



The European Association of Medical devices  
Notified Bodies

# Medical Device Survey 2025

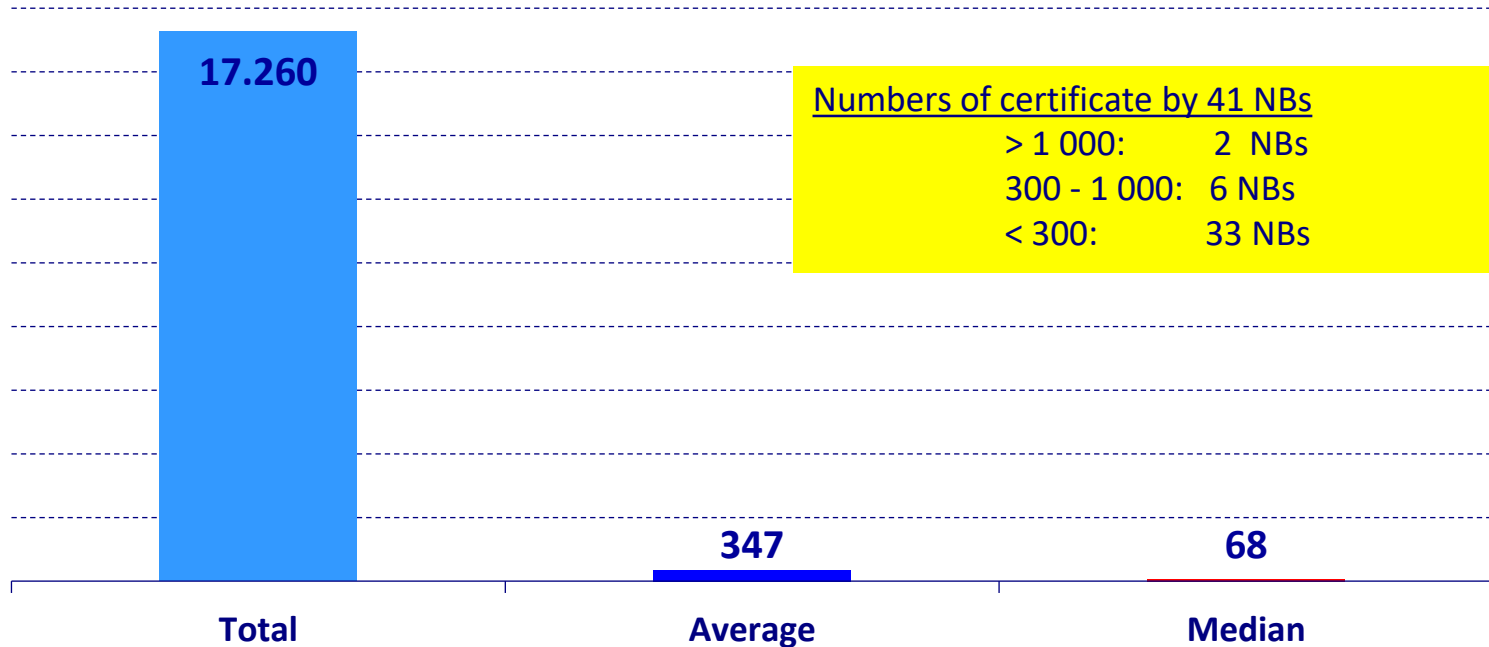
## Data from all 41 designated members

# Medical Device Survey 2025



## ❖ Regulations certificates issued end of 2025

Regulations certificates issued end of 2025



# Medical Device Survey 2025



## ❖ MDR applications and certificates (QMS + Product)

For information,

number of designated members of Team-NB compared to the total number of designated notified bodies:

2020: 16 members / 18 designated NBs

2021: 21 members / 25 designated NBs

2022: 25 members / 36 designated NBs

2023: 32 members / 42 designated NBs

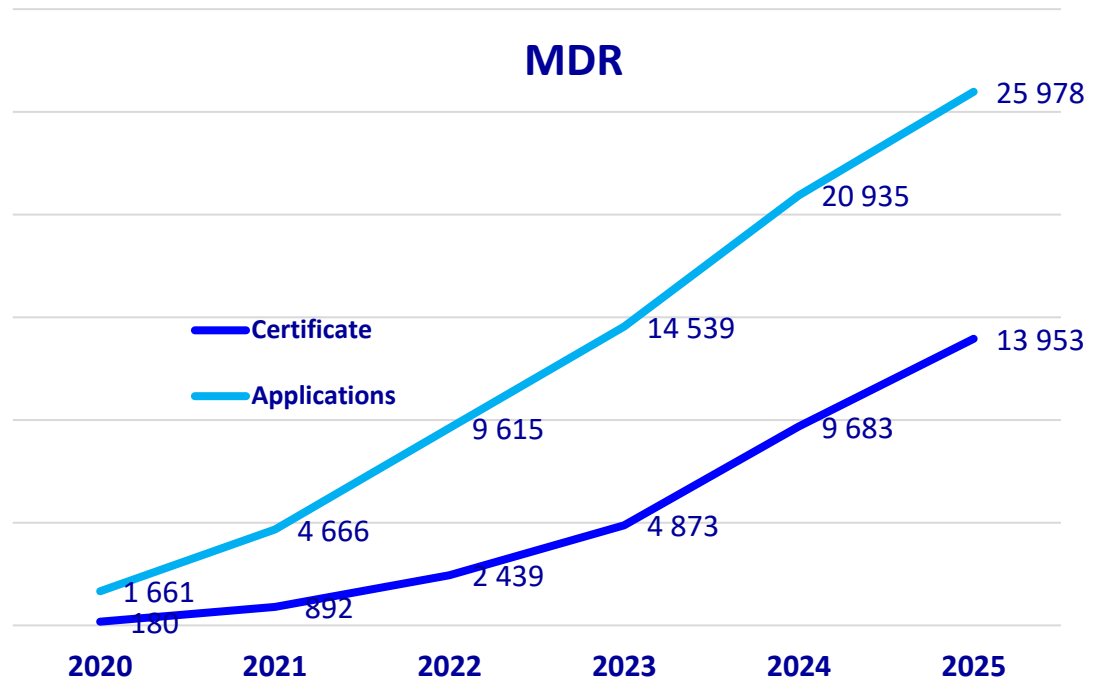
2024: 39 members / 50 designated NBs

2025: 41 members / 52 designated NBs

In comparison with the results of the “Study supporting the monitoring of availability of medical devices on the EU market” presented to December 2025, Team-NB certificates represent

- 81% of the total issued and
- the applications received are representing 84%.

That being said, with data from 41 members out of a total of 52 designated notified bodies, Team-NB represents 79% of the market share.



# Medical Device Survey 2025



## ❖ IVDR applications and certificates

For information,

number of designated members of Team-NB compared to the total number of designated notified bodies:

2020: 4 members / 4 designated NBs

2021: 6 members / 6 designated NBs

2022: 6 members / 7 designated NBs

2023: 10 members / 12 designated NBs

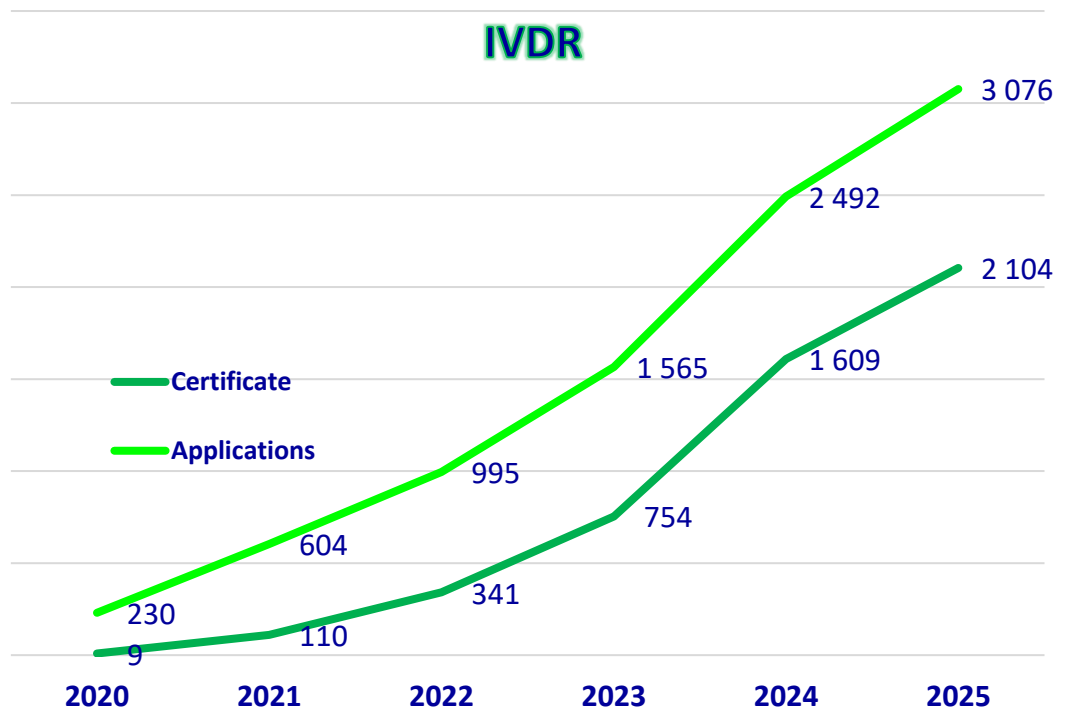
2024: 10 members / 13 designated NBs

2025: 16 members / 19 designated NBs

In comparison with the results of the “Study supporting the monitoring of availability of medical devices on the EU market” presented to December 2025, Team-NB certificates represent

- 95% of the total issued and
- the applications received are representing 86%.

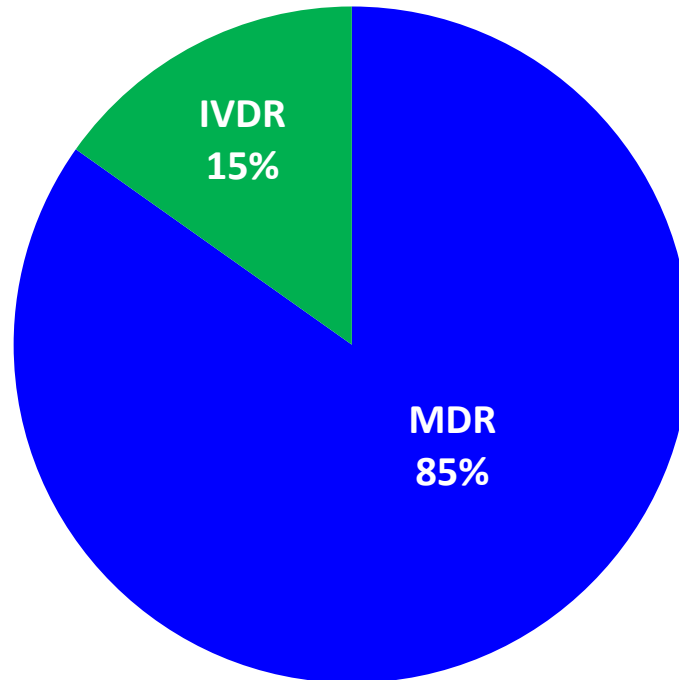
That being said, with data from 16 members out of a total of 19 designated notified bodies, Team-NB represents 84% of the market share.



# Medical Device Survey 2025



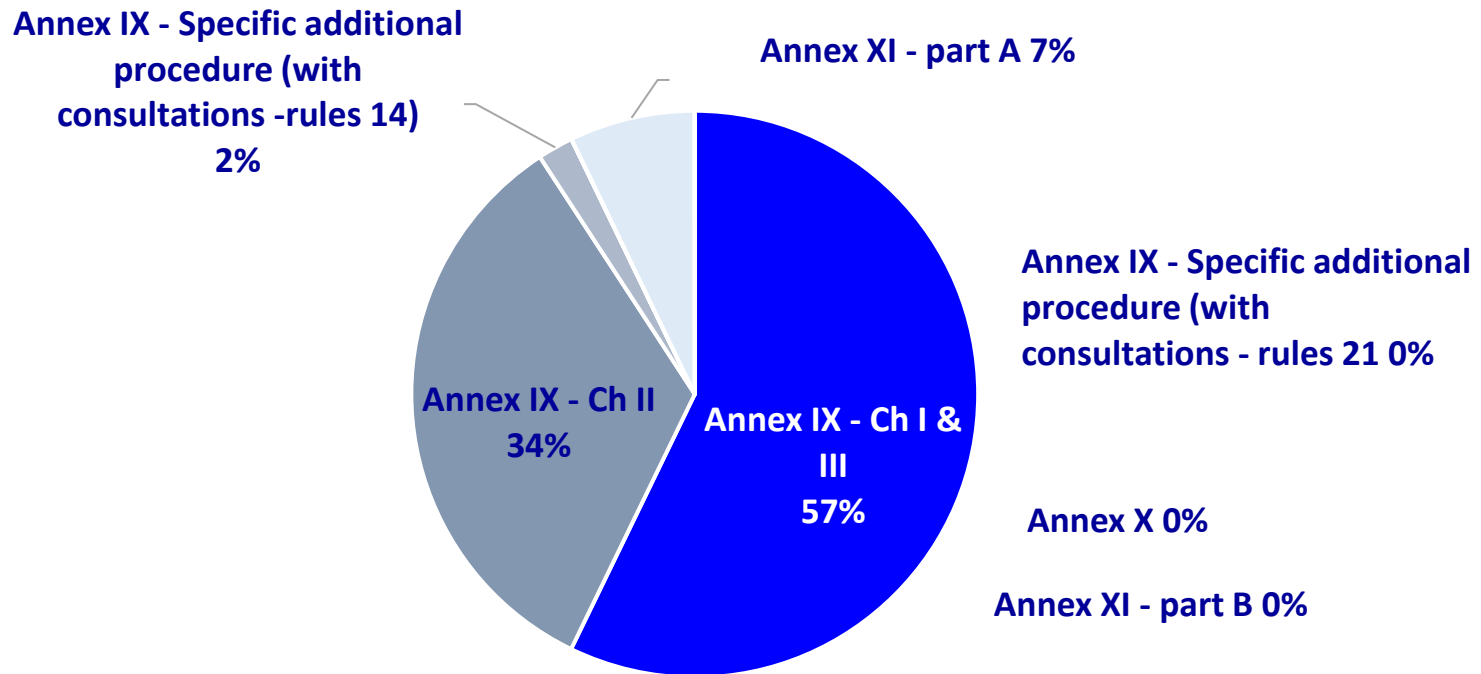
## ❖ Distribution of certificates between different Regulations



# Medical Device Survey 2025



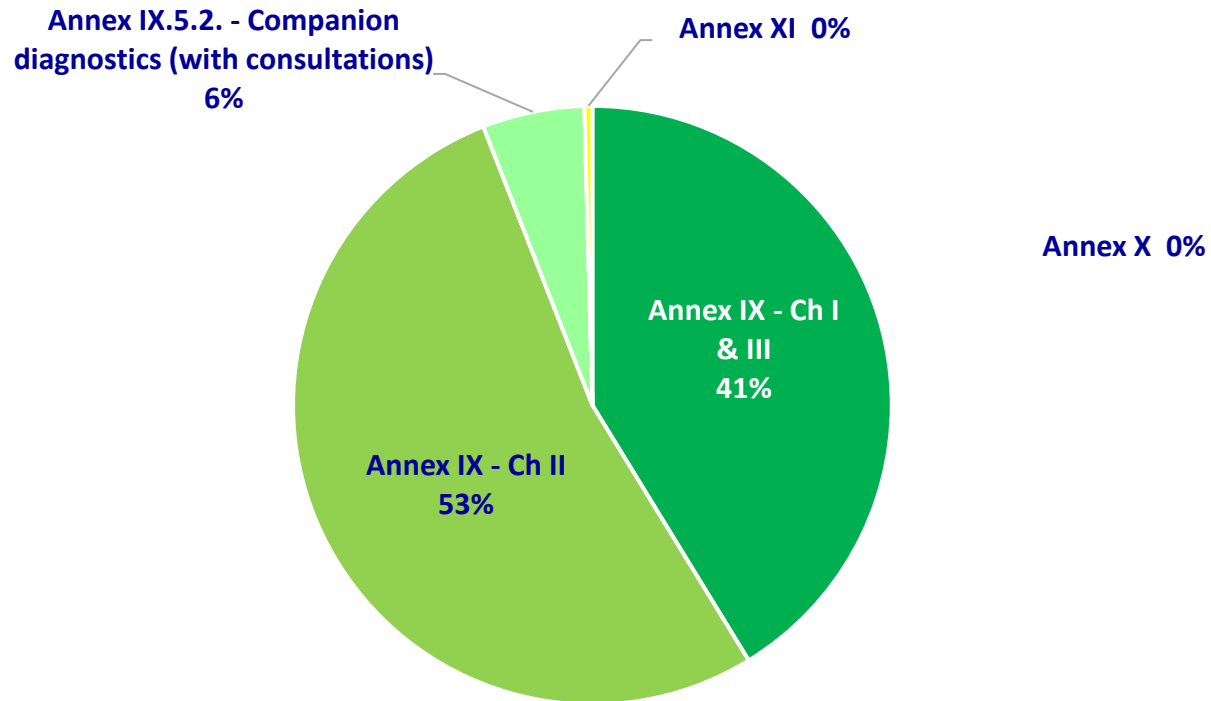
## ❖ Distribution of certificates between different conformity assessment modules under **MDR**



# Medical Device Survey 2025



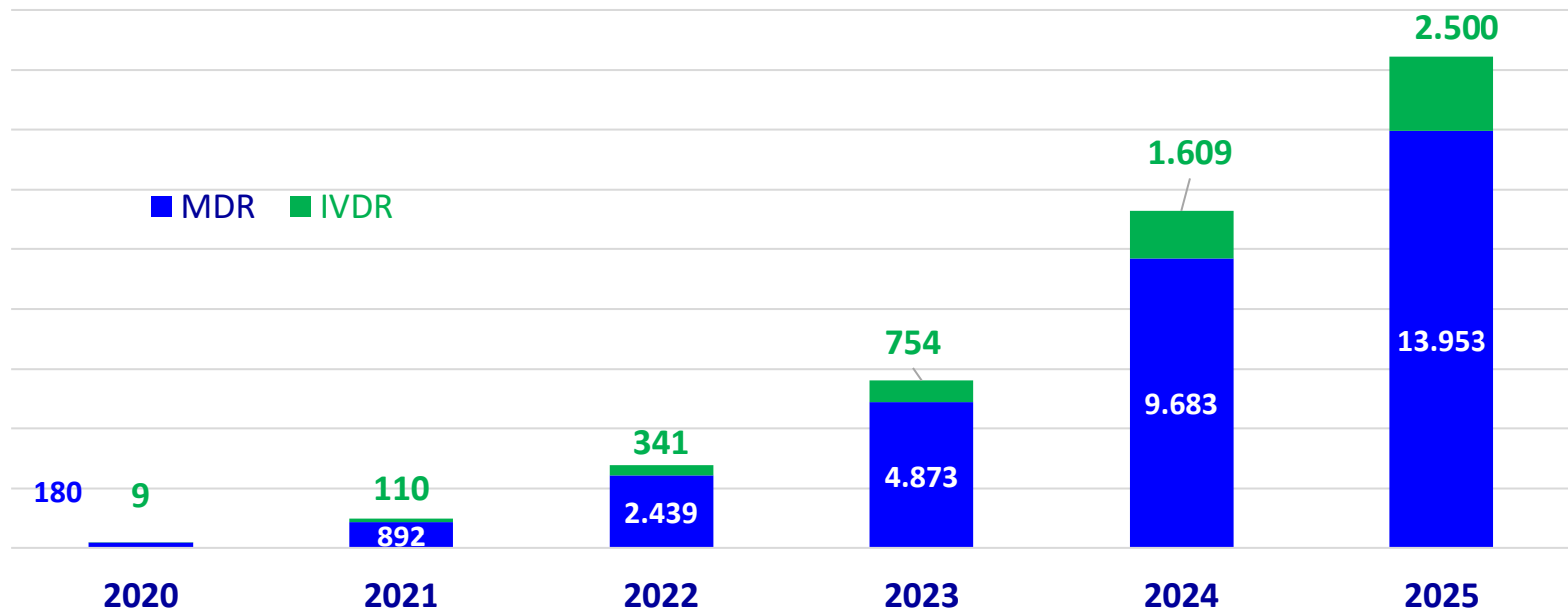
## ❖ Distribution between different conformity assessment modules under **IVDR**



# Medical Device Survey 2025



## ❖ Comparison of issued certificates among regulations

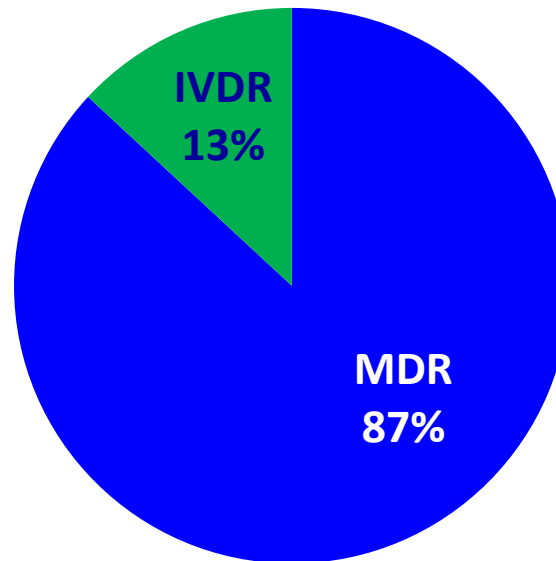


⇒ In 2025, we see a slowdown in growth in the issuance of certificates with **two third** instead of **doubling** in 2023 and 2024.

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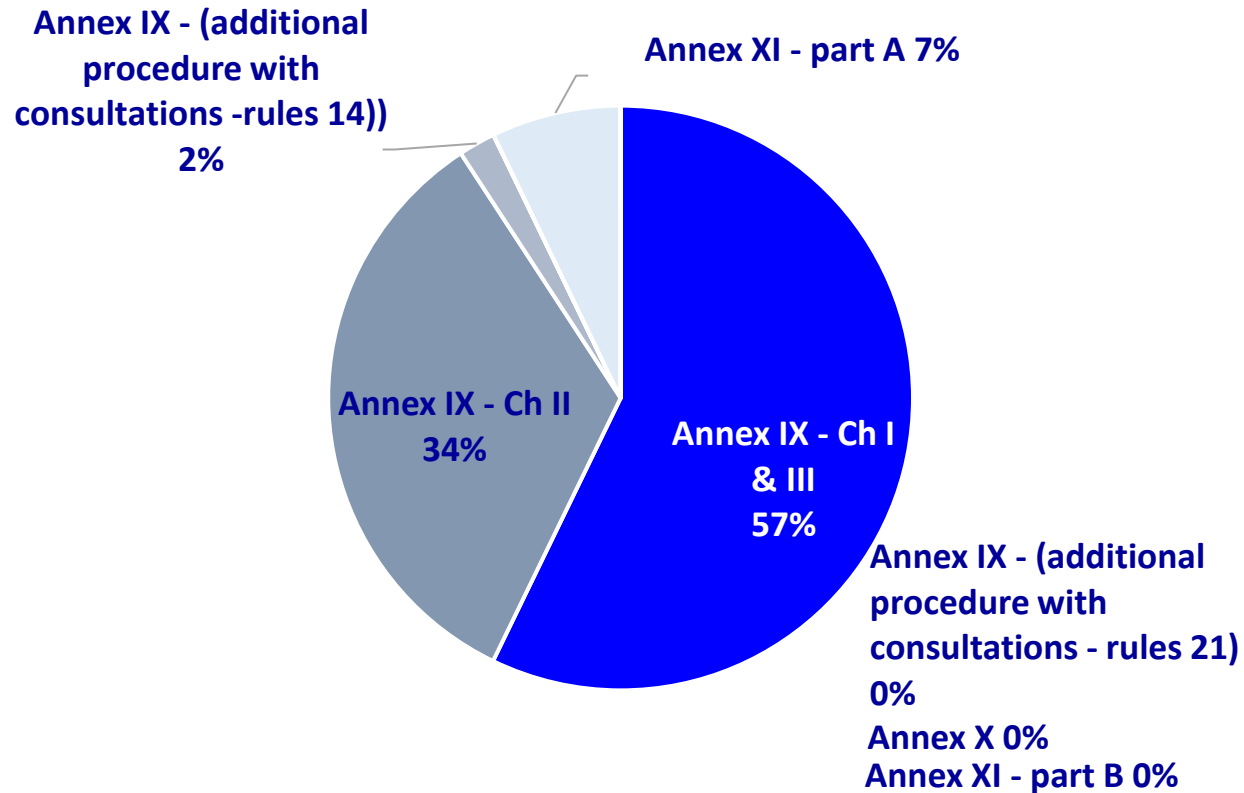
## ❖ Distribution of applications between different Regulations



# Medical Device Survey 2025



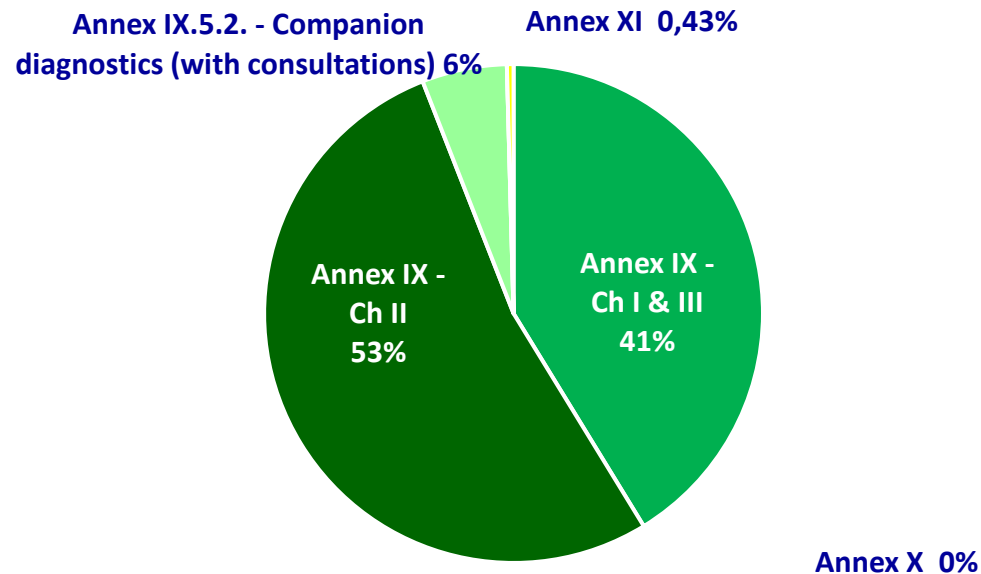
## ❖ Distribution of certificates between different conformity assessment modules under MDR



# Medical Device Survey 2025



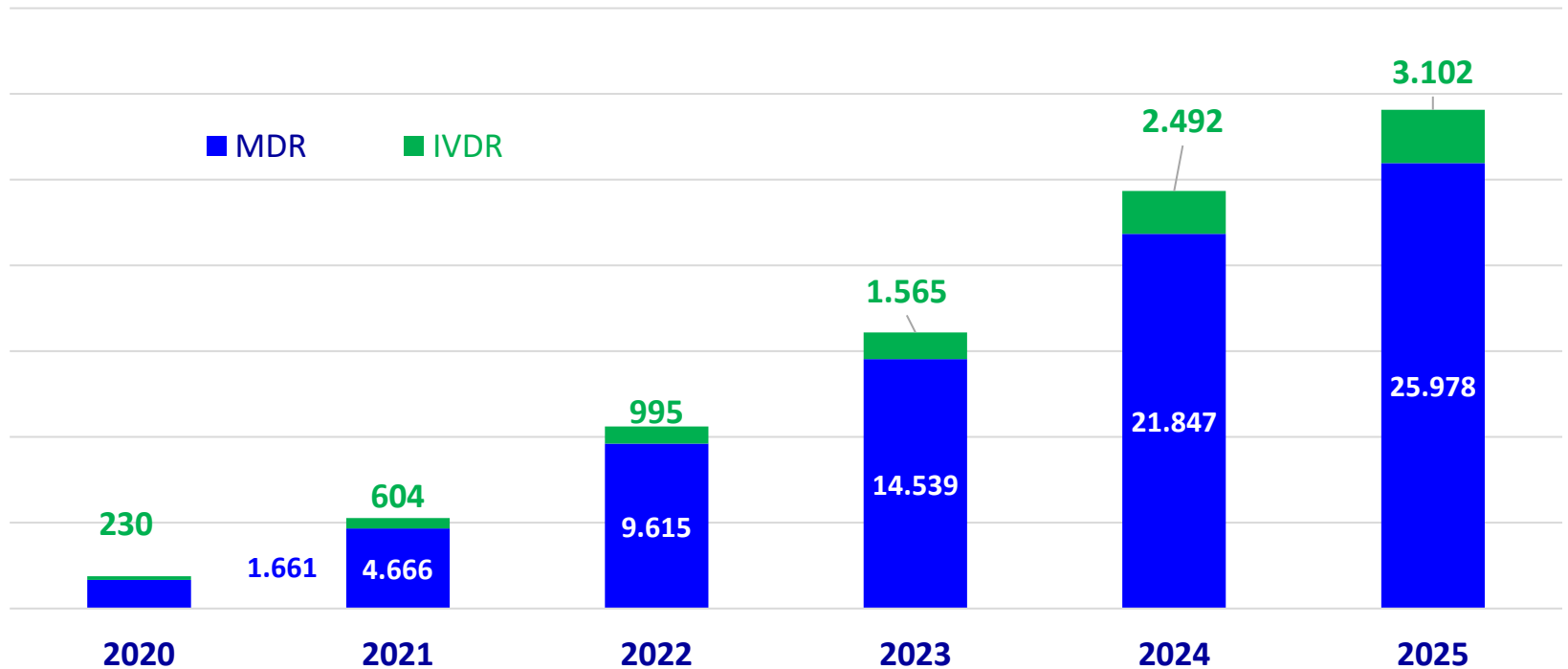
## ❖ Distribution of certificates between different conformity assessment modules under **IVDR**



# Medical Device Survey 2025



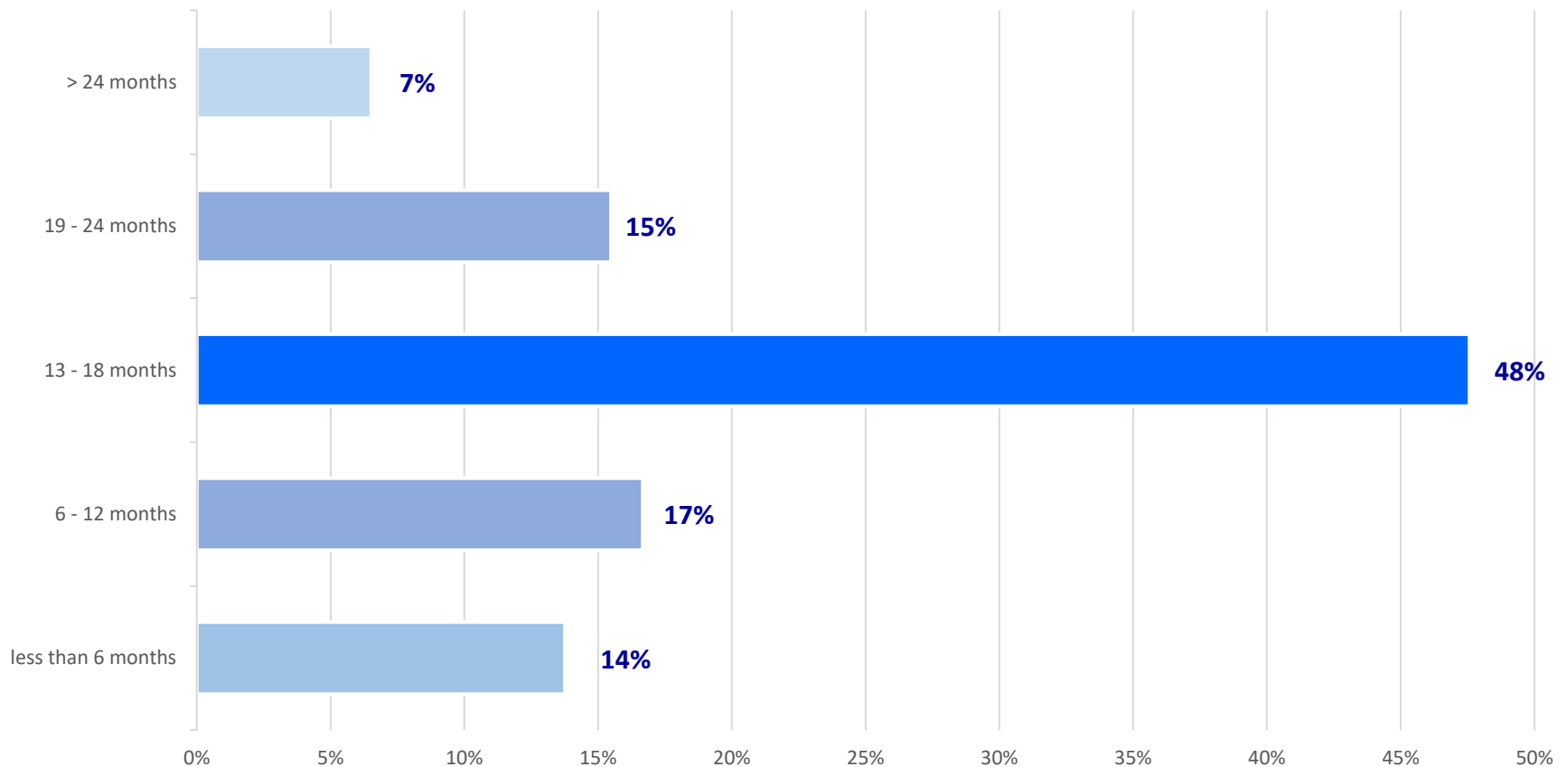
## ❖ Evolution of received applications against Regulations



# Medical Device Survey 2025



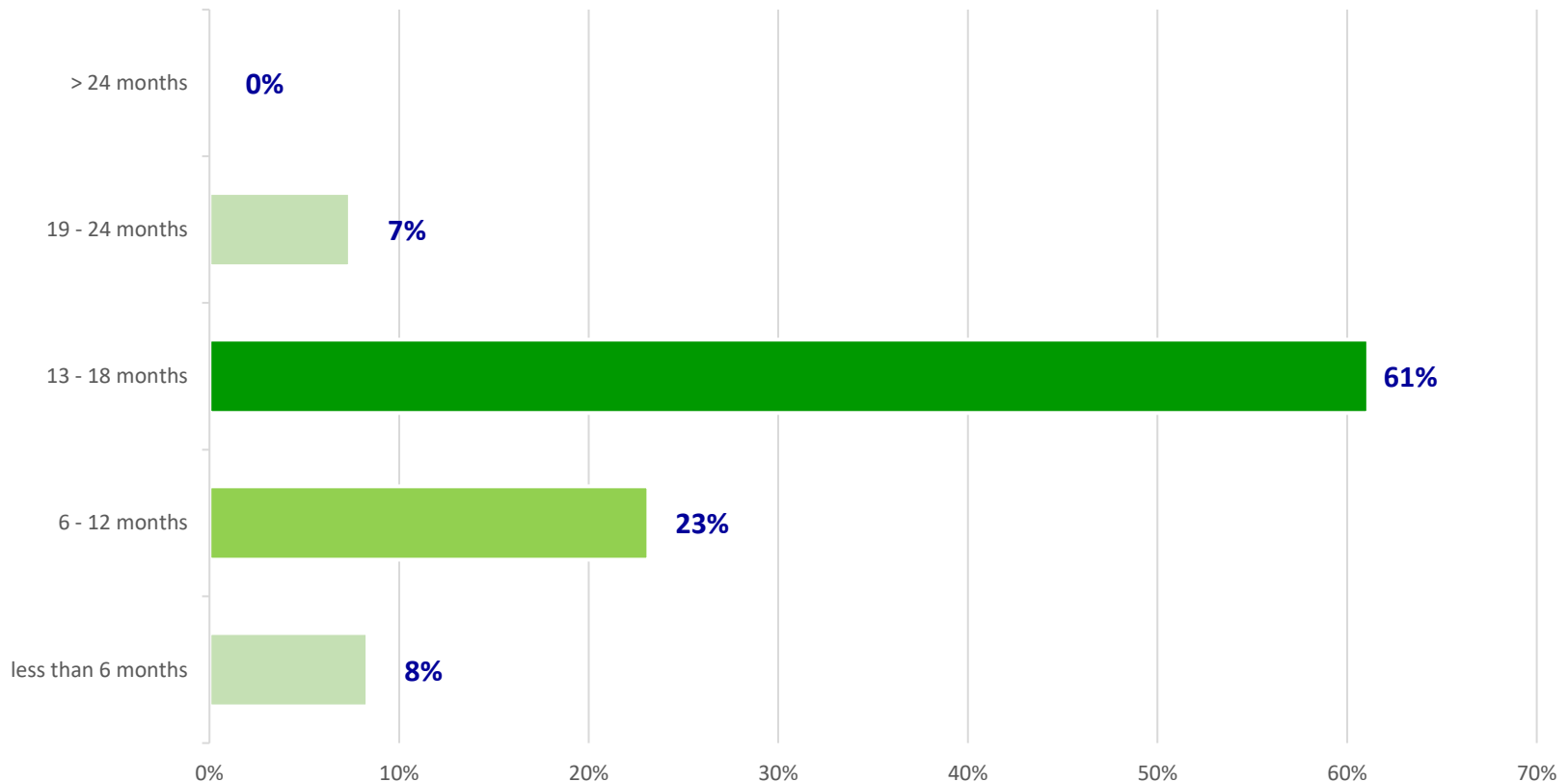
## ❖ Average time to reach issuance of a NEW (not renewal) MDR certificate



# Medical Device Survey 2025



## ❖ Average time to reach issuance of a NEW (not renewal) **IVDR** certificate



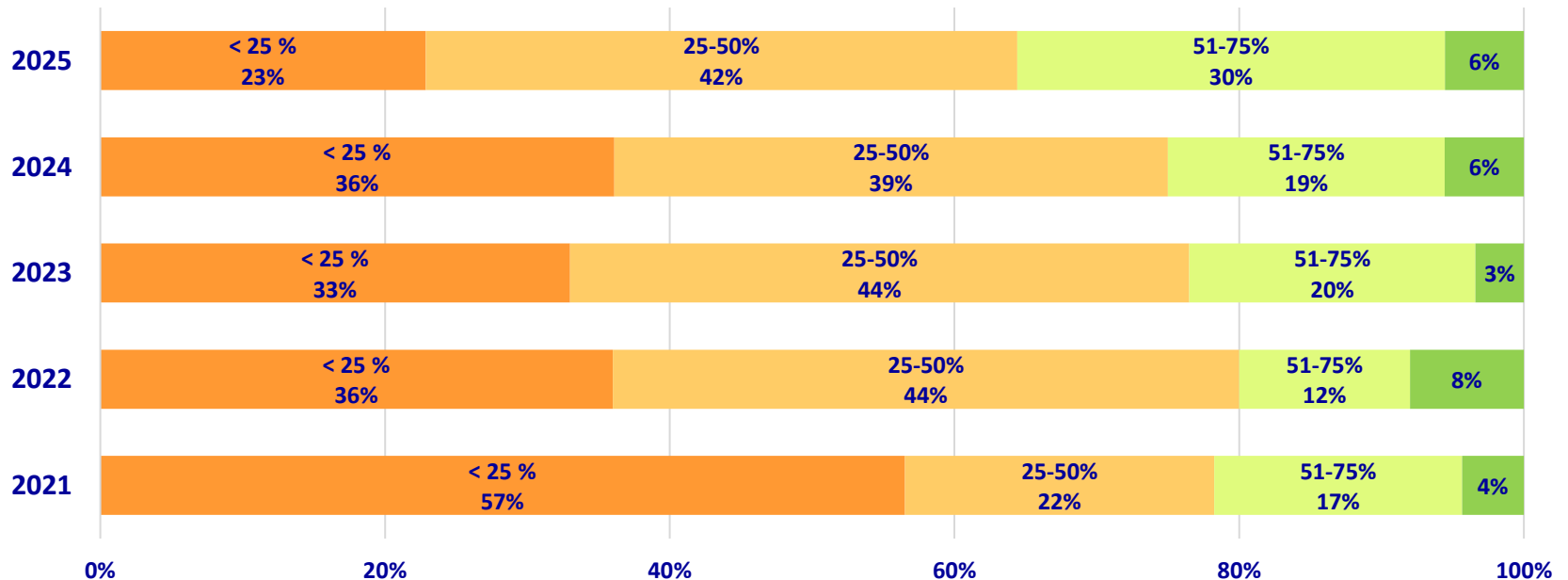
# Medical Device Survey 2025



## MDR Completeness check - evolution

Activity to ensure that complete technical documentation has been received before undertaking the review of its content

⇒ below graph with comparison of completeness over the 5 last years



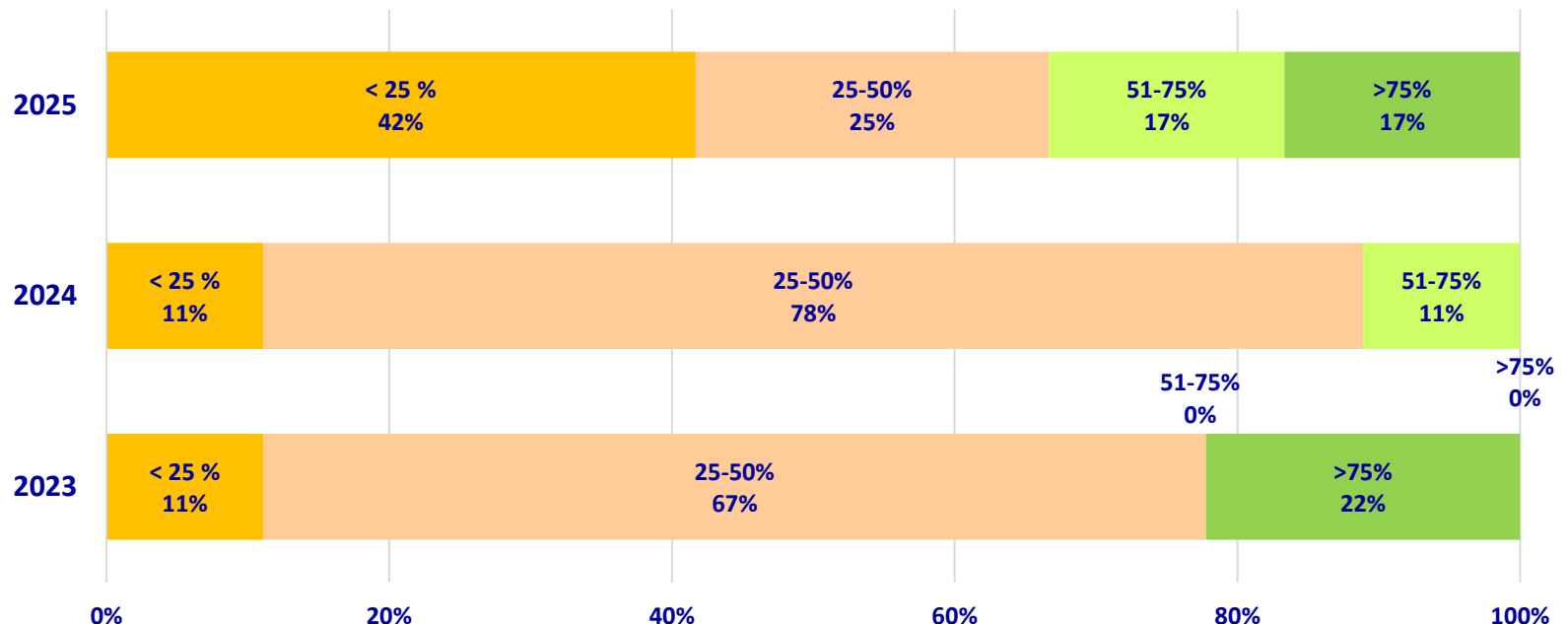
# Medical Device Survey 2025



## ❖ IVDR Completeness check - evolution

Activity to ensure that complete technical documentation has been received before undertaking the review of its content

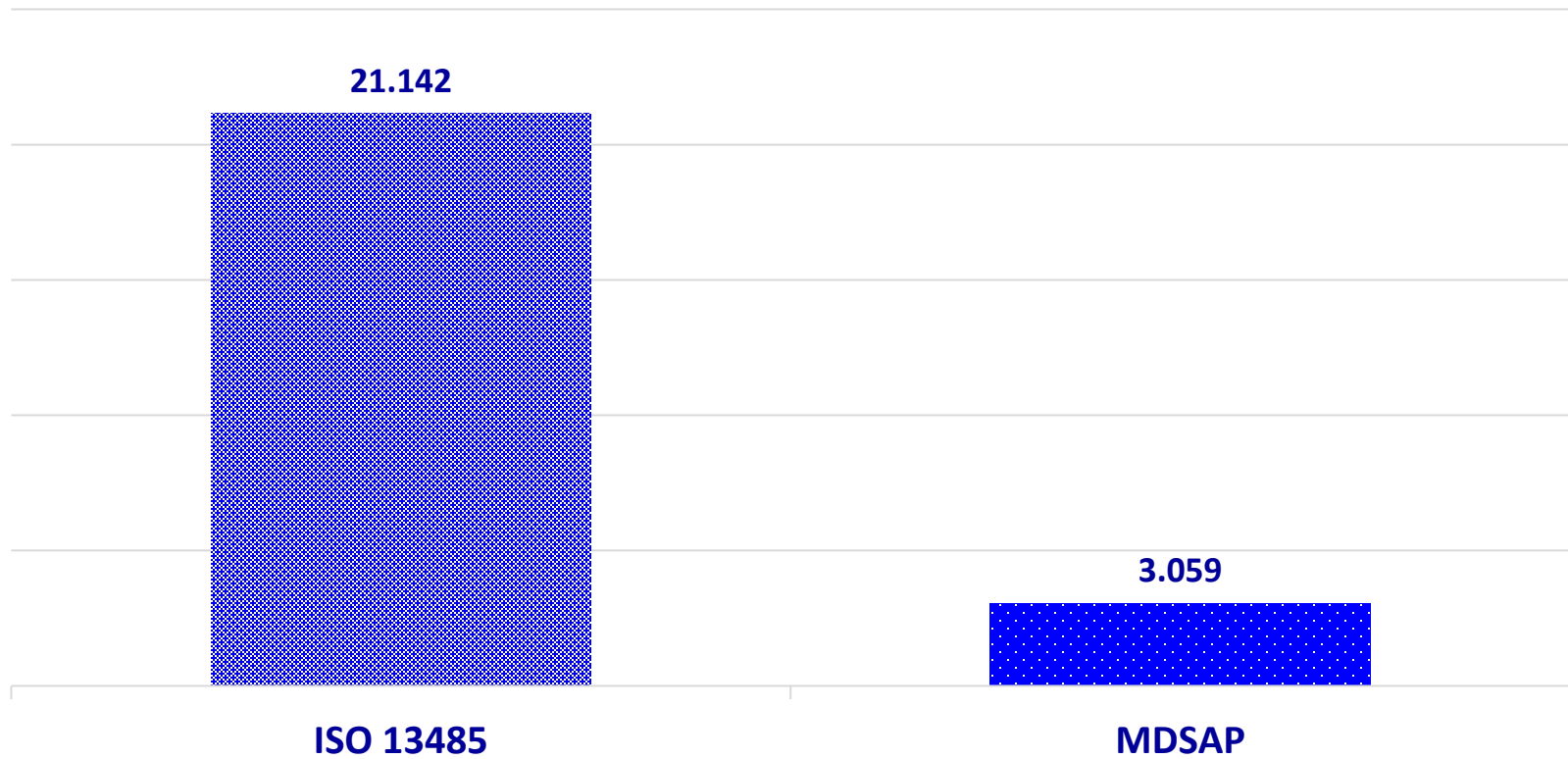
⇒ below graph with comparison of completeness over the 3 last years



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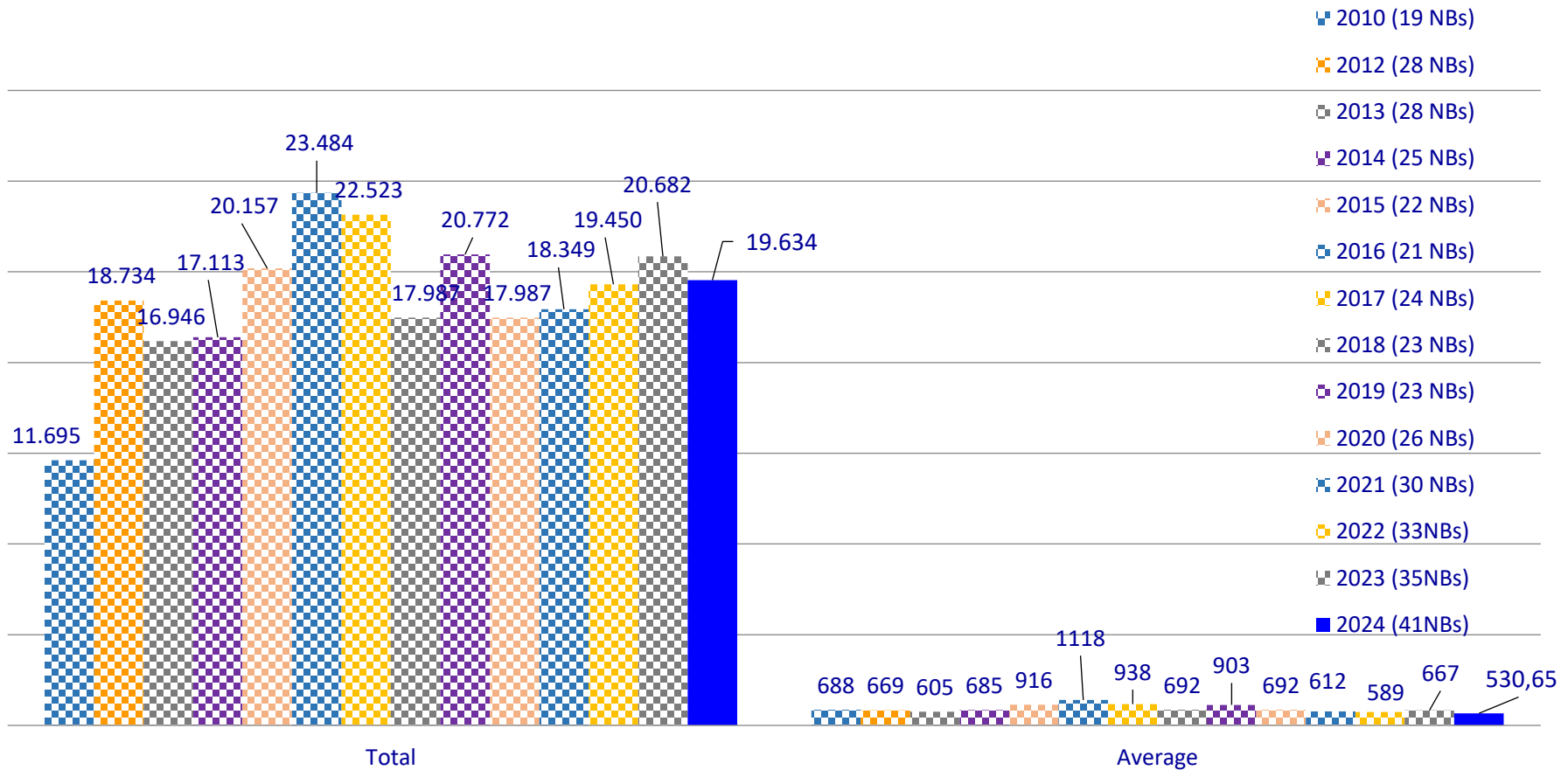
## ❖ Other certifications : ISO 13485 / MDSAP



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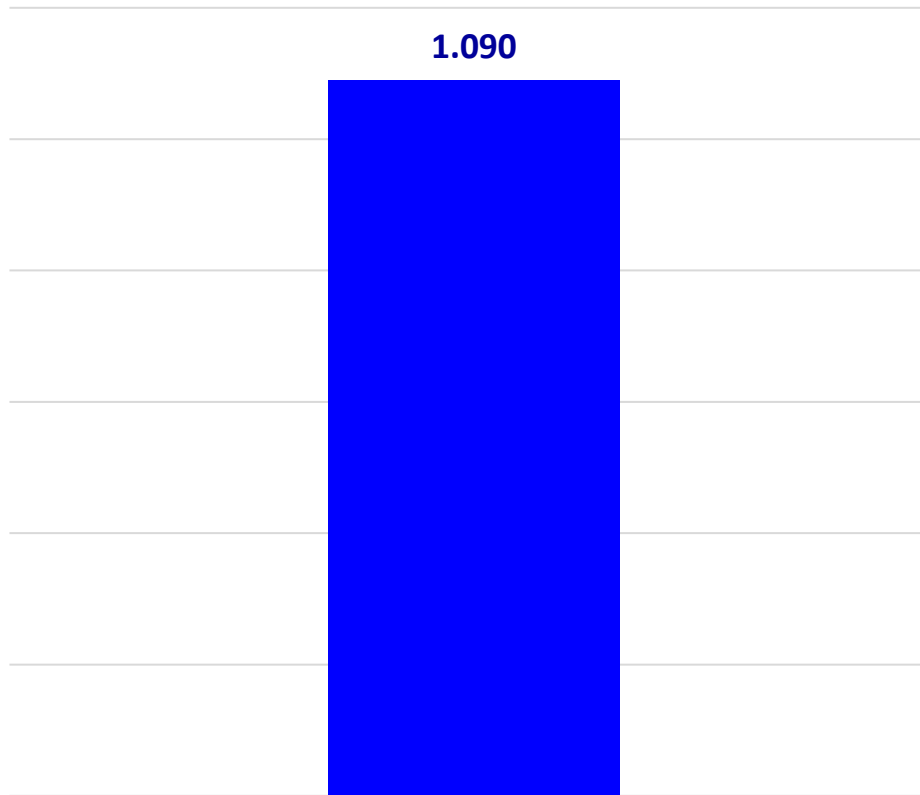
## Valid certificates against ISO 13485 from 2010 to 2025 :



# Medical Device Survey 2025



## ❖ Number of certificates withdrawn in 2025



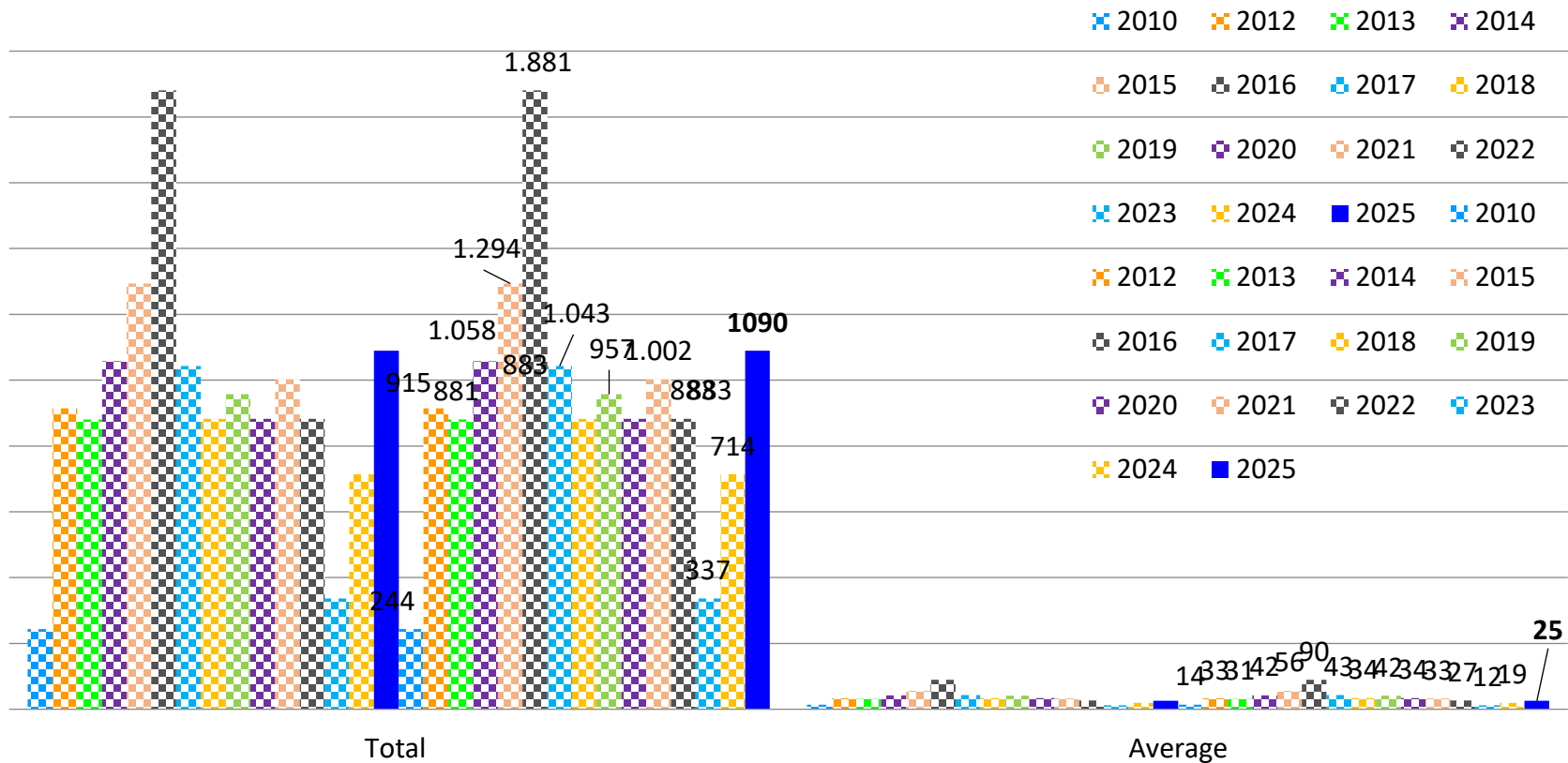
### Reasons for withdrawing:

cessation of activity - cancelled due to end of Directives - contractual obligations not fulfilled, financial issues - not closing the NCs - negative assessment result - Customer refuses audit or contact not possible - No longer manufacturing product liquidations - change of NB - unannounced audits not satisfactory

# Medical Device Survey 2025



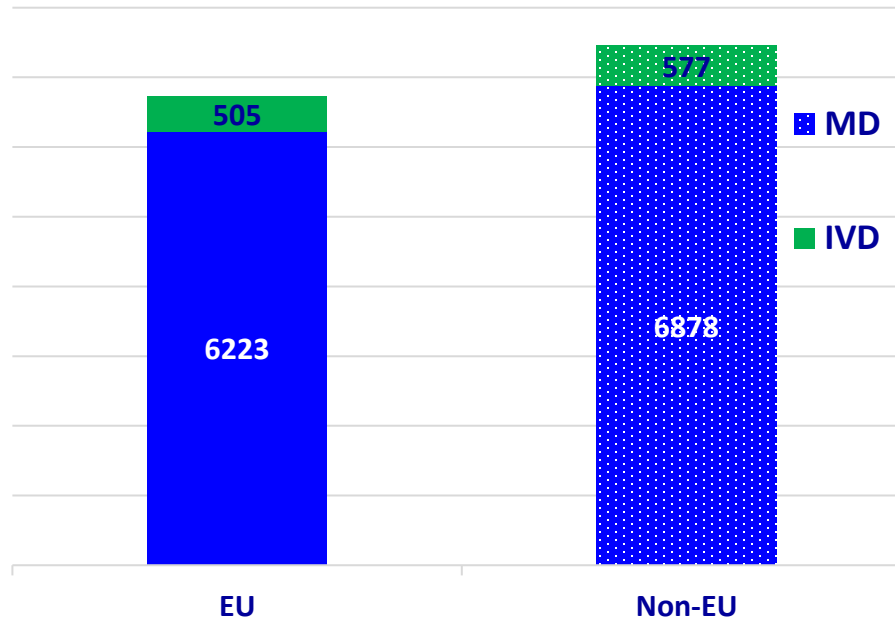
## ❖ Number of certificates withdrawn from 2010 to 2025:



# Medical Device Survey 2025



## ❖ Clients



For clarification, the number of clients is smaller than the number of certificates holders as 1 client can have more than 1 QMS (quality management certificate) (for example: more than 1 plant).

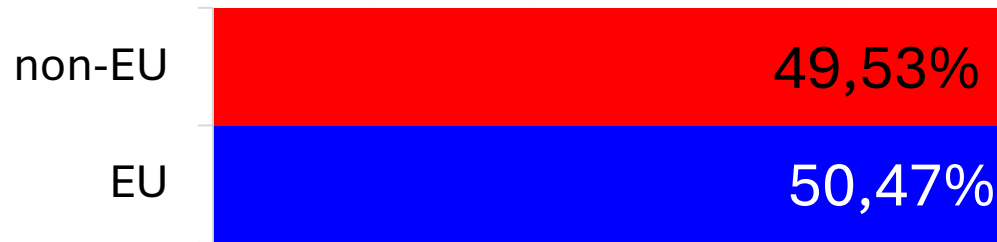
Moreover, during this transition period, some clients could have both a QMS Directive certificate and a QMS Regulation certificate.

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## ❖ Manufacturers sizes

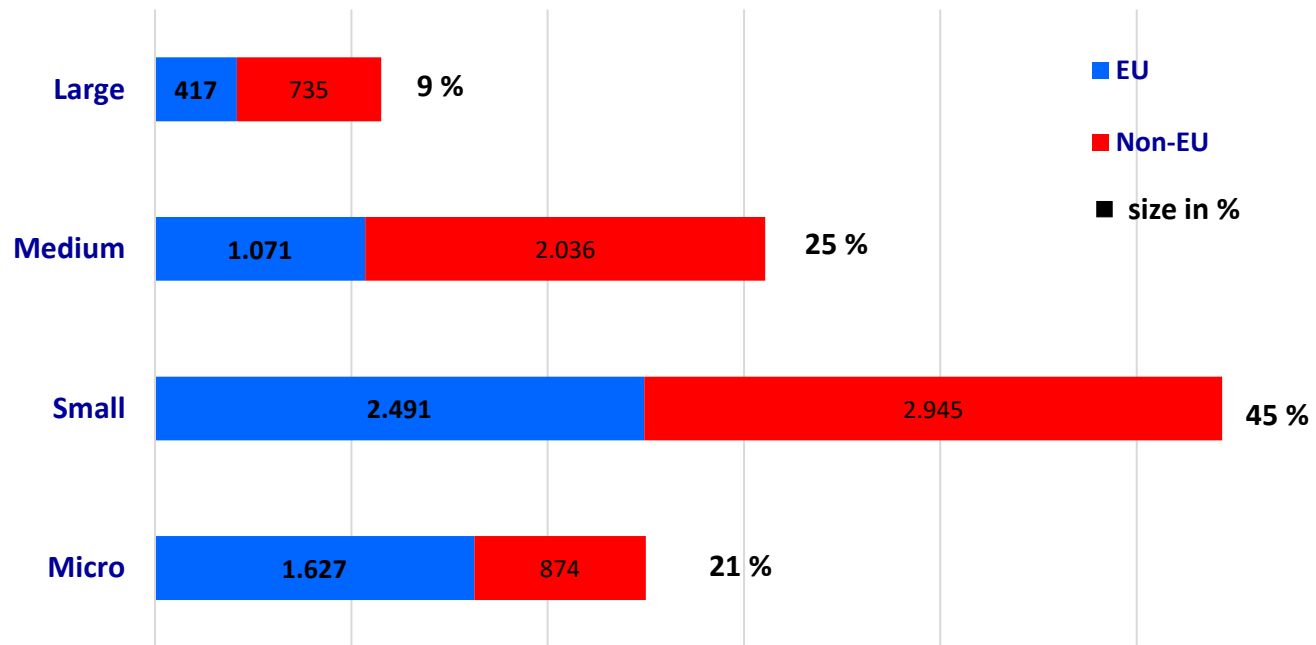
Percentage of micro and small enterprises in EU and outside EU:



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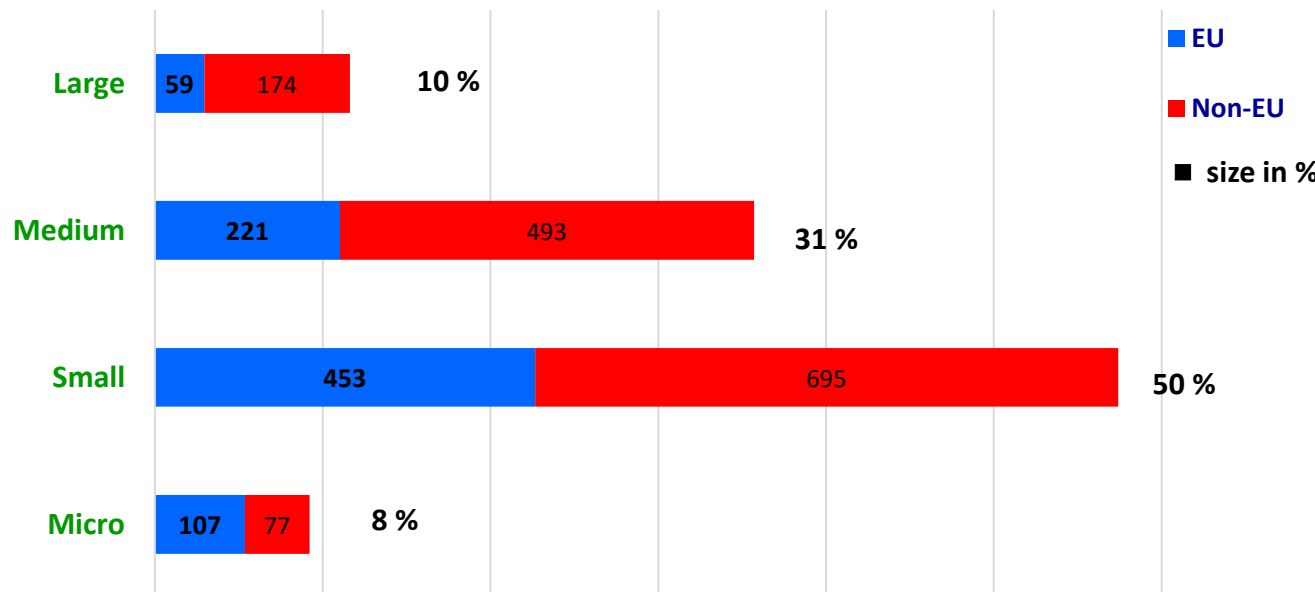
## ❖ MD - Manufactures sizes repartition : percentage of Micro, SMEs and Big companies



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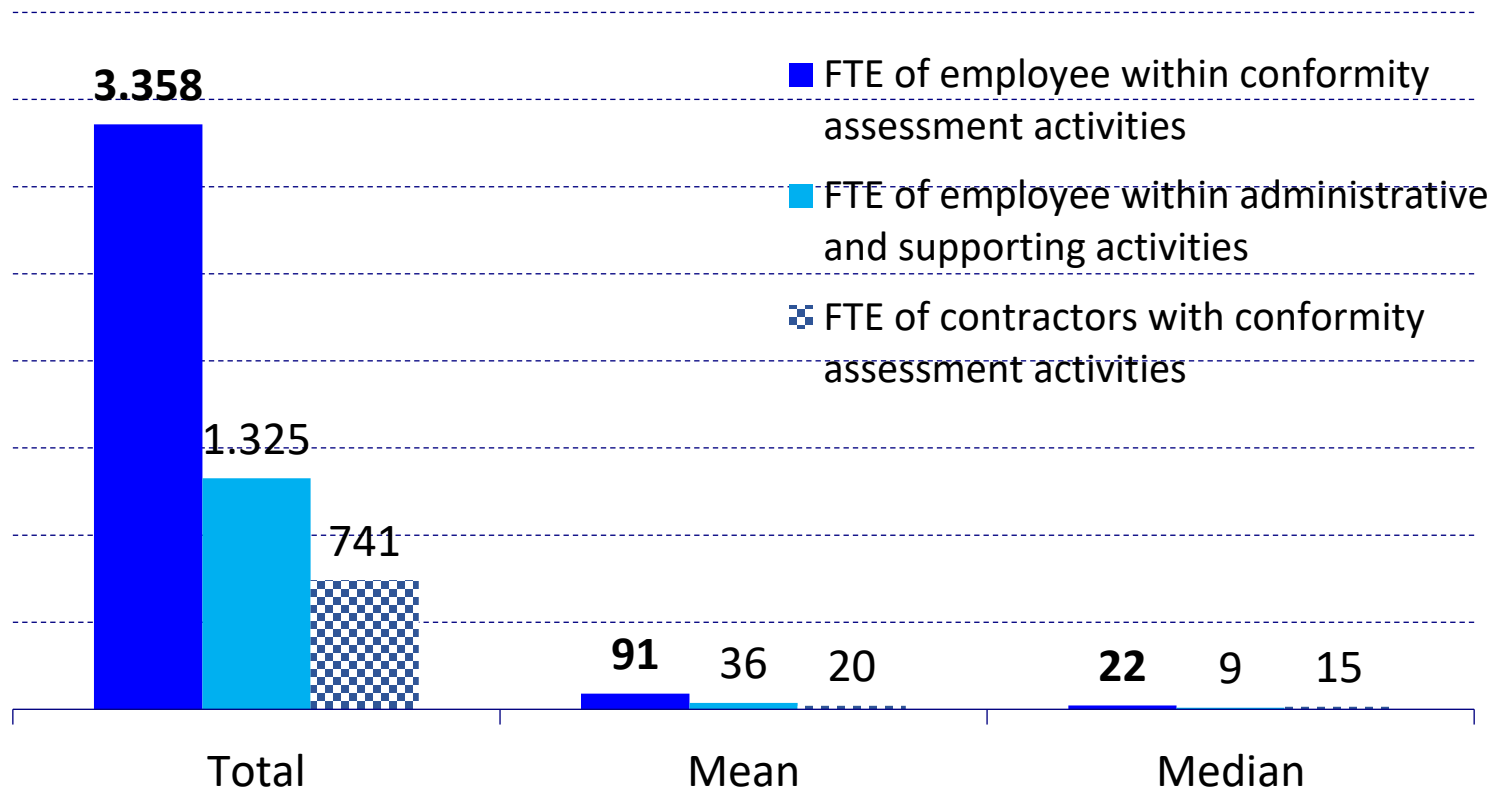
## ❖ IVD - Manufactures sizes repartition : percentage of Micro, SMEs and Big companies



# Medical Device Survey 2025



## ❖ Staff in 2025 (full time equivalent in MD sector)



# Medical Device Survey 2025



## ❖ Staff dedicated to conformity assessments

(full time equivalent in MD sector) - **From 2010 to 2025**



For the first time in over 10 years the number of employees within the company is decreasing.

In particular,  
 - 8% of internal employees for conformity assessment  
 - 21 % of subcontractors.

# Members



Note : some members of the same group are represented by only 1 logo