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

Survey results of the 14th NB survey (MDR/IVDR)
with data status 28 February 2025
(small and medium dataset)

25 July 2025

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.

Gesundheit Österreich GmbH

Areté The Agri-food Intelligence Company

CIVIC CONSULTING

European Commission

Acknowledgements

The study team would like to sincerely thank the following institutions and people for the support in the 14th NB survey:

- All **51 notified bodies** designated under MDR and/or IVDR as of 3 March 2025 that participated in the survey (100% response rate);
- The Directorate General for Health and Food Safety at the European Commission (**DG SANTE**) and the European Health and Digital Executive Agency (**HaDEA**);
- Members of the **MDCG TF on certification capacity monitoring**.

Content

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List of abbreviations (1)

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
CE	Conformité Européenne
DG SANTE	Directorate-General for Health and Food Safety
EC	European Commission
EU	European Union
EURLs	EU reference laboratories
FTE	Full Time Equivalent
FWC	Framework contract
GÖG	Gesundheit Österreich GmbH / Austrian National Public Health Institute
HaDEA	European Health and Digital Executive Agency
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)
LD	Large dataset

List of abbreviations (2)

Abbreviation	Meaning
MD	Medium dataset
MDCG	Medical Device Coordination Group
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)
MFs	Manufacturer(s)
NBs	Notified body / bodies
QMS	Quality Management System
SC	Special contract
SD	Small dataset
SMCS	Single Market Compliance Space
SMEs	Small and medium-sized enterprise(s)
TF	Task Force

About

1. About the study, survey and datasets

- Study supporting the monitoring of availability of medical devices on the EU market
- NB survey overview
- Dashboard
- Preliminary notes
- Survey timeline
- Response rate

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

About

- **Commissioned by:** The European Commission's Directorate-General for Health and Food Safety (DG SANTE) via the European Health and Digital Executive Agency (HaDEA)
- **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 (Gesundheit Österreich GmbH / GÖG) → project lead

Areté The Agri-food Intelligence Company — Areté

CIVIC CONSULTING — Civic Consulting

Supported by experts from the medical devices sector

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NB survey overview

About

NB survey	Survey period (survey launch – survey closure)	Requested dataset* SD = small dataset MD = medium dataset LD = large dataset	Requested data	Response rate (only NBs designated under MDR and/or IVDR)
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%)**
9th NB survey	02/05/2024 - 21/06/2024	SD9	from designation up to 30/04/2024	48 out of 48 NBs **(100%)**
10th NB survey	01/07/2024 - 06/08/2024	SD10 + MD5	from designation up to 30/06/2024	50 out of 50 NBs **(100%)**
11th NB survey	02/09/2024 - 17/10/2024	SD11	from designation up to 31/08/2024	50 out of 50 NBs **(100%)**
12th NB survey	06/11/2024 – 20/12/2024	SD12 + MD6 + LD2 + TE1**	from designation up to 31/10/2024	51 out of 51 NBs **(100%)**
13th NB survey	21/01/2025 – 27/02/2025	SD13 + TE2**	from designation up to 31/12/2024	51 out of 51 NBs **(100%)**
14th NB survey	03/03/2025 – 08/04/2025	SD14 + MD7	from designation up to 28/02/2025	51 out of 51 NBs **(100%)**

Survey results included in the published dashboard

14th 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**.
- The questions asked as part of the **targeted evaluation** are requested only once on behalf of DG SANTE.

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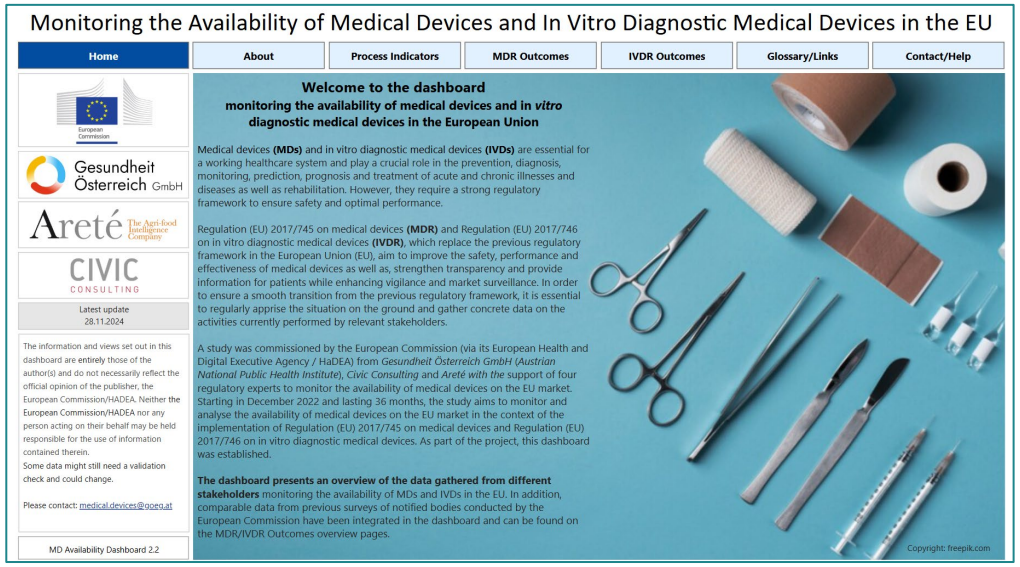
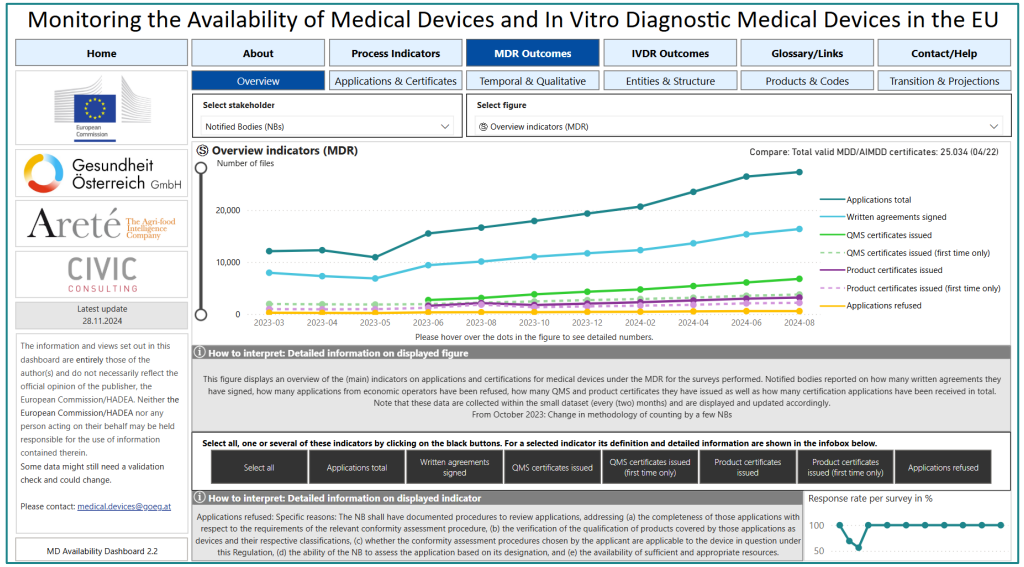
** **About the targeted evaluation:** Evaluations conducted by the European Commission assess how well a specific policy intervention has performed (or is performing) and whether it is still relevant and justified. Evaluations are a key component of the lifecycle of any policy intervention. For the MDR and IVDR, the Commission has a legal obligation to conduct an evaluation of the Regulations by May 2027 (Article 121 MDR/Article 111 IVDR). The Commission has decided to launch a targeted evaluation of the Regulations in 2024. The **12th, 13th NB survey** (conducted in the framework of the 'Study supporting the monitoring of the availability of medical devices on the EU market') were used to ask NBs questions that are relevant for the Targeted Evaluation.

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)
- Instructions for use for the dashboard





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About

Preliminary notes

- **Data content:**
  - The following slides show the results of the **14th NB survey conducted at the beginning of March 2025** with **requested data** from notified bodies designated under MDR and/or IVDR **until 28 February 2025**.
  - These survey results are also compared with previous survey data (see data sources).

- **Data sources:**
  - Data collected between April 2023 and March 2025 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 2025.

Ⓢ The **small dataset** is a small set of questions 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.

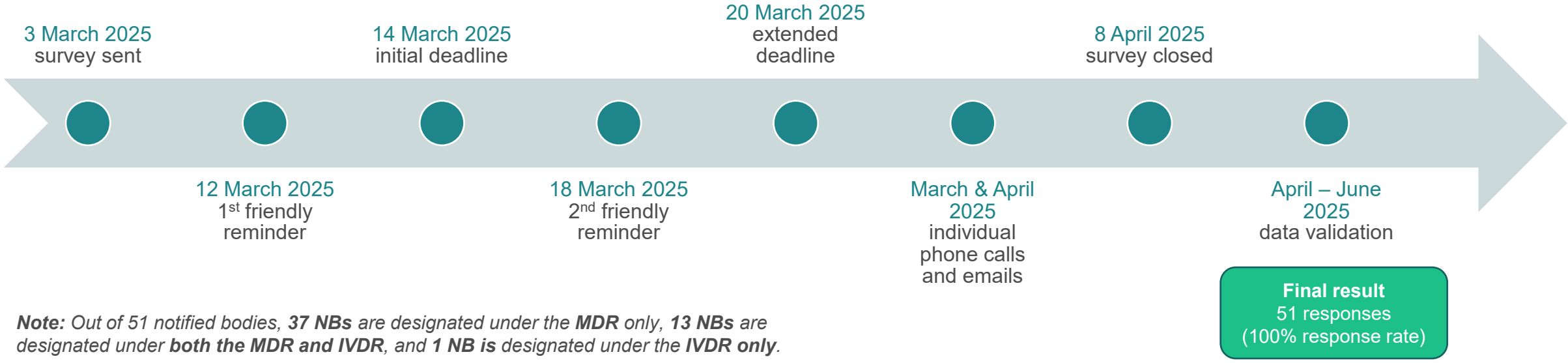
Ⓛ The **large dataset** contains additional data asked to notified bodies **once a year**.

Timeline for the 14th NB survey

(conducted in March 2025 with requested data from designation up to 28/02/2025)

About

51 notified bodies designated under MDR and/or IVDR
(data status: 3 March2025)



Final result
51 responses
(100% response rate)

Note: *Out of 51 notified bodies,* ***37 NBs*** *are designated under the* ***MDR*** *only,* ***13 NBs*** *are designated under* ***both the MDR and IVDR****, and* ***1 NB is*** *designated under the* ***IVDR only****.*

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Response rate for the 14th NB survey

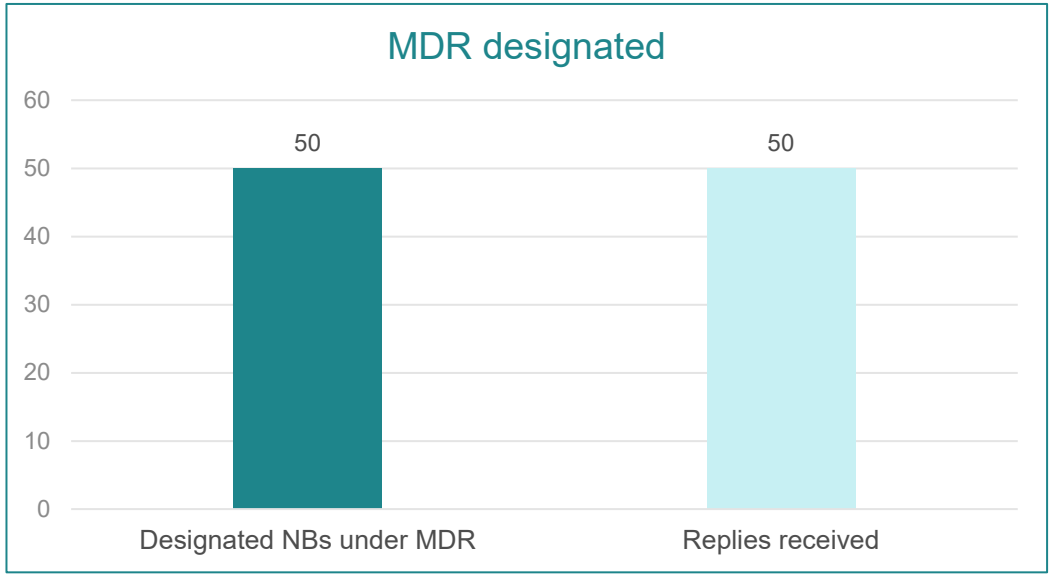
(conducted in March 2025 with requested data from designation up to 28/02/2025)

About

51 out of 51 notified bodies replies received (100% response rate)

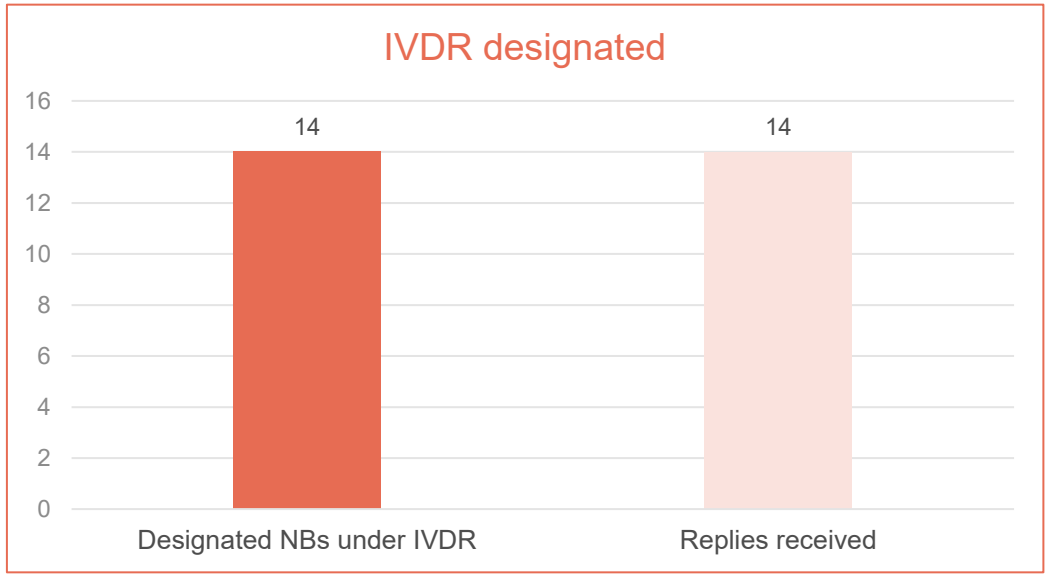
Note: *Out of 51 notified bodies,* ***37 NBs*** *are designated under the* ***MDR*** *only,* ***13 NBs*** *are designated under* ***both the MDR and IVDR****, and* ***1 NB is designated under the IVDR only****.*

MD



100% response rate

IVD



100% response rate

European Commission

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 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.**

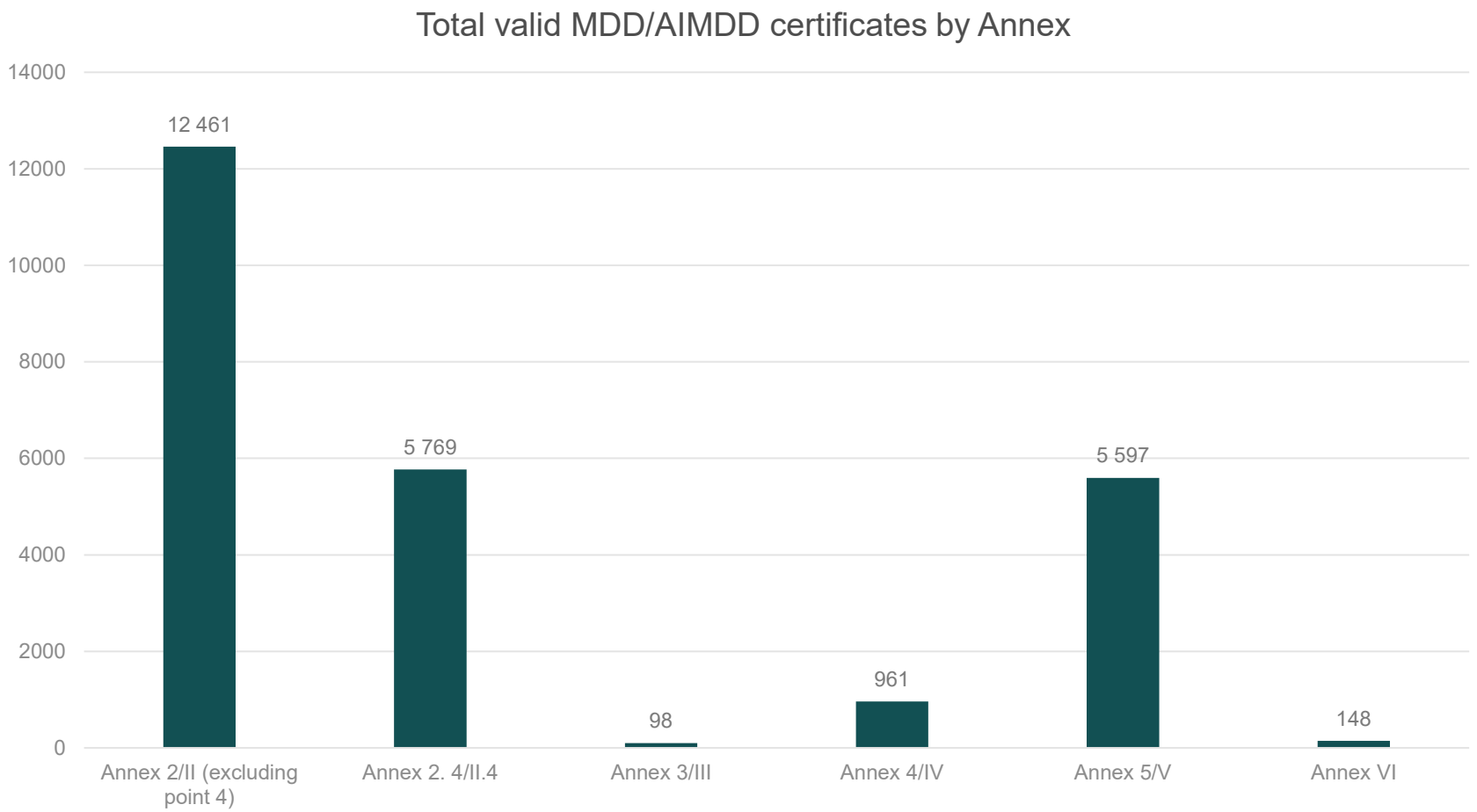
MDD/AIMDD Certificates by Annex (data status: April 2022)

MD

CAVEAT:
Not part of this 14th NB survey, but included for comparison.

MDD/AIMDD Data

Total: 25.034



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Small dataset Ⓢ

The **small dataset** is a small set of questions asked to notified bodies **every two months.**

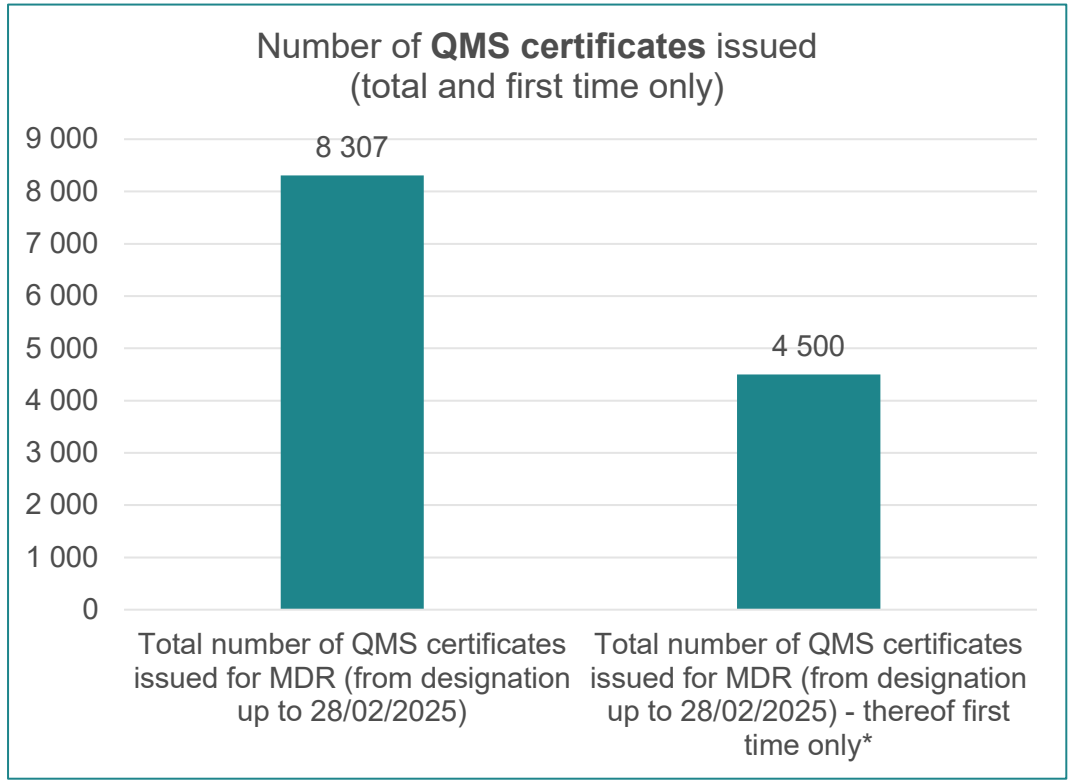
From April to July 2023, it was asked monthly.

MDR applications filed and refused, written agreements signed

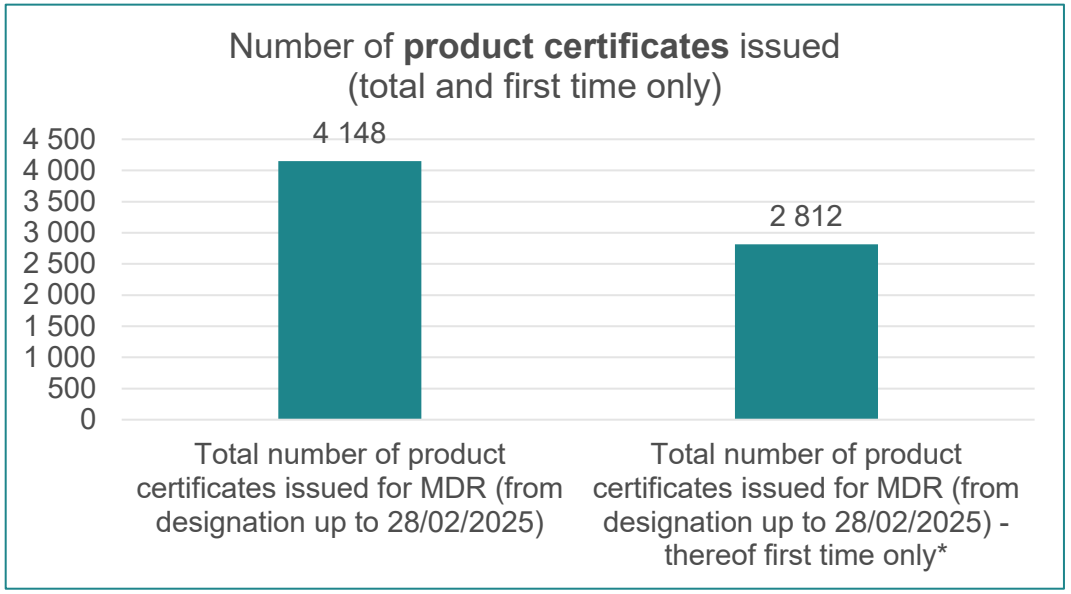
Notes:

- **Designated NBs for MD: 50**
- **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 28/02/2025), 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.
*Change in methodology of counting, changes in data of previous surveys



Note PRODUCT Certificates: This relates to Annex IX Chapter II, Annex X or Annex XI Part B according to MDR.
*Change in methodology of counting, changes in data of previous surveys

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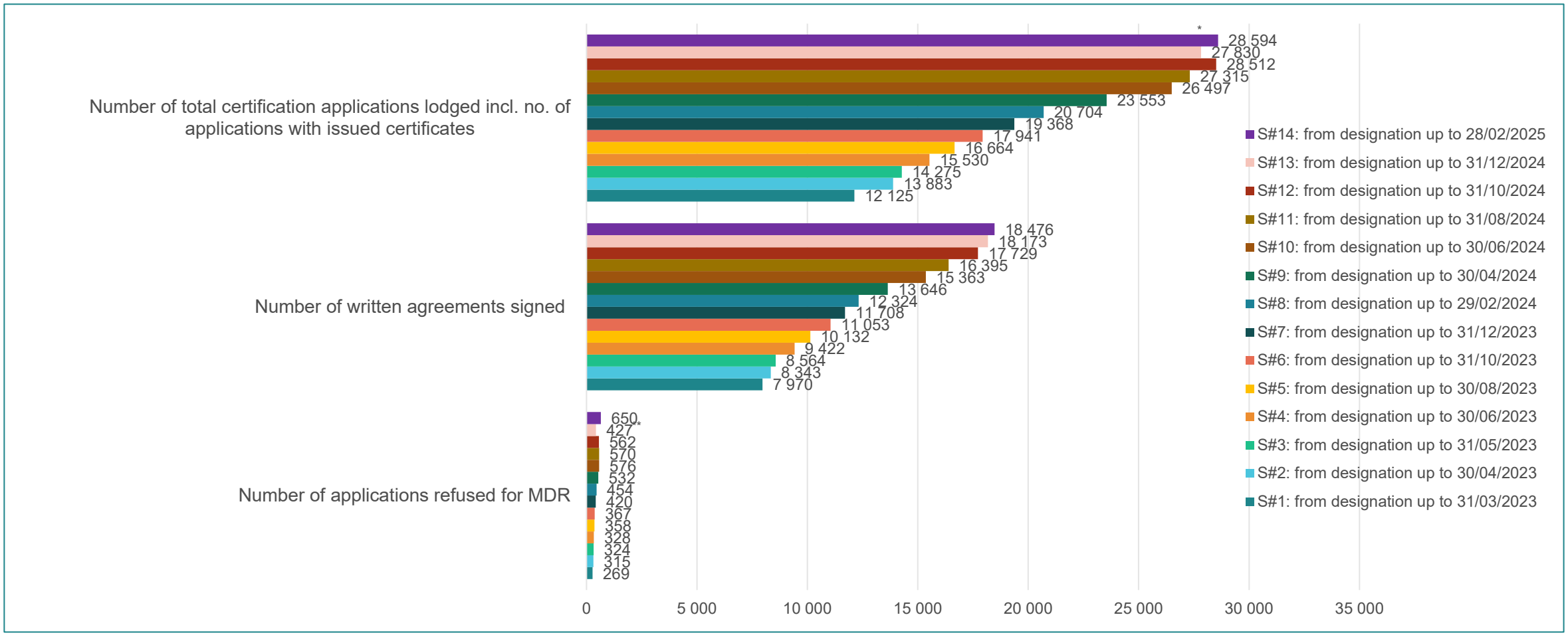
MD

Survey comparison – March 2023 to March 2025



Notes:

- S = Survey; # = number
- Survey **#14:** 50 designated NBs for MD
- Surveys **#2** and **#3** did not reach 100% response rate (#2: ~70%; #3: 56%). In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.
- Change in methodology of counting by a few NBs compared to previous surveys in survey #12 and #13.

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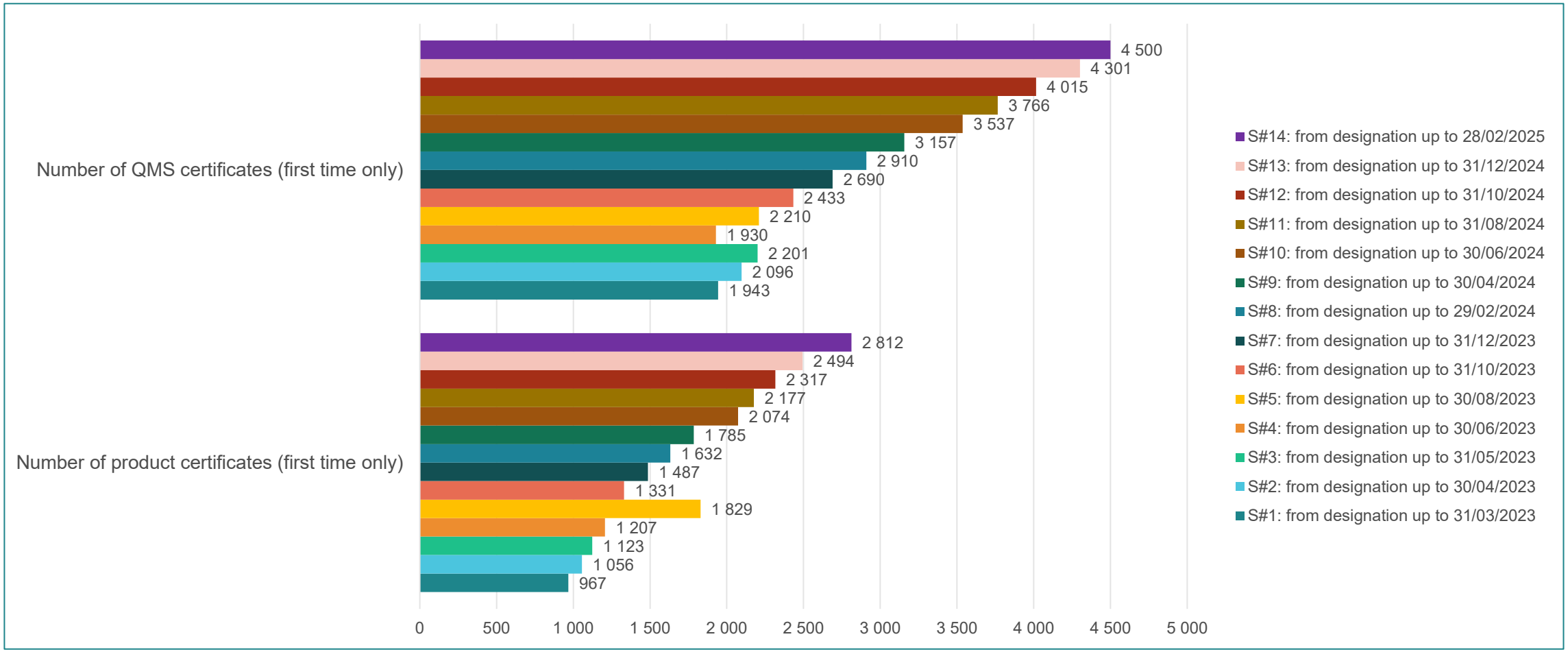
MD

Survey comparison – March 2023 to March 2025



S = Survey; # = number

Notes:

- Survey **#14:** 50 designated NBs for MD
- Surveys **#2** and **#3** did not reach 100% response rate (#2: ~70%; #3: 56%). In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.
- Increase 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 a few NBs compared to previous surveys in survey #4, #5 and #13.

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MD

Medium dataset Ⓜ

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.

MDR applications filed and certificates issued (sum of Annexes)

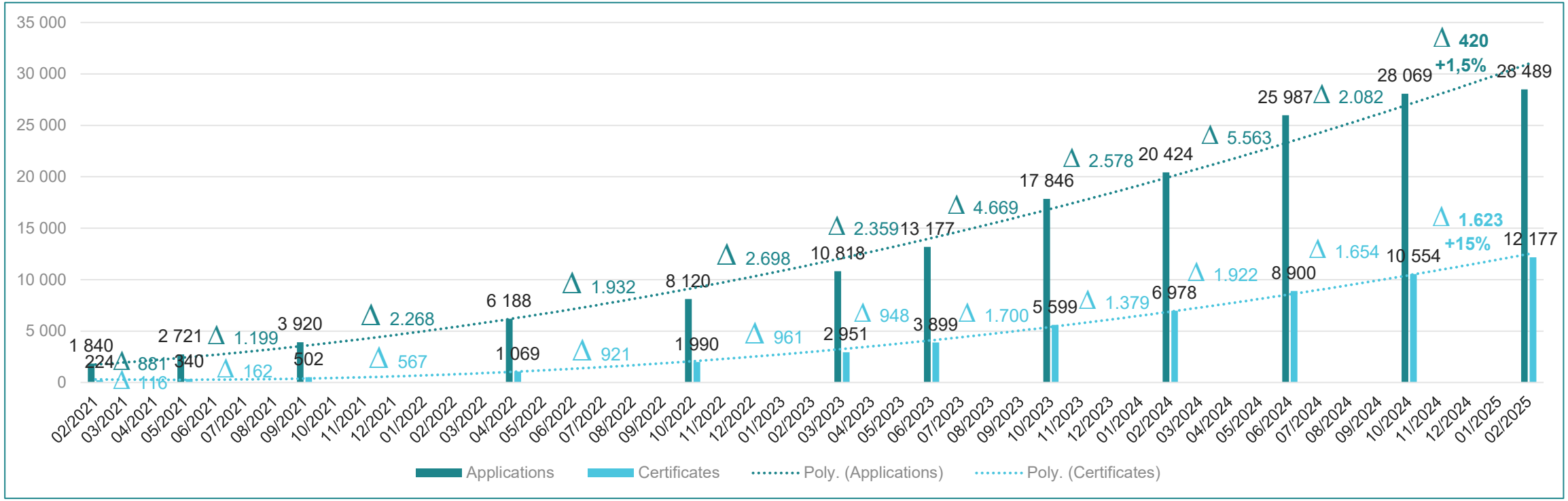
MD

Ⓜ

February 2025

MDR Applications:
Total number of applications filed by Annex Ⓜ: 28.489*

MDR Certificates:
Total number of certificates by Annex Ⓜ: 12.177



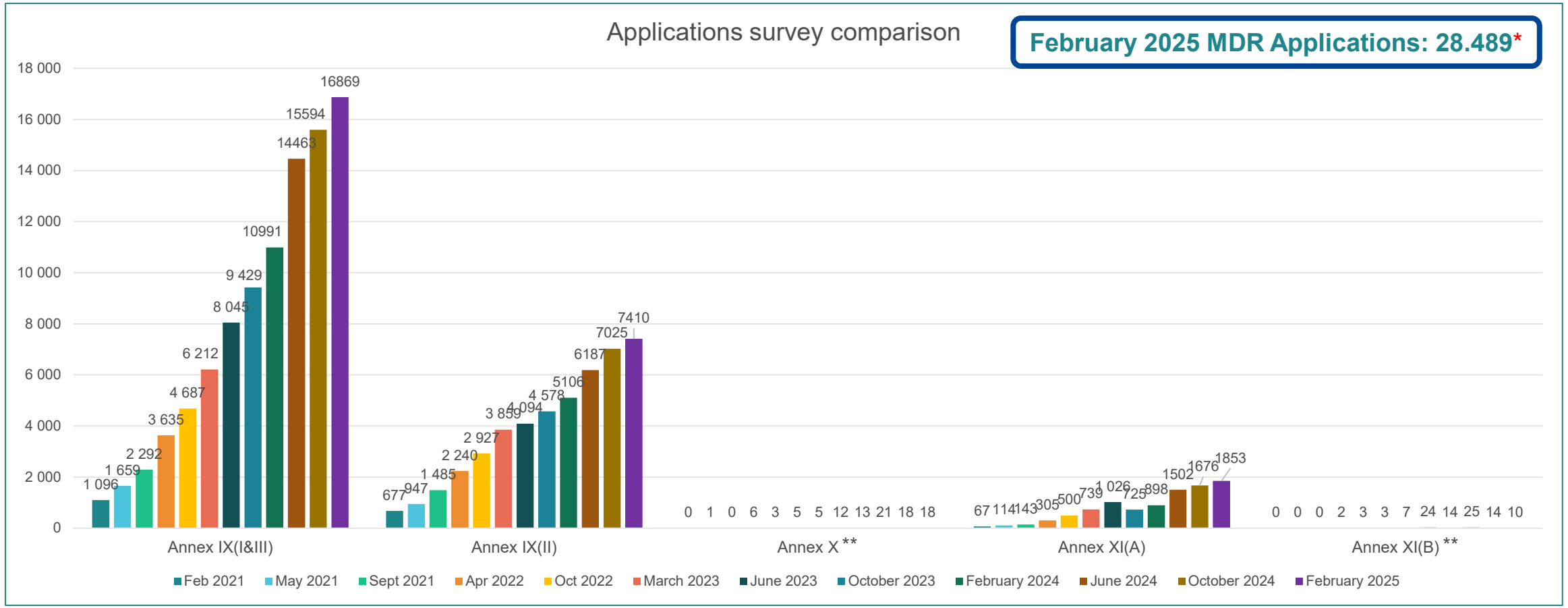
Notes: Designated NBs for MD: 50

* The data shown comes from the medium data set Ⓜ – except for 3 NBs where the total number of applications filed was derived from the small data set Ⓢ, as they are not able to provide complete 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 28/02/2025), 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 28/02/2025) under the MDR.
- The dotted line shows the polynomial trend line (grade 2).

MDR applications by annex – survey comparison

MD



Notes:

- Designated NBs for MD: 50; NBs that included Annex XVI products in the numbers provided: 27
- * The data shown comes from the medium data set Ⓜ – except for 3 NBs where the total number of applications filed was derived from the small data set Ⓢ, as they are not able to provide complete data per Annex.
- ** 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 28/02/2025), 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.

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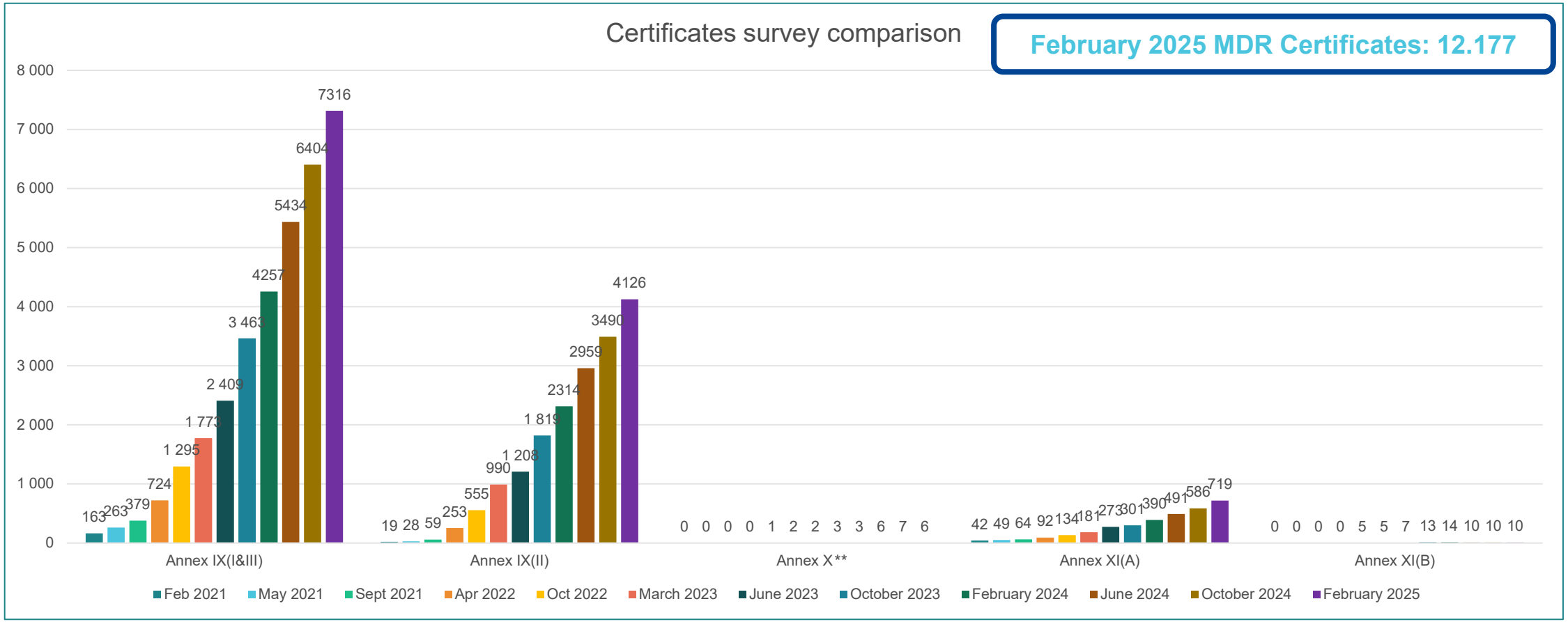
MDR certificates by annex - survey comparison



Notes:

- Designated NBs for MD: 50; NBs that included Annex XVI products in the numbers provided: 27
- * The data shown comes from the medium data set
- ** Change in methodology of counting by one NB. leading to a decrease
- **Certificates issued by annex:** This number includes **certificates issued so far** (from designation up to 28/02/2025) under the MDR **by annex**.

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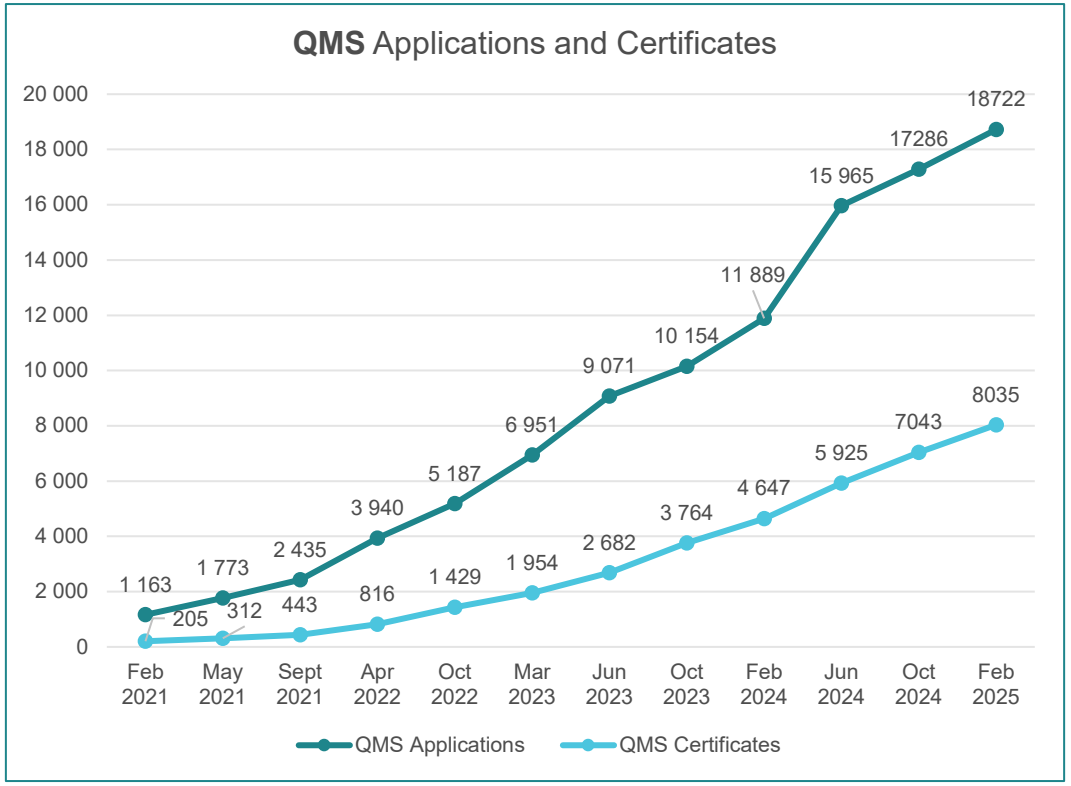
MDR applications and certificates by type (QMS vs Product) – survey comparison

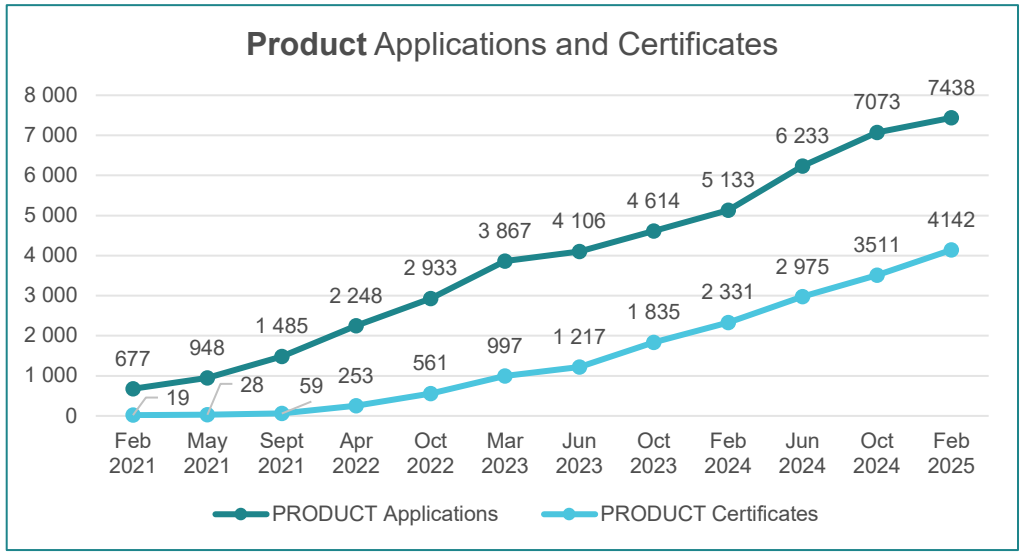
MD

February 2025
MDR Applications: 28.489*
MDR Certificates: 12.177

* The data shown comes from the medium data set (applications and certificates by Annex: 3 NBs could not provide the complete 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: 5.107
Note: This number is included in the total number of applications.

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Specific additional procedures according to Annex IX (II)

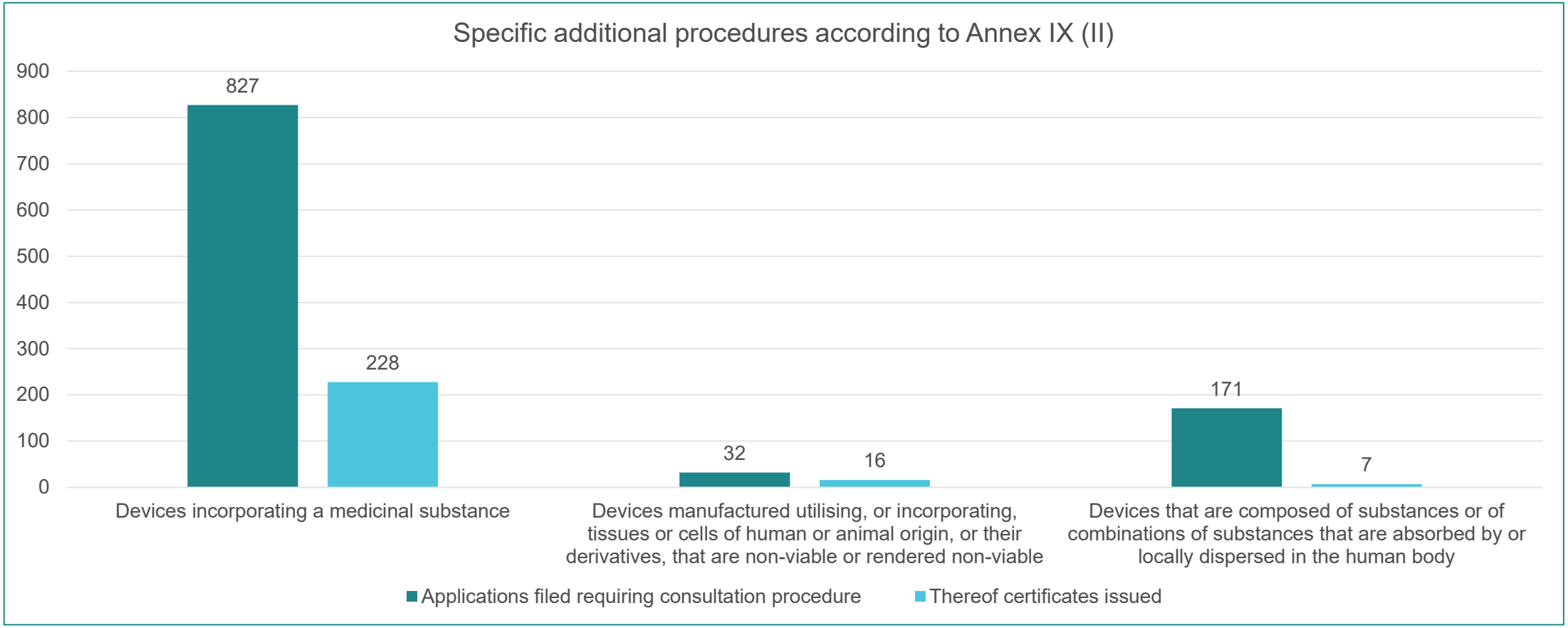
MD

Ⓜ

February 2025

MDR Applications:
Total number of applications filed by Annex Ⓜ: 28.489*

MDR Certificates:
Total number of certificates by Annex Ⓜ: 12.177



Notes:
* The data shown comes from the medium data set Ⓜ – except for 3 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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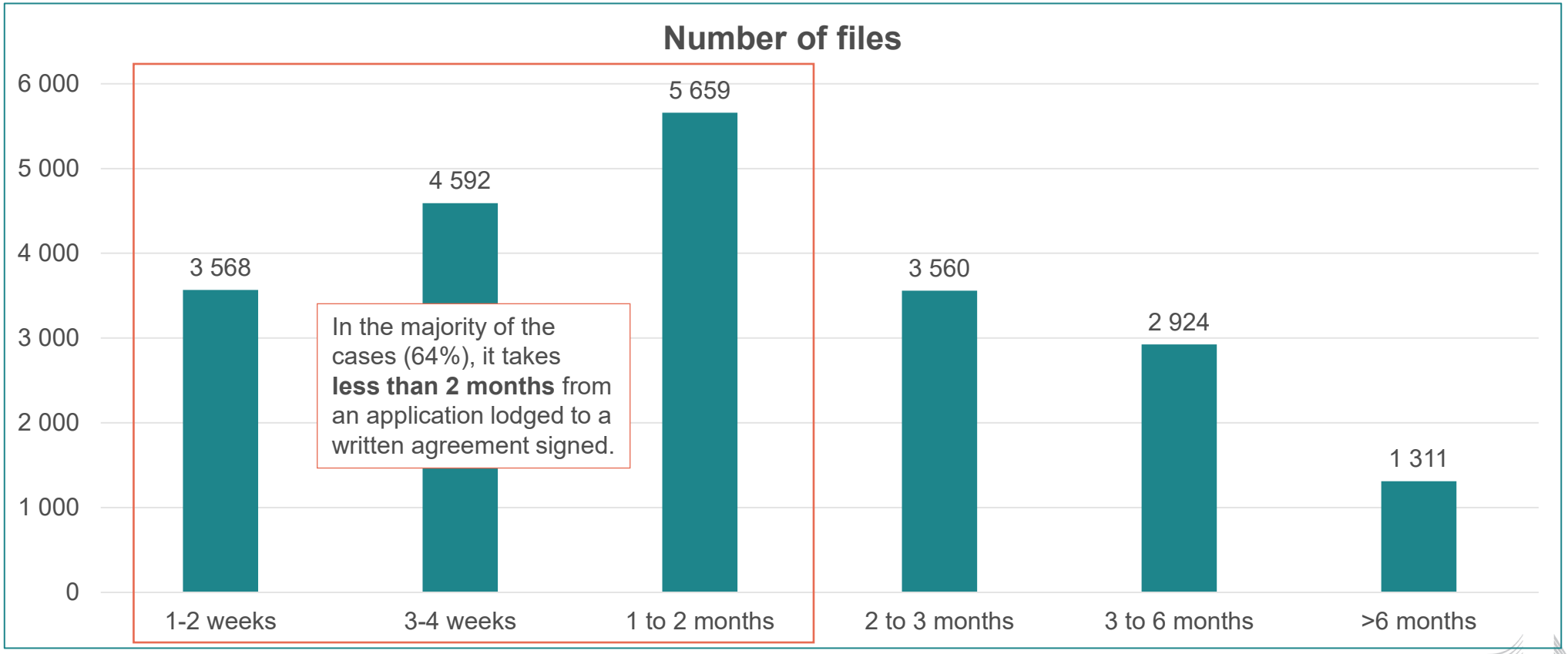
Average timeframe to written agreement signed

MD

Average timeframe between application lodged and written agreement signed:



Note: Data of 50 notified bodies designated under MDR

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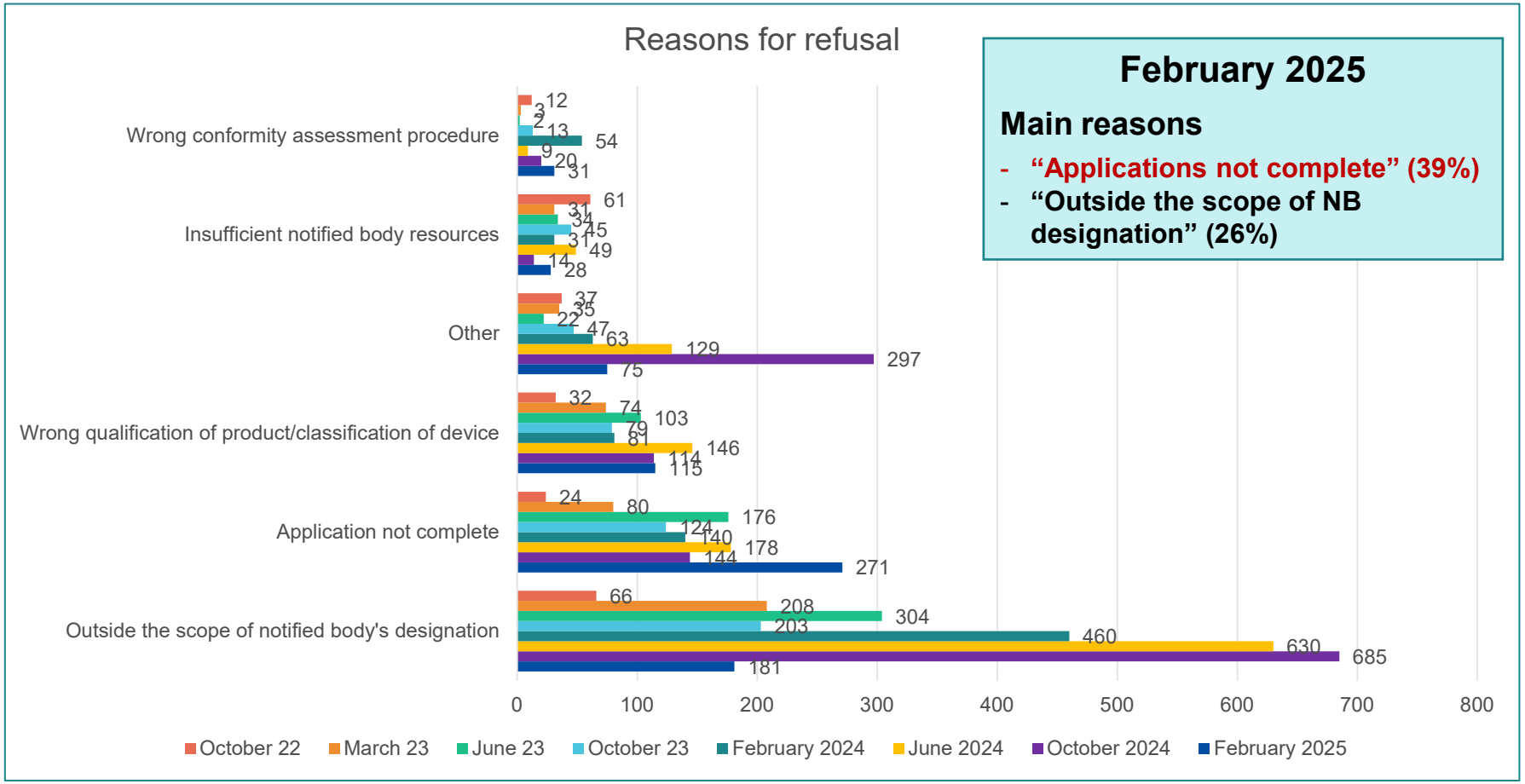
MDR applications - reasons for refusal



February 2025

Main reasons

- **"Applications not complete" (39%)**
- **"Outside the scope of NB designation" (26%)**

Total number of MDR applications:

October 2022: 8120
March 2023: 11.418
June 2023: 13.177
October 2023: 17.846*
February 2024: 20.424*
June 2024: 26.185*
October 2024: 28.069*
February 2025: 28.489*

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

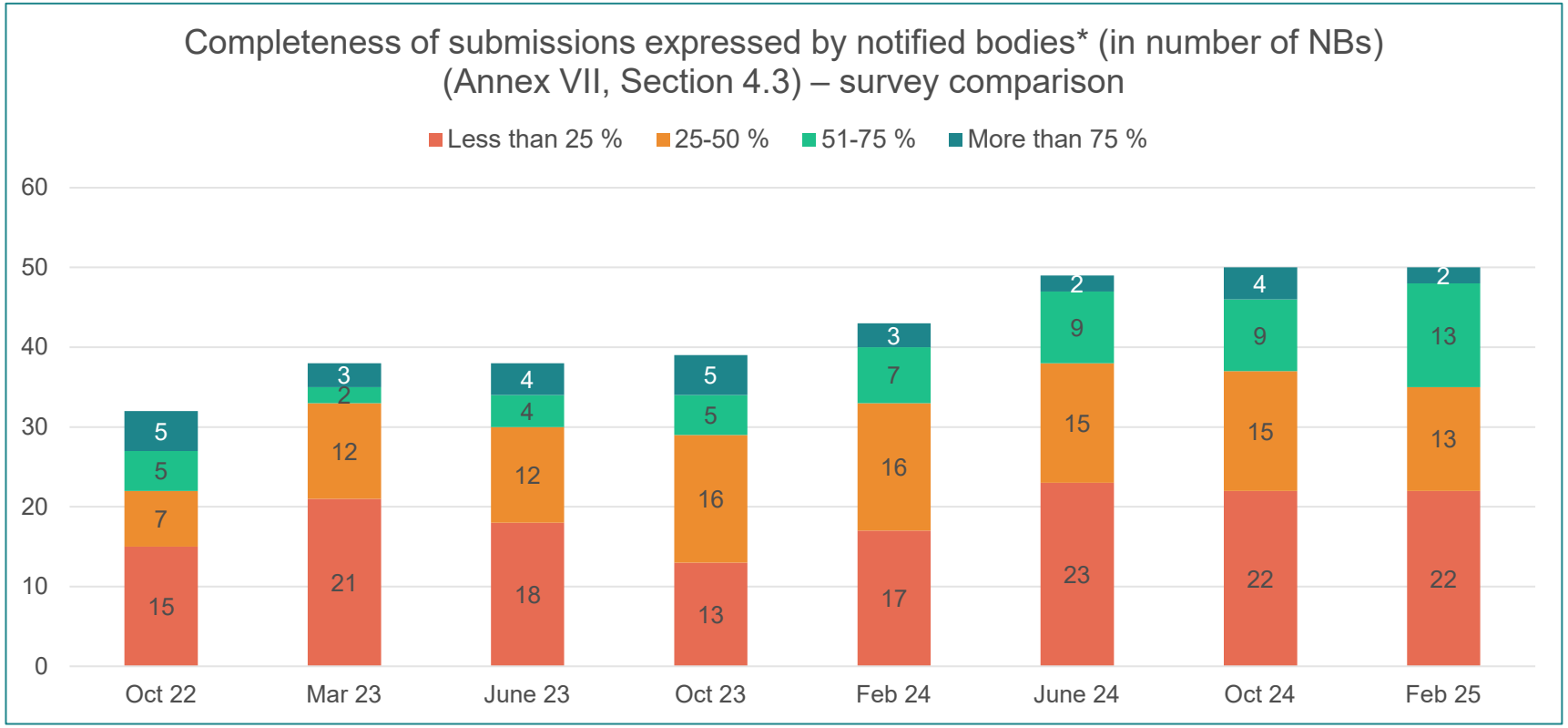
Number of application refusals:**

October 2022: 232
March 2023: 269
June 2023: 328
October 2023: 367
February 2024: 454
June 2024: 620
October 2024: 562
February 2025: 650

Notes:

- Comparison of reasons for refusal in October 2022, March 2023, June 2023, October 2023, February 2024, June 2024, October 2024 and February 2025.
- ** 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 indicated on the graph on this slide.
- February 2025: data of 28 NBs; some stated "other" reasons in February 2025: "withdrawal by the customer", "concerns about violation of Article 7 and/or prejudice; "wrong qualification/classification", "client stopped communication", "Unresolved non-conformities.

Completeness of submissions



*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

Number of notified bodies which report that > 50% of submissions are considered complete:

15 out of 50 NBs designated under MDR in February 2025

Incomplete submissions remain high*

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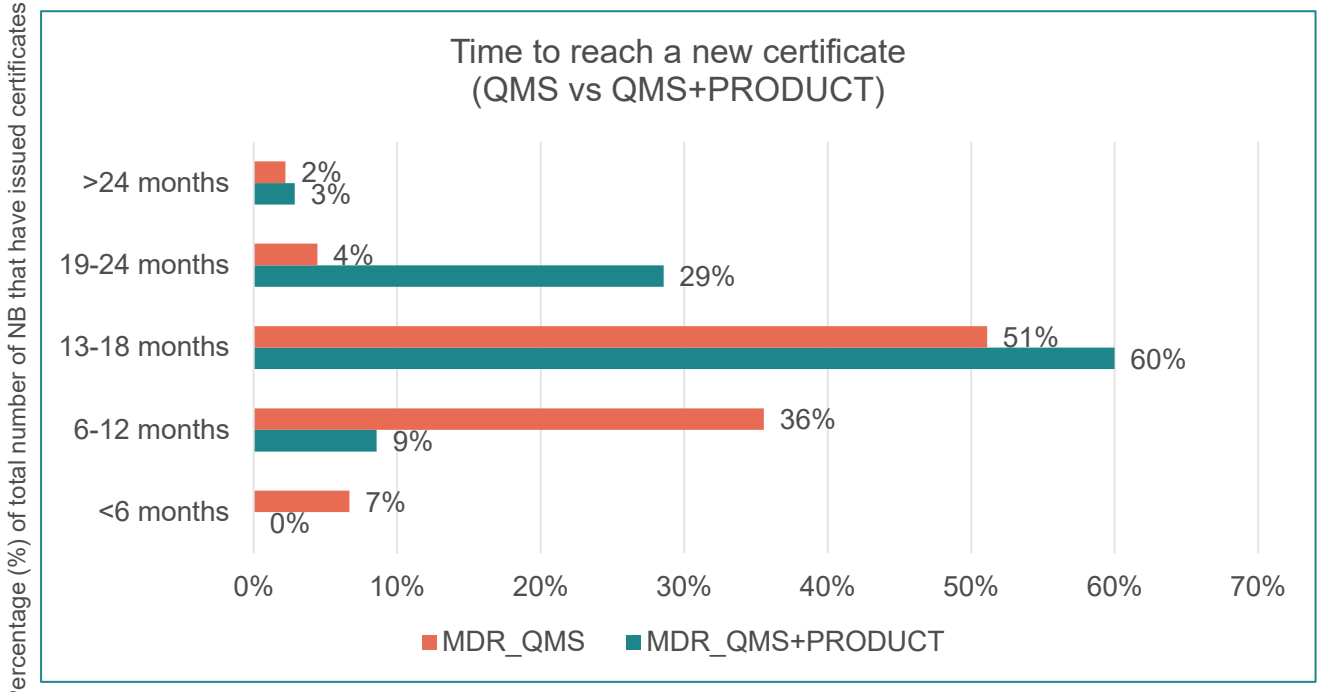
Time to reach a new certificate (QMS vs QMS+PRODUCT)

MD

February 2025
MDR Applications: 28.489*
MDR Certificates: 12.177

* The total number comes from the medium data set Ⓜ – except for 3 NBs where the total number of applications filed was derived from the small data set Ⓢ, as they are not able to provide complete data per Annex



Notes:
QMS+PRODUCT: Data of 35 NBs designated under MDR
QMS: Data of 45 NBs designated under MDR

MDR QMS certificates

- 51% of NBs: 13-18 months to issue a new QMS certificate
- 36% of NBs: 6-12 months

MDR QMS+PRODUCT certificates: longer time

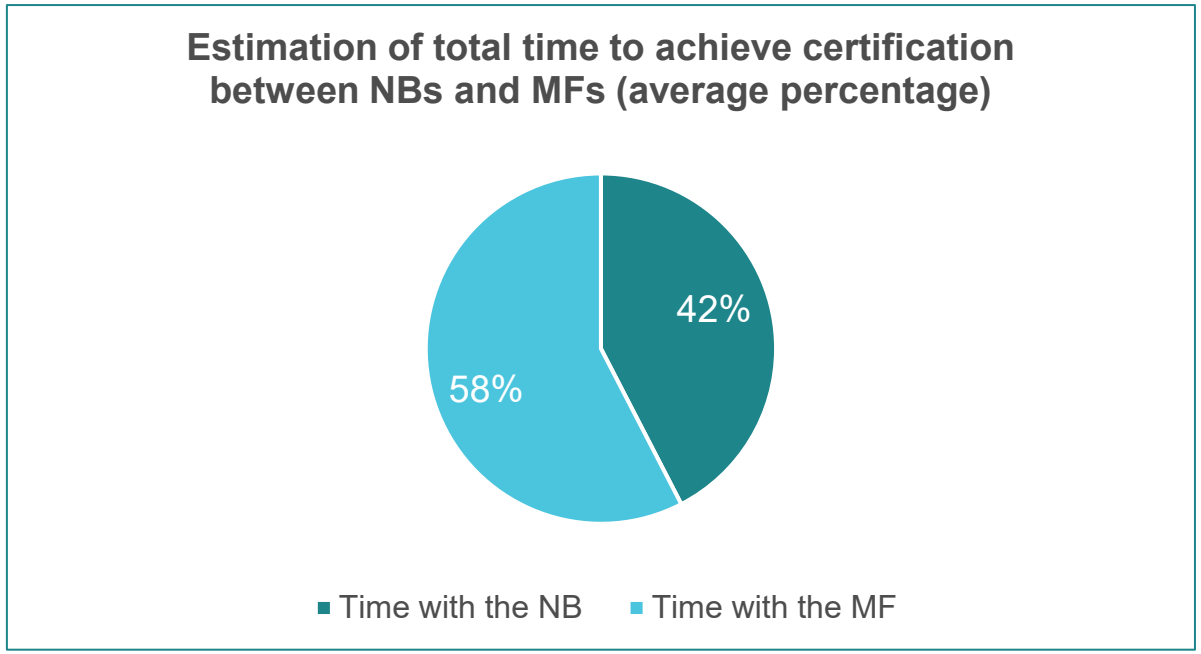
- 60% of NBs: 13-18 months
- 29% of NBs: 19-24 months

- This indicator shows the time to reach issuance of a new EC certificate (from written agreement signed to issuance) under MDR.

European Commission

Estimation of the total time* to achieve certification between NB and MF

* from written agreement signed to issuance of a new certificate



More time with the manufacturer

- **26** out of 44 NBs (59%) indicated >50% of the time with the MF
- **8** out of 44 NBs (18%) indicated that the time is equally divided (50:50) between NB and MF
- **10** out of 44 NBs (23%) indicated >50% of the time with the NB

Time with the notified body

- Minimum value: 10%
- Maximum value: 70%

Time with the manufacturer

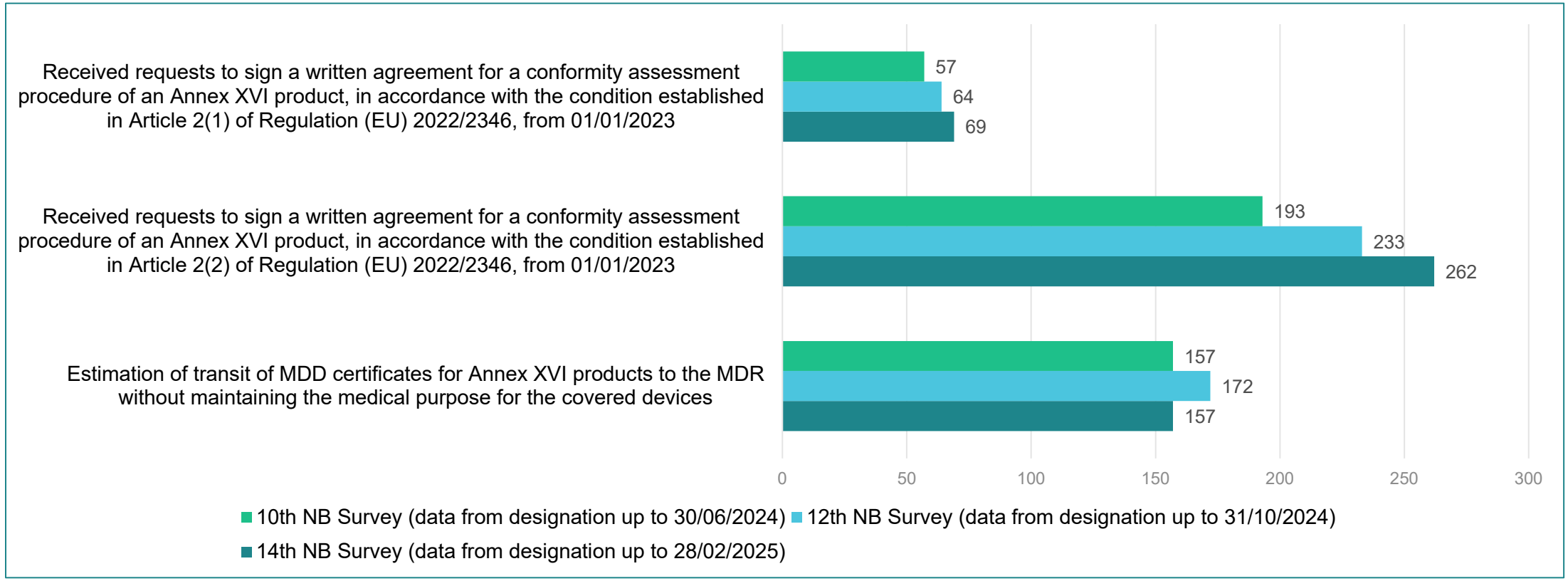
- Minimum value: 30%
- Maximum value: 90%

Notes:

- Data of 44 NBs
- This indicator shows an estimate of the allocation of the total time to certification (from signing the written agreement to issuance) between the notified body and the manufacturer.
- Time with the NB means time for checking the documents including application and technical documentation.
- Time with the MF means time for revising the documents including application and technical documentation.

Questions on Annex XVI products

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

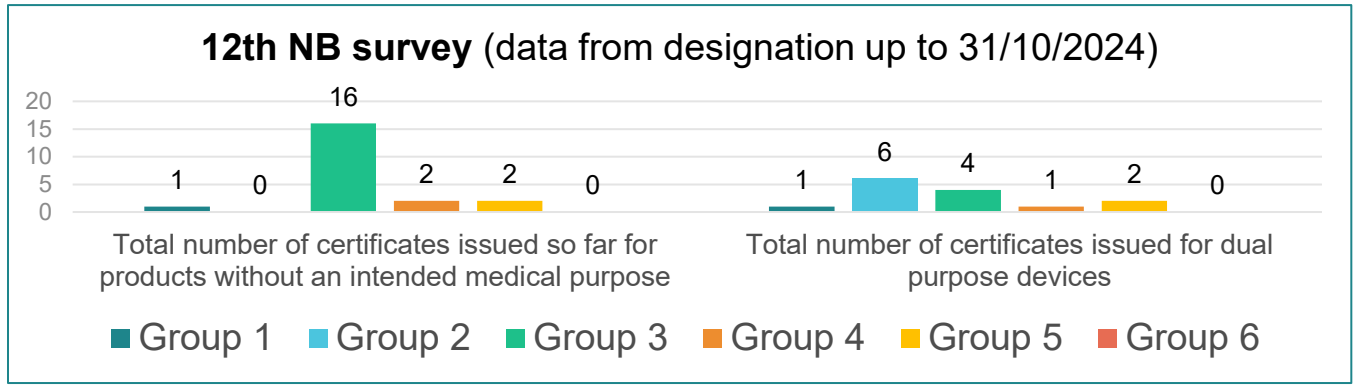


Notes:
10th NB survey: 24 out of 50 NBs entered "0" for all questions relating to Annex XVI products
12th NB survey: 23 out of 50 NBs entered "0" for all questions relating to Annex XVI products.
14th NB survey: 24 out of 50 NBs entered "0" for all questions relating to Annex XVI products.

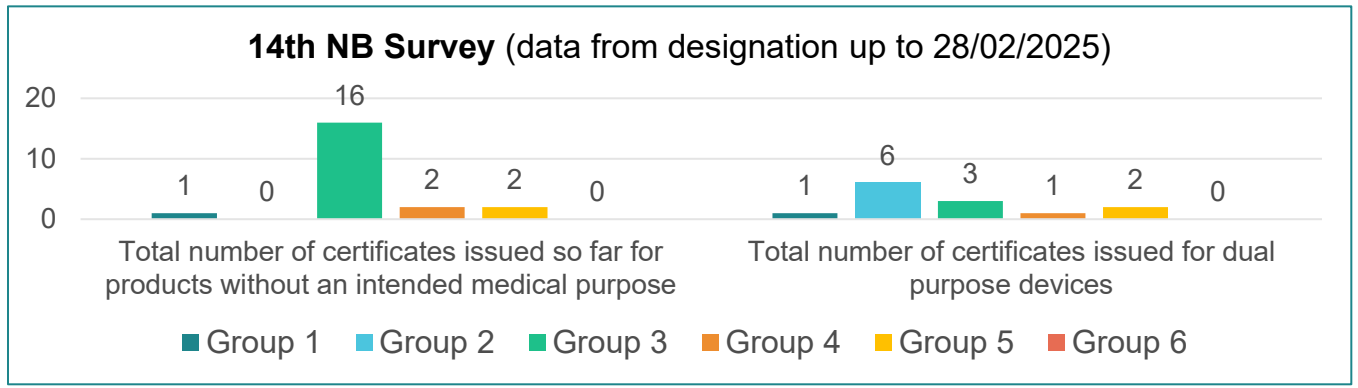
Certificates issued for products without an intended medical purpose* and for dual purpose devices**

MD

* Products **without an intended medical purpose** that are listed in Annex XVI to the MDR are covered by that Regulation from 22 June 2023, which is the date of application of Annex XVI common specifications set out in Commission Implementing Regulation (EU) 2022/2346.
** **Dual purpose devices**: products having both a medical and a non-medical intended purpose



Notes: Data of 6 NBs; 44 out of 50 NBs entered "0" for all groups



Notes: Data of 9 NBs; 41 out of 50 NBs entered "0" for all groups

LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE REFERRED TO IN ARTICLE 1(2) MDR

1. Contact lenses or other items intended to be introduced into or onto the eye.
2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
3. Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.
4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
5. High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.
6. Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

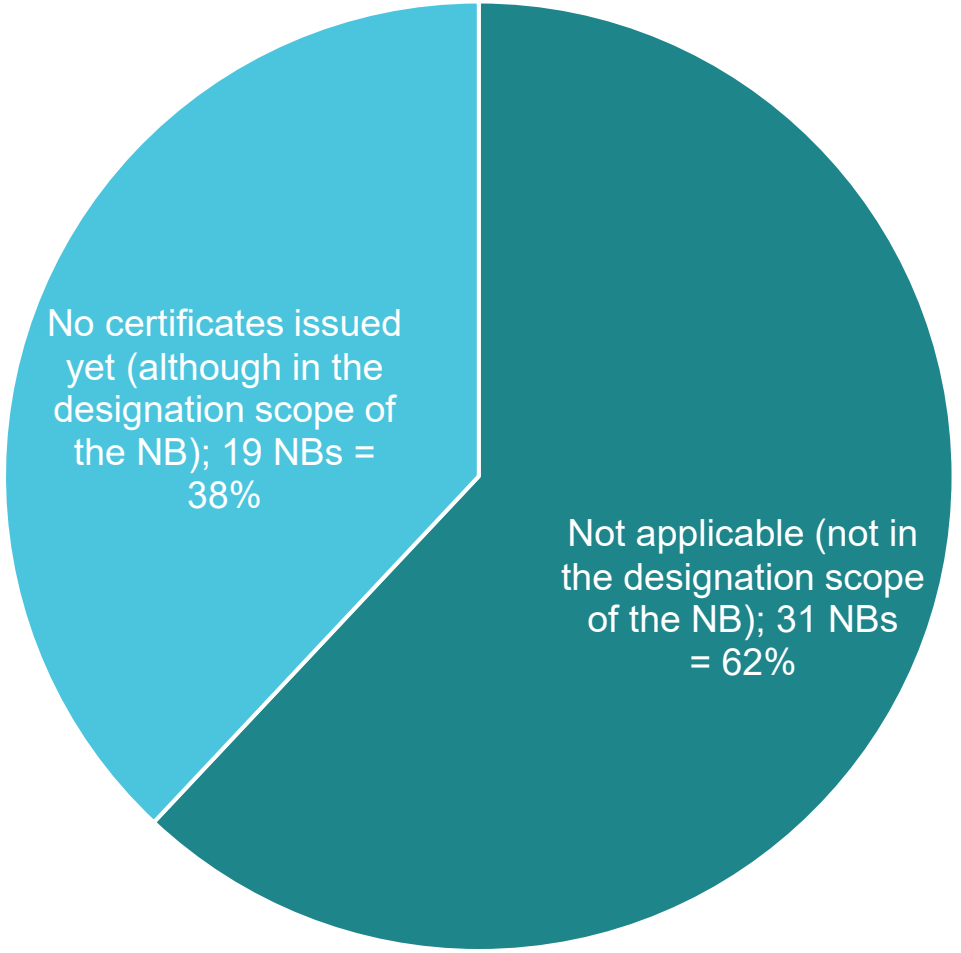
European Commission

Single-use devices and their reprocessing (Article 17 MDR)

MD

No certificate was issued so far for reprocessing of single-use devices

Note: No information available on applications lodged.



Data of 50 NBs designated under MDR

European Commission

Article 117 MDR opinions* - requests received and opinions issued

Notes 12th NB survey:

- Total number of requests for Article 117 MDR opinions for initial market authorization submissions received: data of 20 NBs
- Total number of requests for Article 117 MDR opinions for changes received: data of 5 NBs

Notes 14th NB survey:

- Total number of requests for Article 117 MDR opinions for initial market authorization submissions received: data of 21 NBs
- Total number of requests for Article 117 MDR opinions for changes received: data of 5 NBs

*** Article 117 MDR:** *Where, in accordance with the second subparagraph of Article 1(8) or the second subparagraph of Article 1(9) of Regulation (EU) 2017/745 of the European Parliament and of the Council, a product is governed by this Directive, the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.*
***If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device**, if used separately, **the involvement of a notified body is required** in accordance with Regulation (EU) 2017/745, the authority shall require the applicant to provide an **opinion on the conformity of the device part with the relevant general safety and performance requirements** set out in Annex I to that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question.*

**Change in methodology of counting by one NB

IVD

3. Survey results for in vitro diagnostic medical devices

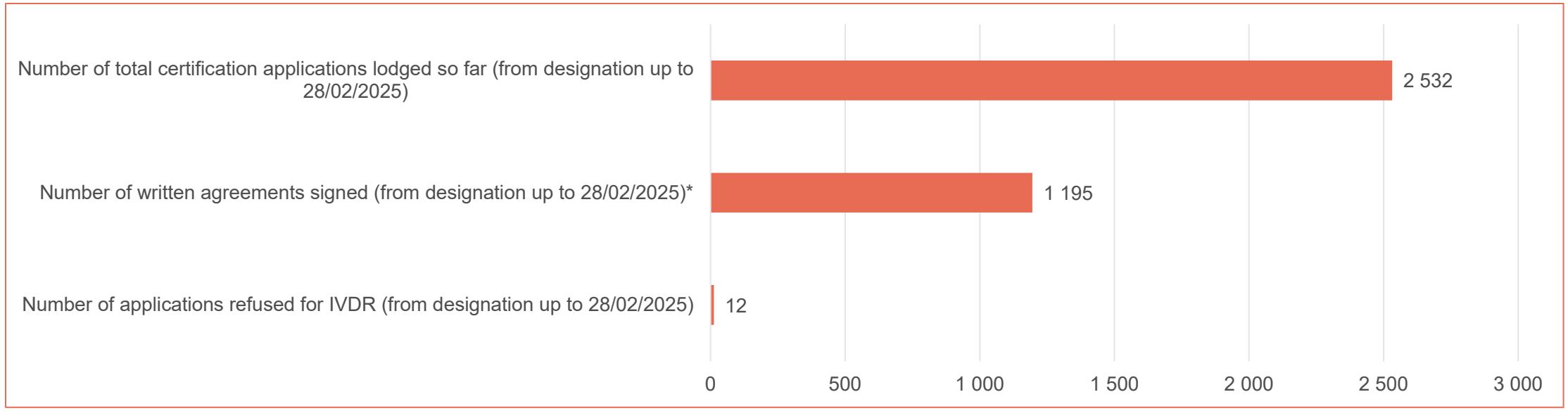
Note:

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

  Ⓢ The **small dataset** is a small set of questions 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**.

IVDR applications filed and refused, written agreements signed

IVD



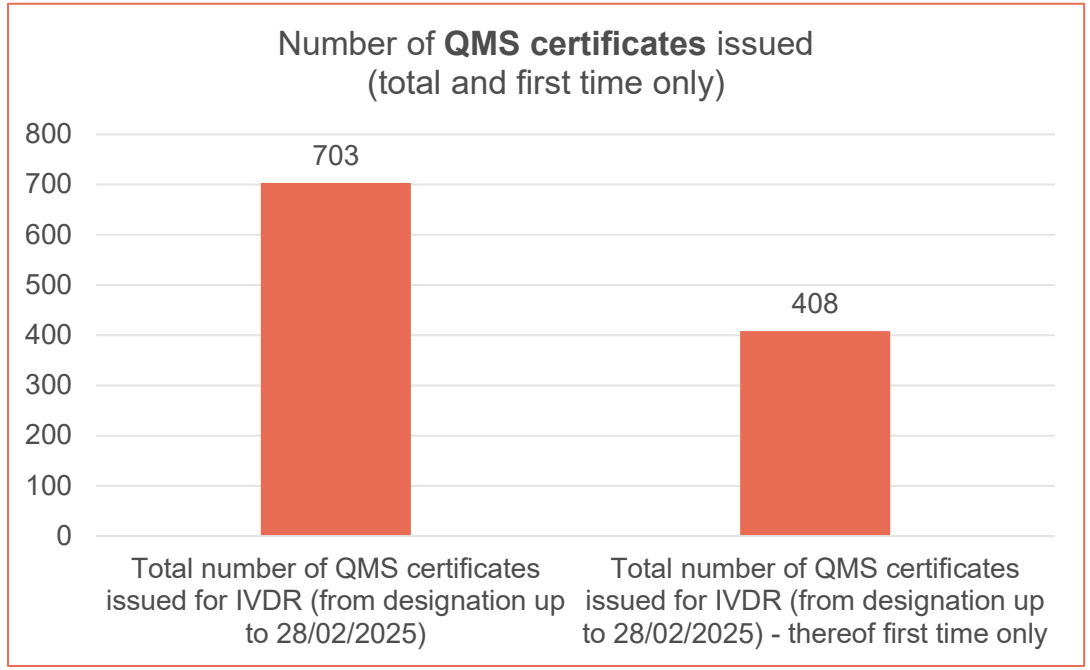
Notes:

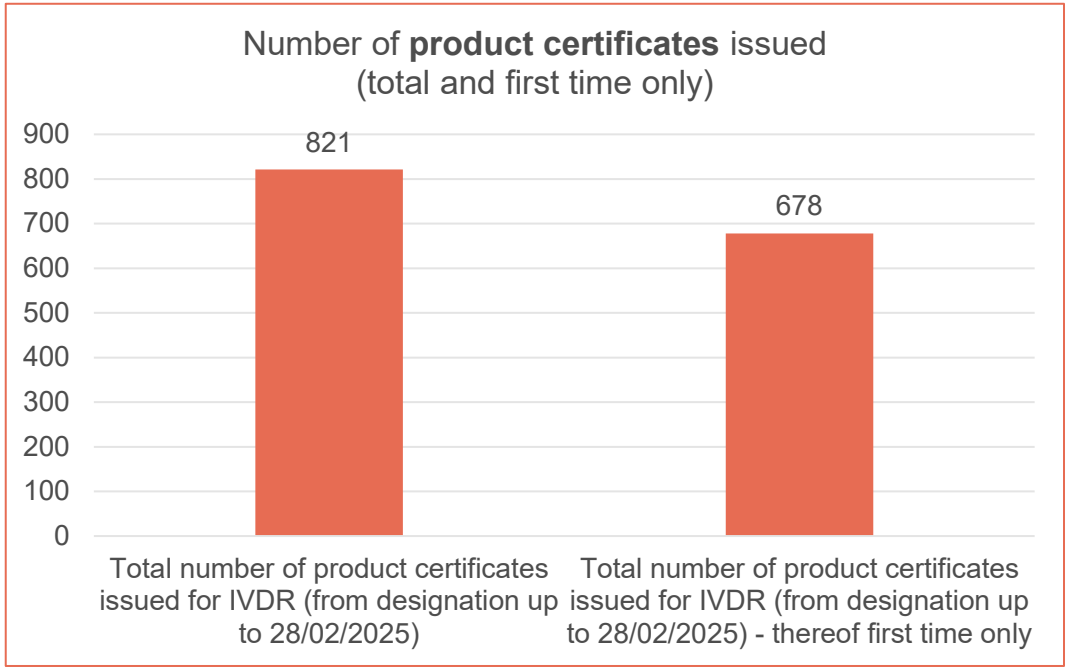
- **Designated NBs for IVD:** 14
- **Applications lodged**: This number includes **all applications lodged (syn. filed) so far** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 28/02/2025), 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.

European Commission

IVDR Number of QMS / product certificates issued

IVD





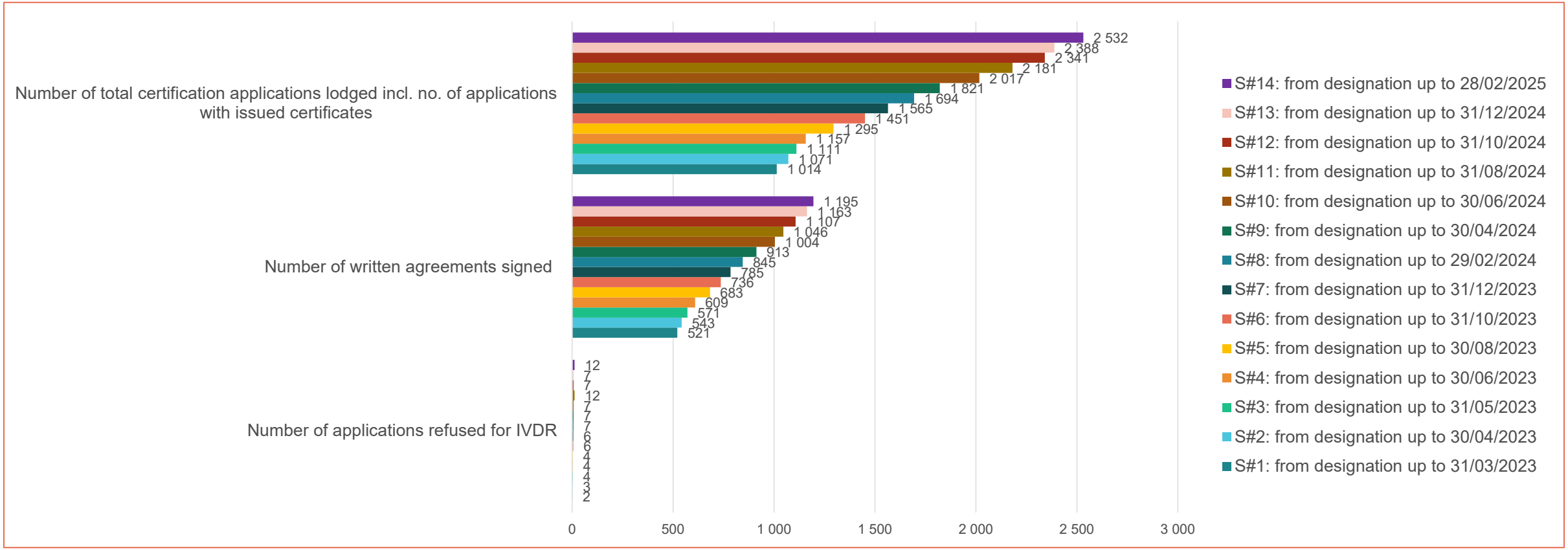
Note QMS Certificates: This relates to Annex IX Chapter I or Annex XI according to IVDR.

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

European Commission

IVD

Survey comparison – March 2023 to March 2025



S = Survey; # = number

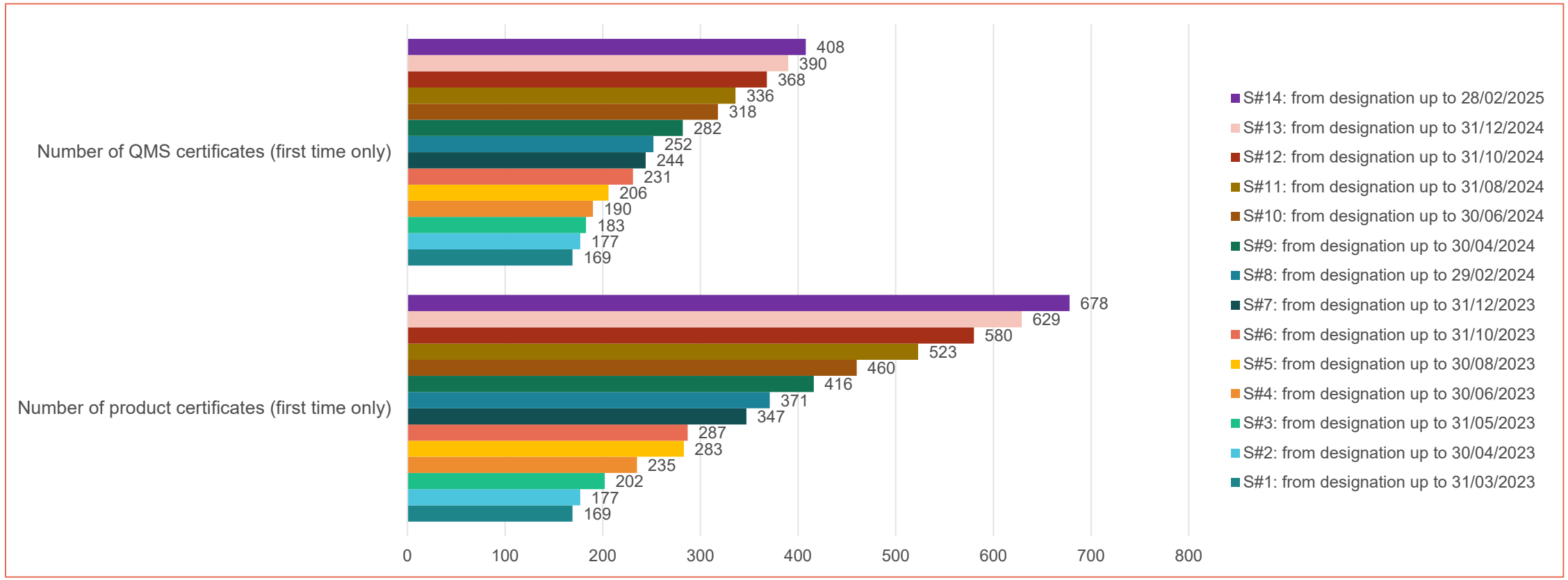
Notes:

- Designated NBs for IVDs: S#1 to S#5: 10; S#6 to S#11: 12; S#12 to S#13: 13; S#14: 14
- Surveys **#2** and **#3** did not reach 100% response rate (S#2: ~70%; S#3: 56%). In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.

European Commission

IVD

Survey comparison – March 2023 to March 2025



S = Survey; # = number

Notes:

- Designated NBs for IVDs: S#1 to S#5: 10; S#6 to S#11: 12; S#12 to S#13: 13; S#14: 14
- Surveys **#2** and **#3** did not reach 100% response rate (S#2: ~70%; S#3: 56%). In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.

European Commission

IVD

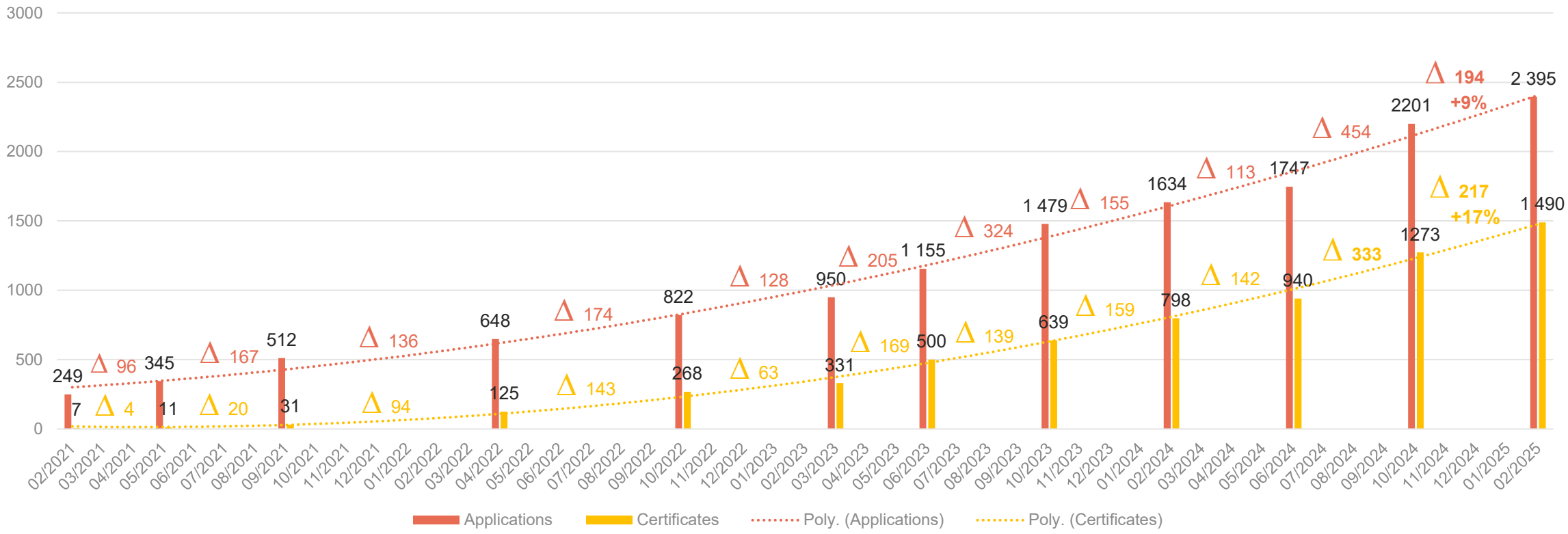
Medium dataset Ⓜ

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.

IVDR applications lodged and certificates issued

February 2025
IVDR Applications: 2.395
IVDR Certificates: 1.490

IVD



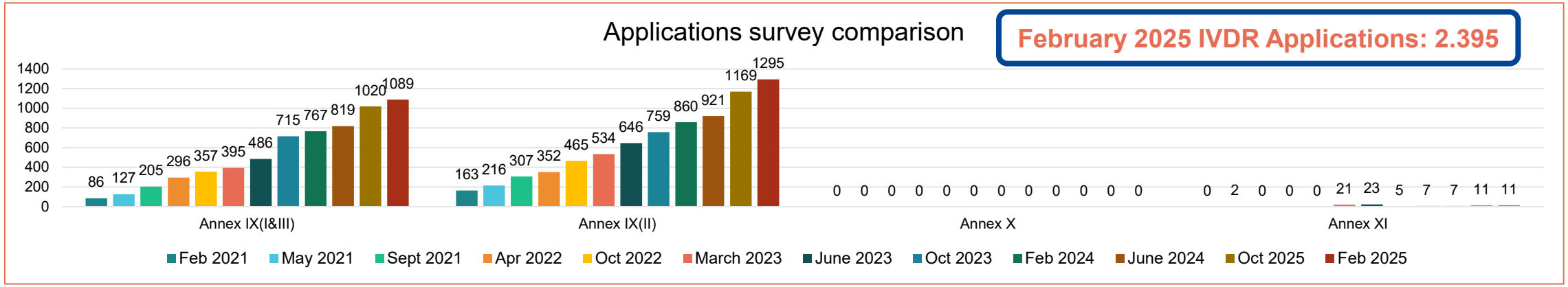
Notes: Designated NBs for IVDR in February 2025: 14

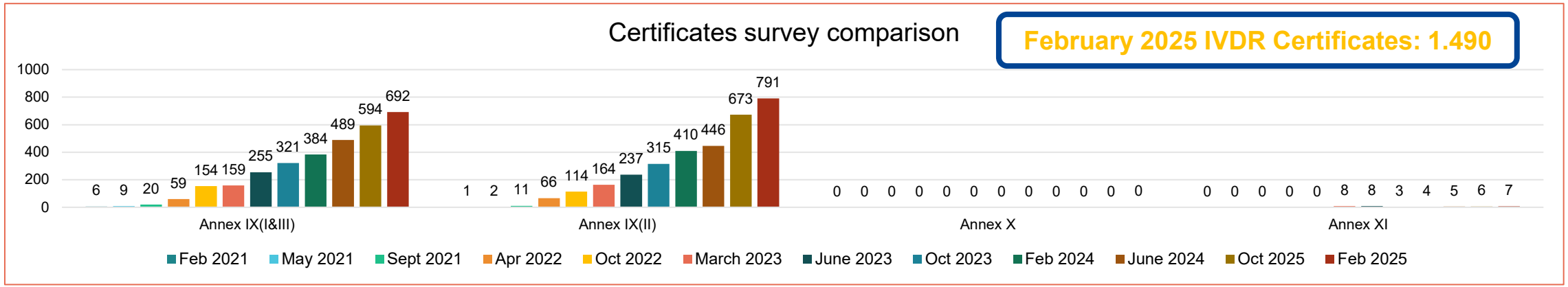
- Δ (Delta) = Difference in IVDR Applications / IVDR Certificates from one survey to the next one
- **Applications lodged**: This number includes **all applications lodged (syn. filed) so far** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 28/02/2025), 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 28/02/2025) under the IVDR.
- The dotted line shows the polynomial trend line (grade 2).

European Commission

IVDR applications and certificates by annex – surveys comparison

IVD





Notes:

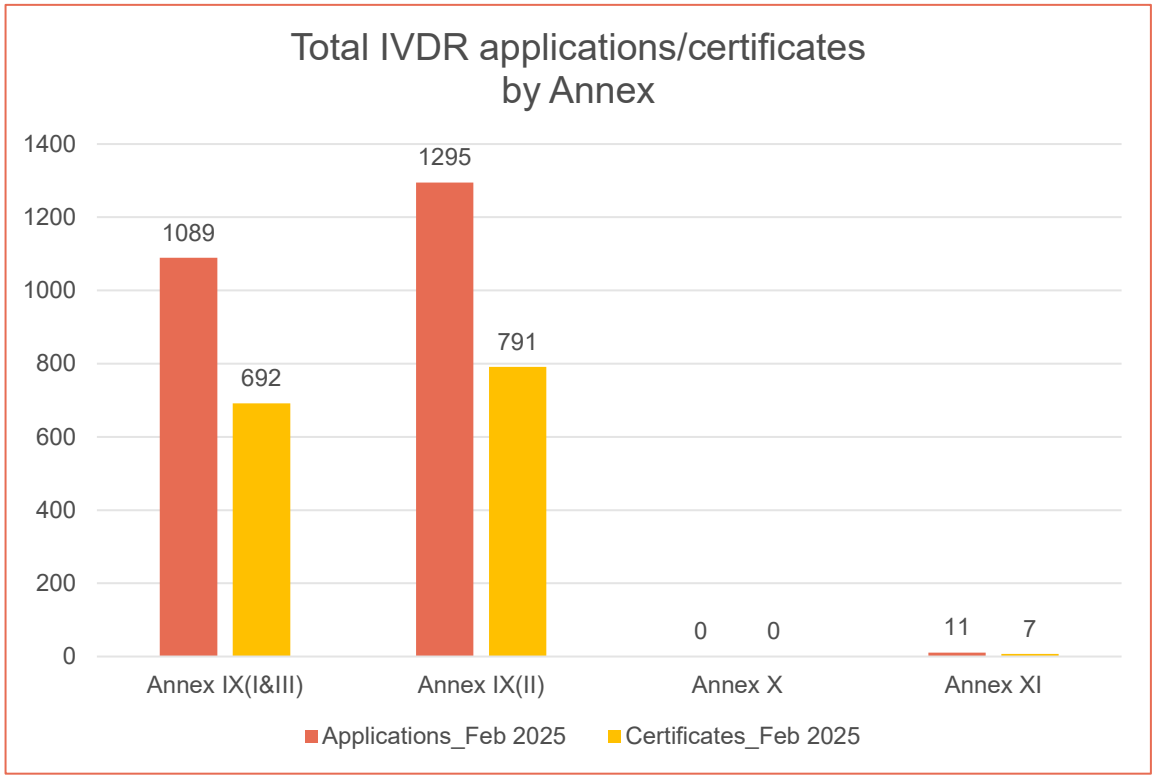
- **Applications lodged by annex**: This number includes **all applications lodged (syn. filed) by annex** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 28/02/2025), 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 28/02/2025) under the IVDR **by annex**.

European Commission

IVDR applications and certificates by annex

IVD

February 2025
IVDR Applications: 2.395
IVDR Certificates: 1.490



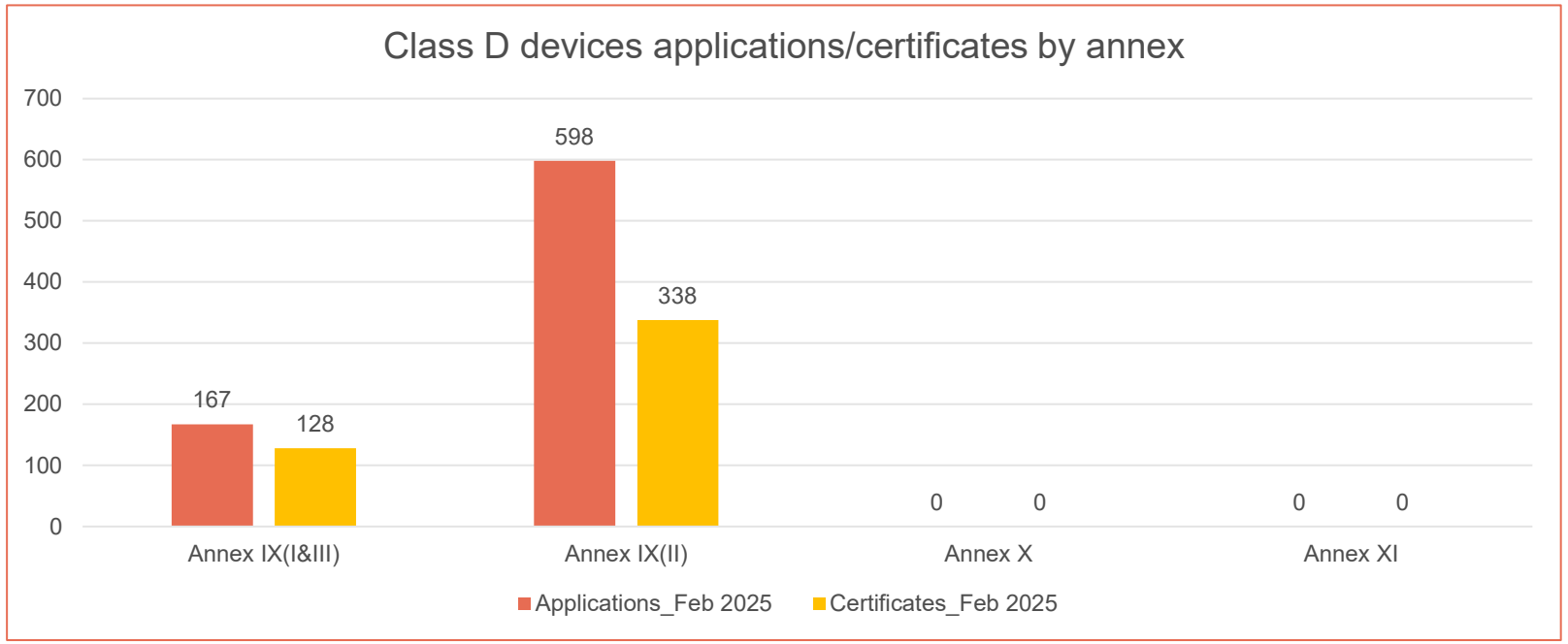
Notes:

- **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 28/02/2025), 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 28/02/2025) under the IVDR by annex.
- **Class D devices** are **included** in the total number of applications/certificates.

European Commission

Class D devices applications and certificates

IVD



February 2025
IVDR Applications: 2.395
IVDR Certificates: 1.490

February 2025:
Total number of Class D devices **Applications**: 765
Total number of Class D devices **Certificates**: 466

Notes:

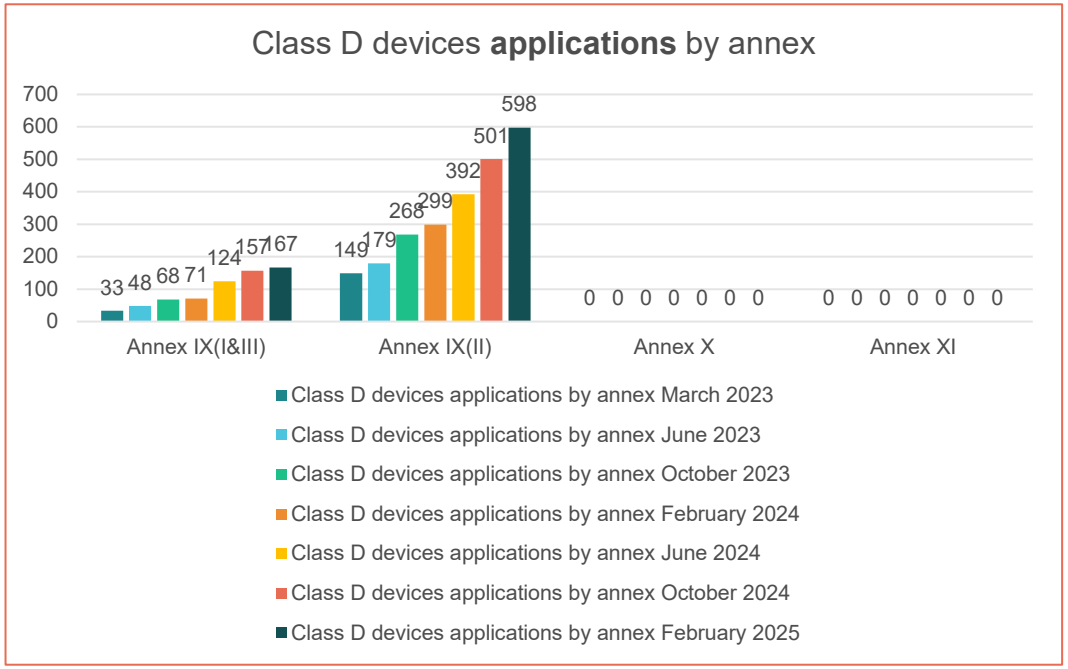
- **Applications lodged by annex:** This number includes all applications lodged (syn. filed) by annex according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 28/02/2025), 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 28/02/2025) 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

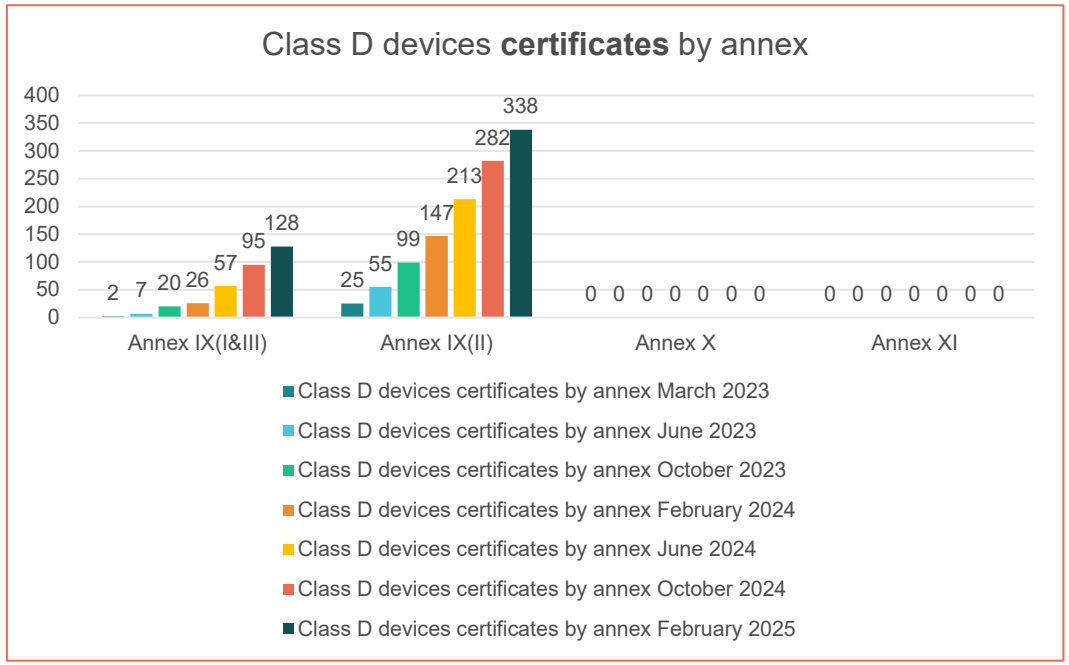
Class D IVDs applications and certificates development

IVD

February 2025:
Total number of Class D devices **Applications**: 765
Total number of Class D devices **Certificates**: 466



Note:
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 **28/02/2025**), 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.



Note:
Certificates issued by annex: This number includes certificates issued so far (from designation up to **28/02/2025**) under the IVDR by annex.

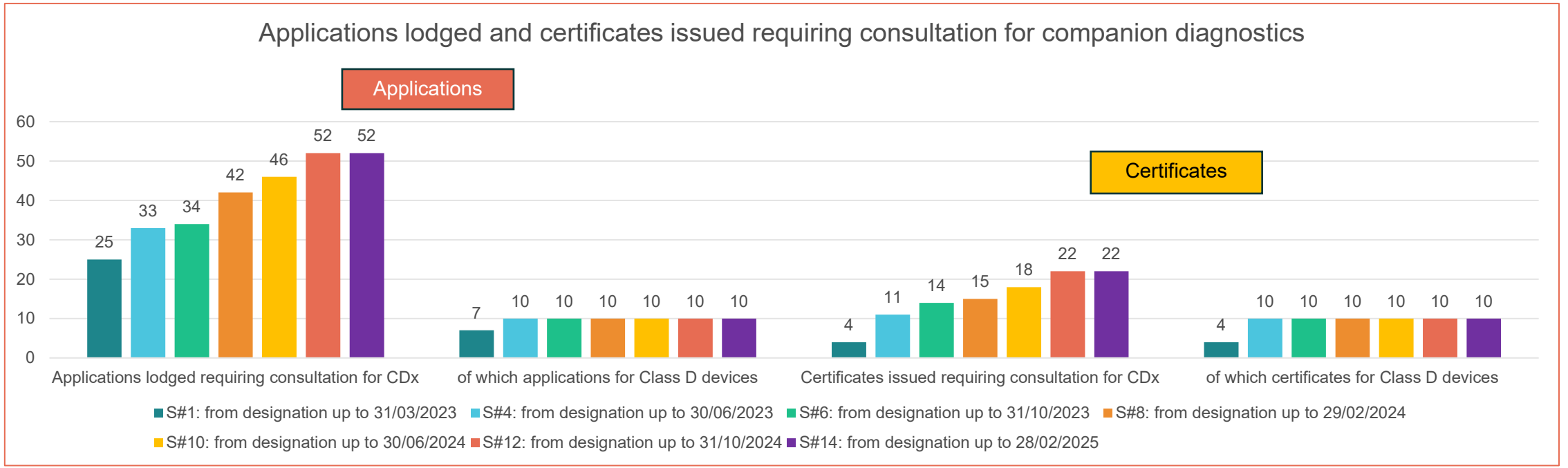
European Commission

Applications and certificates requiring consultation for companion diagnostics (CDx)*

IVD

February 2025:
Class D devices Applications: 765
Class D devices Certificates: 466

February 2025
IVDR Applications: 2.395
IVDR Certificates: 1.490



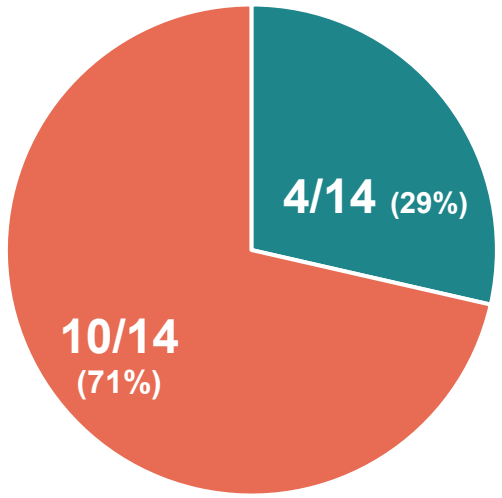
* According to Article 2 (7) IVDR, a companion diagnostic means a *device which is essential for the safe and effective use of a corresponding medicinal product to:*
(a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or
(b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product.

European Commission

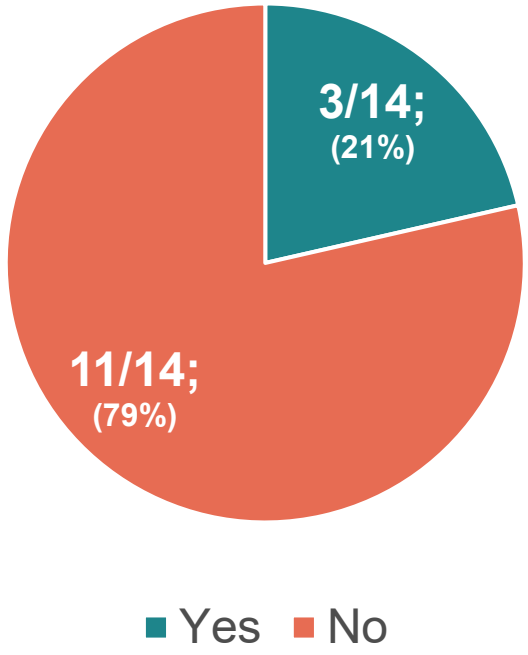
Collaboration with EU reference laboratories (EURLs) on Class D devices (1)

IVD

Number of NBs at which at least one **Class D application** has been lodged from 1 October 2024 within the scope of EURL oversight



Has a **Class D certificate** been issued within the scope of EURL oversight?



Data of 14 NBs designated under IVDR

European Commission

Collaboration with EU reference laboratories (EURLs) on Class D devices (2)

IVD

Class D applications

	Hepatitis and retrovirus	Respiratory viruses	Bacterial pathogens	Herpes virus	TOTAL
Total number of class D devices (covered by an **application lodged** [from 01/10/2024 up to 28/02/2025]) **that fall in the categories of currently designated EURLs**	10	14	0	0	**24**
Number of devices covered by a signed **master services agreement with an EURL for performance verification** (EURL task in IVDR Article 100(2)(a) [as of 28/02/2025]	9	14	0	0	**23**
Number of devices covered by a signed **statement of work with an EURL for performance verification** (EURL task in IVDR Article 100(2)(a)) [as of 28/02/2025]	0	0	0	0	**0**
Number of devices for which **performance verification by EURLs has been scheduled or completed** [as of 28/02/2025]	4	0	0	0	**4**

Data of 4 NBs designated under IVDR

Collaboration with EU reference laboratories (EURLs) on Class D devices (3)

IVD

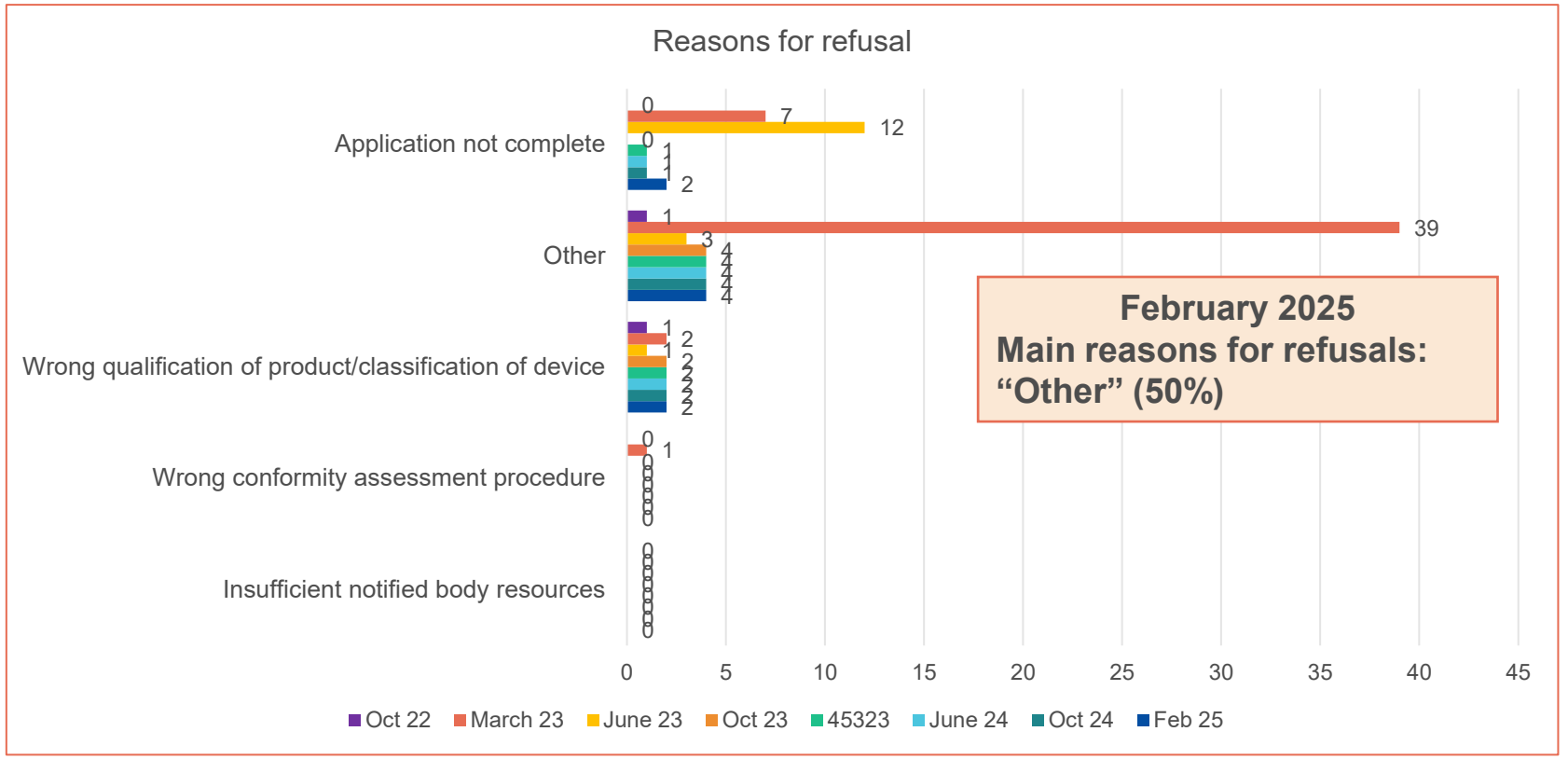
Ⓜ

Class D certificates

	Hepatitis and retrovirus	Respiratory viruses	Bacterial pathogens	Herpes virus	TOTAL
Total number of class D devices (covered by **issued certificates** [as of 28/02/2025]) **that fall in the categories of currently designated EURLs**	169	28	11	14	**222**
Number of devices covered by a signed **master services agreement with an EURL for batch testing** (EURL task in IVDR Article 100(2)(b) [as of 28/02/2025]	100	27	7	5	**139**
Number of devices covered by a signed **statement of work with an EURL for batch testing** (EURL task in IVDR Article 100(2)(b)) [as of 28/02/2025]	75	16	0	0	**91**
Number of devices for which **batch testing by EURLs is taking place** [as of 28/02/2025]	39	2	0	0	**41**

Data of 3 NBs designated under IVDR

IVDR applications - reason for refusal



February 2025
IVDR Applications: 2.395
IVDR Certificates: 1.490

Total number of IVDR application refusals*:
October 2022: 2
March 2023: 49
June 2023: 16
October 2023: 6
February 2024: 7
June 2024: 7
October 2024: 7
February 2025: 12

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, February 2024, June 2024, October 2024 and February 2025. * 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 indicated on the graph on this slide.
- 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"
- June 2024: Reasons were indicated by **one** NB only. "Other" reasons: "nonconformities not solved", "withdrawal of client", "assessment resulted in negative outcome"
- October 2024: Reasons were indicated by **one** NB only. "Other" reasons: "assessment resulted in negative outcome".
- February 2025: Reasons were indicated by **one** NB only. "Other" reasons: : "nonconformities not solved", "refusal of client", "assessment resulted in negative outcome"

IVD

Completeness of submissions

Number of notified bodies which report that > 50% of submissions are considered complete:

3 out of 14 NBs in February 2025

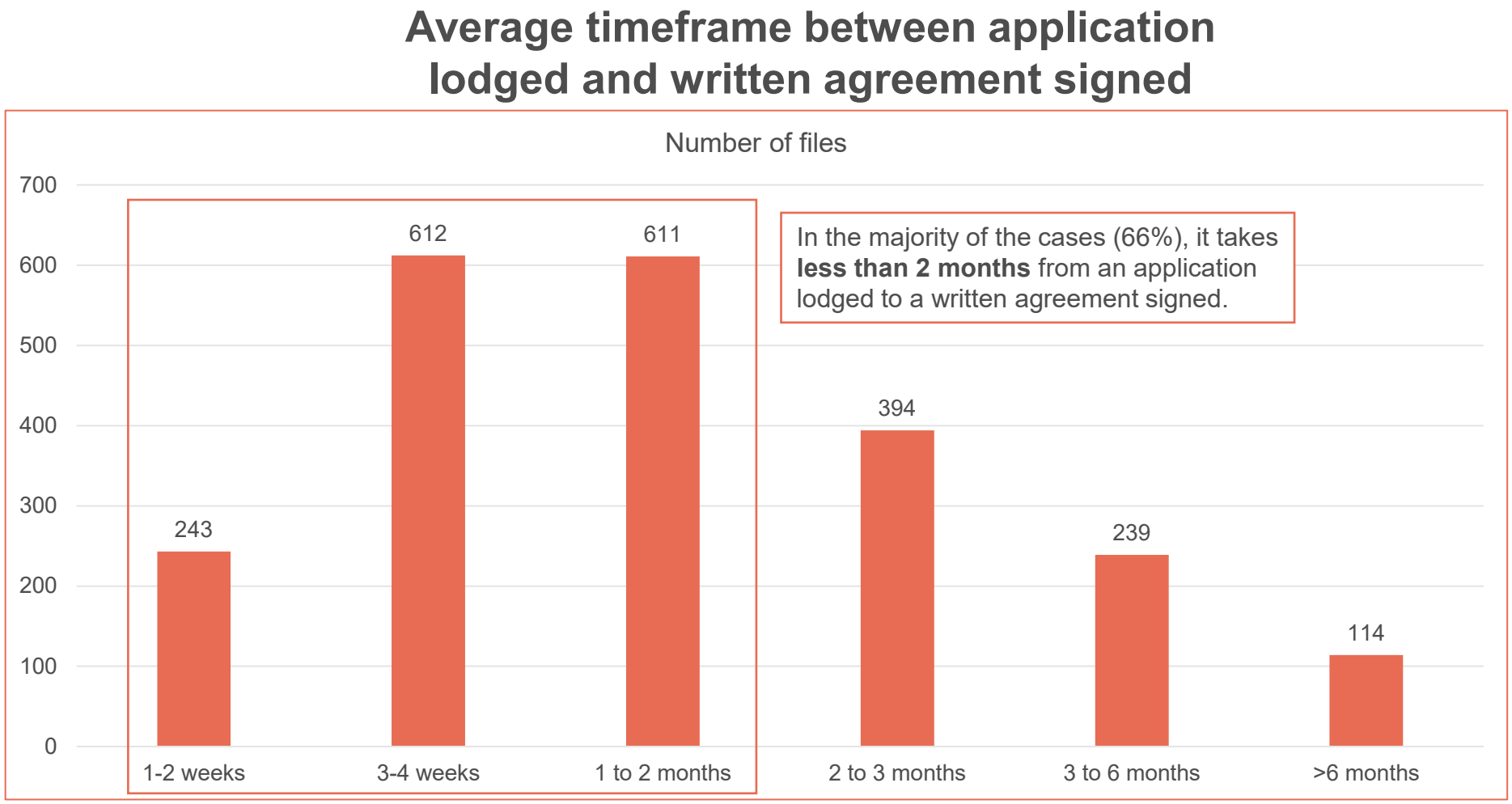
Submissions largely incomplete*

* 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

IVD

Average timeframe to written agreement signed

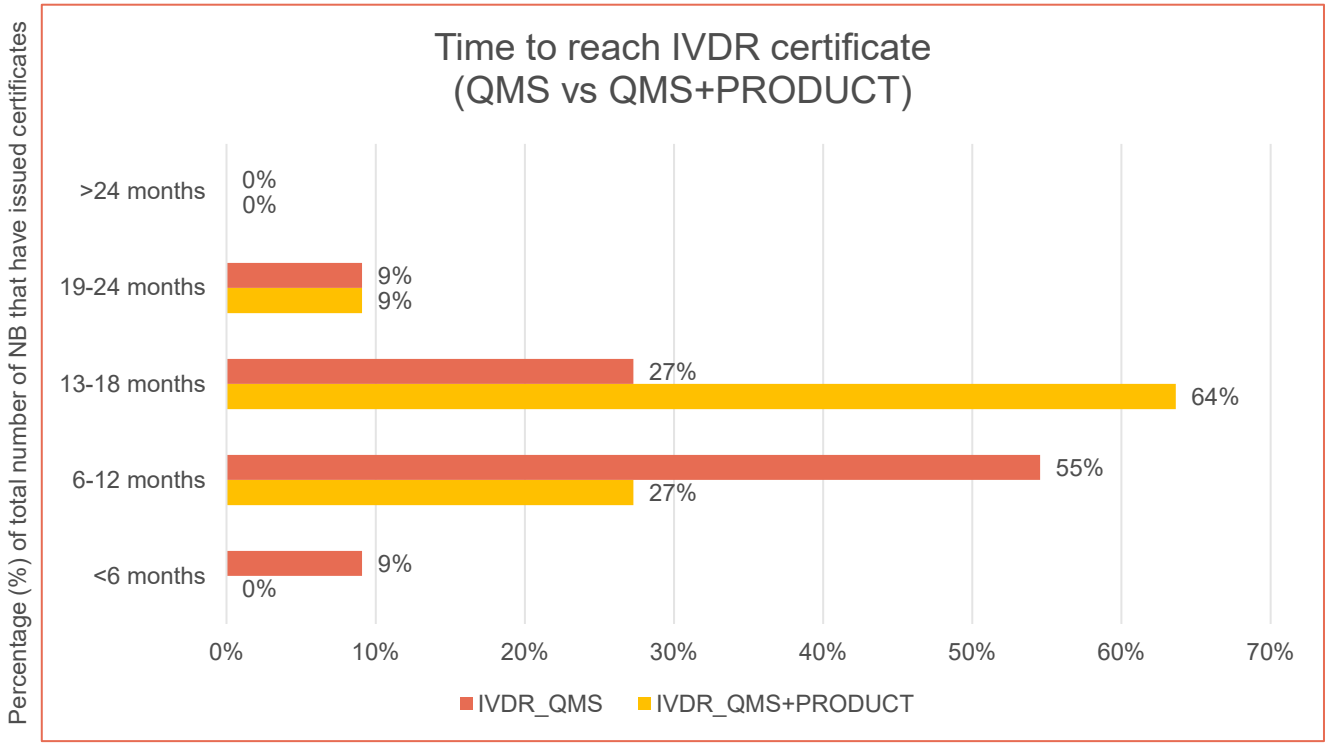


Note: Data of 14 notified bodies designated under IVDR

European Commission

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

IVD



February 2025
IVDR Applications: 2.395
IVDR Certificates: 1.490

IVDR QMS certificates

- For 55% of NBs: 6-12 months to issue a new QMS certificate
- 27% of NBs: 13-18 months

IVDR QMS+PRODUCT certificates: longer time

- 64% of NBs: 13-18 months
- 9% of NBs: 19-24 months

Notes:

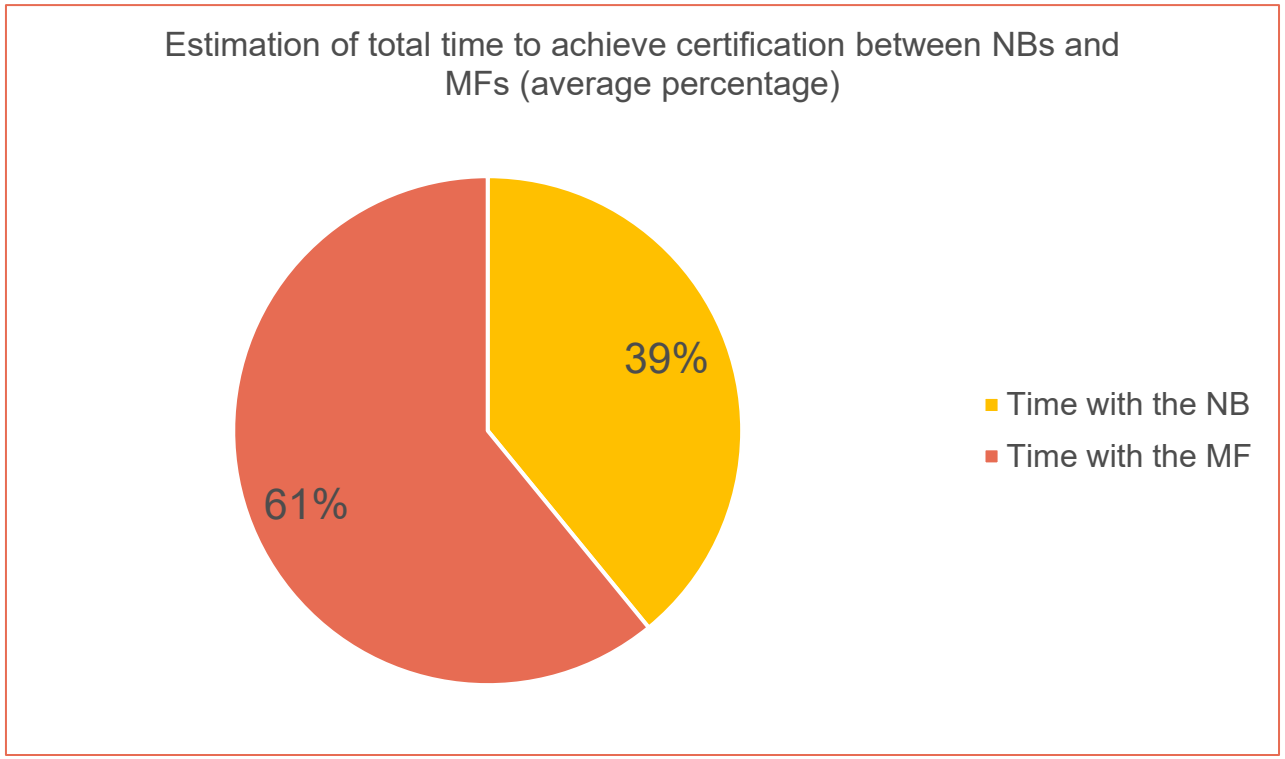
- Data of 11 NBs
- This indicator shows the time to reach issuance of a new EC certificate (from written agreement signed to issuance) under IVDR.
- 3 out of 14 NBs who are designated under the IVDR have not issued certificates yet.

European Commission

IVD

Estimation of the total time* to achieve certification between NB and MF

* from written agreement signed to issuance of a new certificate



More time with the manufacturer

- **7** out of 11 NBs indicated >50% of the time with the MF
- **2** out of 11 NBs indicated >50% of the time with the NB
- **2** out of 11 NBs indicated that the time is equally divided (50:50) between NB and MF

Time with the notified body

- Minimum value: 15%
- Maximum value: 70%

Time with the manufacturer

- Minimum value: 30%
- Maximum value: 85%

Notes:

- Data of 11 NBs
- This indicator shows an estimate of the allocation of the total time to certification (from signing the written agreement to issuance) between the notified body and the manufacturer.
- Time with the NB means time for checking the documents including application and technical documentation.
- Time with the MF means time for revising the documents including application and technical documentation.

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Thank you

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