the complete MDR system.



**The acute problem situation has now reached the consciousness of the responsible political decision-makers at national and European level.**

The MDR system is now to be optimized through a variety of measures in order to avert worse consequences for the industry and patients in the EU.

### Challenges in the implementation of the MDR



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