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MDR and IVDR: What are the Strategies to quickly access the EU market for Start-ups and SMEs

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SME and their key determining factors

- SME often…
  - … are the driver of new technologies/therapies
  - … have many inventions of cutting-edge technologies
  - … have limited resources
  - … have limited human resources and limited regulatory capabilities
  - … require early market entry with their products for sufficient return / reimbursement
  - … does not often have a track record with a lot of products already on the market
  - … are not very active in lobbying/policy making

MDR and IVDR: Key changes

- MDR and IVDR require/trigger…
  - … higher classification of several devices
  - … a mandatory comprehensive quality management system
  - … increased burden for clinical studies & fewer equivalence evidence
  - … UDI and its complex and costly coding system
  - … disclosure of technical file in OEM/OBL situations
  - … increased supervision of Notified Bodies by competent authorities – fewer NB and MDR / IVDR have a quite short transition till May 2020

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- SME need …

… personnel in regulatory and science

… to spend additional efforts for QMS

… to invest in technical requirements for UDI etc.

… to likely conduct costly clinical trials for their cutting-edge innovations

… to secure suitable NB

… face delay in market entry

… to raise money and need to consider partnering

- **What may be the strategies of SME?**

Strategic considerations of SME under MDR/IVDR?

- obtain clarity on transition and implications
- obtain CE Marking before May 2020 – however, device "locked in"
- define regulatory strategy for MDR / IVDR compliance well ahead
- seek early advice from regulatory/legal advisors
- secure/hire the respective regulatory/technical quality expertise
- consider sharing personnel (incl. resp. person for regulatory)
- secure/ search and engage suitable NB
- define the clinical review plan and align early with NB
- plan for costly clinical trials (before and after the CE marking)
- consider early budgeting and & fundraising/partnering
- anything else?

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