

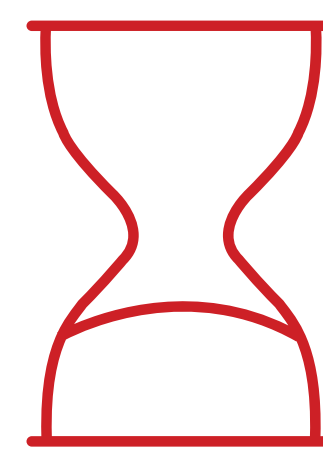
New Regulations Are Reshaping Europe's Medical Device Industry

Updated rules meant to ensure the safety and efficacy of medical devices will raise top-line risks and costs for manufacturers. Here's how they can respond

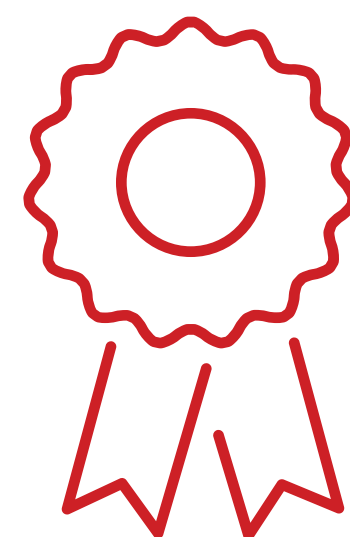
New rules, new risks

By 2025, all medical devices will need to be recertified, creating the following revenue risks.

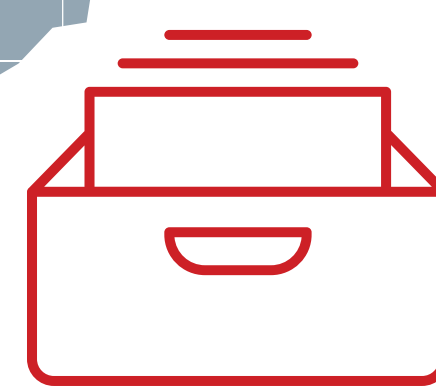
2025



Delays due to capacity constraints at certification bodies



No legacy protections means existing products must be recertified or retired

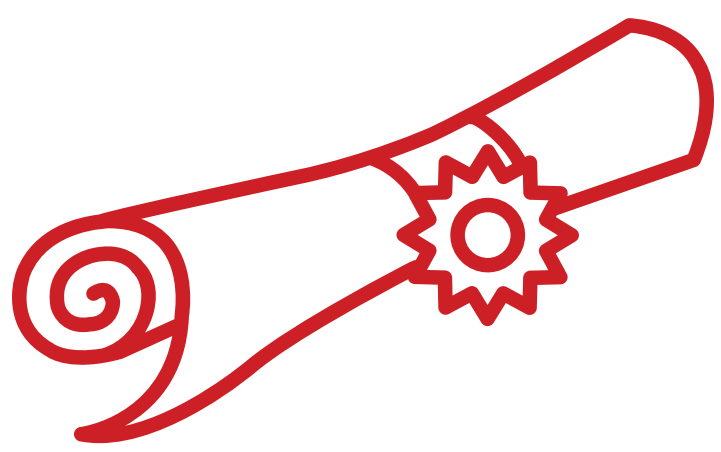


Reclassification that may necessitate additional data and documentation

Higher costs on the horizon

What does it mean for medical device makers?

One-time recertification costs:
5% to 10%
of EU revenue



Ongoing compliance costs for the following actions are

10% to 20%

higher than they were during previous regulation:

- Reviews
- Surveillance
- Quality management
- Compliance
- Unique device identifiers

Four keys to compliance

Leading medtech manufacturers are adapting to new regulations now.



Get rid of obsolete products



Speed up recertification submissions



Acquire clinical data and new capabilities



Take actions to minimize expected cost increases