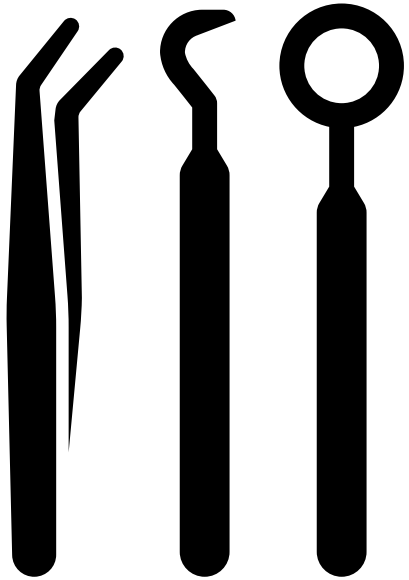
NBCG-Med plenary 09-11 April 2024 Brussels

MDR Concerns – Poll



POLL Question

What are your greatest concerns as of April 2024?

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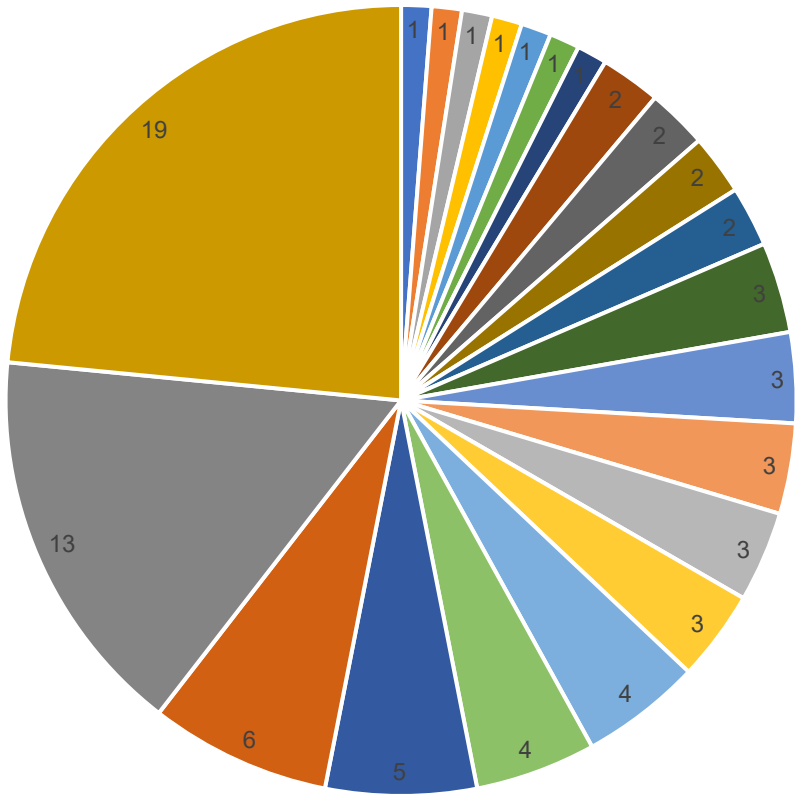
MDR Concerns

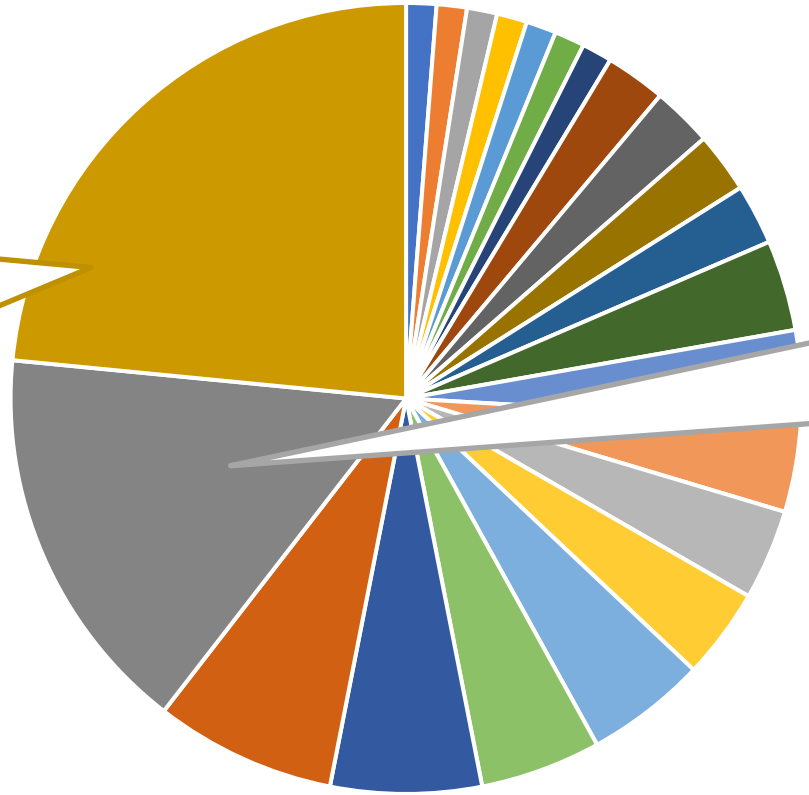


- Expert panels
- Conditions on Certificates
- Definition of device, component, accessory
- Clinical data
- Article 17
- Harmonised standards
- Article 22
- Everyone blaming NBs
- EUDAMED
- Timelines & costs & administrative burden
- PMS, PMCF, PSUR
- Lack of qualified NB resource
- MDCG Guidance
- Basic UDI-DI - combination of devices
- Transfer of certificates
- Too many changes
- Competent Authority
- Classification
- MDR implementation
- Harmonisation of NB
- Manufacturer lack of preparedness
- Too much effort for EU 2023/607 - Directives are obsolete

Results Poll MDR

#1
Too much effort on EU 2023/607:

- MDR applications without real intention to transfer to MDR
- Many change requests for legacy devices
- Appropriate surveillance on devices with `expired´ certificates



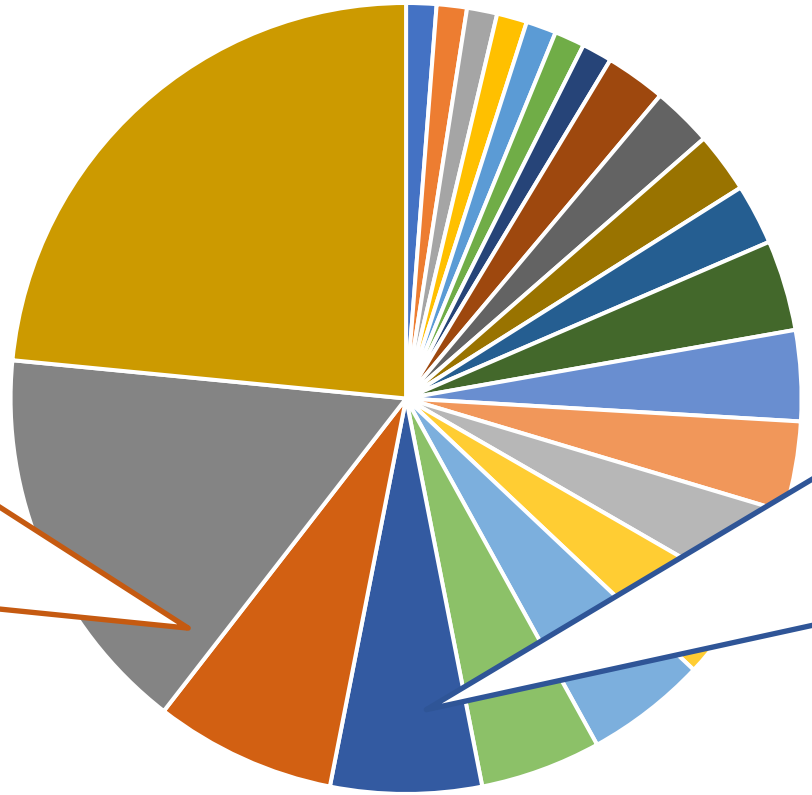
#2
Manufacturers lack of preparedness:

- Not submitting technical documentation
- Lack of response to NB´s requests
- Threats with legal procedures
- Not submitting clinical data

MDR Concerns

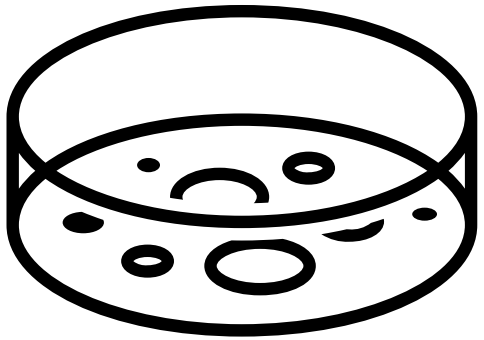
#3
Harmonisation of NBs:
- Substantial change
- Depth of assessment
- Clinical requirements
- MDCG documents optional for some NBs

- Need more opportunities to discuss and align



#4
MDR Implementation:
- Some parts of Regulations not written with practical implementation in mind
- “all NBs are designated and have finished review of all devices within 4 years” not a realistic expectation
- Duplication of data– TD, PSUR, vigilance

IVDR Concerns – Poll



POLL Question

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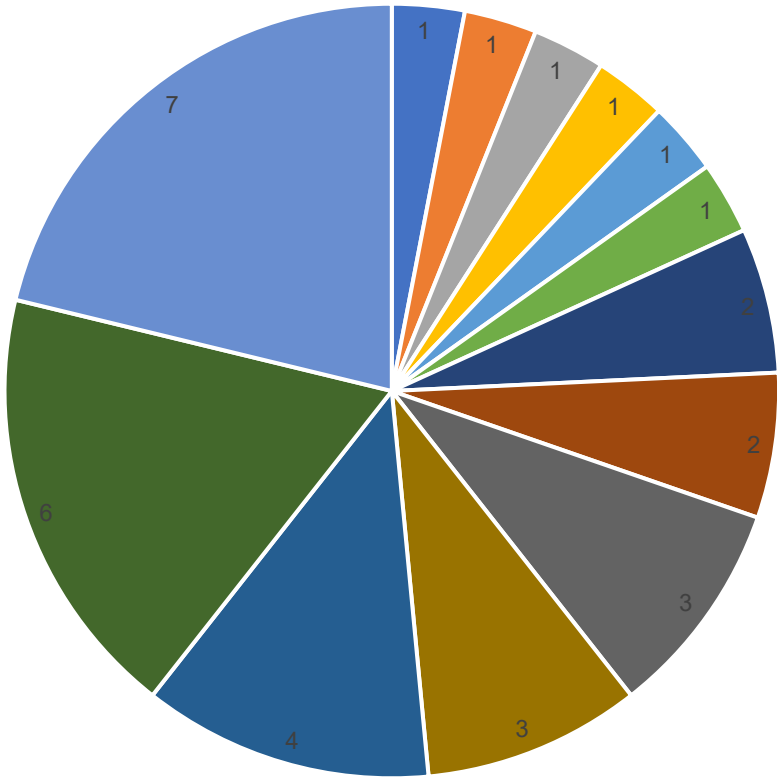
IVDR Concerns

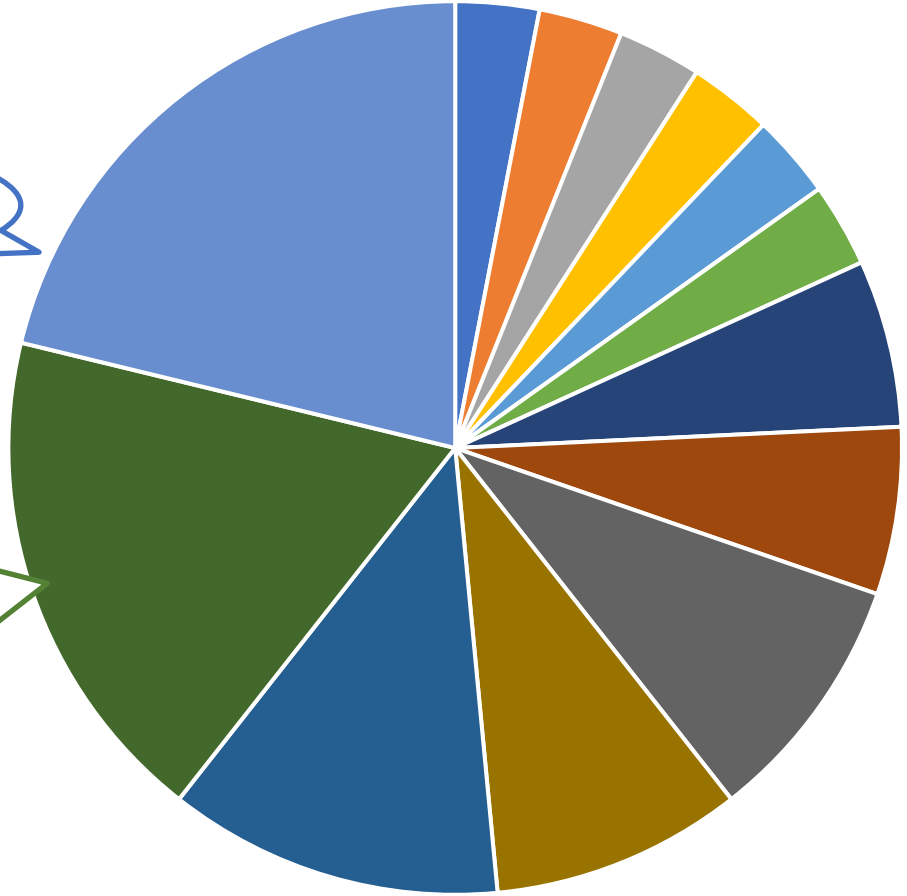


- Everyone blaming NBs
- Too many changes
- Significant Change
- Lack of qualified NB resource
- EUDAMED
- MDCG Guidance
- Basic UDI-DI
- Competent Authority
- IVDR implementation
- Manufacturer lack of preparedness
- Codes in EU 2017/2185
- Too much effort for EU 2024/43 - Directives are obsolete
- EU Reference Labs

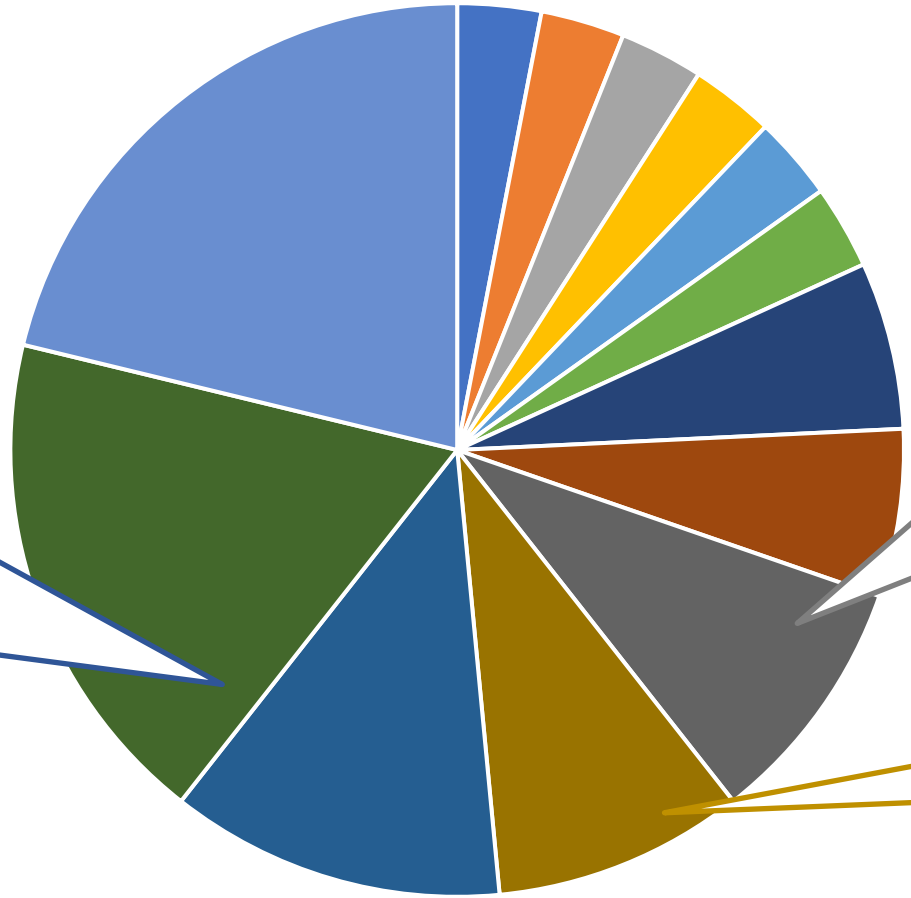
IVDR Concerns

#1
- EU Reference Labs

#2
- Too much effort to implement EU 2024/43 instead of moving to IVDR
- IVDD is obsolete



IVDR Concerns



#3
Codes in EU 2017/2185:
- 5 factor coding too granular
- IVT not always relevant to IVD manufacturing processes
- Lack of clarity on how to apply codes

#4
IVDR Implementation:
- NB Designation Process
- No pathway for NGS and other innovation
- Basic UDI-DI definition

#4
- Manufacturer lack of preparedness


Q
A