



# MDR-Update

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# Who we are

Experience the PULSE of medical technology

MedicalMountains GmbH is an organization that provides **networking** and **support** for all players in the medical technology industry.

- ▶ We promote dialog, combine strengths and create platforms for sharing knowledge.
- ▶ We enable cooperation and synergies through strategic and systematic coordination.

## State of Play

- ▶ Number and capacity of Notified Bodies: ✓
- ▶ Time for transition from MDD to MDR: ✓
- ▶ Clarifying regulatory issues: ✓

But ...



## Unresolved questions

- ▶ Too much effort without relevance to safety and performance requirements,
  - ▶ high costs that are not in proportion to the revenue of products,
  - ▶ lack of predictability and planning security for manufacturers.
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- Position Paper  
„Suggestions for changes by MedicalMountains for more planning security, reasonable effort, and lower costs when implementing the MDR” (July 2024)
  - European Parliament resolution  
„Urgent need to revise the medical devices regulation” (October 2024)



## Possible steps

- ▶ Simplified design of clinical evaluations for medical devices in low-risk classes
- ▶ Practical application of the equivalence principle and “well-established technologies”
- ▶ Adaptation of classification rules 6 and 8
- ▶ Non-significant changes without approval by a notified body
- ▶ Adjustment of PMS reporting intervals
- ▶ Lean processes through eIFU and reduced mandatory languages



## What's to come

- ▶ **EUDAMED**  
From January 2026 on, mandatory use of actor registration, devices, certificates, market surveillance, followed by vigilance from July 2026 (current status).  
→ Major function of the MDR.
- ▶ **AI-Act**  
AI/ML-enabled medical devices are classified as “high-risk”.  
→ Separate regulation beside MDR.
- ▶ **PFAS**  
Restriction proposal carried out by the European Chemicals Agency within REACH.  
→ far-reaching effects on products and processes covered by MDR.



## What to do?

- ▶ **Get all information you can.**
- ▶ **Don't wait. Act.**
- ▶ **Use networks!**



# Keep in touch

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of medical technology

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