



NB Survey on certifications and applications for Directives and Regulations on medical devices and IVDs

DG SANTE

6 April 2021

Medical devices notified bodies – replies received February 2021

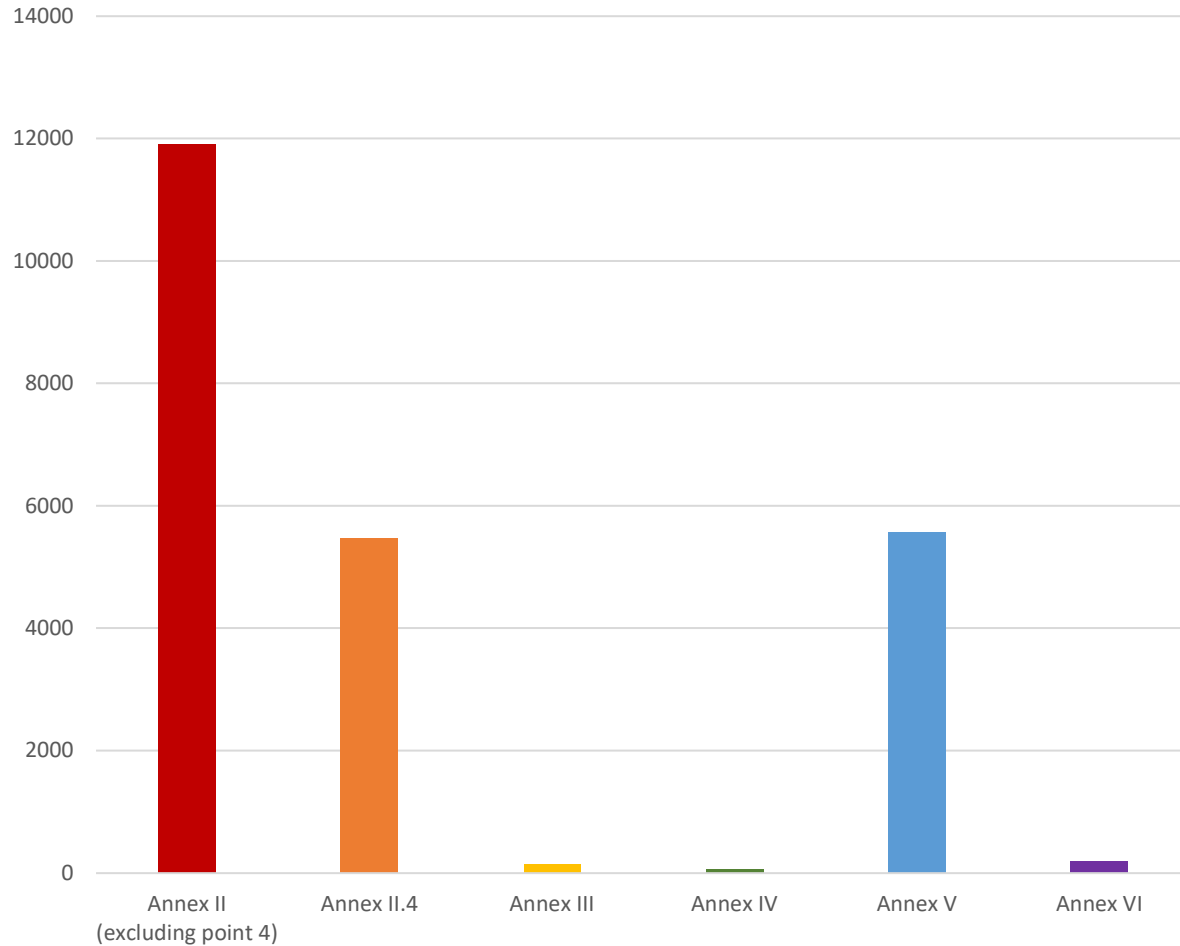
- MDD/AIMDD: 44 replies received - out of 52 notified bodies designated under the MDD, 10 of which also designated under the AIMDD (all notified bodies designated under the AIMDD replied)
- MDR: 17 replies received – out of 18 notified bodies designated under the MDR at the time the survey was launched

AIMDD/MDD data request

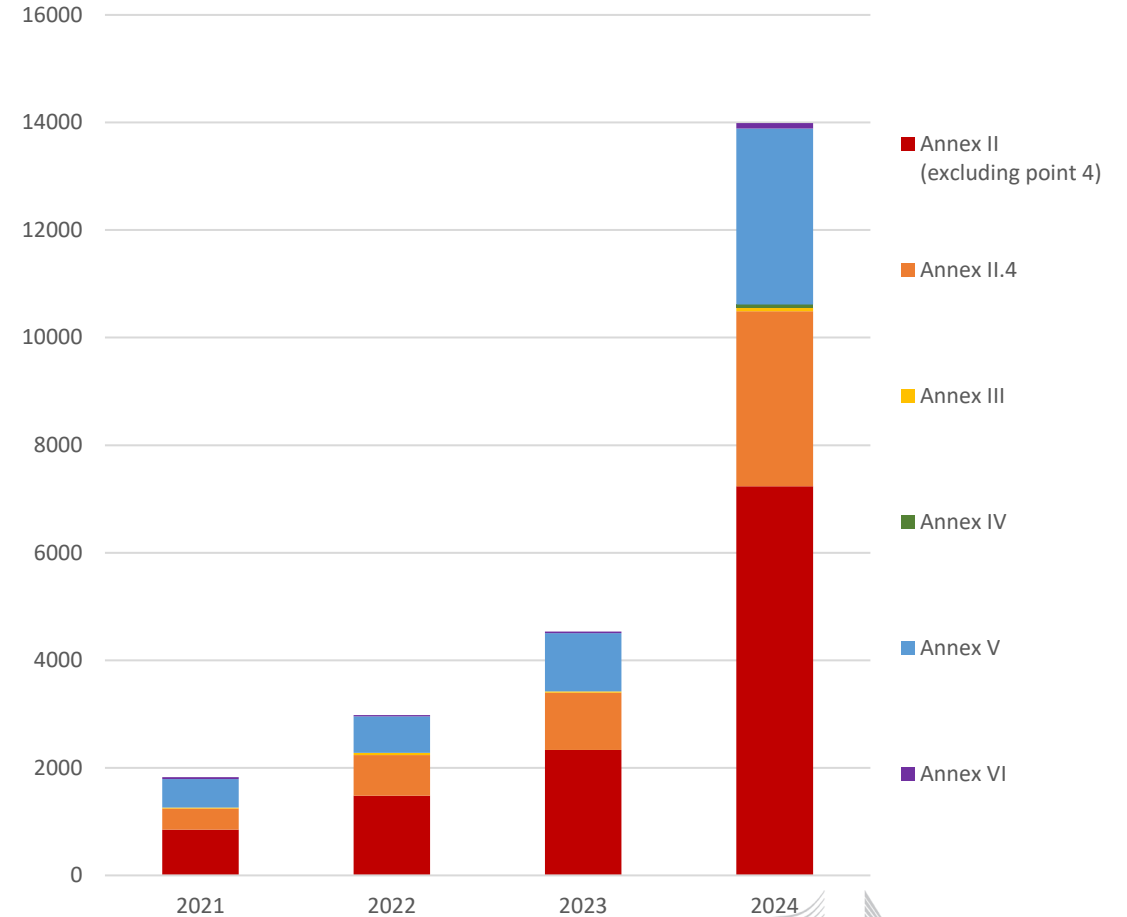
| | CERTIFICATION UNDER AIMDD/MDD | | | | | |
|-----------------------------------|---|--|------|------|------|------|
| | Total Number of valid certificates under AIMDD/MDD by annex | Number of certificates, by year of expiry and by annex | | | | |
| | | 2020 | 2021 | 2022 | 2023 | 2024 |
| Annex 2/II (excluding point 4) | | | | | | |
| Annex 2. 4/II.4 | | | | | | |
| Annex 3/III | | | | | | |
| Annex 4/IV | | N.A | N.A | N.A | N.A | N.A. |
| Annex 5/V | | | | | | |
| Annex VI | | | | | | |

AIMDD/MDD valid certificates (1/3)

Breakdown by Annex

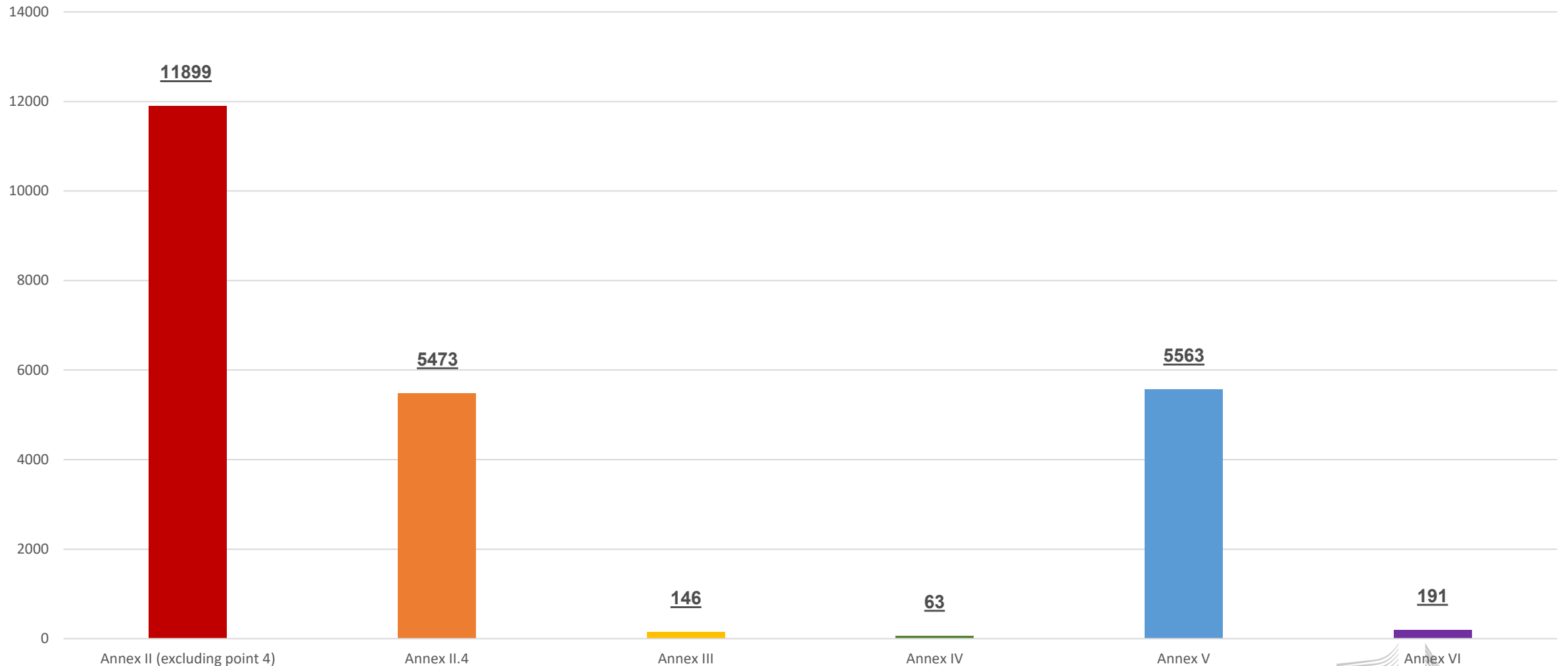


Breakdown by year of expiry



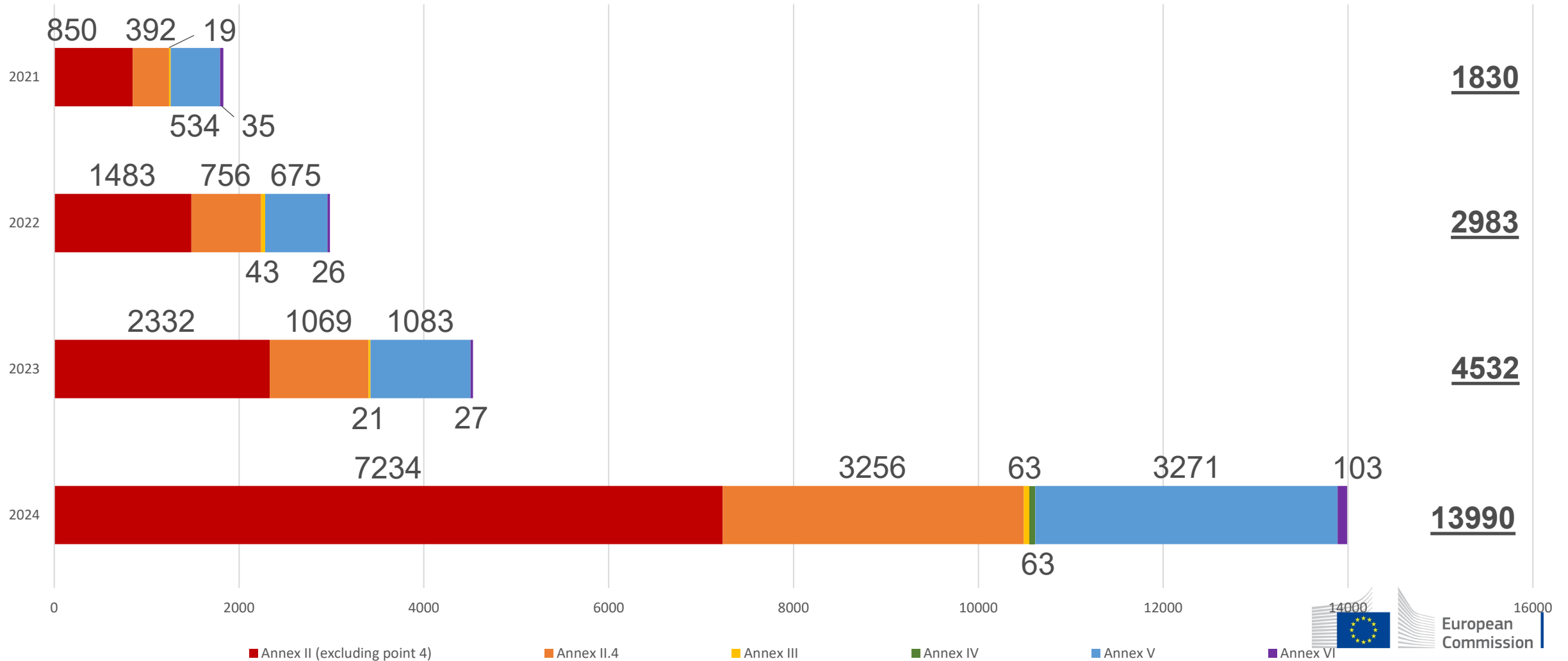
AIMDD/MDD valid certificates (2/3)

Breakdown by Annex



AIMDD/MDD valid certificates (3/3)

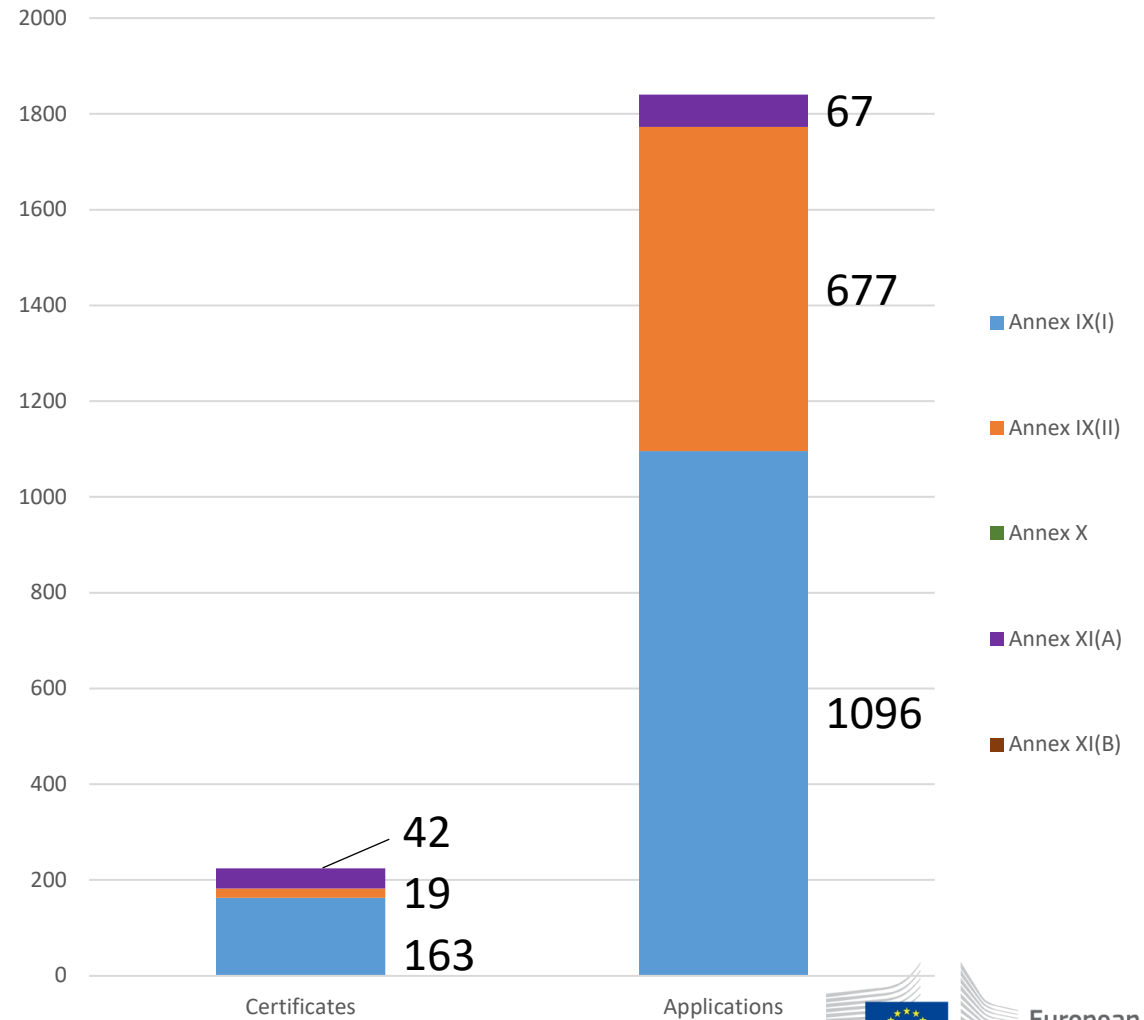
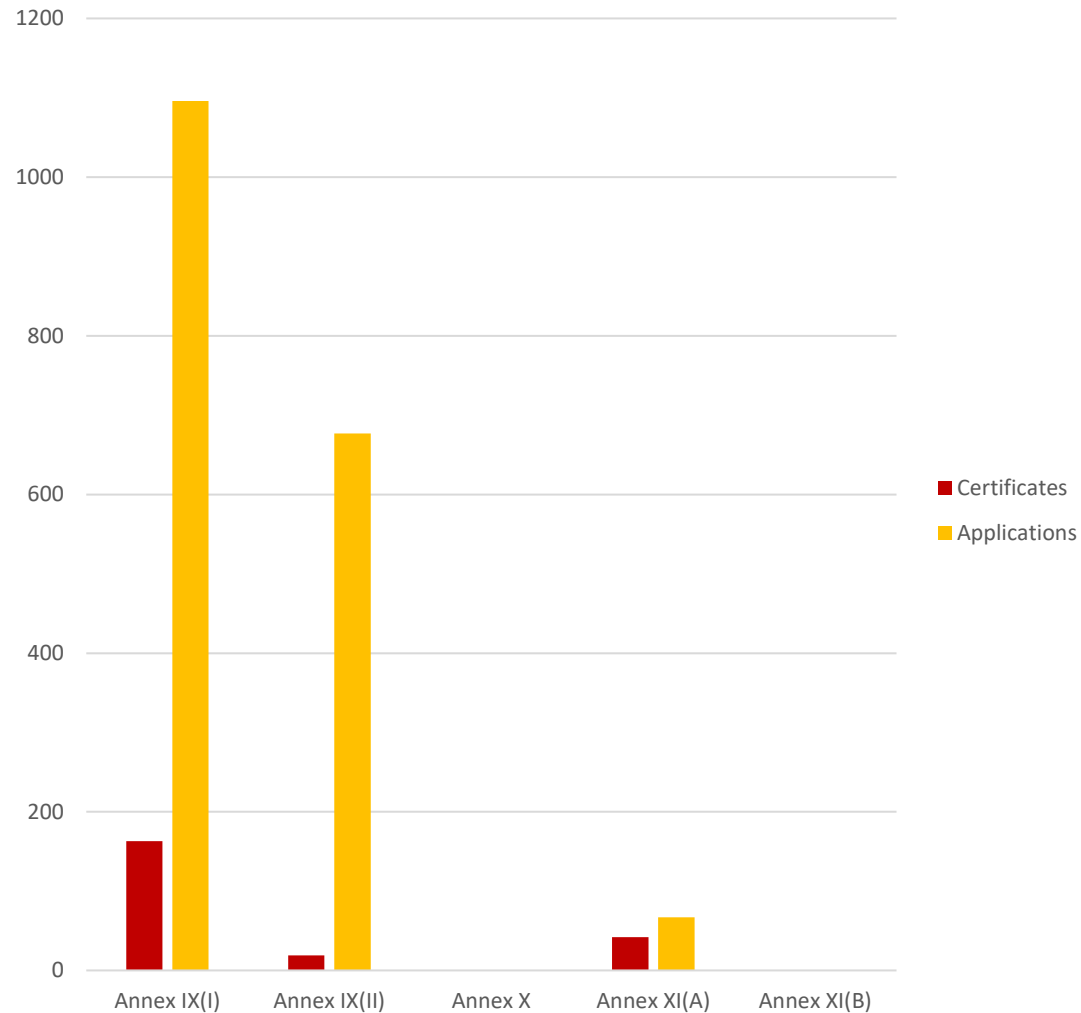
Breakdown by year of expiry



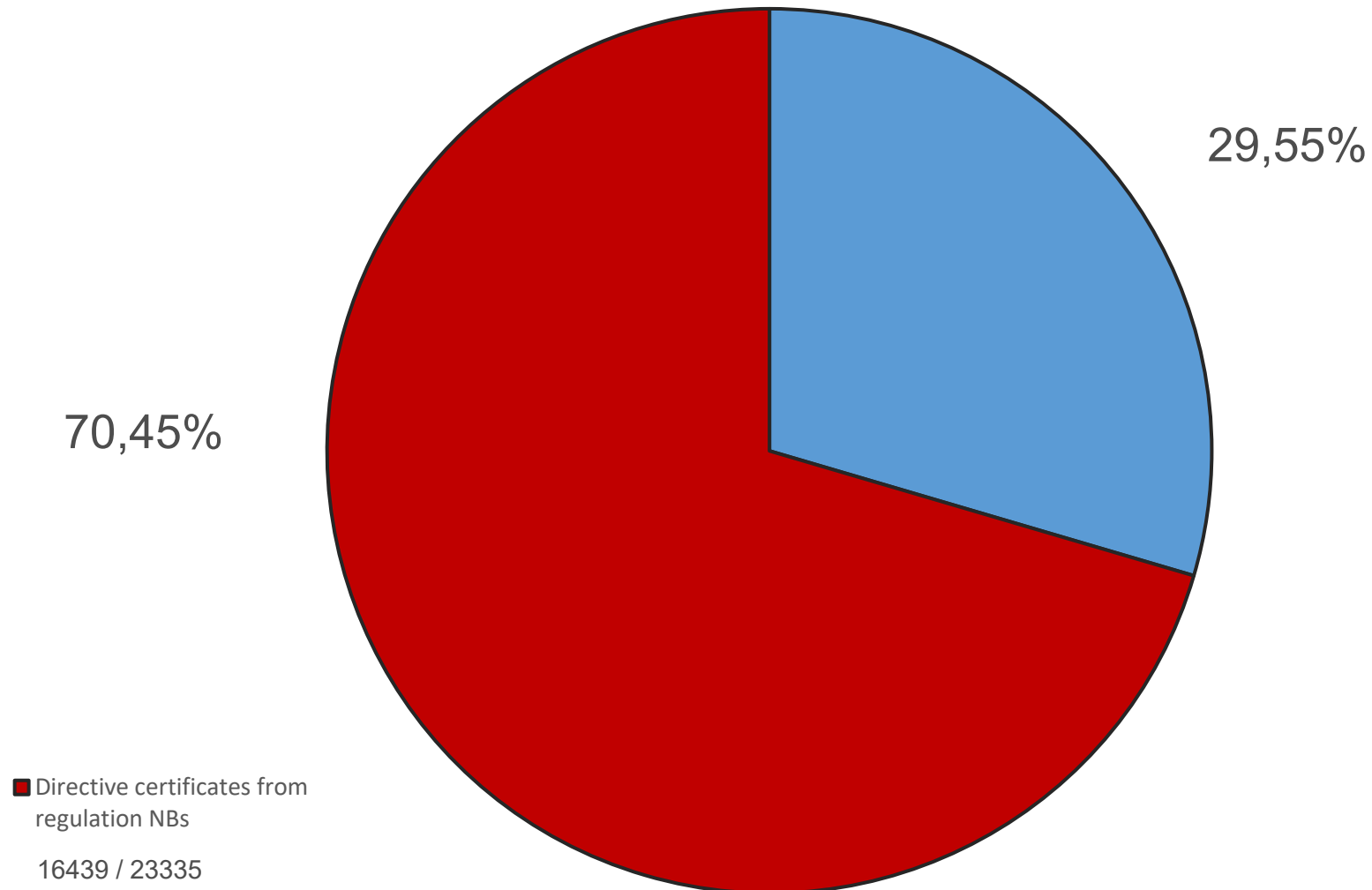
MDR - data request

| | <i>Number of certificates issued under the MDR</i> | <i>Number of application filed under the MDR</i> |
|--------------------|--|--|
| <i>Annex IX(I)</i> | | |
| <i>Annex IX(I)</i> | | |
| <i>Annex X</i> | | |
| <i>Annex XI(A)</i> | | |
| <i>Annex XI(B)</i> | | |

MDR – certificates issued and applications filed



Directive certificates issues by NBs already designated under the MDR



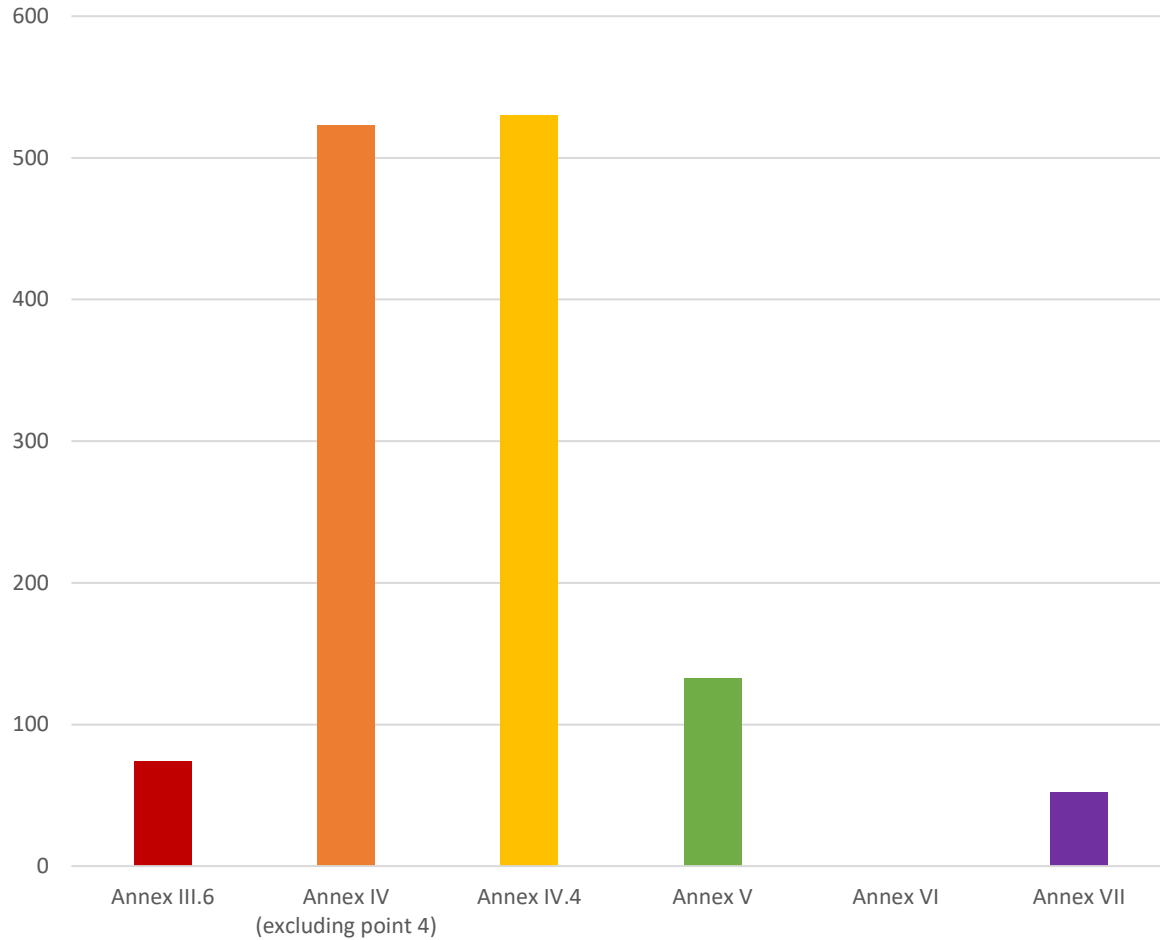
IVD notified bodies – replies received

February 2021

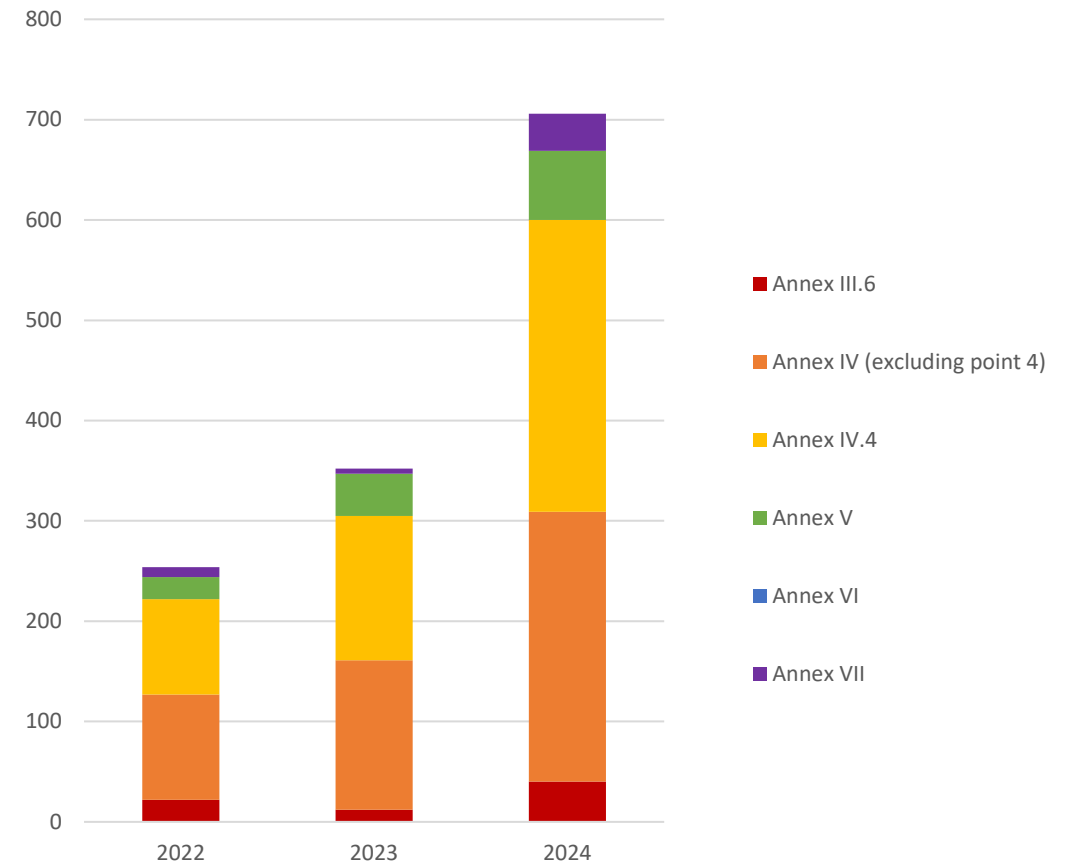
- IVDD: 17 replies received - out of 18 notified bodies designated under the IVDD
- IVDR: 4 replies received – out of 4 notified bodies designated under the IVDR at the time the survey was launched

IVDD – expiring certificates

Breakdown by Annex

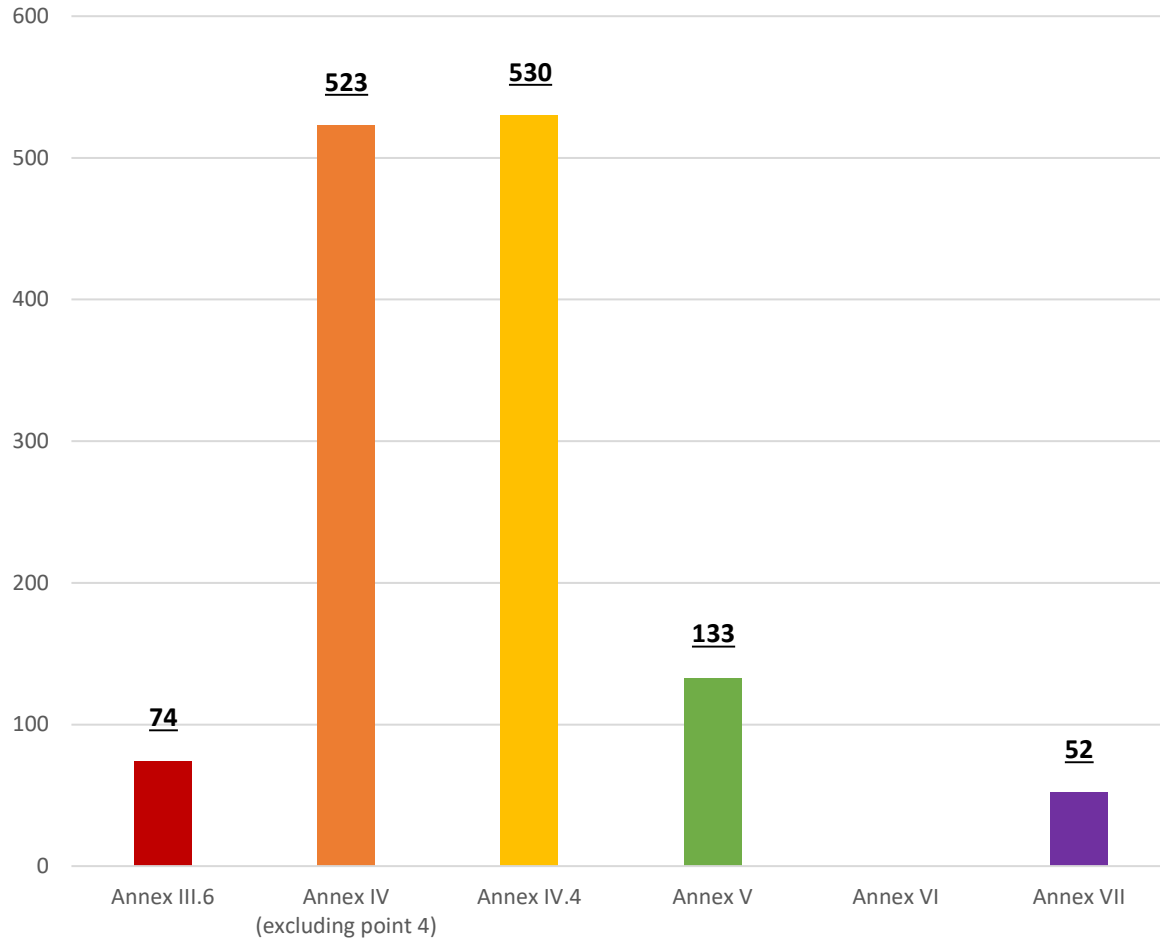


Breakdown by year of expiry

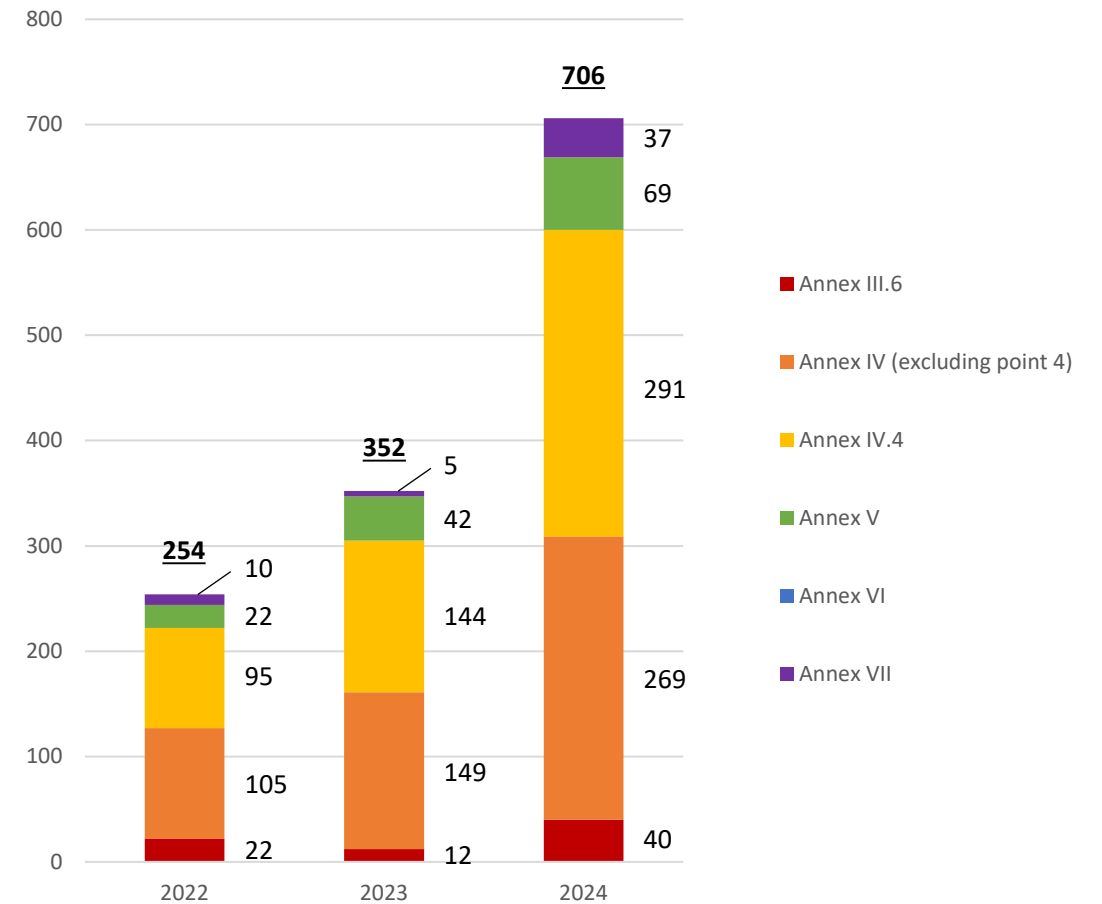


IVDD – expiring certificates

Breakdown by Annex



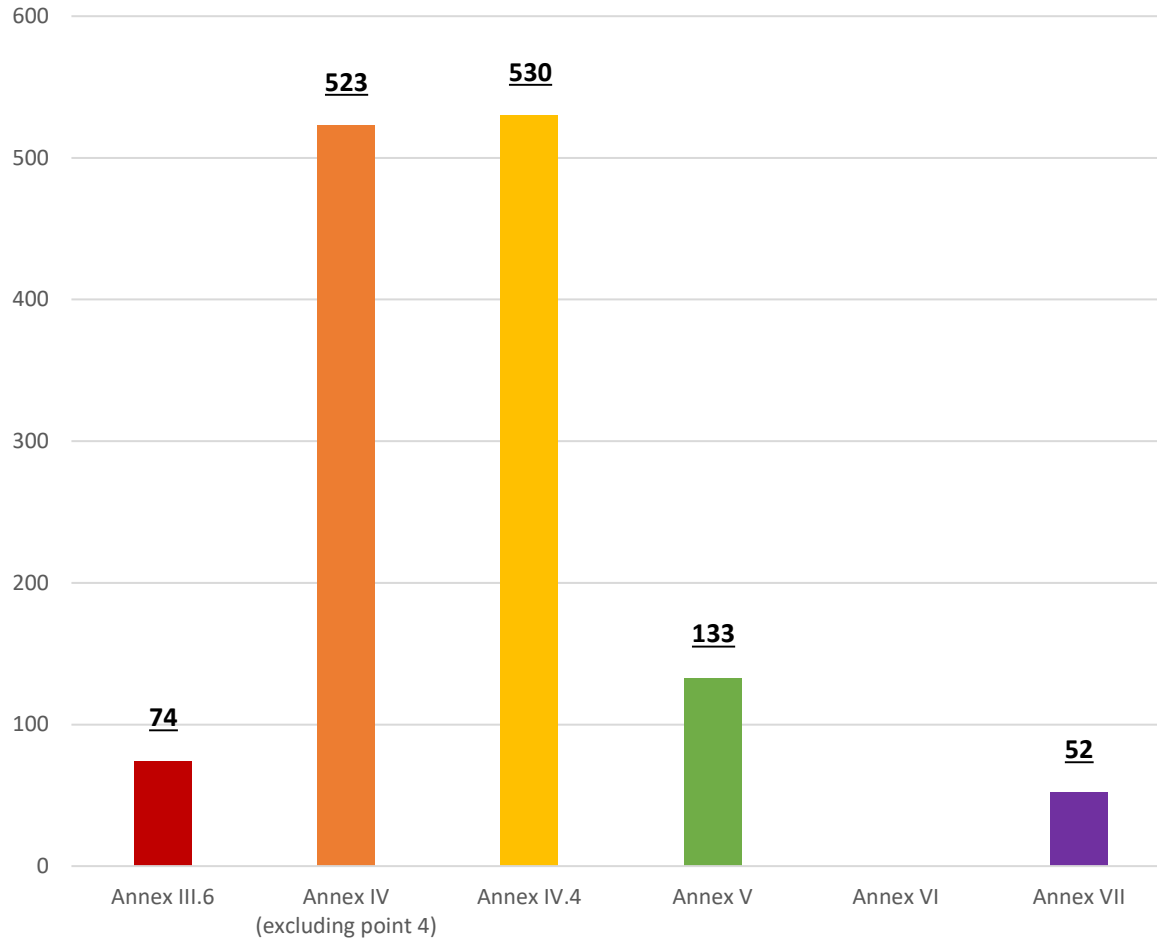
Breakdown by year of expiry



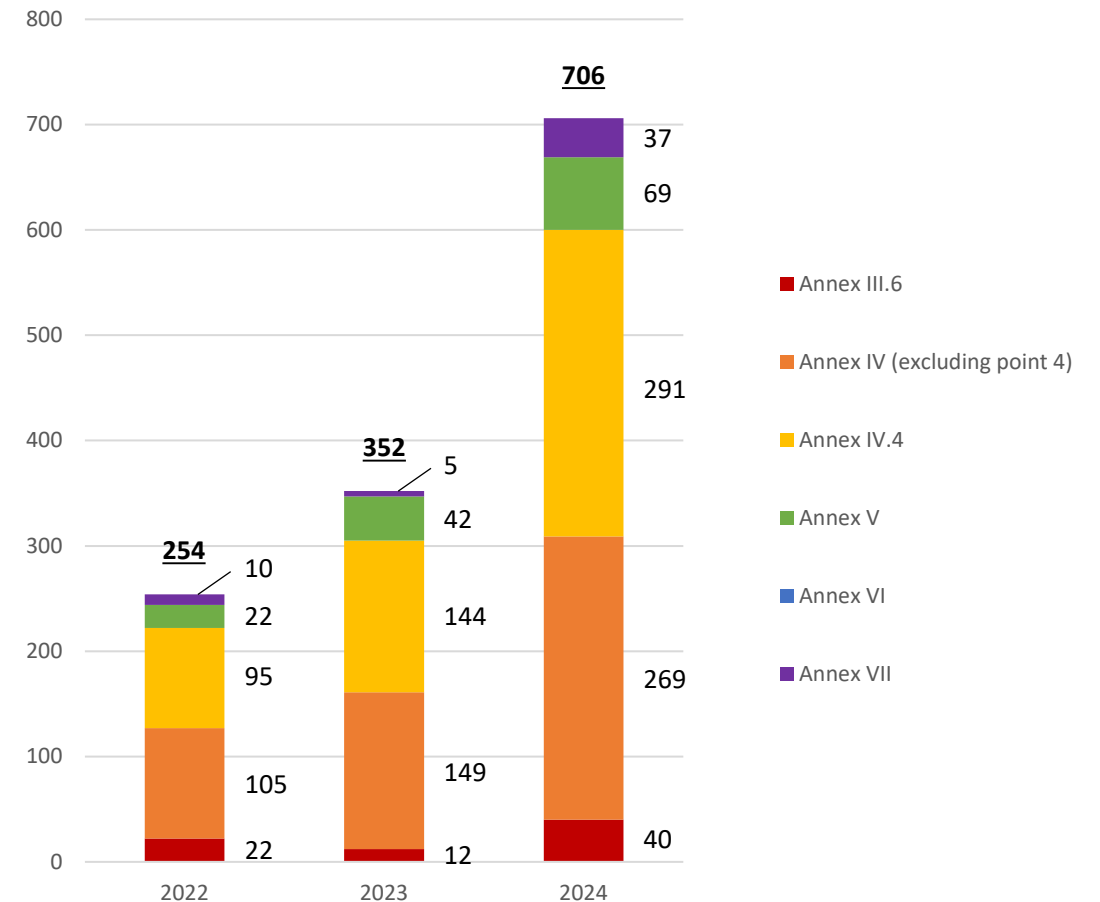
IVDD – expiring certificates

MTE-reported total number of IVDs certified under the IVDD: 2034 (~80% market coverage, IVD=catalogue number/prospective UDI)

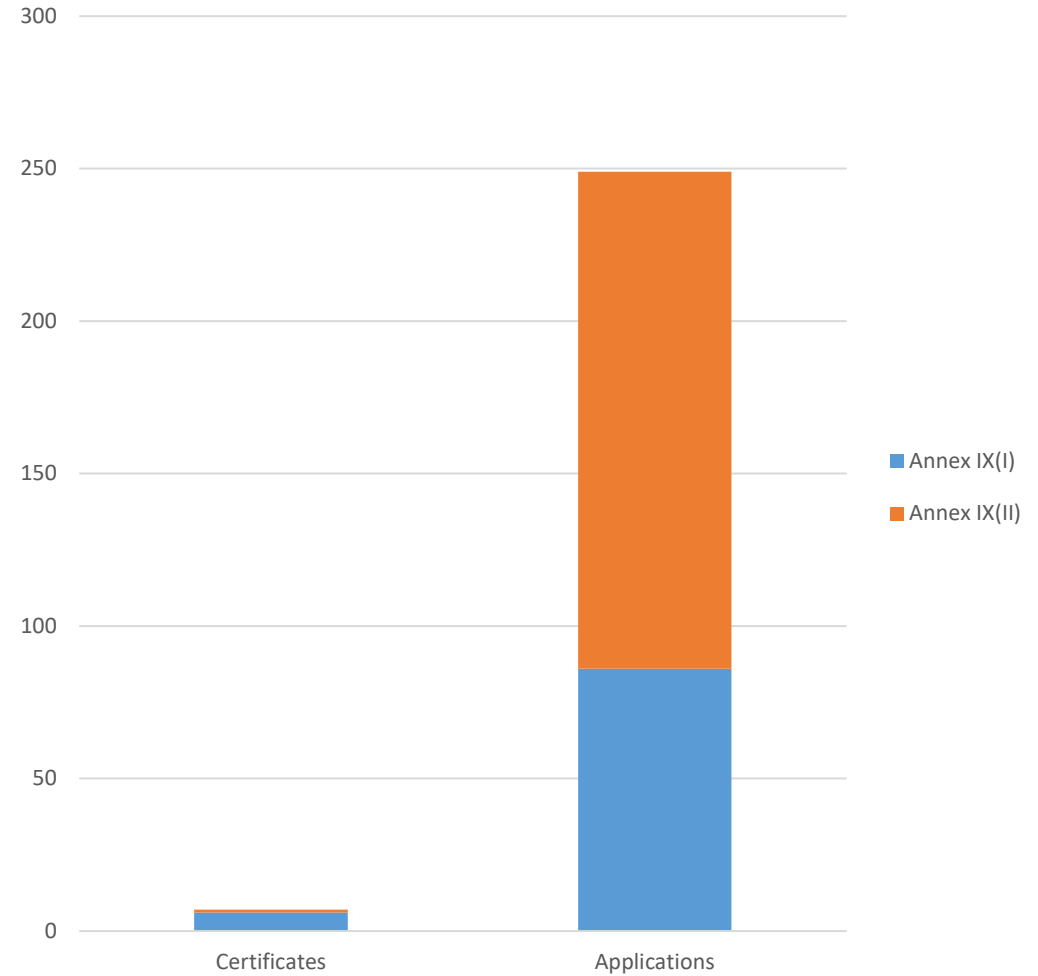
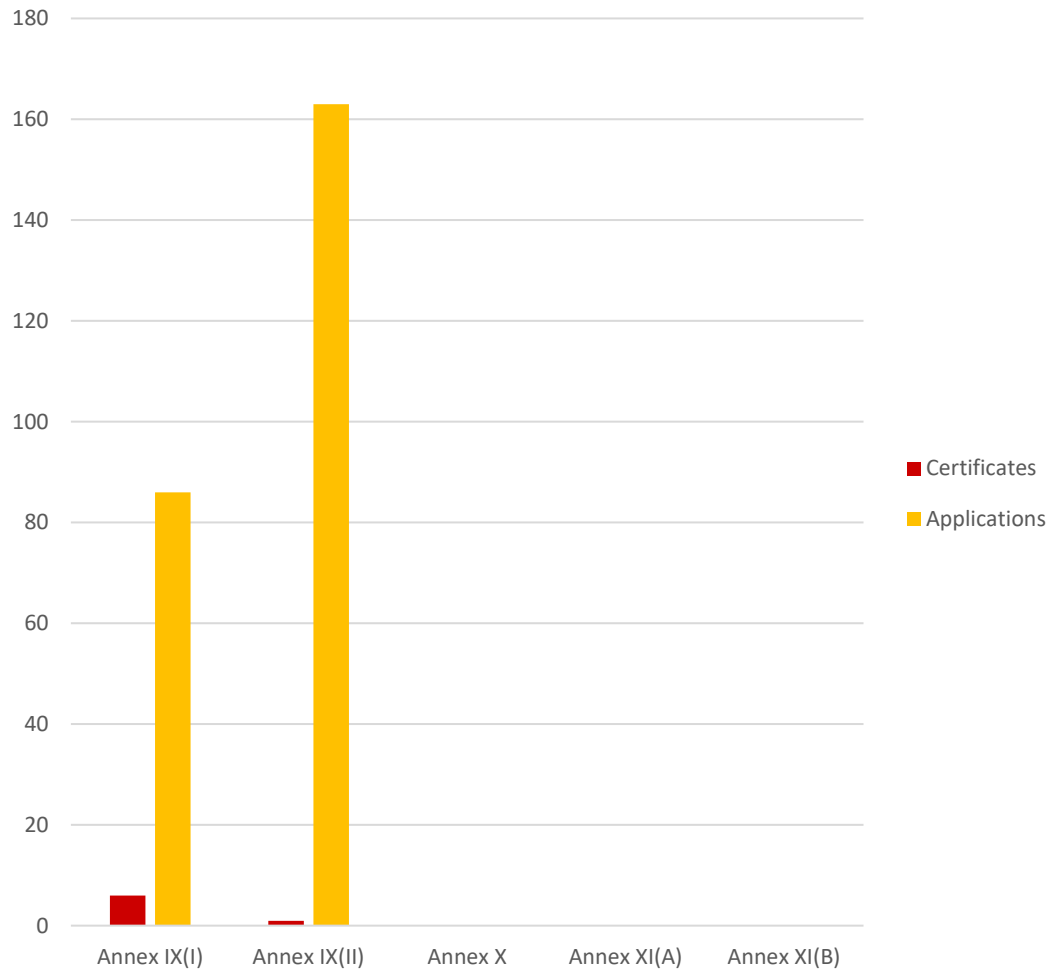
Breakdown by Annex



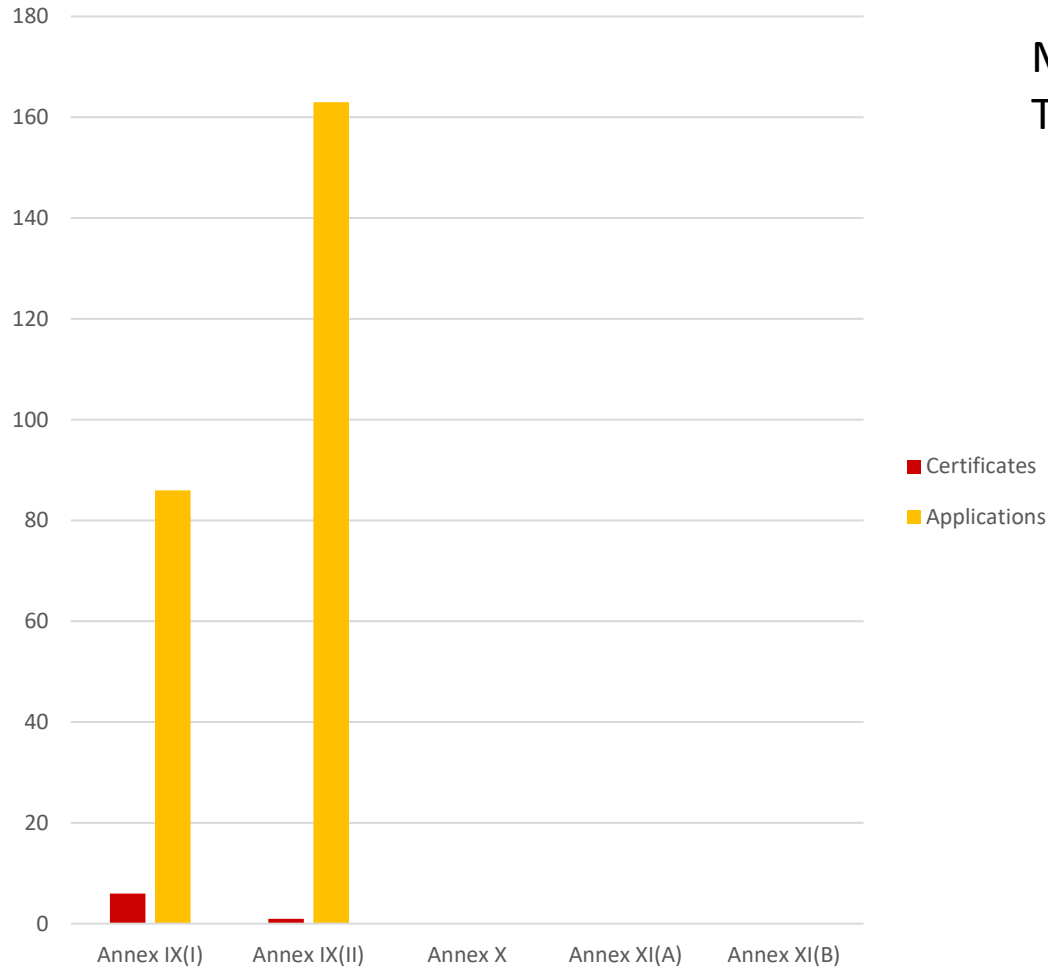
Breakdown by year of expiry



IVDR – applications and certificates issued



IVDR – applications and certificates issued



MTE-reported: Total number of IVDs certified under the IVDD: 2034
Total number of IVDs to be certified for the first time: 18941

