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MDR postponement

How to use the additional time as a chance!

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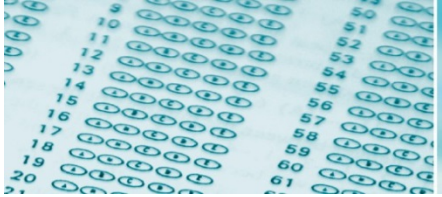

Why is ISS talking about this issue today?

- **We all know about** the additional **burden of the MDR** and that **many devices are still not ready today**
- We also know that **authorities** and **notified bodies will have to implement** the new MDR rules
- **ISS believes** that the MDR postponement **provides a real chance** for the MedTech sector
- This believe is based on our **long-standing experience as a service provider knowing many devices** first-hand

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What should you focus on?

- The MDR-system is still not fully ready and the **MRA between the EU and CH is still unsolved**

  → **Establishment on an EAR (minimize your risk)**

- **The MDCG** has a priority list (**roadmap**) for the implementation

  → **Focus on the top priorities from the CAMD/MDCG roadmap***

- The **new regulation has to be implementented** by Competent Authorities/Designating Authorities ⇨ Notified Bodies ⇨ Manufactures

  → **Follow the MDCG discussions to be able to anticipate what is coming next (e.g. check the MDCG webpage, screen for released documents, sign-up for newsletters)****

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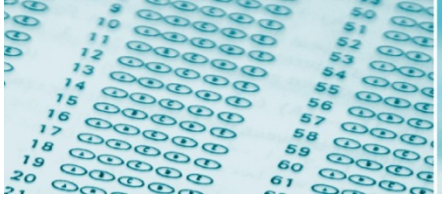

What should you focus on?

- Some MDCG **guidance is missing**
  → Stick to other major guidance docuemts (e.g. US FDA)
  Be aware: MDCG may set new rules

- **Legacy devices** may also **need to fulfill MDR requirements**
  → A legacy device is not safe by definition!
  You need to check in the MDR if you need to fullfil additional requirements (e.g. PMCF)*

- One of **the biggest gaps** is in the field of **clinical data**
  → Check your tech file with focus on clinical data. Your chance:
  Collect clinical data according to current MD directives and use it for MDR certification

* https://www.iss-ag.ch/download_center/factsheets/de/Factsheet_PMCF.pdf

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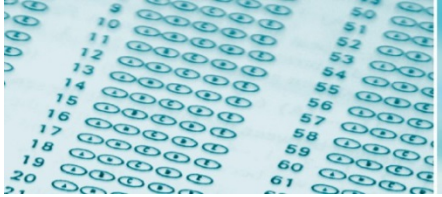

What should you focus on?

- **Software** and other devices like substance based MD will get a whole **new qualification and classification** set up, the rules will be stricter

  → **Think about placing your device on the market under the current directives and use the transission period to build** your knowledge**. Mind the cyber security requirements**

- Your **internal organisation** may need an update

  → **In case you do net yet have a «MDR responsible person» or a «MDR manager», select one**

- You may **need additional knowledge or advice**

  → **Cooperate with other manufacturers, build your knowledge internally or get the external support you need**