8th notified bodies survey on certifications and applications (MDR/IVDR)

Survey results of the 8th NB survey with data status 29 February 2024
(small and medium dataset)

17 May 2024

Disclaimer

- This document was produced in the frame of the SC 2021 P3 03 under the DG SANTE Framework contract (FWC SANTE/2021/OP/0002) for evaluation, impact assessment, monitoring and other related services in relation to health and food policies.
- The information and views set out in this document are those of the author(s) and do not necessarily reflect the official opinion of the Commission/Executive Agency. Neither the Commission/Executive Agency nor any person acting on the Commission's/Executive Agency's behalf may be held responsible for the use which may be made of the information contained therein.
- This presentation includes data and knowledge available at the time of the publication. The study-related dashboard contains the latest information und updates (e.g. further insights, retrospective corrections reported by stakeholders). Data discrepancies between this presentation and the regularly updated dashboard are therefore possible.

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List of abbreviations

Abbreviation	Meaning
AIMDD	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
FTE	Full Time Equivalent
IVDs	In-vitro diagnostic medical device(s)
IVDD	Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices
IVDR	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 (In Vitro Diagnostic Medical Device Regulation)
MDs	Medical device(s)
MDD	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (Medical Device Regulation)
NBs	Notified body / bodies
QMS	Quality Management System
SMCS	Single Market Compliance Space
SME	Small and medium-sized enterprise

About

1. About the study, survey and datasets

- Study supporting the monitoring of availability of medical devices on the EU market
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Study supporting the monitoring of availability of medical devices on the EU market

About

- **Aim:** To support monitoring and analyzing the availability of medical devices on the EU market in the context of the implementation of medical devices and in vitro diagnostic medical devices Regulations from the perspectives of key stakeholders
- **Duration:** 2 December 2022 – 1 December 2025 (36 months)
- **Study team** (contact: medical.devices@goeg.at):

Gesundheit Österreich GmbH (Austrian National Public Health Institute) → project lead

Areté

Civic Consulting

Supported by experts from the medical devices sector

European Commission

About

NB survey overview

NB surveys already conducted by the study team

NB Survey	Survey period (survey launch – survey closure)	Requested dataset* SD = small dataset MD = medium dataset LD = large dataset	Requested data	Response rate
1st NB survey	03/04/2023 - 05/05/2023	SD1 + MD1	from designation up to 31/03/2023	39 out of 39 NBs** **100%**
2nd NB survey	12/05/2023 - 05/06/2023	SD2	from designation up to 30/04/2023	27 out of 39 NBs** **~ 70%**
3rd NB survey	05/06/2023 - 19/06/2023	SD3	from designation up to 31/05/2023	22 out of 39 NBs** **~ 56%**
4th NB survey	03/07/2023 - 28/07/2023	SD4 + MD2	from designation up to 30/06/2023	39 out of 39 NBs** **100%**
5th NB survey	01/09/2023 - 06/10/2023	SD5	from designation up to 31/08/2023	40 out of 40 NBs** **100%**
6th NB survey	03/11/2023 - 22/12/2023	SD6 + MD3 + LD1	from designation up to 31/10/2023	41 out of 41 NBs** **100%**
7th NB survey	08/01/2024 - 05/02/2024	SD7	from designation up to 31/12/2023	45 out of 45 NBs** **100%**
8th NB survey	04/03/2024 - 20/03/2024	SD8 + MD4	from designation up to 29/02/2024	45 out of 45 NBs** **100%**

Survey results included in the published dashboard

8th NB survey results are presented in this PowerPoint presentation

* Datasets:
- The **small dataset** is a small set of questions (6 indicators) asked to notified bodies **every two months.** Note: From April to July 2023, it was asked monthly.
- The **medium dataset** is a set of questions asked to notified bodies **every four months** concerning the activities they have been performing since their designation.
- The **large dataset** contains additional data asked to notified bodies **once a year**.

** designated under MDR and/or IVDR

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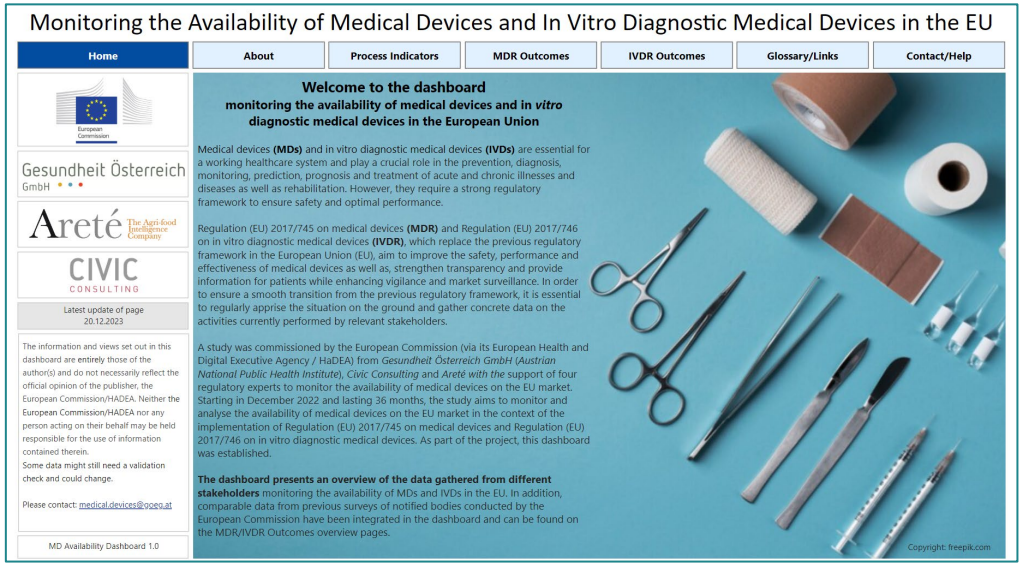
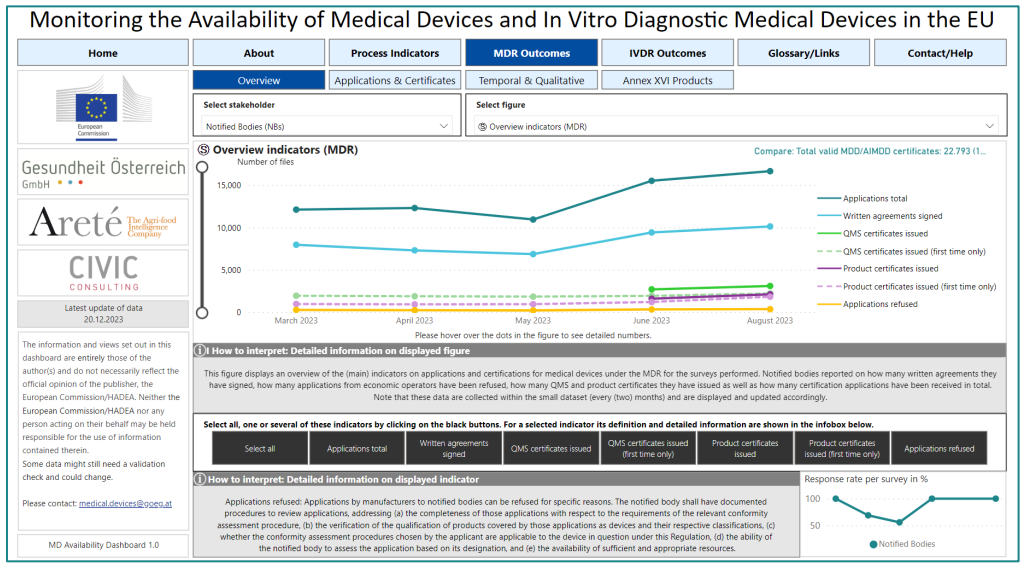
About

Dashboard

- NB survey results are presented in the study-related dashboard
- Available at: [Study supporting the monitoring of availability of medical devices on the EU market - European Commission (europa.eu)]





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About

Preliminary notes

- **Data content:**
  - The following slides show the results of the **8th NB survey conducted at the beginning of March 2024** with **requested data** from notified bodies designated under MDR and/or IVDR **until 29 February 2024**.
  - These survey results are also compared with previous survey data (see data sources).

- **Data sources:**
  - Data collected between April 2023 and March 2024 by the study team
  - Data collected between February 2021 and October 2022 by the European Commission

- **Datasets:**
  - This presentation contains the results of the small and medium datasets collected in March 2024.

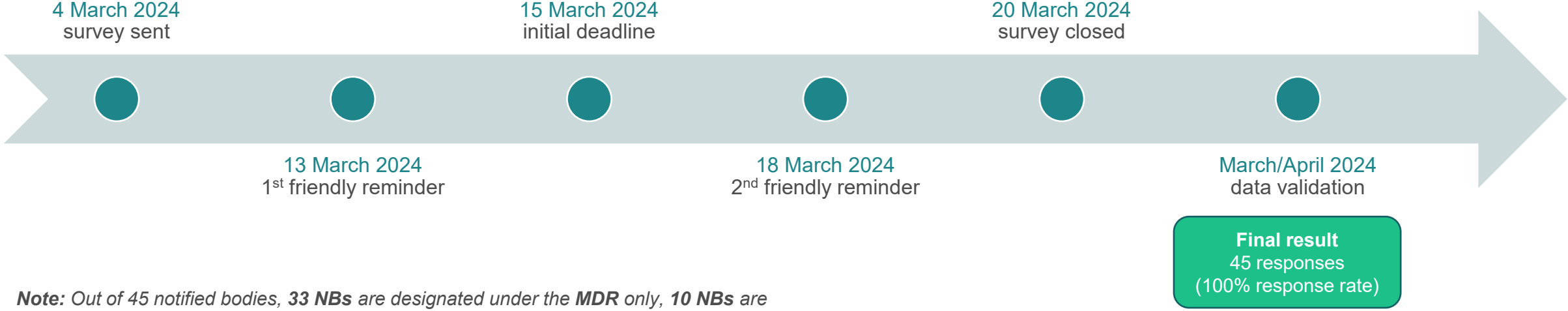
Ⓢ The **small dataset** is a small set of questions (6 indicators) asked to notified bodies **every two months.**
Note: From April to July 2023, it was asked monthly.
Ⓜ The **medium dataset** is a set of questions asked to notified bodies **every four months** concerning the activities they have been performing since their designation.
Ⓛ The **large dataset** (not surveyed in the 8th NB survey) contains additional data asked to notified bodies **once a year**.

Timeline for the 8th NB survey

(conducted in March 2024 with requested data from designation up to 29/02/2024)

About

45 notified bodies designated under MDR and/or IVDR
(Data status: 1 March 2024)



Final result
45 responses
(100% response rate)

Note: *Out of 45 notified bodies,* ***33 NBs*** *are designated under the* ***MDR*** *only,* ***10 NBs*** *are designated under* ***both the MDR and IVDR****, and* ***2 NBs*** *are designated under the* ***IVDR only****.*

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Response rate for the 8th NB survey

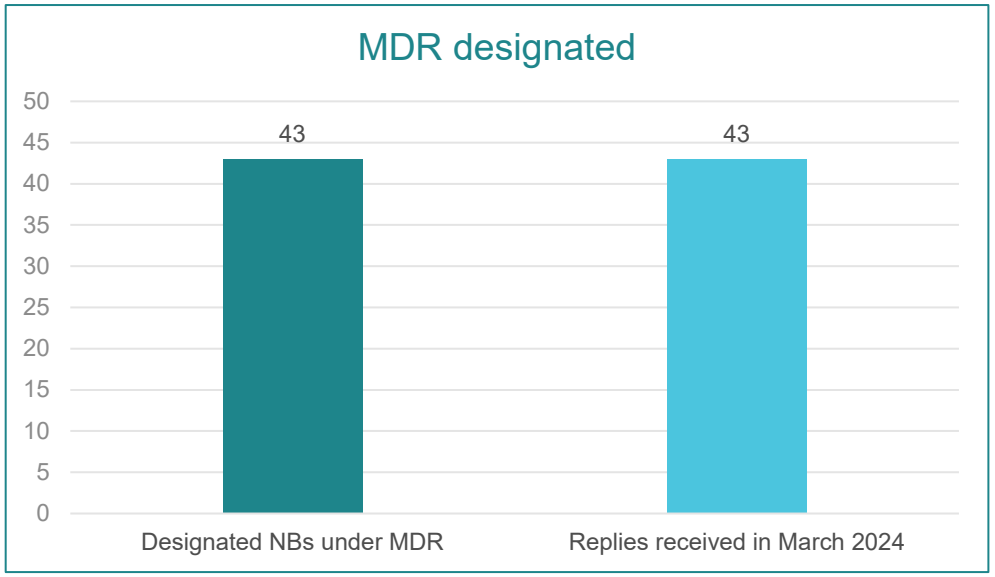
(conducted in March 2024 with requested data from designation up to 29/02/2024)

About

45 out of 45 notified bodies replies received (100% response rate)

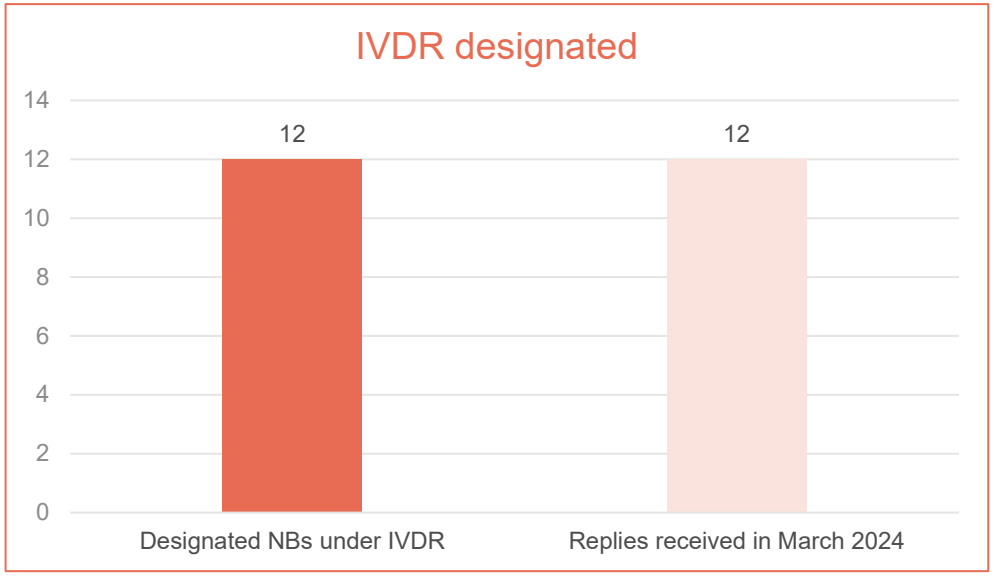
Note: *Out of 45 notified bodies,* ***33 NBs*** *are designated under the* ***MDR*** *only,* ***10 NBs*** *are designated under* ***both the MDR and IVDR****, and* ***2 NBs*** *are designated under the* ***IVDR only****.*

MD



100% response rate

IVD



100% response rate

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MD

2. Survey results for medical devices

Note:

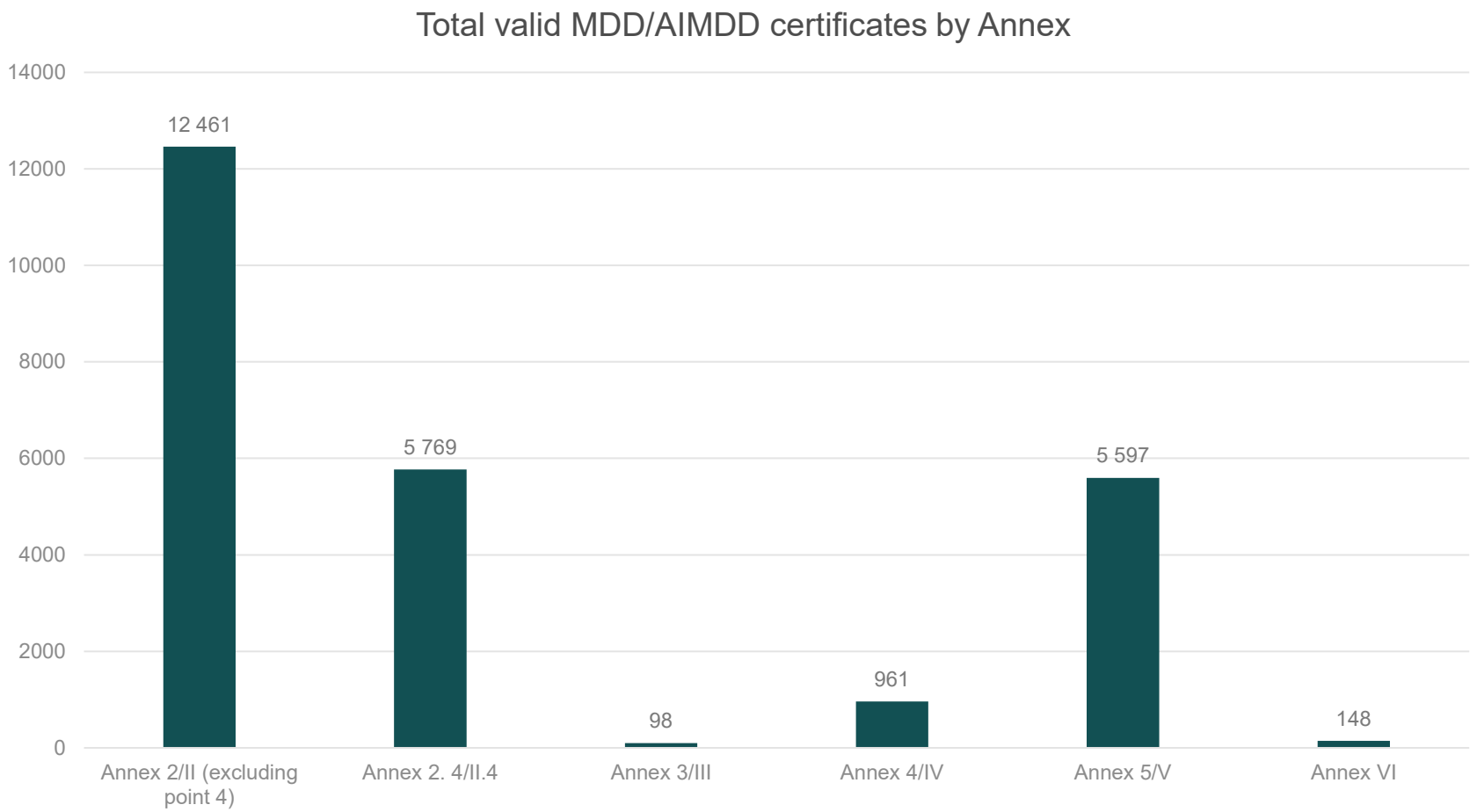
- Thousands separators are represented as dots or blank space (not comma) in the graphs.
- Datasets:

  Ⓢ The **small dataset** is a small set of questions (6 indicators) asked to notified bodies **every two months.**
  Note: From April to July 2023, it was asked monthly.
  Ⓜ The **medium dataset** is a set of questions asked to notified bodies **every four months** concerning the activities they have been performing since their designation.
  Ⓛ The **large dataset** (not surveyed in the 8th NB survey) contains additional data asked to notified bodies **once a year.**

MDD/AIMDD Certificates by Annex (data status: April 2022)

MD

MDD/AIMDD Data



Total: 25.034

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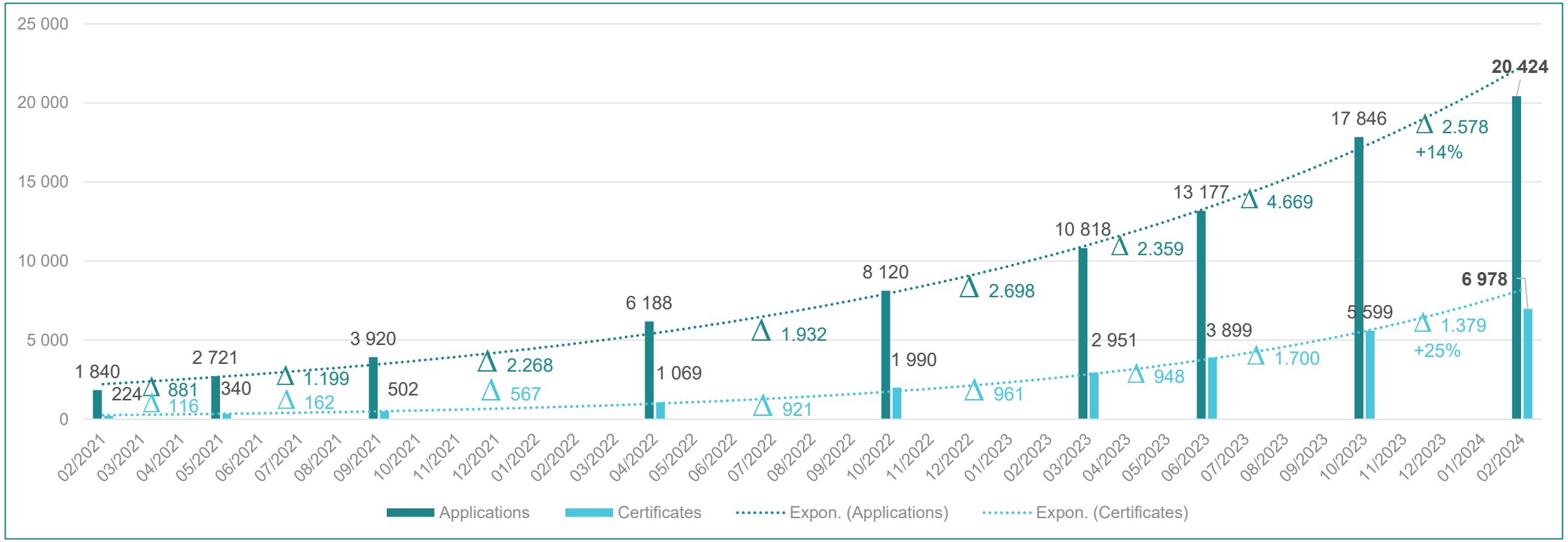
MDR applications filed and certificates issued (sum of Annexes)

MD

February 2024

MDR Applications:
Total number of applications filed by Annex Ⓜ: 20.424*

MDR Certificates:
Total number of certificates by Annex Ⓜ: 6.978



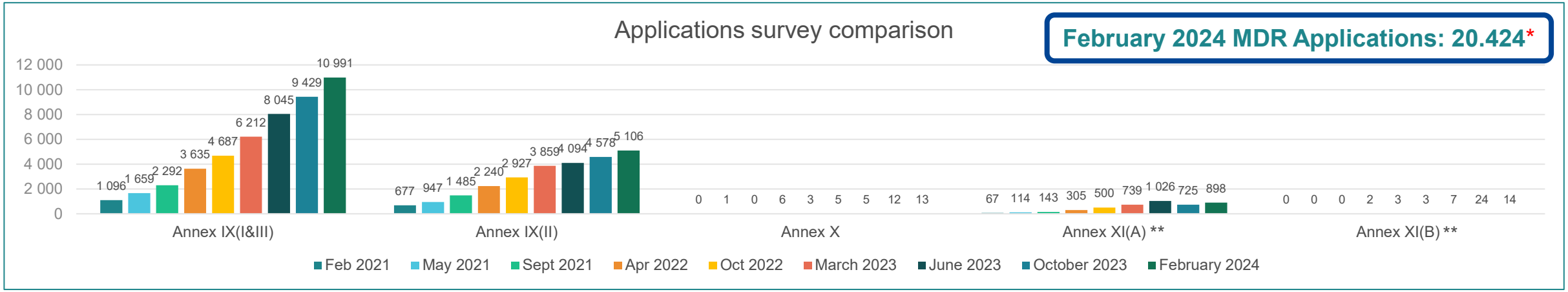
Notes: February 2024: Designated NBs for MD: 43; NBs that included Annex XVI products in the numbers provided: 20

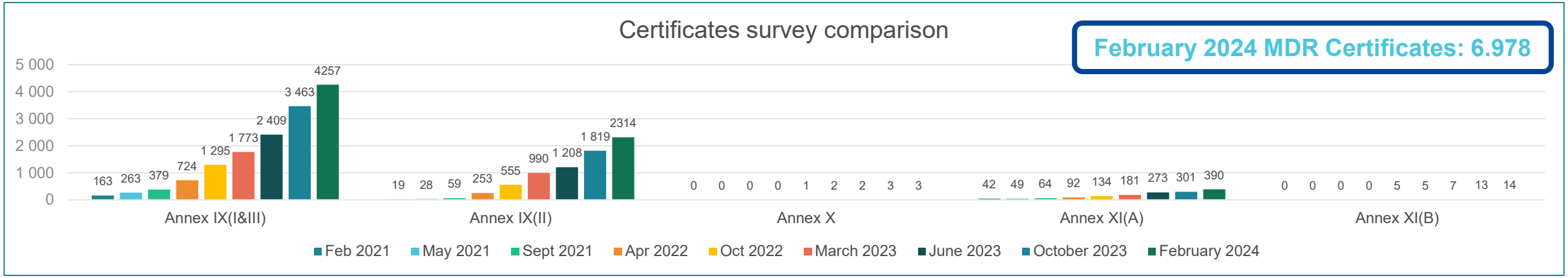
* The data shown comes from the medium data set Ⓜ – except for 2 NBs where the total number of applications filed was derived from the small data set Ⓢ since they could not provide the data per Annex.

- Δ (Delta) = Difference in MDR Applications / MDR Certificates from one survey to the next one
- **Applications filed**: This number includes **all applications filed (syn. lodged) so far** according to MDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 29/02/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
- **Certificates issued:** This number includes **certificates issued so far** (from designation up 29/02/2024) under the MDR.

MDR applications and certificates by annex survey comparison

MD





Notes:

- Designated NBs for MD: 43; NBs that included Annex XVI products in the numbers provided: 20
- * The data shown comes from the medium data set (applications and certificates by Annex: 2 NBs could not provide the application information by Annex; hence the total number of applications is higher → see number in the small data set)
- ** Change in methodology of counting by a few NBs, leading to decreases.
- **Applications lodged by annex**: This number includes **all applications lodged (syn. filed) by annex** according to MDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 29/02/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
- **Certificates issued by annex:** This number includes **certificates issued so far** (from designation up to 29/02/2024) under the MDR **by annex**.

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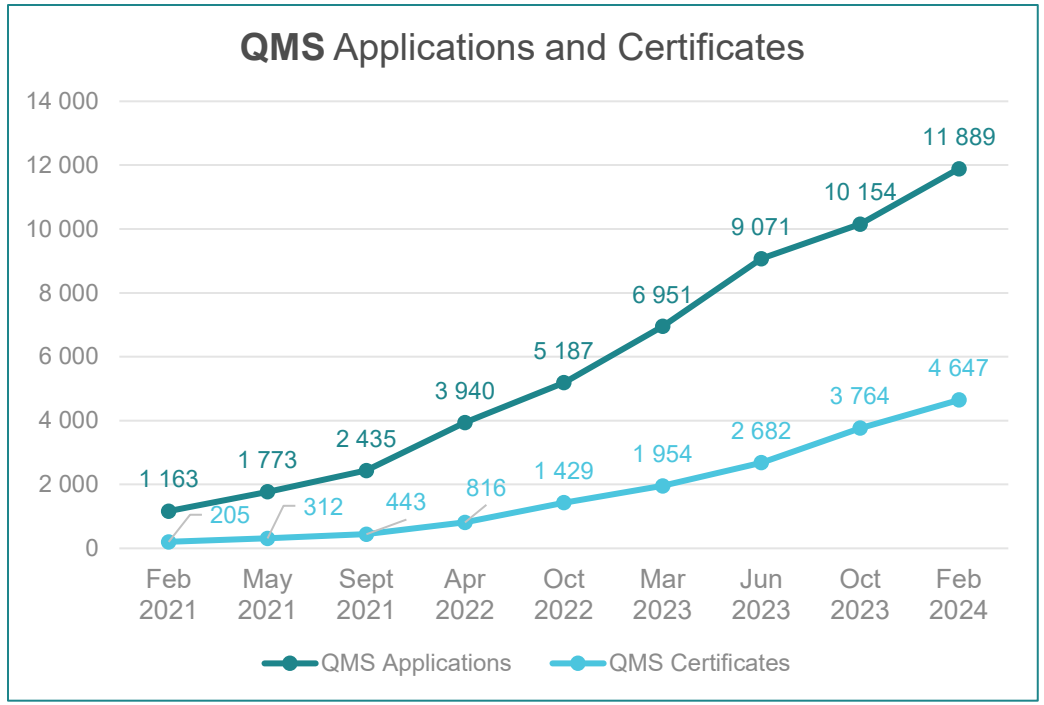
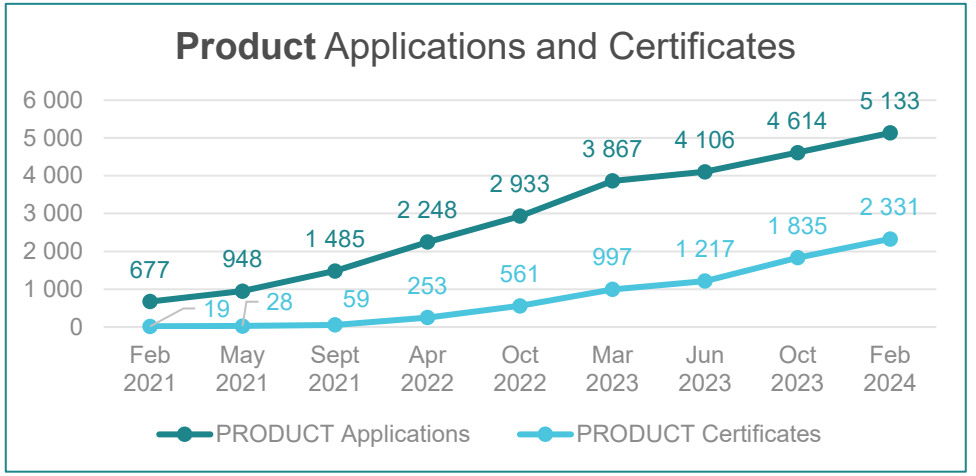
MDR applications and certificates by type (QMS vs Product) – survey comparison

MD

February 2024
MDR Applications: 20.424*
MDR Certificates: 6.978

* The data shown comes from the medium data set (applications and certificates by Annex: Two NBs could not provide the application information by Annex; hence the total number of applications is higher - see number in the small data set).





Note QMS Applications and Certificates: This relates to Annex IX Chapter I or Annex XI Part A according to MDR.

Note PRODUCT Applications and Certificates: This relates to Annex IX Chapter II, Annex X or Annex XI Part B according to MDR.

Total number of applications lodged for changes received for already MDR issued certificates: 2.535

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Specific additional procedures according to Annex IX (II)

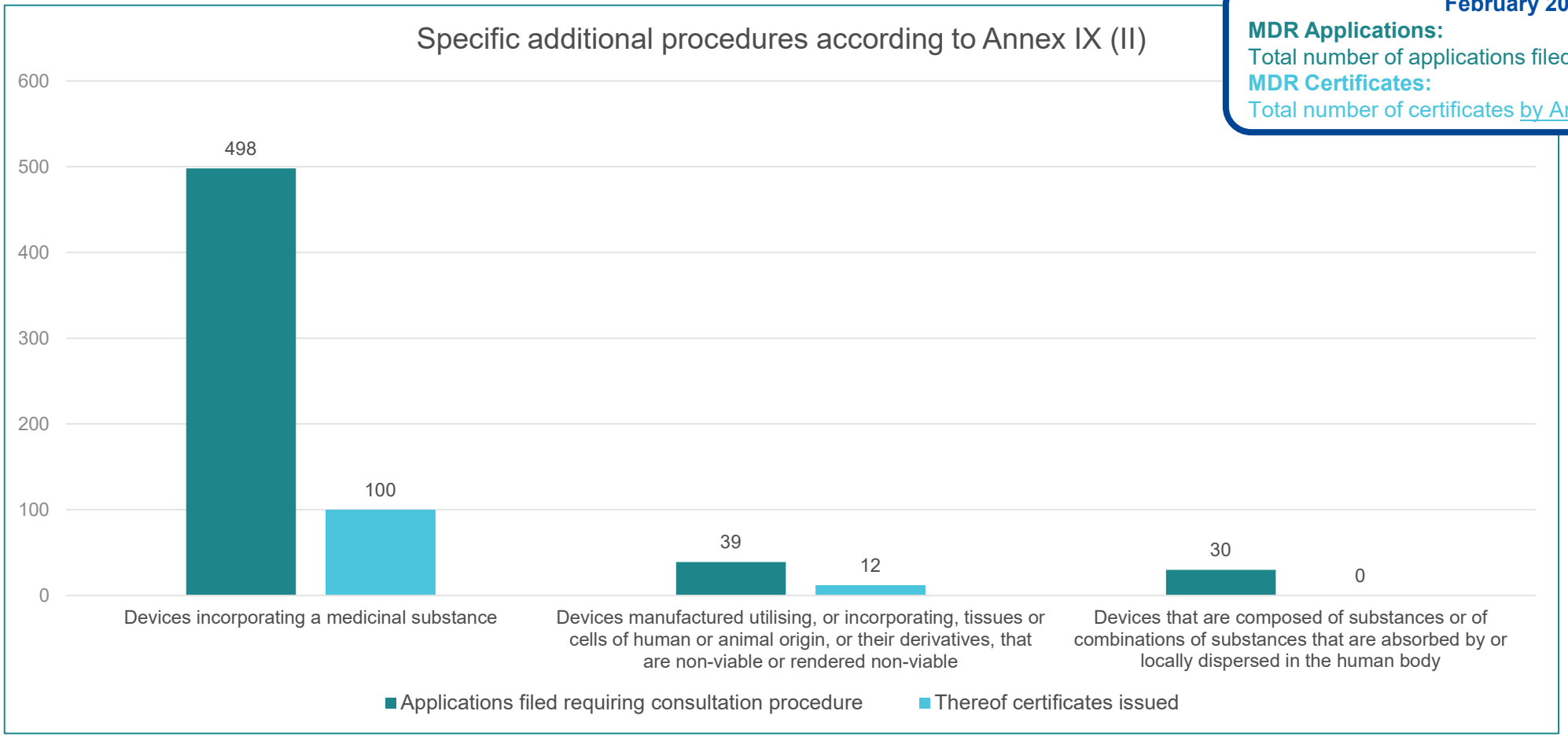
MD

Ⓜ

February 2024

MDR Applications:
Total number of applications filed by Annex Ⓜ: 20.424*

MDR Certificates:
Total number of certificates by Annex Ⓜ: 6.978



Notes:
* The data shown comes from the medium data set Ⓜ – except for 2 NBs where the total number of applications filed was derived from the small data set Ⓢ since they could not provide the data per Annex.

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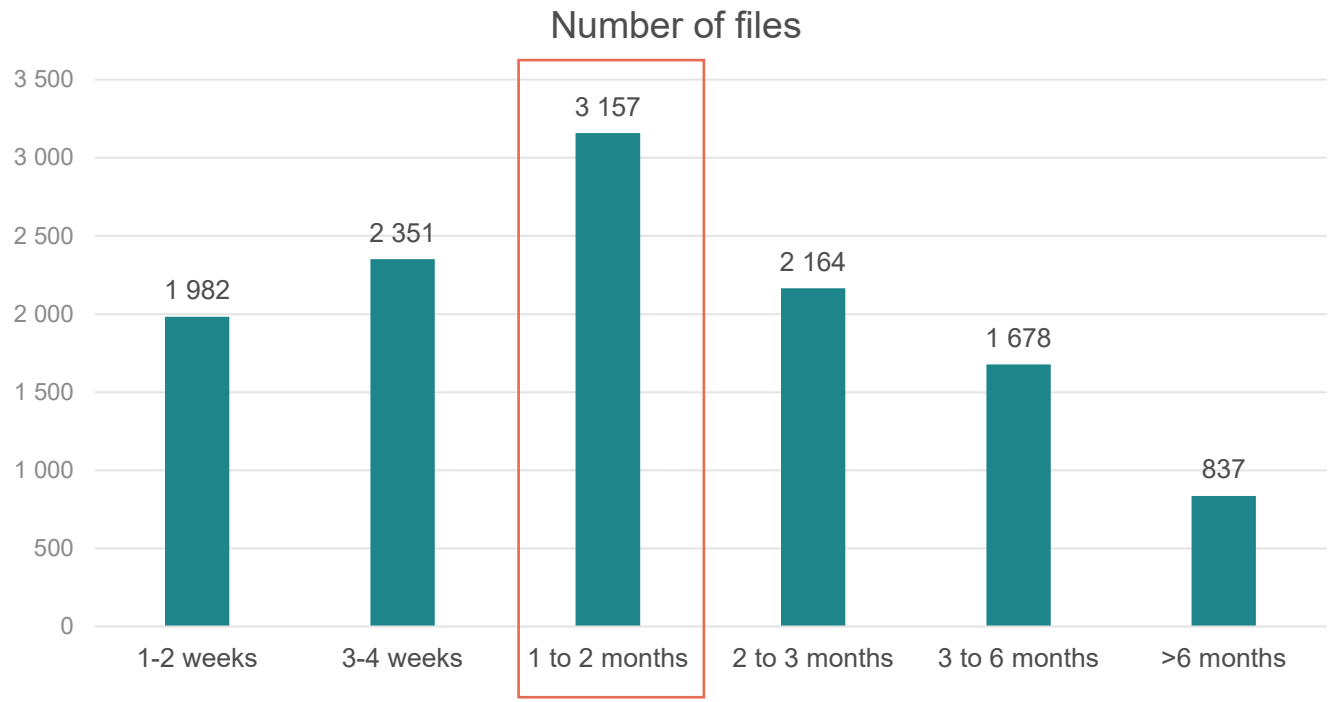
Average timeframe to written agreement signed

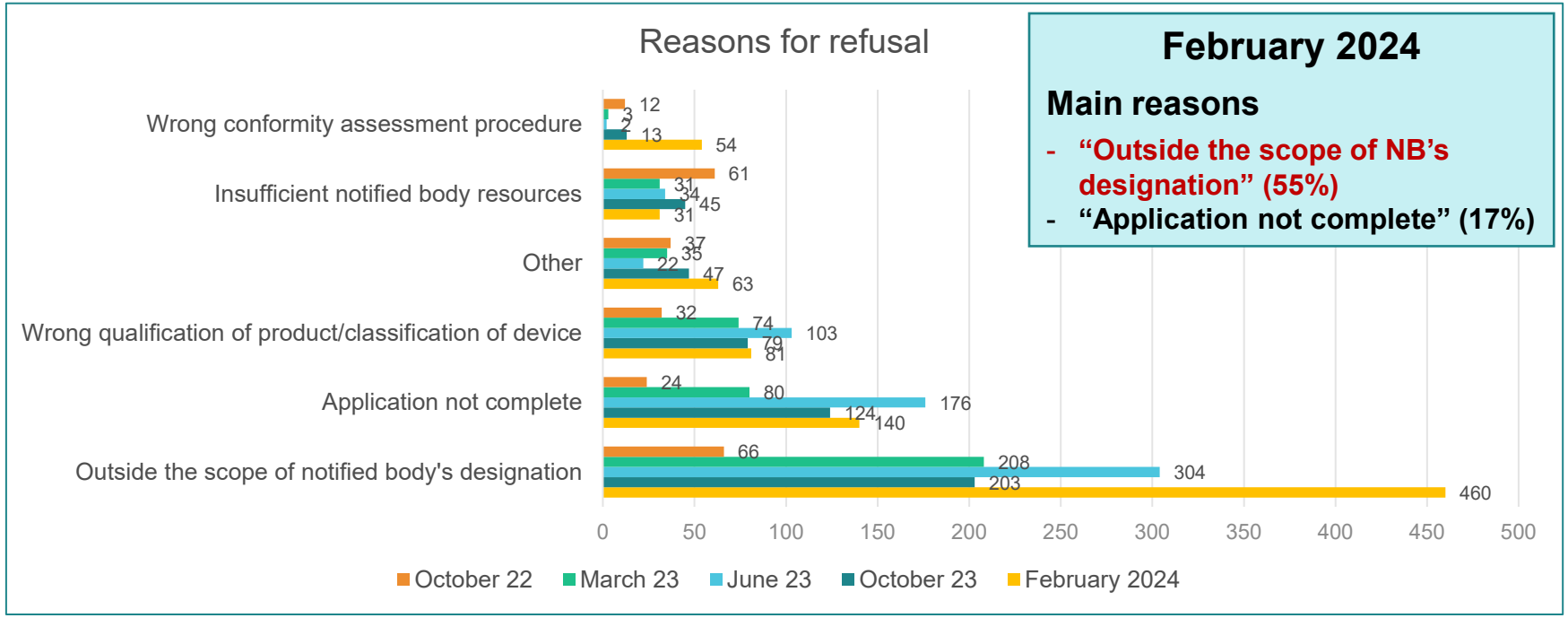
Average timeframe between application lodged and written agreement signed:



In the majority of the cases (62%), it takes **less than 2 months** from an application lodged to a written agreement signed.

Note: Data of 40 notified bodies

MDR applications - reason for refusal



February 2024

Main reasons

- **"Outside the scope of NB's designation" (55%)**
- **"Application not complete" (17%)**

Total number of MDR applications:
October 2022: 8120
March 2023: 11.418
June 2023: 13.177
October 2023: 17.846*
February 2024: 20.424*

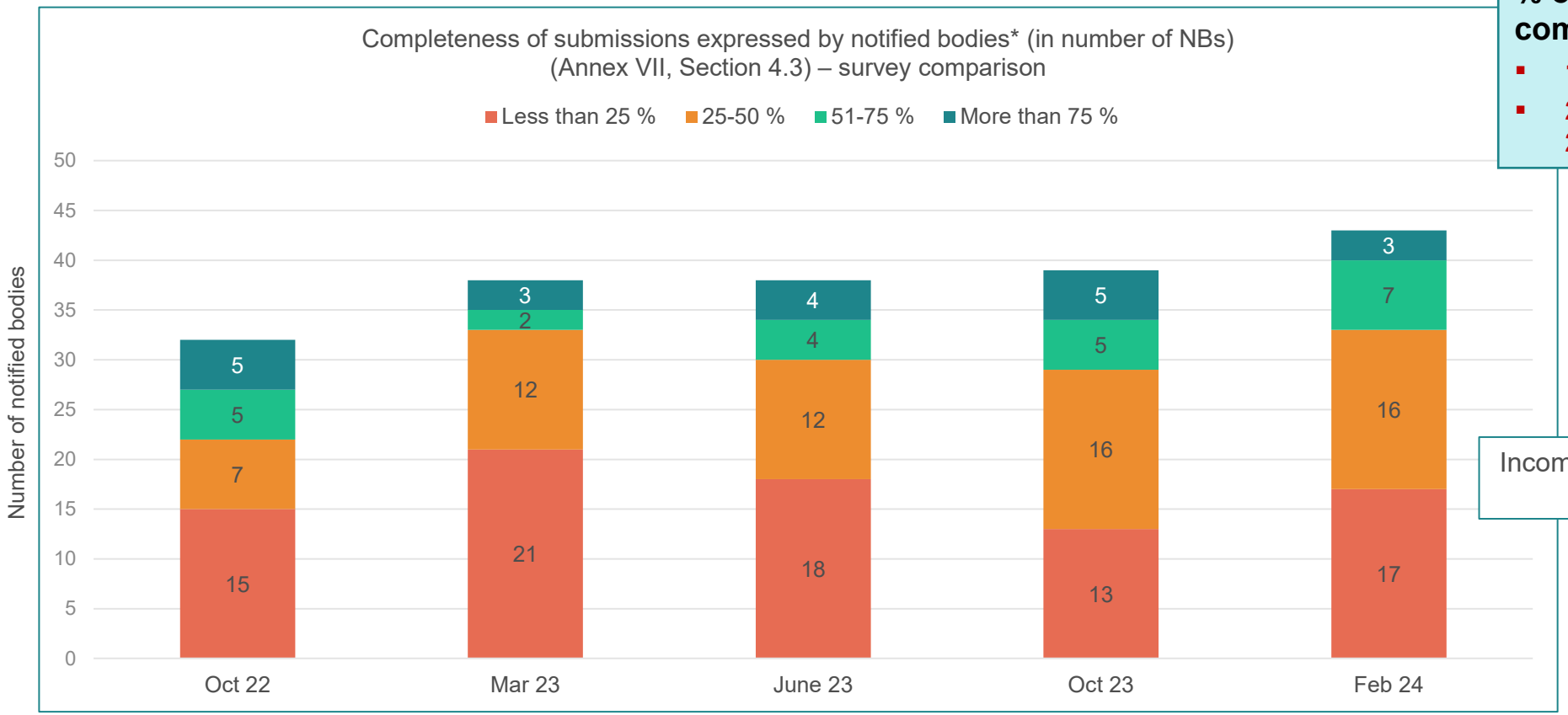
* The data shown comes from the medium data set Ⓜ – except for 2 NBs where the total number of applications filed was derived from the small data set Ⓢ since they could not provide the data per Annex.

Application refusals:**
October 2022: 232
March 2023: 269
June 2023: 328
October 2023: 367
February 2024: 454

Notes:

- Comparison of reasons for refusal in October 2022, March 2023, June 2023, October 2023 and February 2024.
- ** Applications can have multiple reasons for refusal; the total number shown is derived from the small data set and differ from the figures in the medium data set.
- February 2024: data of 25 NBs; some stated "other" reasons in February 2024: "Withdrawal/cancellation of the application by the manufacturer", "customer did not respond on e-mails and phone calls", "PMS plan not at MDR level", "multiple presence of critical suppliers in different states.", "Unresolved non-conformities", "unacceptable language"
- October 2023: data of 24 NBs: some stated „other" reasons in October 2023: "Withdrawal by the customer", "Unresolved non-conformities", "Customer refused audit", "incorrect codes", "not a medical device", "PMS plan not at MDR level", "client stopped communication", "the client rejected the offer", customer did not respond on e-mails and phone calls", "manufacturer was unable to prove the given indication of use was achieved without pharmacological and metabolical means by ingredients", "customer has voluntarily requested to cancel MDR application.", "product did not meet essential requirements despite comprehensive feedback by the NB"
- June 2023: data of 24 NBs; some stated "other" reasons in June 2023: "Withdrawal by the customer", "Unresolved non-conformities", "PMS plan not at MDR level", "customer did not respond on e-mails and phone calls", "manufacturer was unable to prove the given indication of use was achieved without pharmacological and metabolical means by ingredients", "customer has voluntarily requested to cancel MDR application.", "product did not meet essential requirements despite comprehensive feedback by the NB"
- March 2023: data of 19 NBs; some stated "other" reasons in March 2023: "withdrawal of the application by the manufacturer - not ready for MDR, due to economic reasons, etc.", "customer did not respond on e-mails and phone calls", "manufacturer was unable to prove the given indication of use was achieved without pharmacological and metabolical means by ingredients", "customer has voluntarily requested to cancel MDR application.", "product did not meet essential requirements despite comprehensive feedback by the NB", "PMS plan not at MDR level"

Completeness of submissions



% of submissions with completeness rate > 50%

- **13% (of NBs) in March 2023**
- **23% (of NBs) in February 2024**

Incomplete submissions remain high*

*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

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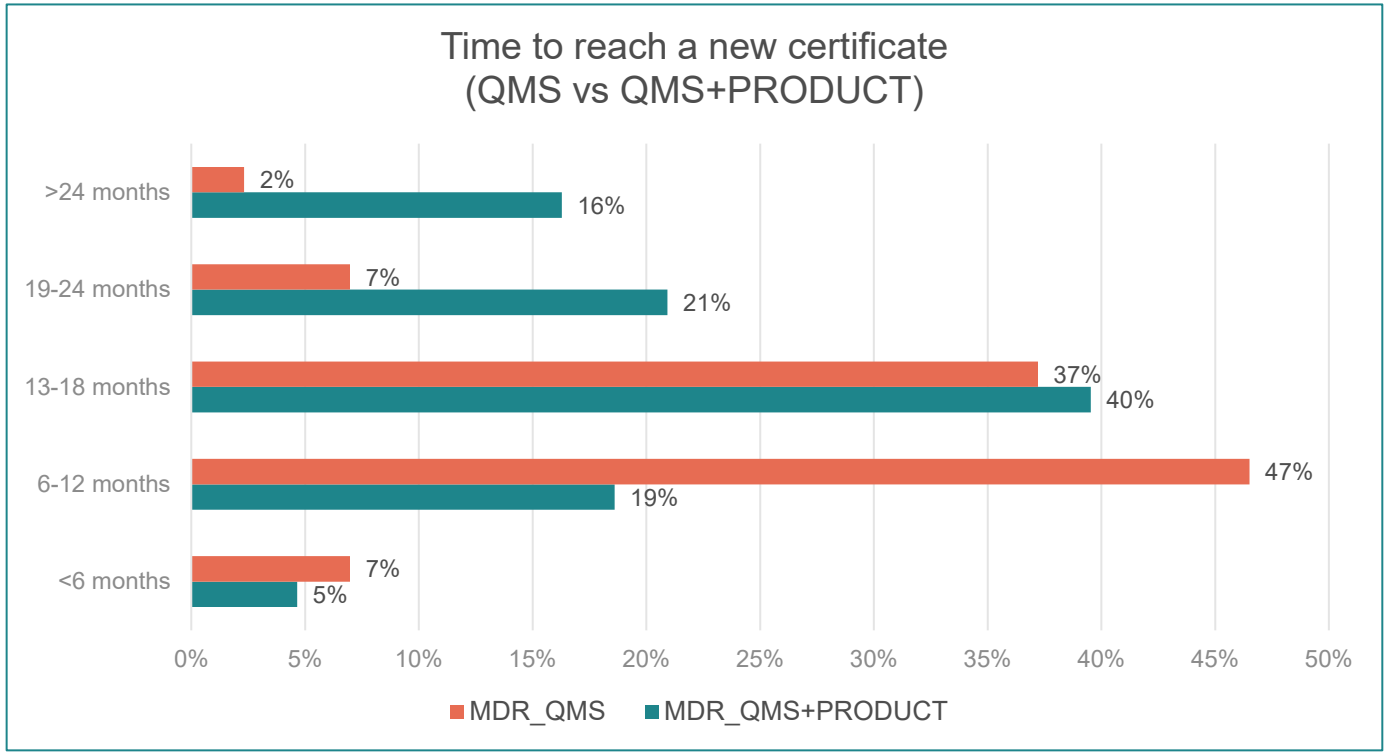
Time to reach a new certificate (QMS vs QMS+PRODUCT)

MD



February 2024
MDR Applications: 20.424*
MDR Certificates: 6.978

MDR QMS certificates:

- For 47% of NBs: 6-12 months to issue a new QMS certificate
- For 46% of NBs: ≥ 13 months (max: 24 months)

MDR QMS+PRODUCT certificates: longer time

- For 40% of NBs: 13-18 months to issue a new product certificate
- For 77% of NBs: ≥ 13 months

Notes:

* The data shown comes from the medium data set Ⓜ – except for 2 NBs where the total number of applications filed was derived from the small data set Ⓢ since they could not provide the data per Annex.

- This indicator shows the time to reach issuance of a new EC certificate (from written agreement signed to issuance) under MDR.
- Some NBs have not issued a certificate yet, so the indicated time frame is an estimation.
- One NB stated that time from agreement to certificate varies a lot.
- One NB stated to observe time periods to be increasing.

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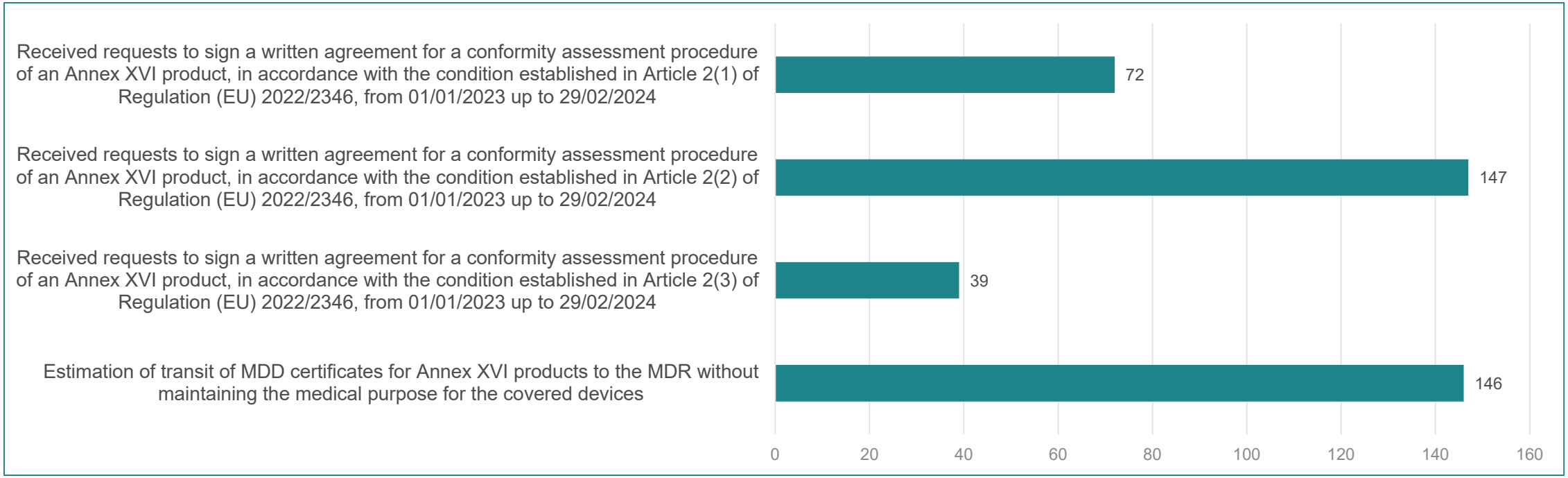
Questions on Annex XVI products

(products with no intended medical purpose that fall under the scope of the MDR)



Notes:

- 19 out of 43 NBs entered "0" for all questions relating to Annex XVI products.

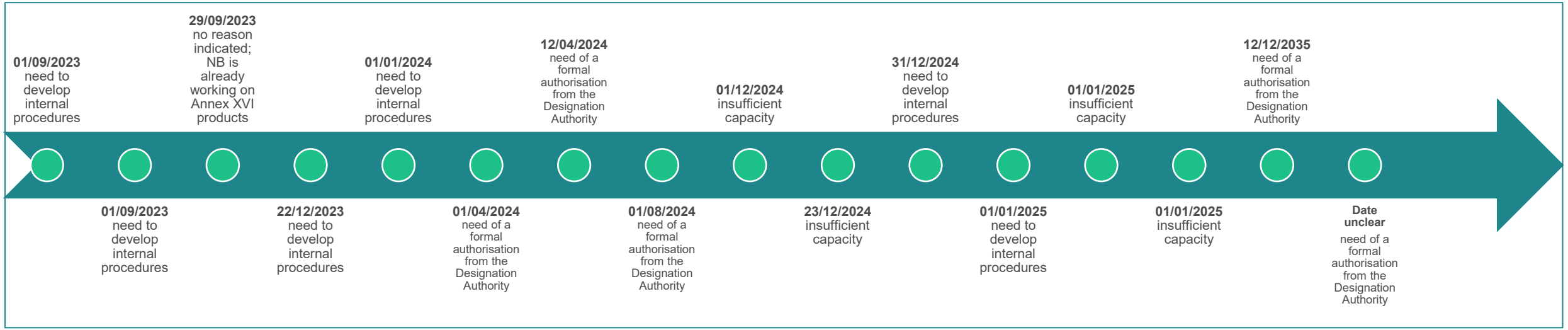
Questions on Annex XVI products

(products with no intended medical purpose that fall under the scope of the MDR)

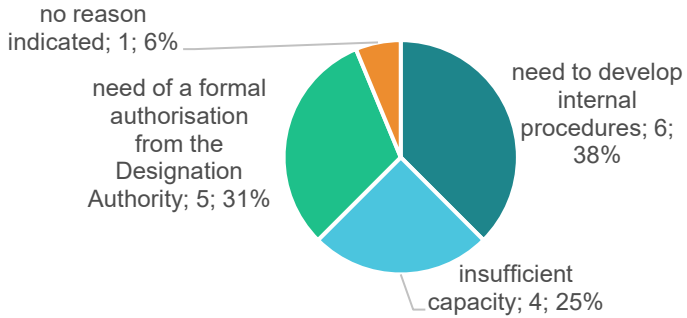
From which **date** can the NB work on Annex XVI products?

- **27 out of 43** NBs can already work on Annex XVI products from 22 June 2023 on
- **16 out of 43** NBs have stated another date and/or reason for delay

Data of 43 NBs designated under MDR



Reasons for delay



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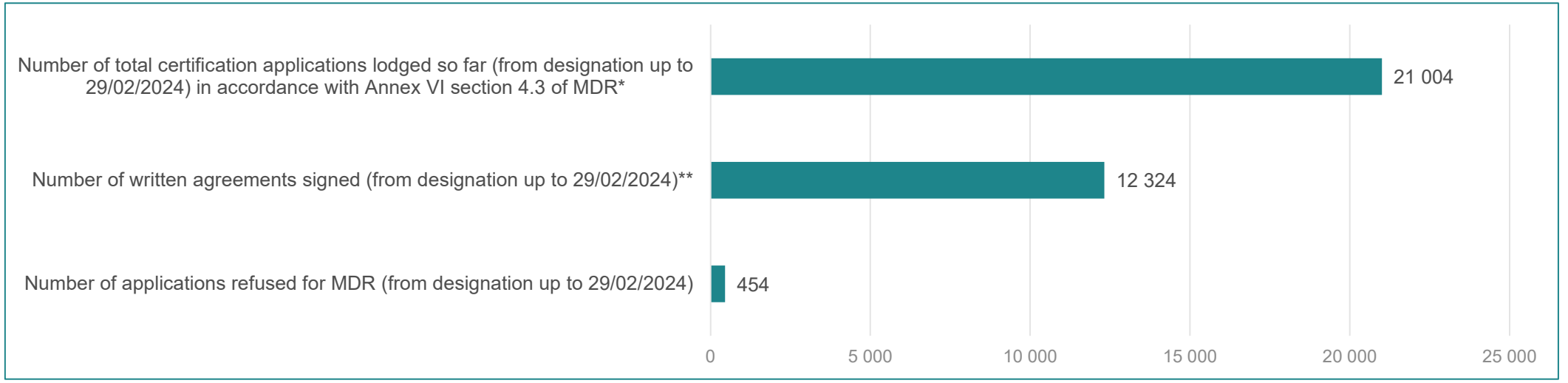
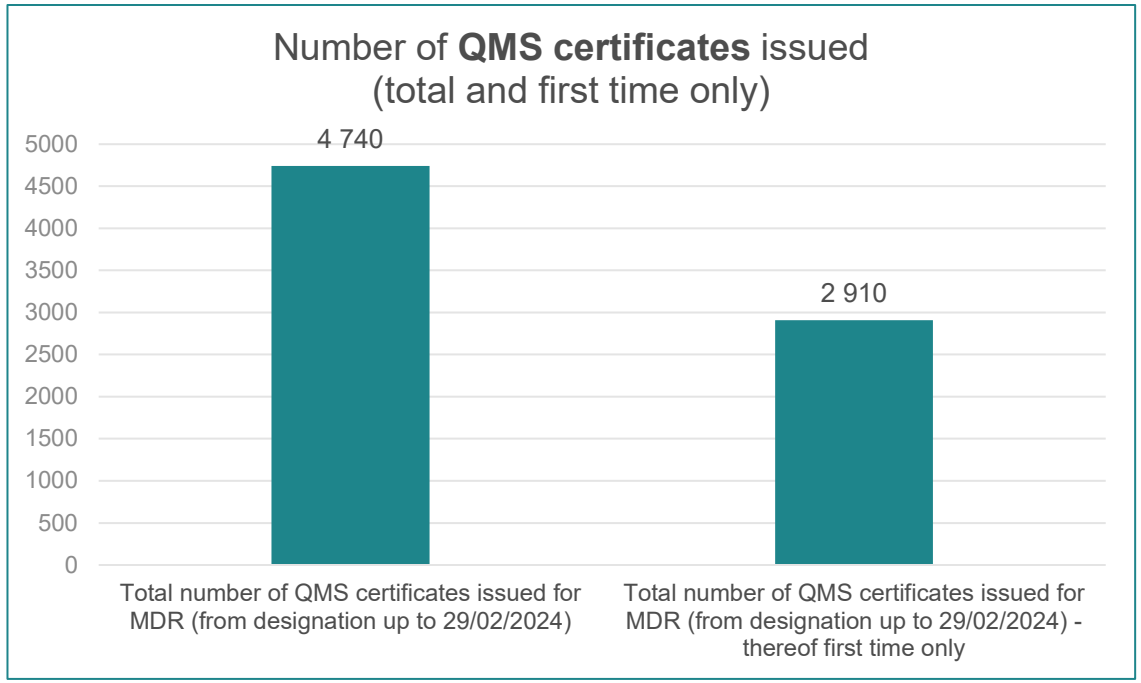
MDR applications filed and refused, written agreements signed

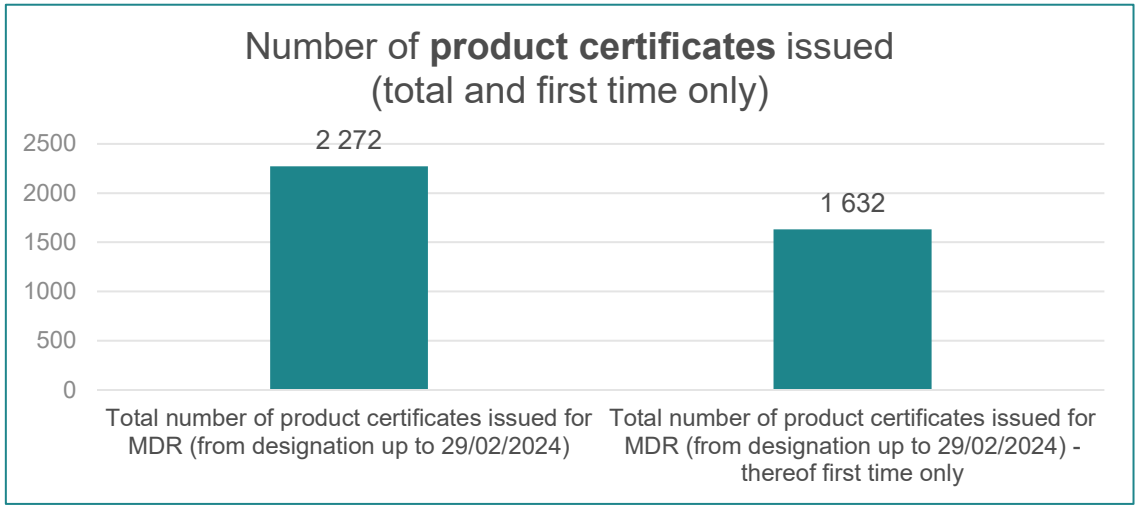


Notes:

- **Designated NBs for MD: 43**
- *** Applications lodged**: This number includes **all applications lodged (syn. filed) so far** according to MDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 29/02/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included.
- **** Written agreements signed:** This refers to the number of written agreements (contracts) between a NB and a manufacturer signed by both parties.

MDR number of QMS / product certificates issued

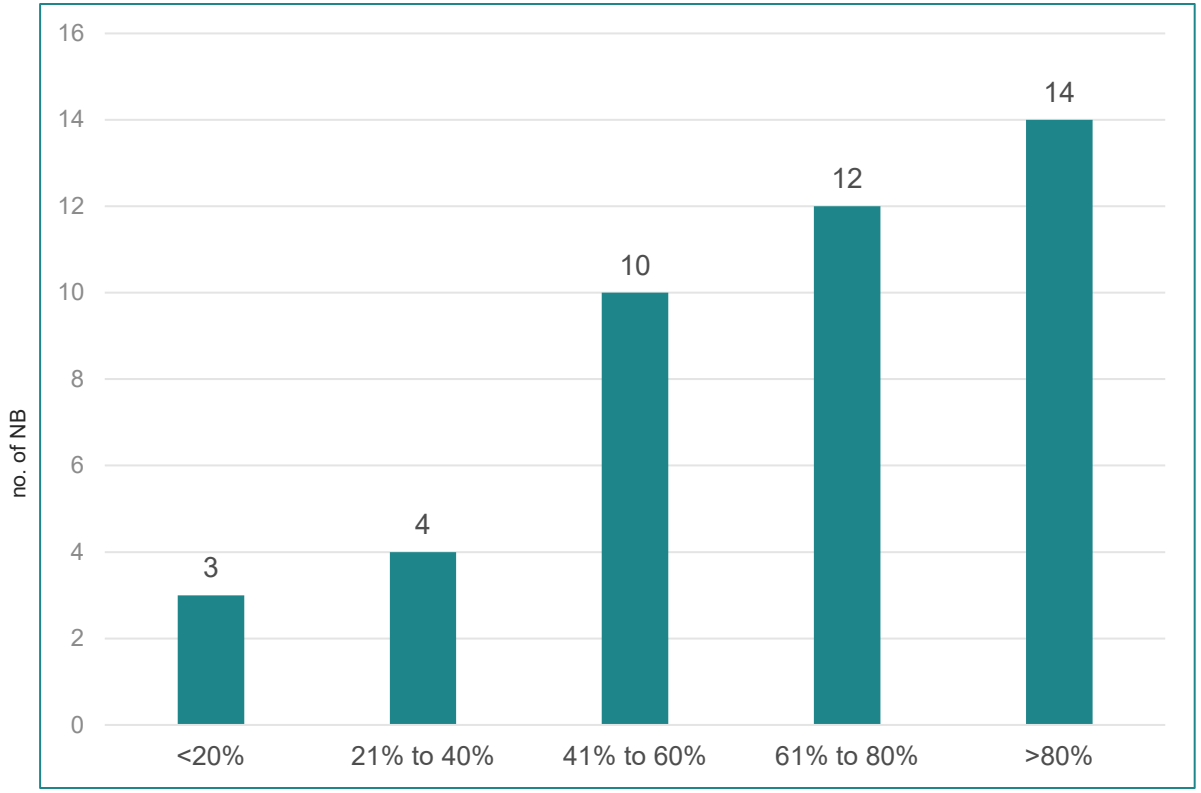




Note QMS Certificates: This relates to Annex IX Chapter I or Annex XI Part A according to MDR.

Note PRODUCT Certificates: This relates to Annex IX Chapter II, Annex X or Annex XI Part B according to MDR.

Estimation - Scope of the (AI)MDD certificates covered by MDR applications (on average)



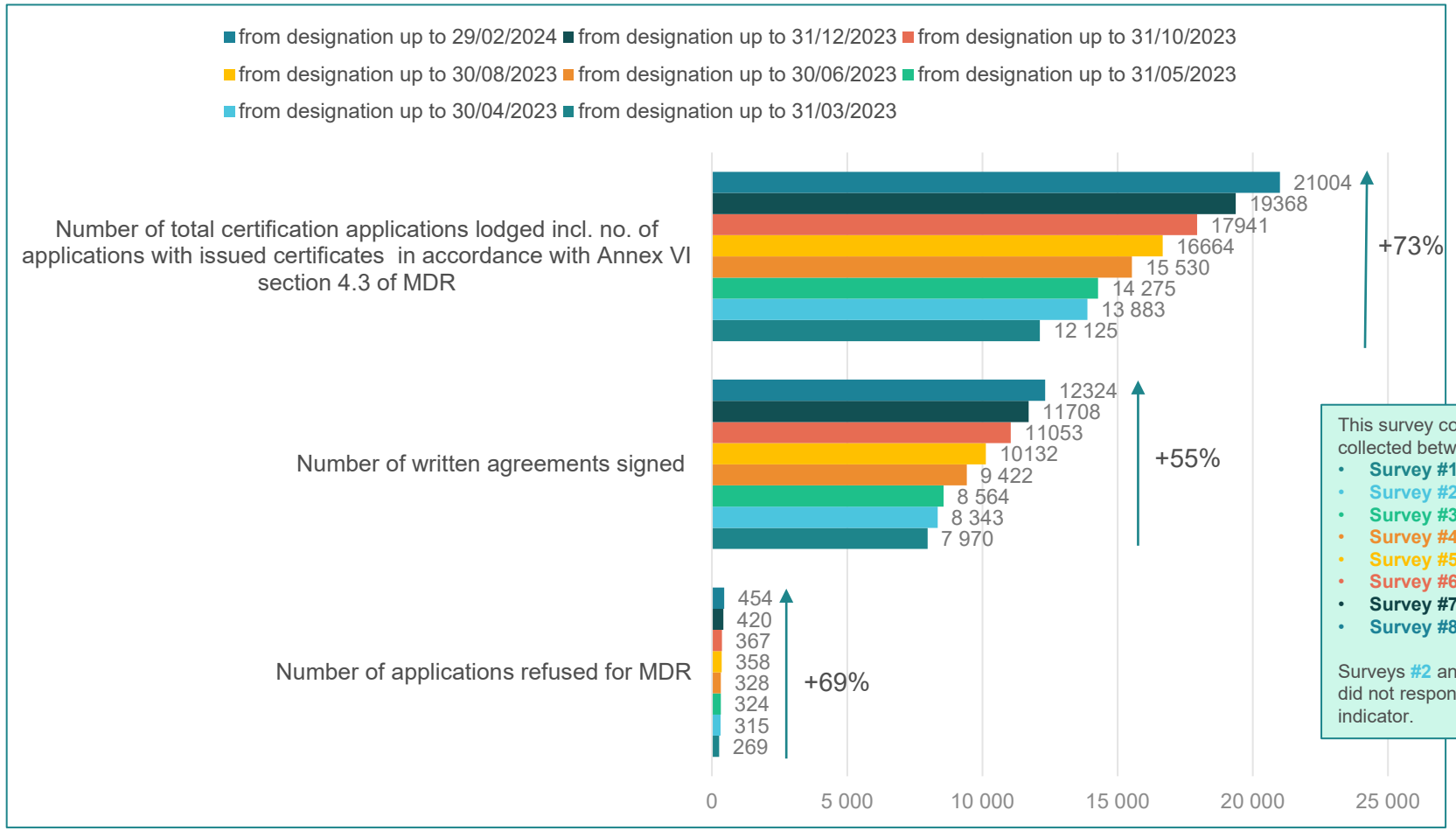
- **10 out of 43 NBs (23%)** reported that **41-60%** of the MDR applications cover the scope of (AI)MDD certificates
- **26 out of 43 NBs (60%)** indicated that MDR applications **cover more than 60%** of the scope of (AI)MDD certificates.

Calculation:
- meaning of scope coverage: MDD certificate covers 100 products, MDR application covers 50 products then coverage of the MDR = 50% of the MDD cert

Meaning of average:
- MDR application n°1 covers 1 product on 10 (MDD cert) = 10%
- MDR application n°2 covers 50 products on 100 (MDD cert) = 50%
- MDR application n°3 covers 4 products on 12 (MDD cert) = 33%
=> so average % = 31% => between 21% and 40%

Survey comparison – March 2023 to February 2024

MD



This survey comparison includes data from the small dataset (6 indicators) collected between April 2023 and March 2024 by the study team:

- **Survey #1:** data from designation up to 31/03/2023 (100% response rate)
- **Survey #2:** data from designation up to 30/04/2023 (~ 70% response rate)
- **Survey #3:** data from designation up to 31/05/2023 (~ 56% response rate)
- **Survey #4:** data from designation up to 30/06/2023 (100% response rate)
- **Survey #5:** data from designation up to 30/08/2023 (100% response rate)
- **Survey #6:** data from designation up to 31/10/2023 (100% response rate)
- **Survey #7:** data from designation up to 31/12/2023 (100% response rate)
- **Survey #8:** data from designation up to 29/02/2024 (100% response rate)

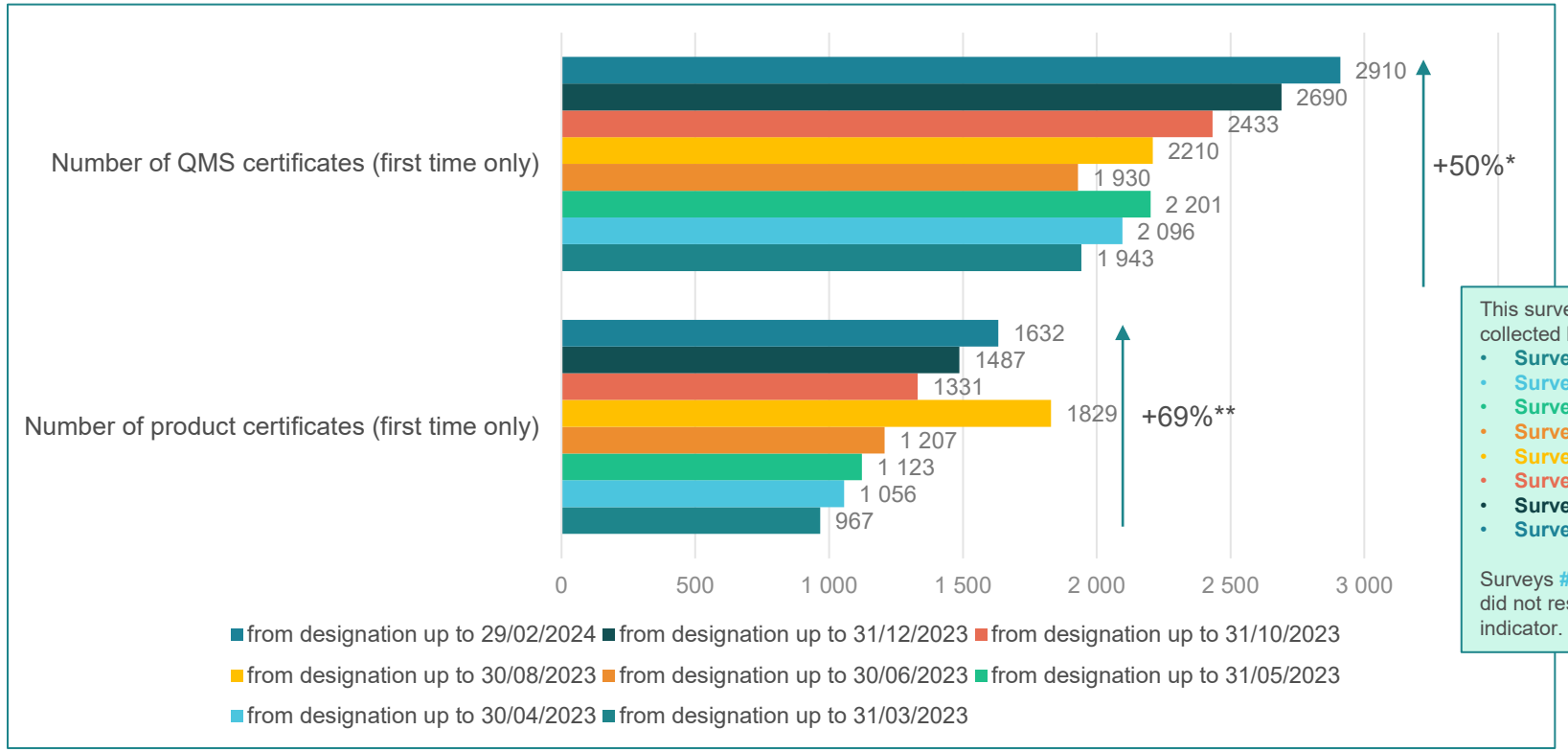
Surveys #2 and #3 did not reach 100% response rate. In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.

Notes:

- Designated NBs for MD for all survey rounds: 43; different response rates for each survey round (see info box above).

European Commission

Survey comparison – March 2023 to February 2024



This survey comparison includes data from the small dataset (6 indicators) collected between April 2023 and March 2024 by the study team:

- **Survey #1:** data from designation up to 31/03/2023 (100% response rate)
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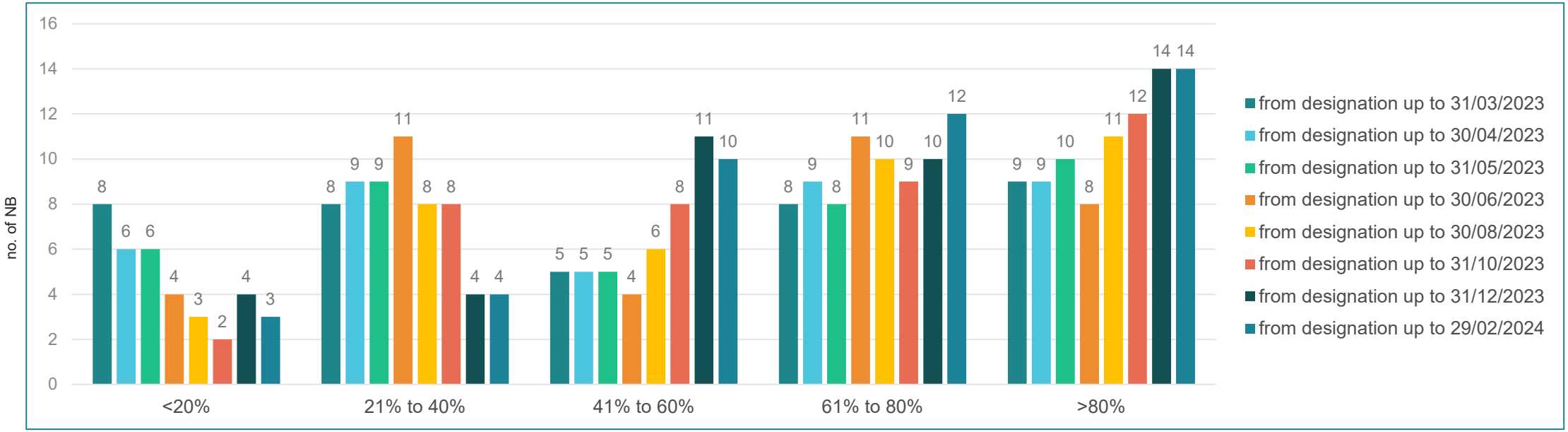
Notes:

- Designated NBs for MD for all survey rounds: 43; different response rates for each survey round (see info box above)
- * Increase of 13% from survey #1 to #3; In survey #4, the questionnaire was redesigned, and the question on "total number of certificates issued" (in addition to "first time only") was included in the small dataset. The redesign of the questionnaire helped the NBs to better assess the number of first-time only certificates. Therefore, the numbers of the previous surveys might be an overestimation.
- ** Change in methodology of counting by few NBs compared to previous surveys.

European Commission

Survey comparison – March 2023 to February 2024
Estimation - Scope of the (AI)MDD certificates covered by MDR applications (on average)



Calculation:
- meaning of scope coverage: MDD certificate covers 100 products, MDR application covers 50 products then coverage of the MDR = 50% of the MDD cert

Meaning of average:
- MDR application n°1 covers 1 product on 10 (MDD cert) = 10%
- MDR application n°2 covers 50 products on 100 (MDD cert) = 50%
- MDR application n°3 covers 4 products on 12 (MDD cert) = 33%
=> so average % = 31% => between 21% and 40%

IVD

3. Survey results for in vitro diagnostic medical devices

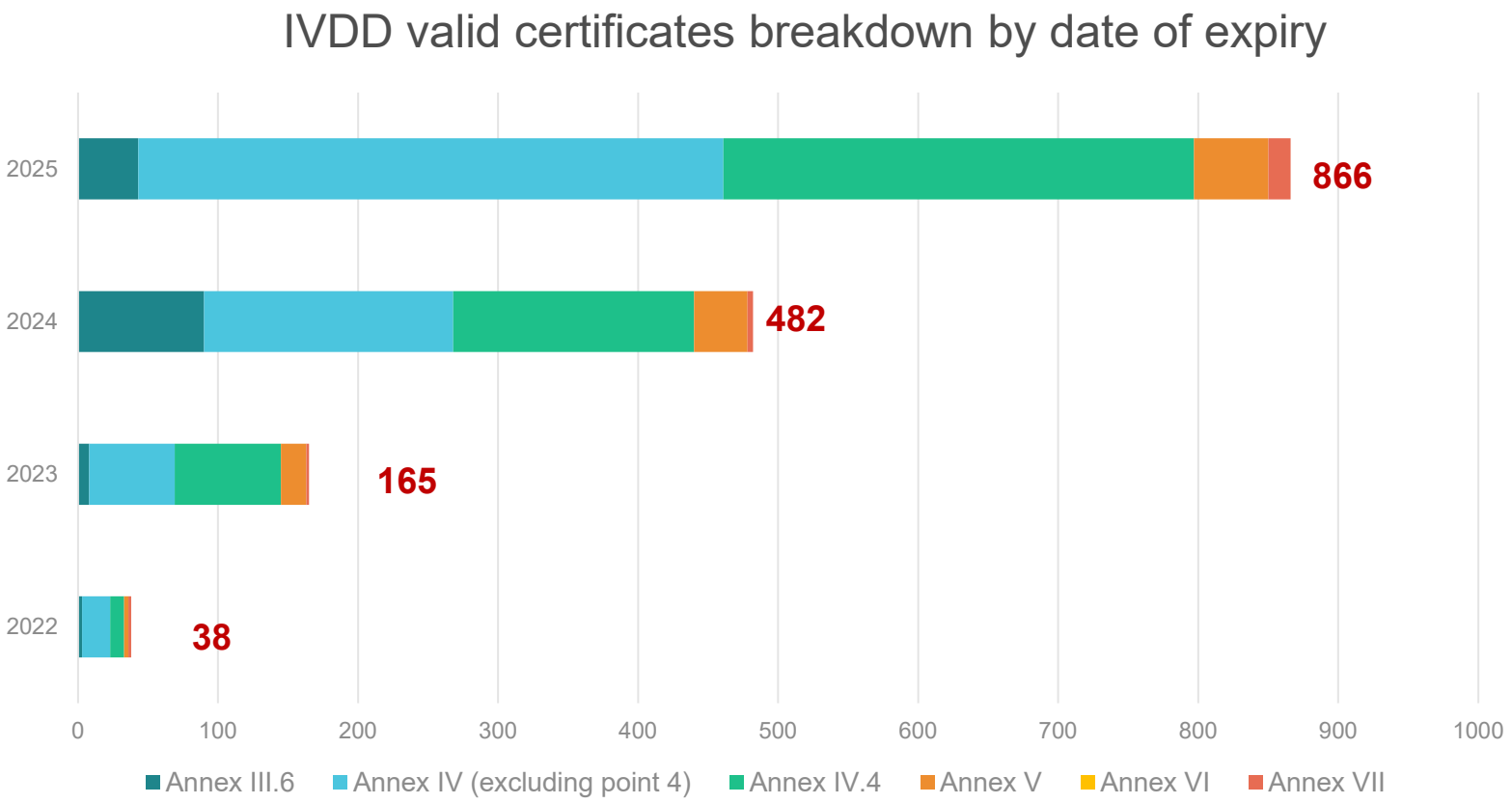
Note:

- Thousands separators are represented as dots or blank space (not comma) in the graphs.
- Datasets:

  Ⓢ The **small dataset** is a small set of questions (6 indicators) asked to notified bodies **every two months.**
  Note: From April to July 2023, it was asked monthly.
  Ⓜ The **medium dataset** is a set of questions asked to notified bodies **every four months** concerning the activities they have been performing since their designation.
  Ⓛ The **large dataset** contains additional data asked to notified bodies **once a year**.

IVDD Certificates by date of expiry (data status: October 2022)

IVD



IVDD Data
Data from survey of October 2022
(20 out of 21 replies received from NB designated under IVDD)

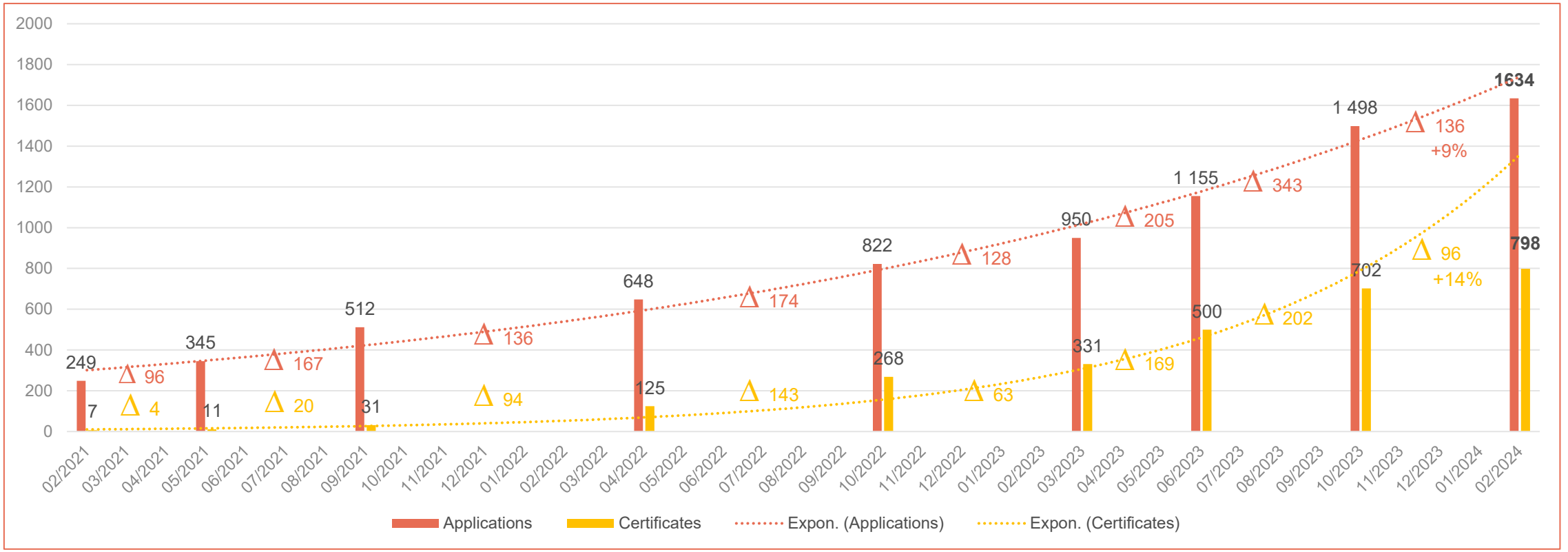
Tot. valid IVDD certificates 1.551

European Commission

IVDR applications lodged and certificates issued

IVD

February 2024
IVDR Applications: 1.634
IVDR Certificates: 798



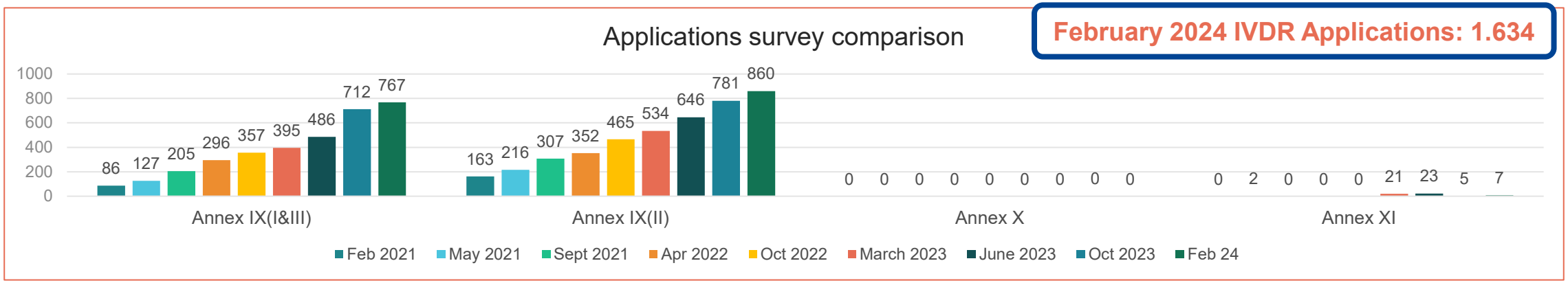
Notes: Designated NBs for IVDR: 12

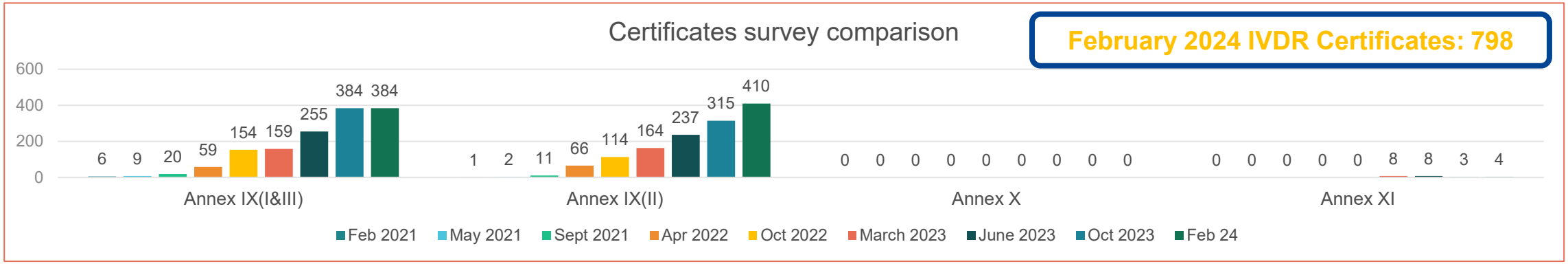
- Δ (Delta) = Difference in IVDR Applications / IVDR Certificates from one survey to the next one
- **Applications lodged**: This number includes **all applications lodged (syn. filed) so far** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 29/02/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing IVDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
- **Certificates issued:** This number includes **certificates issued so far** (from designation up to 29/02/2024) under the IVDR.

European Commission

IVDR applications and certificates by annex – surveys comparison

IVD





Notes:

- **Applications lodged by annex**: This number includes **all applications lodged (syn. filed) by annex** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 29/02/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing IVDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
- **Certificates issued by annex:** This number includes **certificates issued so far** (from designation up to 29/02/2024) under the IVDR **by annex**.

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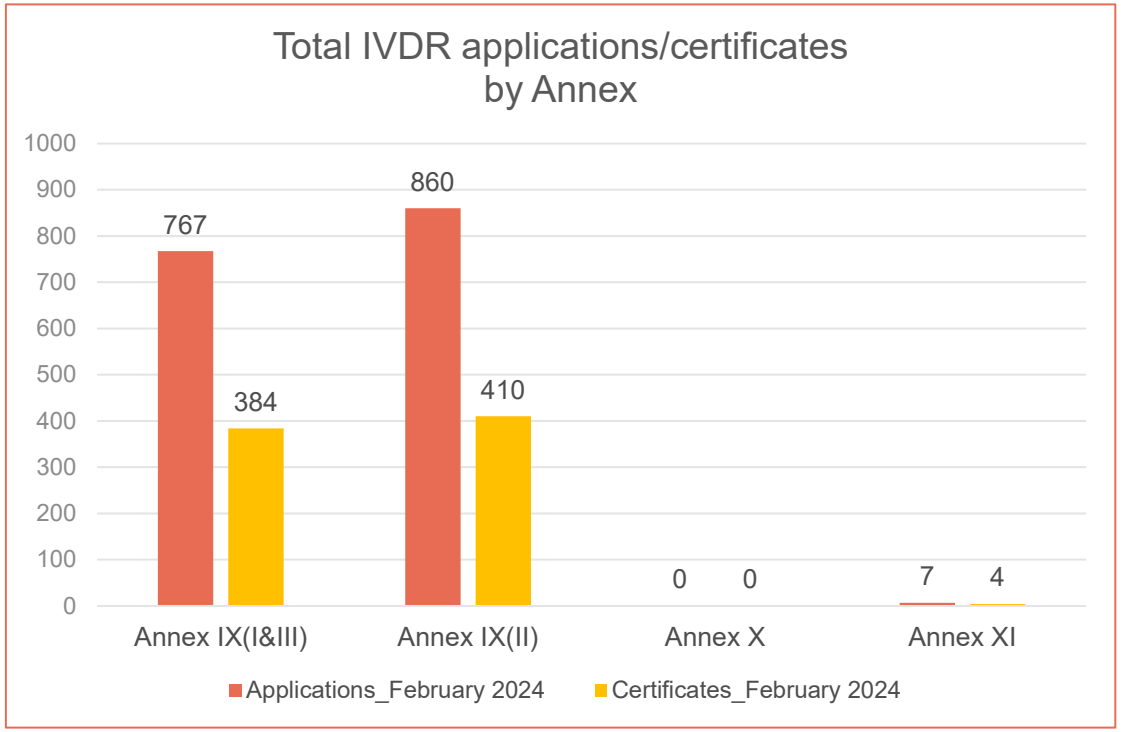
IVDR applications and certificates by annex

IVD

Ⓜ

February 2024
IVDR Applications: 1.634
IVDR Certificates: 798



Notes:

- **Applications lodged by annex:** This number includes all applications lodged (syn. filed) by annex according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in NANDO to the date of the survey up to 29/02/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
- **Certificates issued by annex**: This number includes certificates issued so far (from designation up to 29/02/2024) under the IVDR by annex.
- **Class D devices** are **included** in the total number of applications/certificates.

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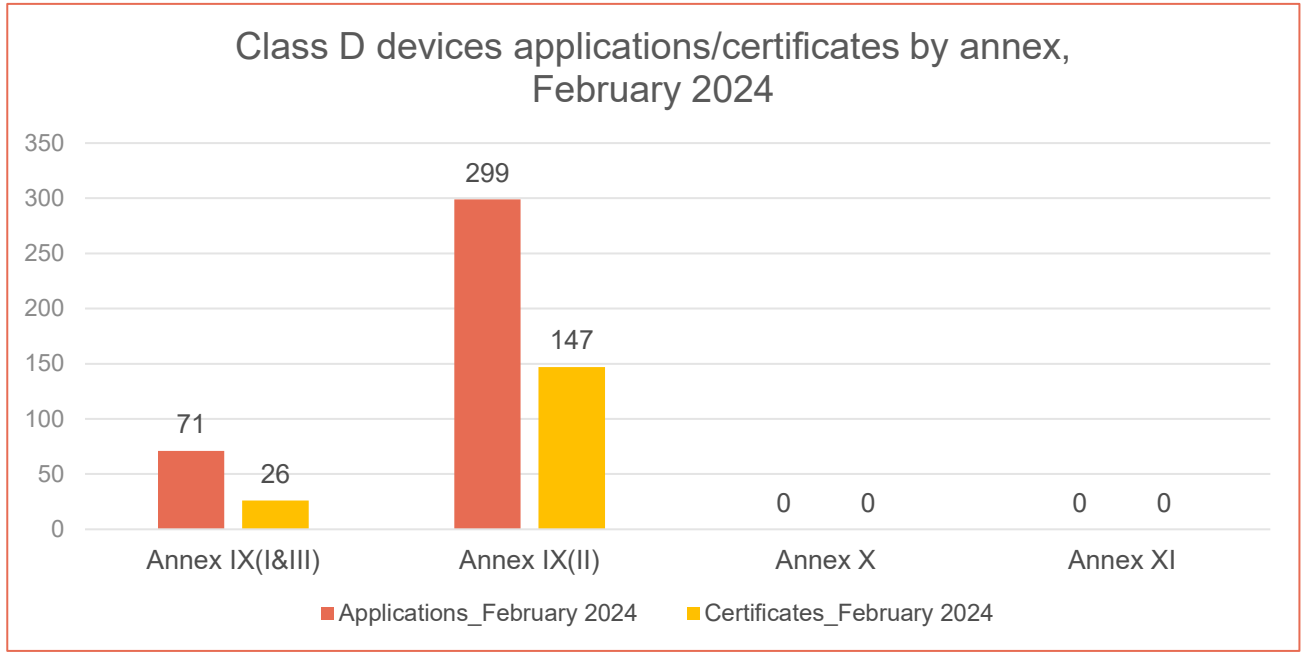
Class D devices applications and certificates

IVD



February 2024
IVDR Applications: 1.634
IVDR Certificates: 798

February 2024:
Class D devices Applications: 370
Class D devices Certificates: 173

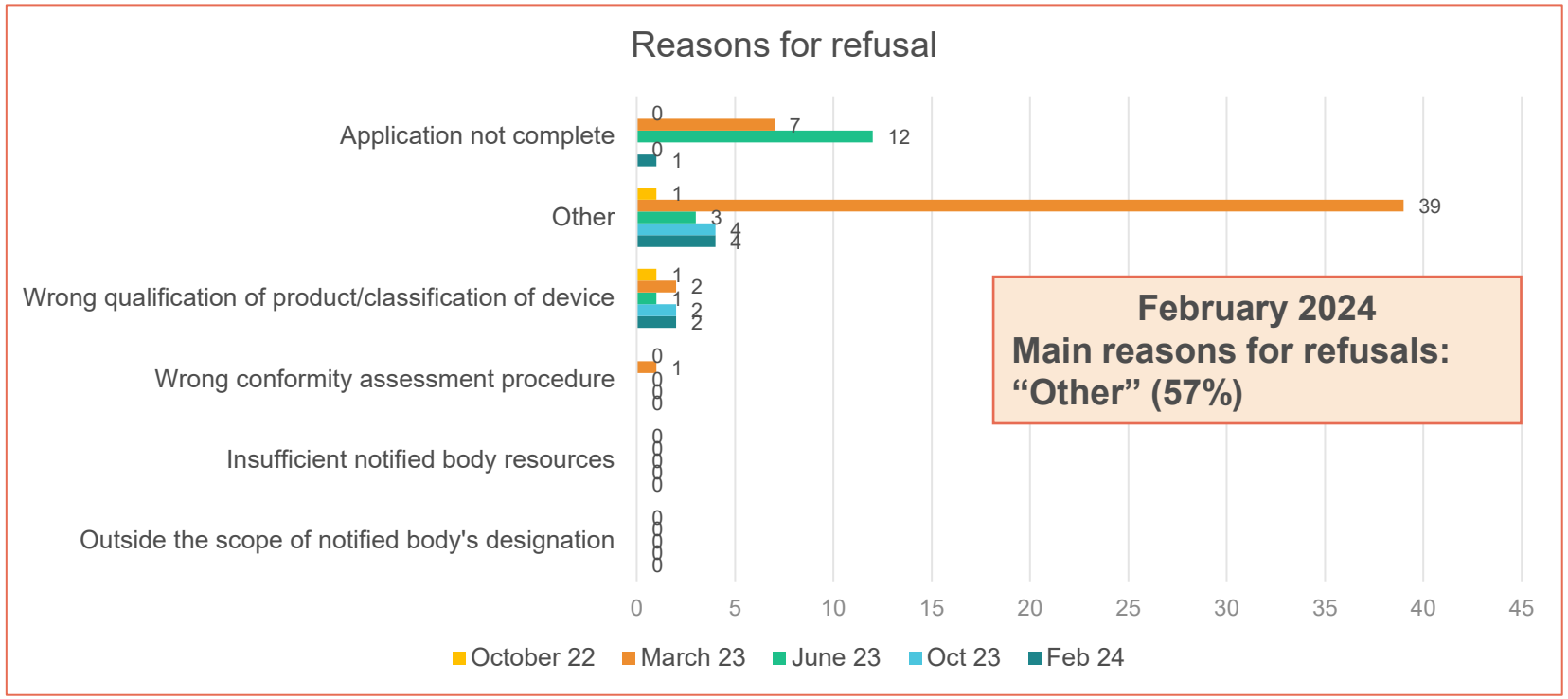
Notes:

- **Applications lodged by annex:** This number includes all applications lodged (syn. filed) by annex according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 29/02/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing IVDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
- **Certificates issued by annex**: This number includes certificates issued so far (from designation up to 29/02/2024) under the IVDR by annex.
- Data for Annex XI has changed compared to previous surveys because of a change in methodology of counting by NBs.

European Commission

IVD

IVDR applications - reason for refusal



February 2024
IVDR Applications: 1.634
IVDR Certificates: 798

Total number of IVDR application refusals:
October 2022: 2
March 2023: 49
June 2023: 16
October 2023: 6
February 2024: 7

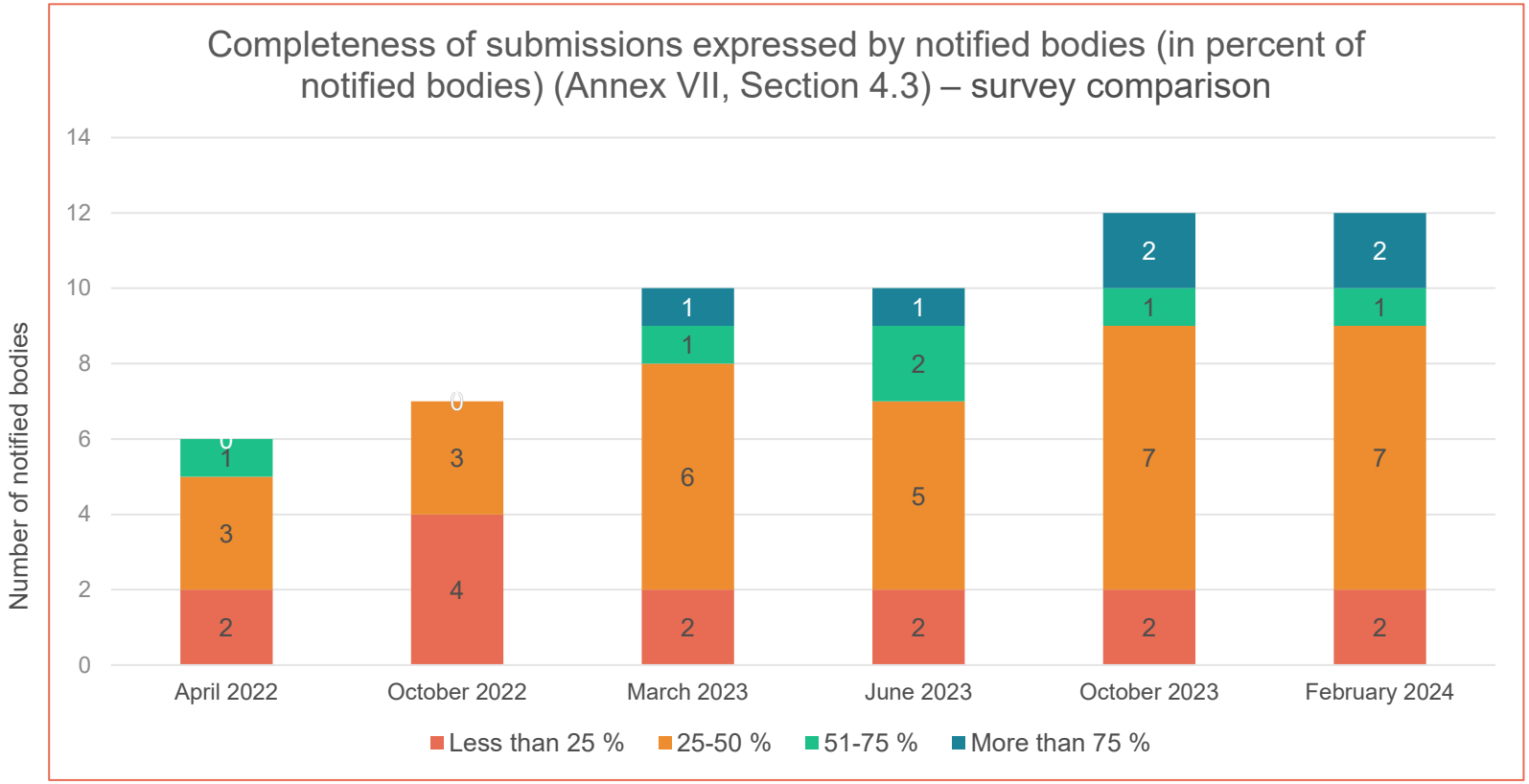
Notes:

- This graph compares the total number of applications that have been refused under IVDR by reason of refusal in October 2022, March 2023, June 2023, October 2023 and February 2024.
- Applications can have multiple reasons for refusal.
- March 2023: Reasons were indicated by **one** NB only. "Other" reasons: "application withdrawn by the manufacturer (not yet ready for the IVDR, due to economic reasons,…)"
- June 2023: Reasons were indicated by **two** NBs only. "Other" reasons: "nonconformities not solved", "withdrawal of client", "assessment resulted in negative outcome"
- October 2023: Reasons were indicated by **two** NBs only. "Other" reasons: "nonconformities not solved", "withdrawal of client", "assessment resulted in negative outcome"
- February 2024: Reasons were indicated by **three** NBs only. "Other" reasons: "nonconformities not solved", "withdrawal of client", "assessment resulted in negative outcome"

European Commission

IVD

Completeness of submissions



% of submissions with completeness rate > 50%: for 3 out of 12 NBs in February 2024

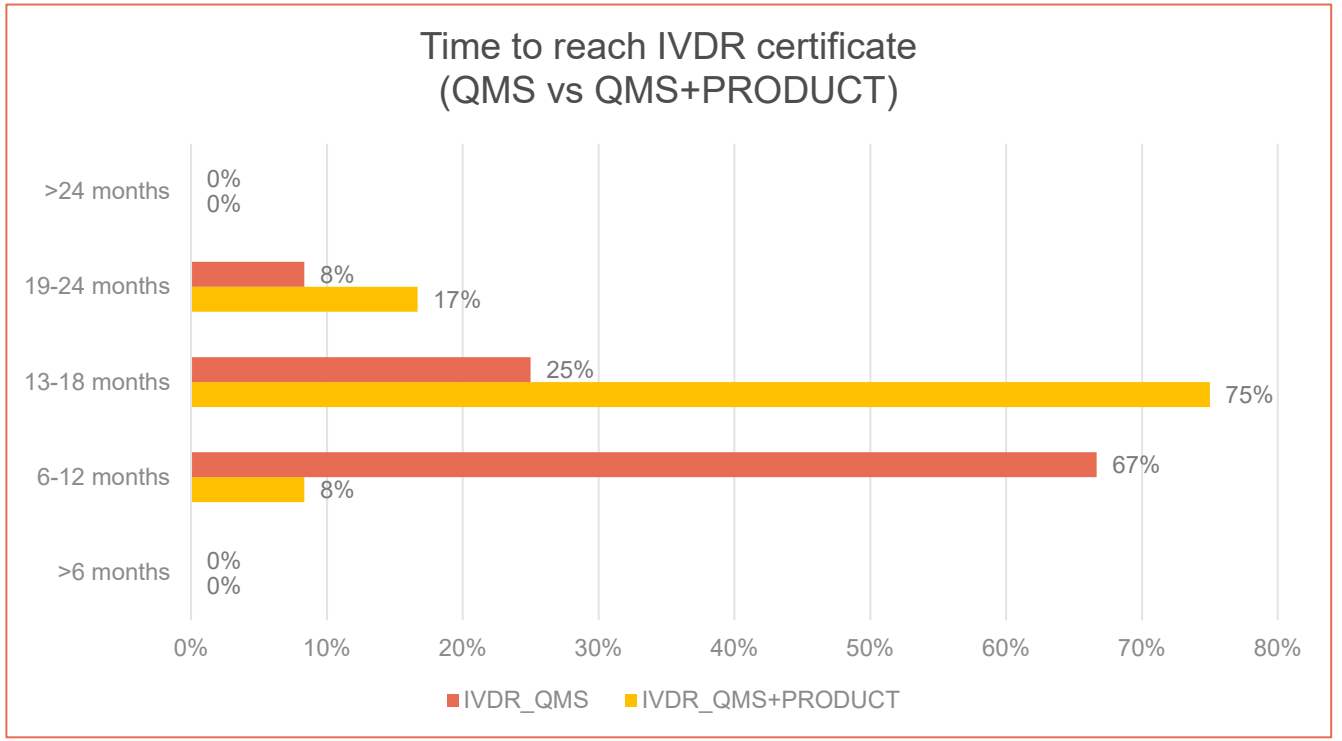
Submissions largely incomplete*

* 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

European Commission

Time to reach a certificate

IVD



February 2024
IVDR Applications: 1.634
IVDR Certificates: 798

IVDR QMS certificates

- For 67% of NBs: 6-12 months to issue a new QMS certificate
- 25% of NBs: 13-18 months

IVDR QMS+PRODUCT certificates: longer time

- 75% of NBs: 13-18 months
- 17% of NBs: 19-24 months

Notes:

- Data of 12 NBs
- This indicator shows the time to reach issuance of a new EC certificate (from written agreement signed to issuance) under IVDR.
- One NB specifically pointed out that this is an estimate as they have not issued certificates yet.

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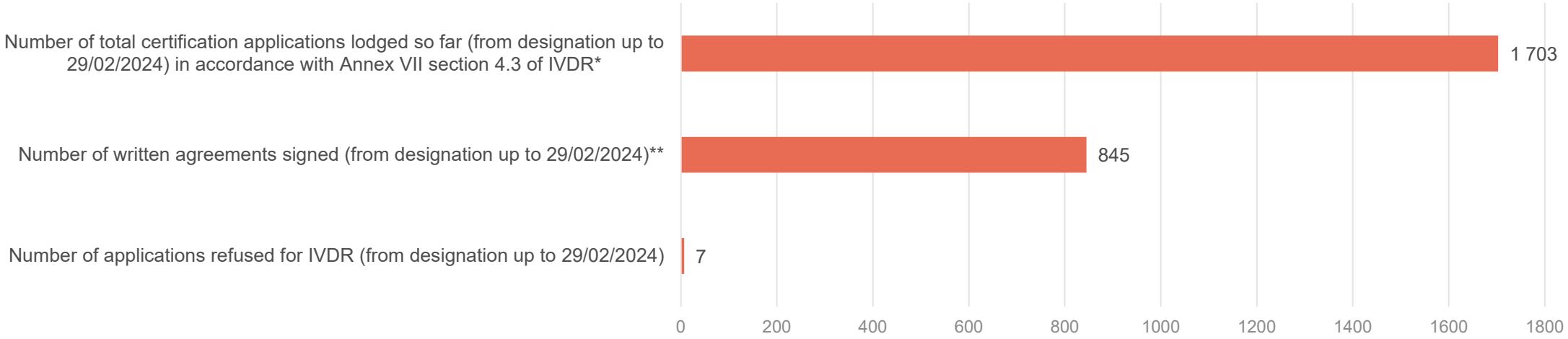
IVDR applications filed and refused, written agreements signed

IVD



Notes:

- **Designated NBs for IVD:** 12
- *** Applications lodged**: This number includes **all applications lodged (syn. filed) so far** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 29/02/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included.
- **** Written agreements signed:** This refers to the number of written agreements (contracts) between a NB and a manufacturer signed by both parties.

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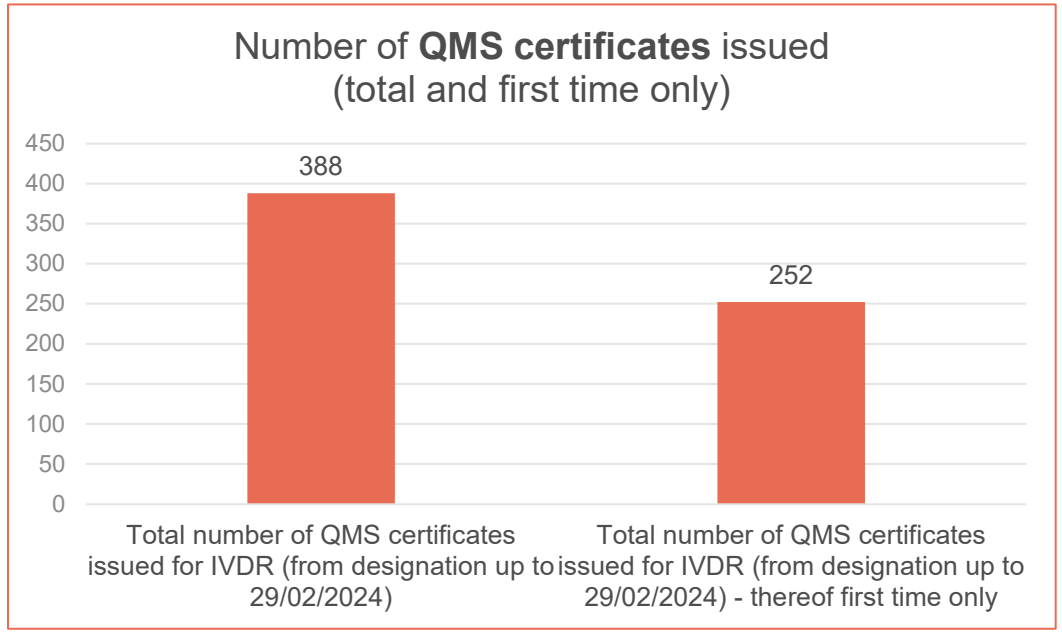
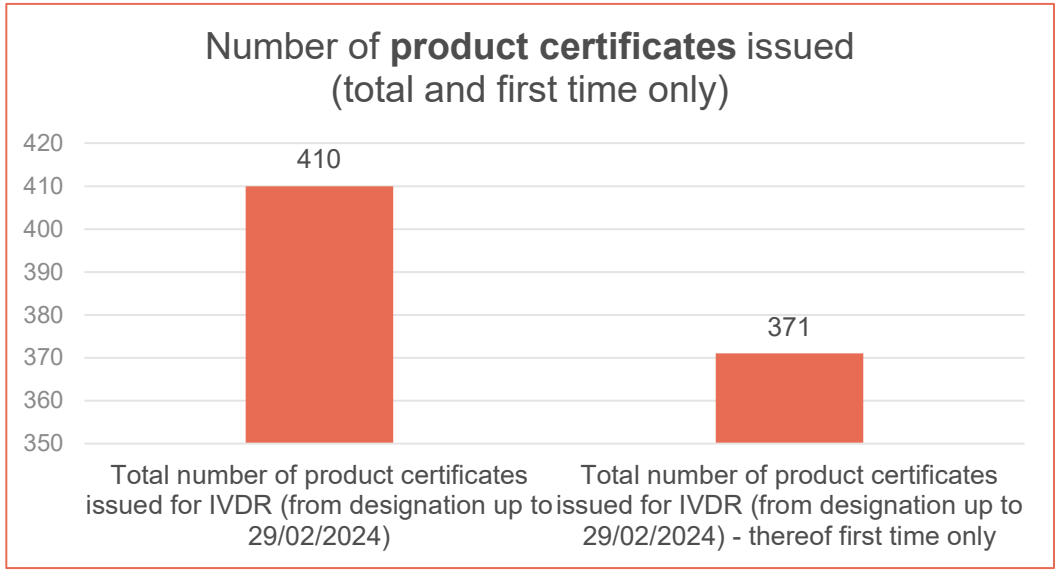
IVDR Number of QMS / product certificates issued

IVD





Note QMS Certificates: This relates to Annex IX Chapter I or Annex XI according to IVDR.

Note PRODUCT Certificates: This relates to Annex IX Chapter II, Annex X or Annex XI according to IVDR.

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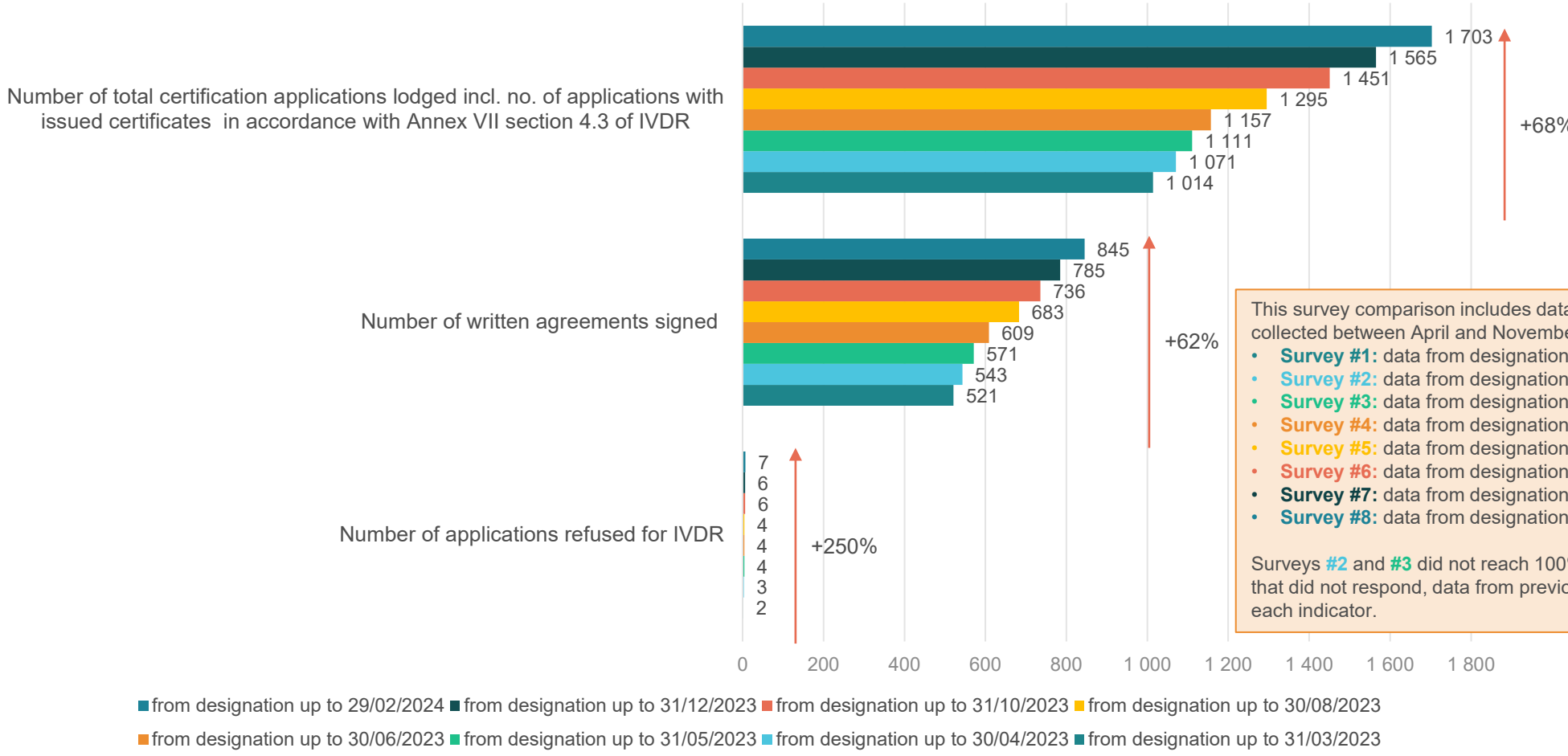
IVD

Survey comparison – March 2023 to February 2024



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Surveys #2 and #3 did not reach 100% response rate. In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.

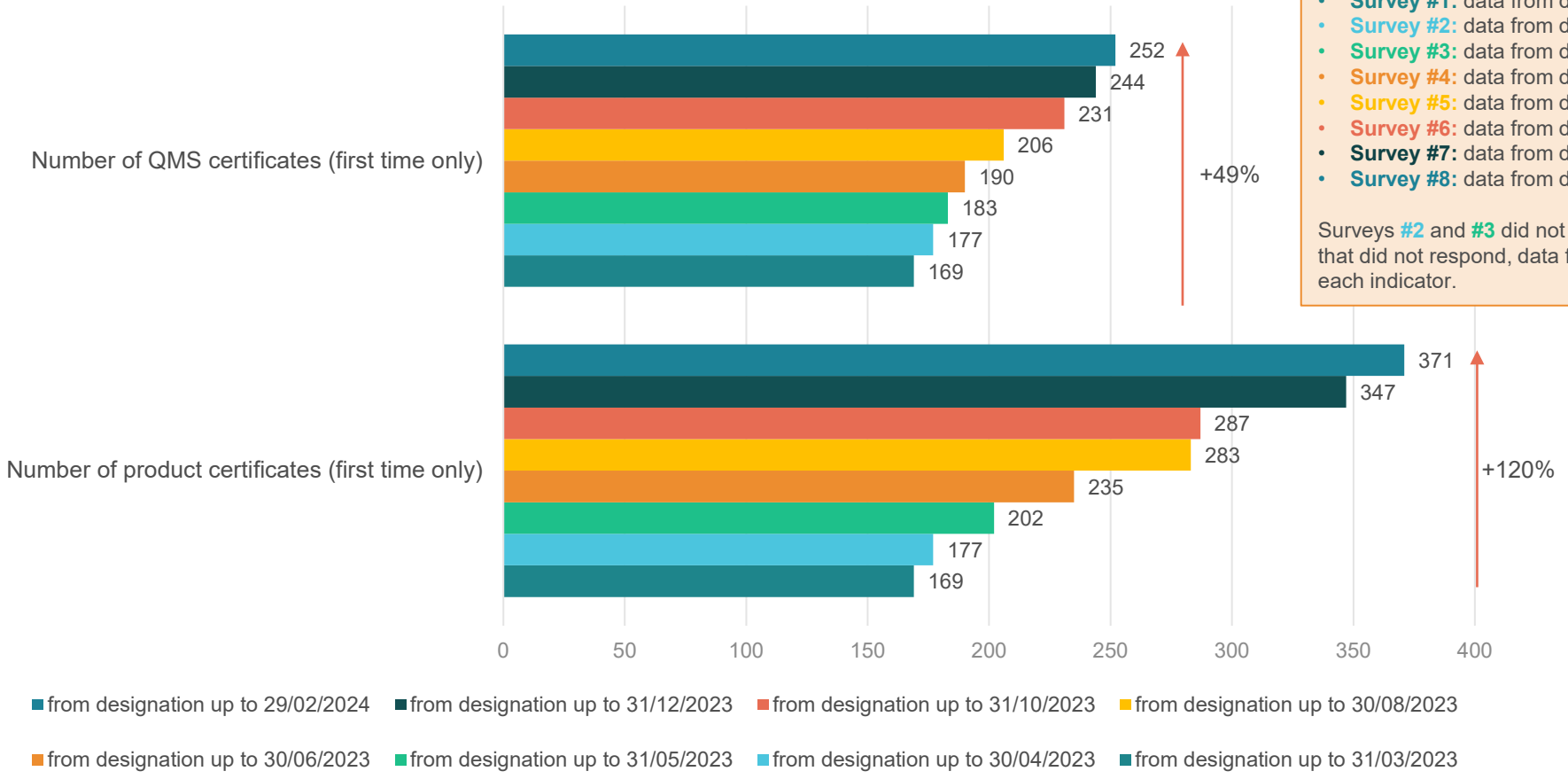
Notes:

- Designated NBs for survey #1 to #5: 10
- Designated NBS for survey #6 to #8 : 12

European Commission

IVD

Survey comparison – March 2023 to February 2024



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Thank you

Contact for questions: medical.devices@goeg.at

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