



The European Association of Medical devices  
Notified Bodies

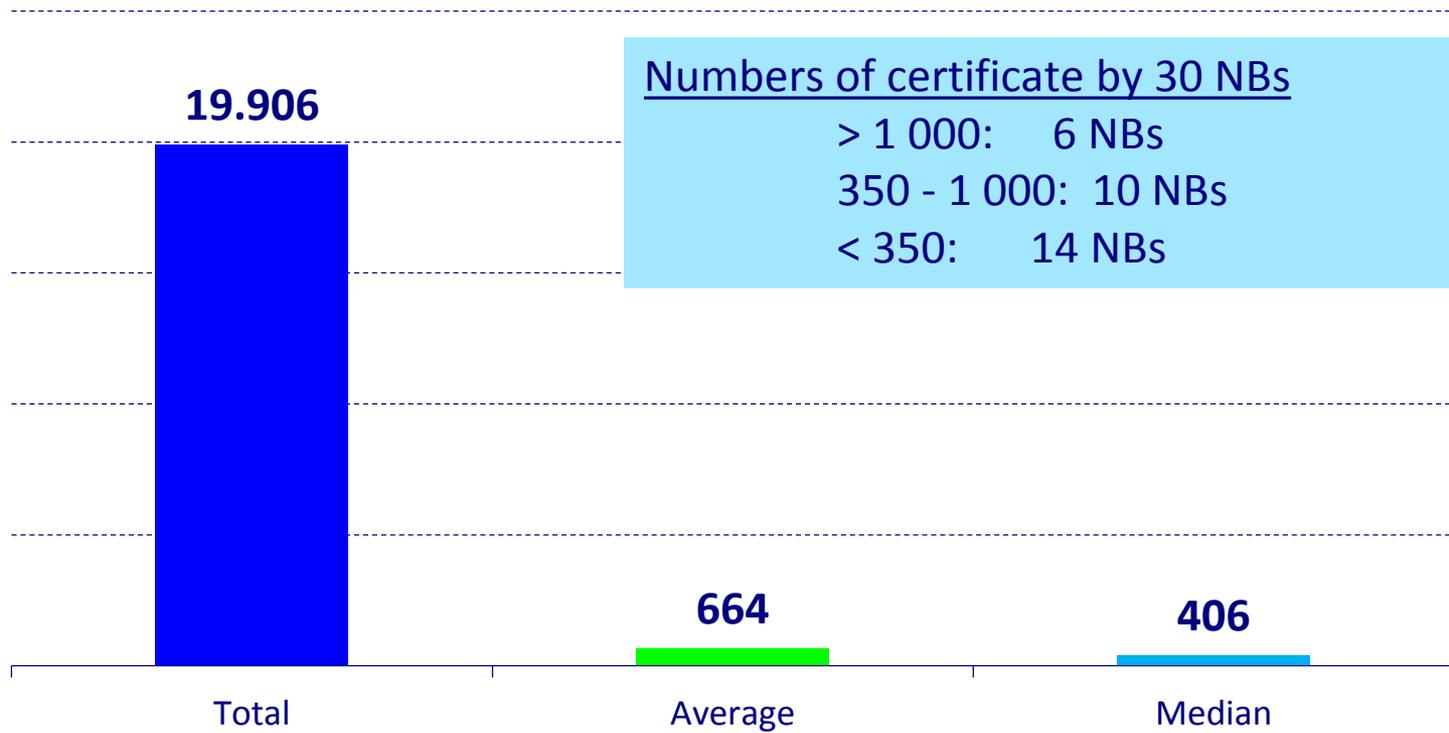
# Medical Device Survey 2021

## Data from all members (end 2021)

# Medical Device Survey 2021



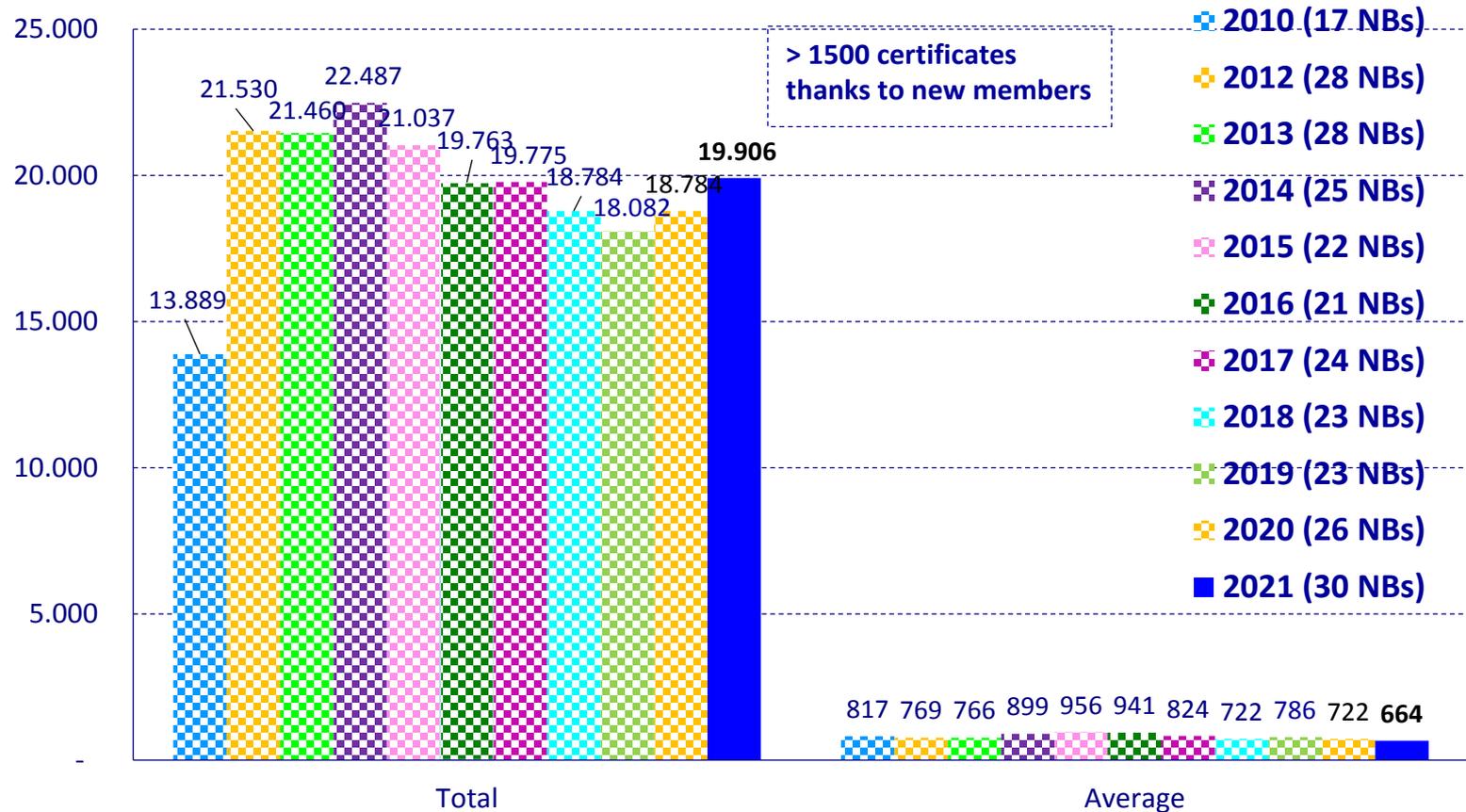
## ❖ Valid certificates at end of 2021



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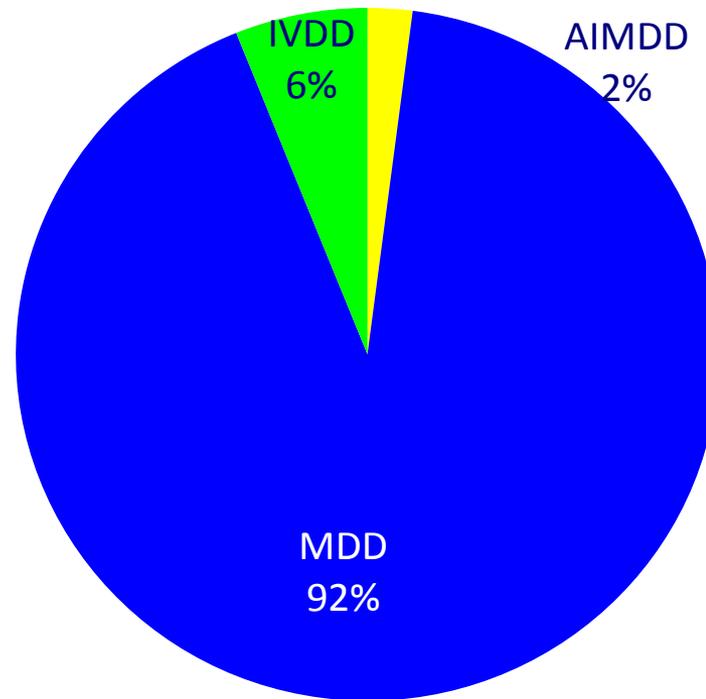
## Valid CE certificates issued from 2010 to 2021



# Medical Device Survey 2021



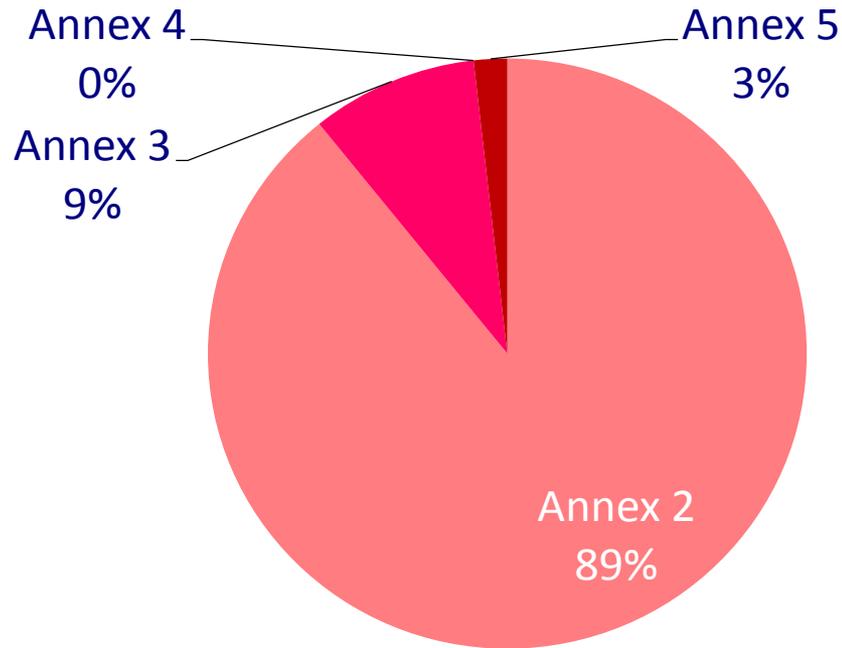
## ❖ Distribution of certificates between different directives



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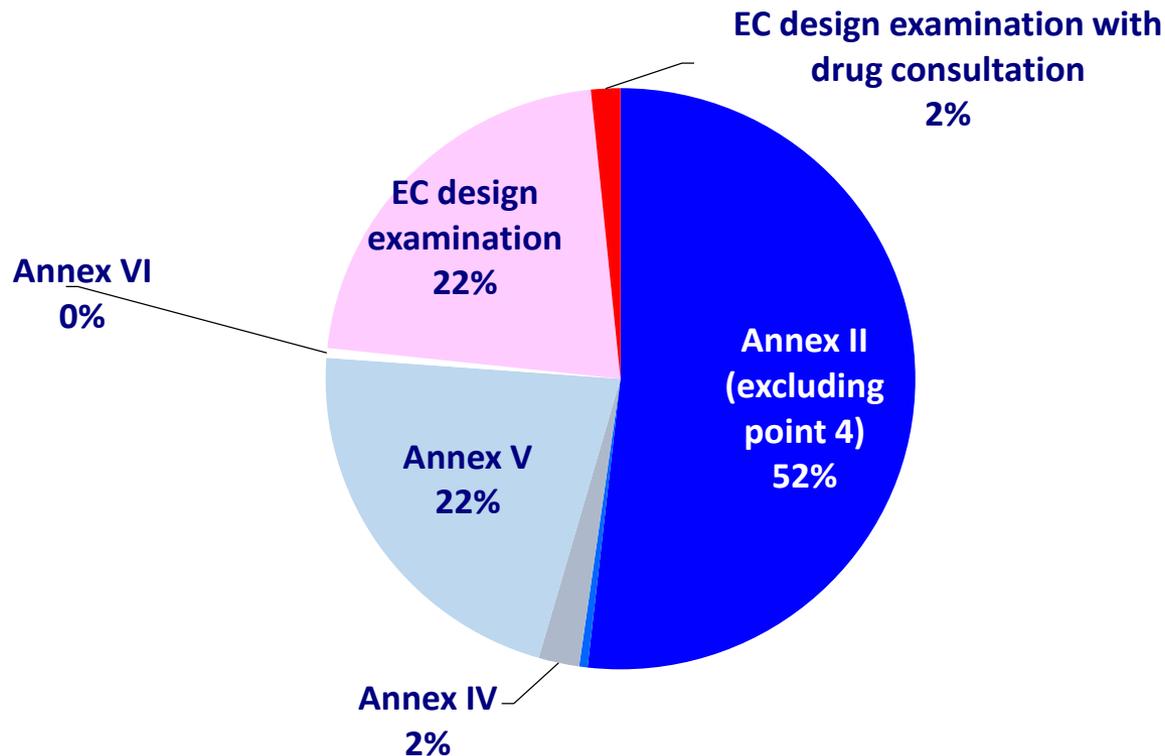
## ❖ Distribution between different conformity assessment modules under AIMDD



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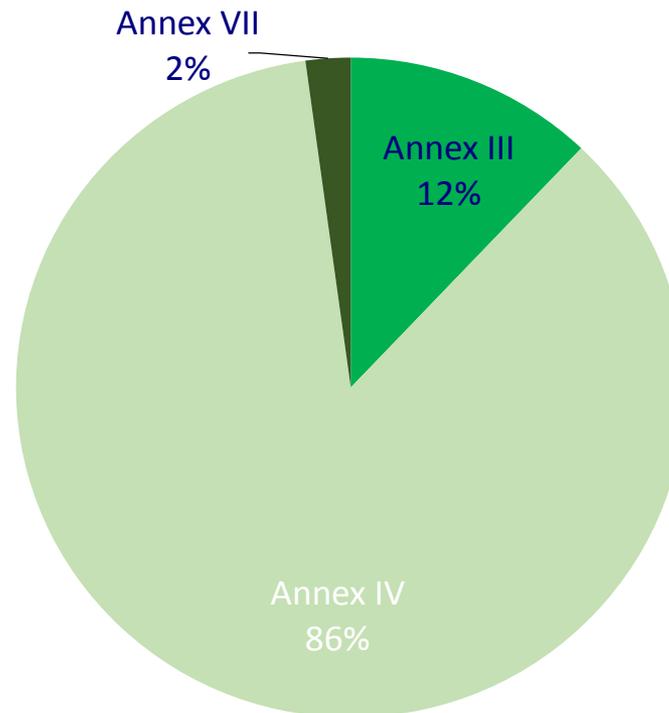
## ❖ Distribution between different conformity assessment modules under MDD



# Medical Device Survey 2021



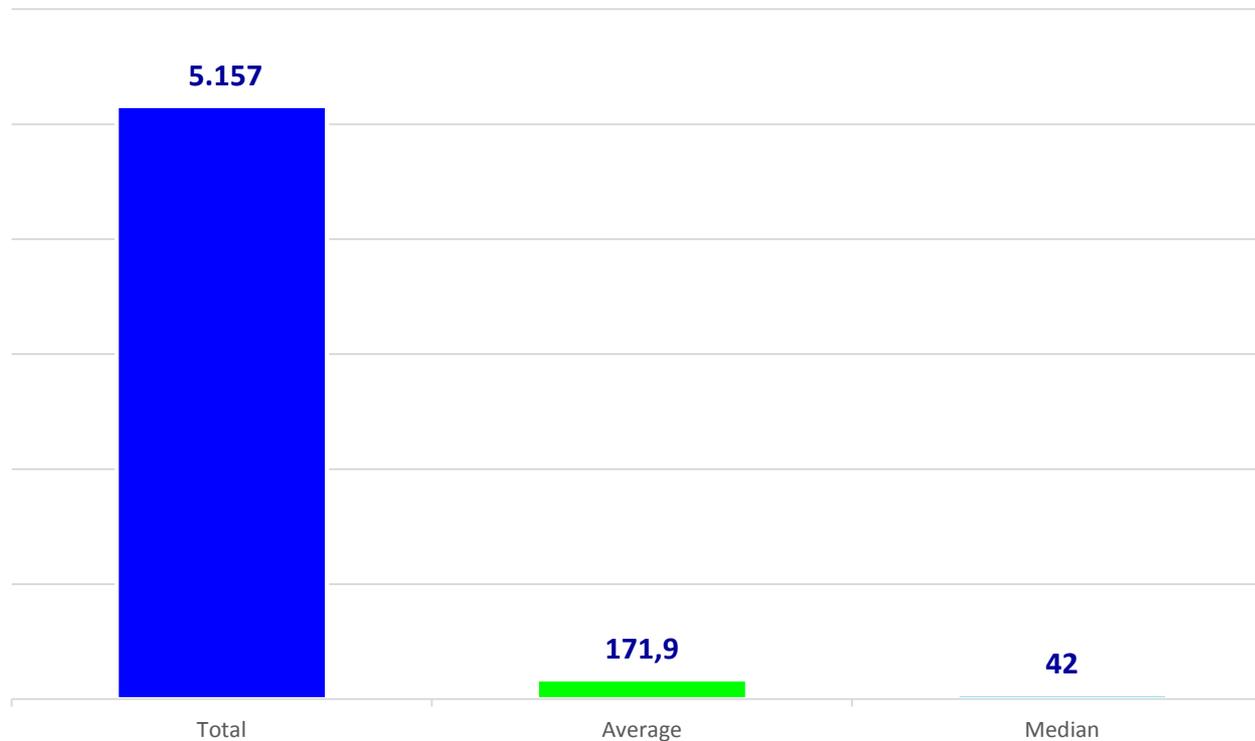
## ❖ Distribution between different conformity assessment modules under IVDD



# Medical Device Survey 2021



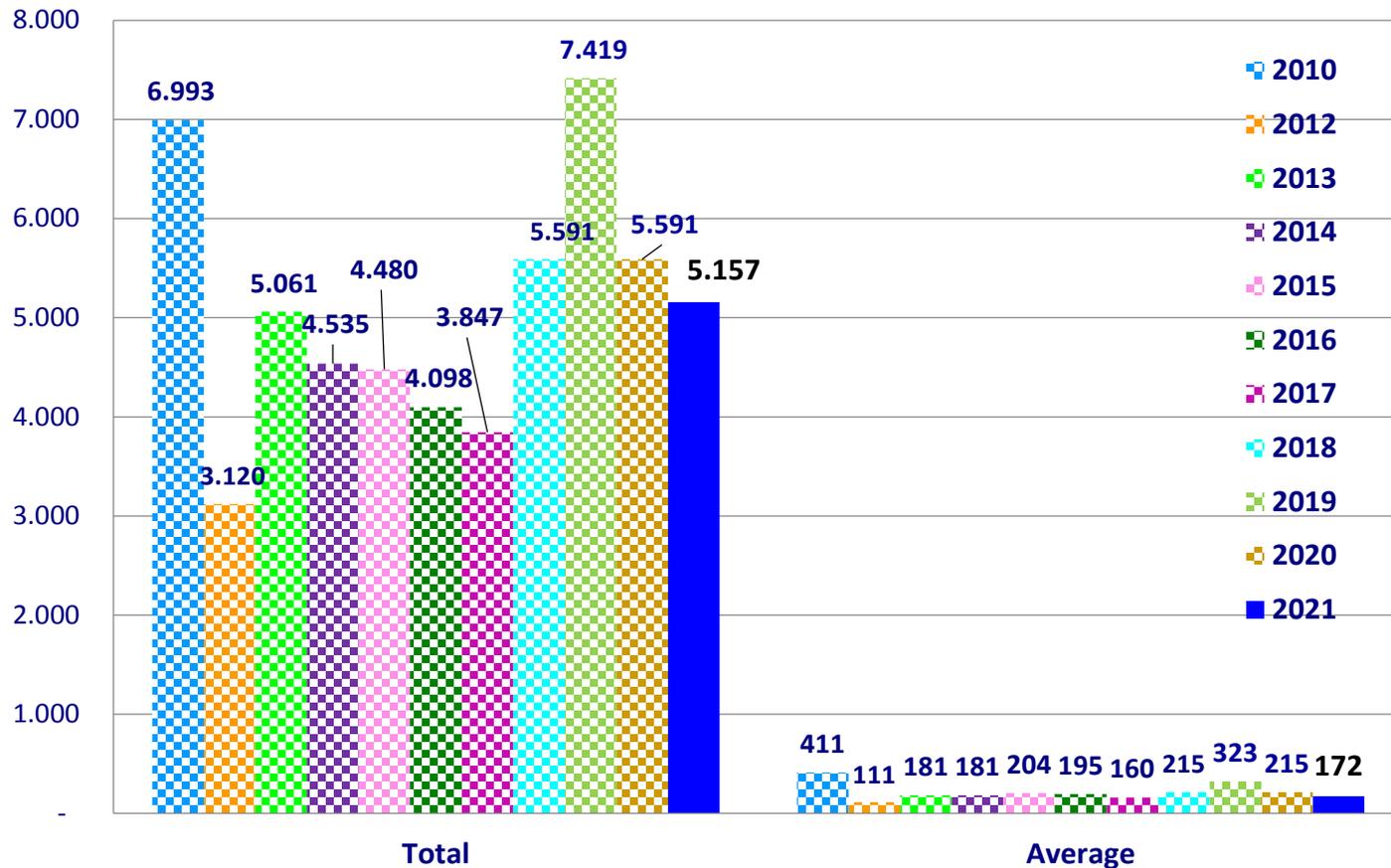
## ❖ New directives certificates issued in 2021 - mainly renewals



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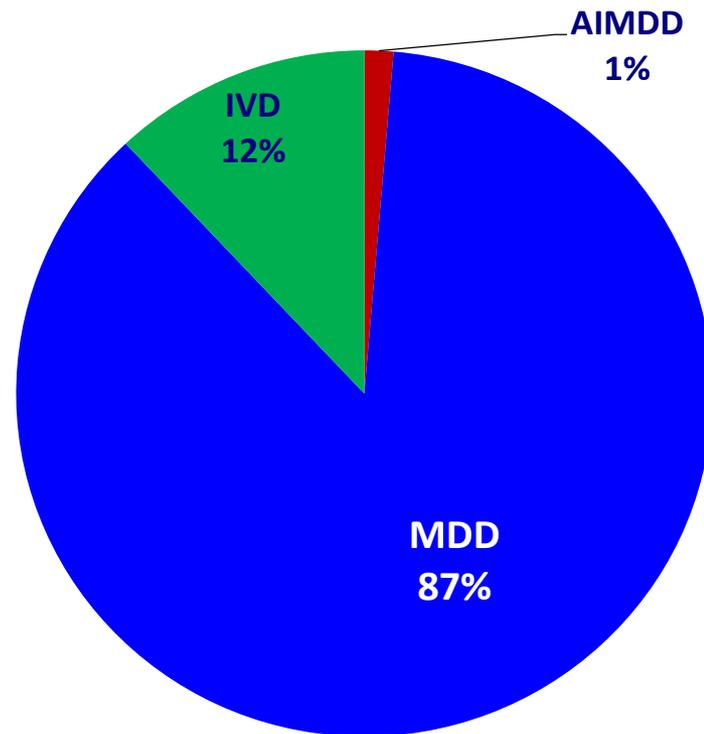
## ❖ New CE certificates issued from 2010 to 2021



# Medical Device Survey 2021



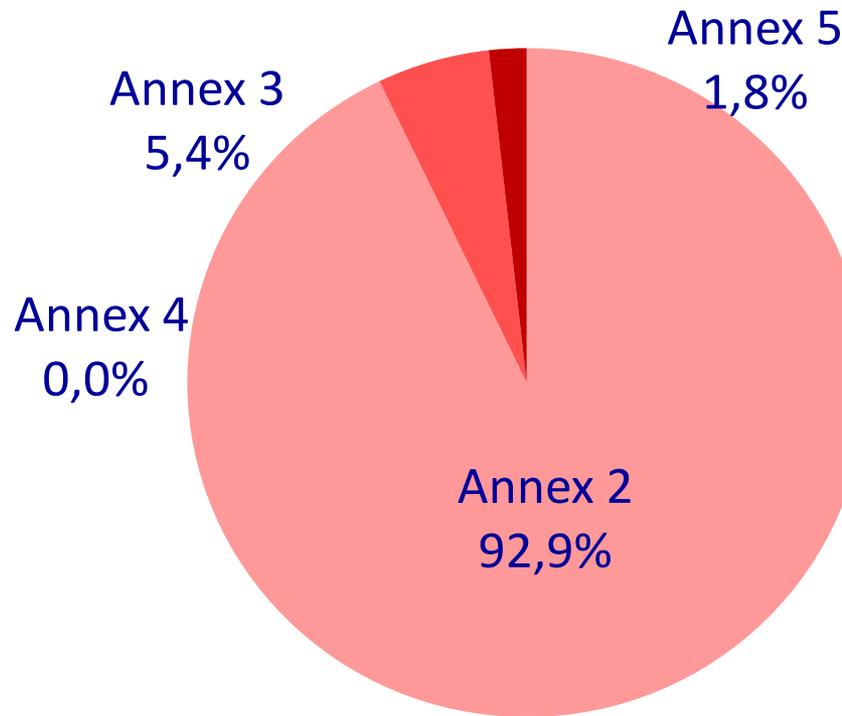
## ❖ Distribution between different directives in 2021



# Medical Device Survey 2021



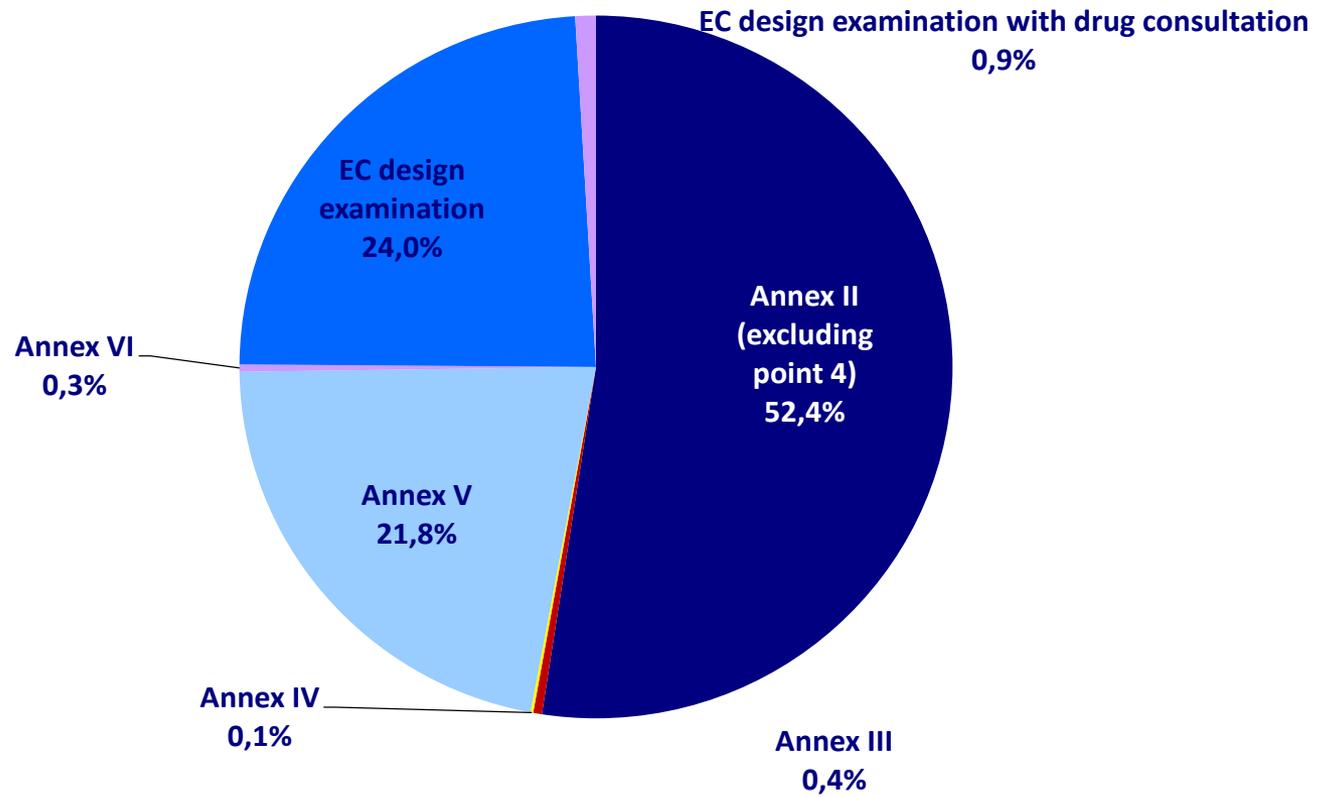
## ❖ Distribution between different conformity assessment modules under AIMDD in 2021



# Medical Device Survey 2021



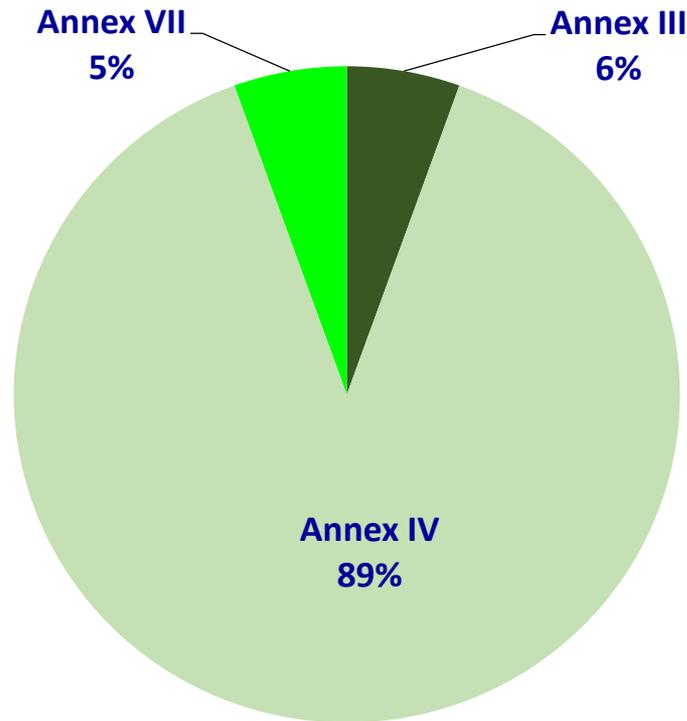
## ❖ Distribution between different conformity assessment modules under MDD in 2021



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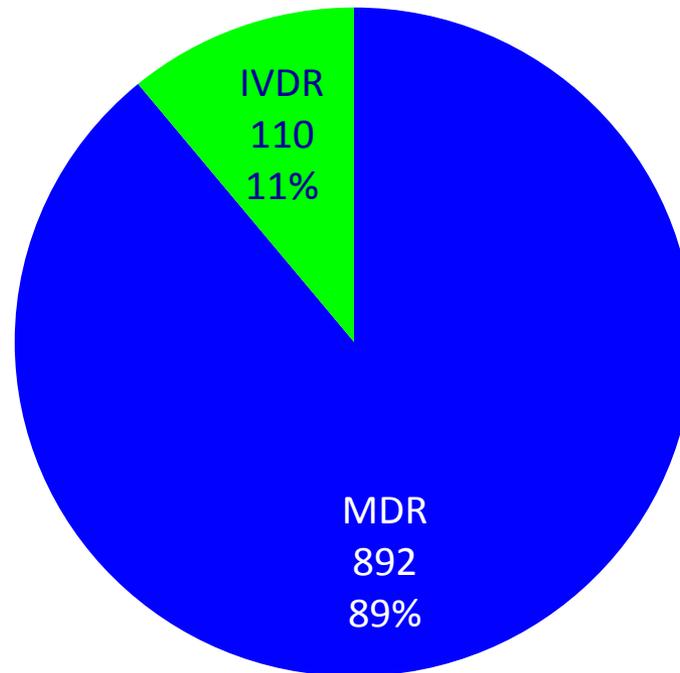
## ❖ Distribution between different conformity assessment modules under IVDD in 2021



# Medical Device Survey 2021



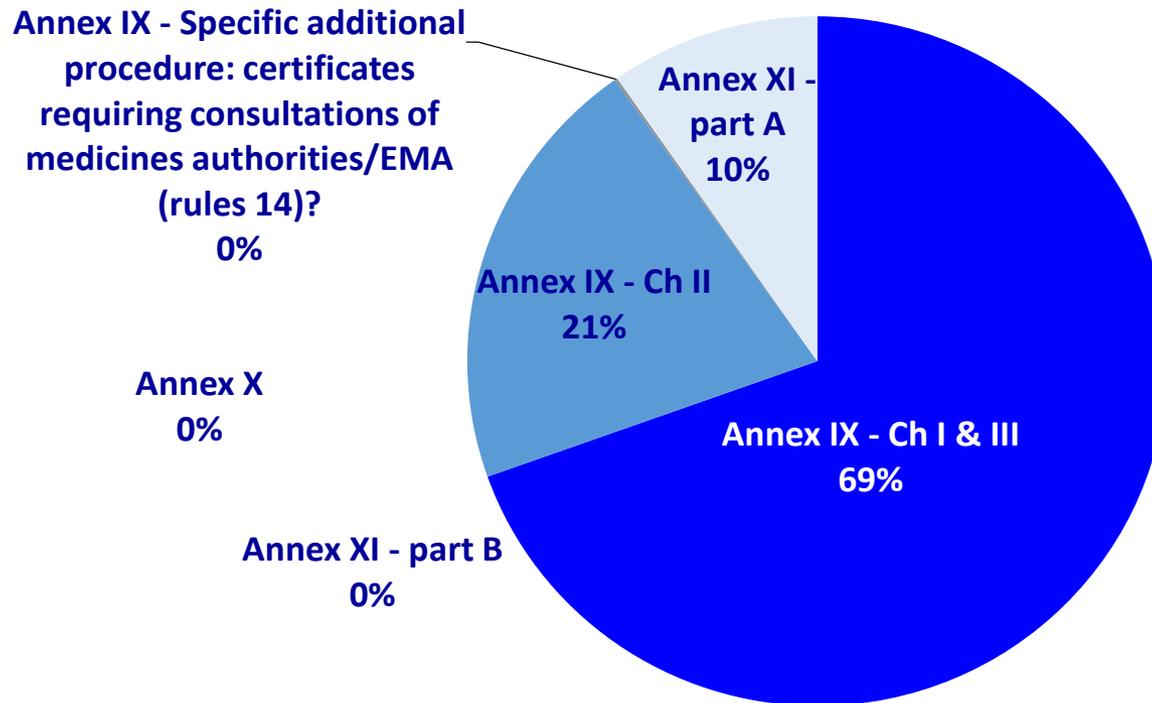
## ❖ Distribution of certificates between different regulations



# Medical Device Survey 2021



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



➔ 5,6% MDR certificates issued in comparison with total valid AIMDD + MDD certificates at end 2021

# Medical Device Survey 2021



## ❖ Distribution between different conformity assessment modules under IVDR

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

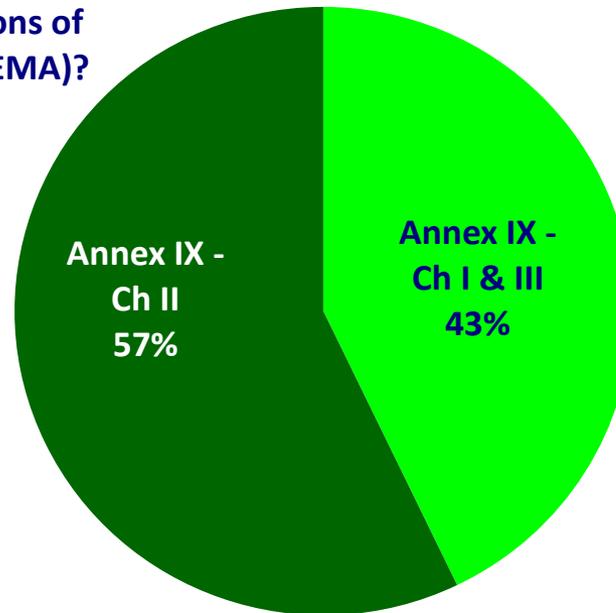
0%

Annex X

0%

Annex XI

0%

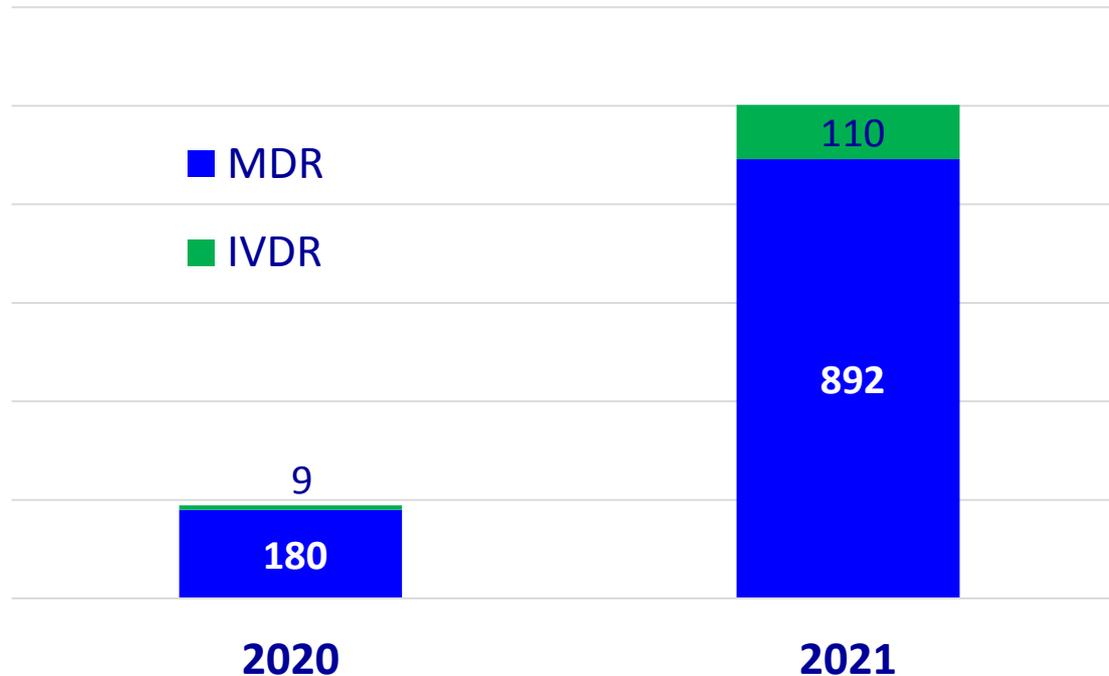


➔ 2,7% IVDR certificates issued in comparison with total valid IVDD certificates at end 2021

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## ❖ Comparison of issued certificates among regulations

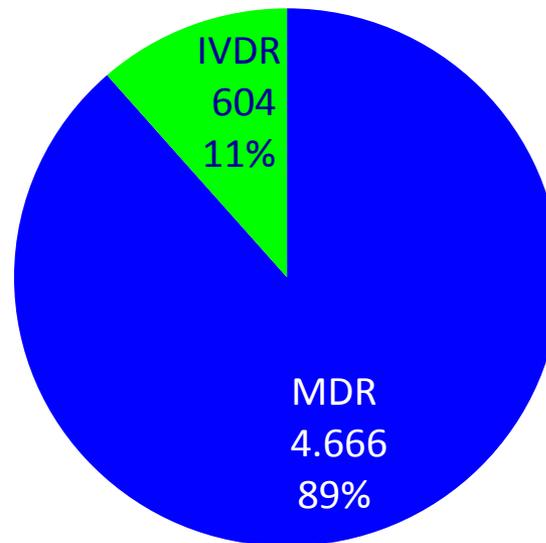


⇒ **5 fold** increase in issuance of **Regulations** certificates between 2020 and 2021

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## ❖ Distribution of applications between different regulations

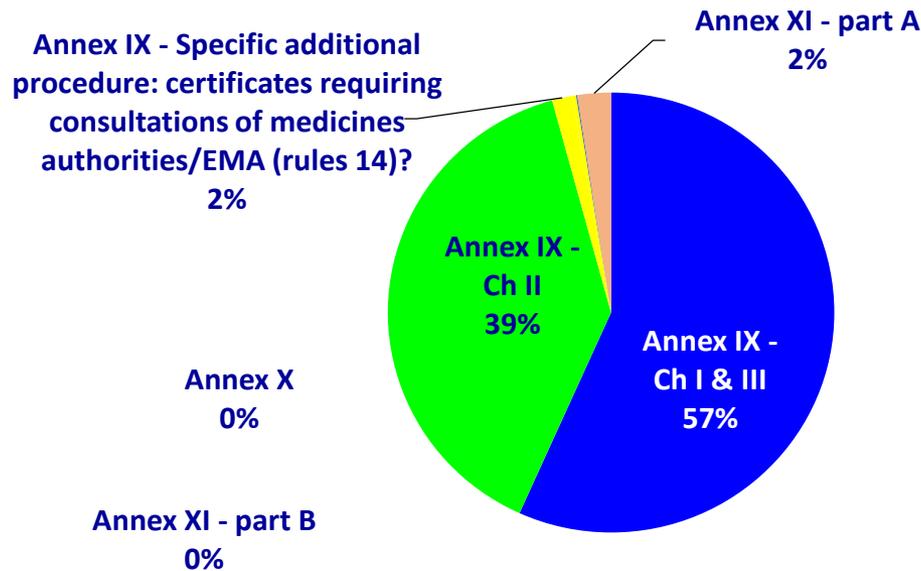


➔ 23,3% **regulations** applications received at end 2021 in comparison with total valid **directives** certificates

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

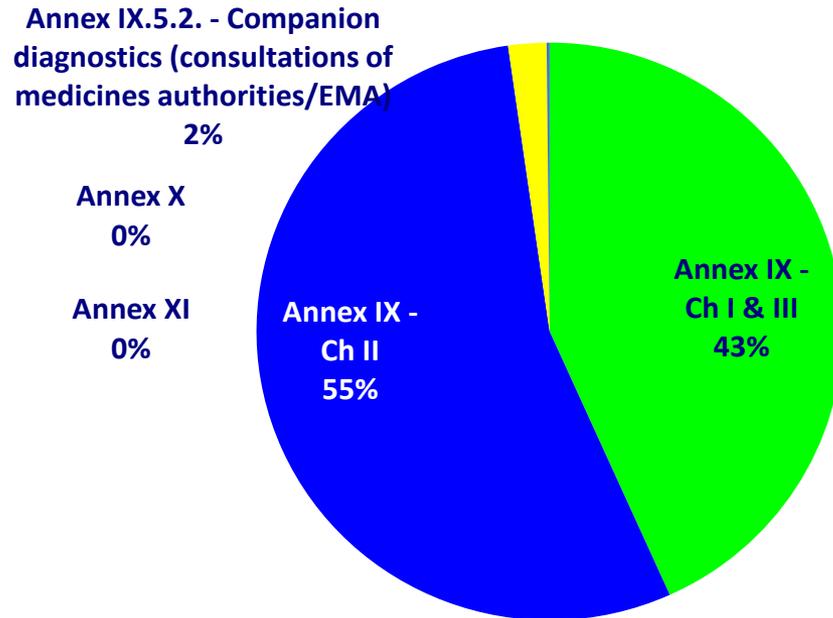


➔ 26,3% MDR applications received at end 2021 in comparison with total valid AIMDD + MDD certificates

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

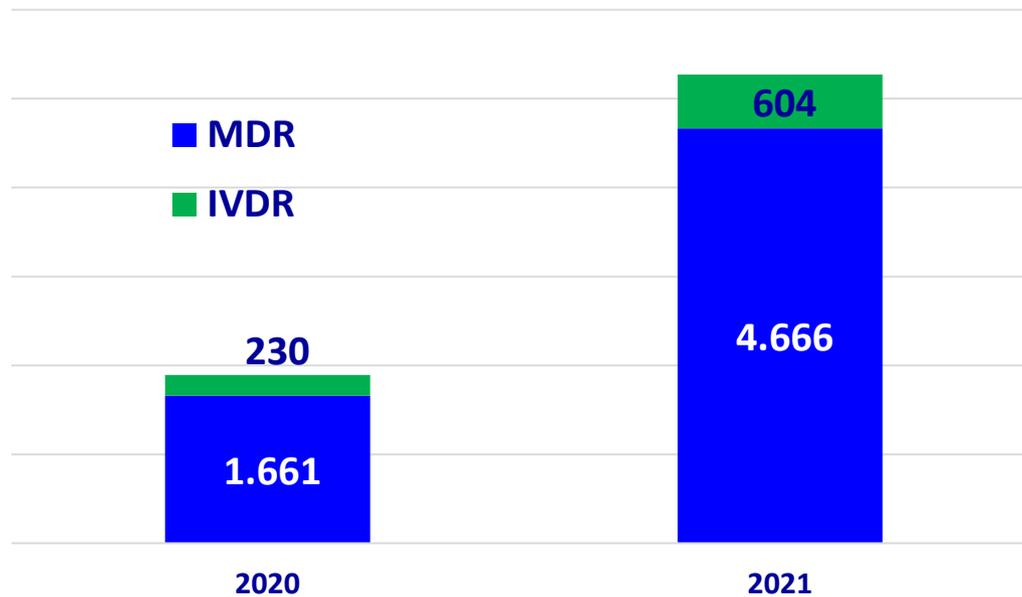


➔ 14,9% IVDR applications received at end 2021 in comparison with total valid IVDD certificates

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## ❖ Comparison of received applications against regulations



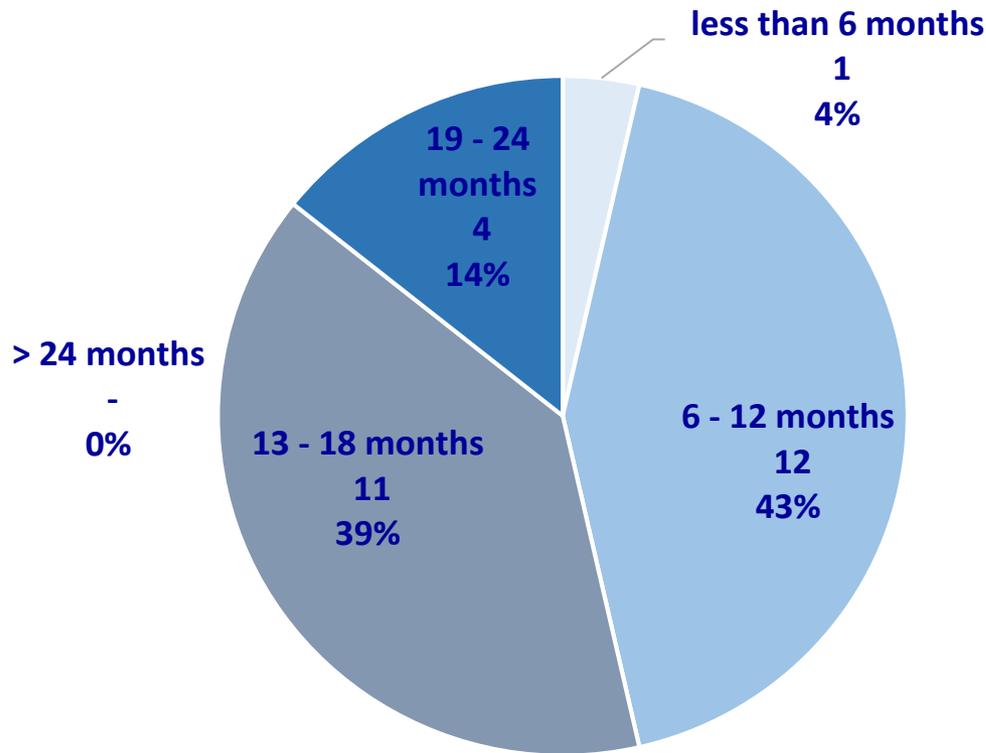
64% increase in receipt of applications against Regulations between 2020 and 2021

⇒ **Time flies: Still a lot of application to be received**

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



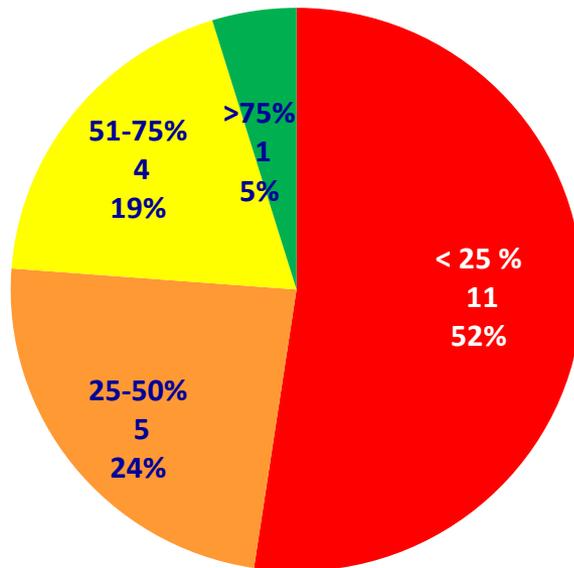
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## ❖ Completeness check

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

⇒ below graph with deemed satisfactory submissions (no request for any additional information)



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

[Not yet applied by 5 NBs (19%) as not yet designated against regulations]

⇒ **75 % of notified bodies indicate that at least half of the TD submitted are deemed incomplete, and request additional information to start the assessment.**

### Legend

1<sup>st</sup> line: Level of completeness check (<25% - 25-50% - 51-75% - >75%)

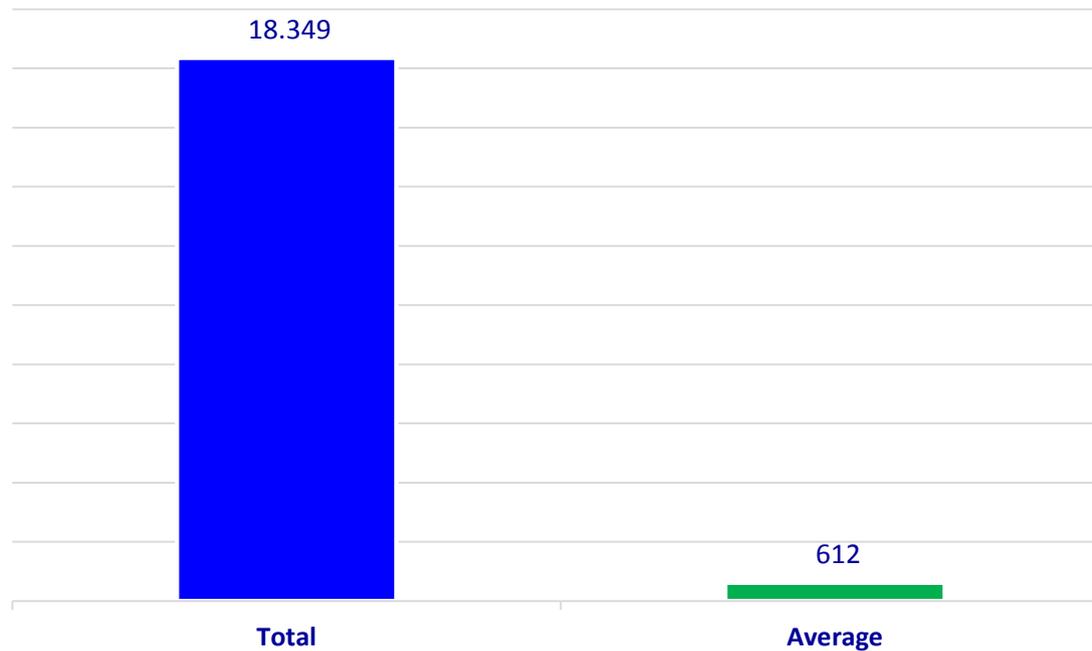
2<sup>nd</sup> line: number of NBs responding

3<sup>rd</sup> line: percentage of the technical documentation completion

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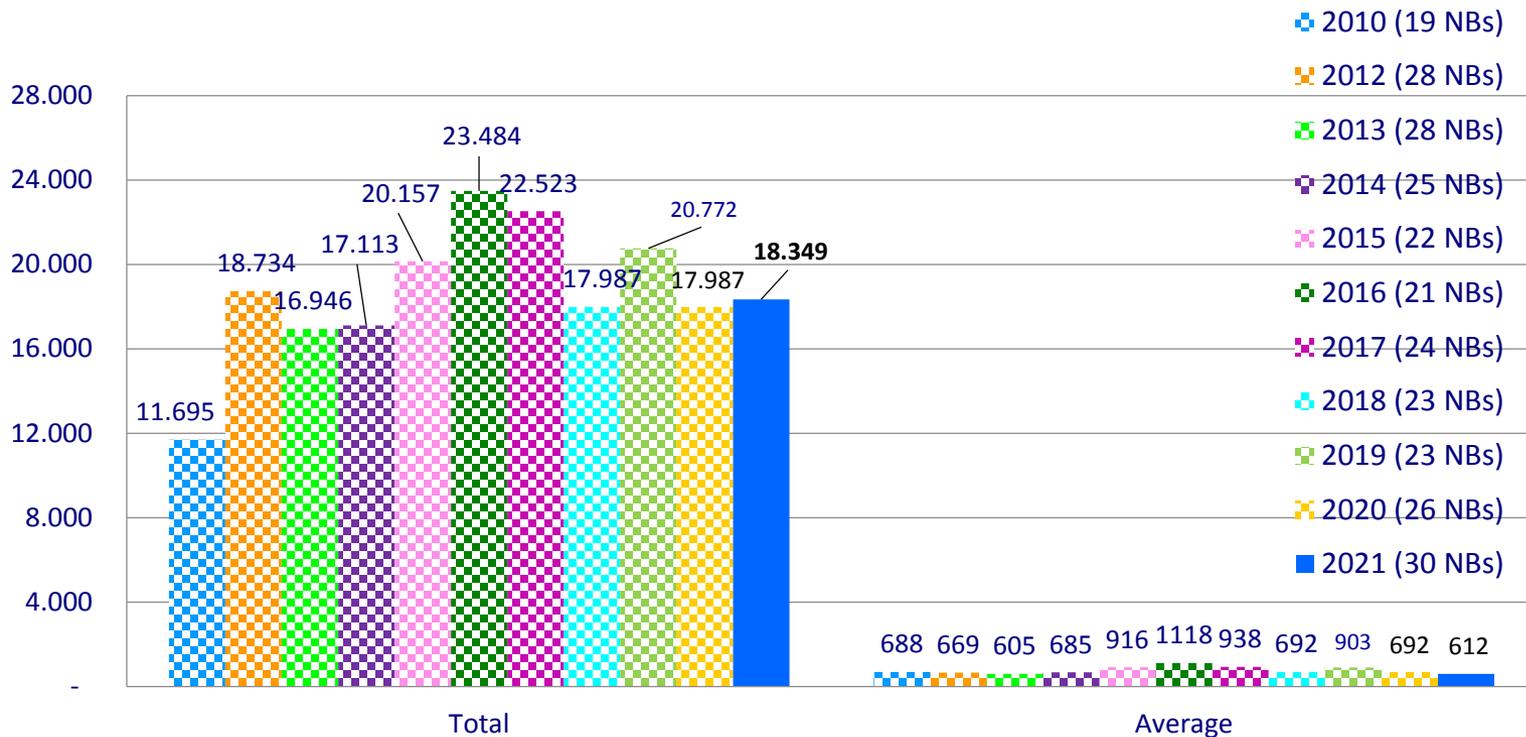
## ❖ Valid certificates against ISO 13485



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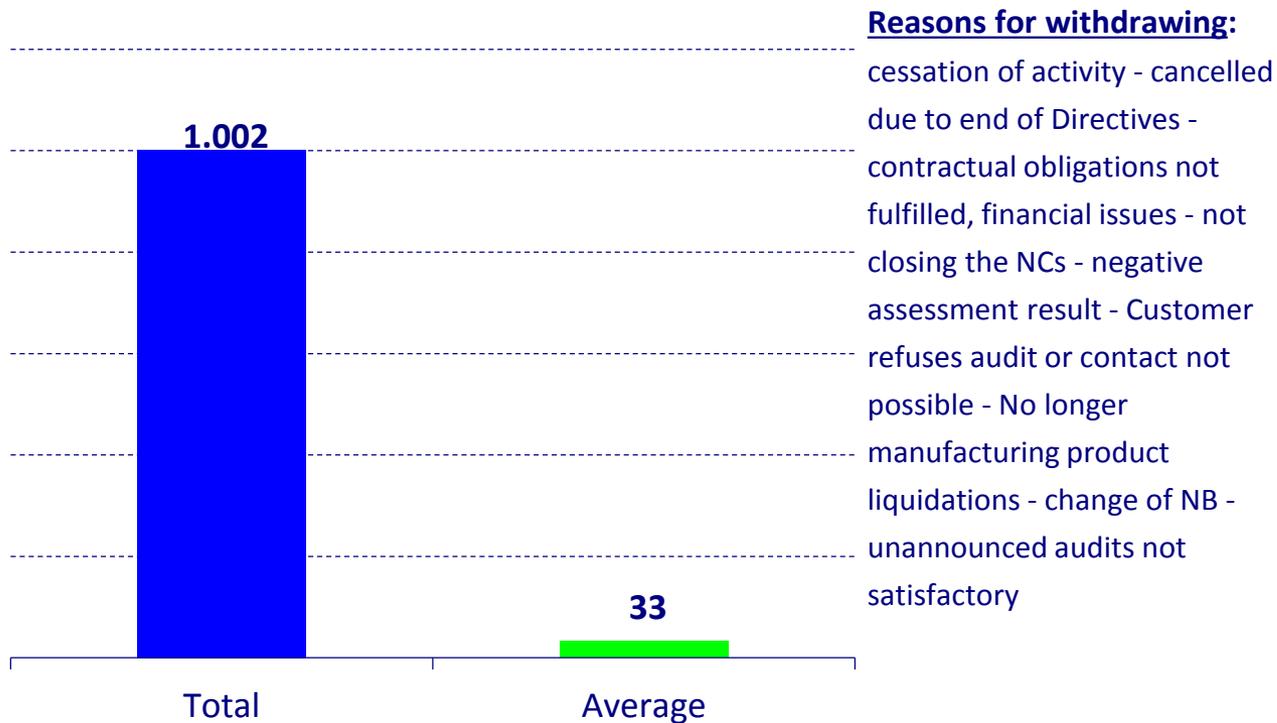
## Valid certificates against ISO 13485 from 2010 to 2021 :



# Medical Device Survey 2021



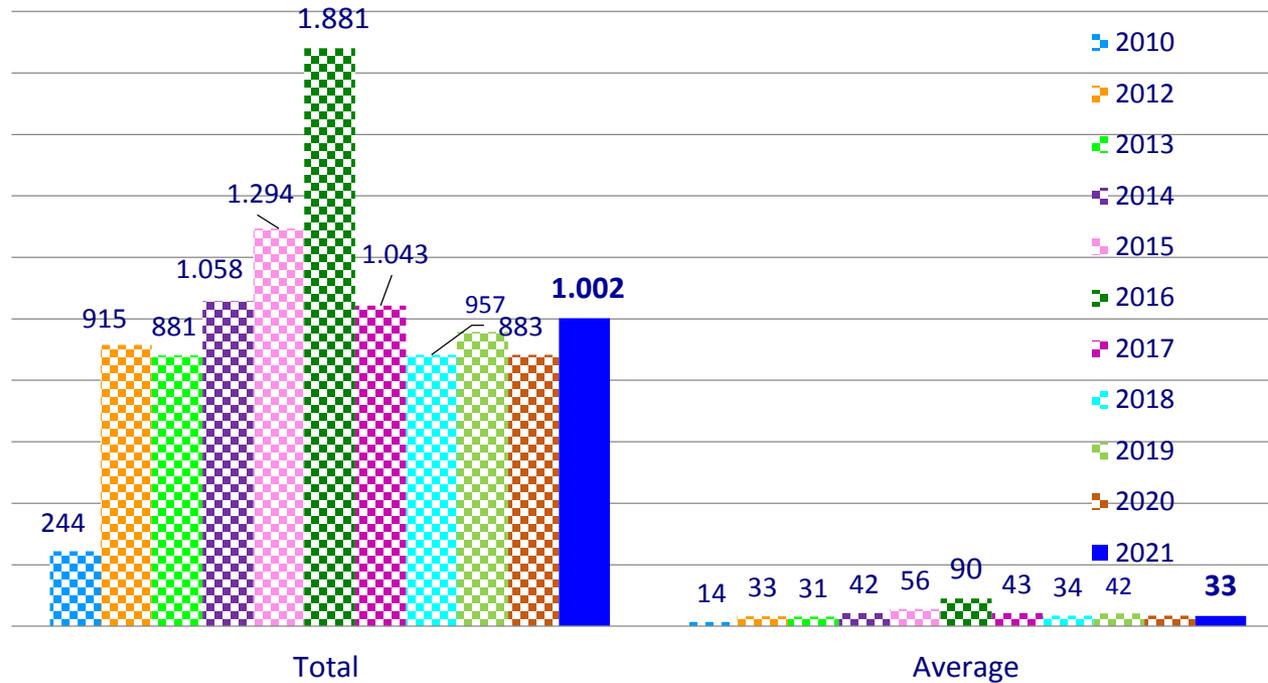
## ❖ Number of certificates withdrawn in 2021



# Medical Device Survey 2021



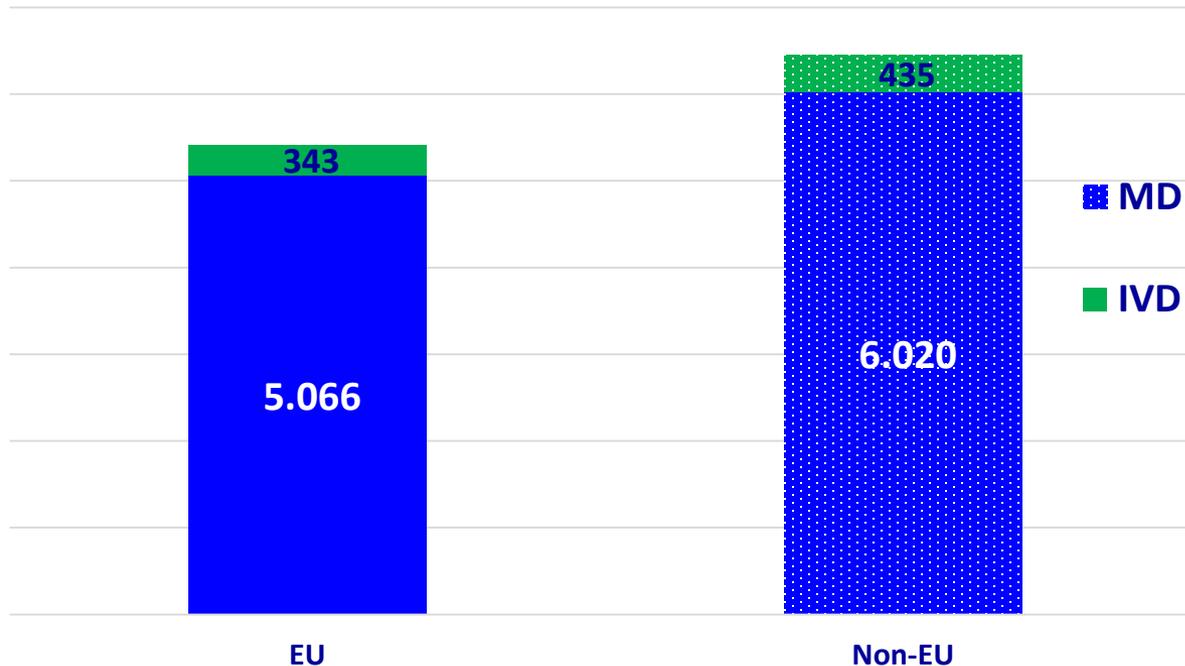
## ❖ Number of certificates withdrawn from 2010 to 2021



# Medical Device Survey 2021



## ❖ 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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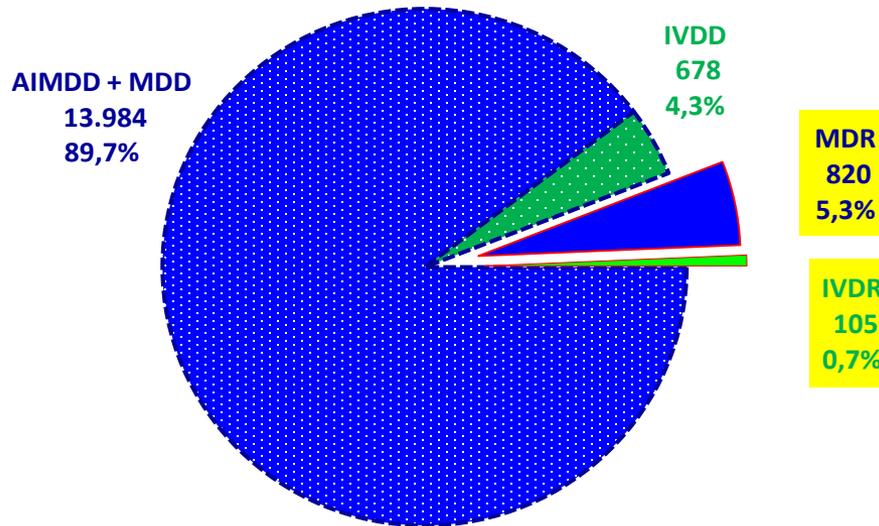


## ❖ Certification holders

Legend:

dotted pattern = directives

plain pattern = regulations



### Estimation of number of Certification holders under Directives in 2021

= 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 2021

= 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).

**Total certification holders estimated to**

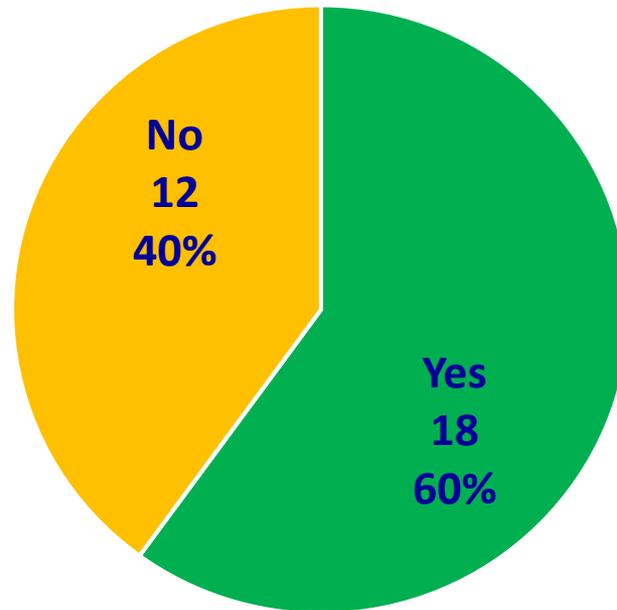
**14 662 / 30 NBs**

**Based on QMS (quality Management System) certificates**

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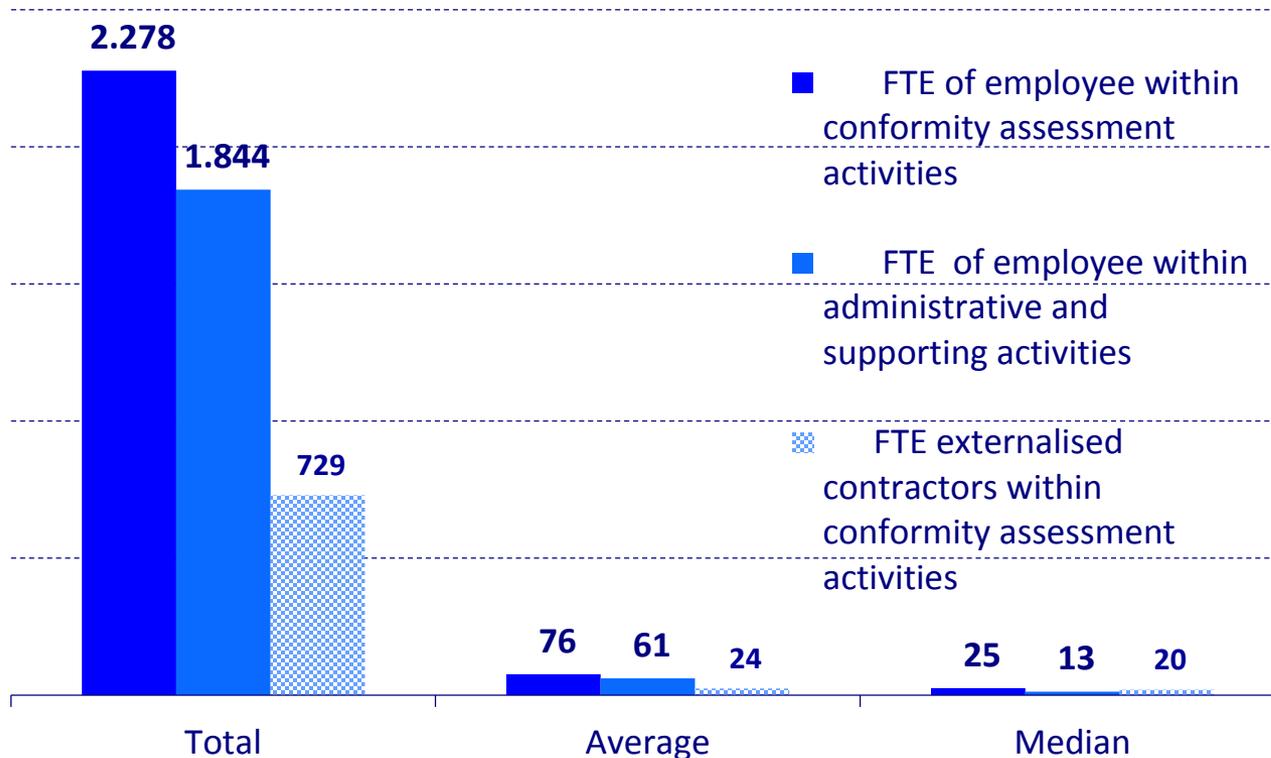
❖ Clients of the NB are SMEs at more than 50%



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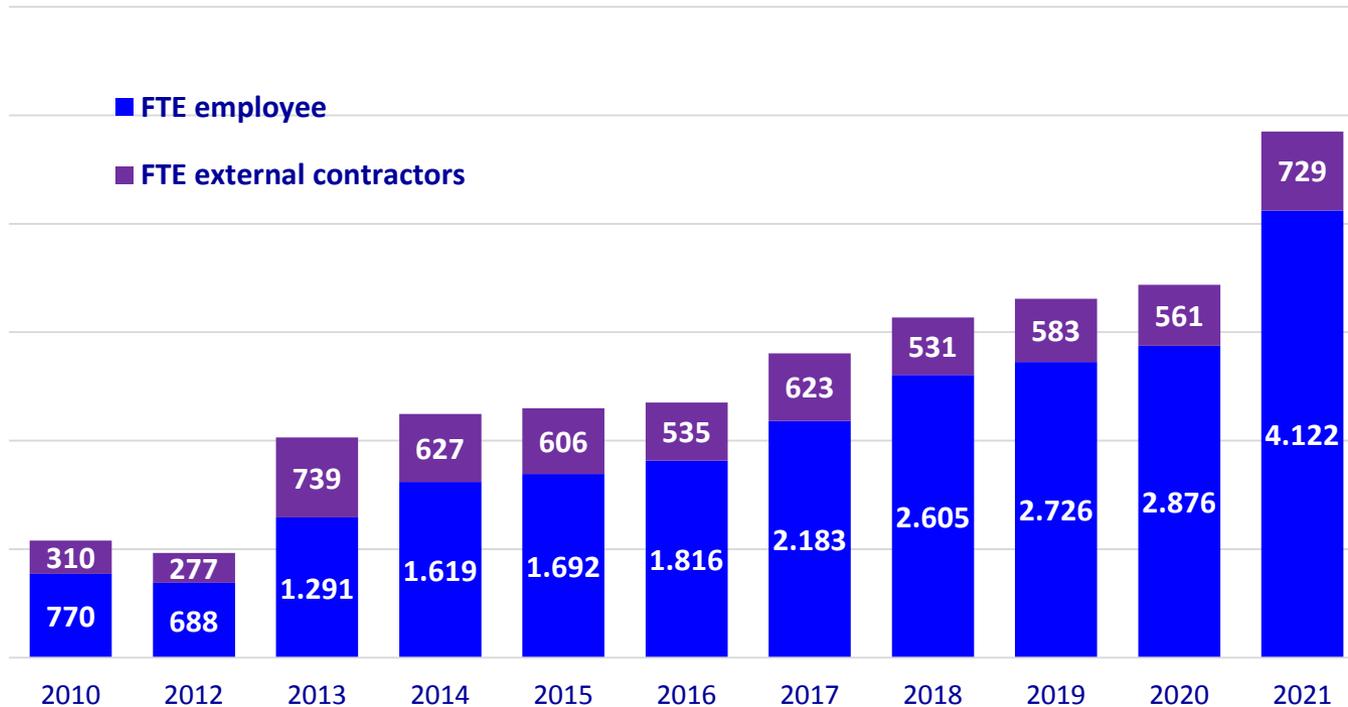
## ❖ Staff in 2021 (full time equivalent in MD sector)



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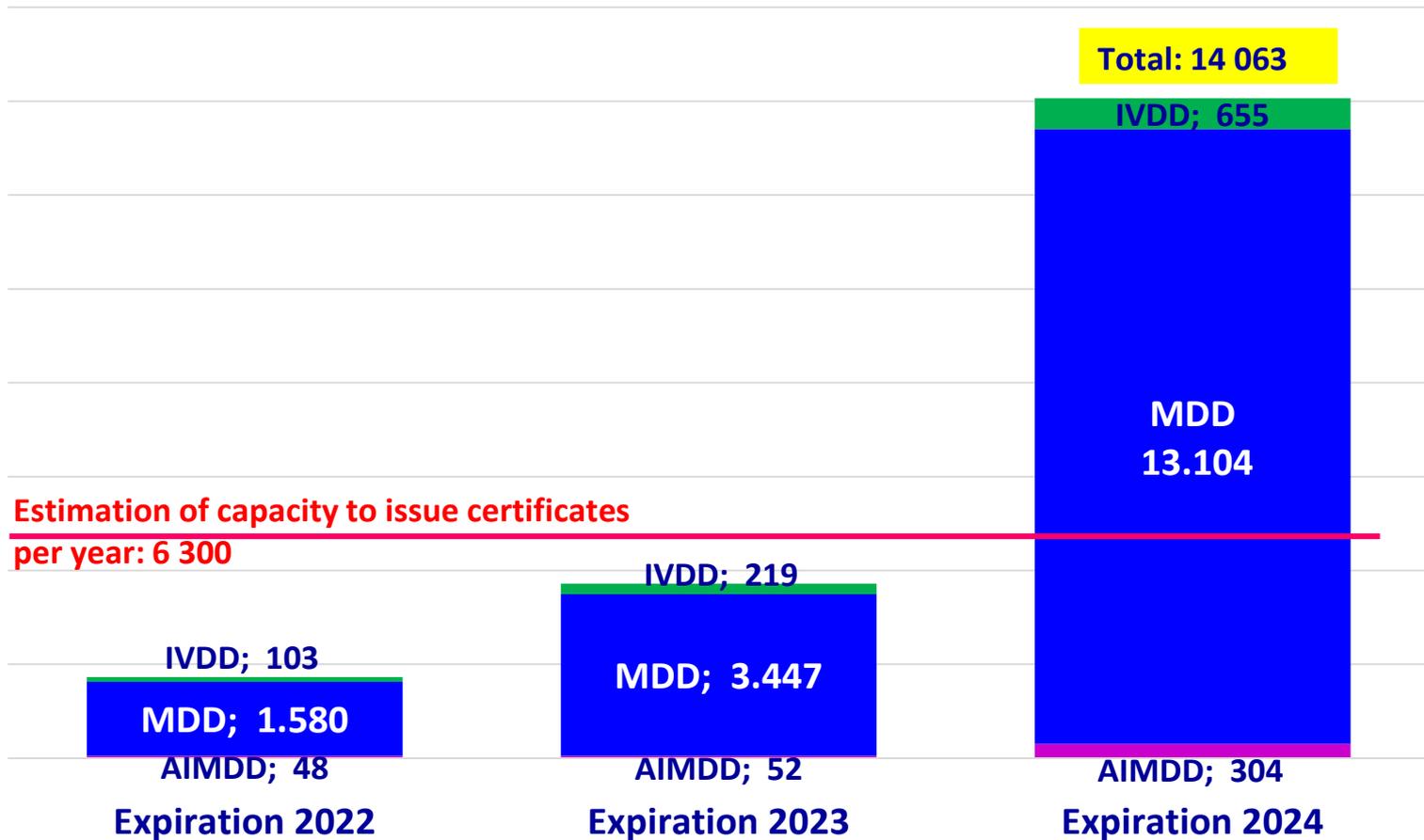
## ❖ Staff (Full Time Equivalent in MD sector): From 2010 to 2021



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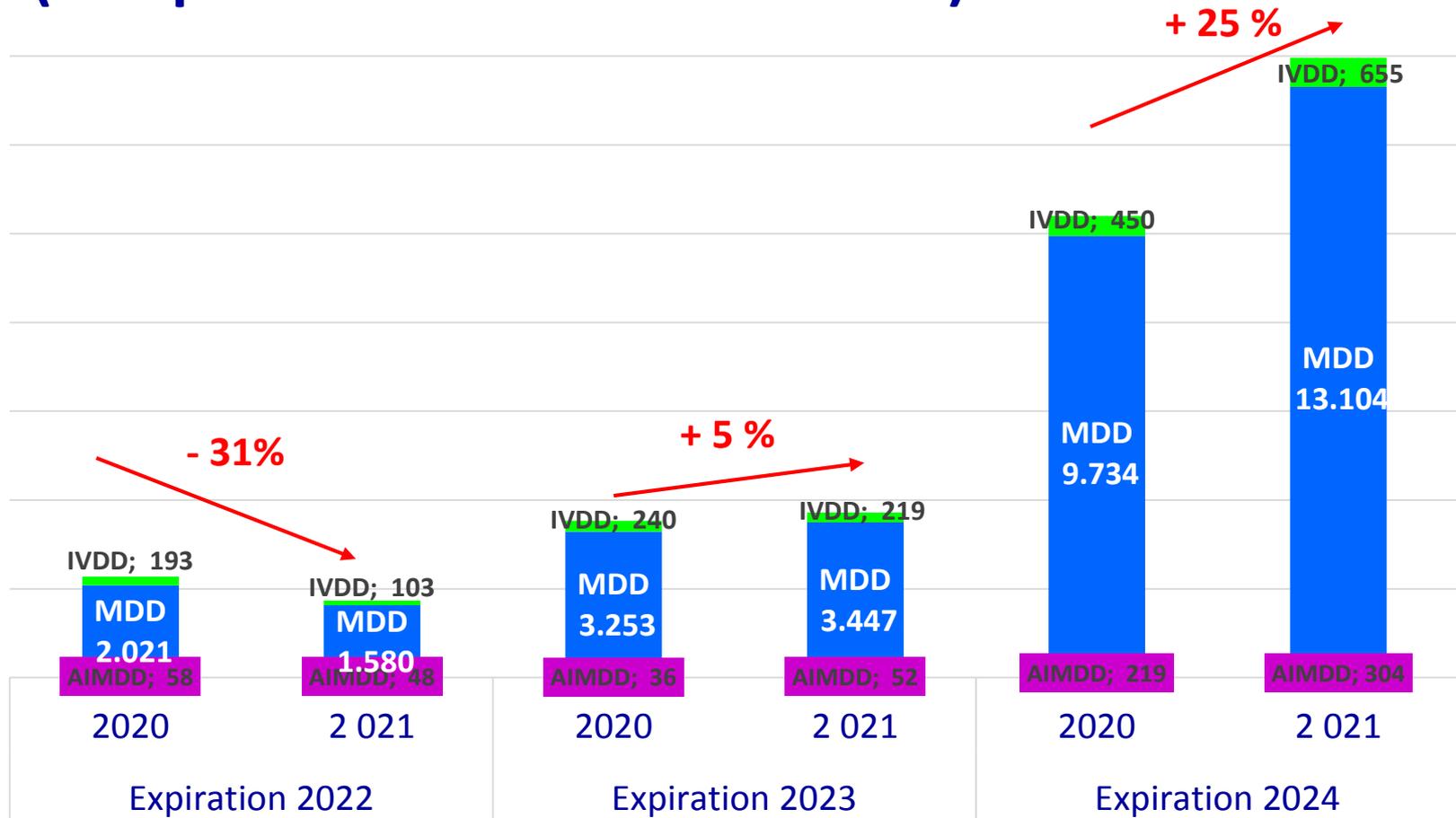
## ❖ Expiring Directives certificates at end of 2021



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## ❖ Trends in expiring Directives certificates (comparison data 2020 and 2021)



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## ❖ Certificates evolution from Directives to Regulations (including applications)



- Directives certificates increasing (thanks to new members)
  - Regulation certificates increasing (> 4 times)
  - Regulation applications increasing (2,5 times)
- ⇒ Still numerous certificates to be transfer against MDR (> 95%) and applications to be received (75%)

- Directive certificates : small increase
  - Regulation certificates increasing (17 times)
  - Regulation applications increasing (> 2,5 times)
- ⇒ Transfer against IVDR (>90%) + new certificates against IVD Regulation tremendous

# Members



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