



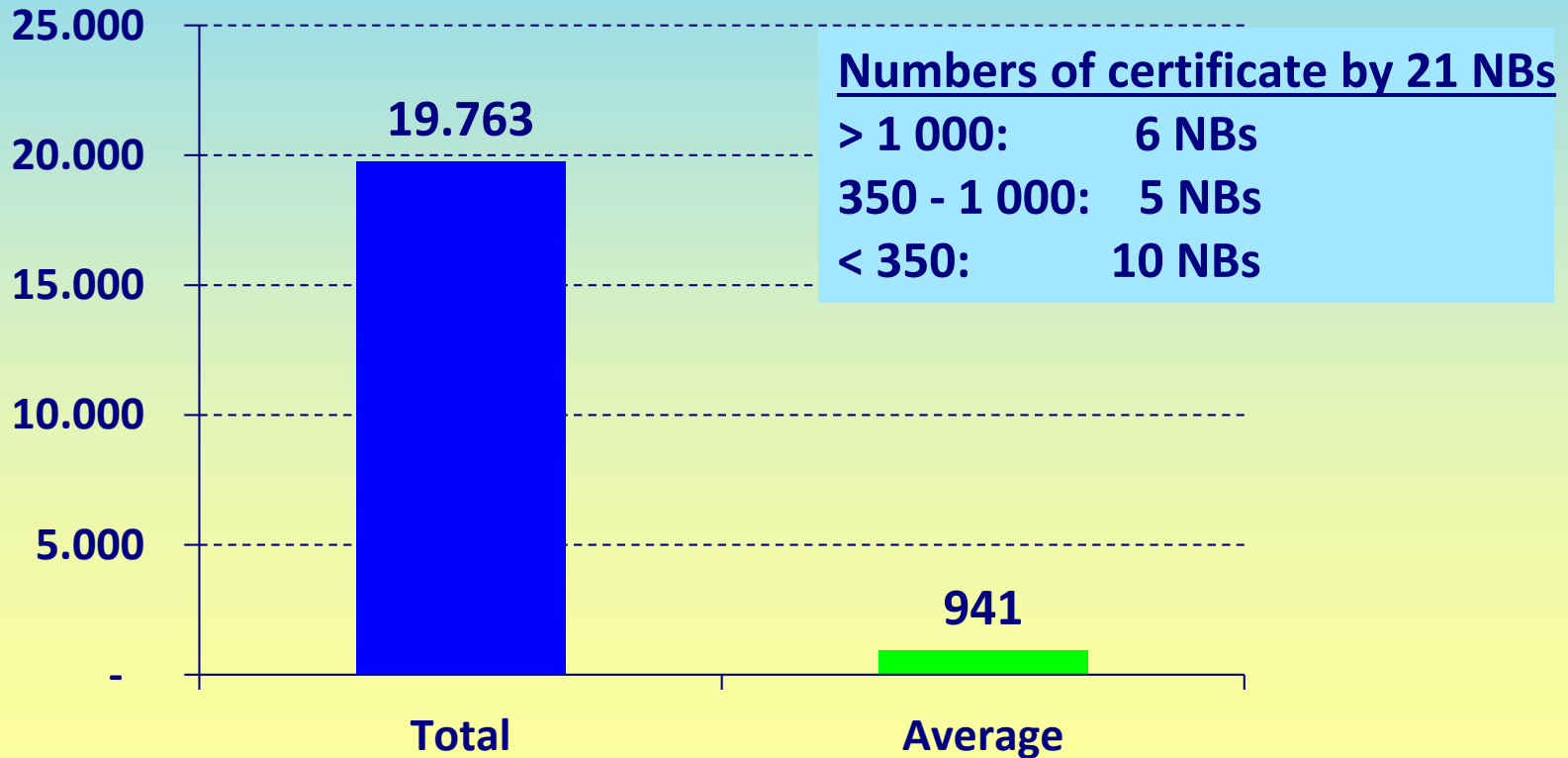
The European Association Medical devices
Notified Bodies

Medical Device Survey 2016

Data from 21 NBs

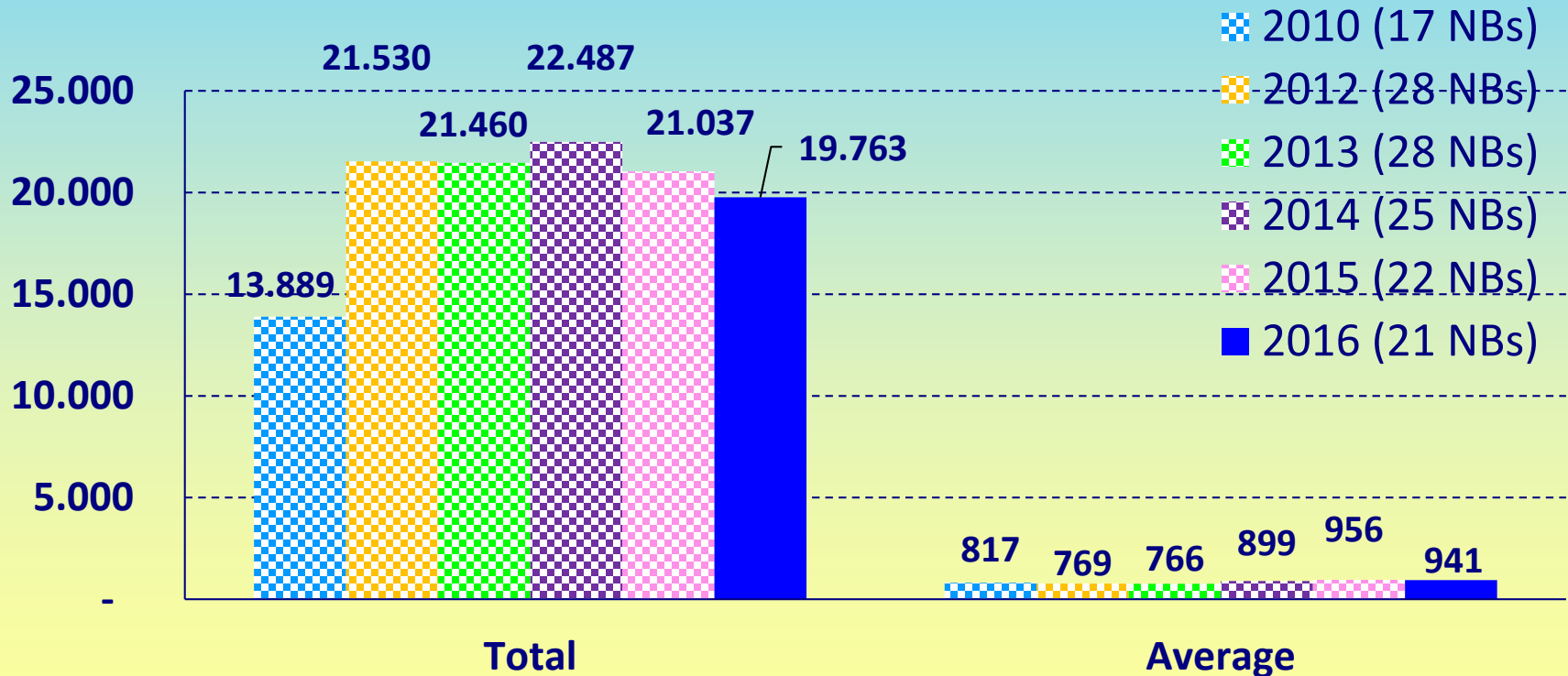
Medical Device Survey 2016

➤ Valid certificates issued end of 2016



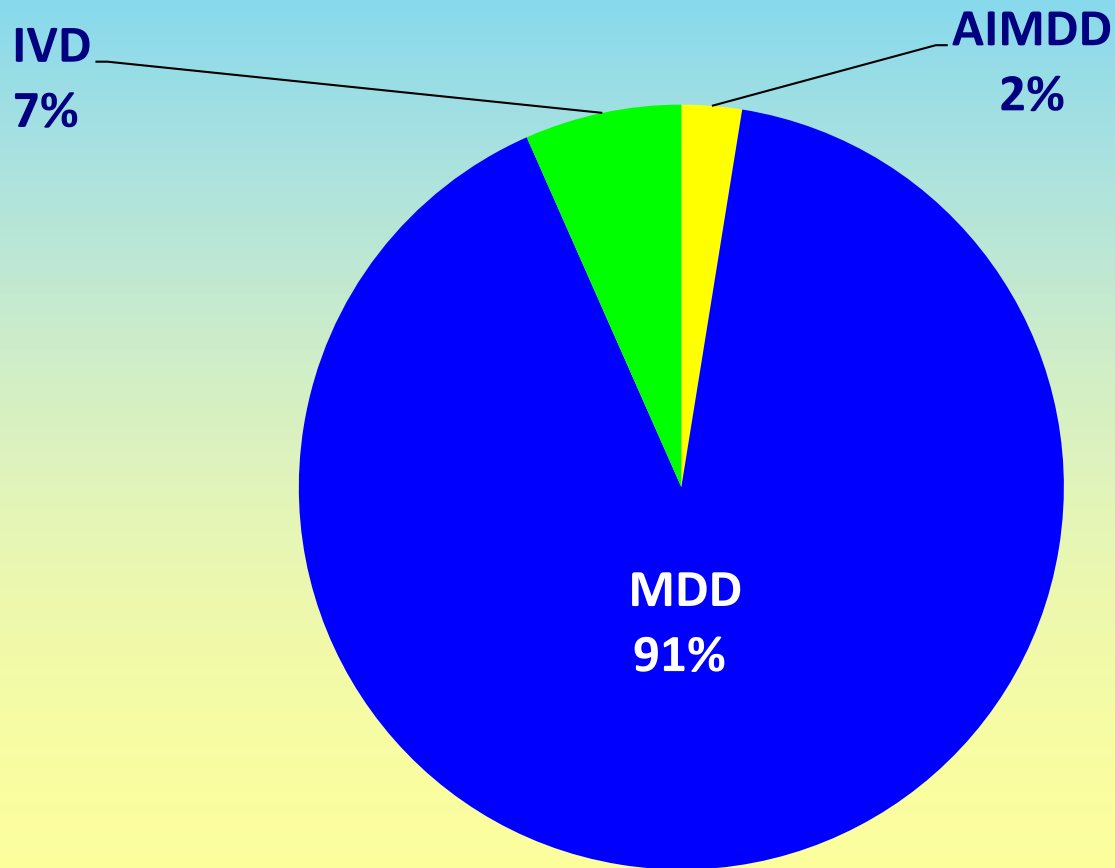
Medical Device Survey 2016

➤ Valid certificates issued 2010 – 12 – 13 – 14 – 15 - 16



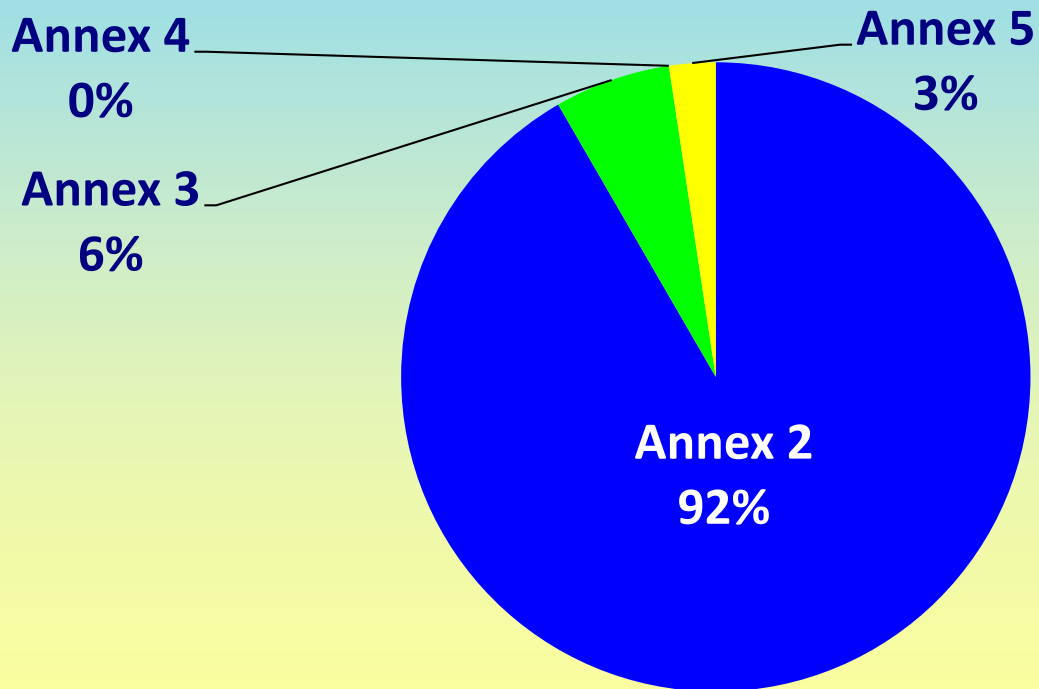
Medical Device Survey 2016

➤ Distribution between different directives



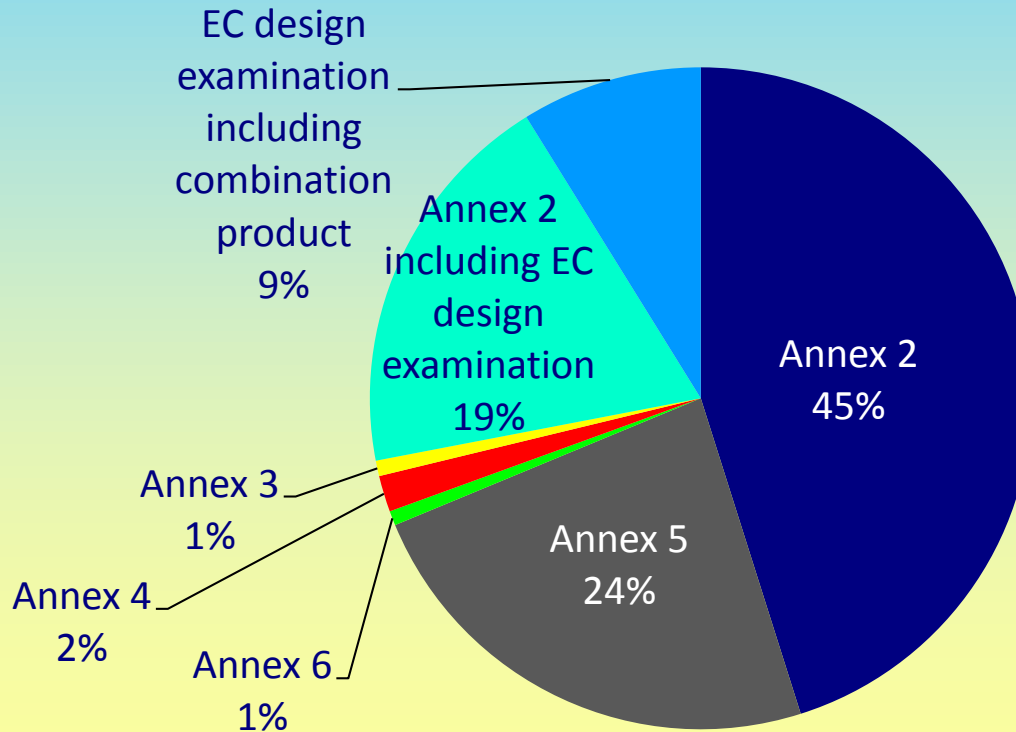
Medical Device Survey 2016

➤ Distribution between different conformity assessment modules under AIMDD



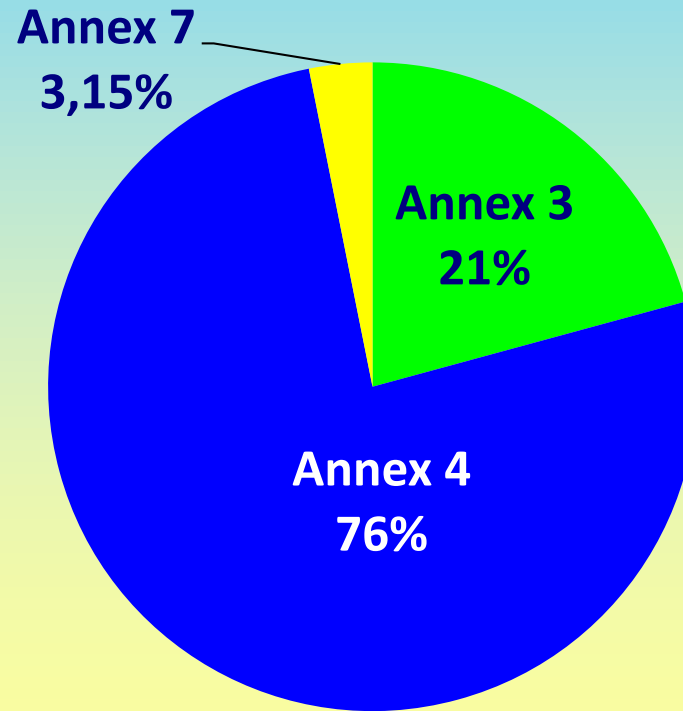
Medical Device Survey 2016

➤ Distribution between different conformity assessment modules under MDD



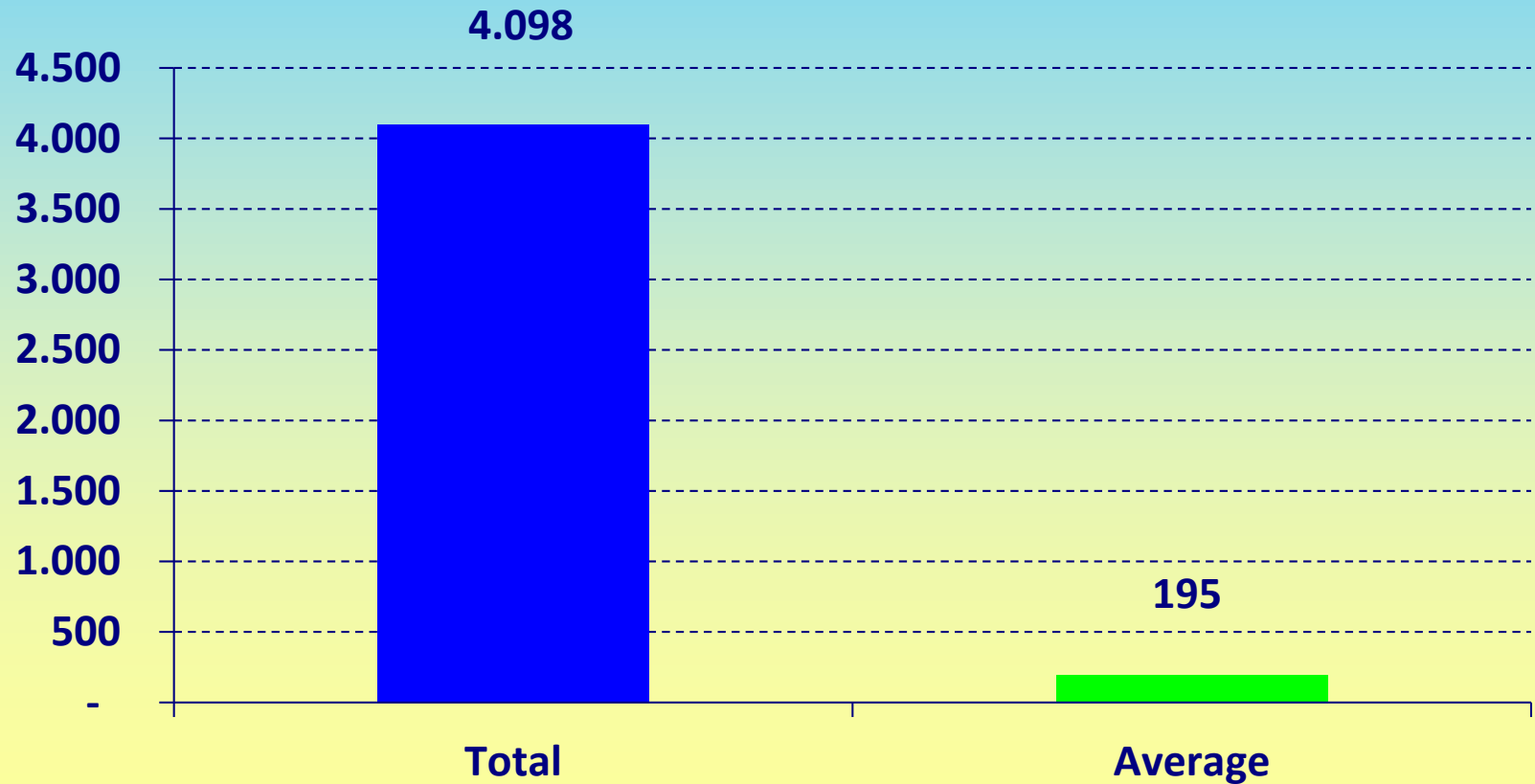
Medical Device Survey 2016

➤ Distribution between different conformity assessment modules under IVDD



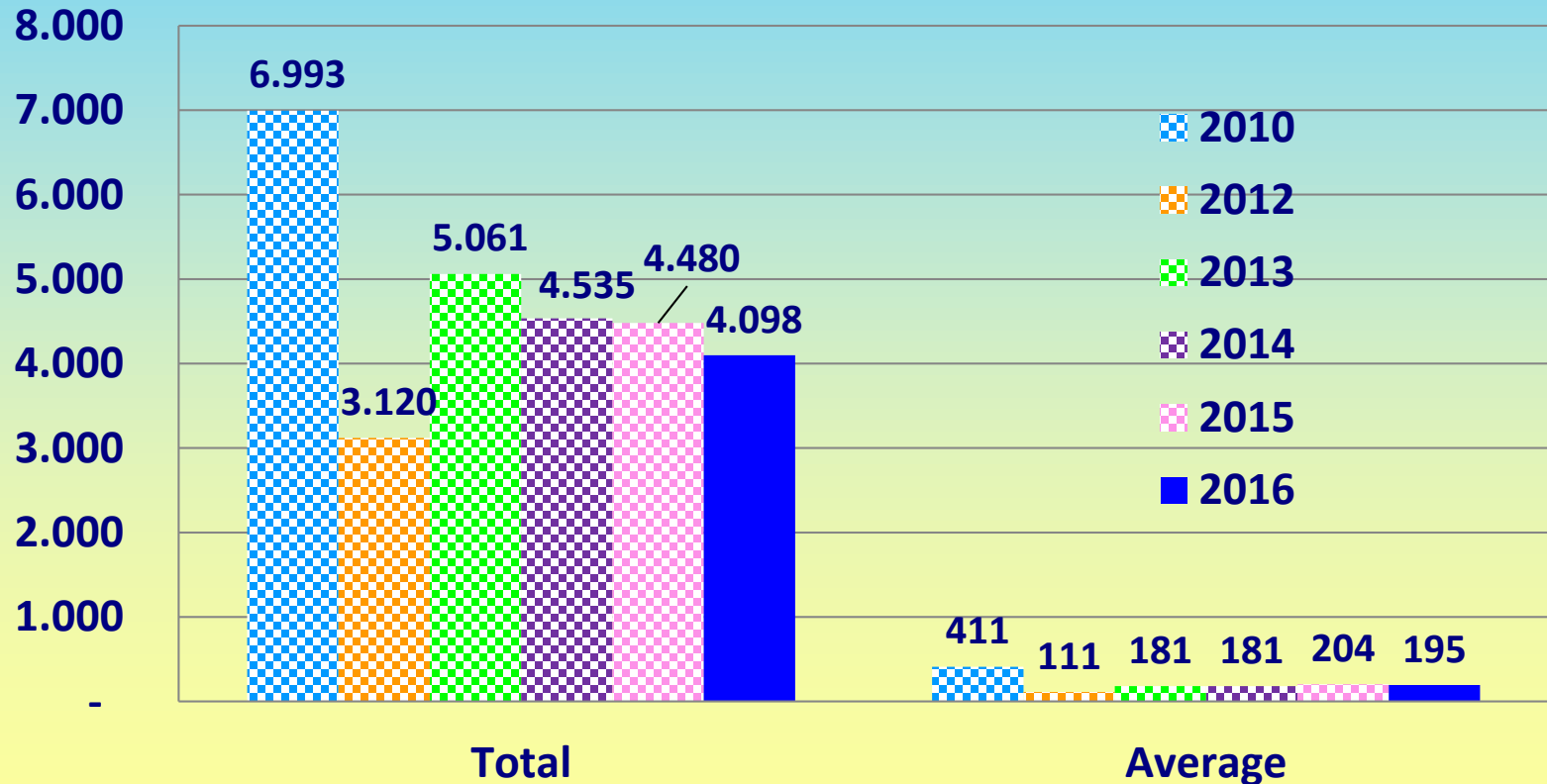
Medical Device Survey 2016

➤ New certificates issued in 2016



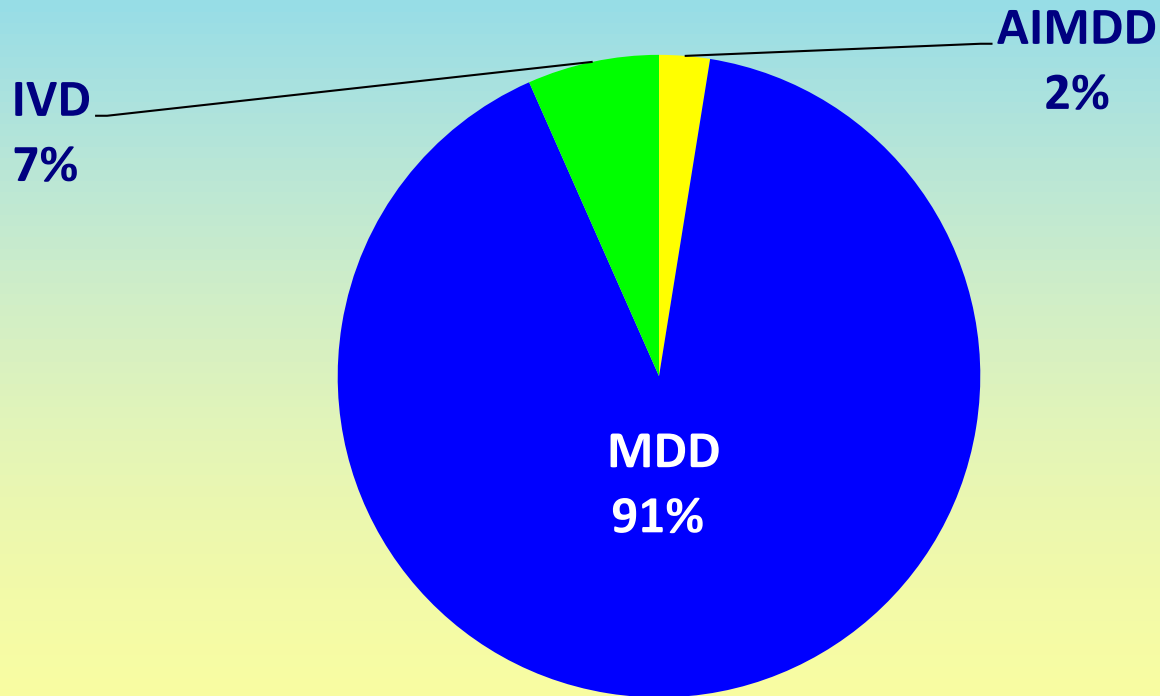
Medical Device Survey 2016

➤ New certificates issued 2010 – 12 – 13 – 14 – 15 - 16



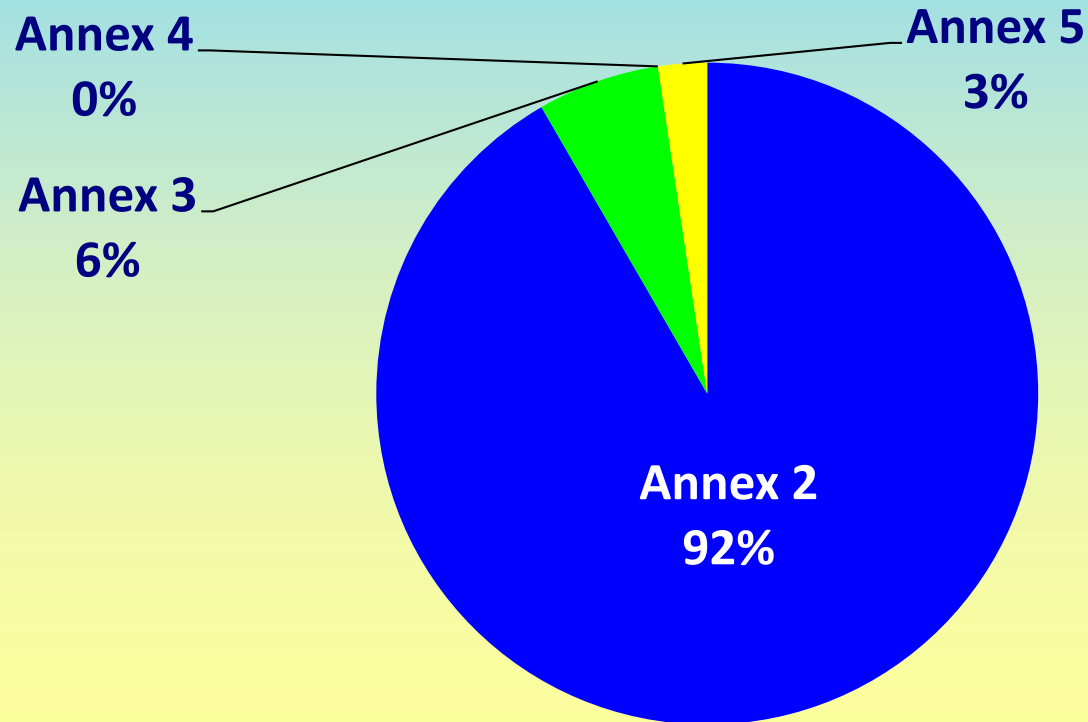
Medical Device Survey 2016

➤ Distribution between different directives in 2016



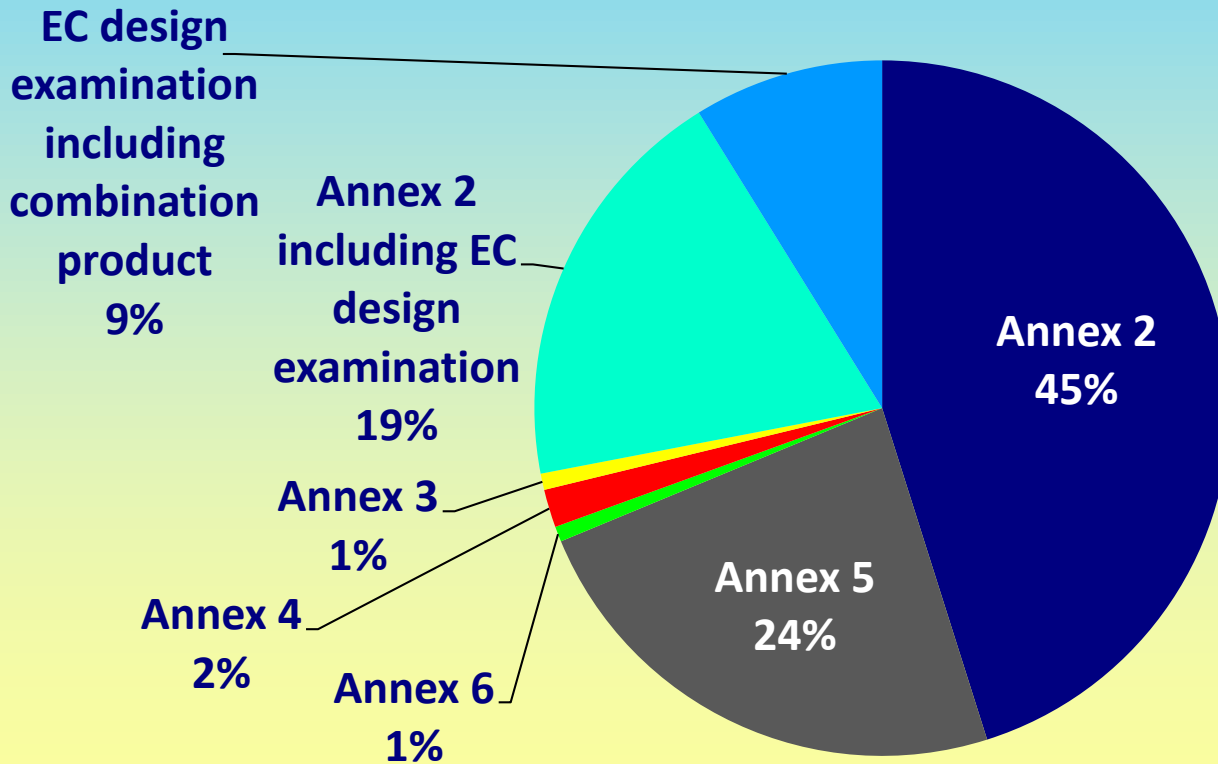
Medical Device Survey 2016

- **Distribution between different conformity assessment modules under AIMDD in 2016**



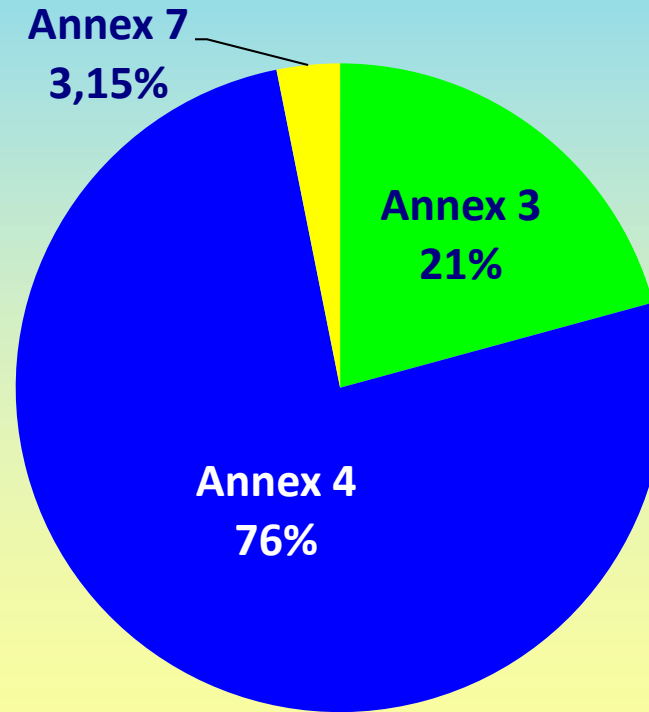
Medical Device Survey 2016

➤ Distribution between different conformity assessment modules under MDD in 2016



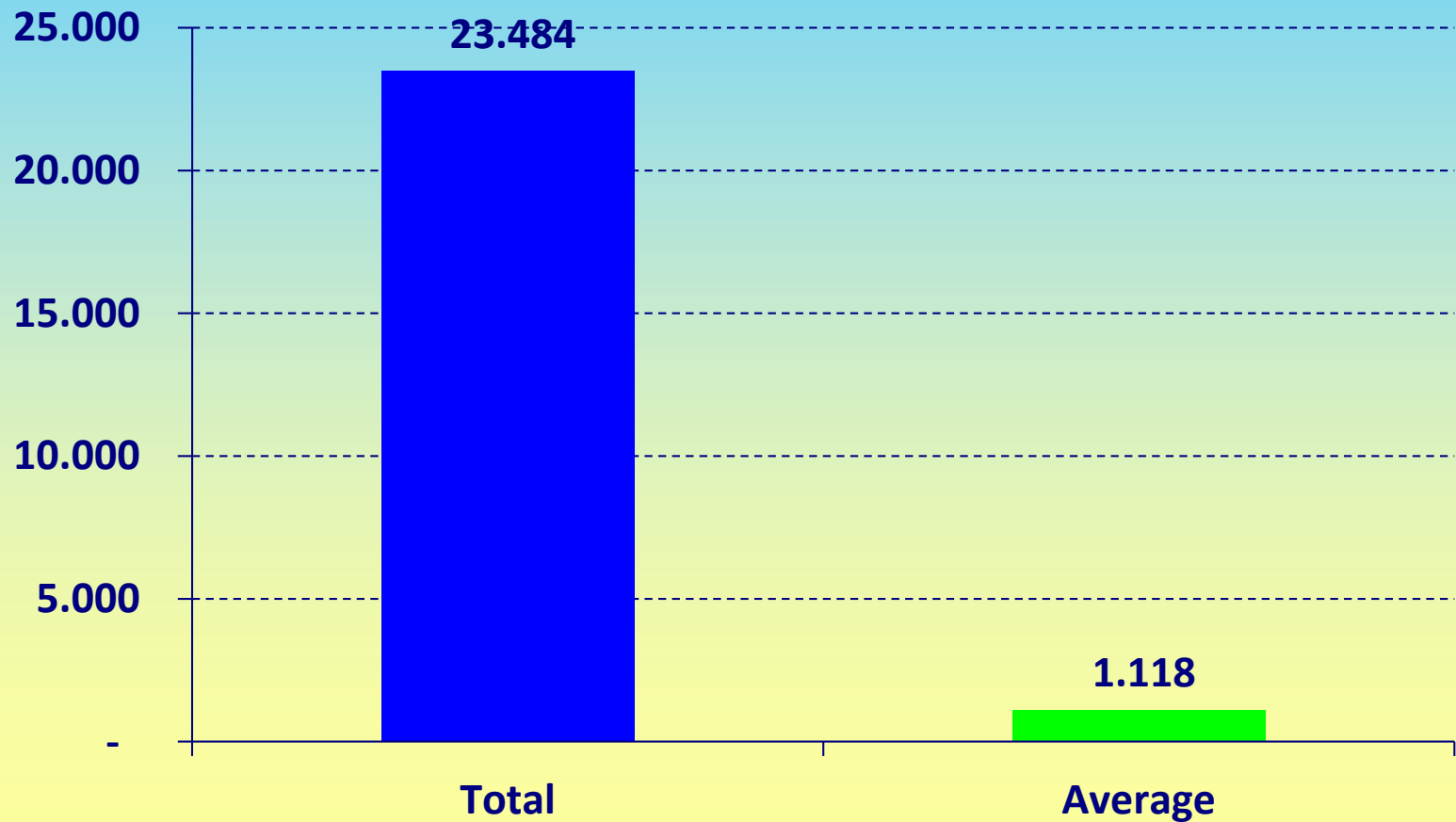
Medical Device Survey 2016

- **Distribution between different conformity assessment modules under IVDD in 2016**



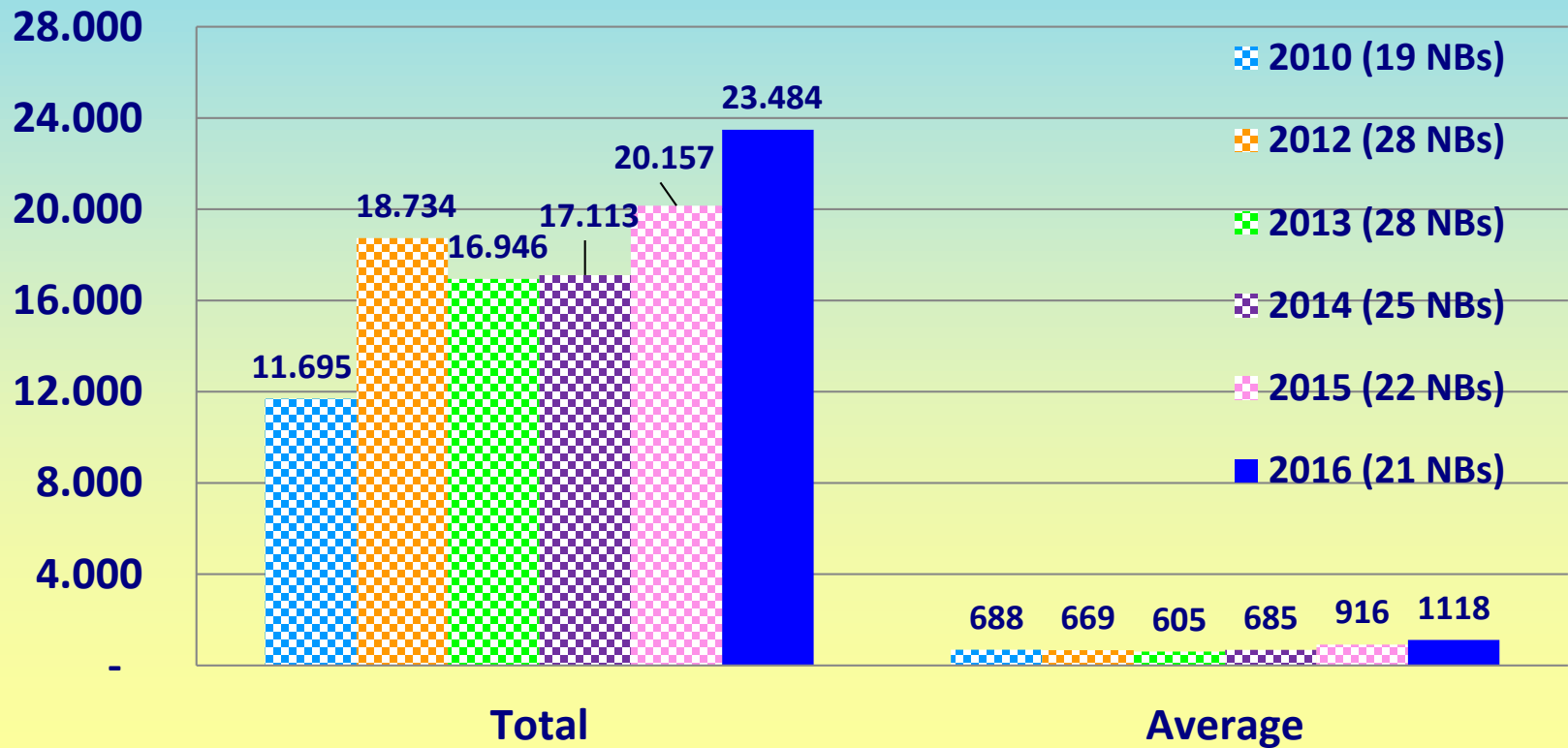
Medical Device Survey 2016

➤ Valid certificates against ISO 13485



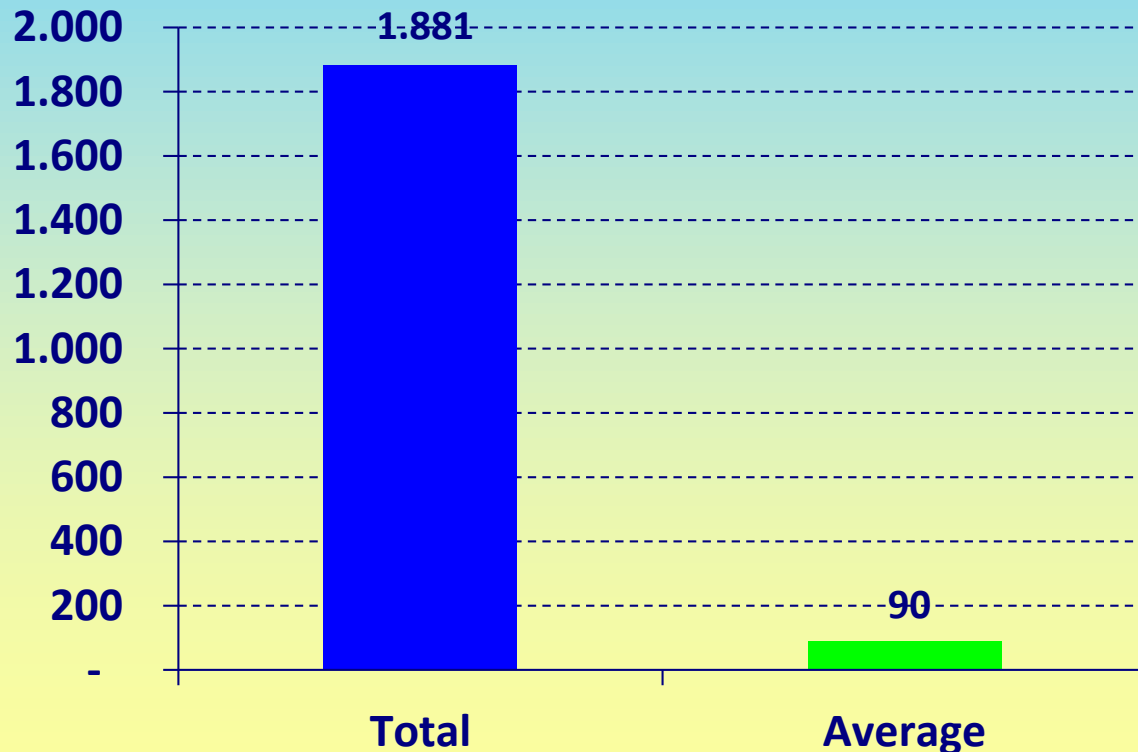
Medical Device Survey 2016

➤ Valid certificates against ISO 13485: 2010 – 12 – 13 – 14 – 15 – 16



Medical Device Survey 2016

➤ Number of certificates withdrawn in 2016

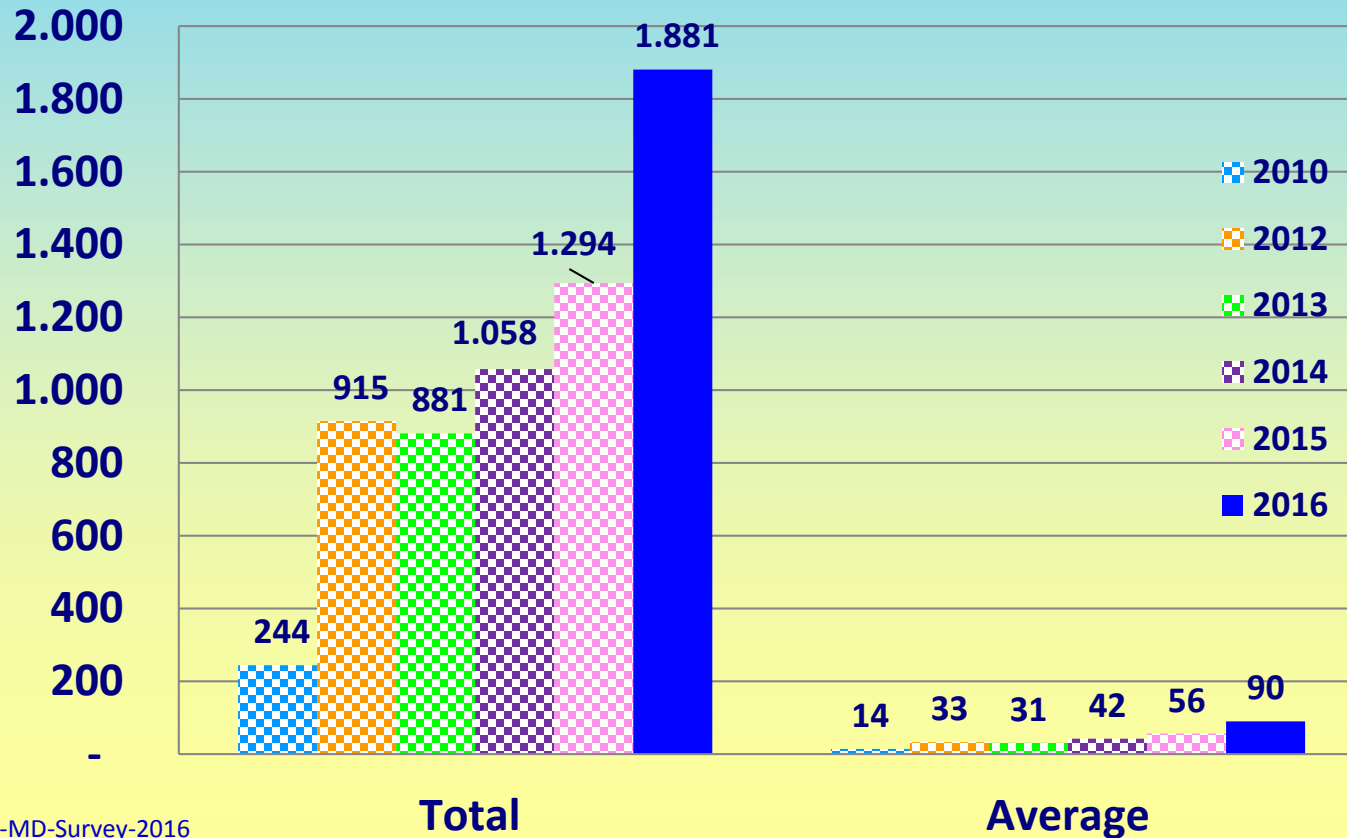


Reasons for withdrawing:

- OBL reduction,
- transferred NB,
- closure of location,
- company reorganisation,
- NB too expensive
- bankrupt,
- voluntary cancellation
- requirements not met / non-conformities not closed
- lack of payment

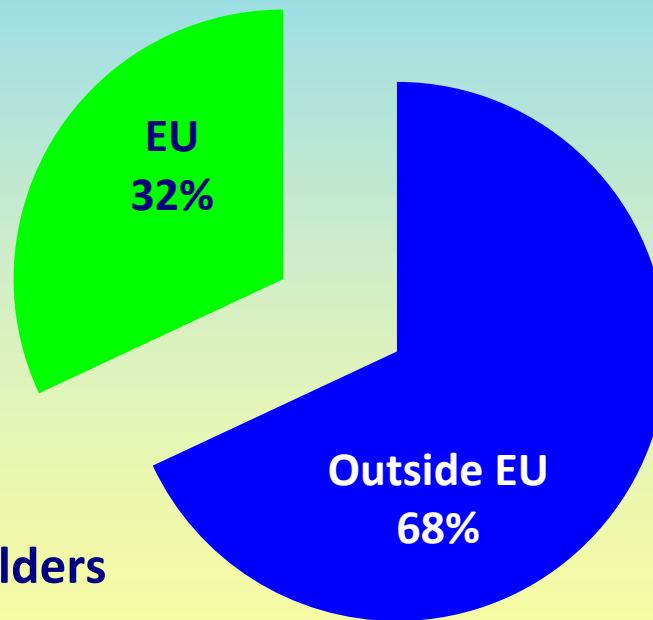
Medical Device Survey 2016

➤ Number of certificates withdrawn in 2010 – 12 – 13 – 14 – 15 – 16



Medical Device Survey 2016

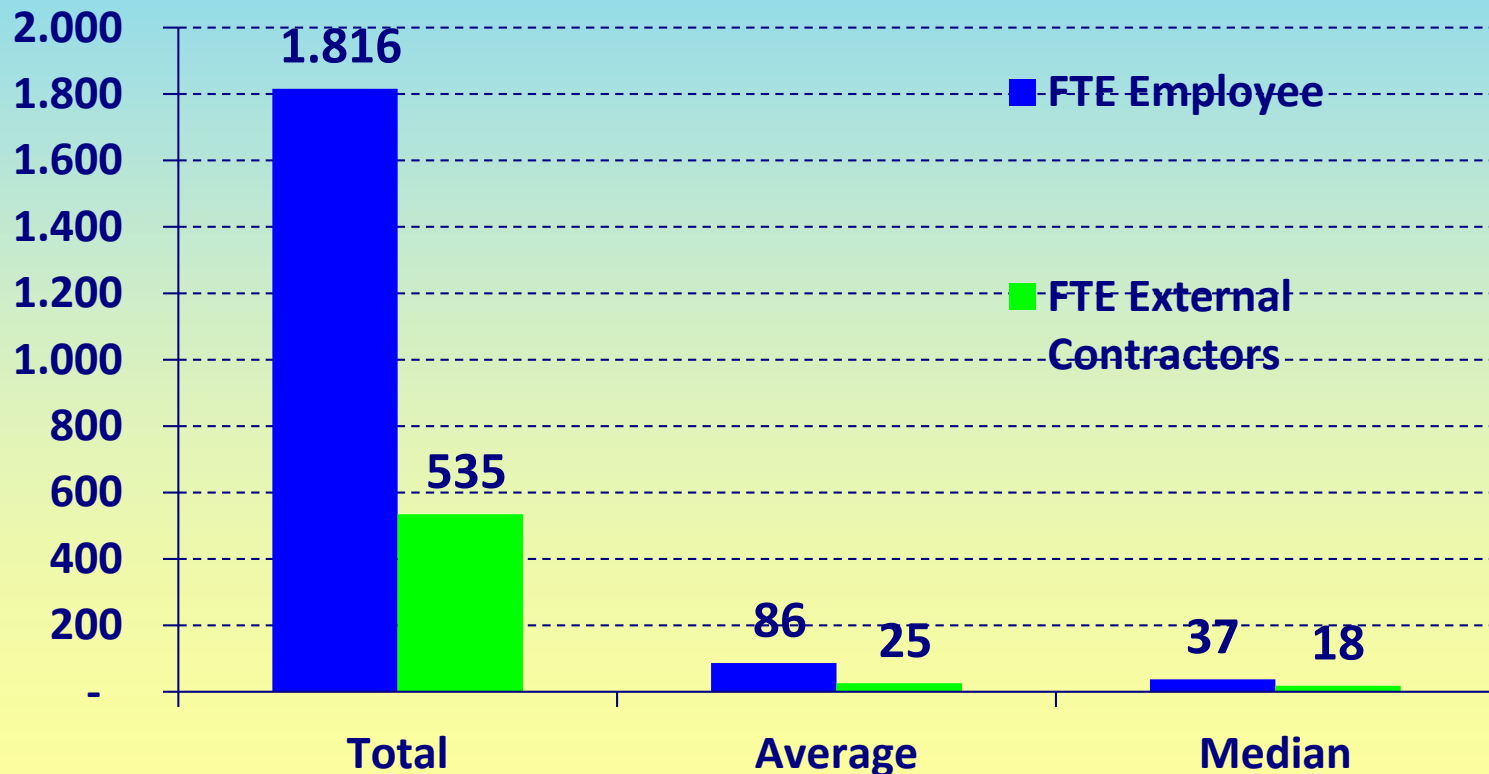
➤ Certification holders



**Total certification holders
estimated to
28248 / 21 NBs**

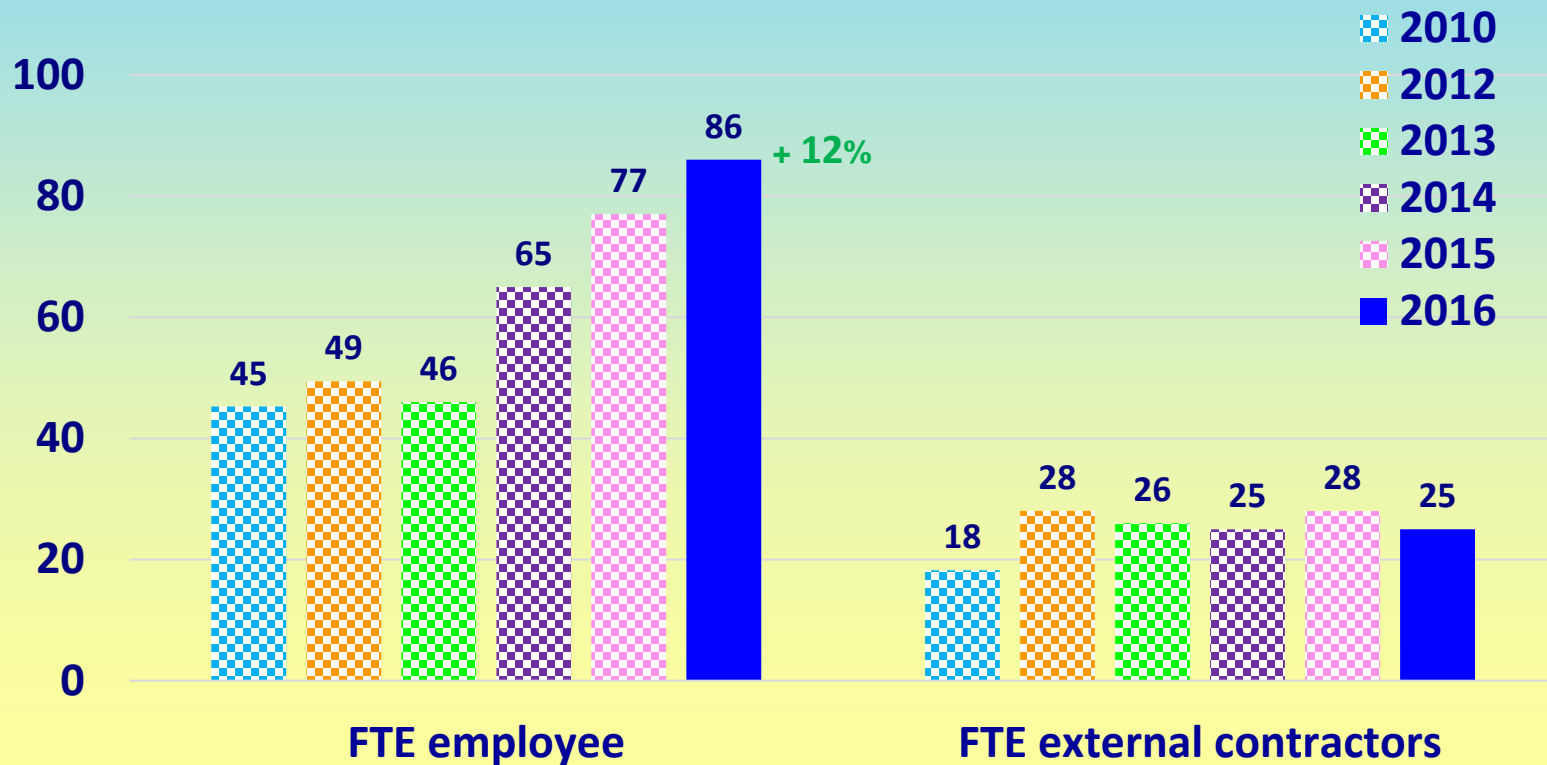
Medical Device Survey 2016

➤ Staff in 2016 (full time equivalent in MD sector)



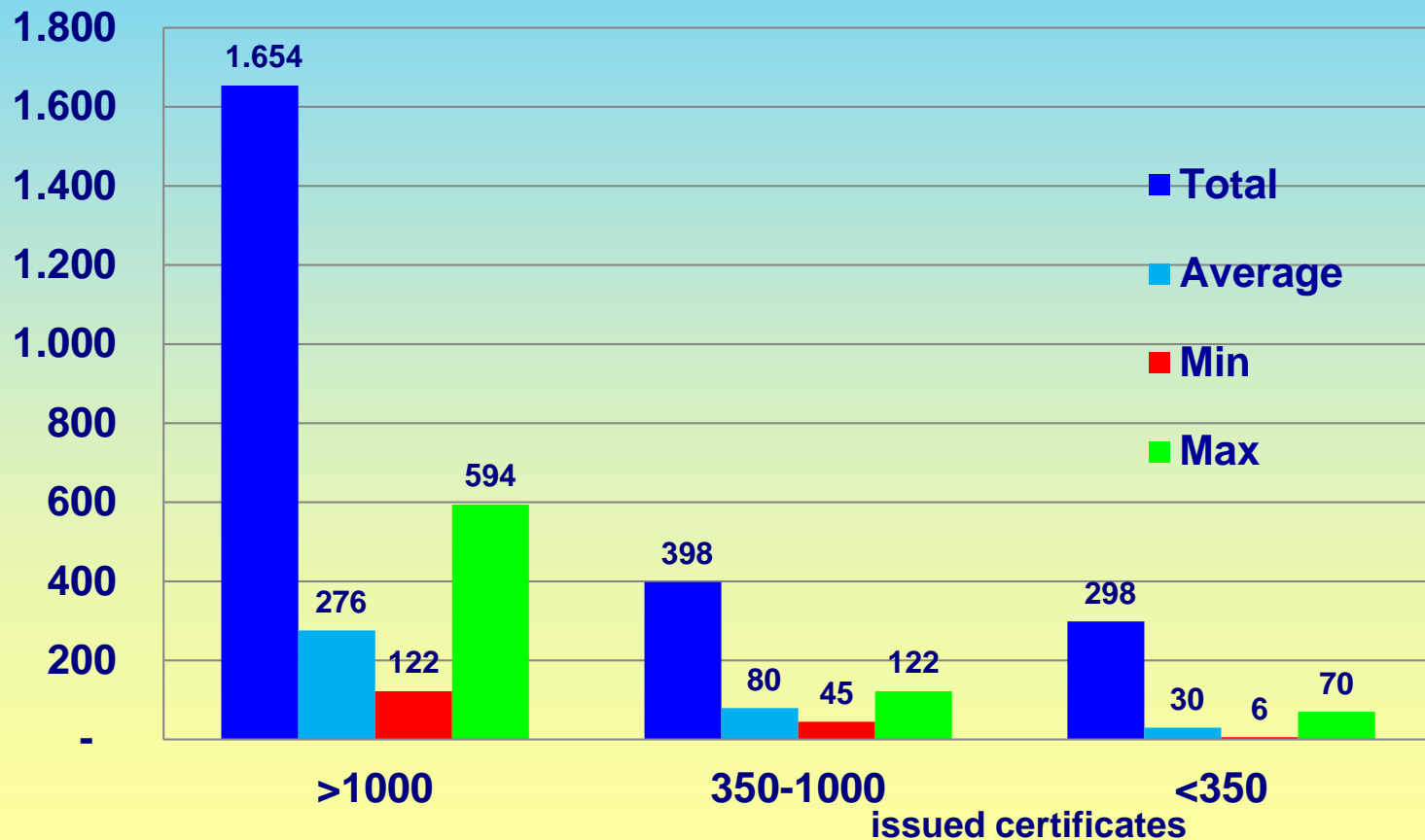
Medical Device Survey 2016

➤ Staff (Average Full Time Equivalent in MD sector): 2010 – 12 – 13 – 14 – 15 – 16



Medical Device Survey 2016

➤ Total personnel capacity in 2016 (by NBs size)



Members

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