



The European Association of Medical devices
Notified Bodies

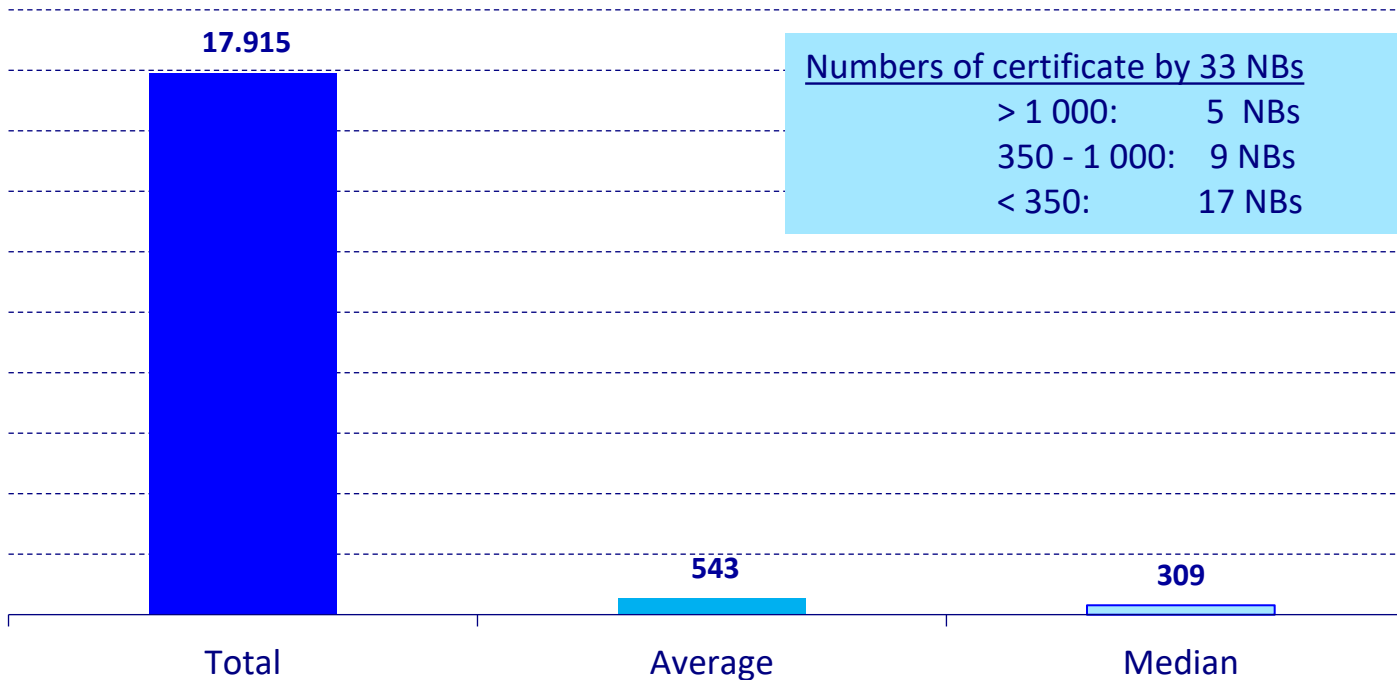
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Data from all 33 members (end 2022)

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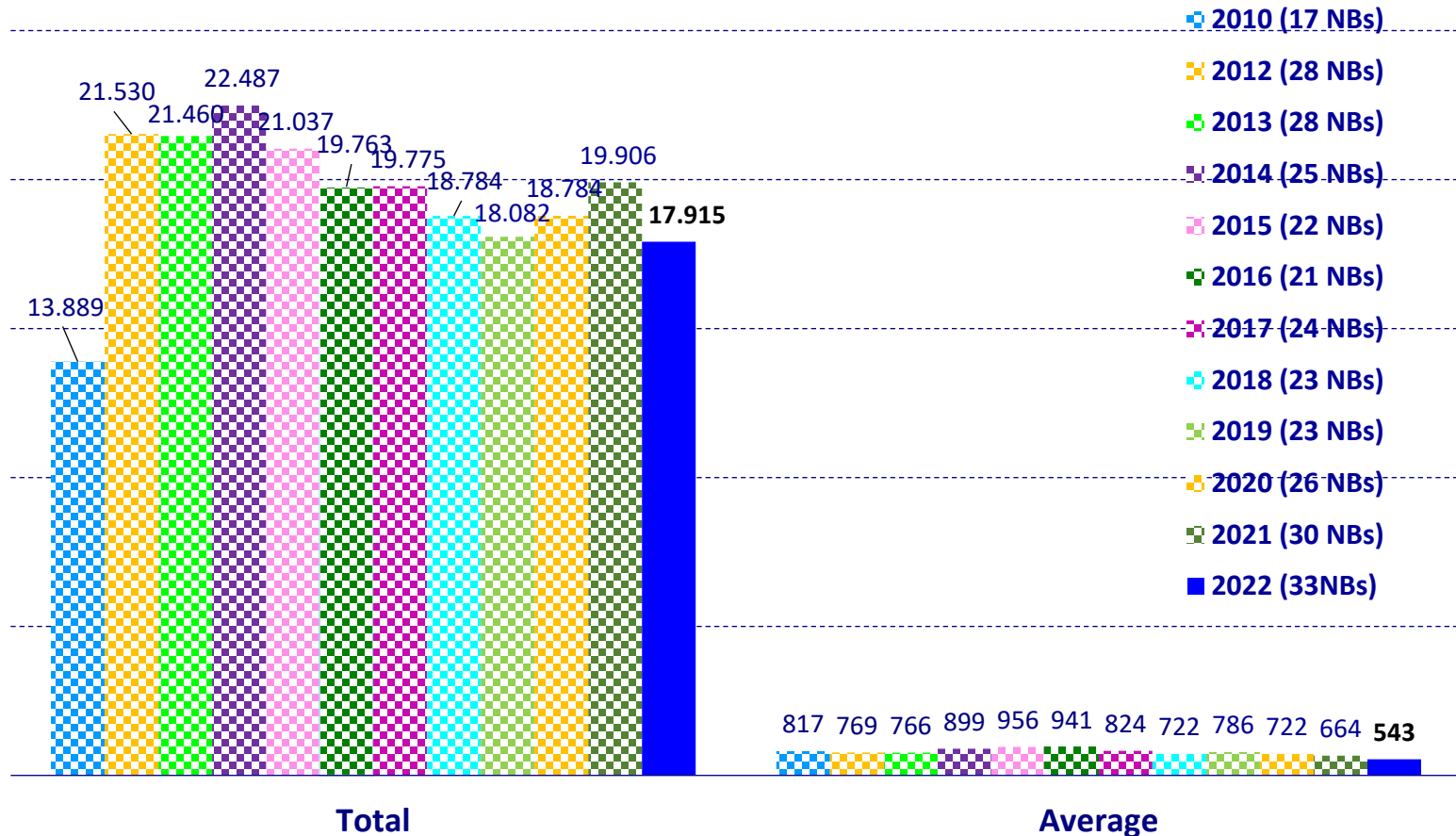
❖ Valid certificates at end of 2022



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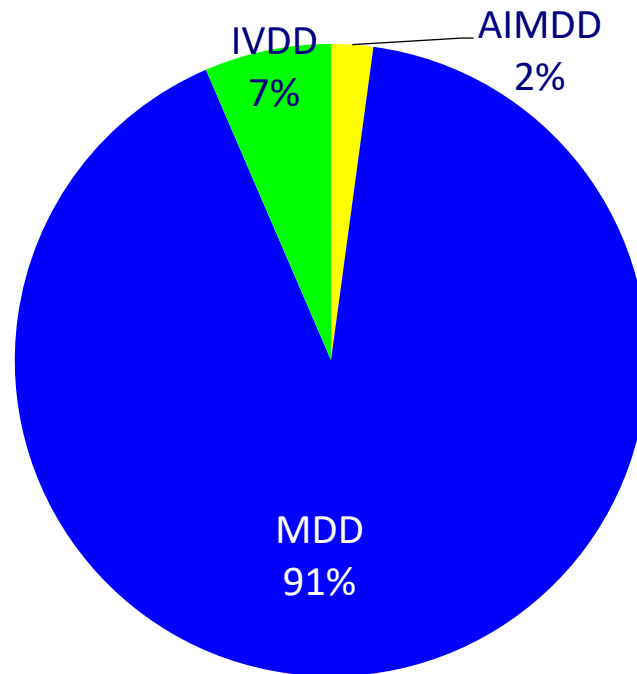
Valid CE certificates issued from 2010 to 2022



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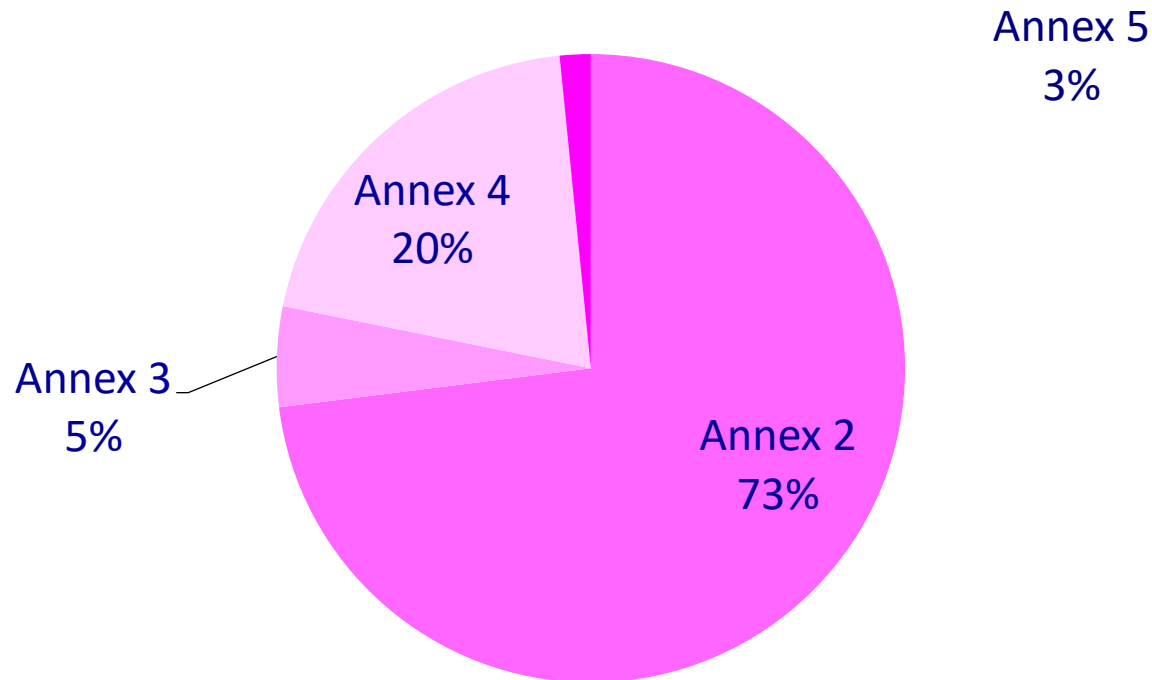
❖ Distribution of certificates between different directives



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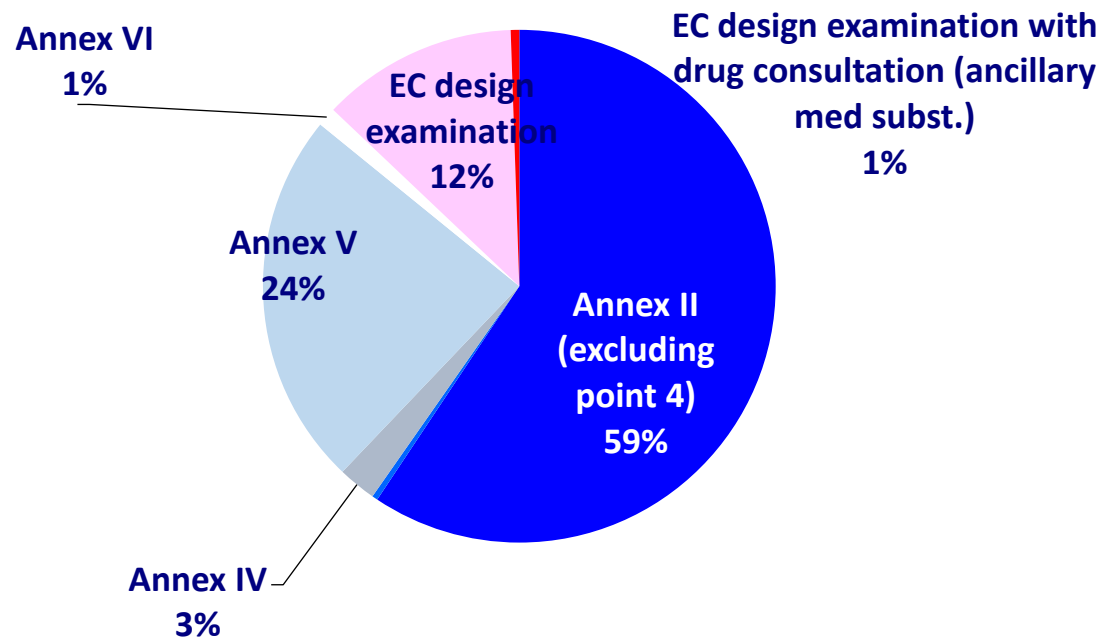
❖ Distribution between different conformity assessment modules under AIMDD



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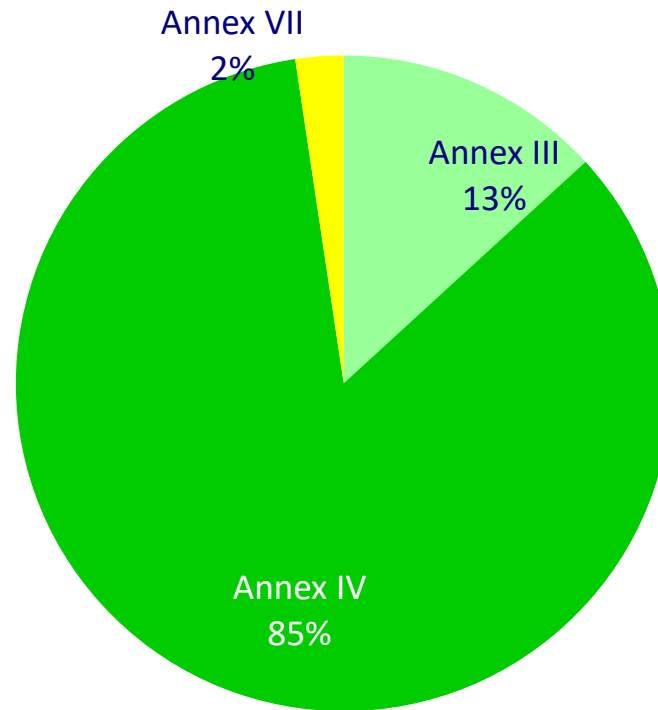
❖ Distribution between different conformity assessment modules under MDD



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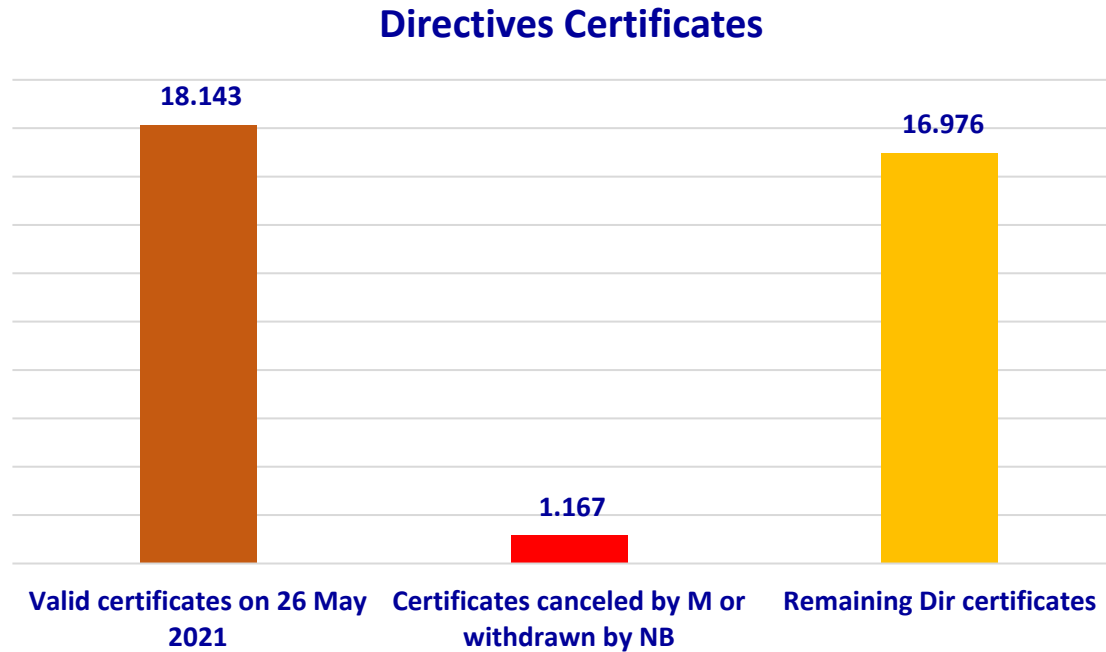
❖ Distribution between different conformity assessment modules under IVDD



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❖ Directives certificates remaining end 2022

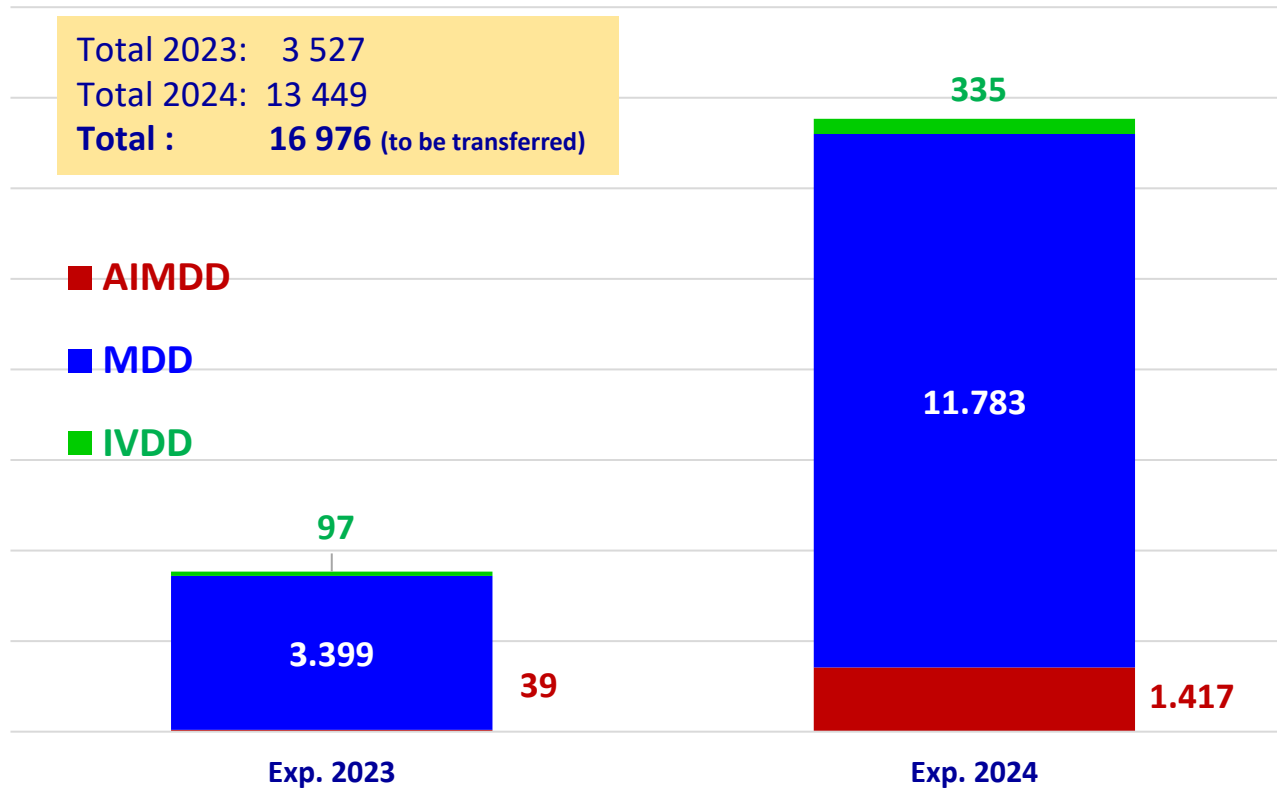


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❖ Directives certificates expiration

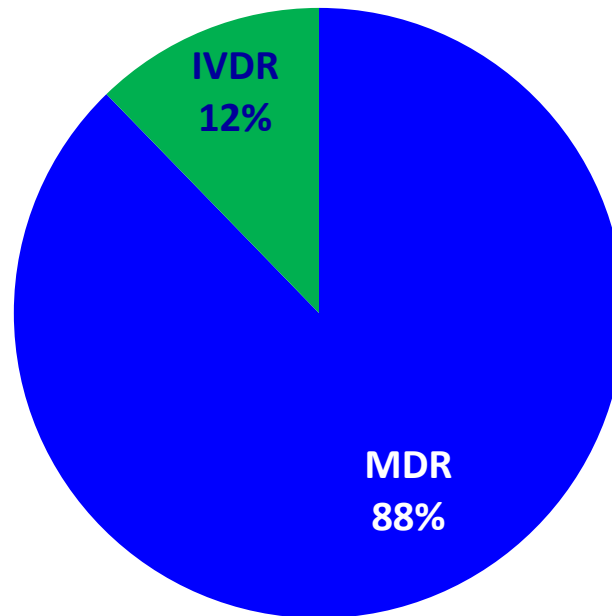
Directives certificates expiration



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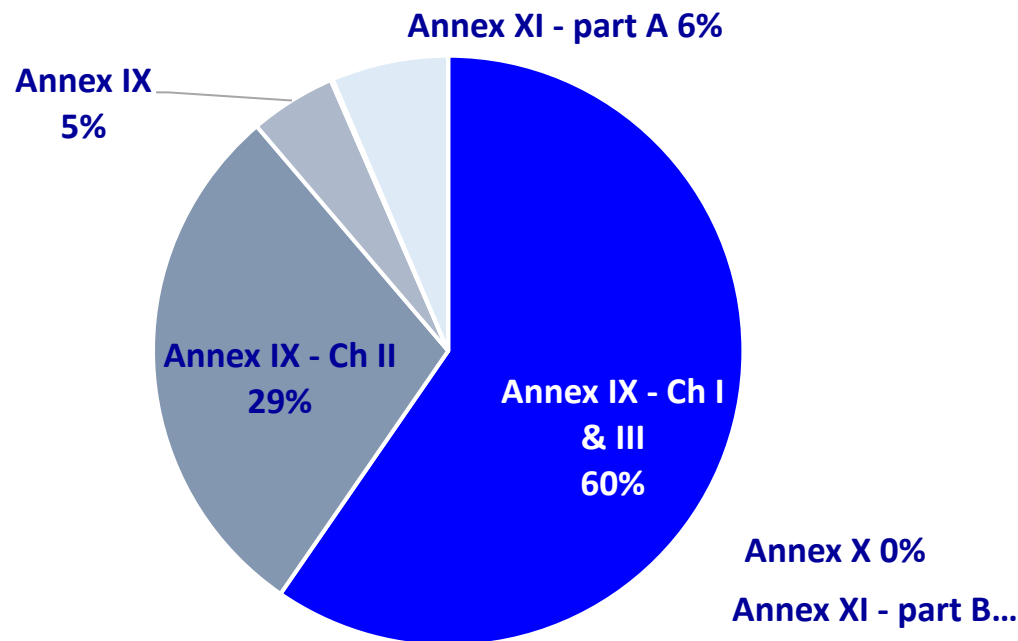
❖ Distribution of certificates between different regulations



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❖ Distribution of certificates between different conformity assessment modules under MDR

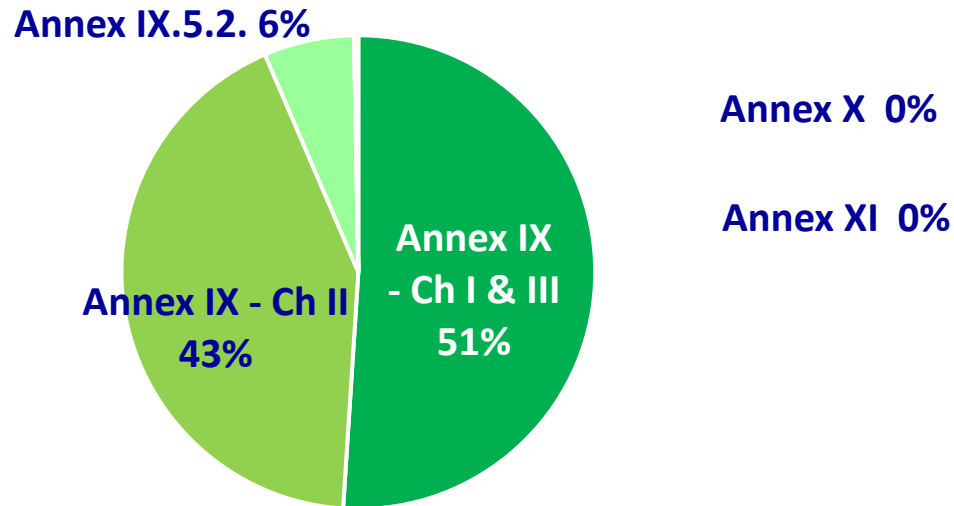


➔ 17% MDR certificates issued in comparison with total valid AIMDD + MDD certificates at end 2022

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❖ Distribution between different conformity assessment modules under IVDR

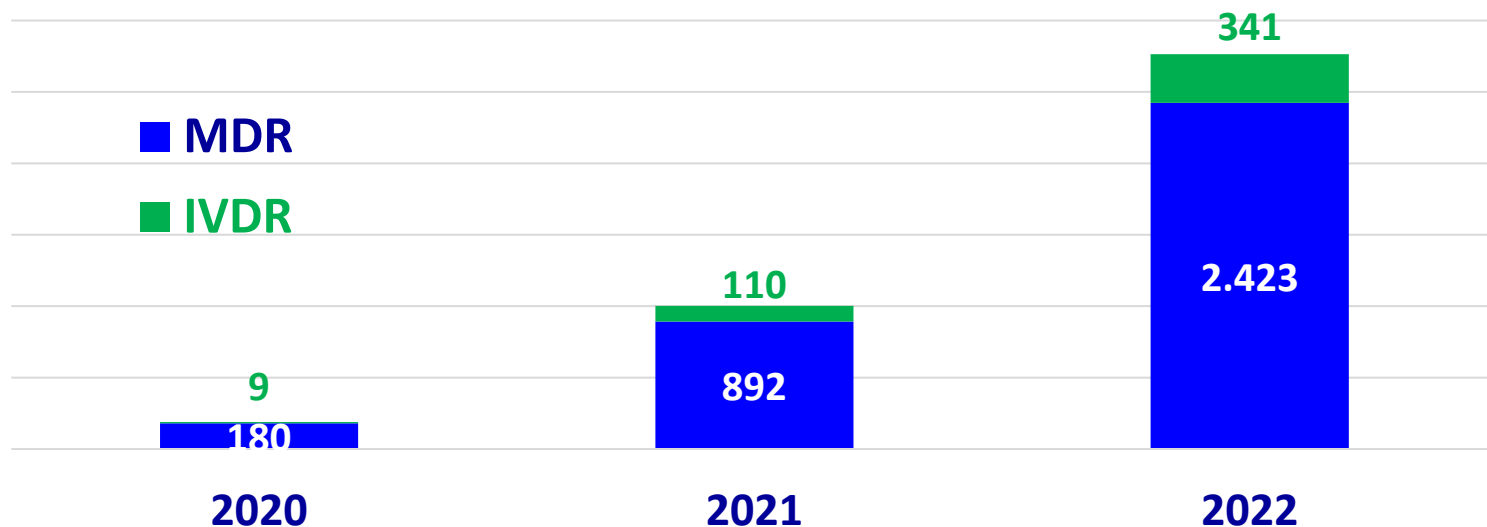


➔ 35 % IVDR certificates issued in comparison with total valid IVDD certificates at end 2022

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❖ Comparison of issued certificates among regulations

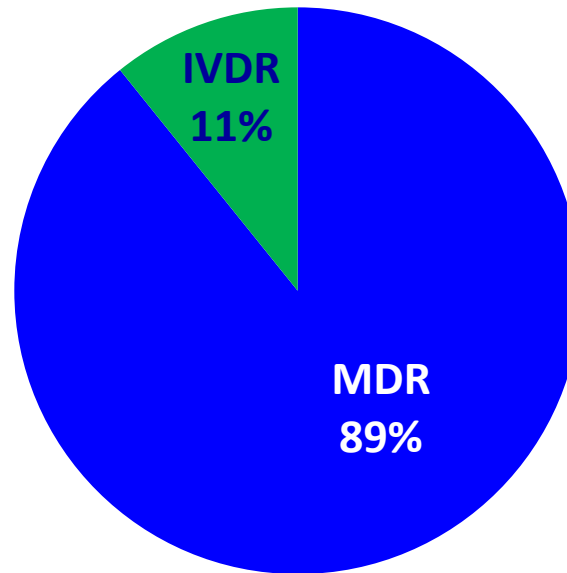


⇒ **2,7 fold** increase in issuance of **Regulations** certificates between 2021 and 2022

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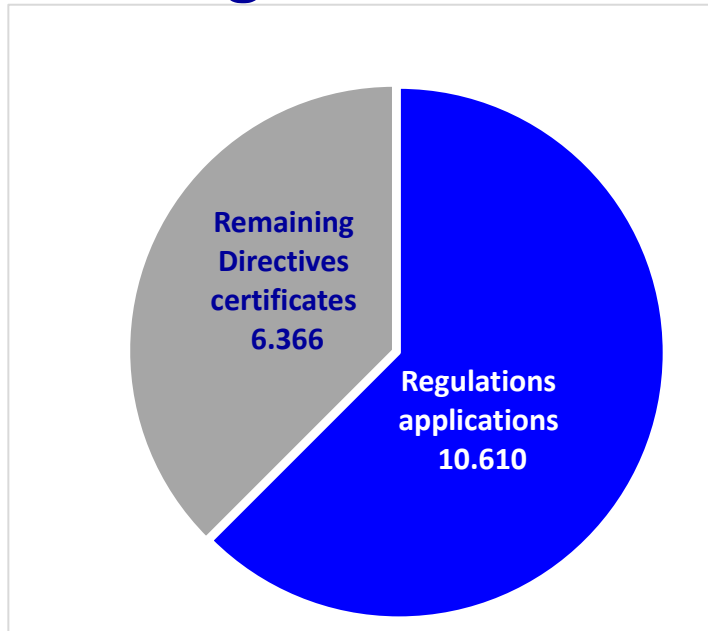
❖ Distribution of applications between different regulations



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❖ Regulations **applications** versus Directives remaining certificates



To be noticed

Does not take scopes into consideration

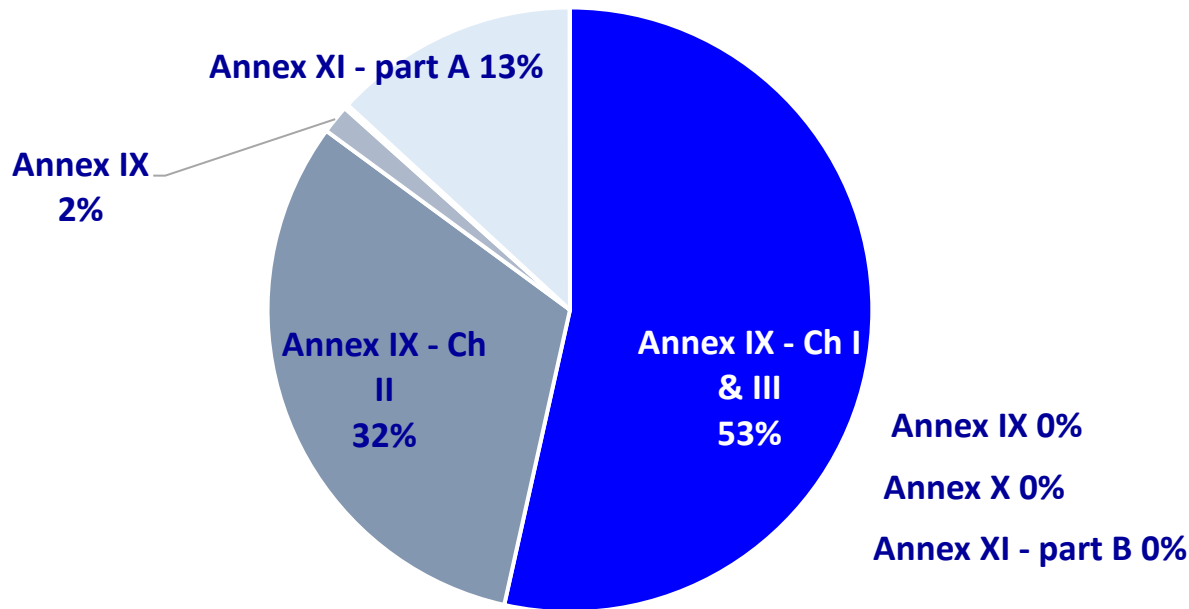
(although Regulations applications scope received often much smaller than Directives scopes)

➔ 63% **regulations** applications received at end 2022 in comparison with total valid **directives** certificates

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❖ Distribution of applications between different conformity assessment modules under MDR

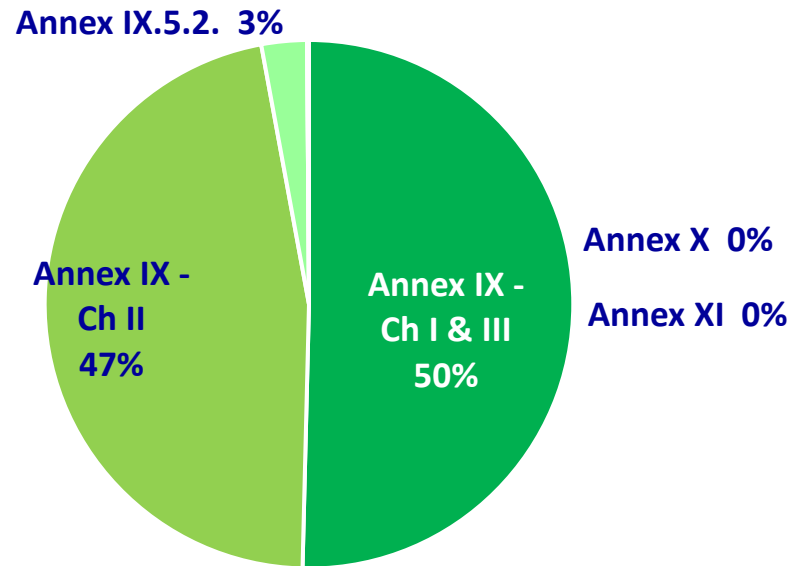


➔ 68 % MDR applications received at end 2022 in comparison with total valid AIMDD + MDD certificates

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❖ Distribution of applications between different conformity assessment modules under IVDR

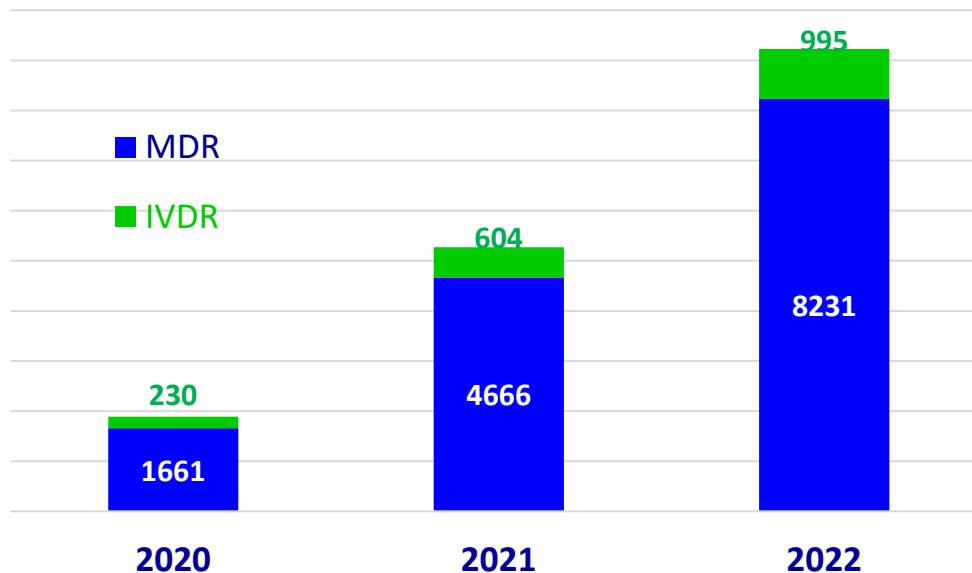


➔ 121 % IVDR applications received at end 2022 in comparison with total valid IVDD certificates

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❖ Comparison of received applications against regulations



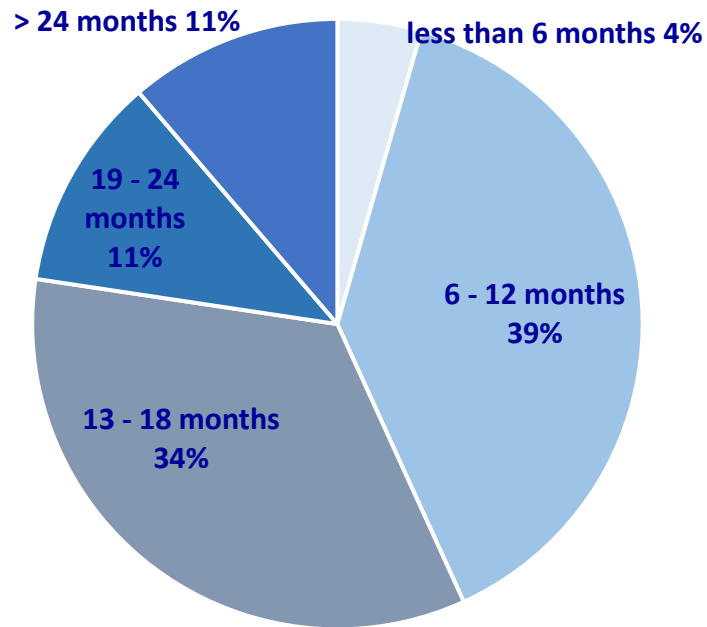
75% increase in receipt of applications against Regulations between 2021 and 2022

⇒ **Time flies: Still 55% of applications to be received**

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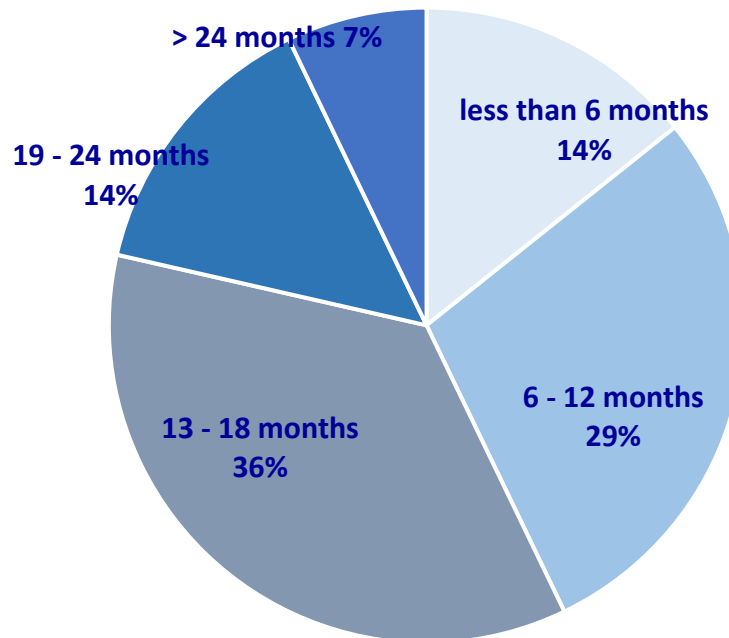
❖ Average time to reach issuance of a NEW (not renewal) MDR certificate



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



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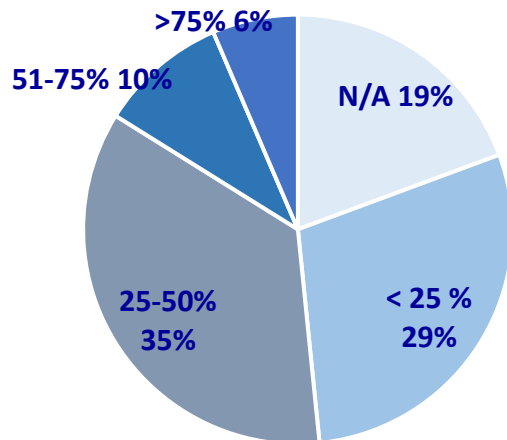
❖ Completeness check

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

⇒ below graphs with level of completeness

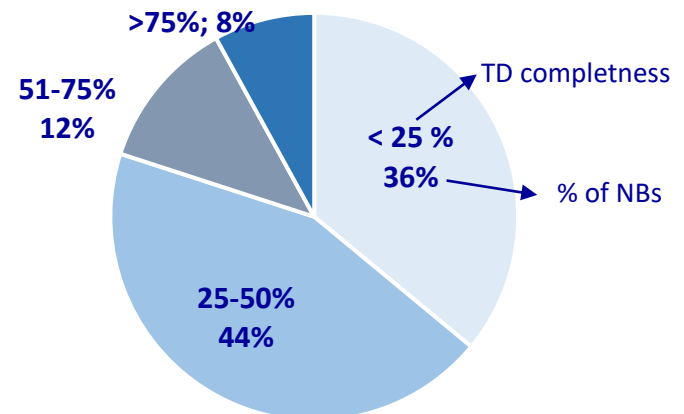
81% of NBs are doing the test

[Not yet applied by non designated against regulations]



⚠ On the basis of the NBs doing the check (81%).

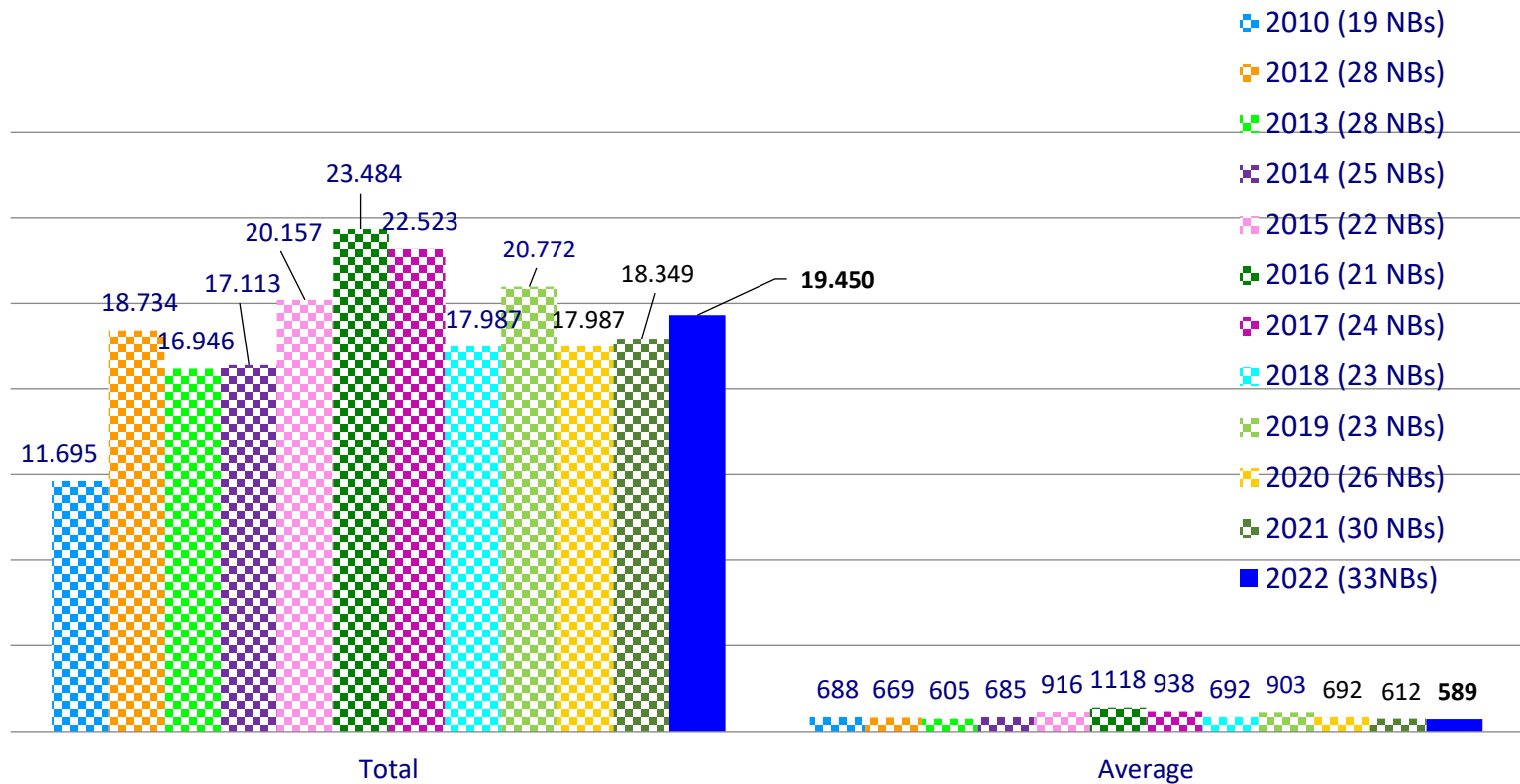
⇒ 80 % of NBs indicate that the TDs submitted are missing half of the needed information.



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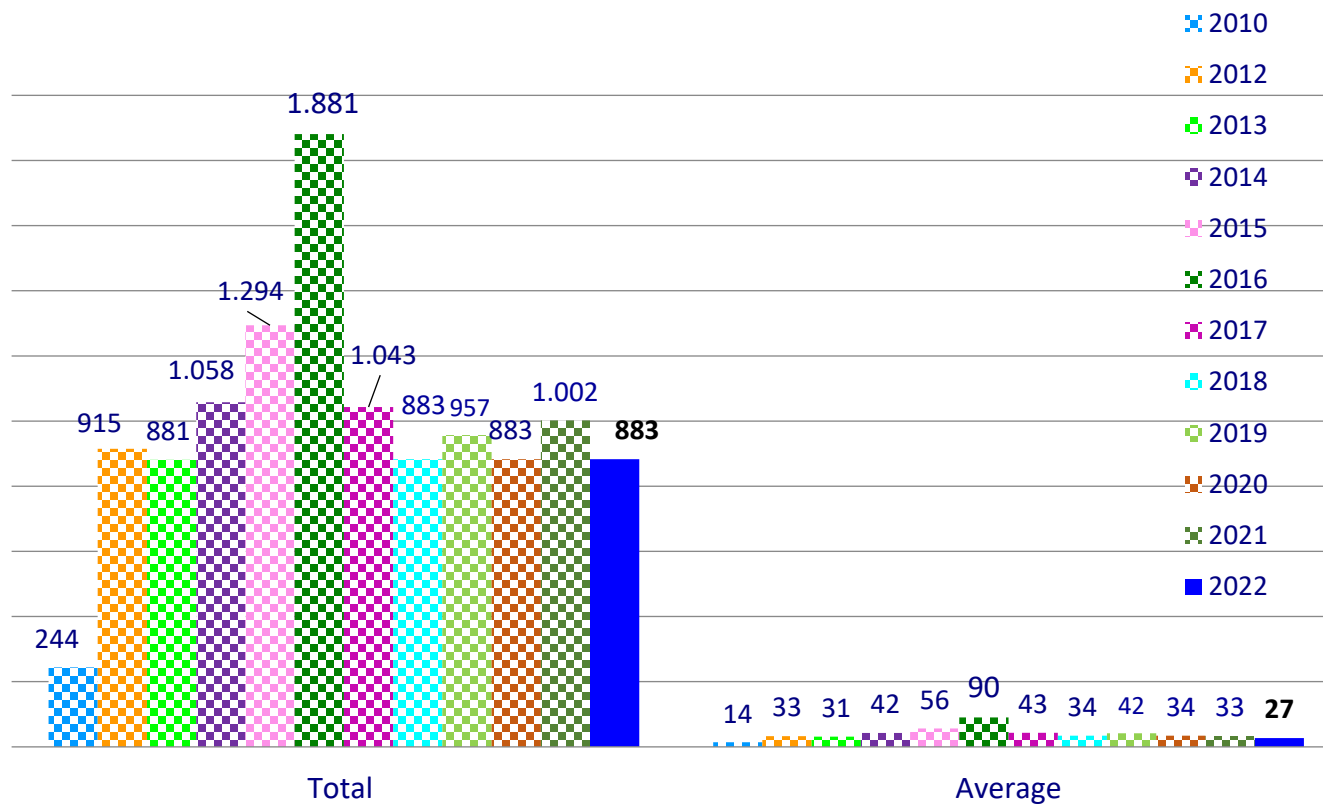


❖ Valid certificates against ISO 13485 from 2010 to 2022 :



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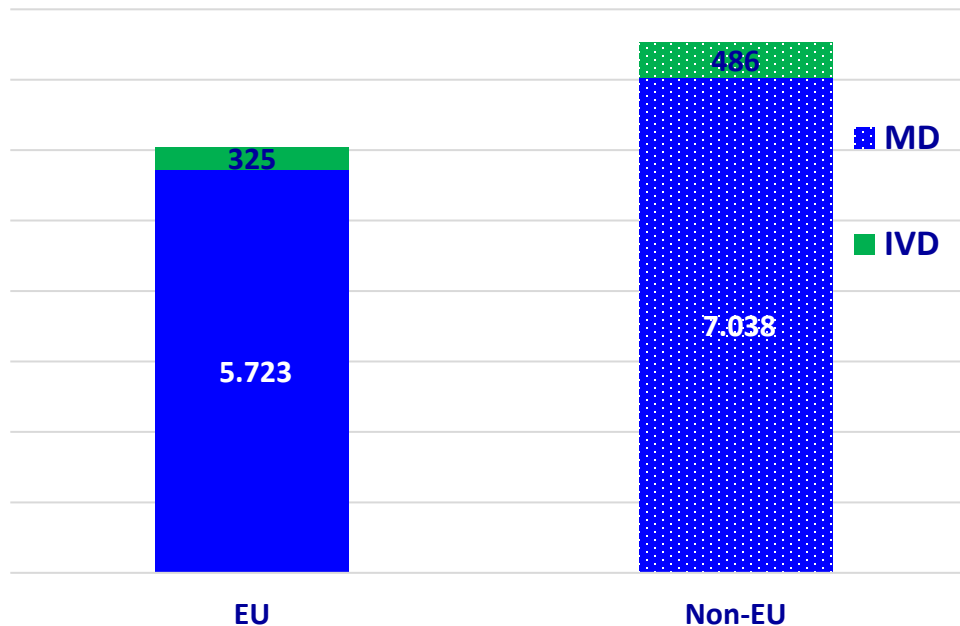
❖ Number of certificates withdrawn in 2022 from 2010 to 2022 :



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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 have both a QMS Directive certificate and a QMS Regulation certificate.

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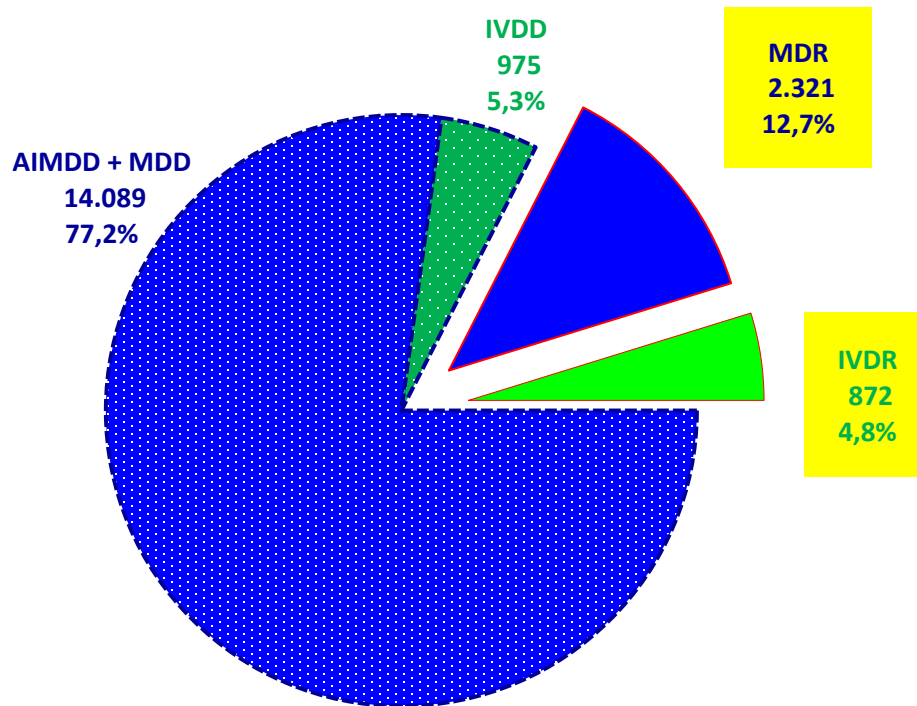


❖ Certification holders

Legend:

dotted pattern = directives

plain pattern = regulations



Estimation of number of Certification holders under Directives in 2022

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

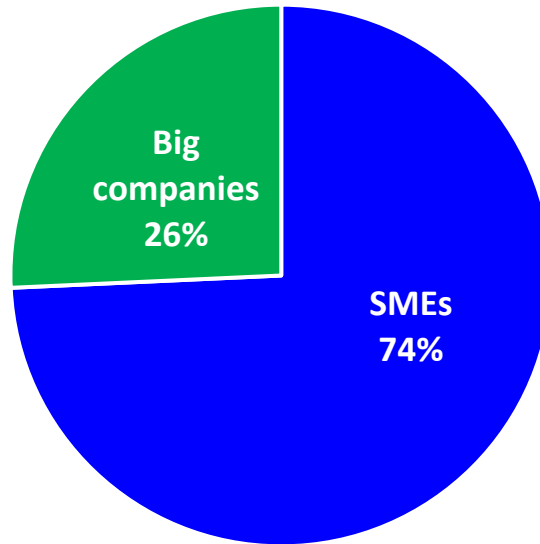
Estimation of number of Certification holders under Regulations in 2022

= 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

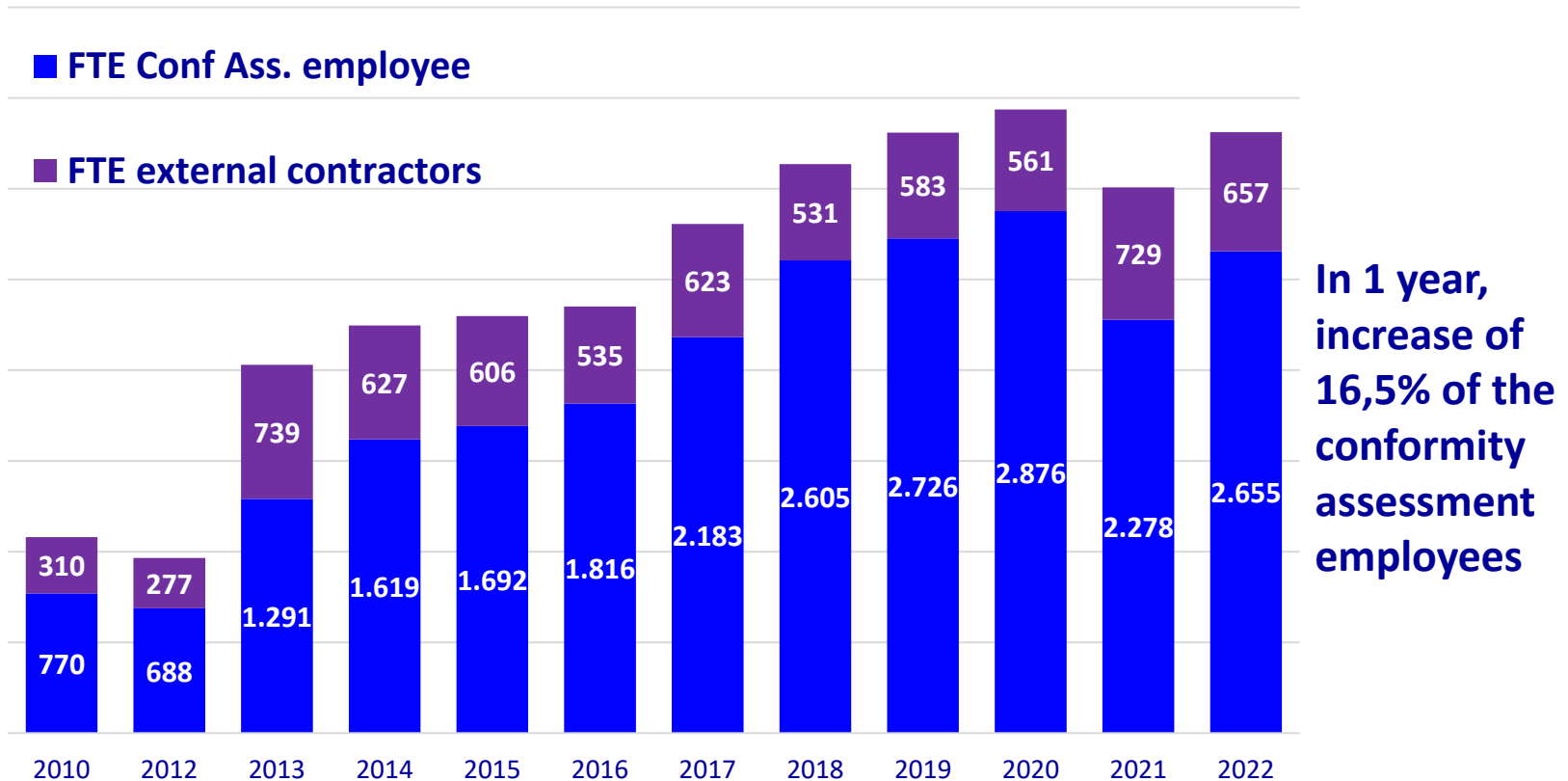


Responses of 29 members
with 27 NBs indicating
that
SMEs represent minimum
50% of their activities

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❖ Staff dedicated to conformity assessments (full time equivalent in MD sector) - From 2010 to 2022



Members



ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.
NATIONAL EVALUATION CENTER
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