



Notified Bodies Survey on certifications and applications (MDR/IVDR)

MDCG & Stakeholders

19 May 2022

Survey on certifications and applications

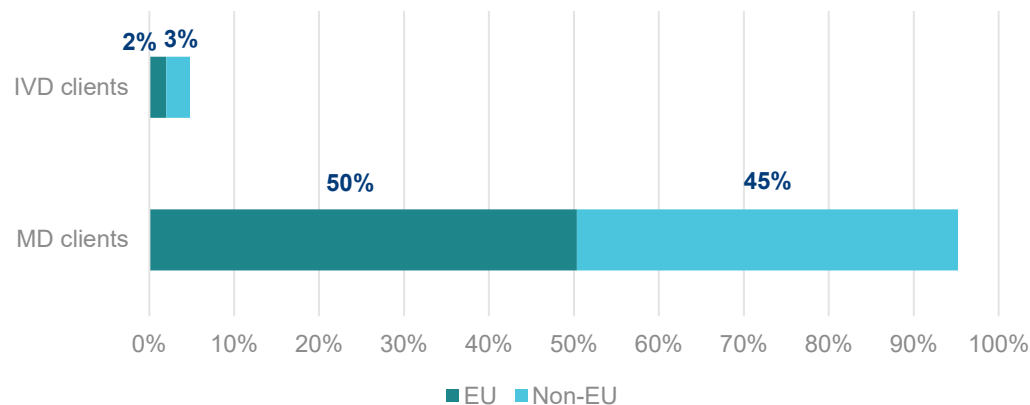
General data of Notified bodies replies received – April 2022

52 replies received – out of 52 notified bodies

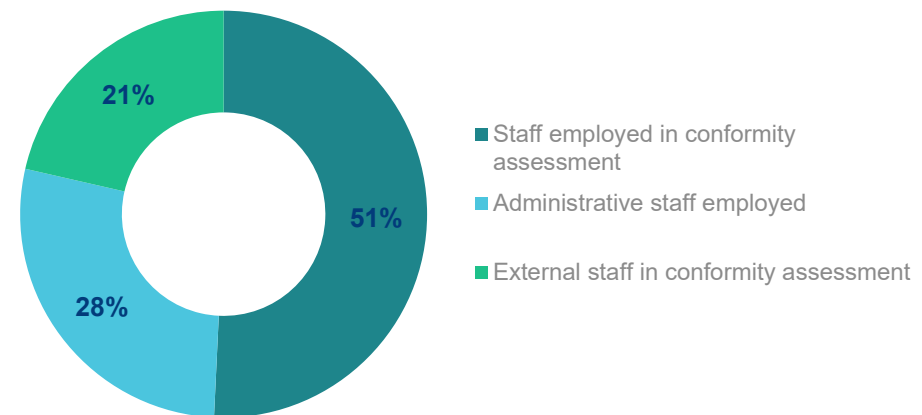
AIMDD designated	18
MDD designated	49
MDR designated	28
IVDD designated	21
IVDR designated	7

Data on staff and clients:

% MD/IVD clients EU and non-EU



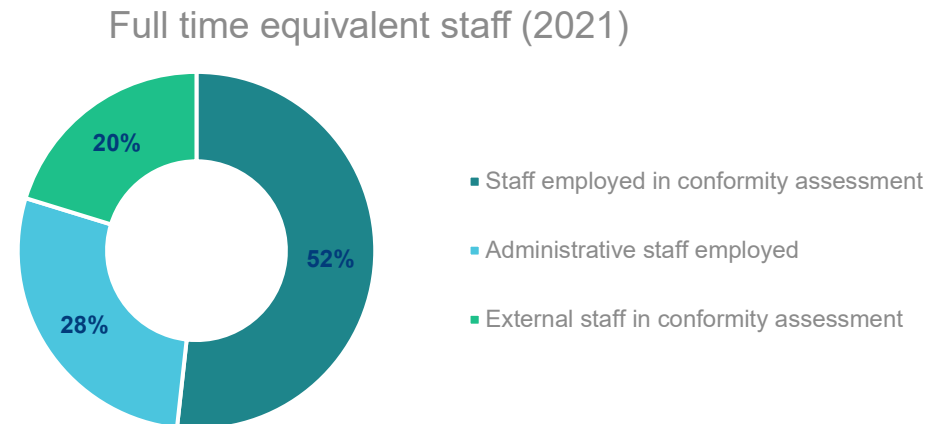
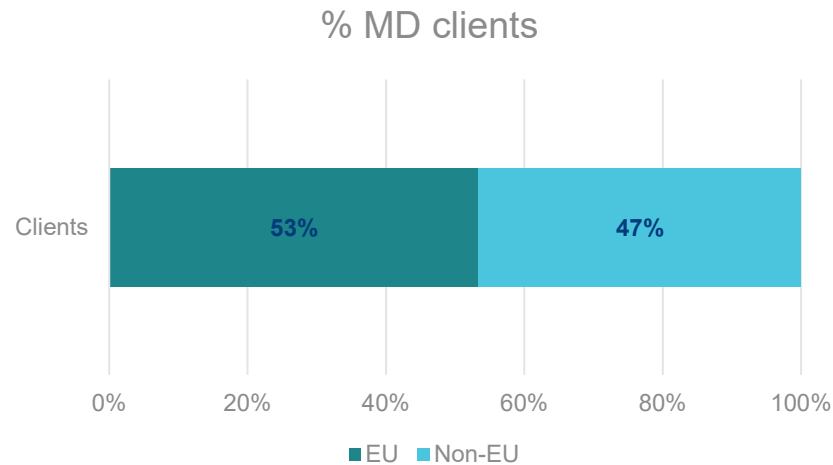
Full time equivalent staff (2021)



Survey on certifications and applications

MD Notified bodies replies received – April 2022

- MDD/AIMDD: **49 replies received – out of 49 notified bodies** designated under the MDD (all notified bodies designated under the AIMDD replied)
- MDR: **28 replies received – out of 28 notified bodies** designated under the MDR



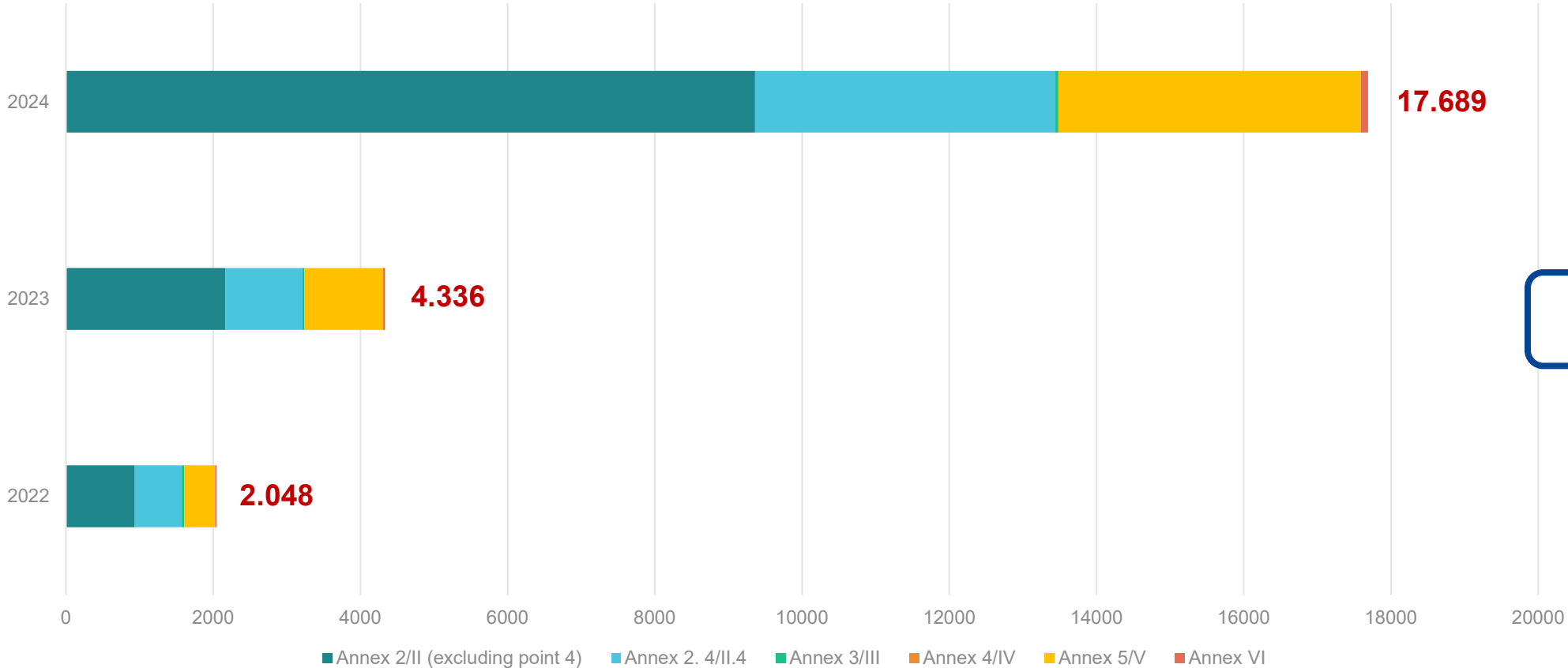
89% of NBs: majority of clients are SMEs

Survey on certifications and applications

MDD/AIMDD Certificates – April 2022

MDD/AIMDD Data (1)

MDD/AIMDD valid certificates breakdown by date of expiry

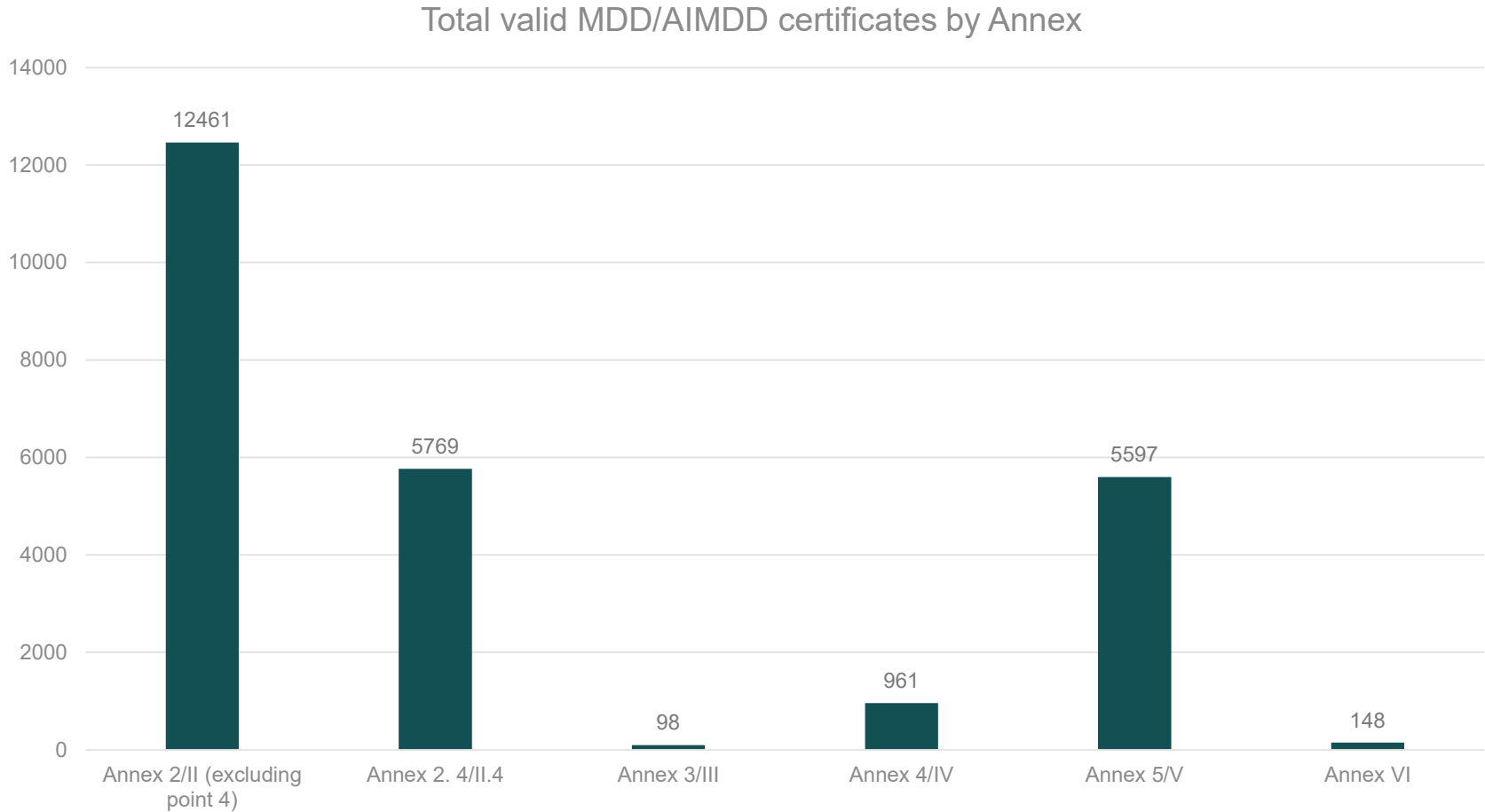


Tot. 24.073
(Annex 4/IV not included)

Survey on certifications and applications

MDD/AIMDD Certificates by Annex

MDD/AIMDD Data (2)

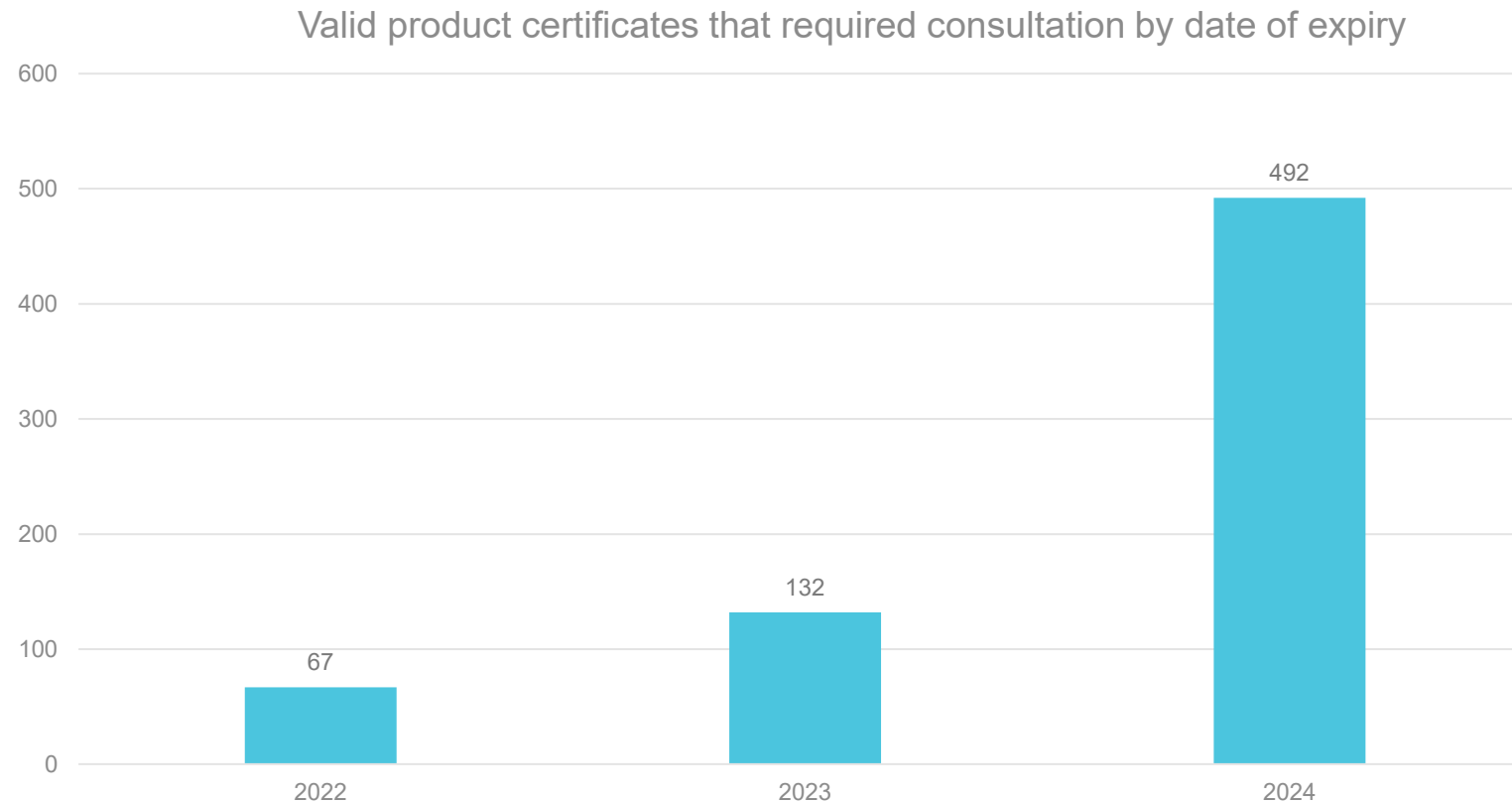


Tot. 25.034

Survey on certifications and applications

MDD/AIMDD Certificates – April 2022

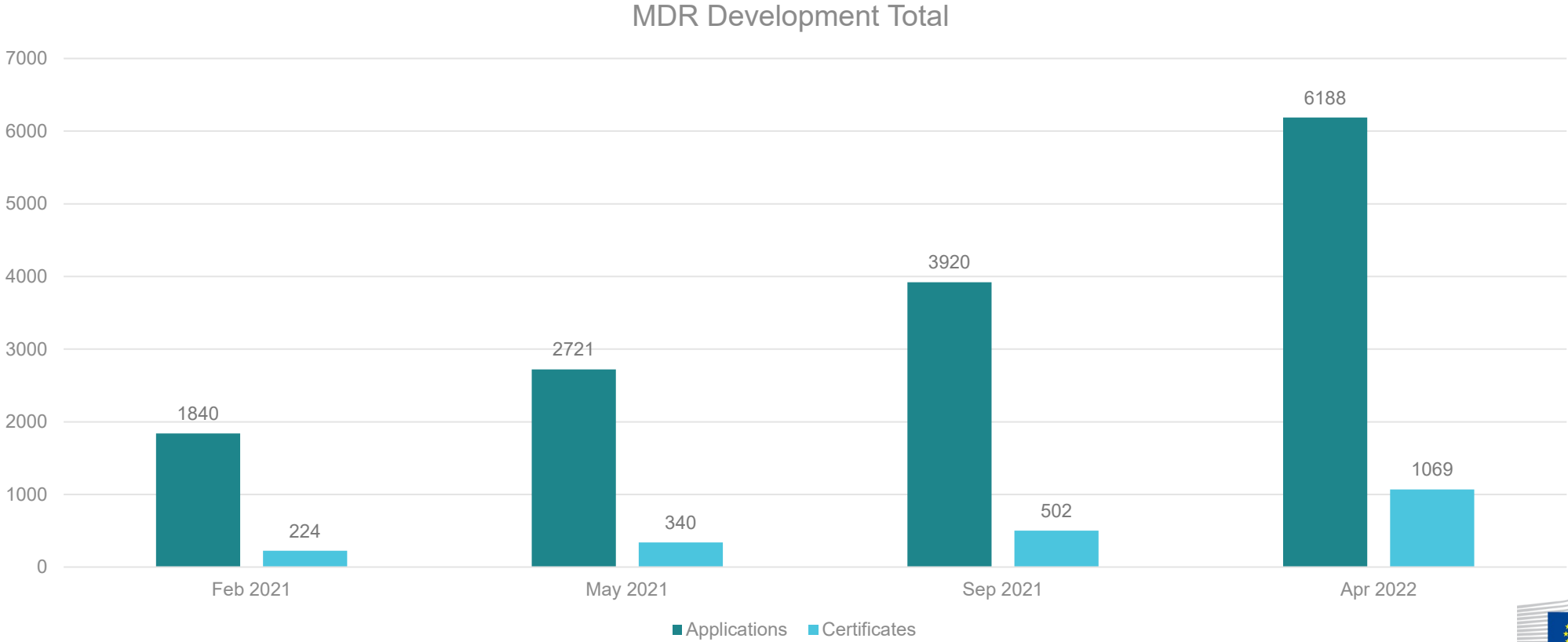
MDD/AIMDD Data (3)



Survey on certifications and applications

MDR Applications filed and Certificates issued

MDR Data (1)

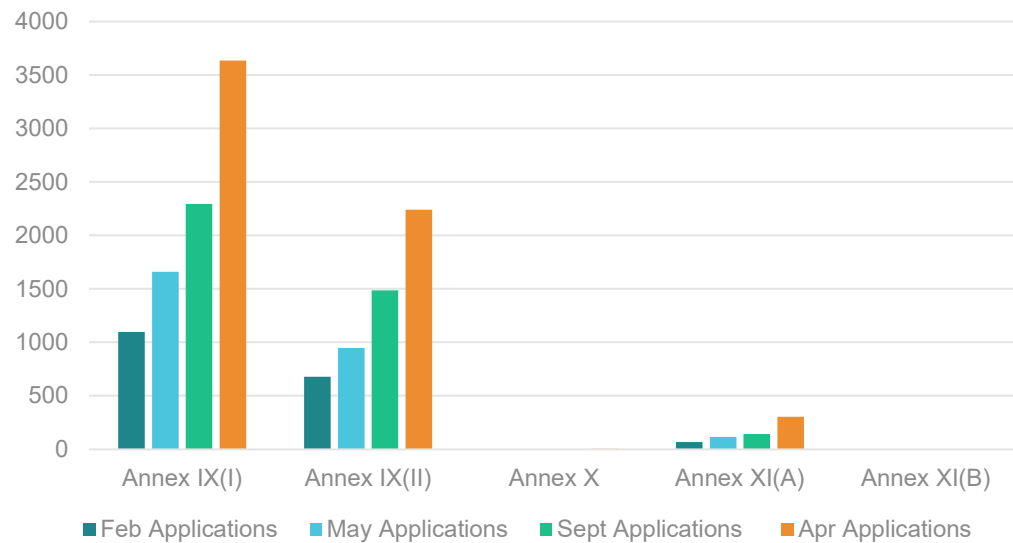


Survey on certifications and applications

MDR Data (2)

MDR Certificates and Applications by Annex – Comparison each survey

Applications Total by Annex



Certificates Total by Annex

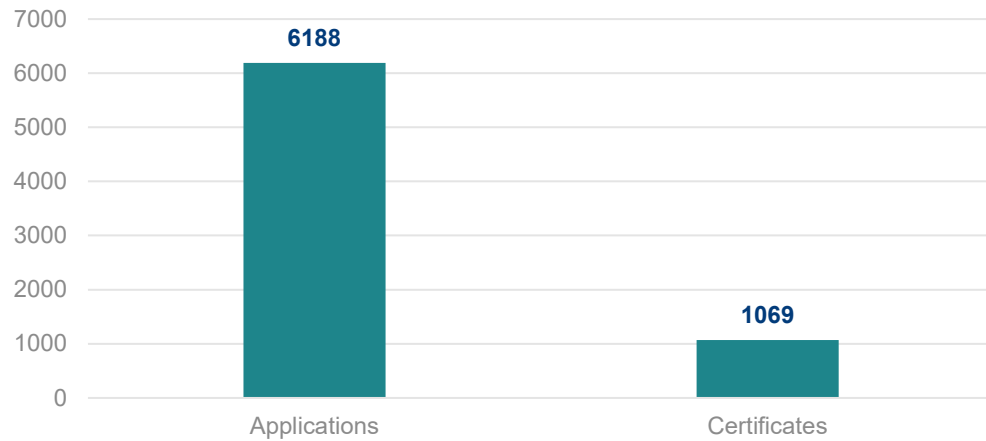


Survey on certifications and applications

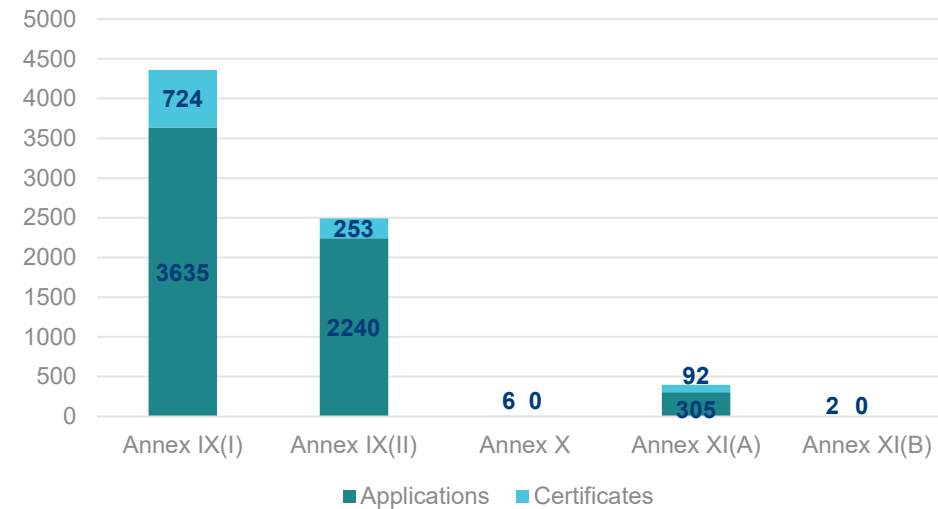
MDR Data (3)

MDR Certificates and Applications

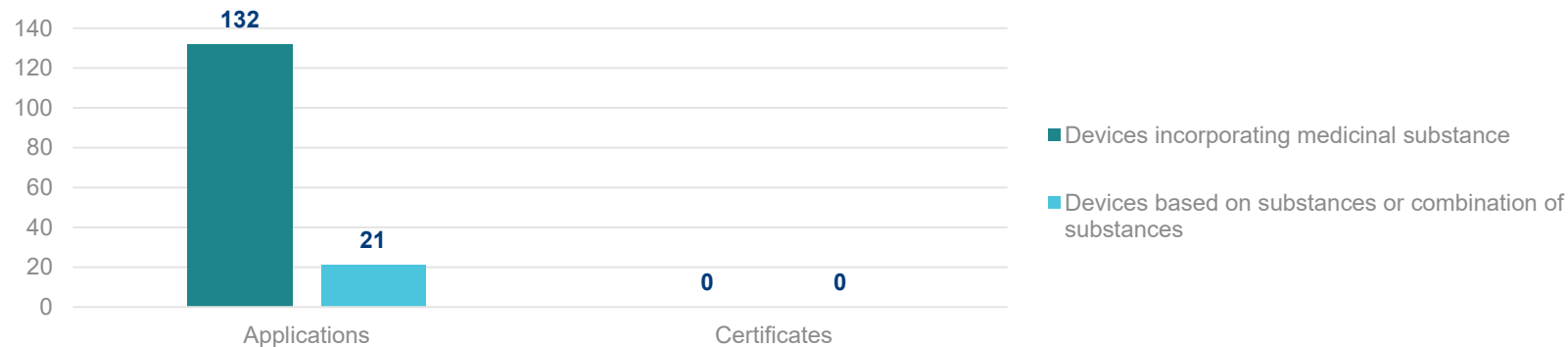
Total MDR applications/certificates



Total MDR applications/certificates by annex



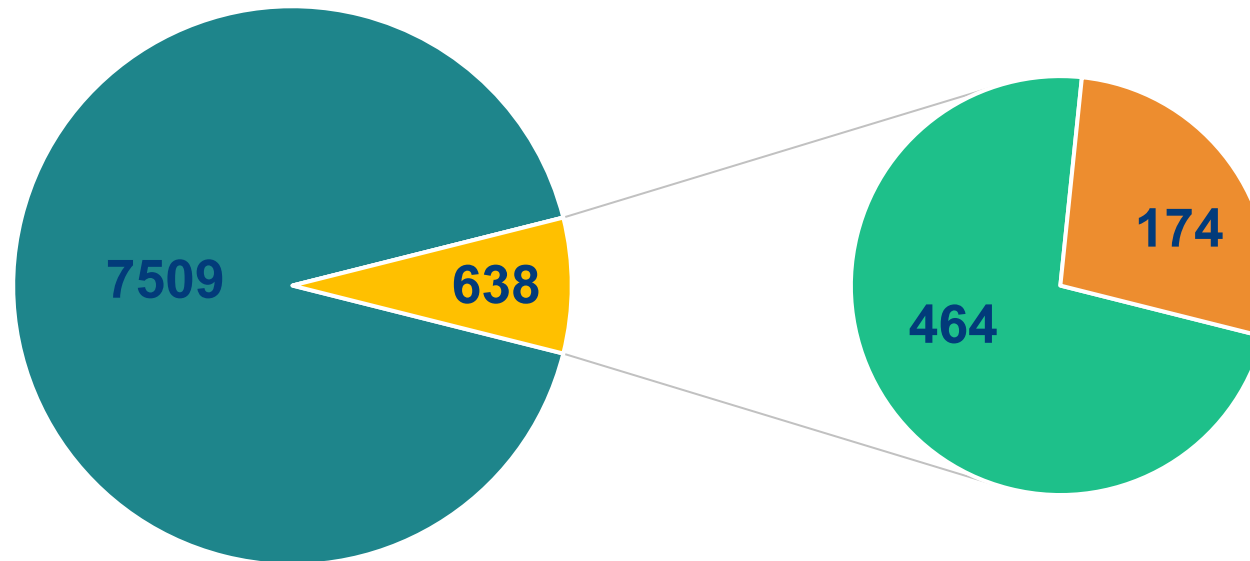
Total MDR applications/certificates requiring consultation procedure



Survey on certifications and applications

Certificates issued in 2021: **8.147**

MDR/MDD/AIMDD certificates issued in 2021

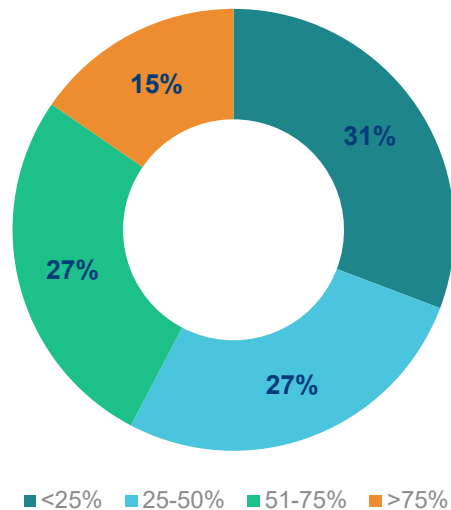


■ MDD/AIMDD Certificates ■ MDR QMS certificates ■ MDR product certificates

Survey on certifications and applications

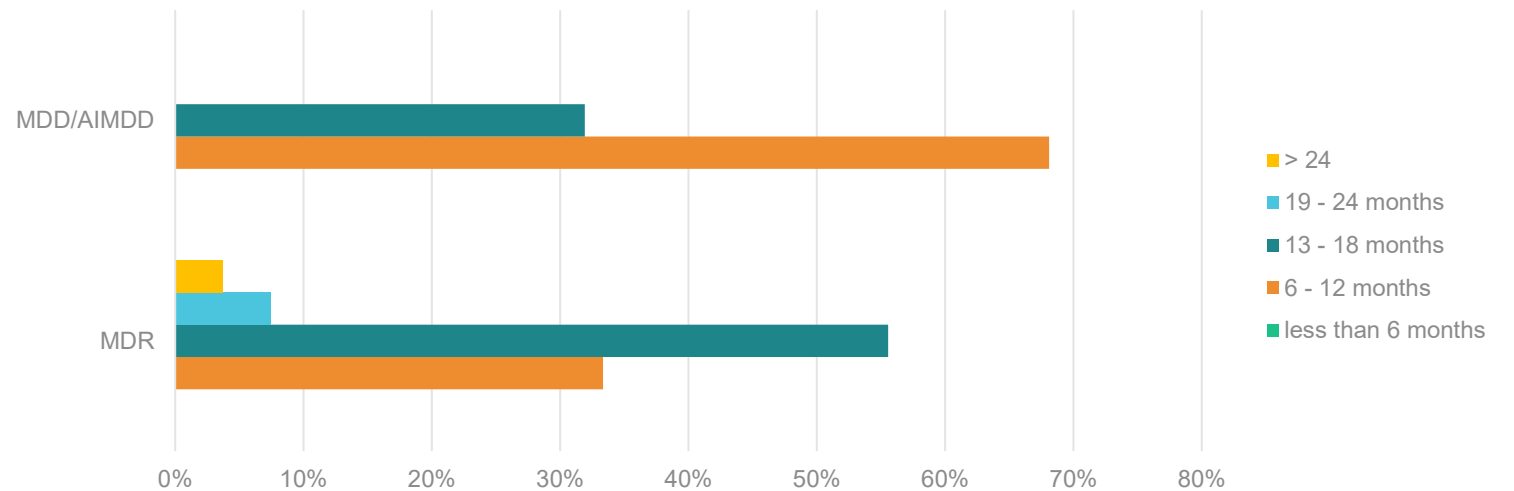
MDR completeness check and time to reach certification (Directive vs Regulation)

MDR Completeness check* (Annex VII, Section 4.3)



3/5 of NBs: less than 50% of submission are satisfactory in terms of documentation

Time to reach certification (Directive vs Regulation)

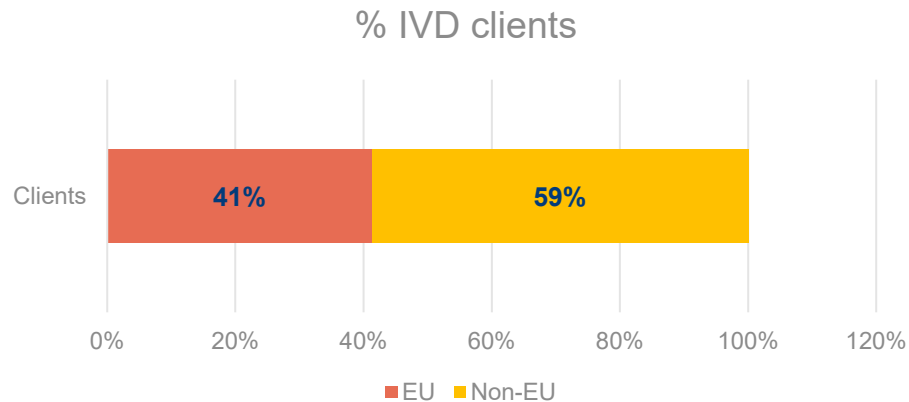


*Estimated percentage of submissions which were deemed satisfactory in terms of documentation provided (before undertaking the review of its content) without requesting for any additional information

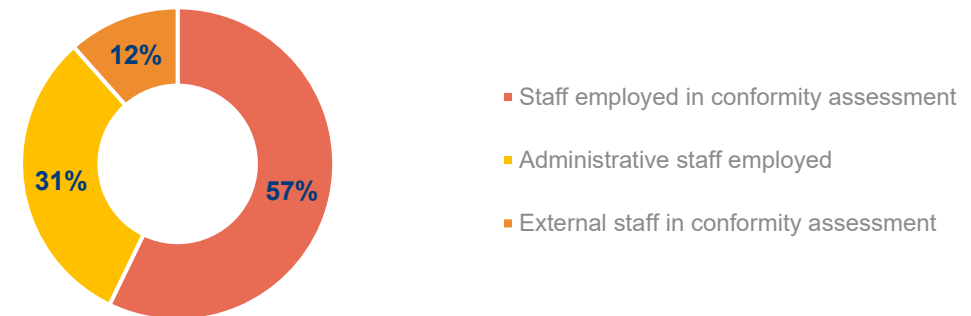
Survey on certifications and applications

IVD Notified bodies replies received – April 2022

- IVDD: **21 replies received – out of 21 notified bodies** designated under the IVDD
- IVDR: **7 replies received – out of 7 notified bodies** designated under the IVDR



Full time equivalent staff (2021)



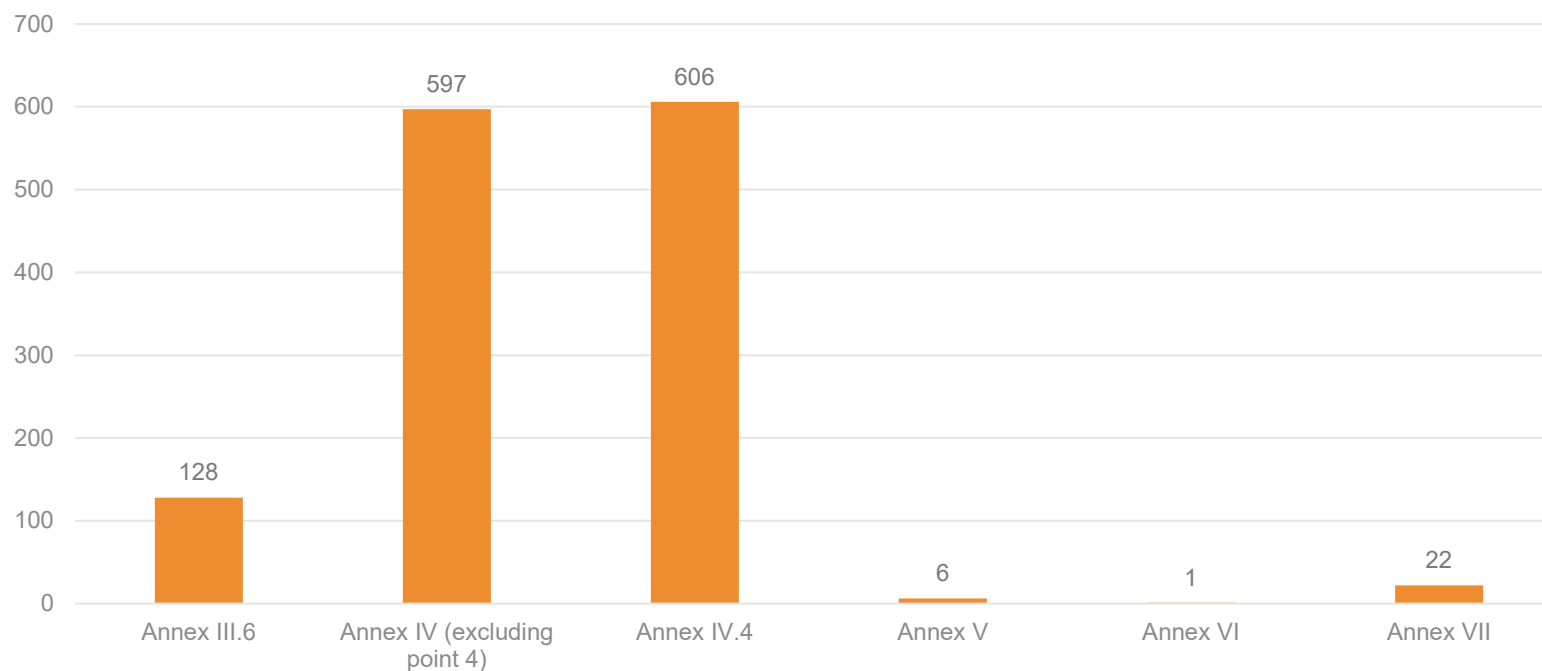
84% of NBs: majority of clients are SMEs

Survey on certifications and applications

IVDD Certificates by Annex

IVDD Data

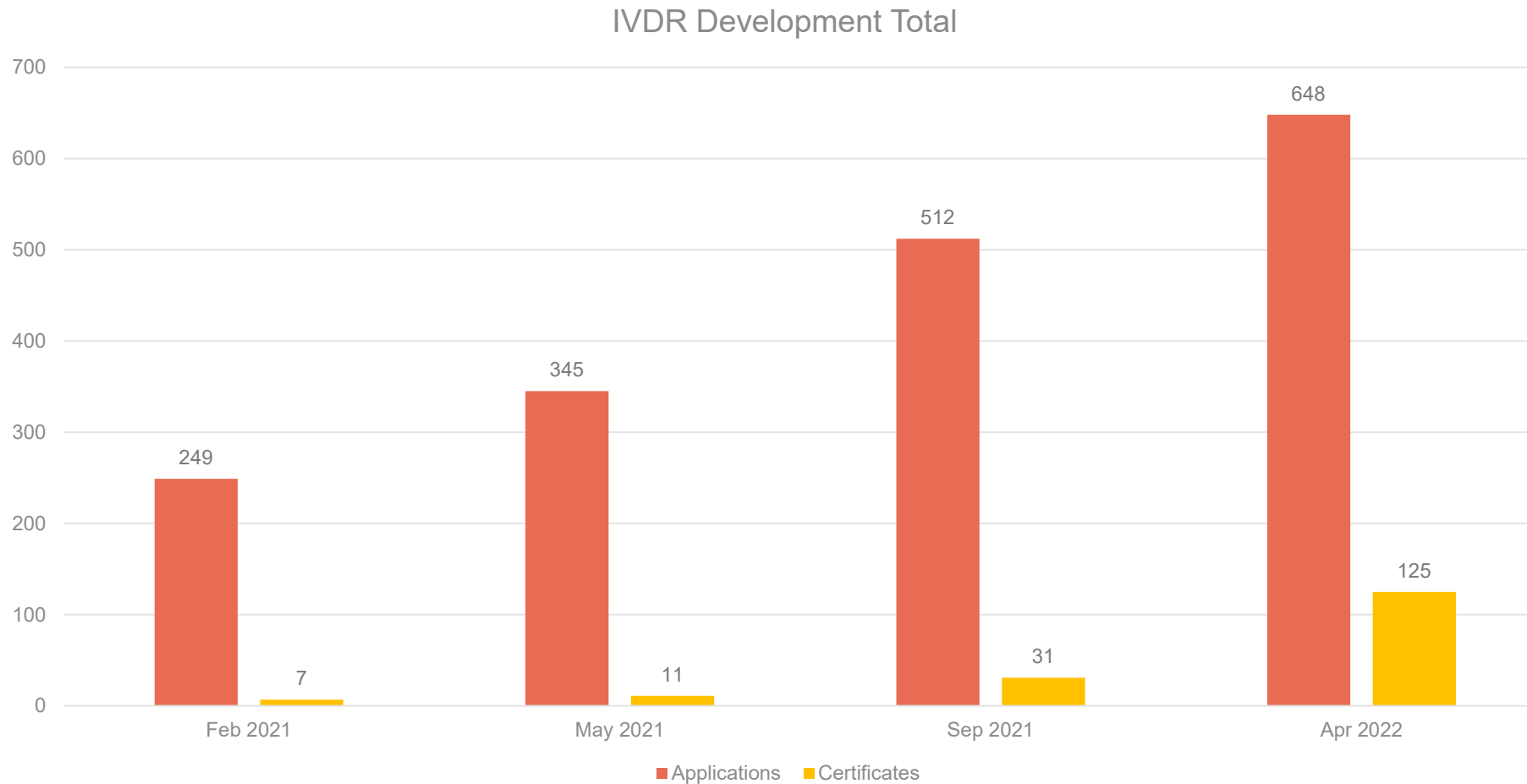
Total valid IVDD certificates by Annex

**Tot. 1.360**

Survey on certifications and applications

IVDR Data (1)

IVDR Applications filed and Certificates issued

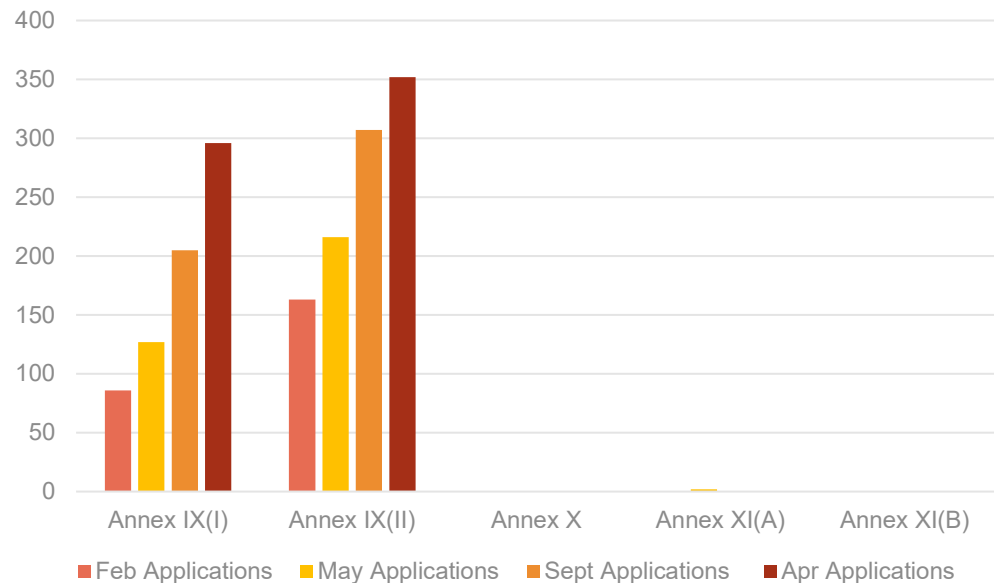


Survey on certifications and applications

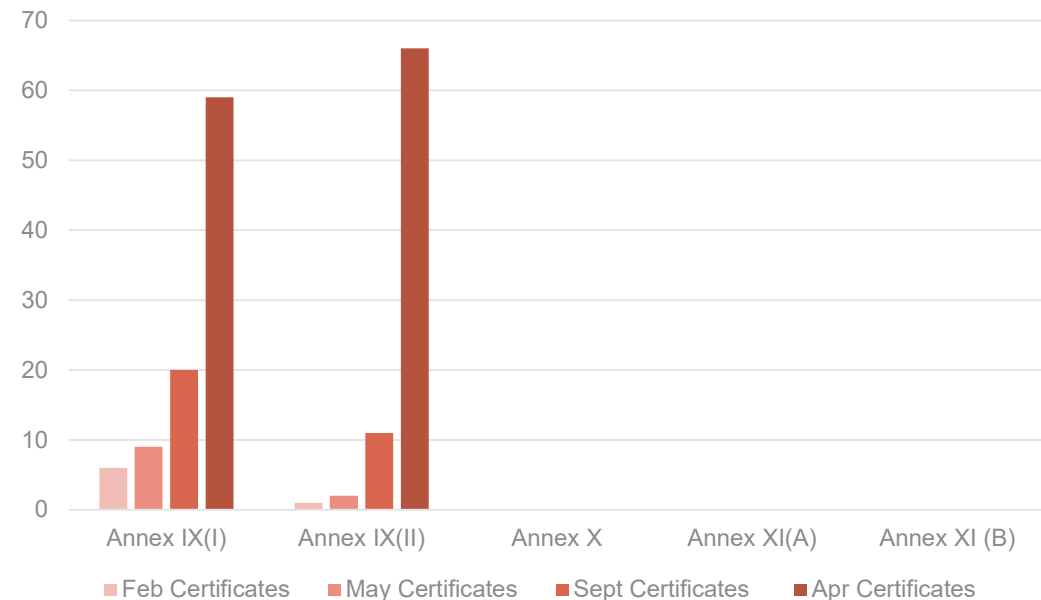
IVDR Data (2)

IVDR Certificates and Applications by Annex – Comparison each survey

Applications Total by Annex



Certificates Total by Annex

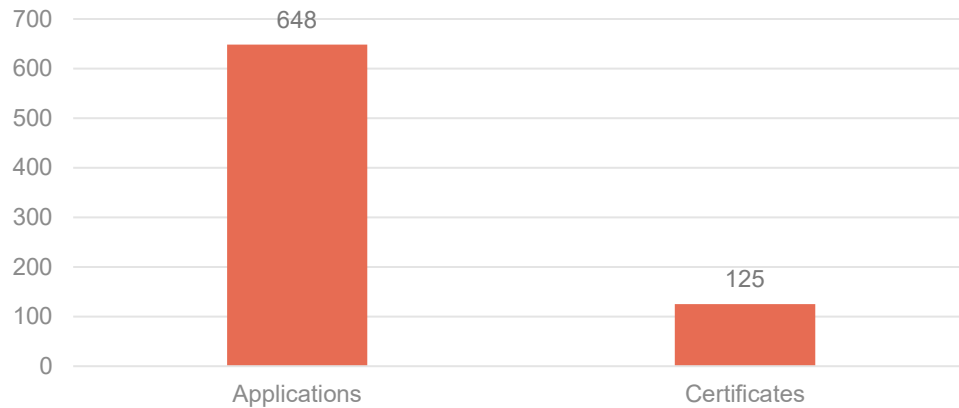


Survey on certifications and applications

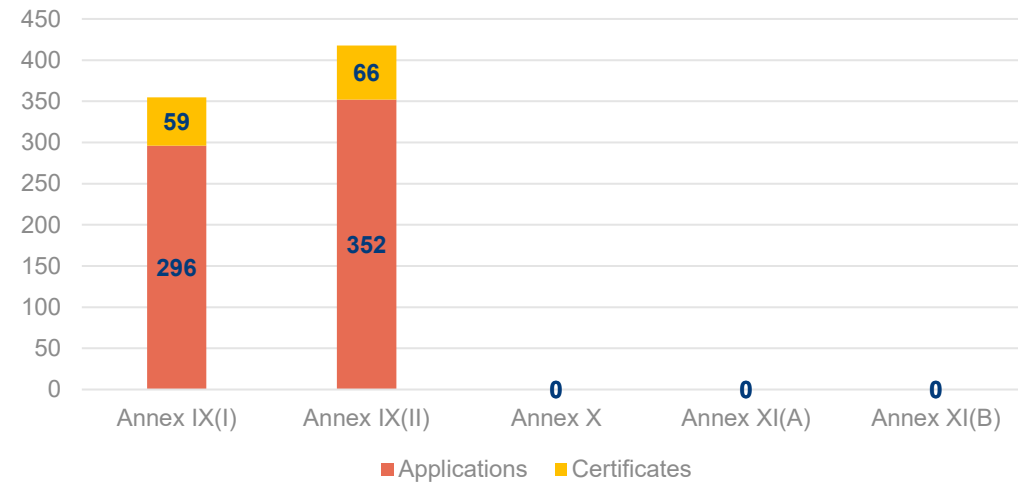
IVDR Data (3)

IVDR Certificates and Applications

Total IVDR applications/certificates



Total IVDR applications/certificates by annex



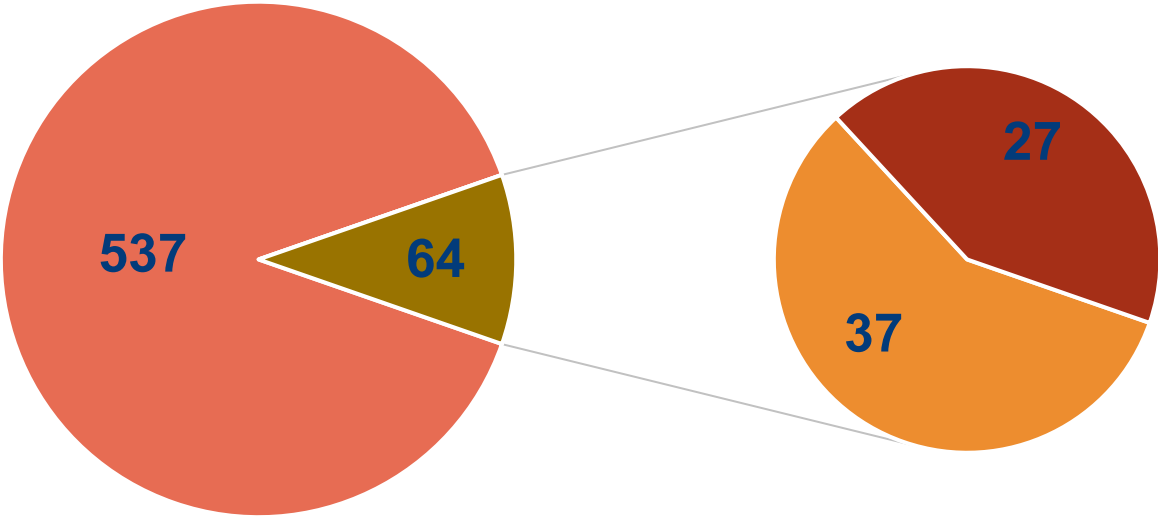
Companion diagnostic devices requiring consultation



Survey on certifications and applications

Certificates issued in 2021: **601**

IVDR/IVDD certificates issued in 2021

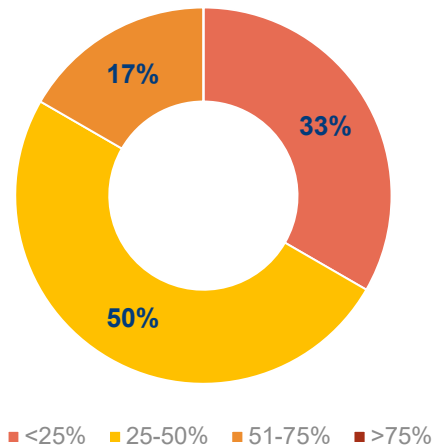


■ IVDD Certificates ■ IVDR QMS certificates ■ IVDR product certificates

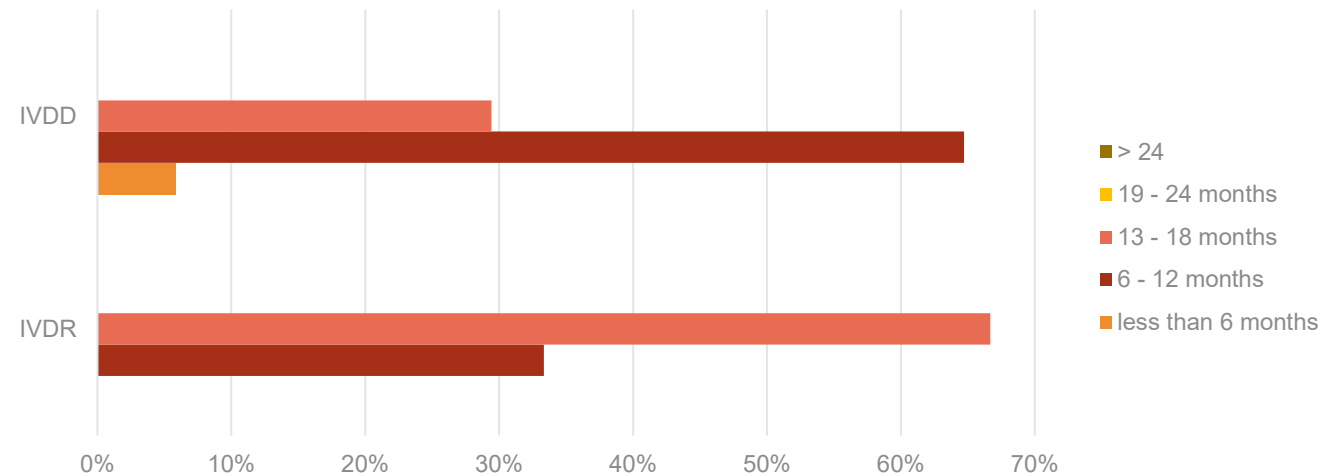
Survey on certifications and applications

IVDR completeness check and time to reach a certificate (Directive vs Regulation)

IVDR Completeness check* (Annex VII, Section 4.3)



Time to reach certification (Directive vs Regulation)



4/5 of NBs: less than 50% of submission are satisfactory in terms of documentation

*Estimated percentage of submissions which were deemed satisfactory in terms of documentation provided (before undertaking the review of its content) without requesting for any additional information

Thank you



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