



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

MDCG & Stakeholders

24 Oct 2022

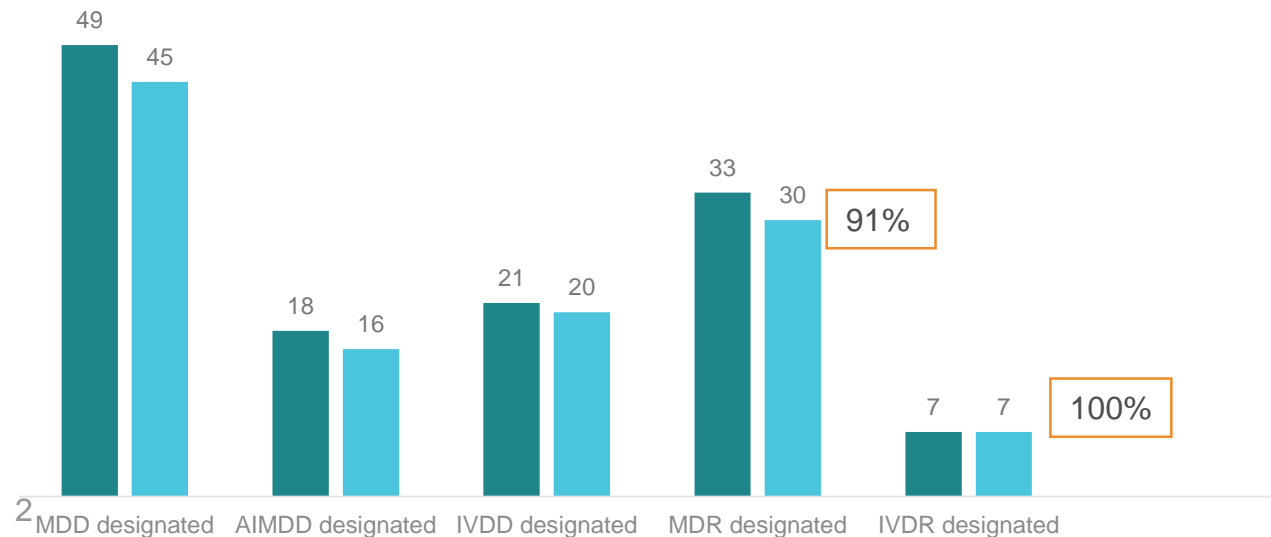
Survey on certifications and applications

General data of Notified bodies replies received – October 2022

47 replies received* – out of 51 notified bodies

Replies received_Oct 2022

■ Designated NBs ■ Replies received_Oct 2022



*Missing replies: data from previous survey (April 2022) have been considered. MDR applications and certificates may be slightly underestimated (1 out of the 3 missing NB recently MDR designated).

Survey on certifications and applications

General data of Notified bodies replies received – October 2022

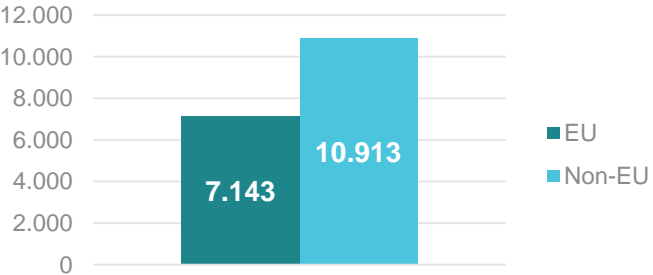
47 replies received – out of 51 notified bodies

AIMDD designated	16 replies out of 18 NBs
MDD designated	45 replies out of 49 NBs
MDR designated	30 replies out of 33 NBs

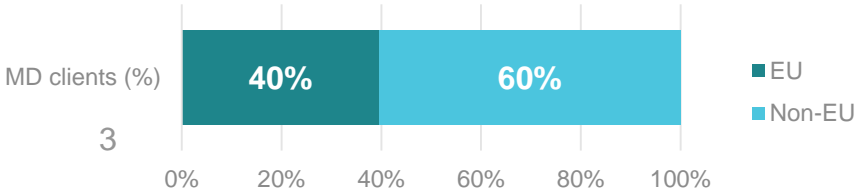
Data from survey of October 2022

Data from previous survey (April 2022)

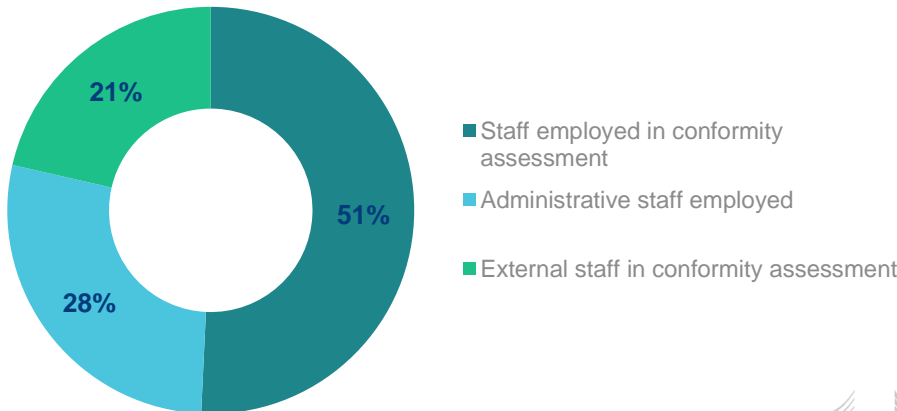
MD Clients



% MD clients



Full time equivalent staff (2021)



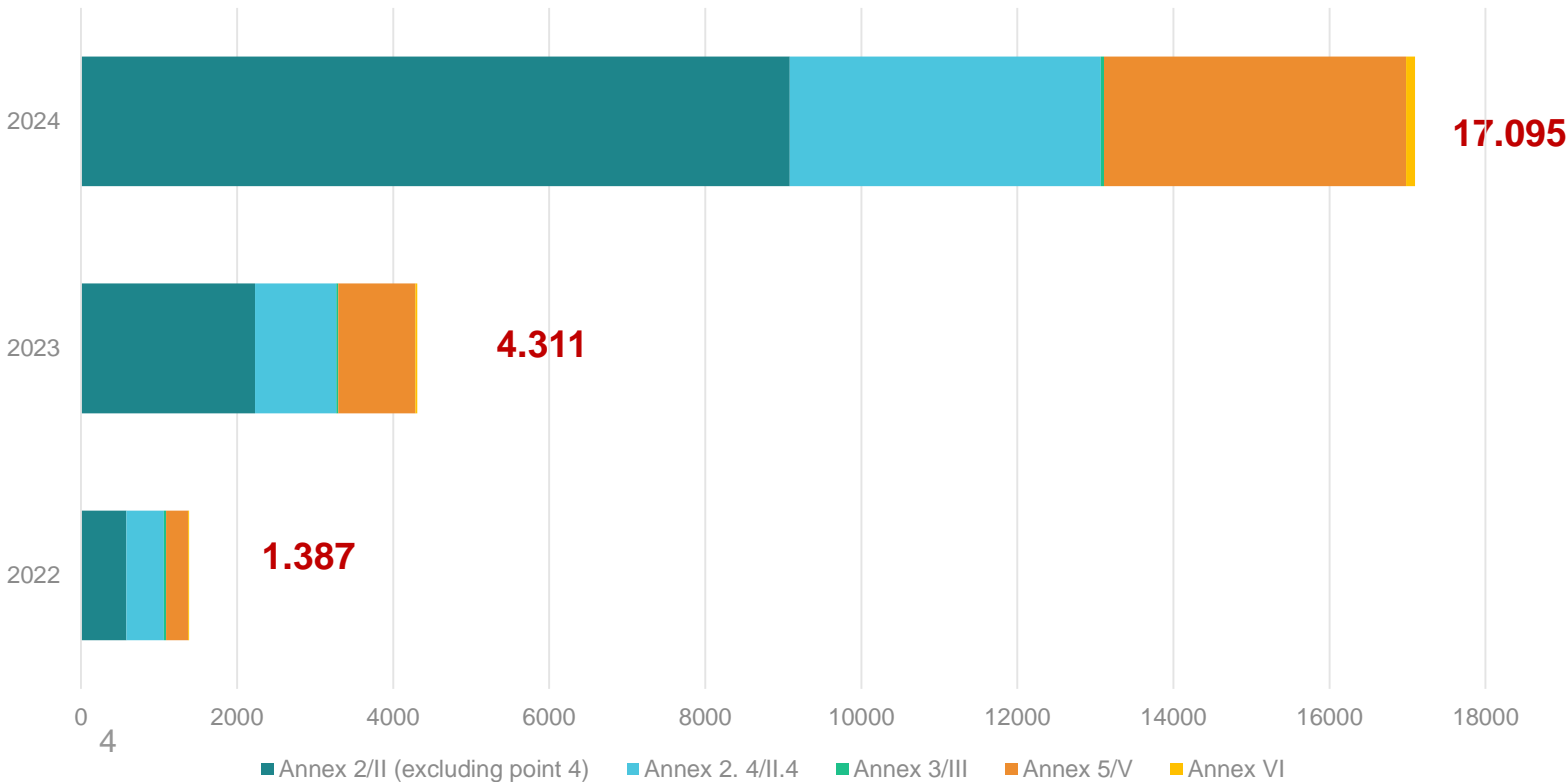
89% of NBs: majority of clients are SMEs

Survey on certifications and applications

MDD/AIMDD Data (1/2)

MDD/AIMDD Certificates – October 2022

MDD/AIMDD valid certificates breakdown by date of expiry



Total valid MDD/AIMDD certificates (excluded Annex 4/IV*): 22.793**

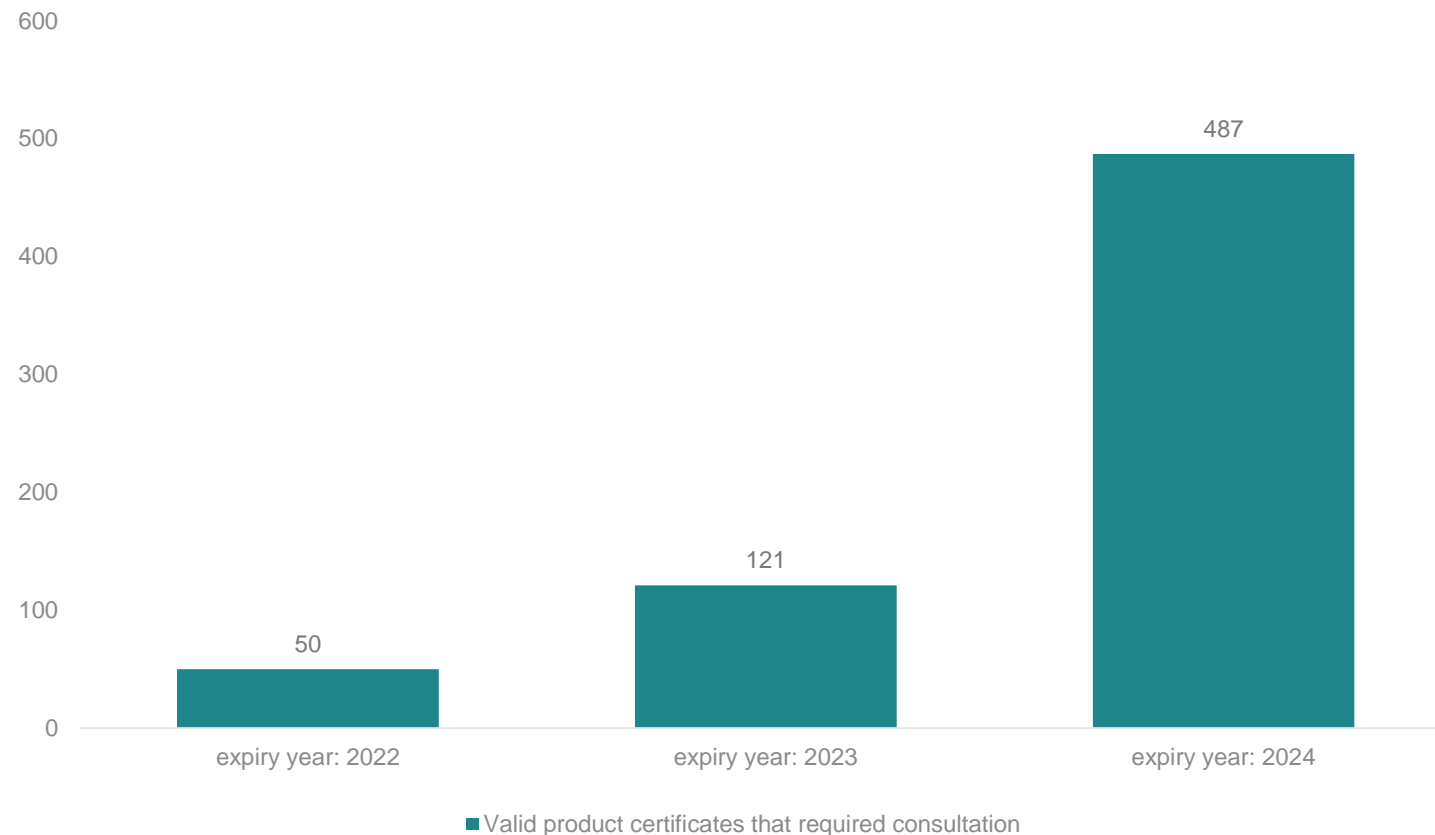
*Annex 4/IV certificates :363

** 24.073 in April 2022

Survey on certifications and applications

MDD/AIMDD Certificates requiring consultation for ancillary medicinal substances – October 2022

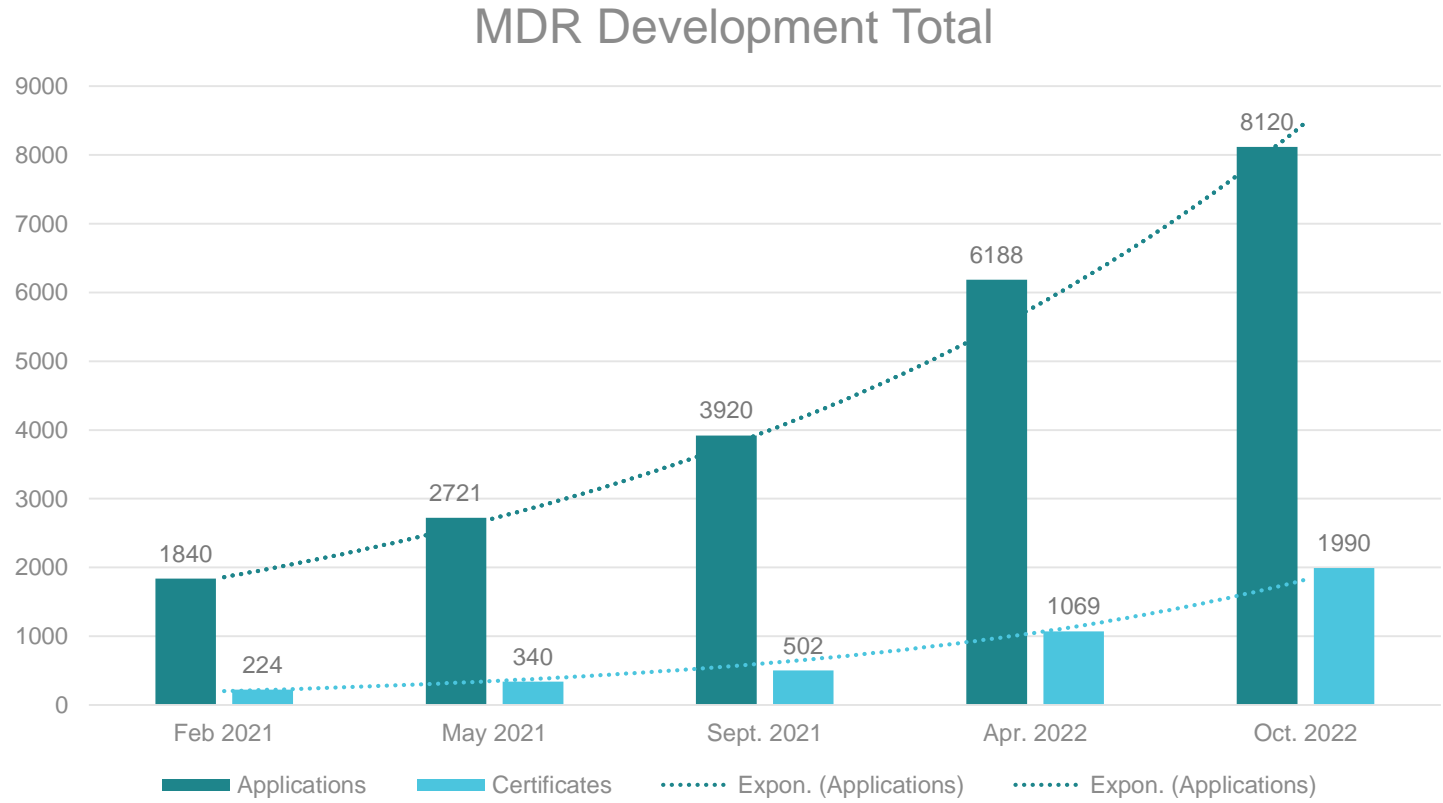
MDD/AIMDD Data (2/2)



Survey on certifications and applications

MDR Applications filed and Certificates issued

MDR Data (1/5)



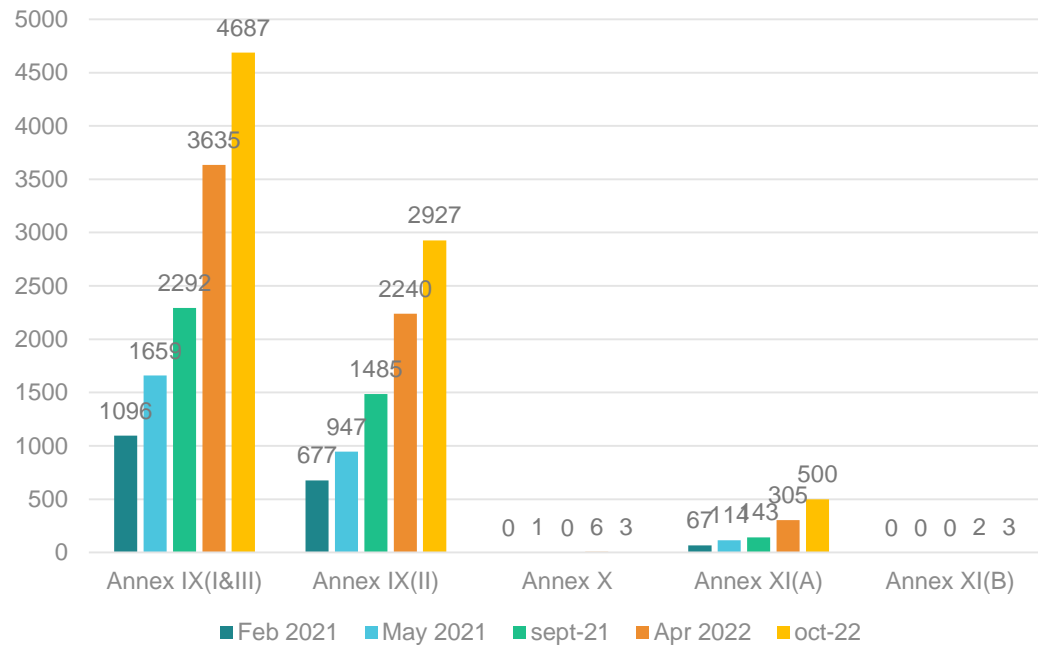
October 2022
MDR Applications: 8.120
MDR Certificates: 1.990

Survey on certifications and applications

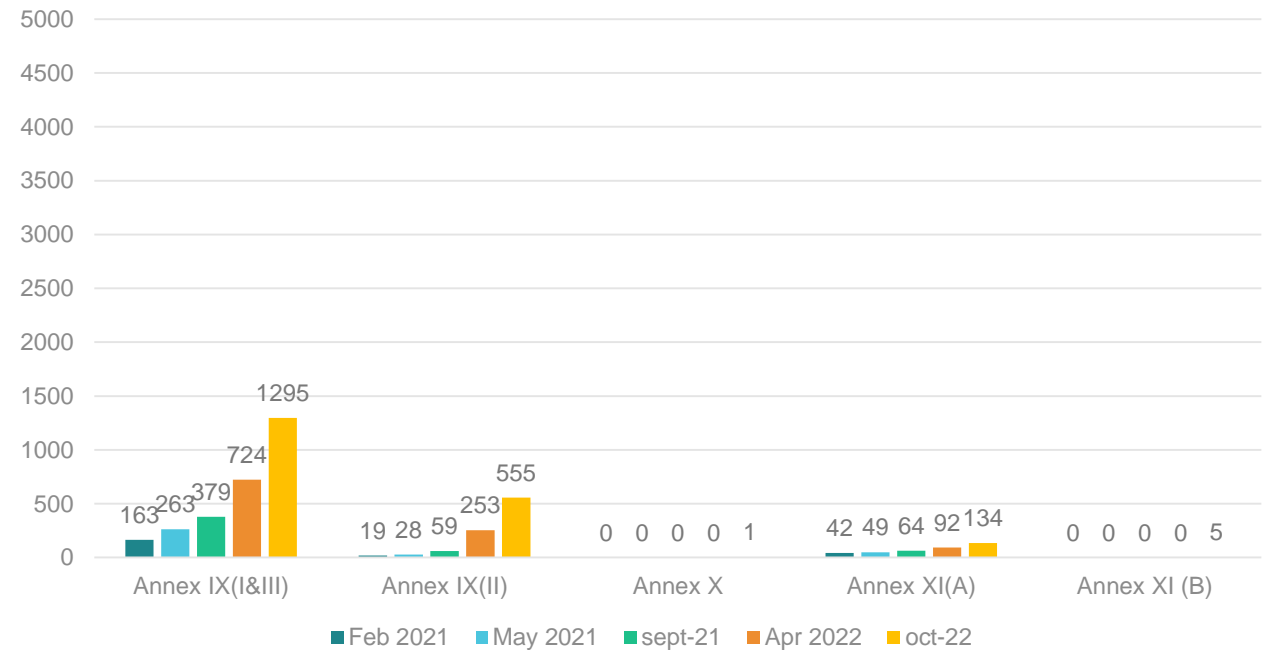
MDR Applications and Certificates by Annex – Surveys comparison

MDR Data (2/5)

Applications surveys comparison



Certificates surveys comparison



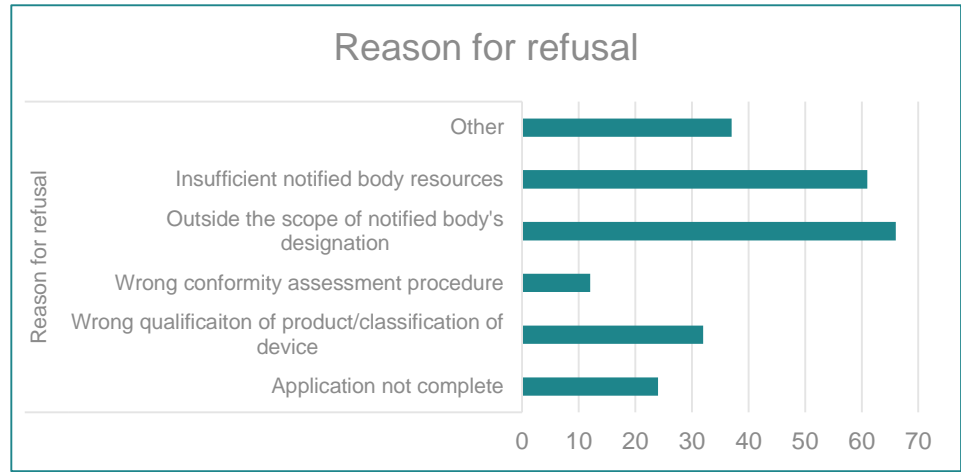
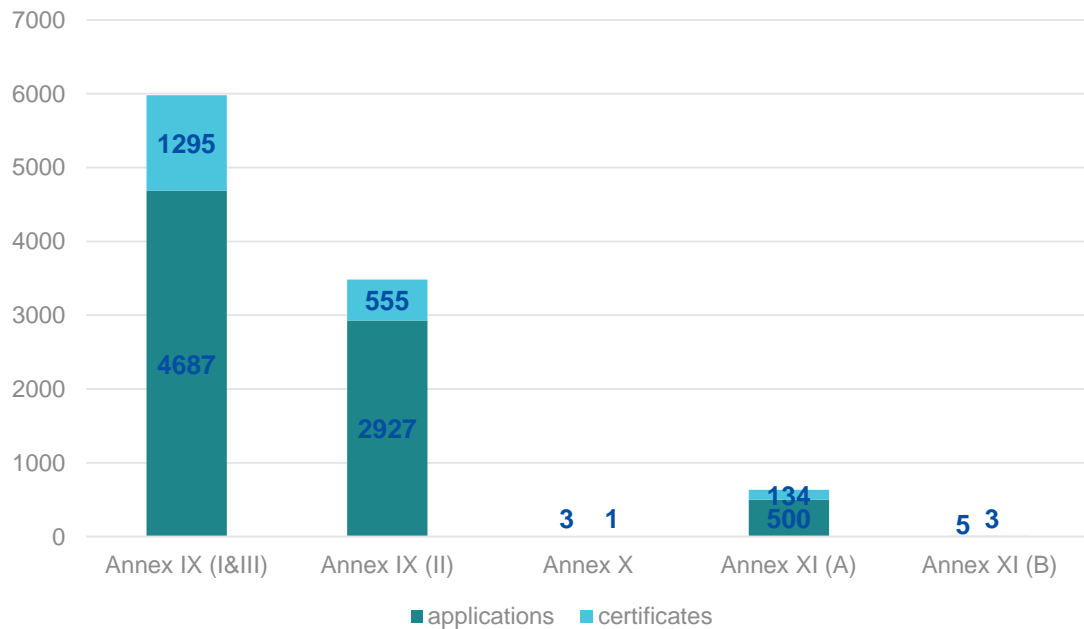
Survey on certifications and applications

MDR Certificates and Applications - October 2022

MDR Data (3/5)

MDR Applications : 8.120
MDR Certificates: 1.990

Total MDR applications/certificates by annex

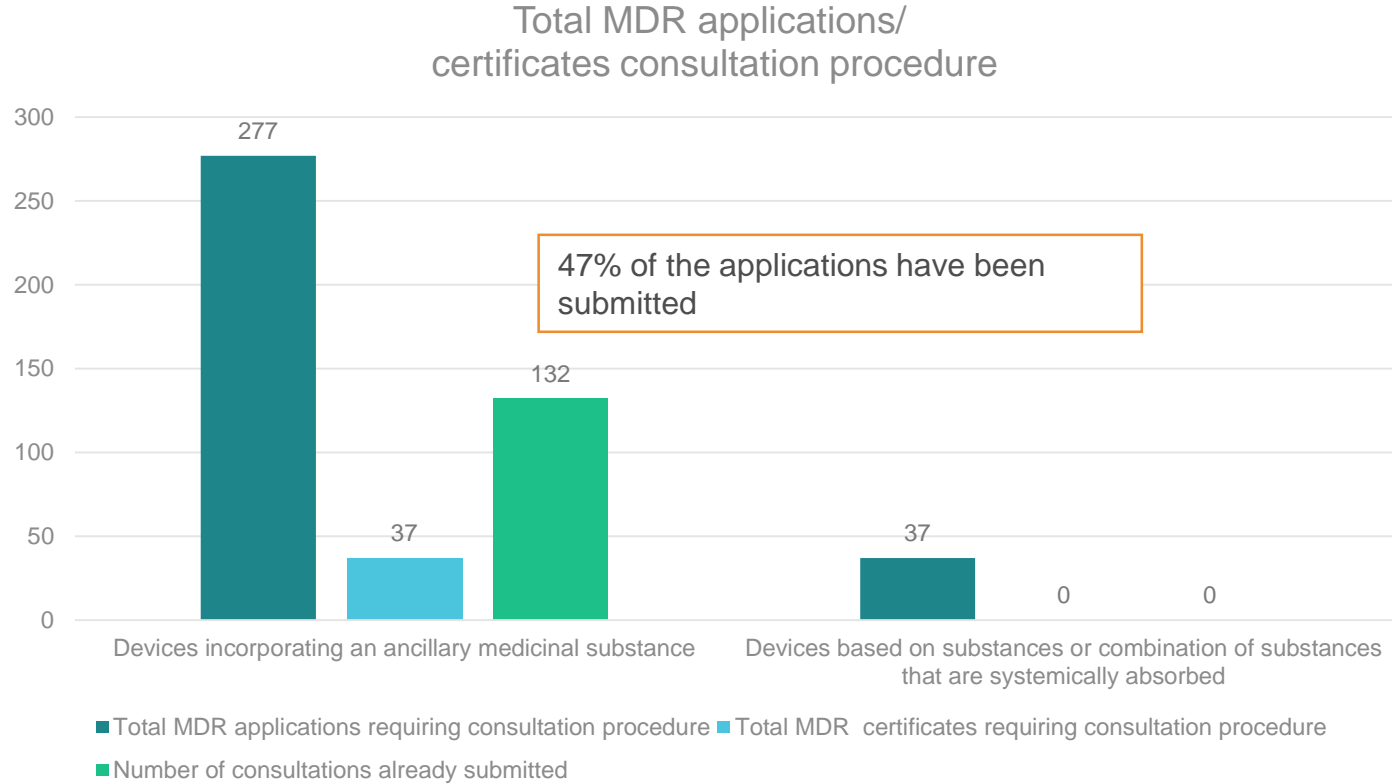


Note: the number of refusal reason "insufficient NB resources" is due to mainly one NB which has indicated 60 refusals.

Survey on certifications and applications

MDR Certificates and Applications - October 2022

MDR Data (4/5)



MDR Applications: 8.120
MDR Certificates: 1.990

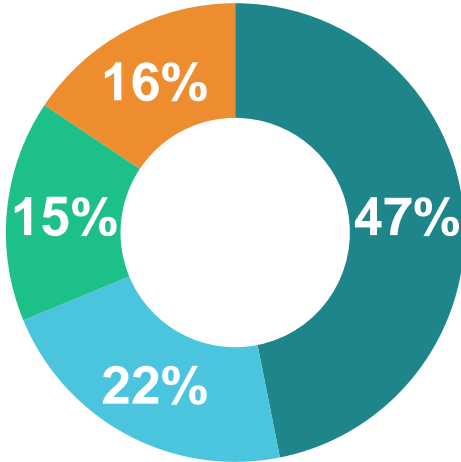
Survey on certifications and applications

MDR completeness check and time to reach certification (QMS+PRODUCT vs QMS)

MDR Data (5/5)

MDR Completeness check (Annex VII, Section 4.3)

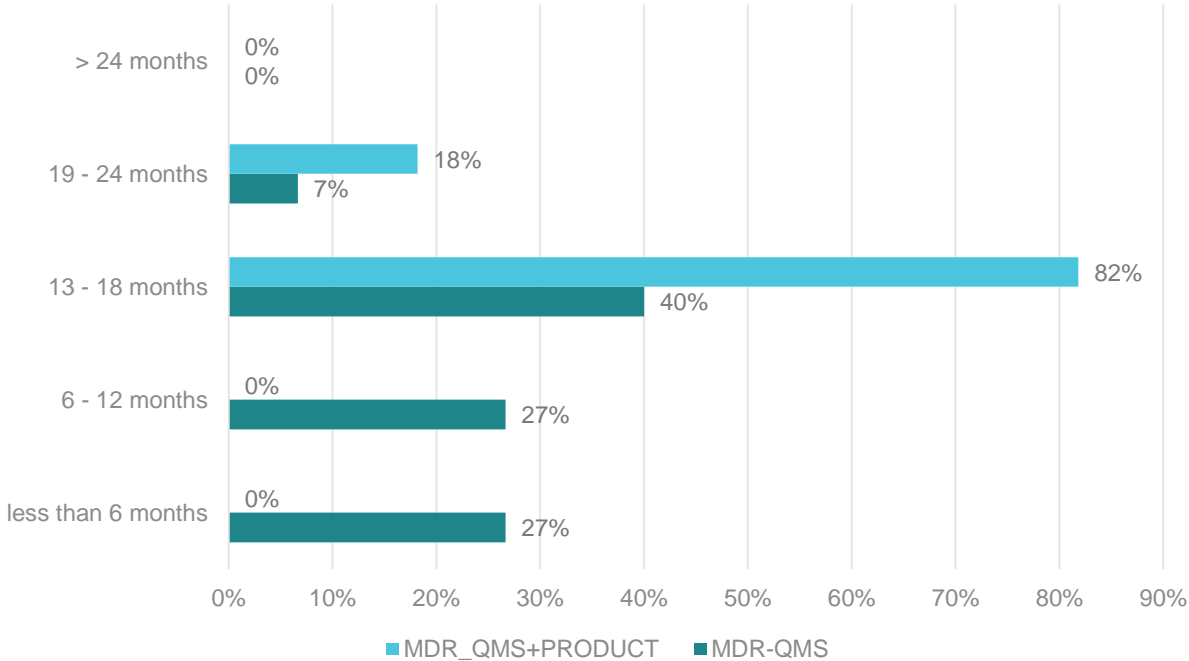
<25% 25-50% 51-75% >75%



Several submissions deemed incomplete*

10 *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

Time to reach a Certificate (QMS+PRODUCT vs QMS)

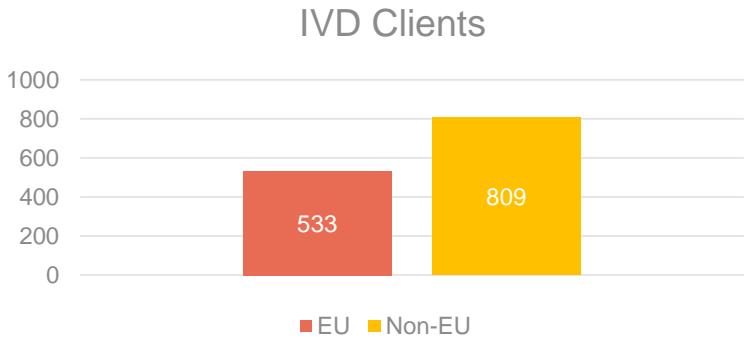


Survey on certifications and applications

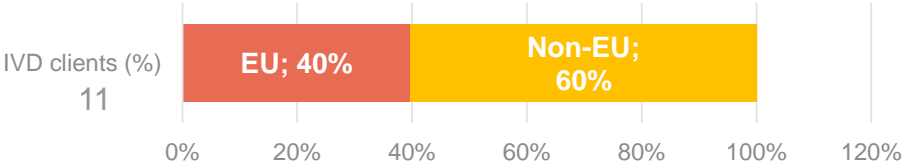
IVD Notified bodies replies received – October 2022

- IVDD: **20 replies received – out of 21 notified bodies** designated under the IVDD
- IVDR: **7 replies received – out of 7 notified bodies** designated under the IVDR

Data from survey of October 2022

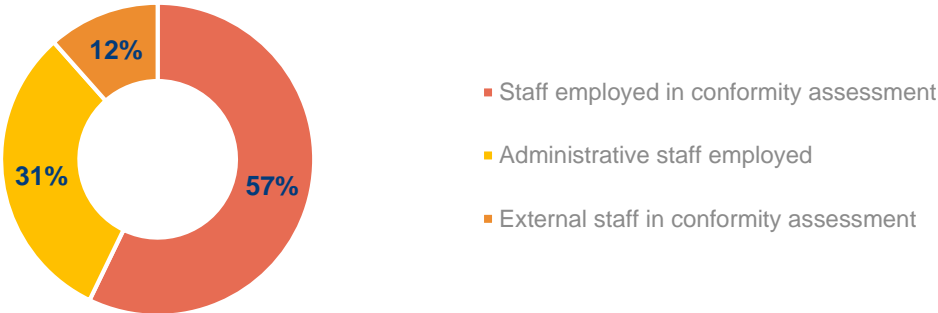


IVD clients (%)



Data from previous survey (April 2022)

Full time equivalent staff (2021)



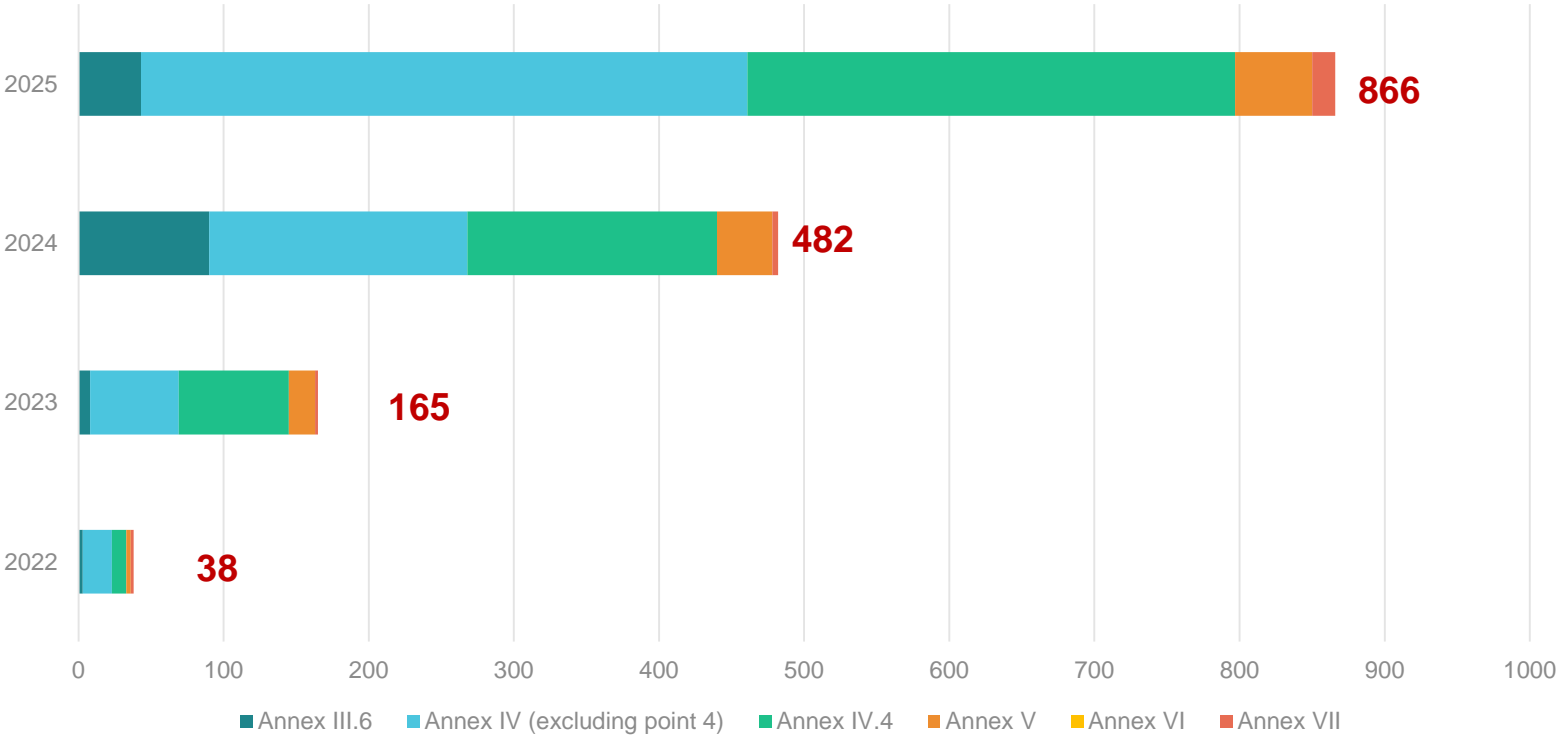
84% of NBs: majority of clients are SMEs

Survey on certifications and applications

IVDD Certificates by date of expiry

IVDD Data

IVDD valid certificates breakdown by date of expiry



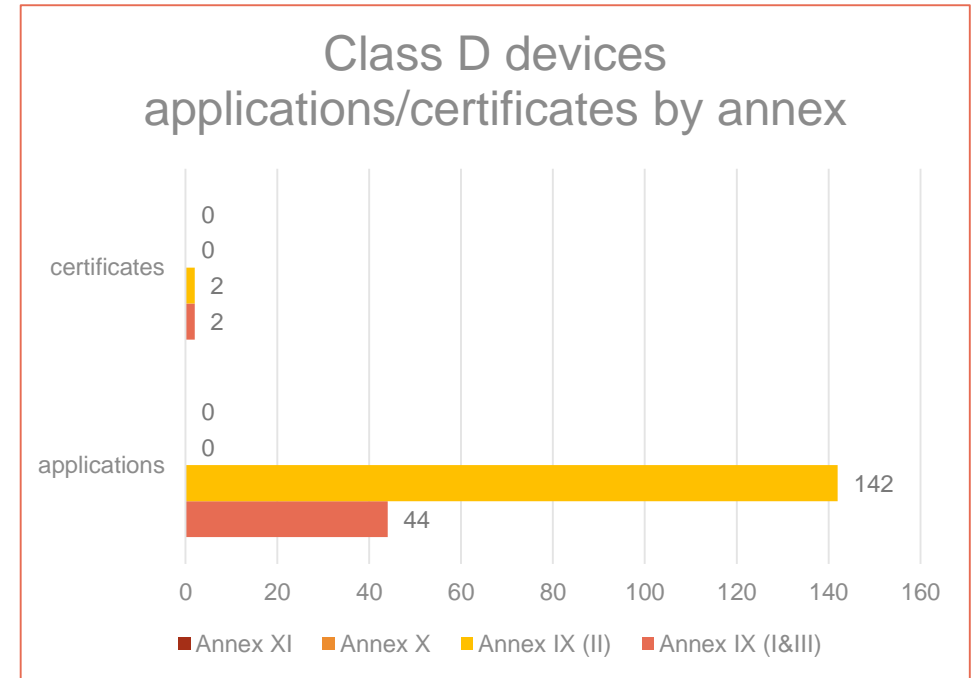
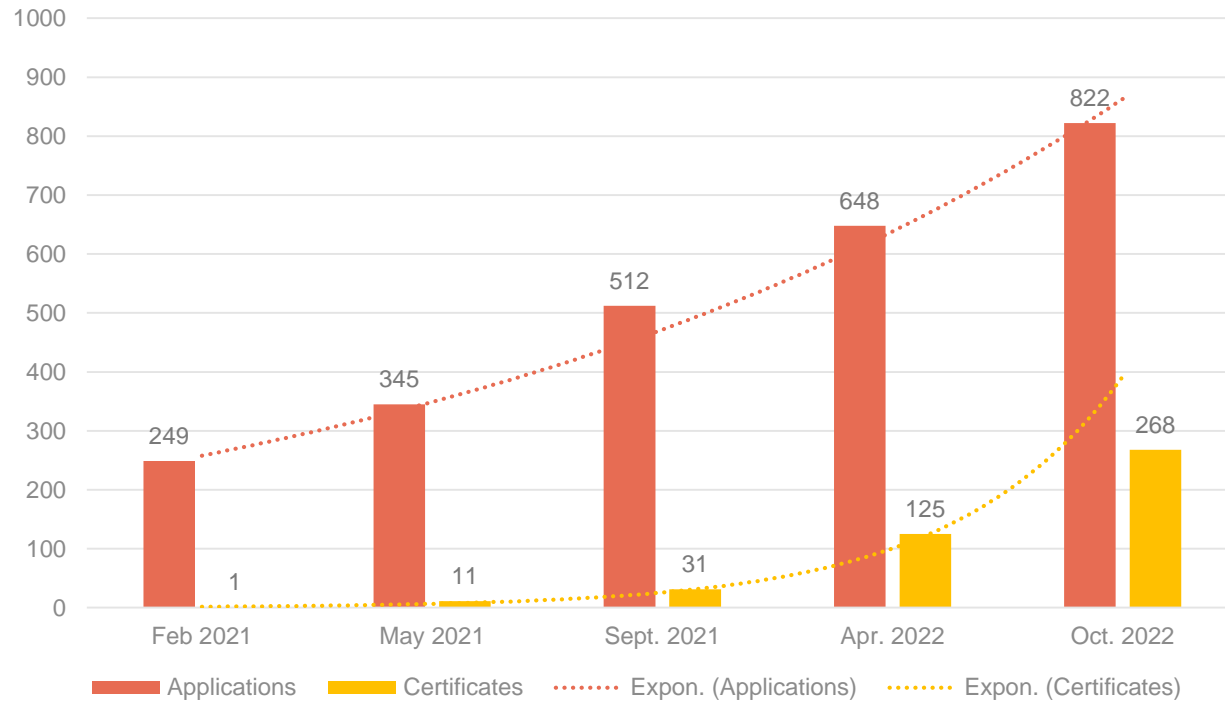
Tot. valid IVDD certificates 1.551

Survey on certifications and applications

IVDR Applications and Certificates

IVDR Data (1/5)

IVDR Development Total

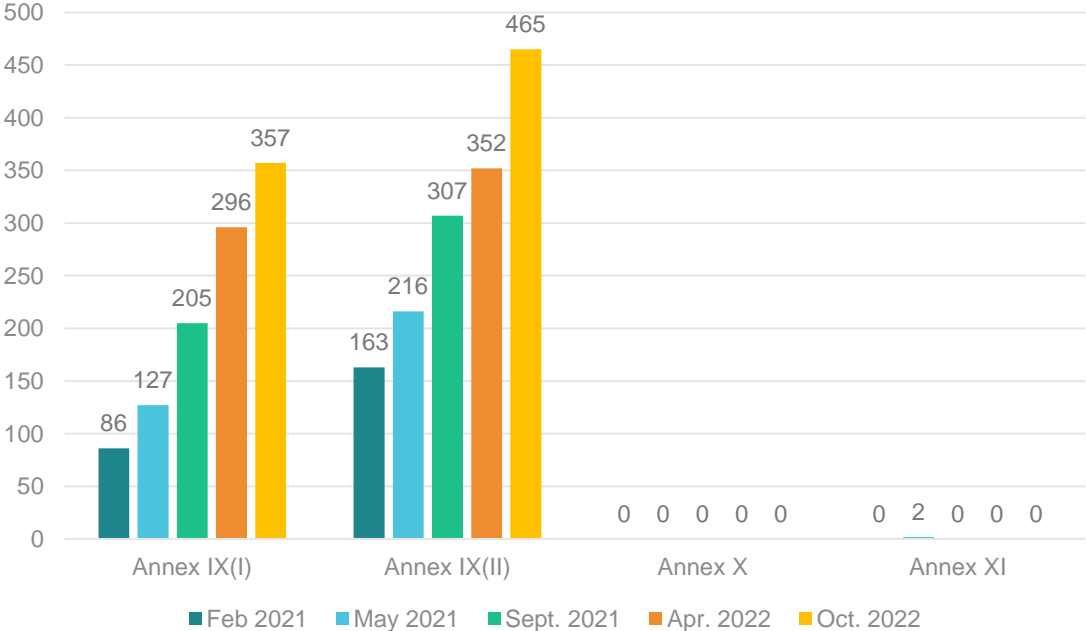


Survey on certifications and applications

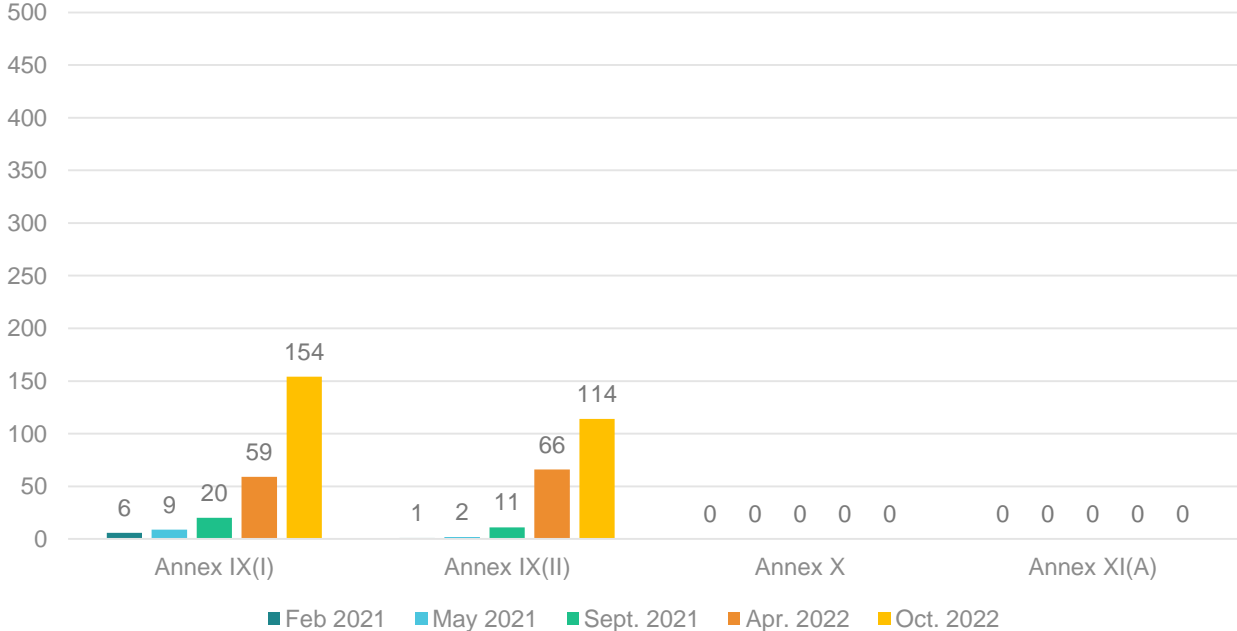
IVDR Applications and Certificates by Annex – Surveys comparison

IVDR Data (2/5)

Applications surveys comparison



Certificates surveys comparison

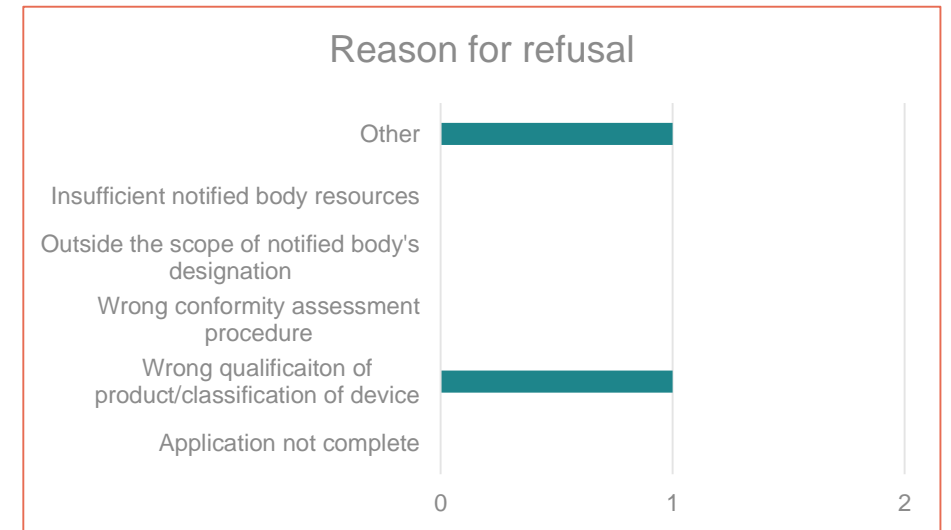
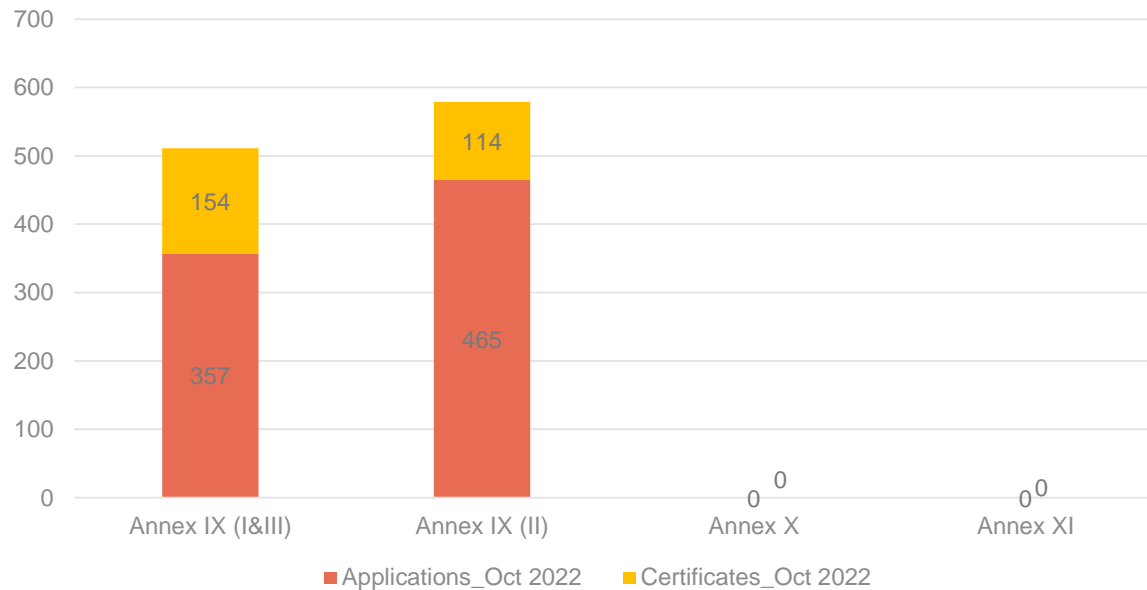


Survey on certifications and applications

IVDR Applications and Certificates by Annex

IVDR Data (3/5)

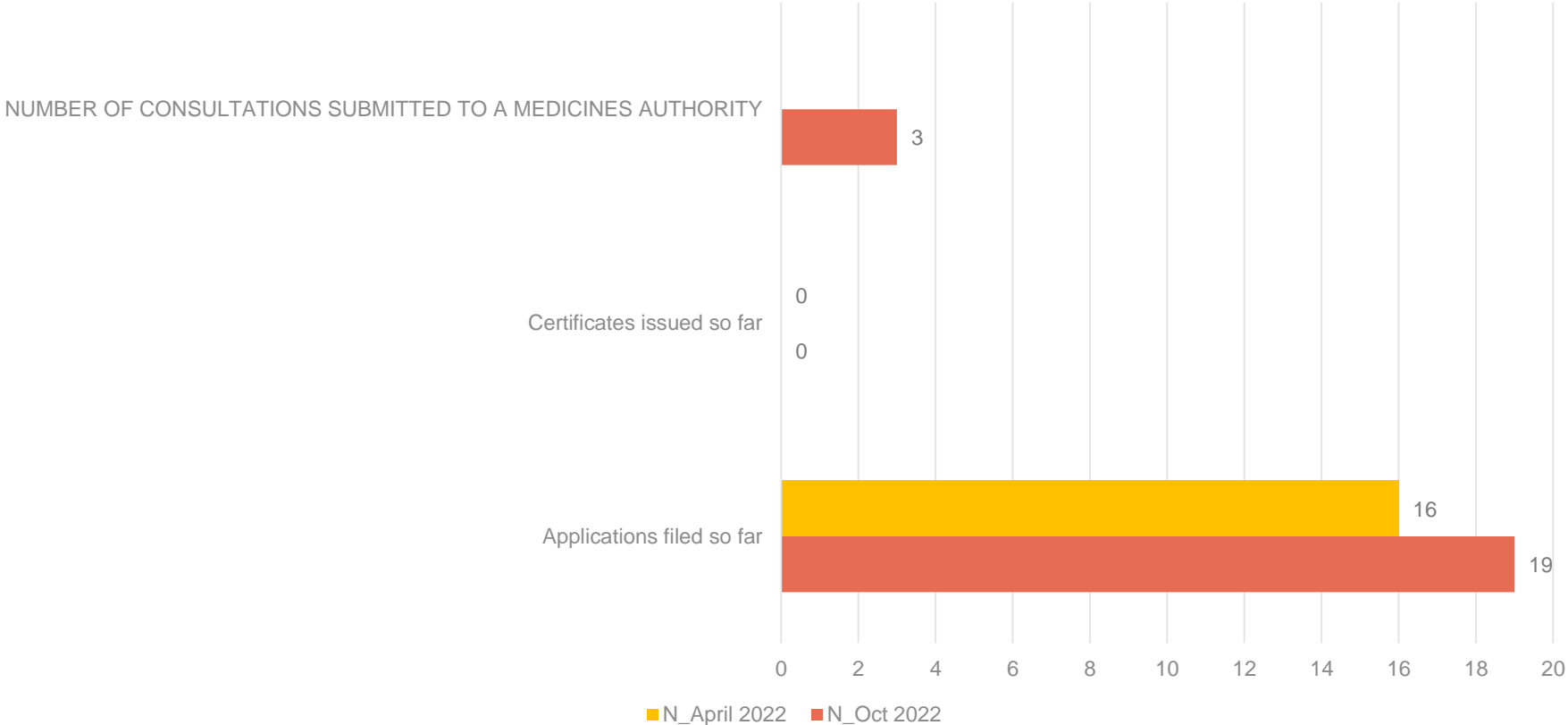
Total IVDR applications/certificates by annex



Survey on certifications and applications

IVDR Applications and Certificates – Companion diagnostic devices requiring consultation

IVDR Data (4/5)



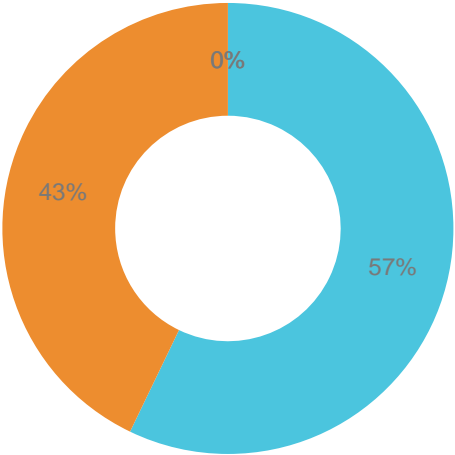
Survey on certifications and applications

IVDR completeness check and time to reach a certificate

IVDR Data (5/5)

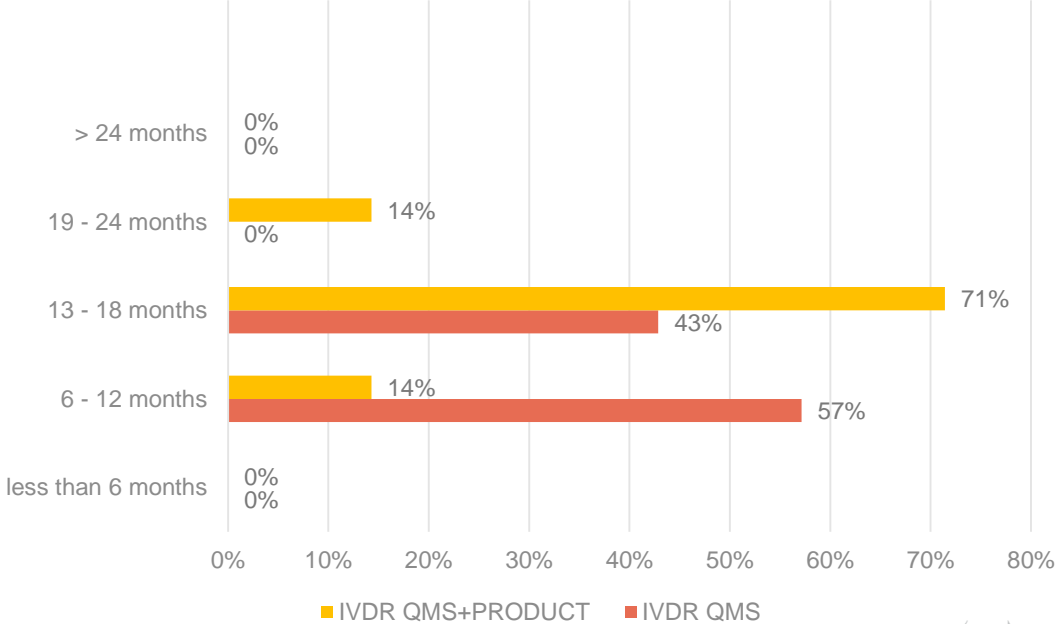
IVDR Completeness check (Annex VII, Section 4.3)

<25% 25-50% 51-75% >75%



Submissions largely incomplete*

Time to reach IVDR Certificate (QMS+PRODUCT vs QMS)



17 *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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