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
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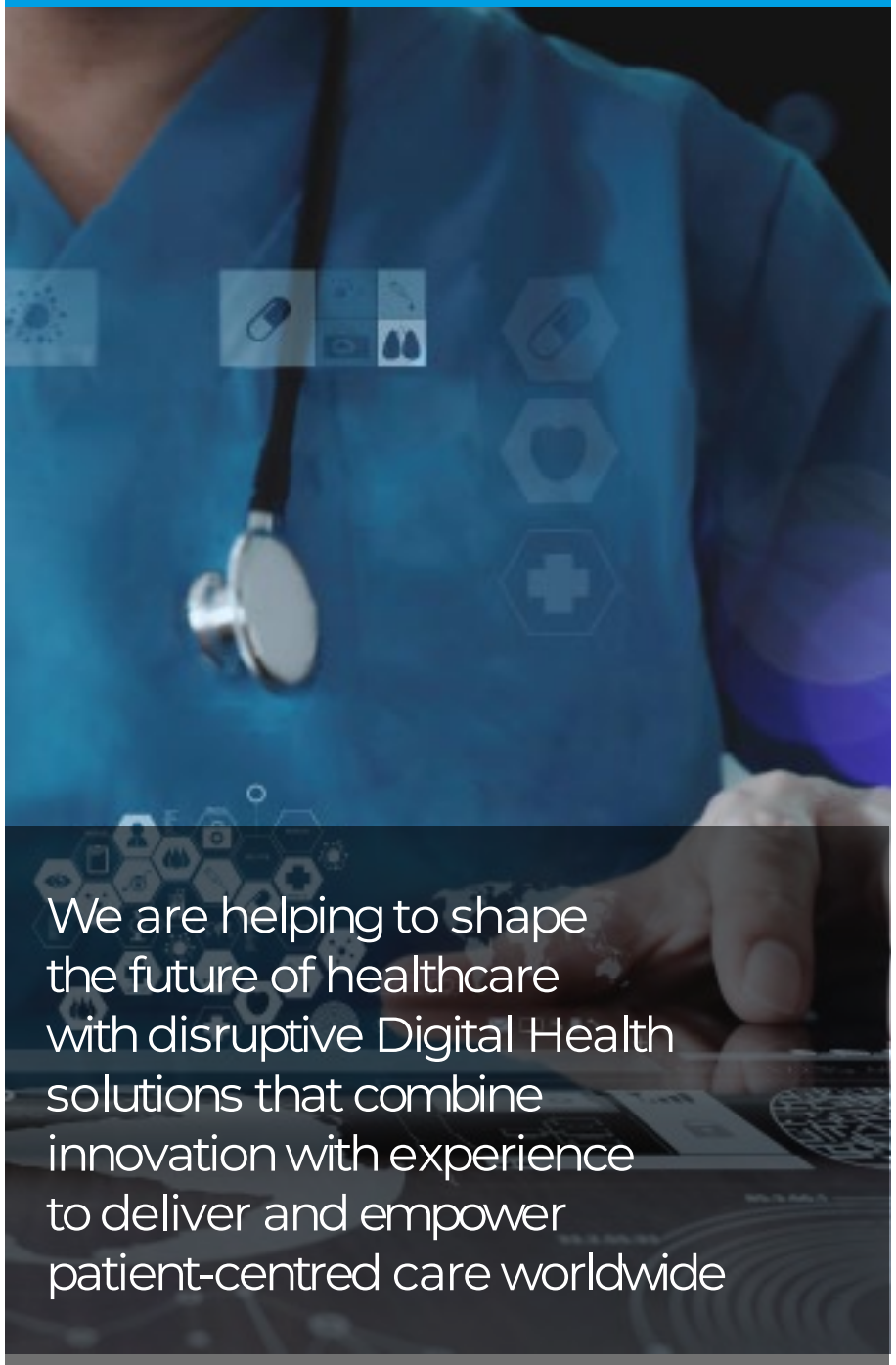

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The impact of MDR on SaMDs

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

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

NEED TO BE ASSESSED

MDR classification higher than Class I? (Rule 11)

NO

- MDR class I DoC required
- Must comply with MDR's requirements

YES

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

Acronyms:
MDR – EU Medical Device Regulation 2017/745
SaMD – Software as Medical Device
MDD – Medical Device Directive 93/42/EEC
DoC – Declaration of Conformity
PMS – Post-Market Surveillance

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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

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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

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THANK YOU

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