Advantages and drawbacks of the new Medical Device Regulation: new challenges for a digital health company

Day 2 – 2021 Thought Leader EHTEL Symposium
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Skills and interests:
• Requirements elicitation
• SaMD design
• AI, Multi-view learning
• Big Data in healthcare

We are helping to shape the future of healthcare with disruptive Digital Health solutions that combine innovation with experience to deliver and empower patient-centred care worldwide.
The impact of MDR on SaMDs

Rule 11: what does this mean for digital health companies?

Class I device with MDD DoC drawn up before 26 May 2021

• MDR class I DoC required
• Must comply with MDR’s requirements

May be placed on the market until May 2024, but...

1. There should not be significant changes in the design and intended purpose
2. Must comply with the new requirements for PMS, traceability and liability

NEED TO BE ASSESSED
Who benefits from the new EU Regulation?

- Trustworthy solutions backed up by relevant clinical data
- Competitive advantage for certified manufacturers
- Real-world, measurable, and meaningful clinical benefits for individuals
Is it that simple?

Change takes effort.

- Overloaded Notified Bodies
- Overloaded in-house professionals
- Risk of investment loss
- Risk of fines and penalties
- Additional financial damage in case of negative media exposure
THANK YOU

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