



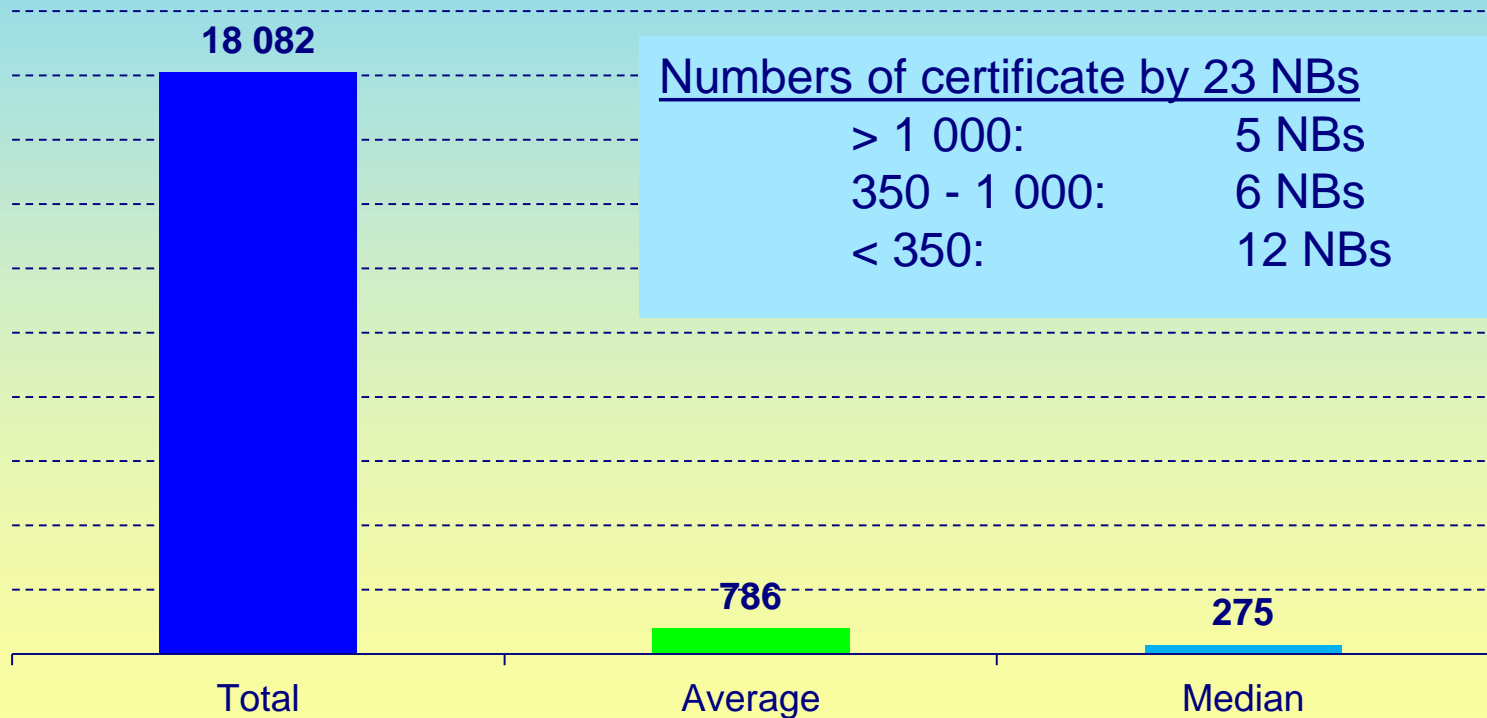
The European Association Medical devices  
Notified Bodies

## Medical Device Survey 2019

Data from all members (end 2019)

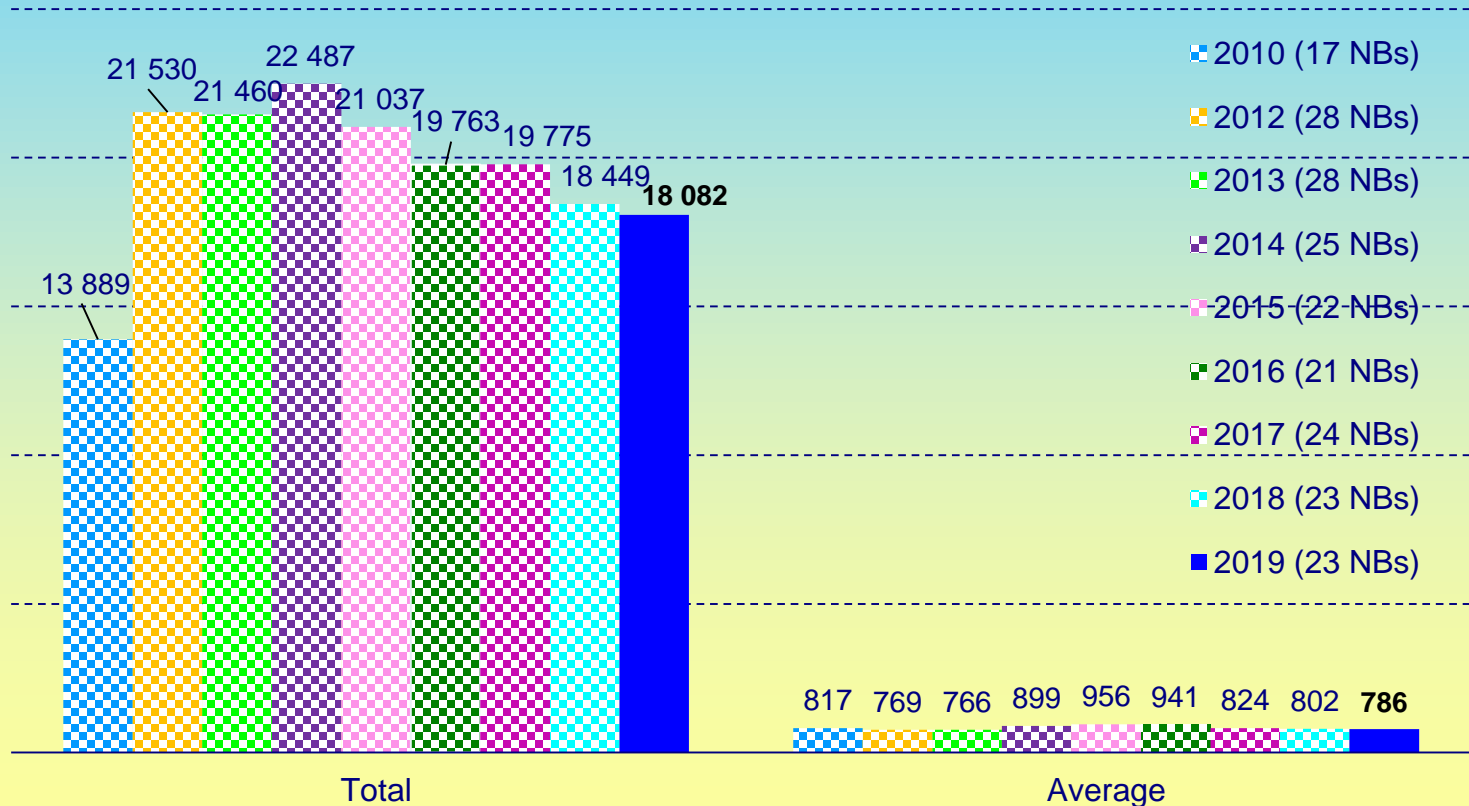
# Medical Device Survey 2019

## ➤ Valid certificates at end of 2019



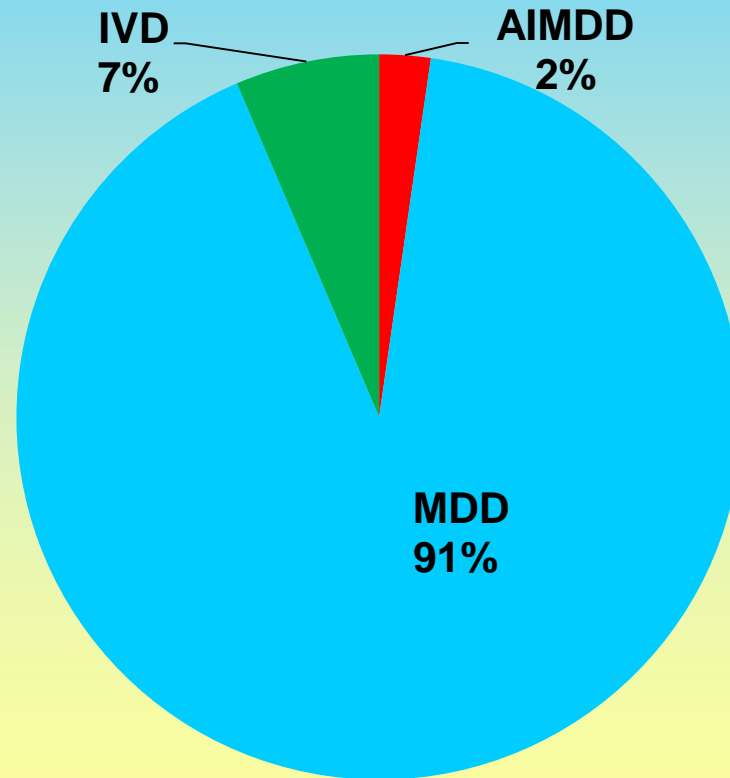
# Medical Device Survey 2019

## ➤ Valid CE certificates issued from 2010 to 2019



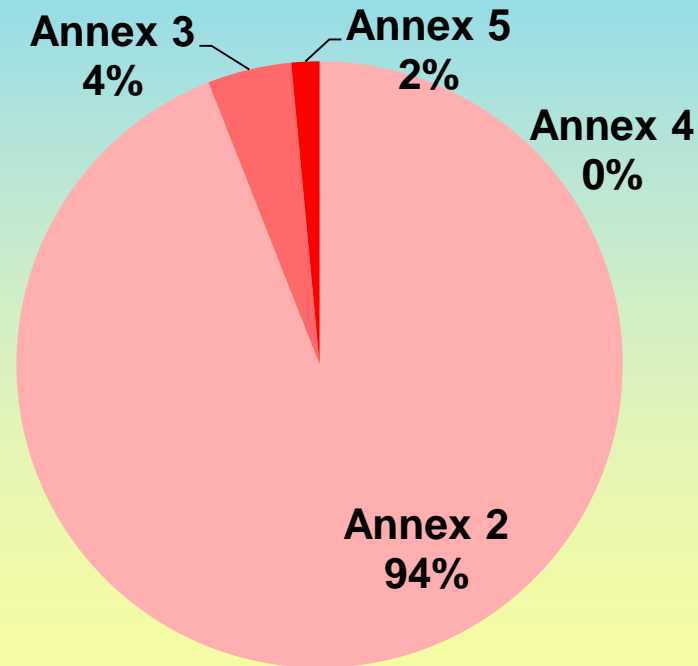
# Medical Device Survey 2019

## ➤ Distribution between different directives



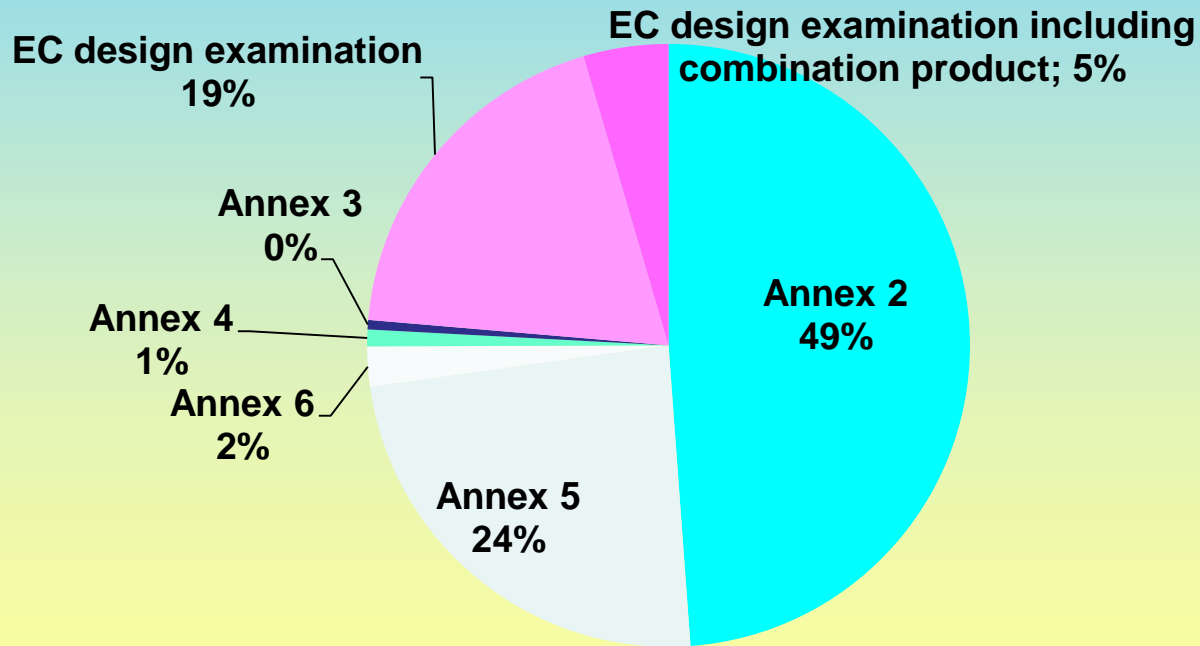
# Medical Device Survey 2019

## ➤ Distribution between different conformity assessment modules under AIMDD



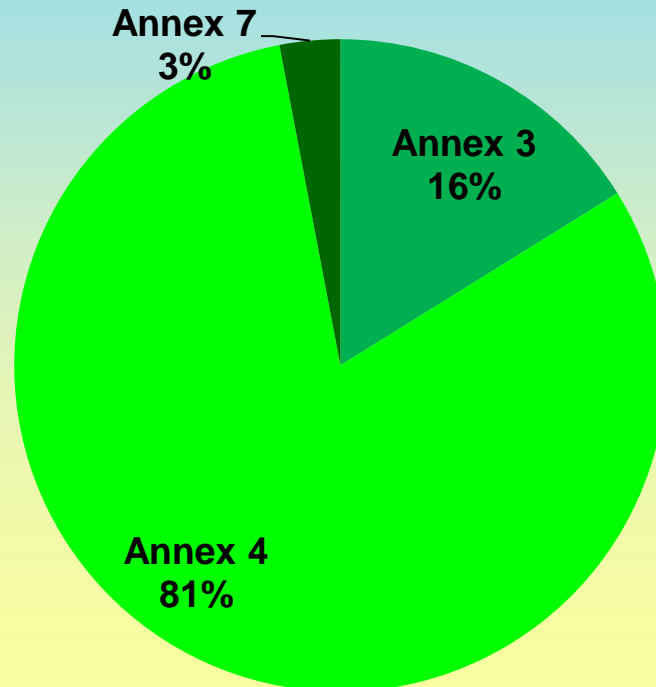
# Medical Device Survey 2019

## ➤ Distribution between different conformity assessment modules under MDD



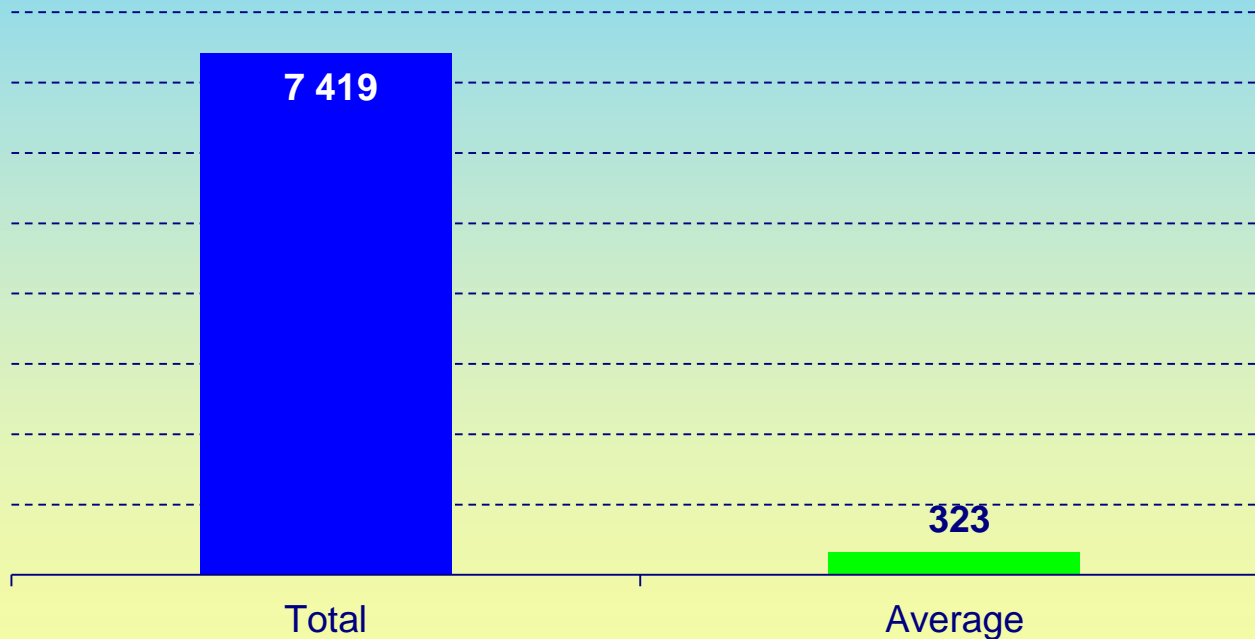
# Medical Device Survey 2019

➤ **Distribution between different conformity assessment modules under IVDD**



# Medical Device Survey 2019

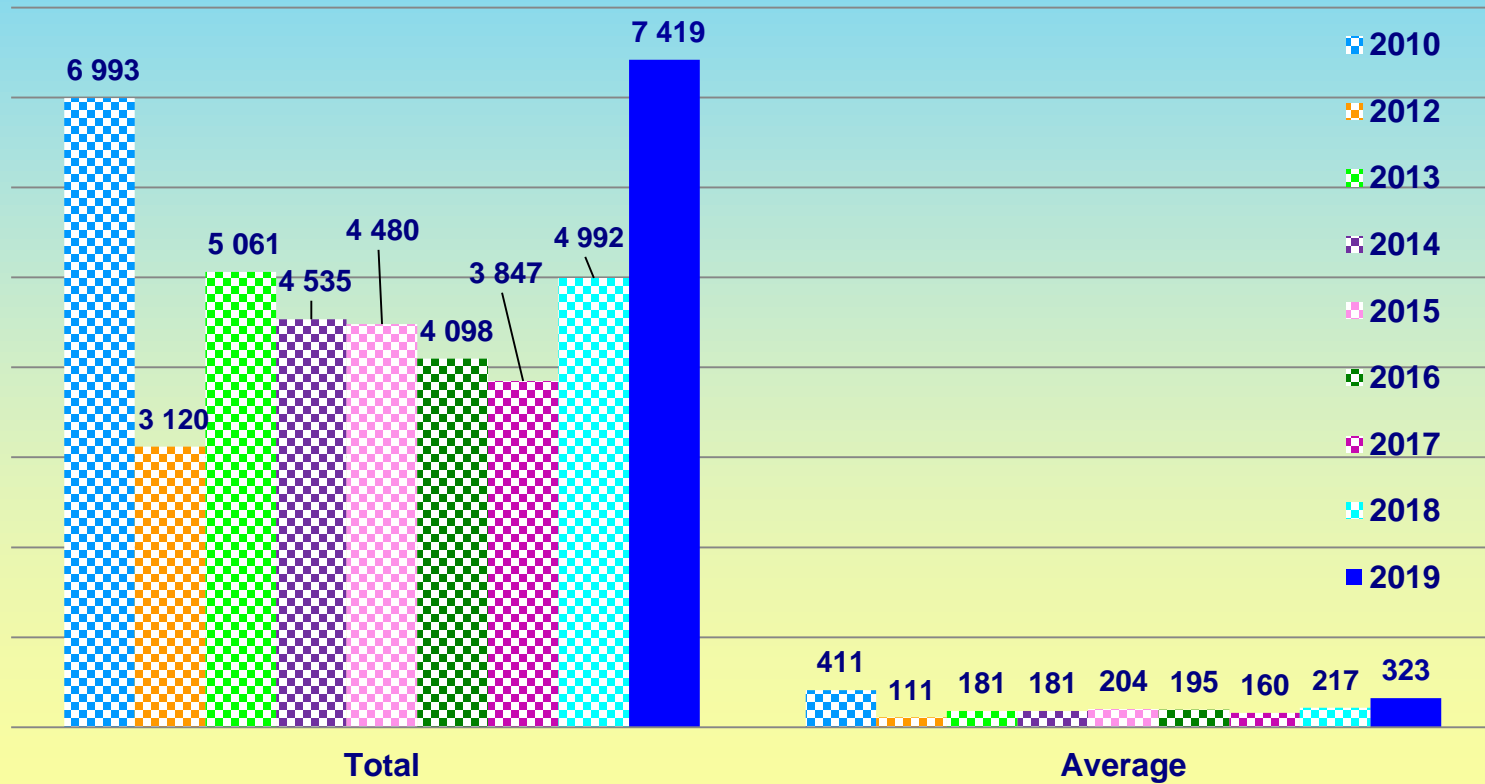
## ➤ New certificates issued in 2019





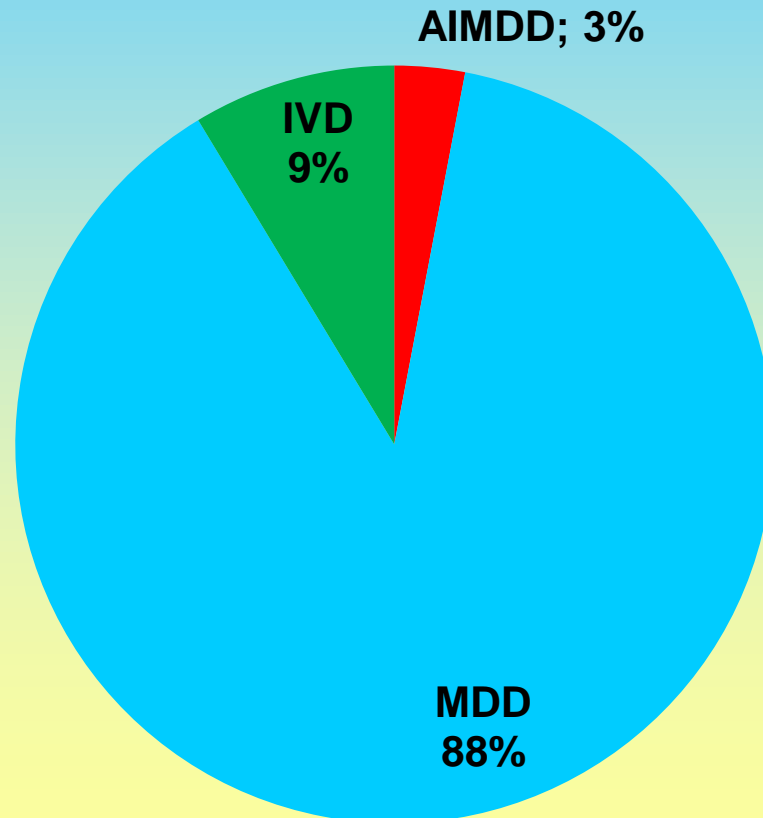
# Medical Device Survey 2019

## ➤ New CE certificates issued from 2010 to 2019



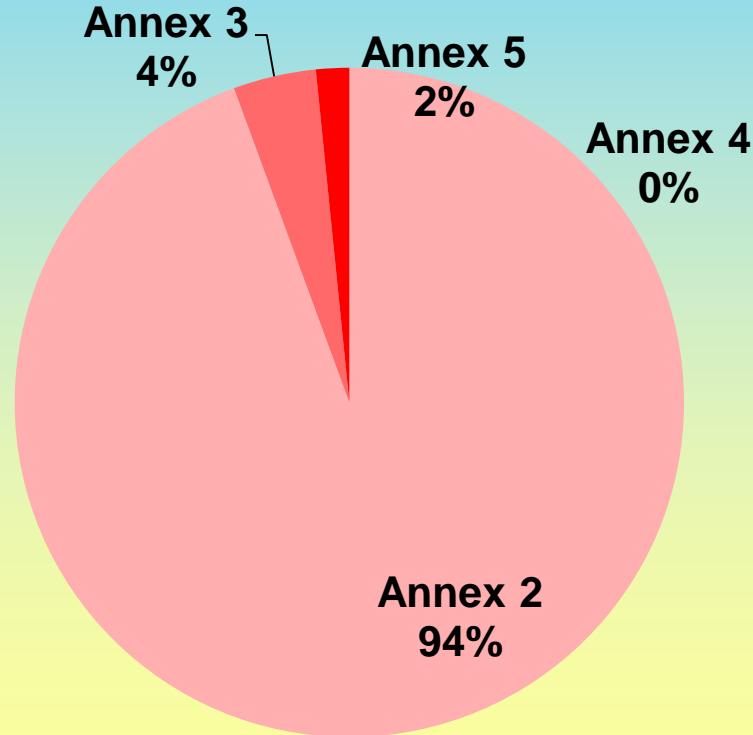
# Medical Device Survey 2019

## ➤ Distribution between different directives in 2019



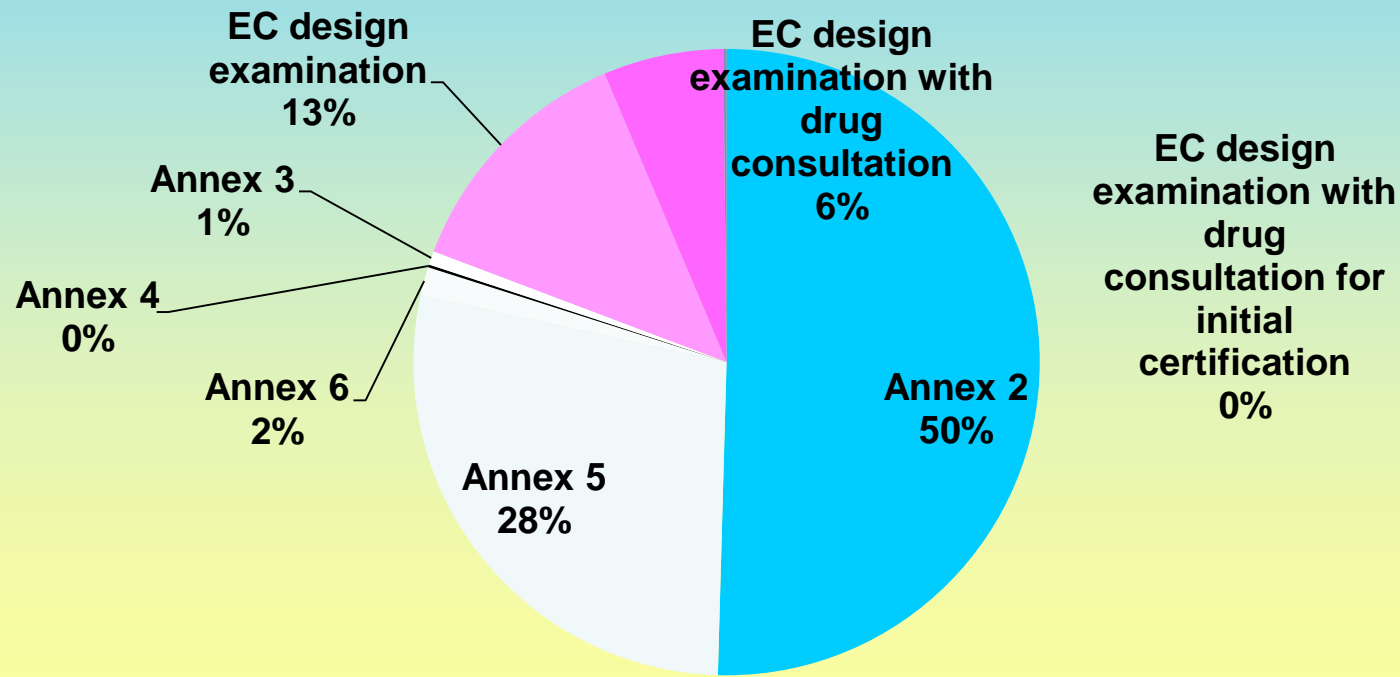
# Medical Device Survey 2019

- **Distribution between different conformity assessment modules under AIMDD in 2019**



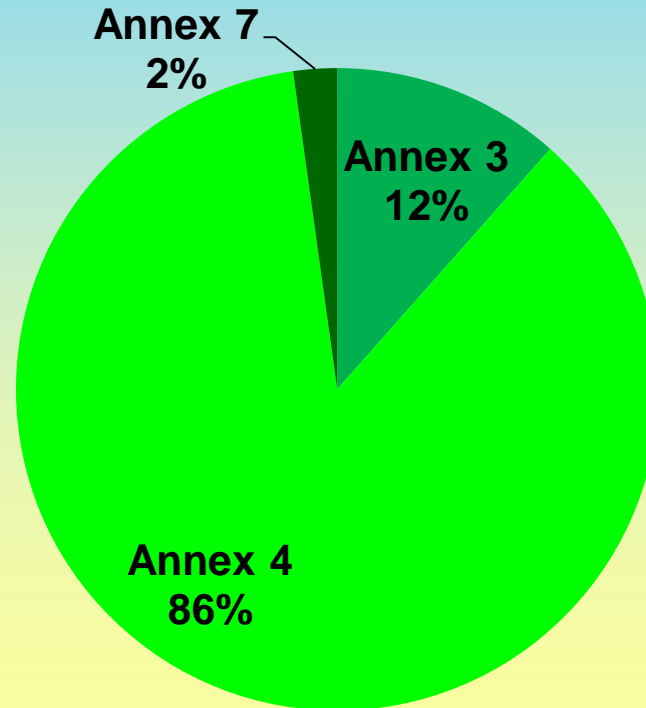
# Medical Device Survey 2019

## ➤ Distribution between different conformity assessment modules under MDD in 2019



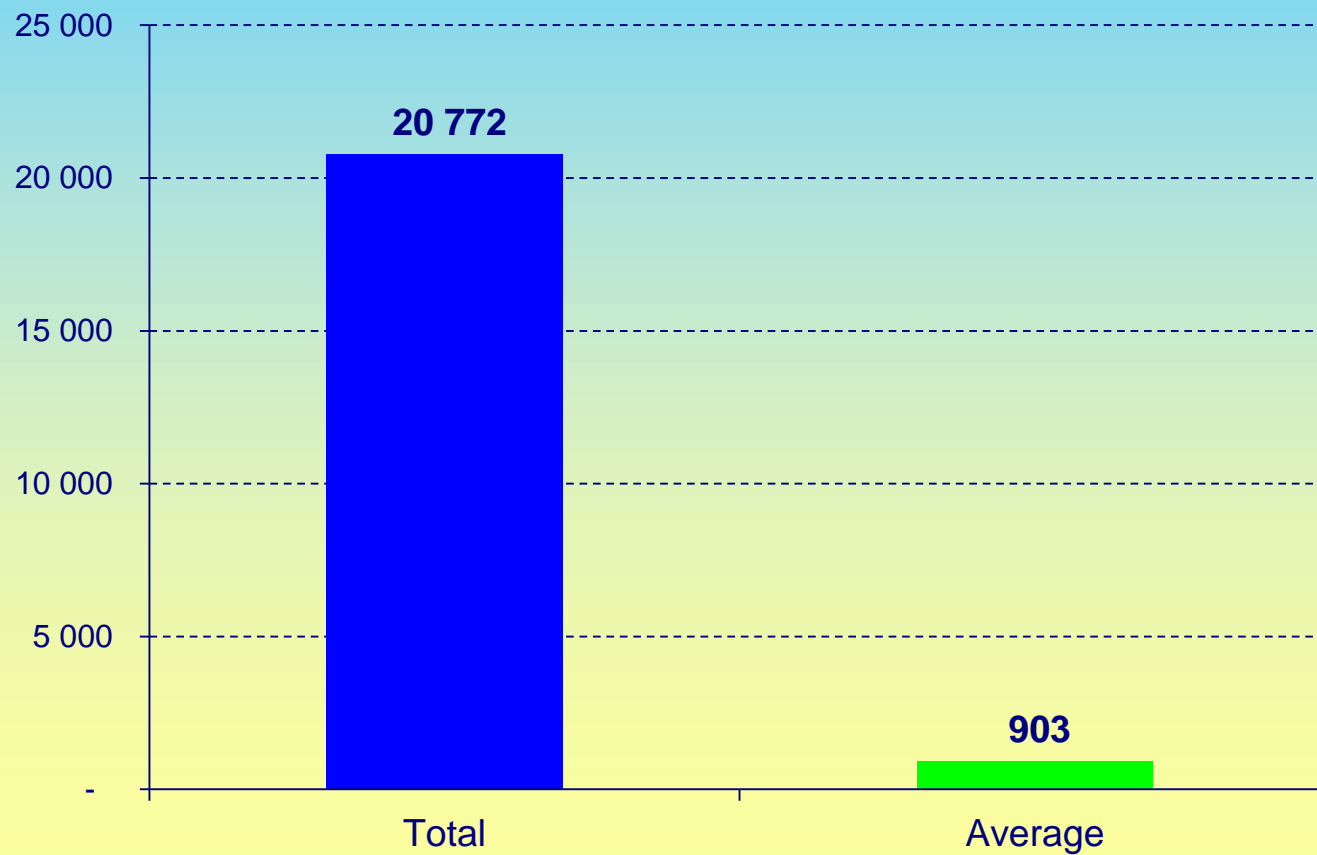
# Medical Device Survey 2019

- **Distribution between different conformity assessment modules under IVDD in 2019**



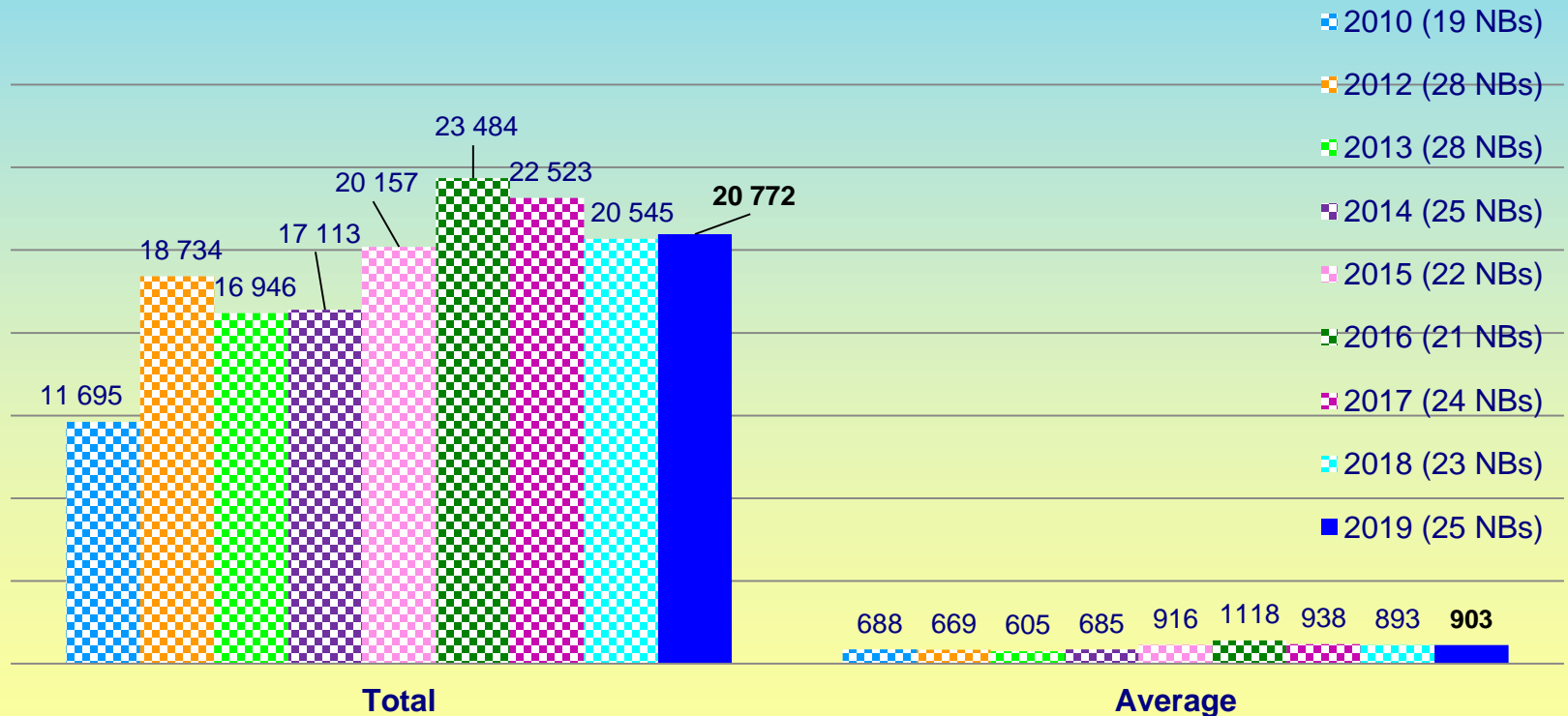
# Medical Device Survey 2019

## ➤ Valid certificates against ISO 13485



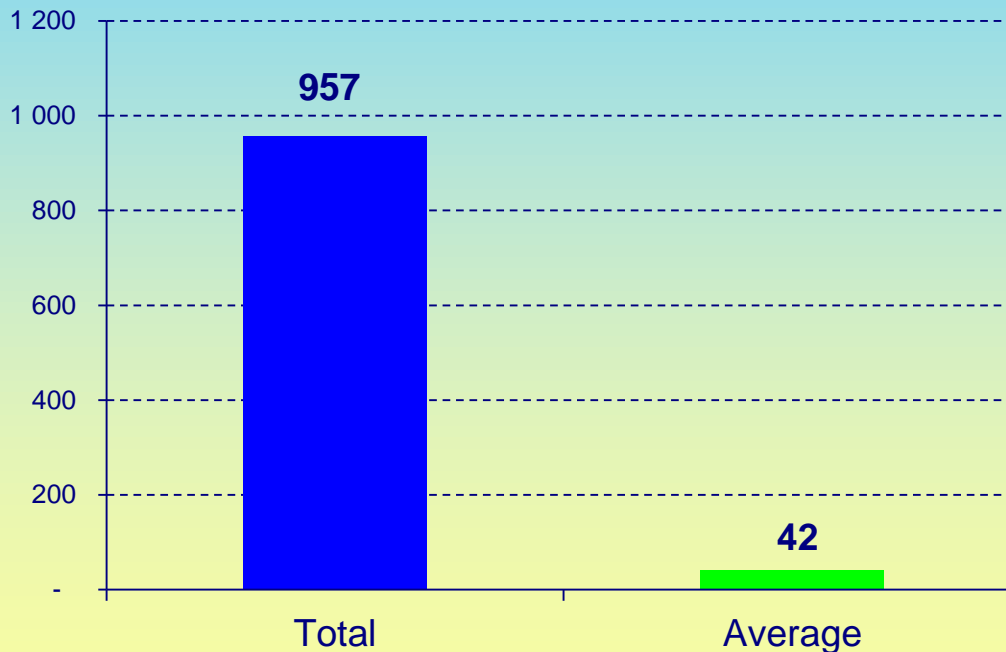
# Medical Device Survey 2019

## ➤ Valid certificates against ISO 13485 from 2010 to 2019 :



# Medical Device Survey 2019

## ➤ Number of certificates withdrawn in 2019



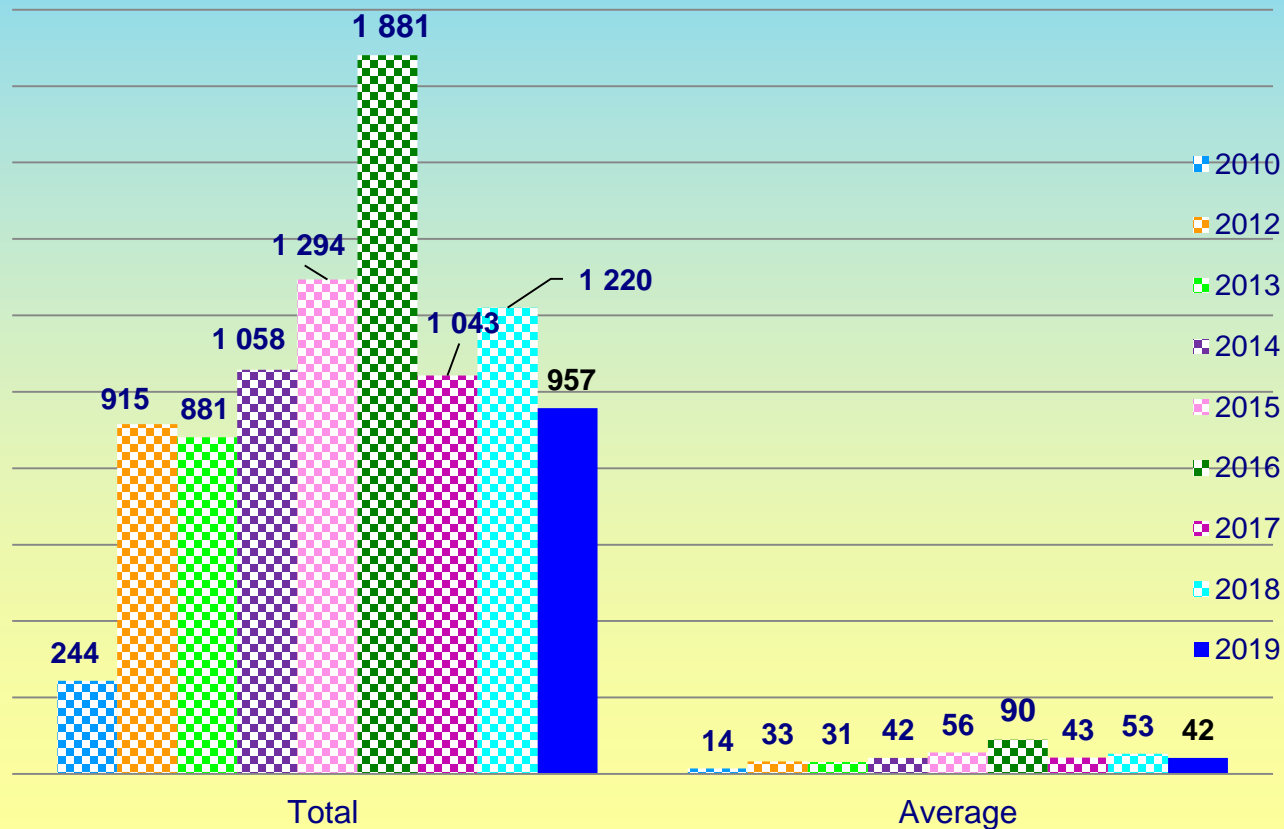
### Reasons for withdrawing:

- cessation of activity
- financial issues
- not closing the NCs / negative assessment result
- Customer refuses audit or contact not possible
- Transfer / no longer manufacturing product
- merges and acquisitions
- Liquidations
- change of NB – BREXIT
- NB too expensive
- Scheme restructure
- Enforced cancellation



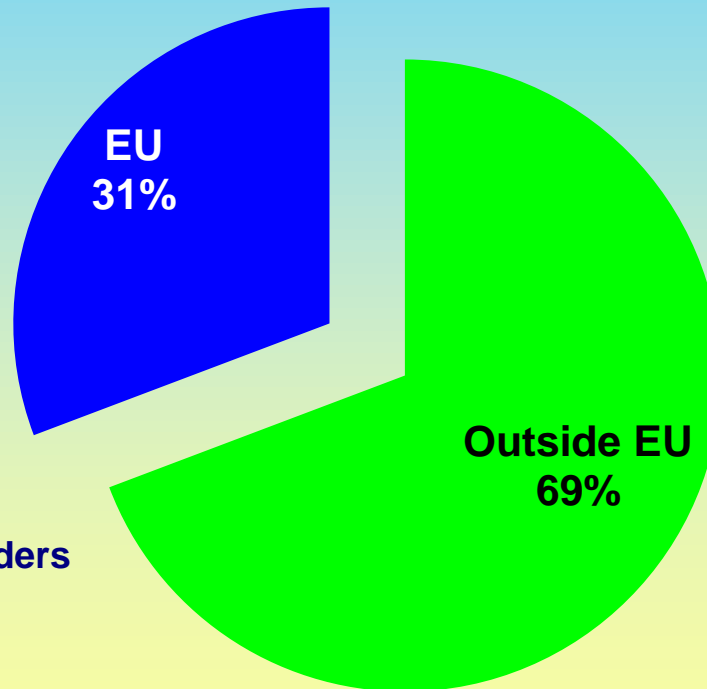
# Medical Device Survey 2018

## ➤ Number of certificates withdrawn from 2010 to 2019



# Medical Device Survey 2019

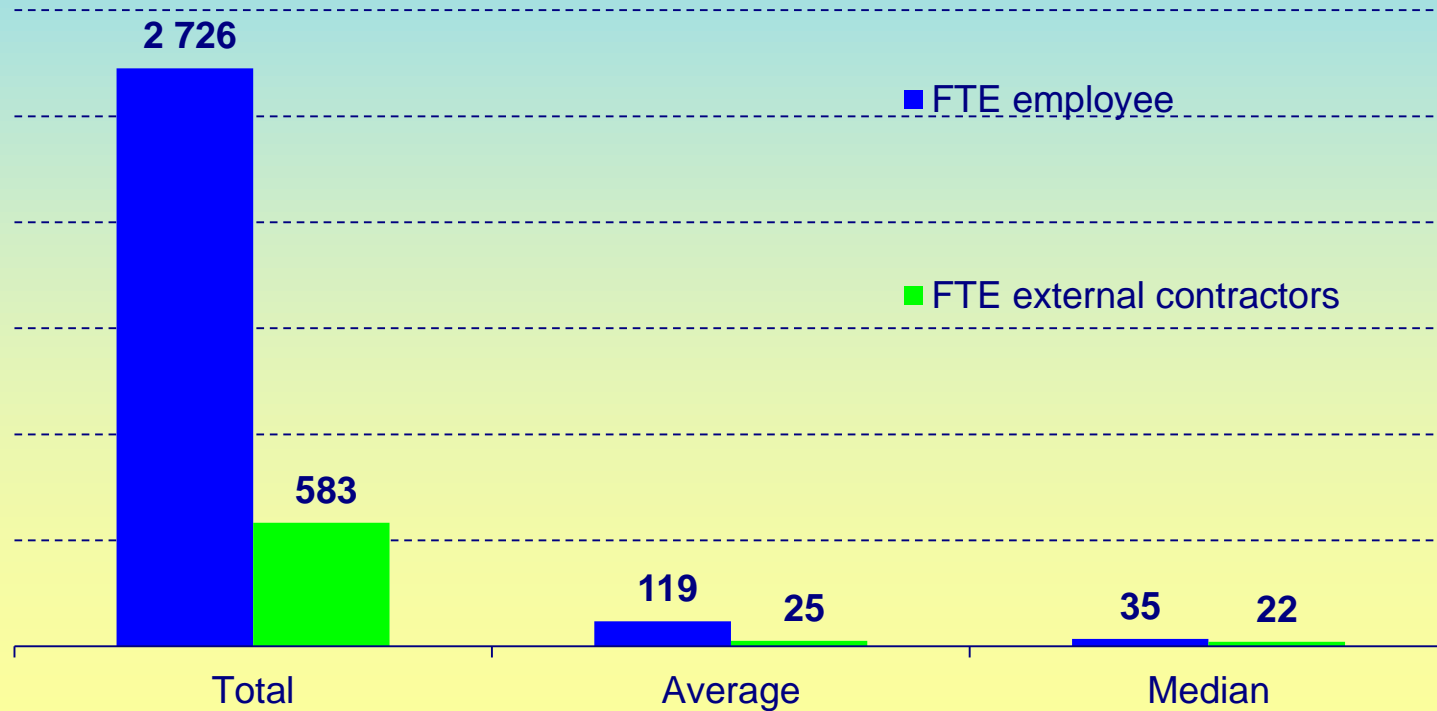
## ➤ Certification holders



Total certification holders  
estimated to  
18 082 / 23 NBs

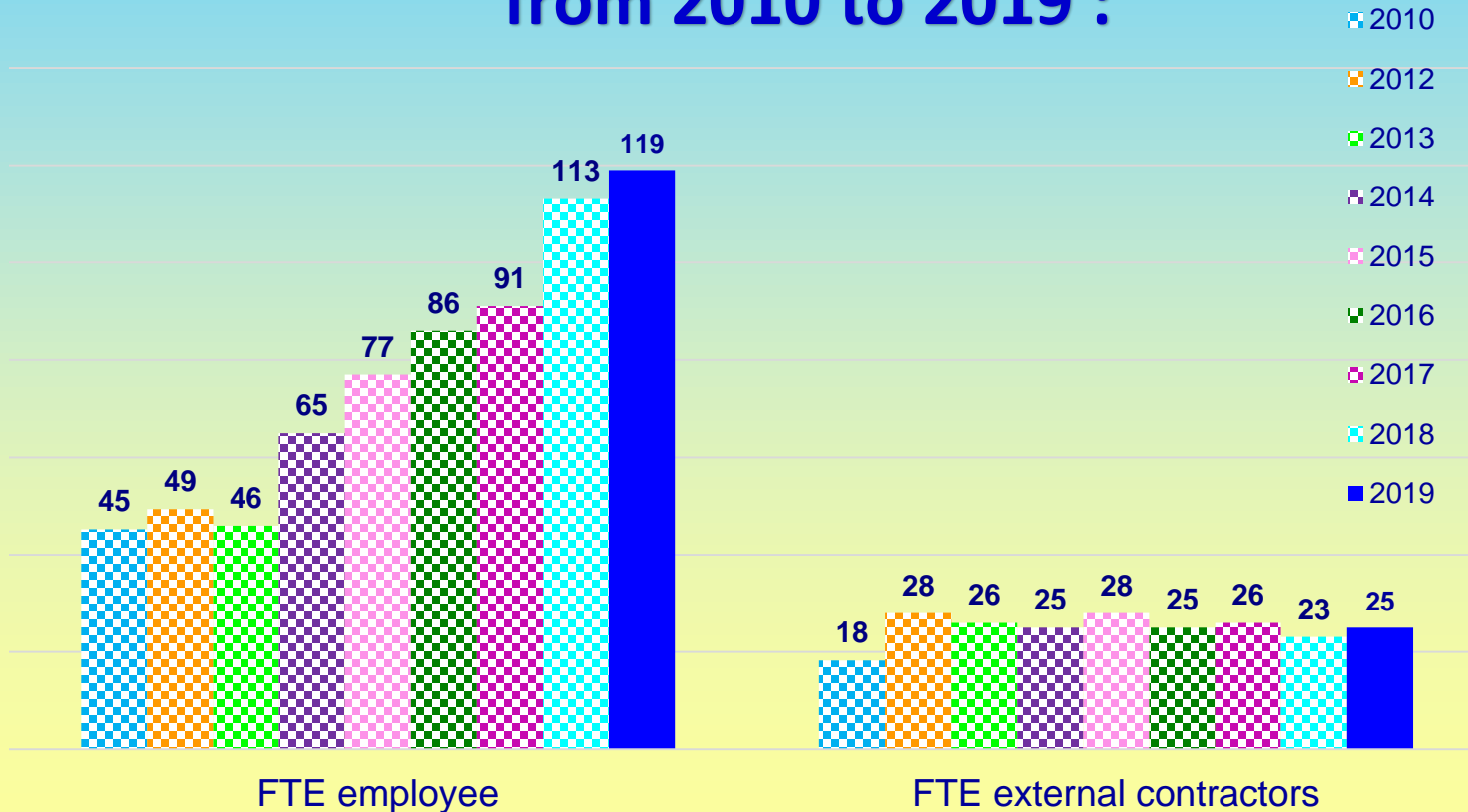
# Medical Device Survey 2019

## ➤ Staff in 2019 (full time equivalent in MD sector)



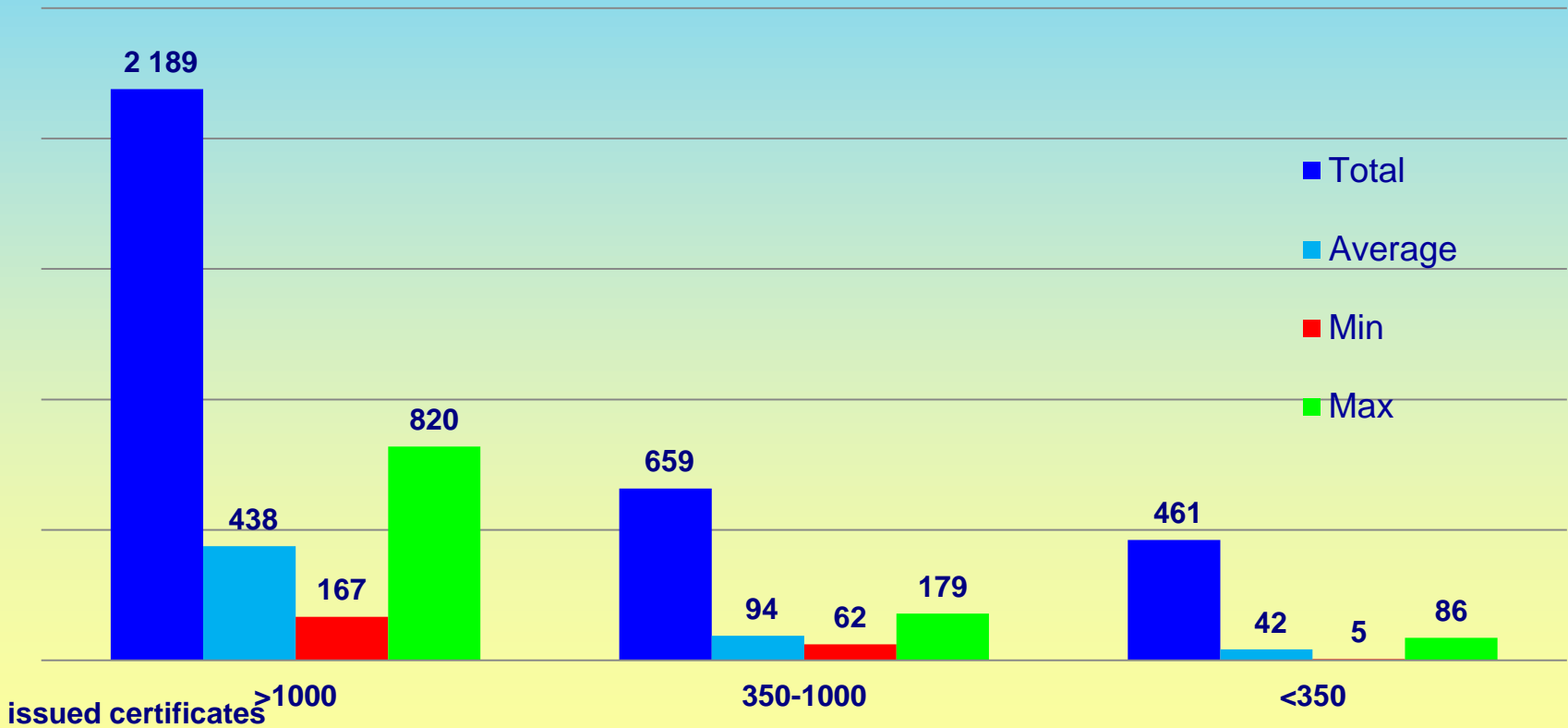
# Medical Device Survey 2019

## ➤ Staff (Average Full Time Equivalent in MD sector): from 2010 to 2019 :



# Medical Device Survey 2019

## ➤ Total personnel capacity in 2019 (by NBs size)



# Members



...making excellence a habit.™

DARE!!



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NATIONAL EVALUATION CENTER OF QUALITY & TECHNOLOGY IN HEALTH S.A.



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