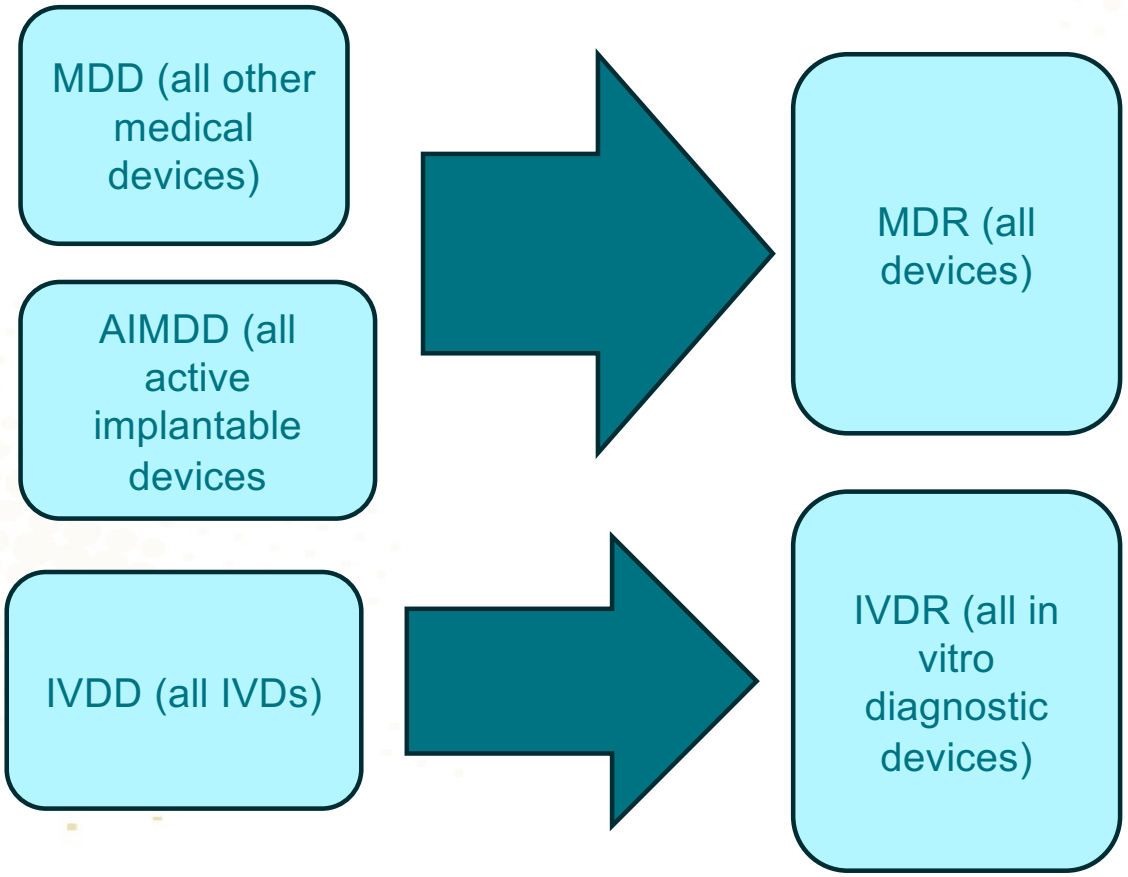
AXON
science based lawyers

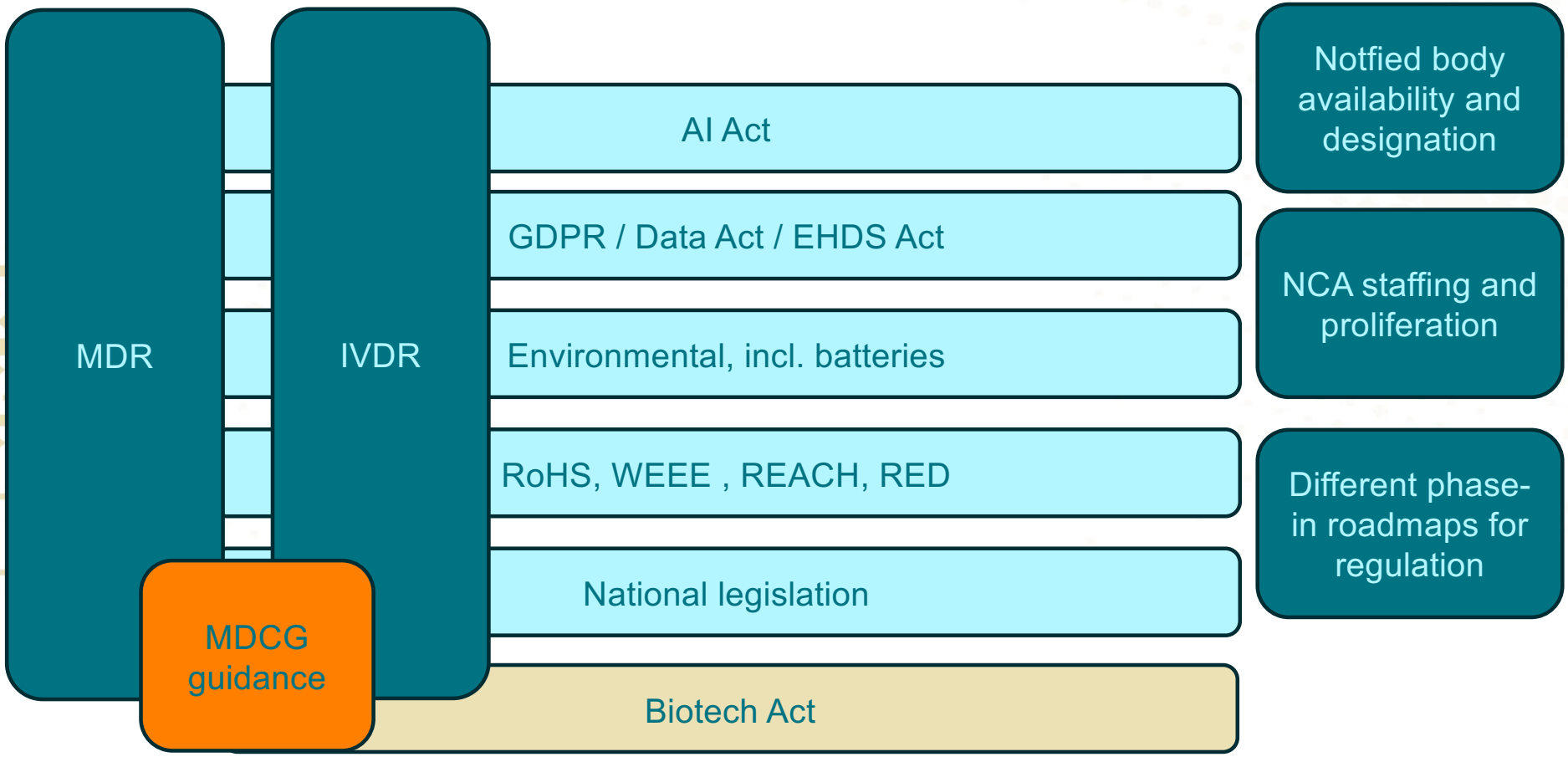
Understanding MDR/IVDR: insights and practical experience BIRR's regulatory journey

MDR en IVDR



- Originally proposed in September 2012 – 5 years in legislative procedure
- MDR and IVDR in effect May 2017
- Applicable as of 2021
- Both still in complex transitional regime for devices and IVDs already approved under old directives

The MDR and IVDR lasagna / spaghetti



What does this mean for SMEs and health institutions?

- SMEs take longer and must invest more in obtaining CE marking
  - The more complex the device, the more horizontal regulation applies

- Health institutions must adhere to in-house produced devices rules and EU guidance, resulting in de facto CE equivalent regulatory burden **and** justify lack of commercial equivalent

- Use of non-compliant devices (off-label, without CE or non-compliant in-house): **illegal**
  - Risks for healthcare practitioner, hospital and for patient

- Regulatory slips ups with notified bodies can take considerable time to remedy
  - A full new conformity assessment may need to be followed, at considerable costs and delay
  - Different devices have different conformity assessment pathways based on risk class and characteristics
  - System is not set up to quickly correct problems
  - Notified bodies are controlled at arm's length
  - Notified bodies are not allowed to tell you what and how to do things

EU in distress: Competitiveness Compass

Innovation

Decarbonization and competitive-ness

Resilience and economic security

- Simplification
- Removing single market barriers
- Savings and Investment Union
- Promoting skills and quality jobs
- Better coordinating policies at EU and national level

COM(2025) 30 final, 29 January 2025

MDR and IVDR will be revised – soon?

- 16 December revision proposal to be published by Commission
- What is interesting for reproductive medicine?
  - Class I reusable surgical instruments no longer Ir
  - Clinical data and equivalence less burdensome
  - Duration of certificates
  - Qualification and classification centrally
  - Neutral ombudsman for issues between manufacturers and notified bodies
  - More Common Specifications for specific products
  - Simplification of Eudamed
  - Better interface with AI Act

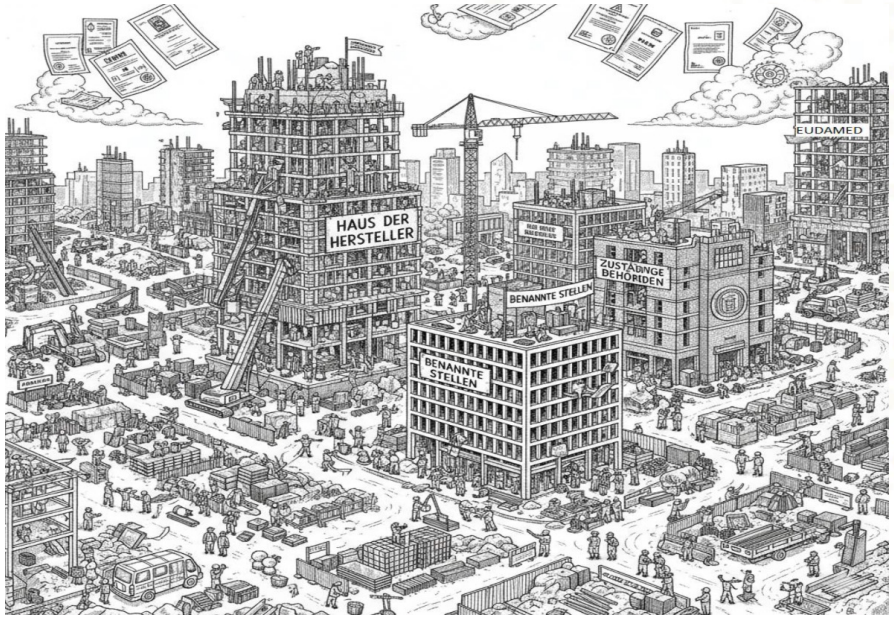


Image: Matthias Neuman, BMG

MDR and IVDR changes will follow co-decision law making procedure

- Expect the whole process to take two – three years (unclear if this includes transitional period)
- Uncertainty about Member State positions and wishes – some Member States are planning to put their mark on the end result
- Everyone wants less bureaucracy but there is considerable resistance when it comes to specifics and details

Happy end to this fairytale?

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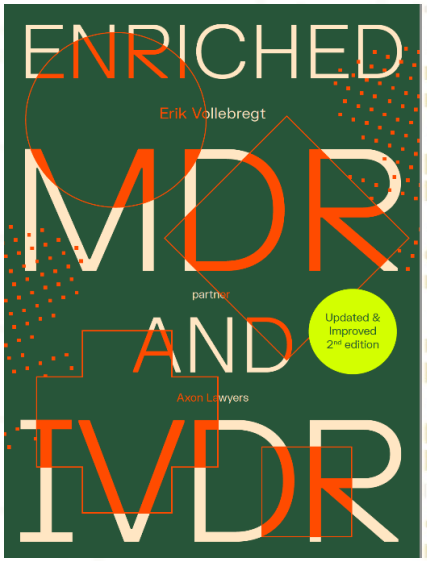

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Van 15:00 tot 15:30 Ask me anything bij stand BIRR

Discussion based on ‘overheard’ statements and questions

- “MDR and IVDR allow health institutions a wide discretion for using CE marked devices for other purposes than labeled”
- “A health institution can change a medical device or IVD as it considers necessary”
- “Companies with devices under the MDD or IVDD directives do not have to do anything for the near future”