



The European Association of Medical devices
Notified Bodies

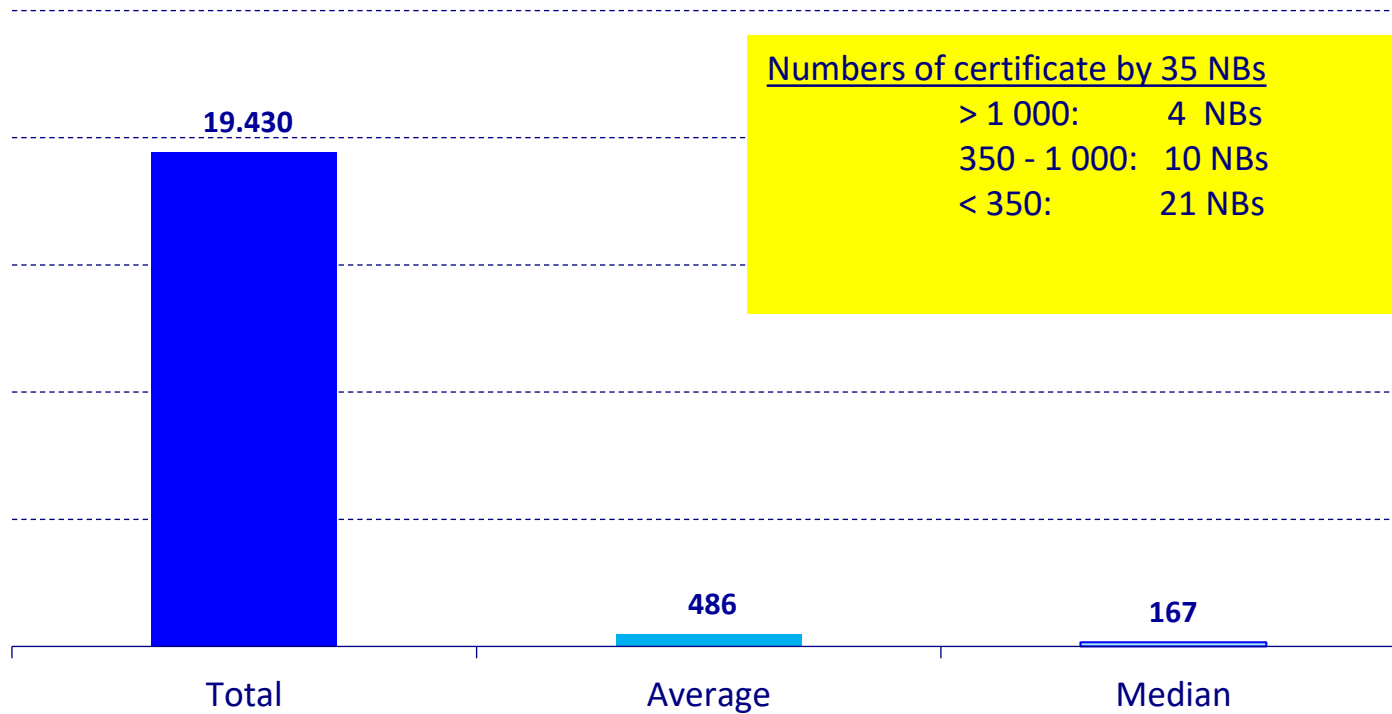
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Data from all 35 members (end 2023)

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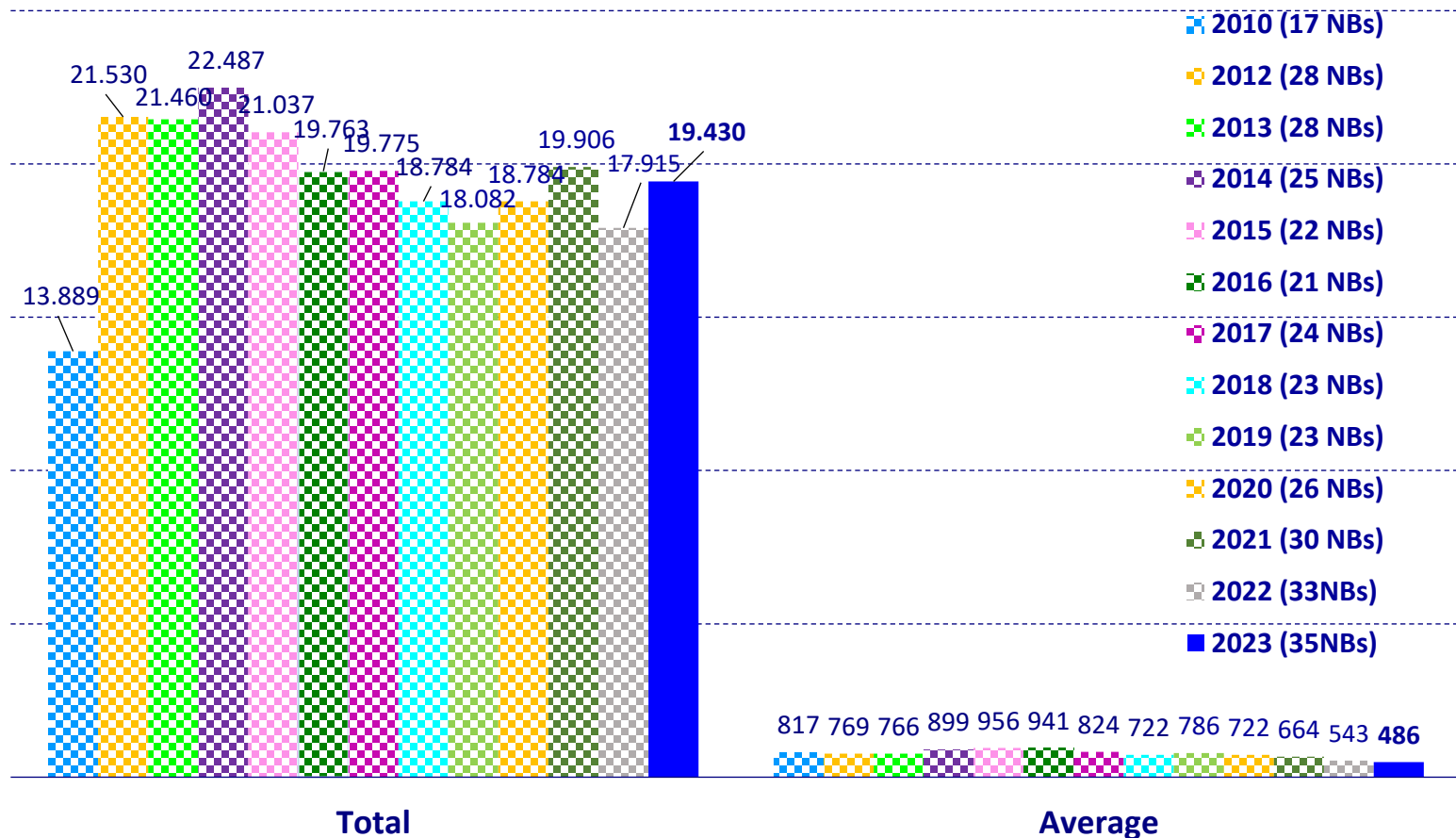
❖ Valid certificates at end of 2023



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Valid CE certificates issued from 2010 to 2023



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❖ MDR applications and certificates (QMS + Product)

For information,

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

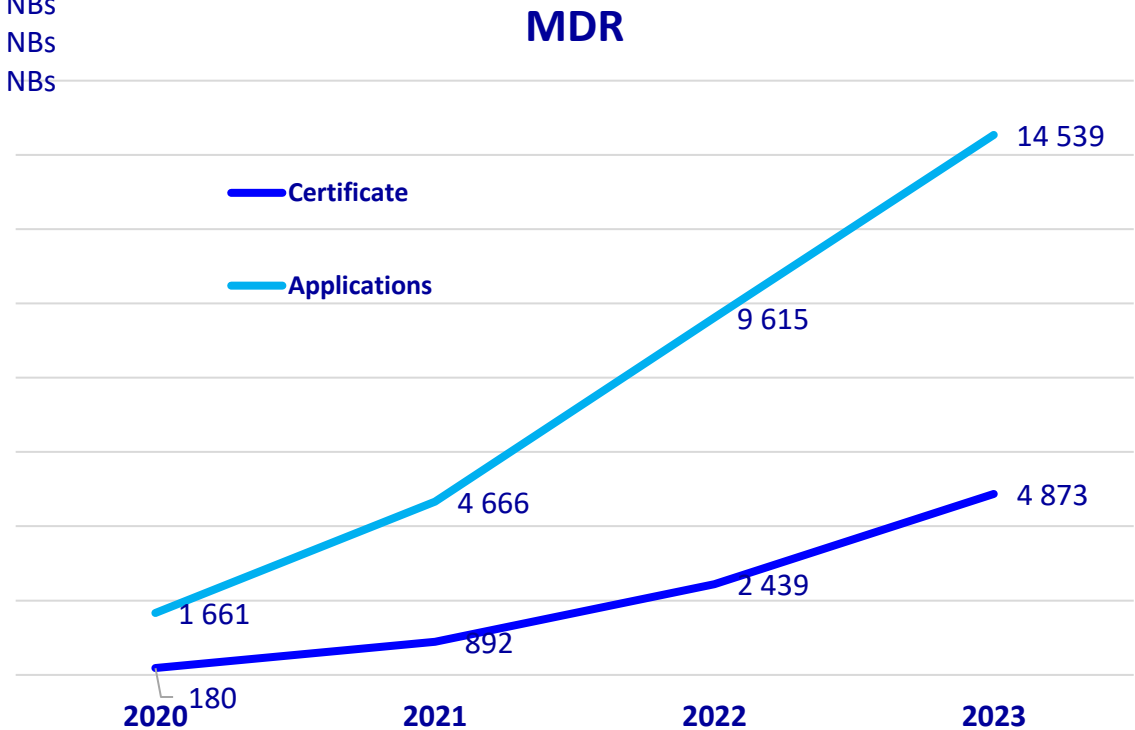
2020: 16 members / 18 designated NBs

2021: 21 members / 25 designated NBs

2022: 25 members / 36 designated NBs

2023: 32 members / 42 designated NBs

In comparison



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❖ IVDR applications and certificates

For information,

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

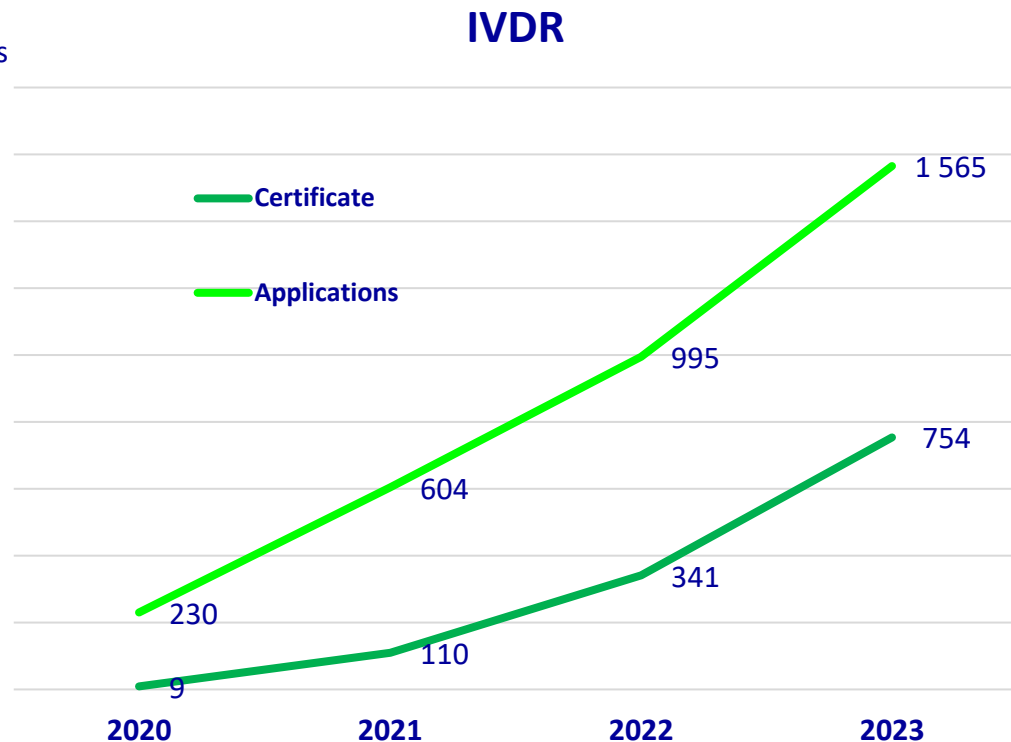
2020: 4 members / 4 designated NBs

2021: 6 members / 6 designated NBs

2022: 6 members / 7 designated NBs

2023: 10 members / 12 designated NBs

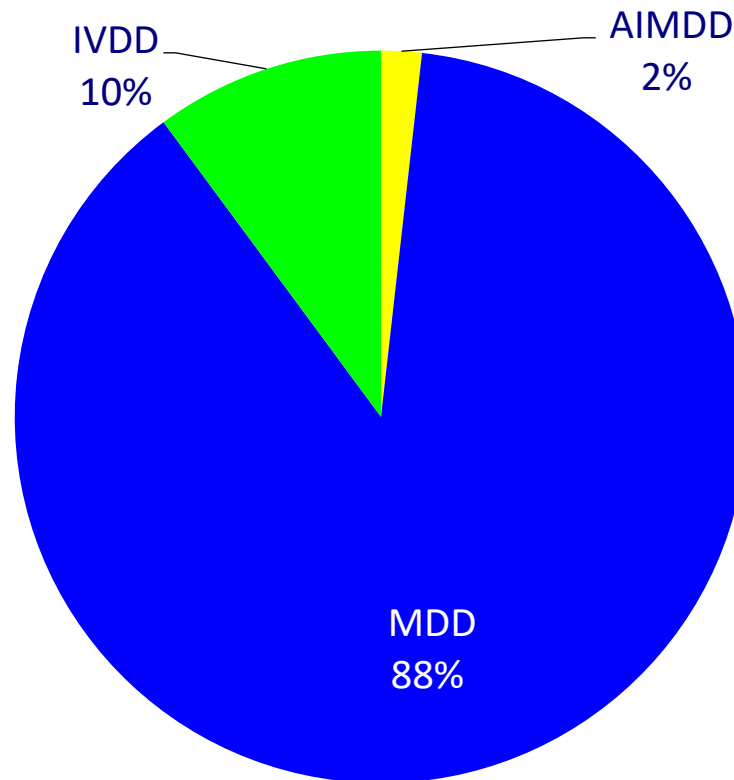
In comparison



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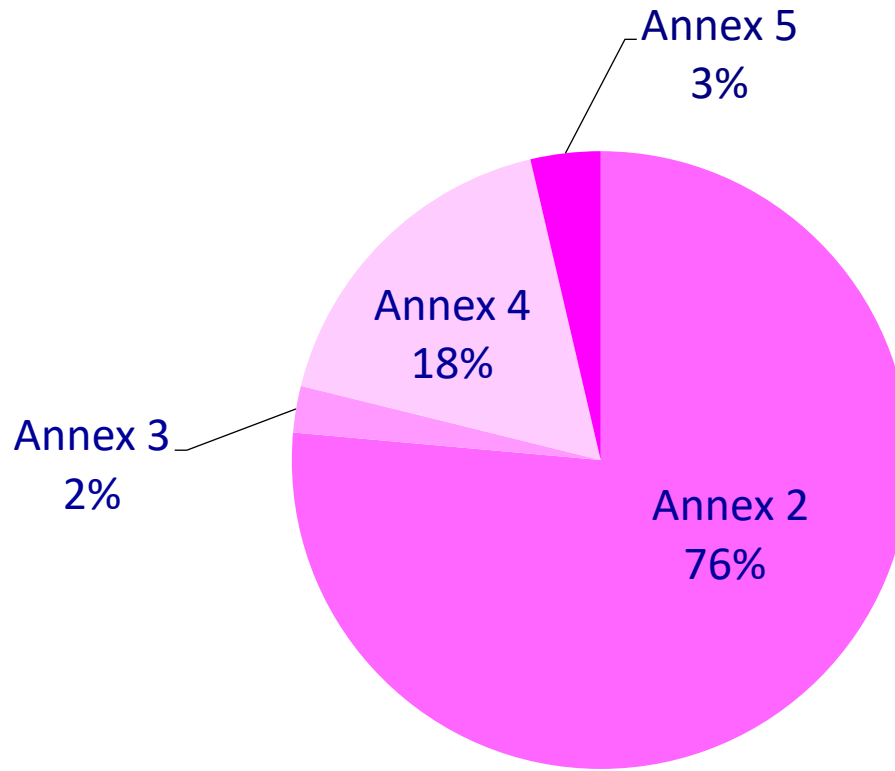
❖ Distribution of certificates between different Directives



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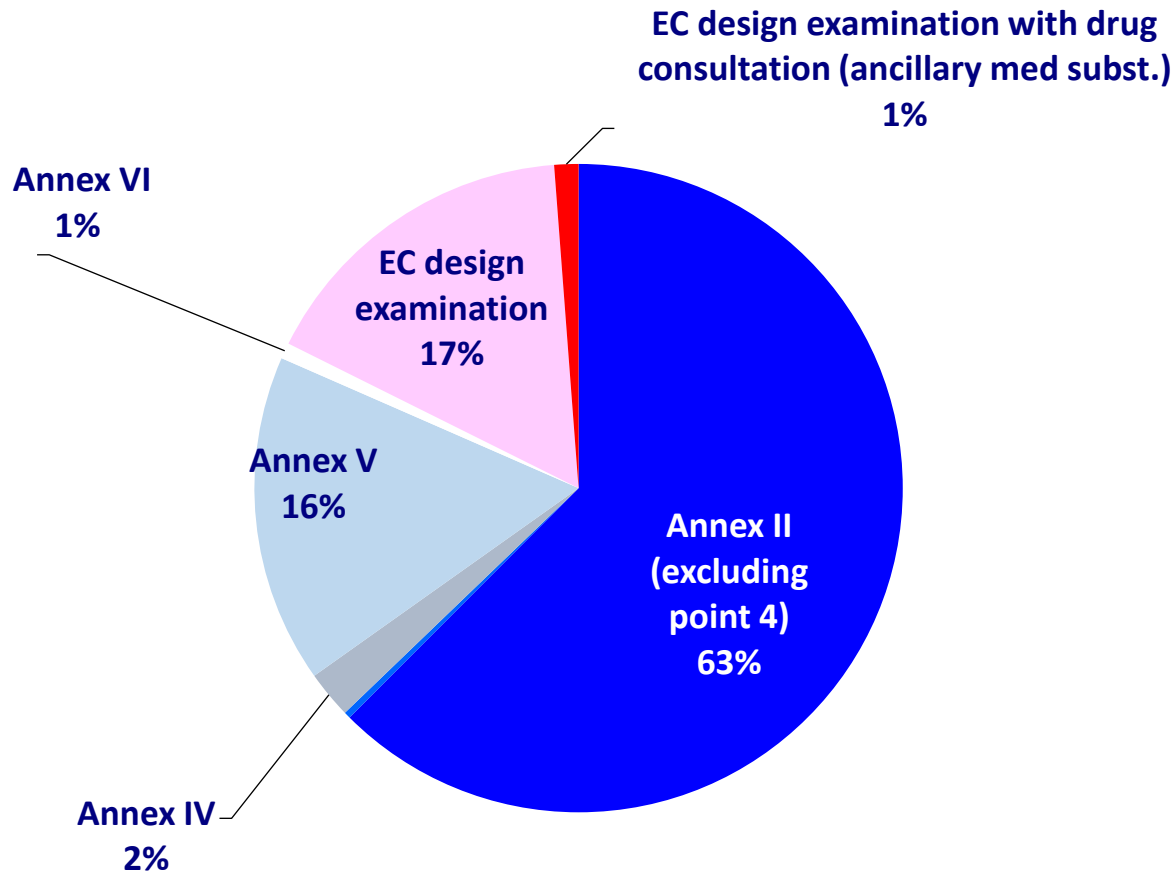
❖ Distribution between different conformity assessment modules under AIMDD



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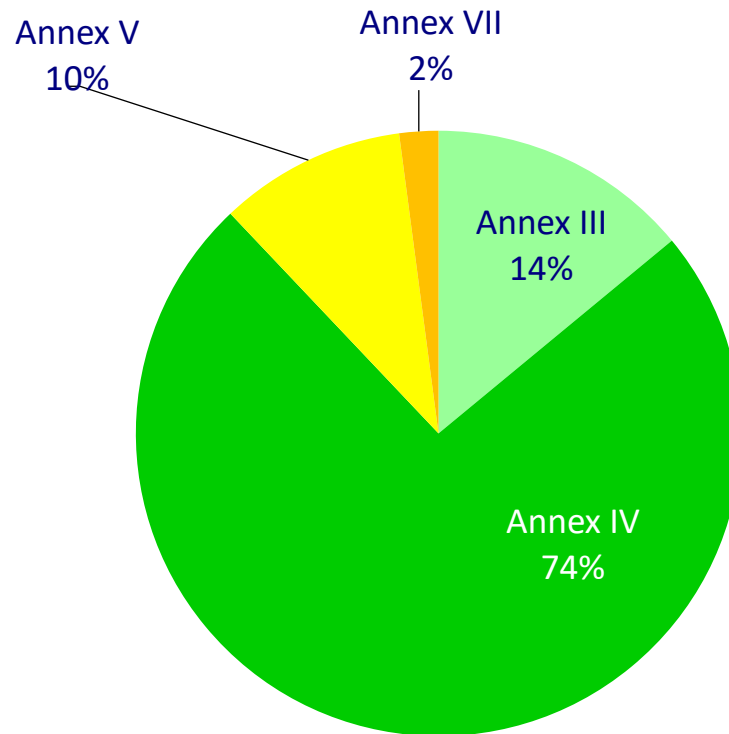
❖ Distribution between different conformity assessment modules under MDD



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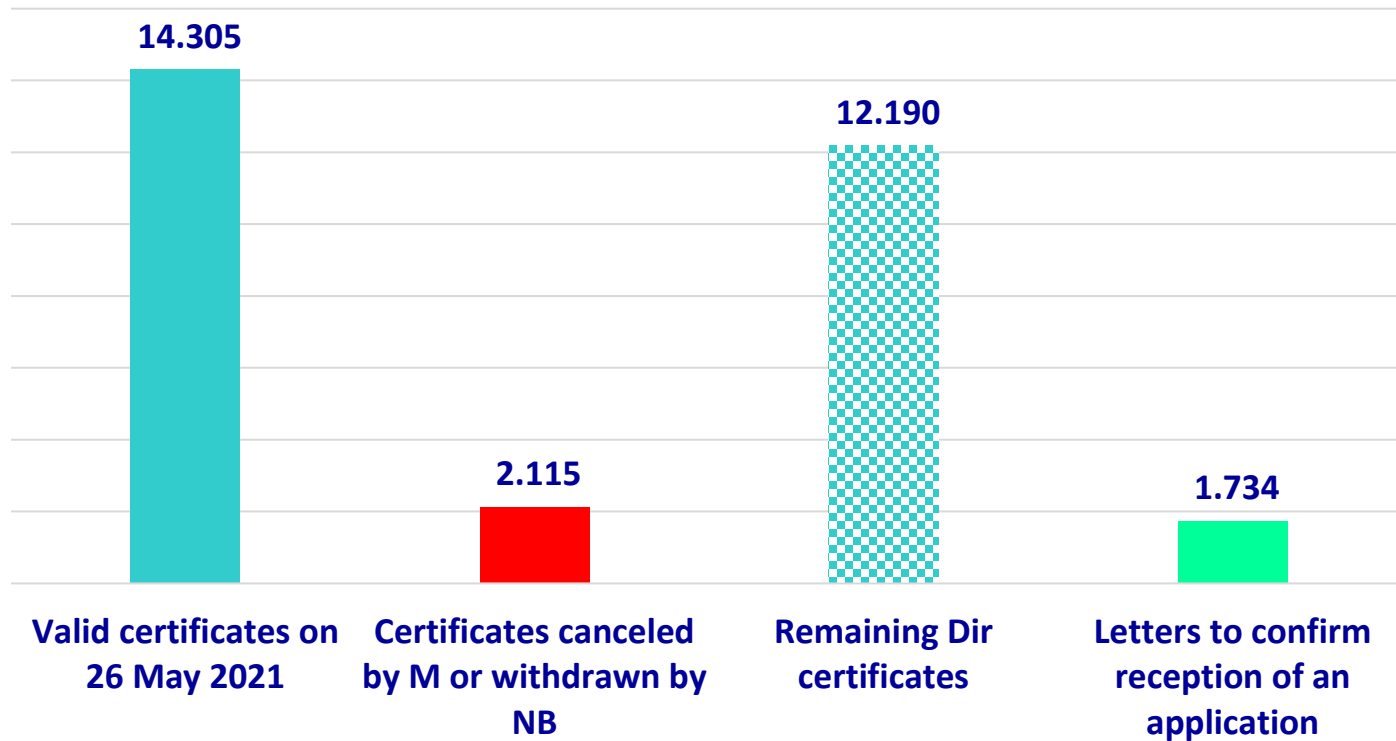
❖ Distribution between different conformity assessment modules under IVDD



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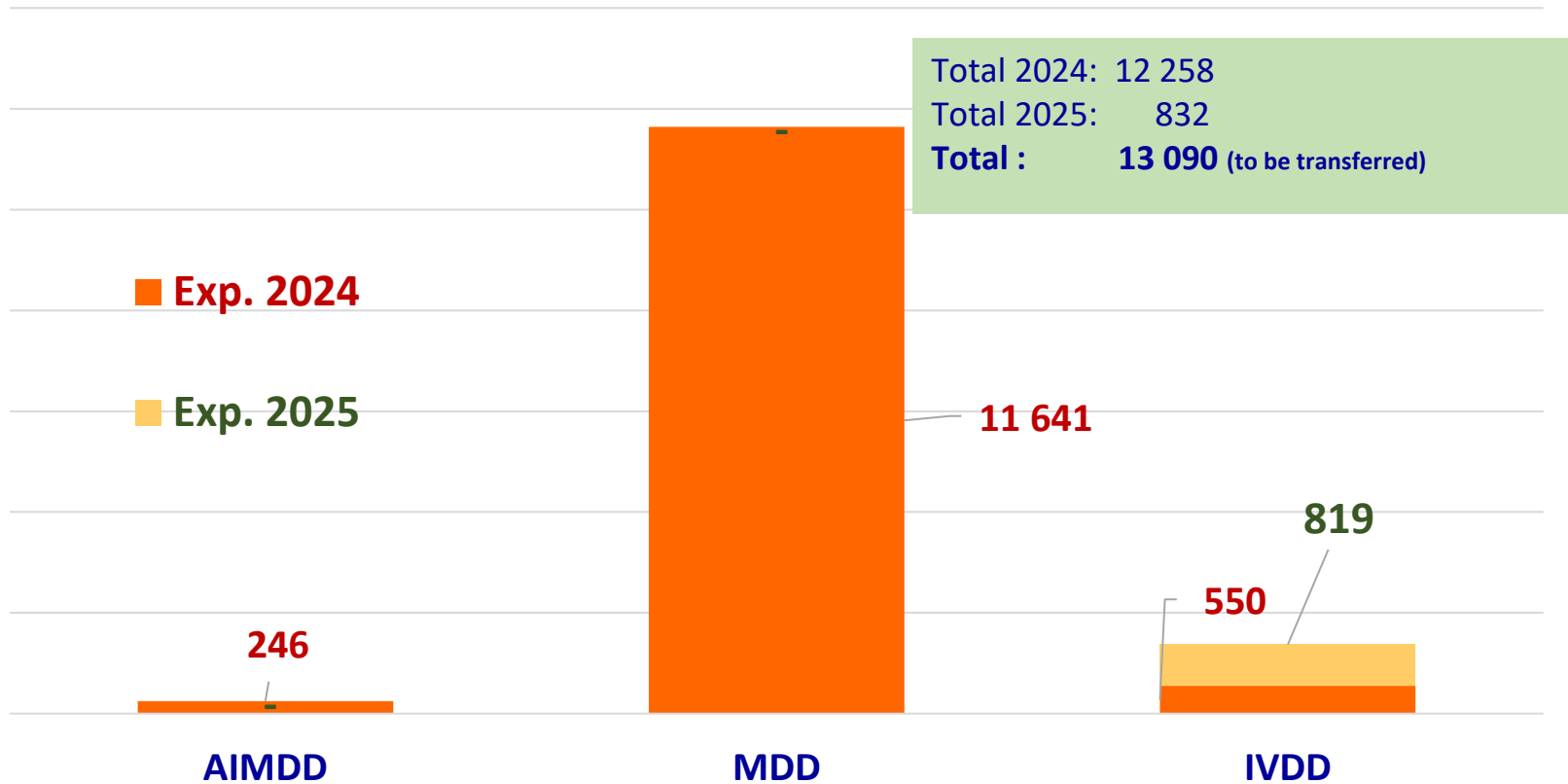
❖ Directives certificates remaining end 2023 and letters to confirm reception of an application



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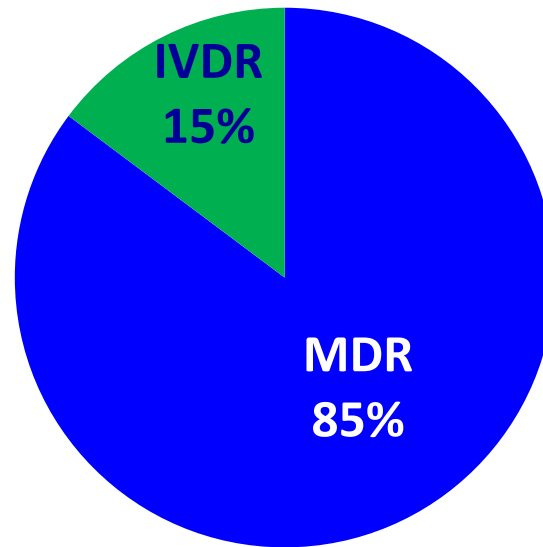
❖ Directives certificates expiration



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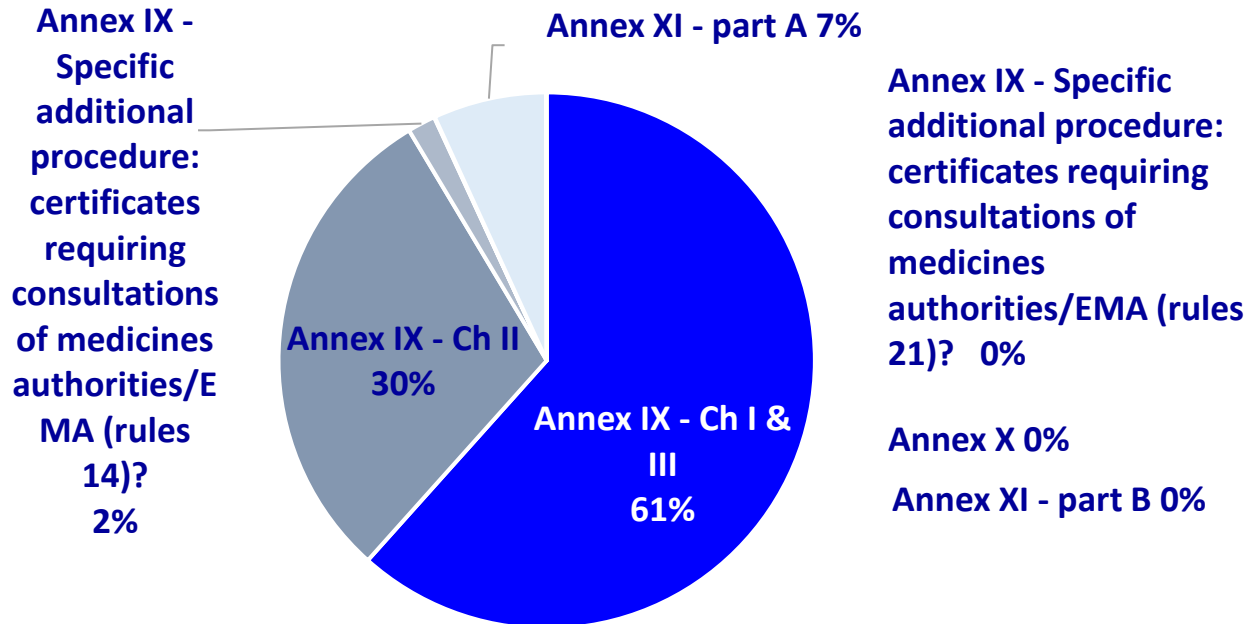
❖ Distribution of certificates between different Regulations



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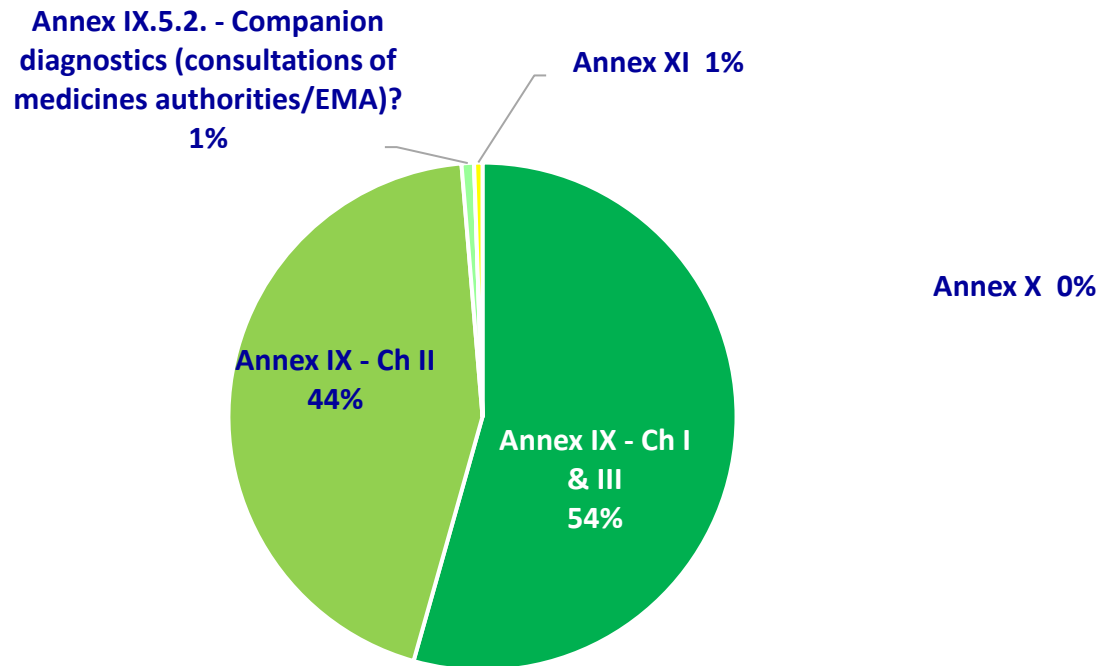
❖ Distribution of certificates between different conformity assessment modules under **MDR**



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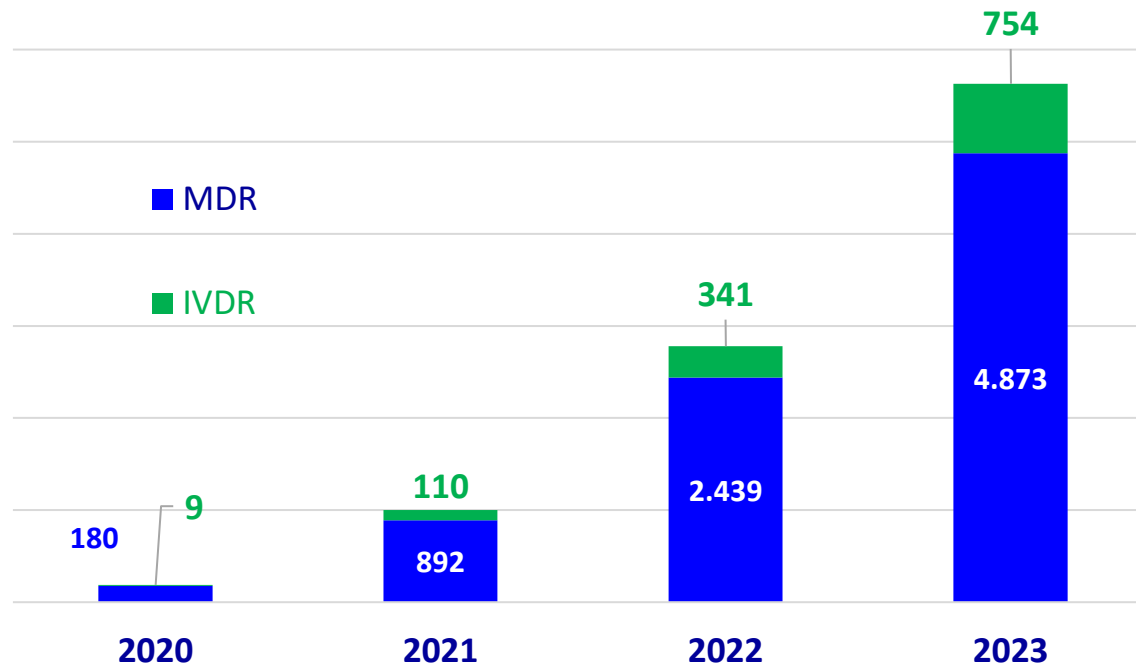
❖ Distribution between different conformity assessment modules under **IVDR**



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❖ Comparison of issued certificates among regulations

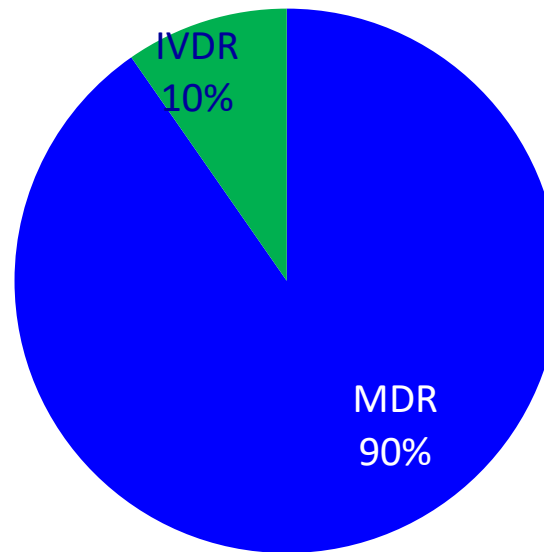


⇒ **2 fold** increase in issuance of **Regulations** certificates between 2022 and 2023

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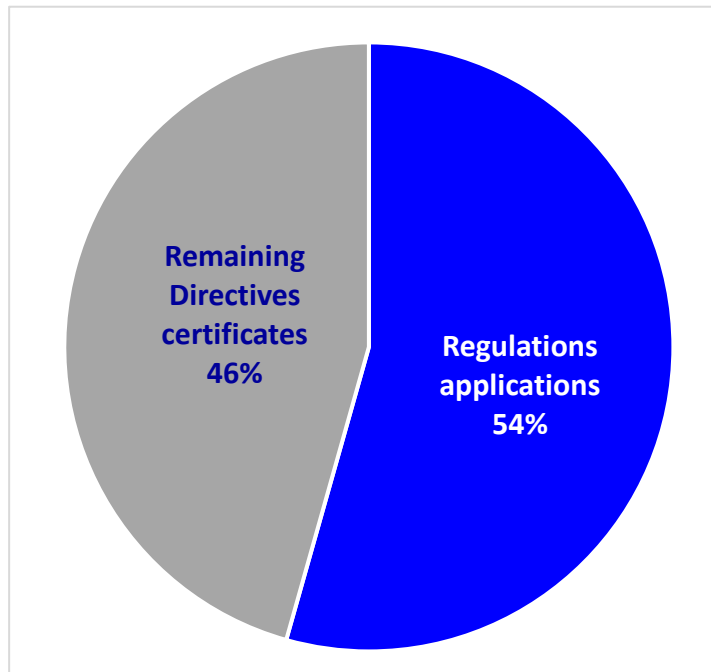
❖ Distribution of applications between different Regulations



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❖ Regulations **applications** versus Directives remaining certificates



To be noticed

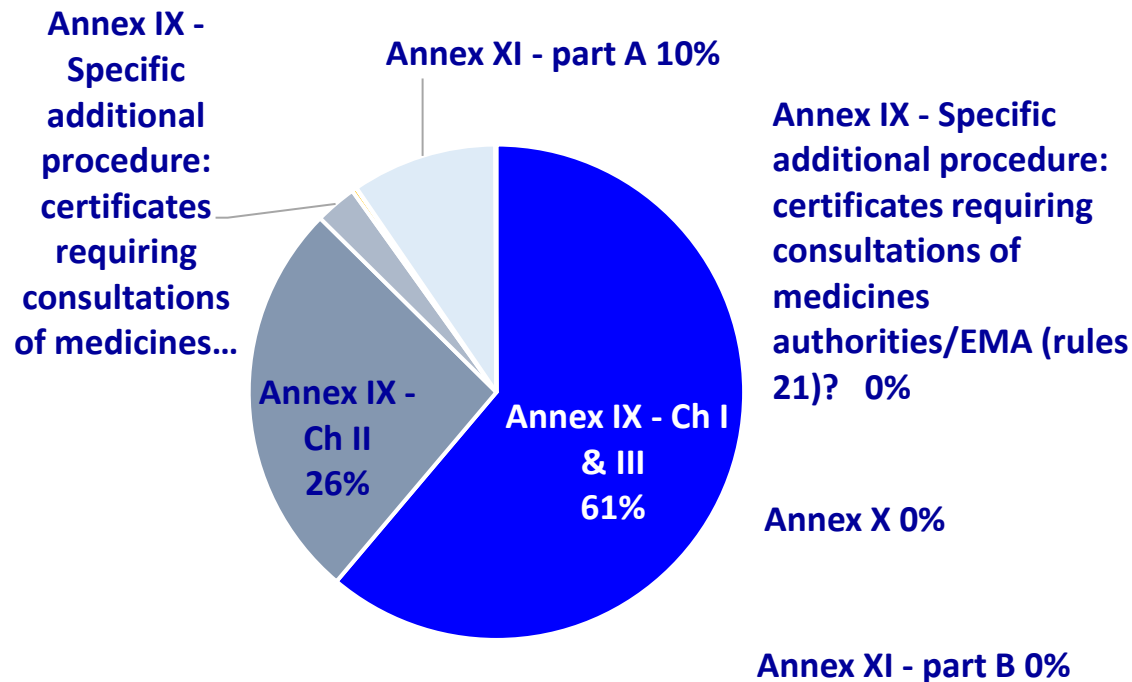
Does not take scopes into consideration

(although Regulations applications scope received often much smaller than Directives scopes)

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❖ Distribution of applications between different conformity assessment modules under MDR



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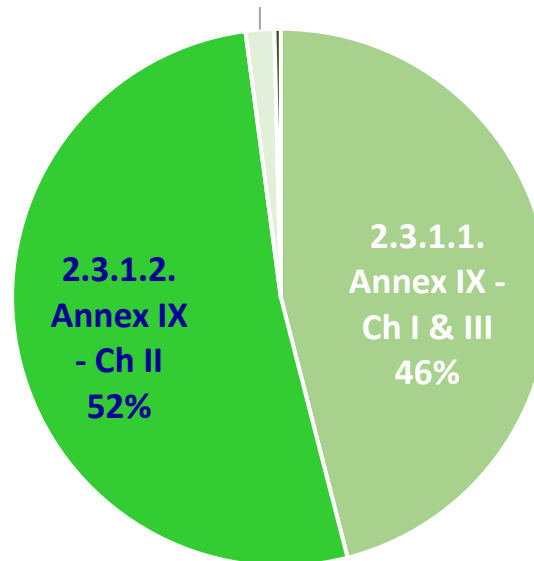


❖ Distribution of applications between different conformity assessment modules under **IVDR**

2.3.1.3. Annex IX.5.2. - Companion diagnostics (consultations of medicines authorities/EMA)? 2%

2.3.1.4. Annex X 0%

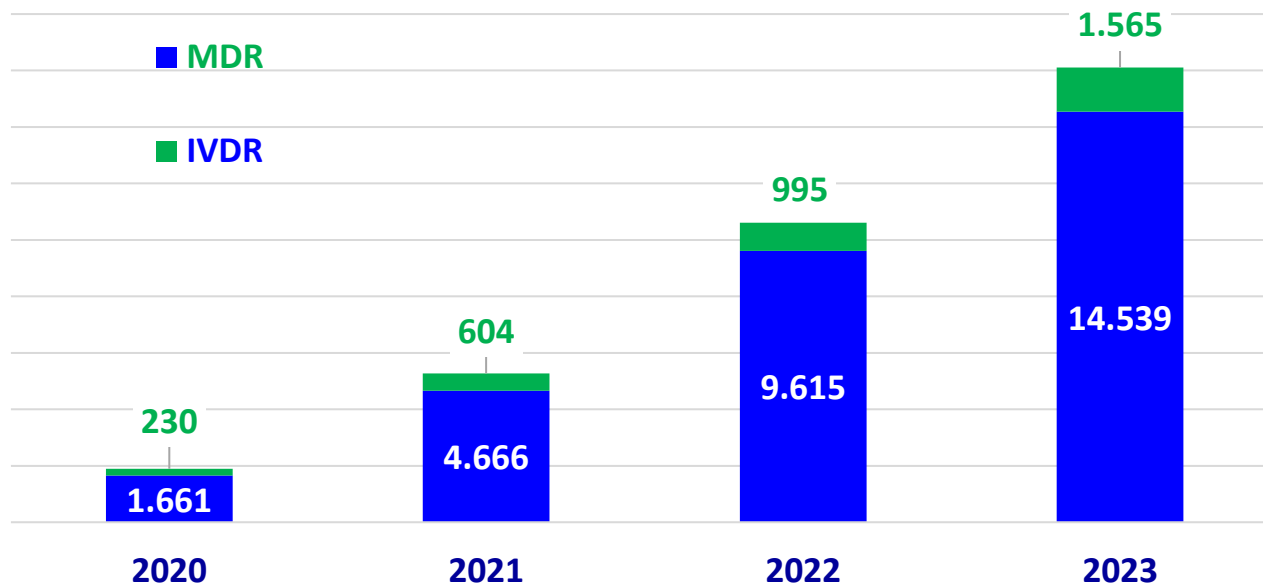
2.3.1.5. Annex XI 0%



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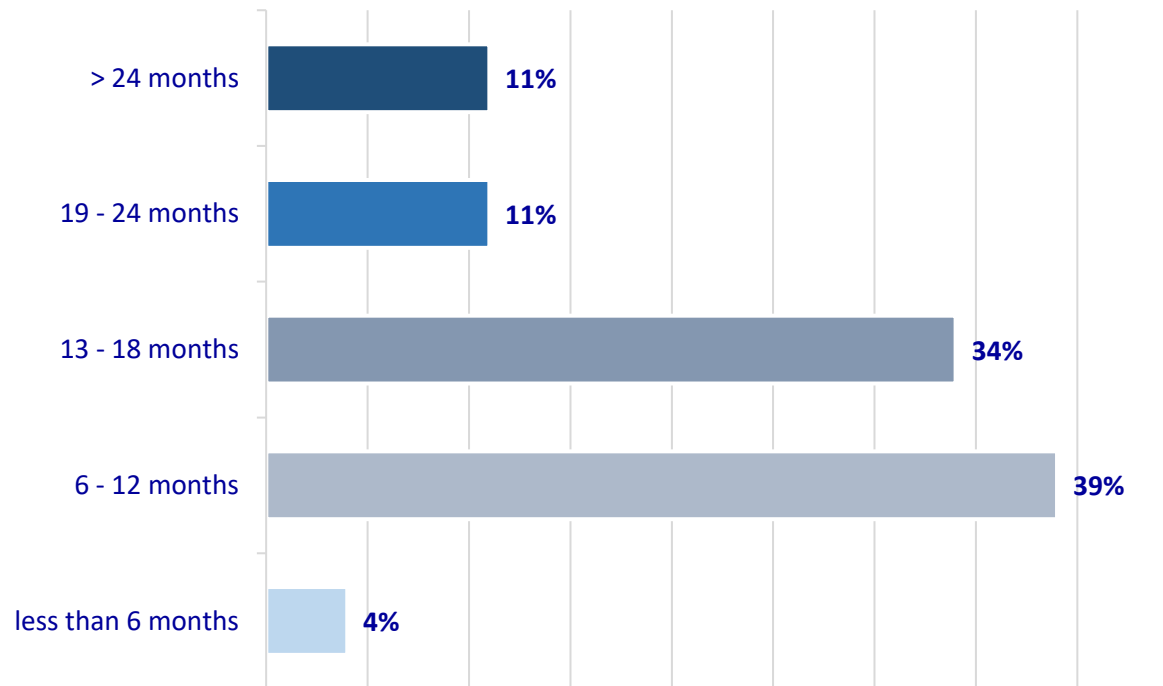
❖ Evolution of received applications against Regulations



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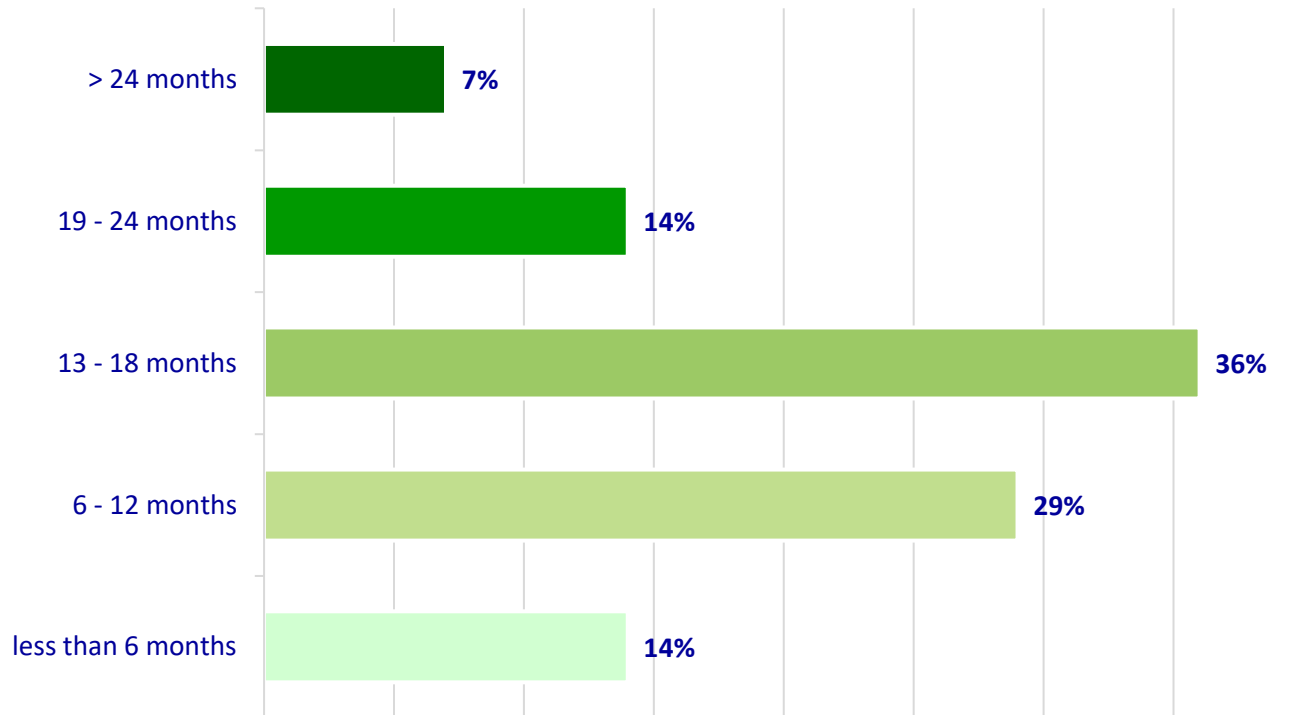
❖ Average time to reach issuance of a NEW (not renewal) MDR certificate



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



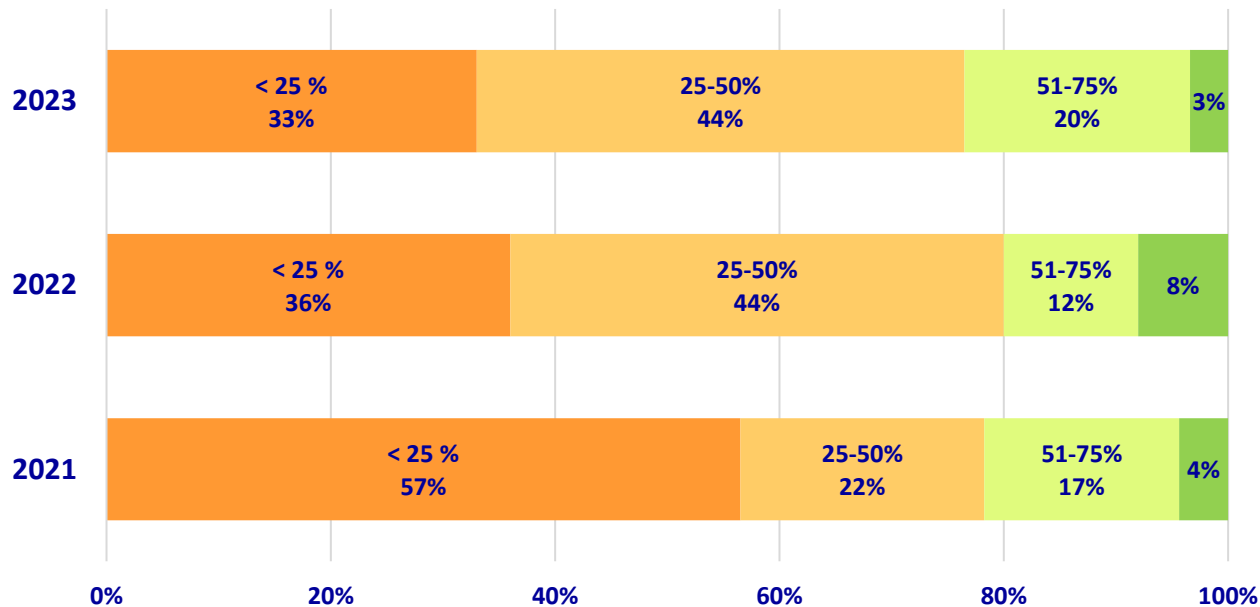
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❖ Completeness check - evolution

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

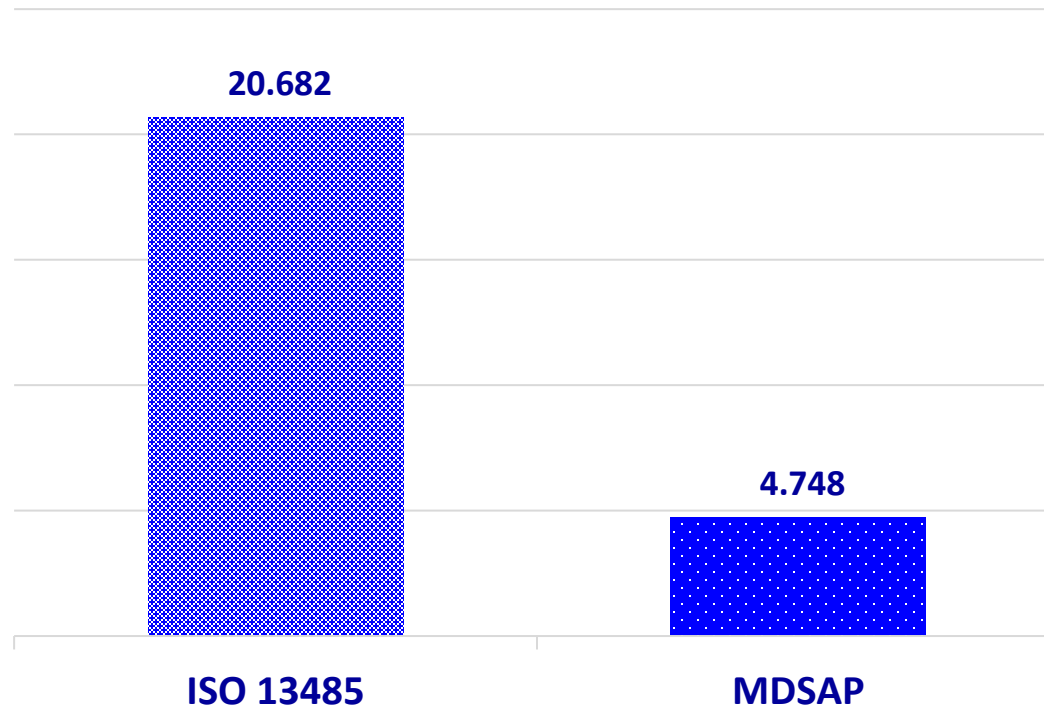
⇒ below graph with comparison of completeness over the 3 last years



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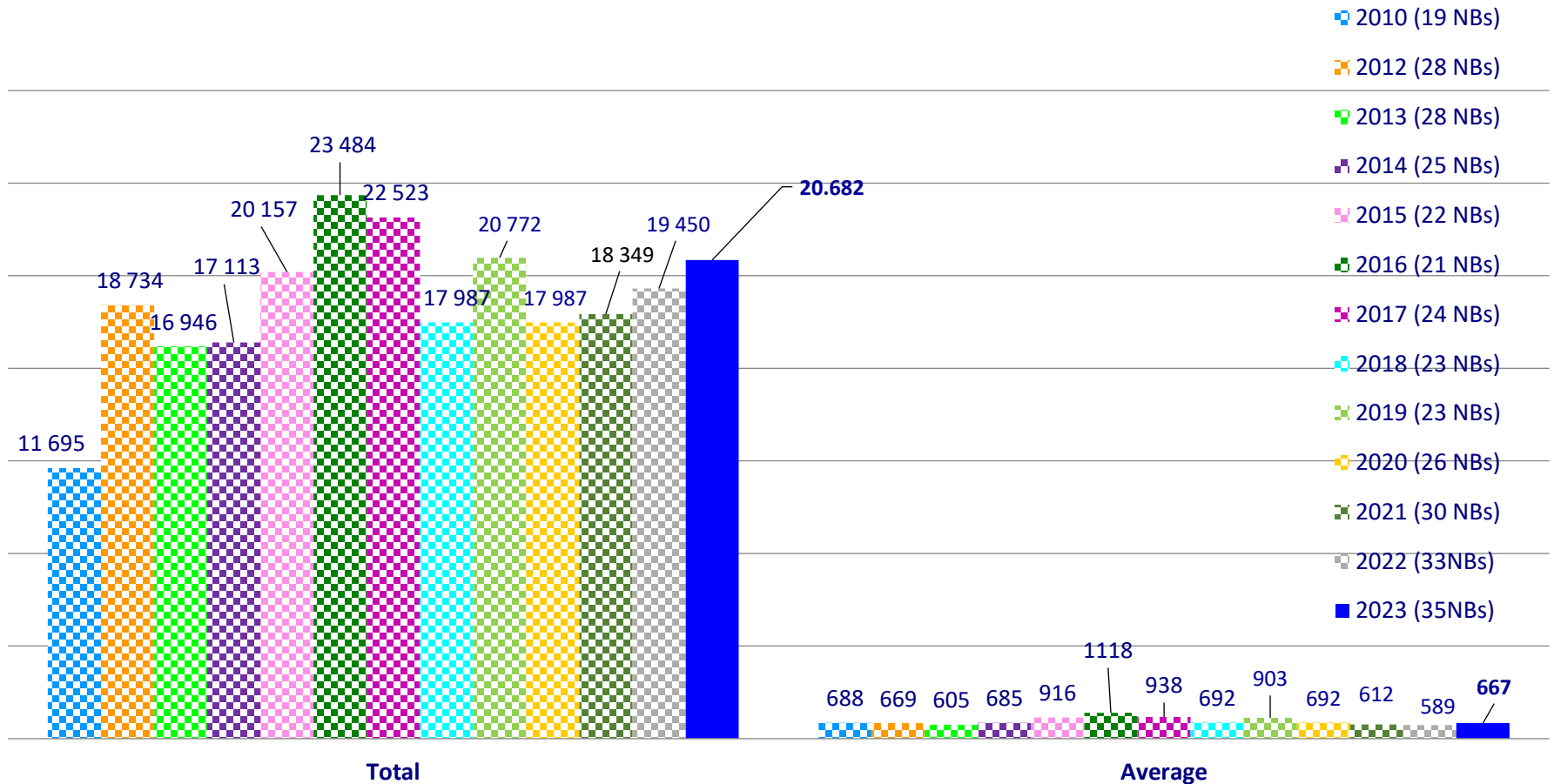
❖ Other certifications : ISO 13485 / MDSAP



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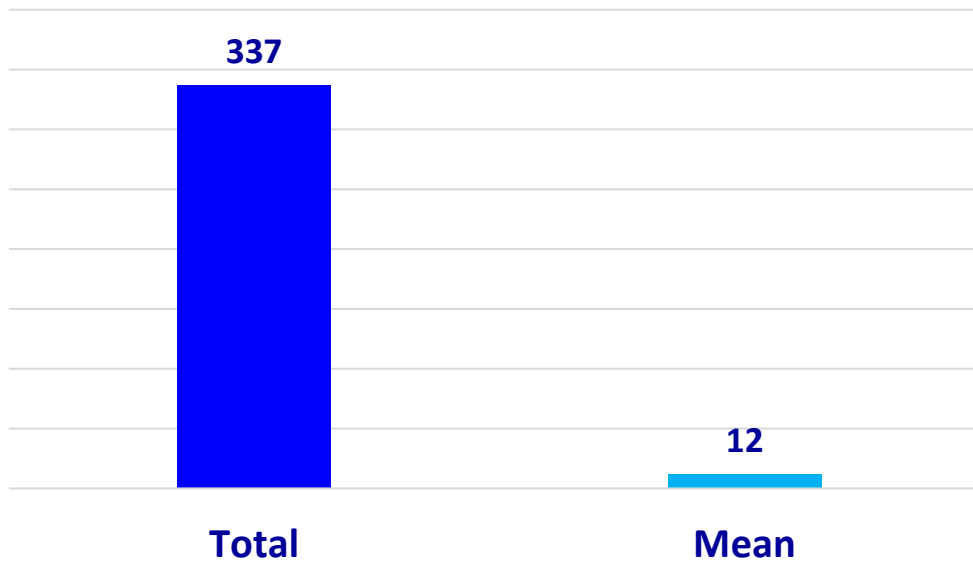
Valid certificates against ISO 13485 from 2010 to 2023 :



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❖ Number of certificates withdrawn in 2023



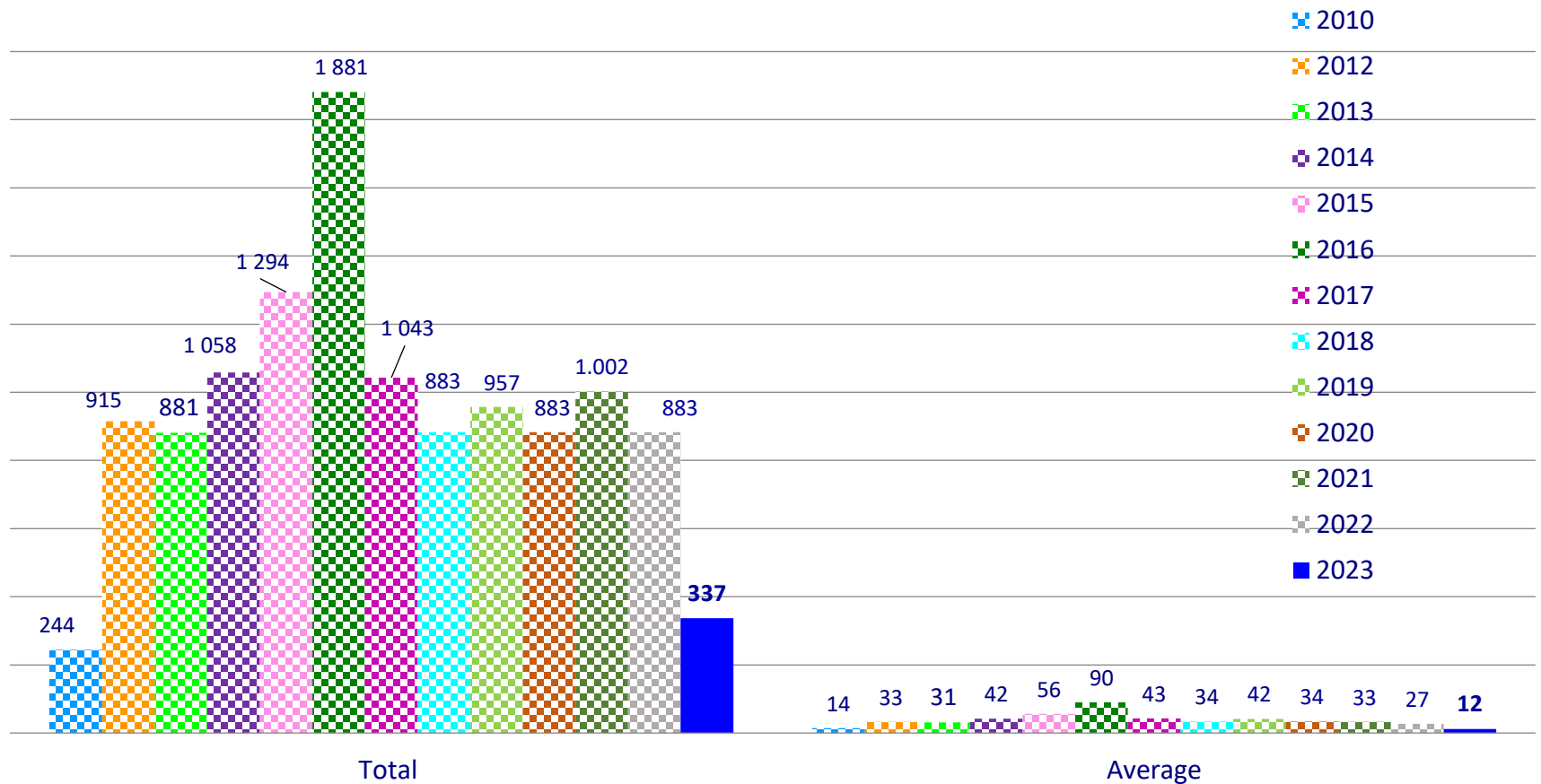
Reasons for withdrawing:

- Cancelled due to end of Directives
- Cessation of activity
- Change of NB
- Clients request
- Contractual obligations not fulfilled
- Financial issues
- No longer manufacturing product
- Non conformities not closed

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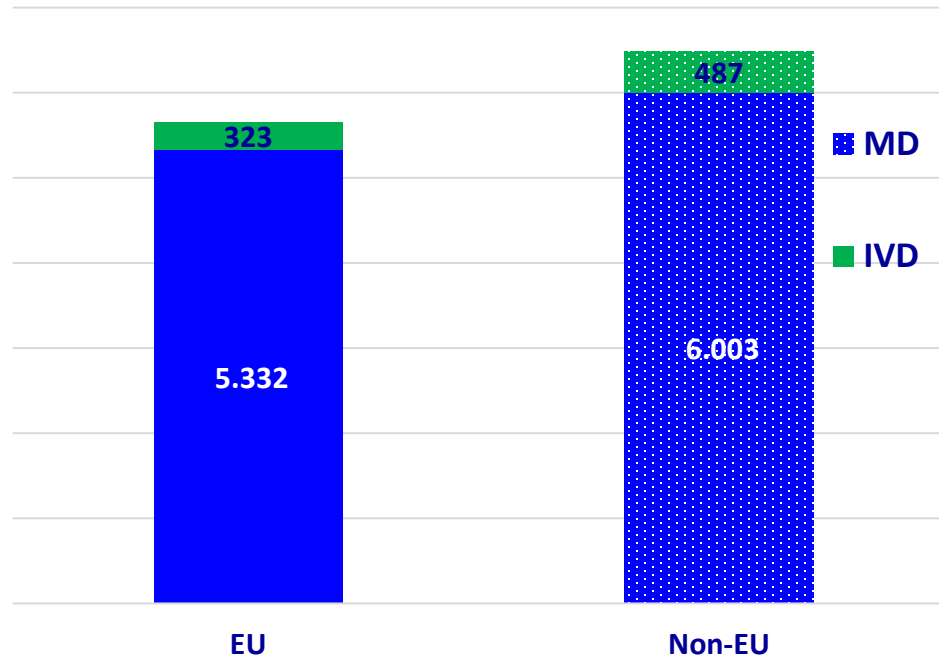
❖ Number of certificates withdrawn from 2010 to 2023 :



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❖ 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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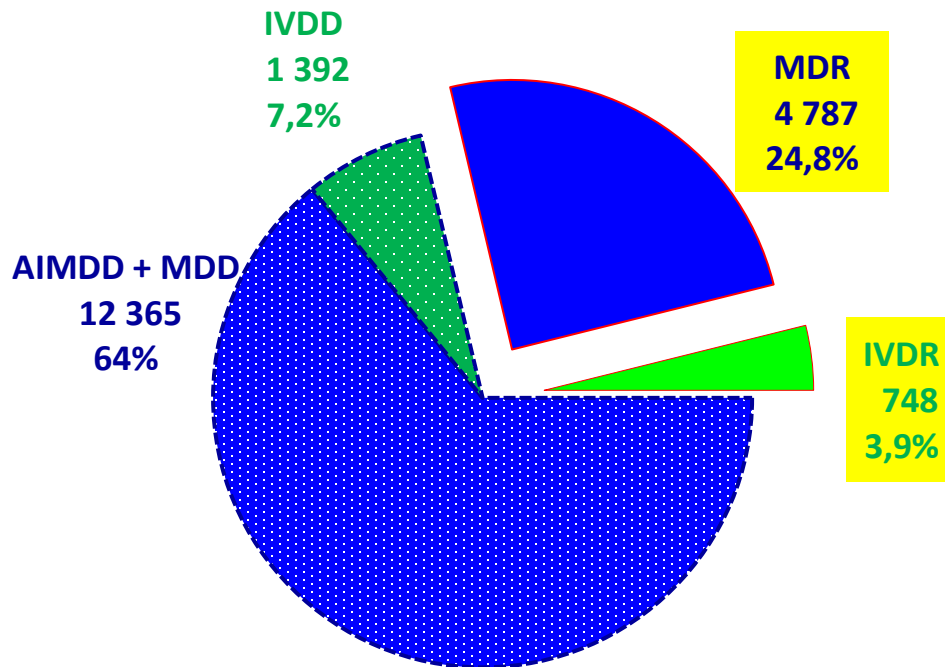


❖ Certification holders

Legend:

dotted pattern = Directives

plain pattern = Regulations



Estimation of number of Certification holders under Directives in 2023

= number of QMS certificates (AIMDD – Annex 2 & 5, MDD = Annex II, V & VI and IVDD = Annex 4).

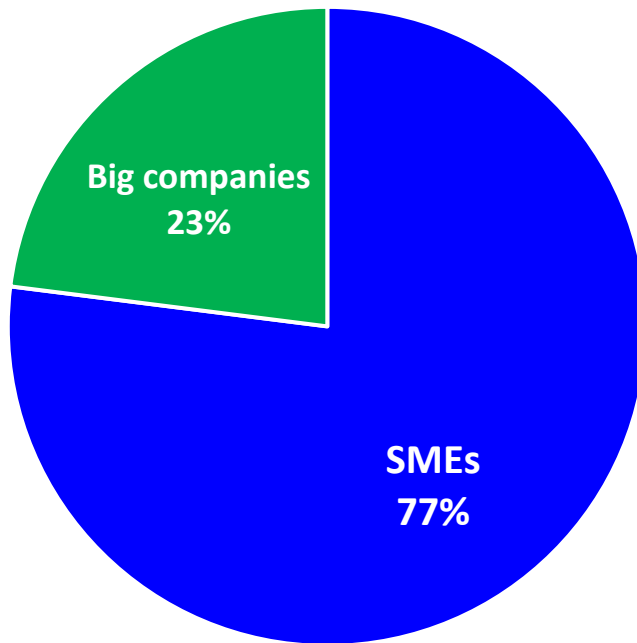
Estimation of number of Certification holders under Regulations in 2023

= number of QMS certificates MDR (= Annex IX - Ch I & III + Annex IX - Ch II + Annex XI - part A) and IVDR (= Annex IX - Ch I & III + Annex IX - Ch II + Annex XI).

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❖ Clients of the NBs: percentage of SMEs versus Big companies

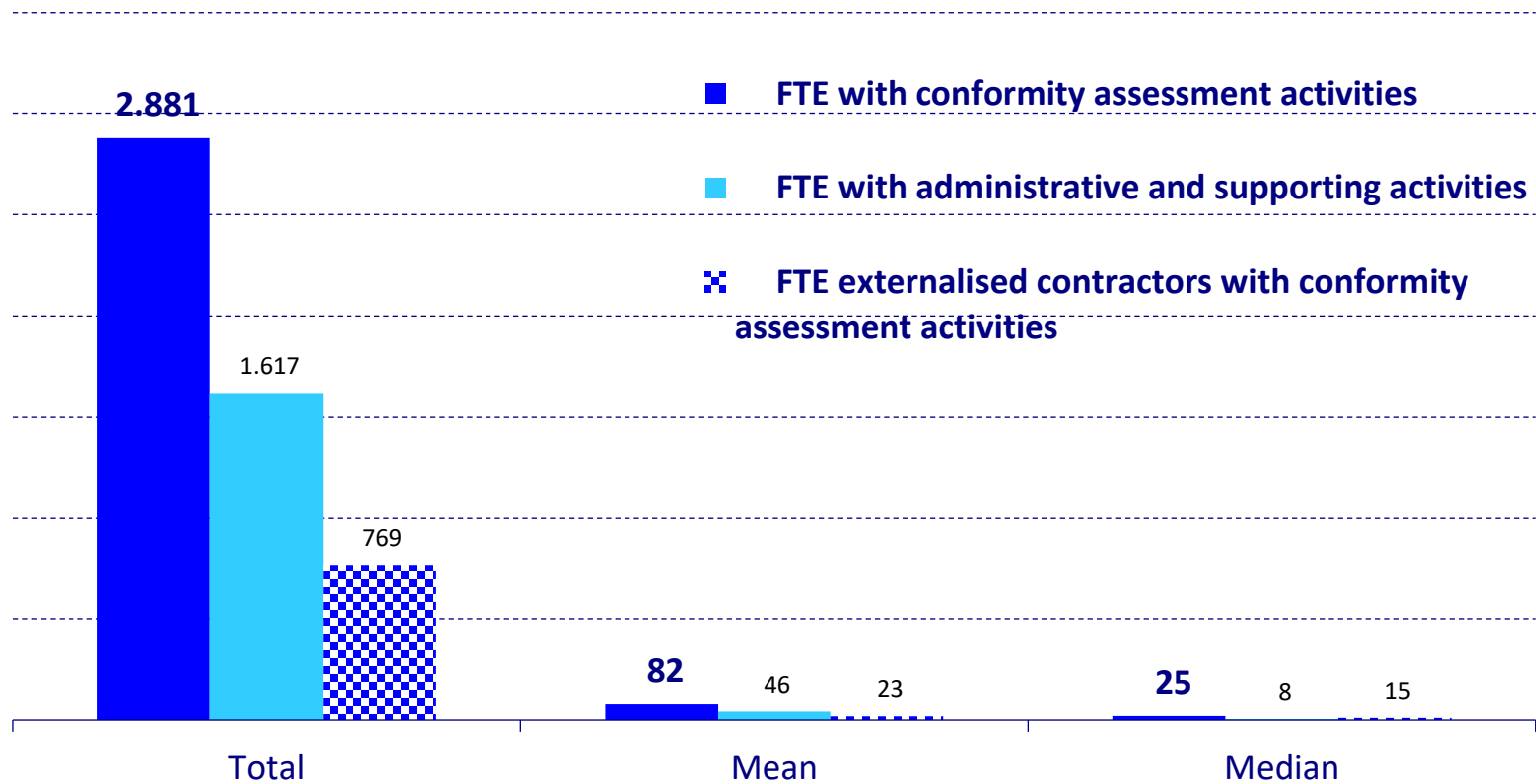


Responses of 29 members
with 27 NBs indicating
that
SMEs represent minimum
50% of their activities

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❖ Staff in 2023 (full time equivalent in MD sector)



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❖ Staff dedicated to conformity assessments

(full time equivalent in MD sector) - **From 2010 to 2023**



In 1 year, increase of

- 10,2% of the conformity assessment employees and contractors and
- 22% of the administrative support

Members



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