10th notified bodies survey on certifications and applications (MDR/IVDR)

Survey results of the 10th NB survey with data status 30 June 2024
(small and medium dataset)

30 October 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.
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- 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

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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)
MFs	Manufacturer(s)
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

- **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

NB surveys already conducted by the study team

About

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%**
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%**

Survey results included in the published dashboard

10th 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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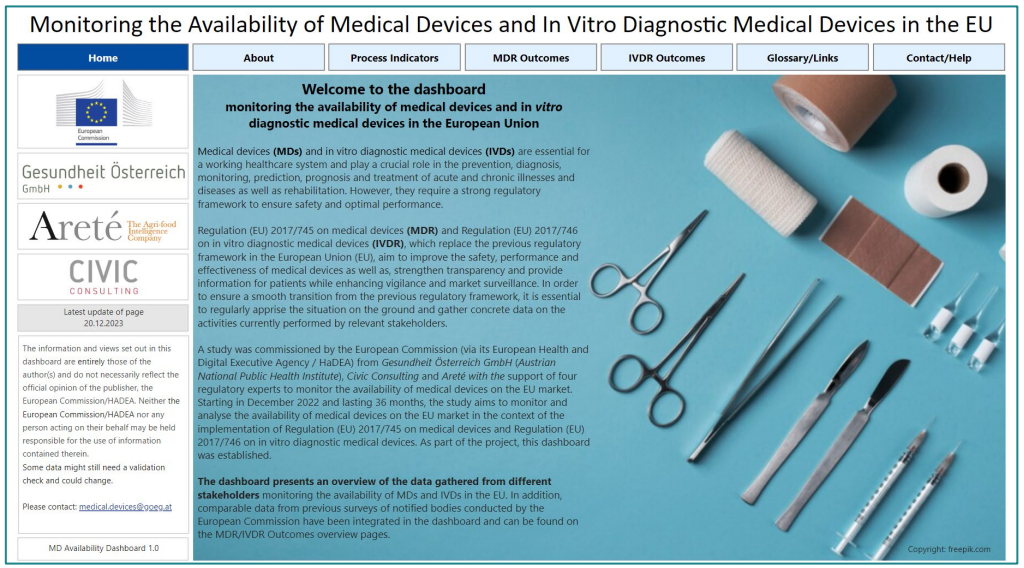
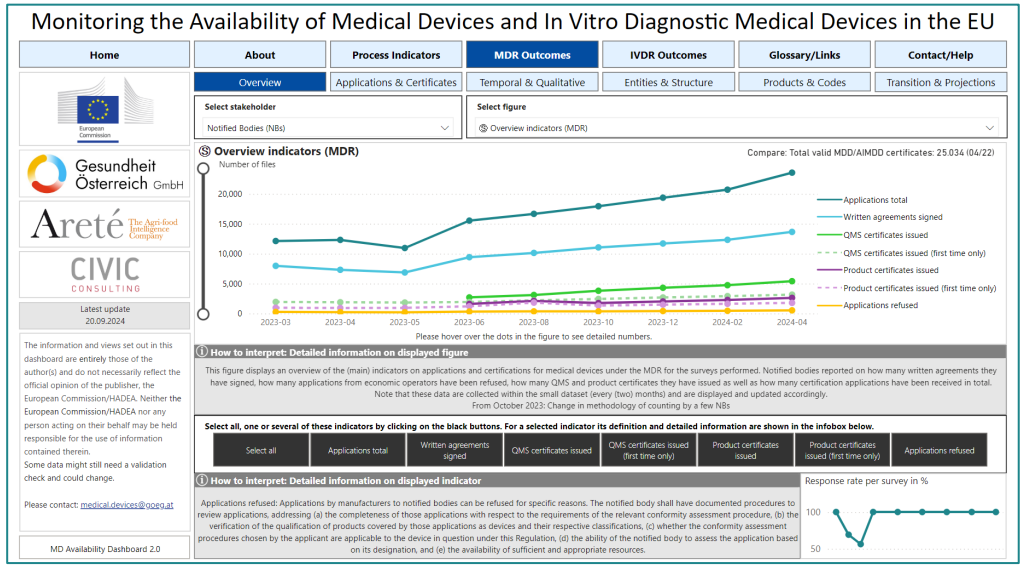
About

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 **10th NB survey conducted at the beginning of July 2024** with **requested data** from notified bodies designated under MDR and/or IVDR **until 30 June 2024**.
  - These survey results are also compared with previous survey data (see data sources).

- **Data sources:**
  - Data collected between April 2023 and July/August 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 July/August 2024.

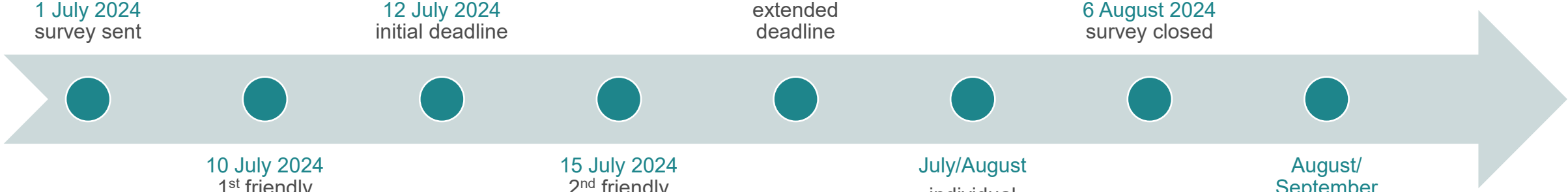
Ⓢ The **small dataset** is a small set of questions (6 indicators) asked to notified bodies **every two months.**
Note: From April to July 2023, it was asked monthly.
Ⓜ The **medium dataset** is a set of questions asked to notified bodies **every four months** concerning the activities they have been performing since their designation.
Ⓛ The **large dataset** (not surveyed in the 10th NB survey) contains additional data asked to notified bodies **once a year**.

Timeline for the 10th NB survey

(conducted in July/August 2024 with requested data from designation up to 30/06/2024)

About

50 notified bodies designated under MDR and/or IVDR
(data status: 1 July 2024)



1 July 2024
survey sent

10 July 2024
1st friendly reminder

12 July 2024
initial deadline

15 July 2024
2nd friendly reminder

17 July 2024
extended deadline

July/August
individual phone calls and emails

6 August 2024
survey closed

August/ September 2024
data validation

Note: *Out of 50 notified bodies,* ***38 NBs*** *are designated under the* ***MDR*** *only,* ***11 NBs*** *are designated under* ***both the MDR and IVDR****, and* ***1 NB is*** *designated under the* ***IVDR only****.*

Final result
50 responses
(100% response rate)

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Response rate for the 10th NB survey

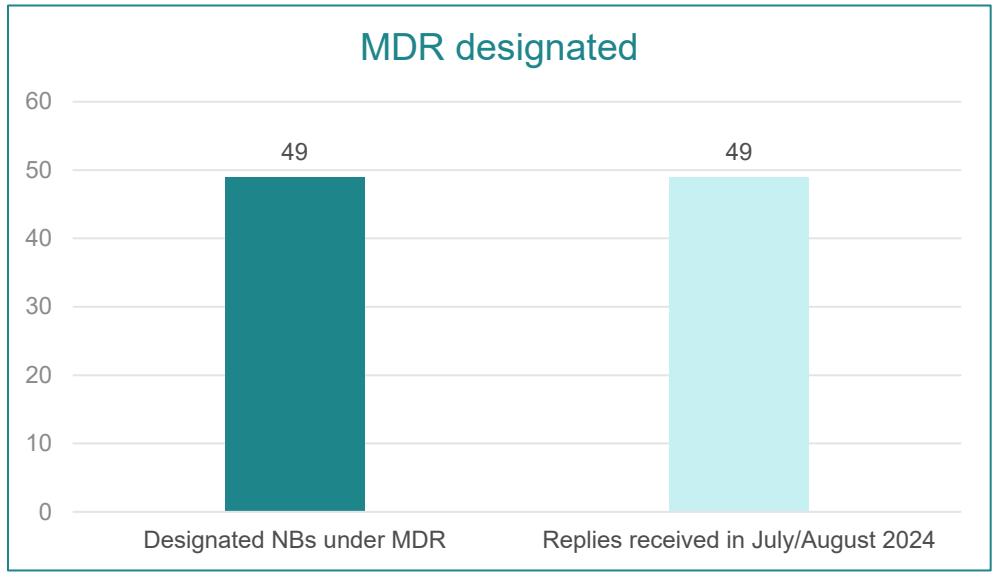
(conducted in July/August 2024 with requested data from designation up to 30/06/2024)

About

50 out of 50 notified bodies replies received (100% response rate)

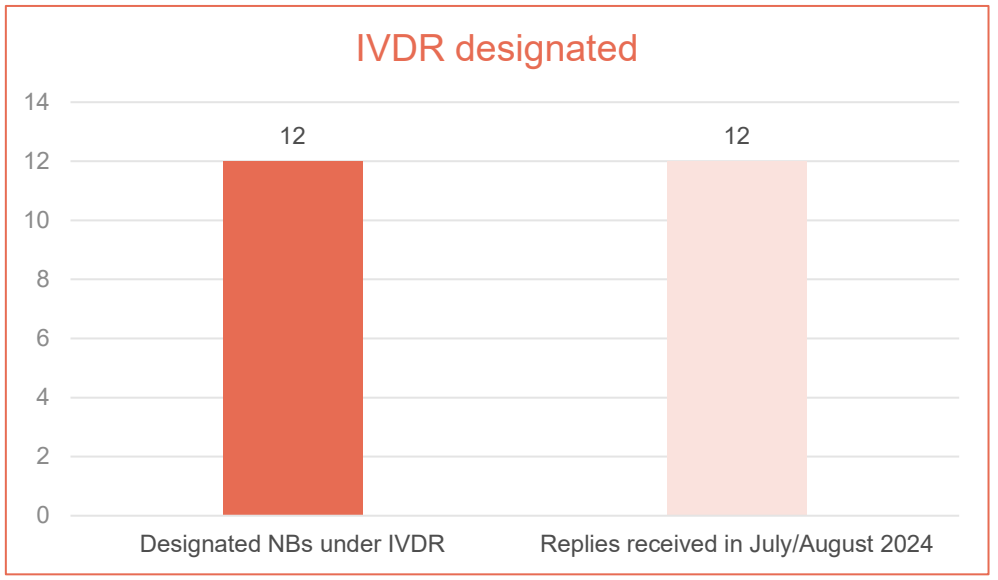
Note: *Out of 50 notified bodies,* ***38 NBs*** *are designated under the* ***MDR*** *only,* ***11 NBs*** *are designated under* ***both the MDR and IVDR****, and* ***1 NB is designated under the IVDR only****.*

MD



100% response rate

IVD



100% response rate

European Commission

MD

2. Survey results for medical devices

Note:

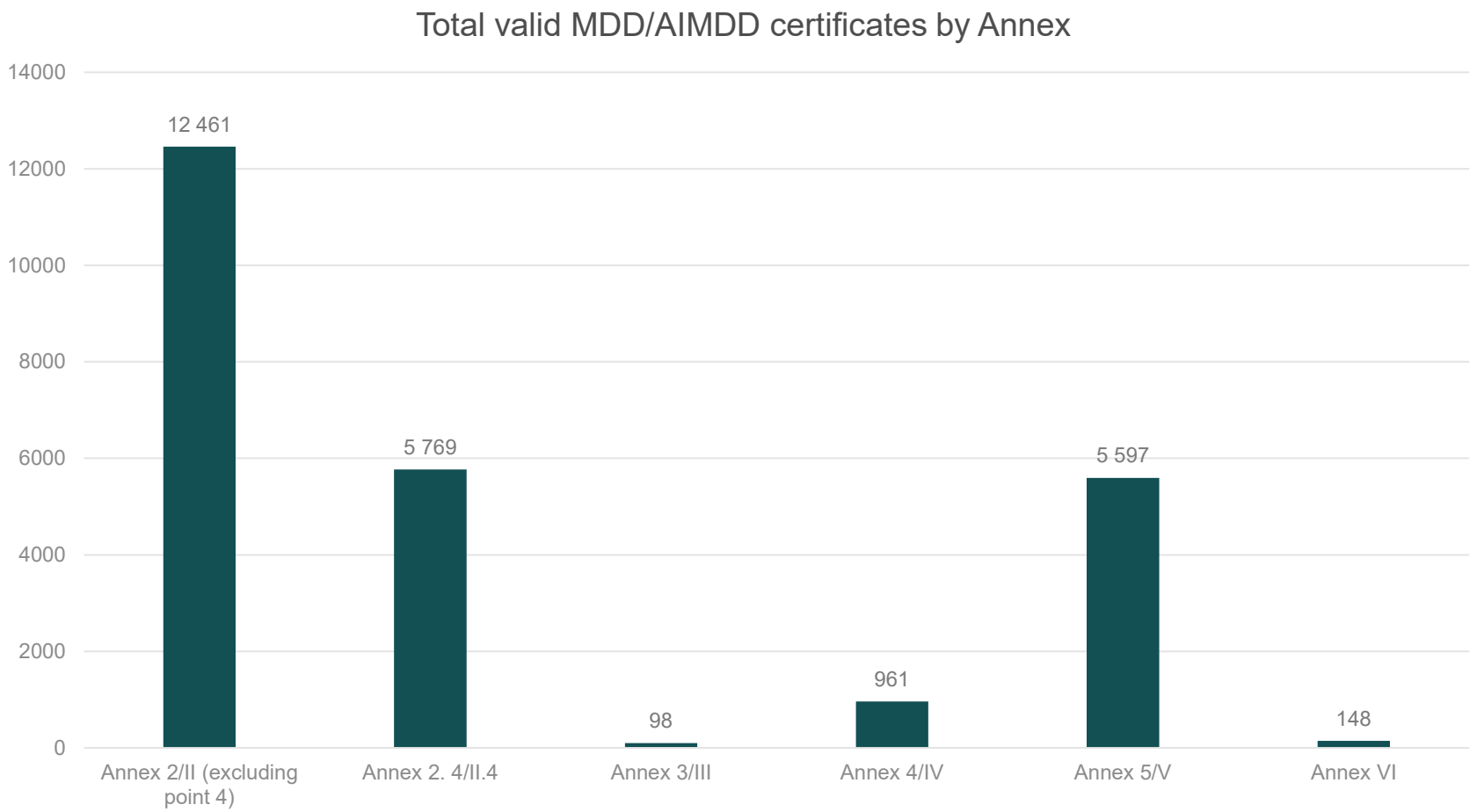
- Thousands separators are represented as dots or blank space (not comma) in the graphs.
- Datasets:

  Ⓢ The **small dataset** is a small set of questions (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 10th 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)

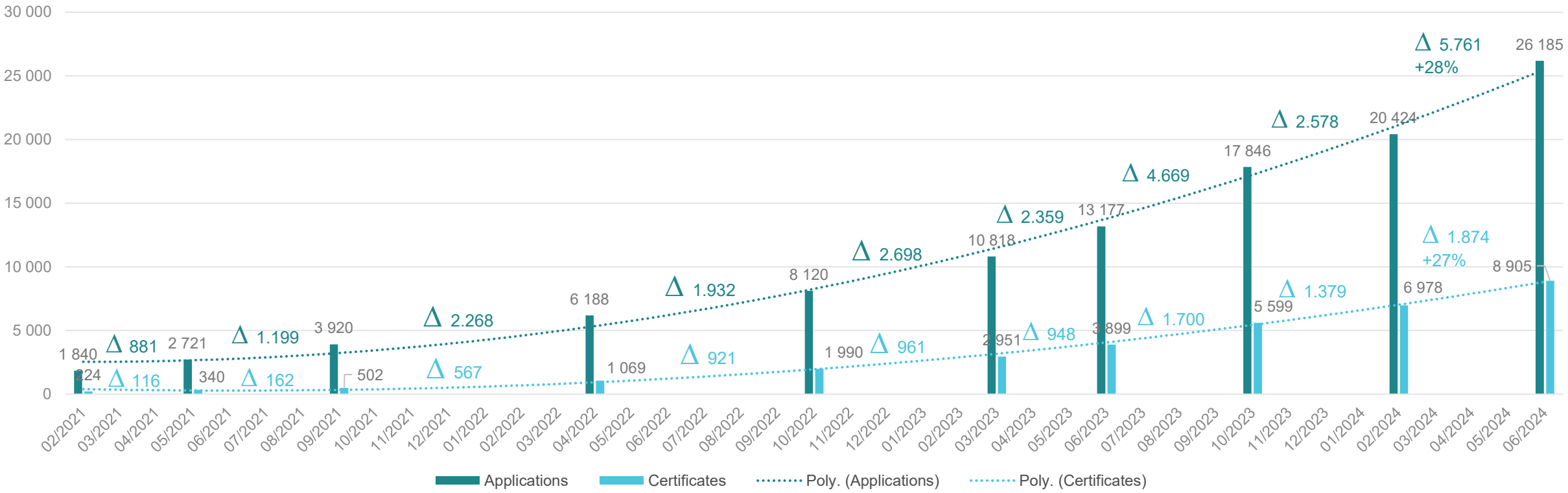
MD

Ⓜ

June 2024

MDR Applications:
Total number of applications filed by Annex Ⓜ: 26.185*

MDR Certificates:
Total number of certificates by Annex Ⓜ: 8.905



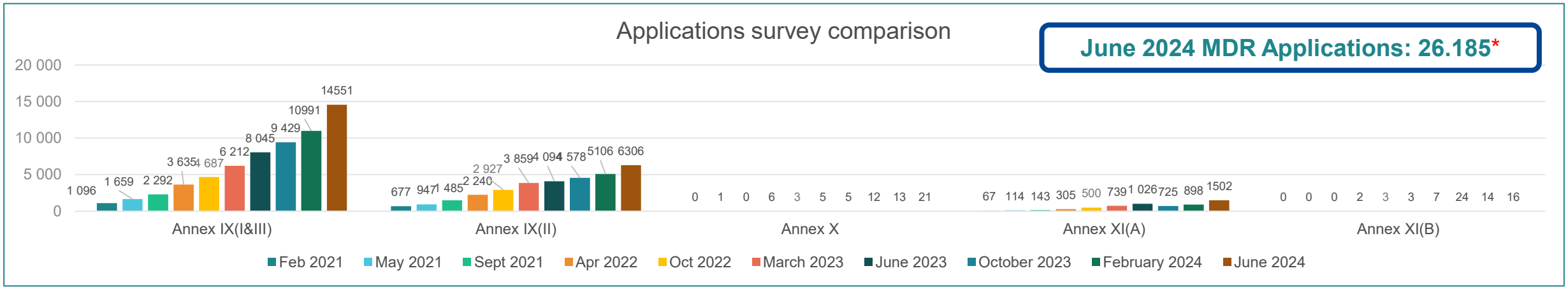
Notes: Designated NBs for MD: 49

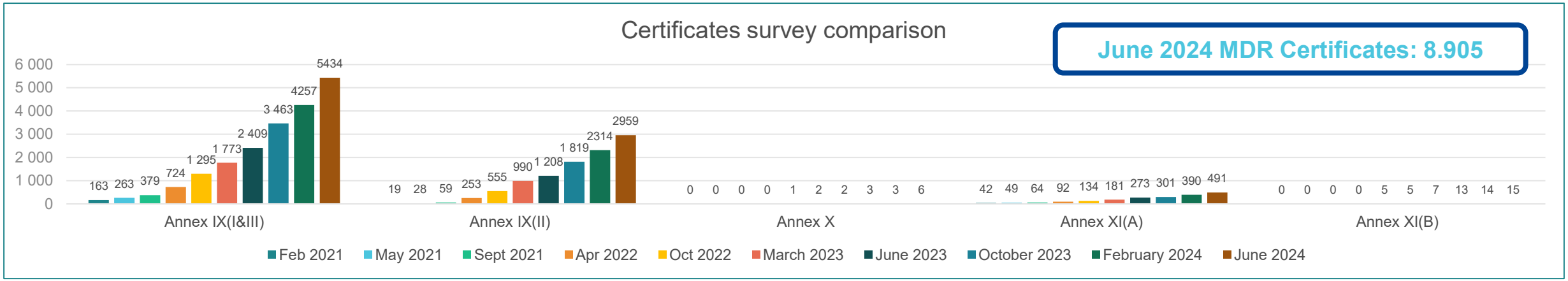
* The data shown comes from the medium data set Ⓜ – except for 2 NBs where the total number of applications filed was derived from the small data set Ⓢ since they could not provide the data per Annex.

- 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 30/06/2024), 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 30/06/2024) under the MDR.
- The dotted line shows the polynomial trend line (grade 2).

MDR applications and certificates by annex survey comparison

MD





Notes:

- Designated NBs for MD: 49; 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 30/06/2024), 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 30/06/2024) under the MDR **by annex**.

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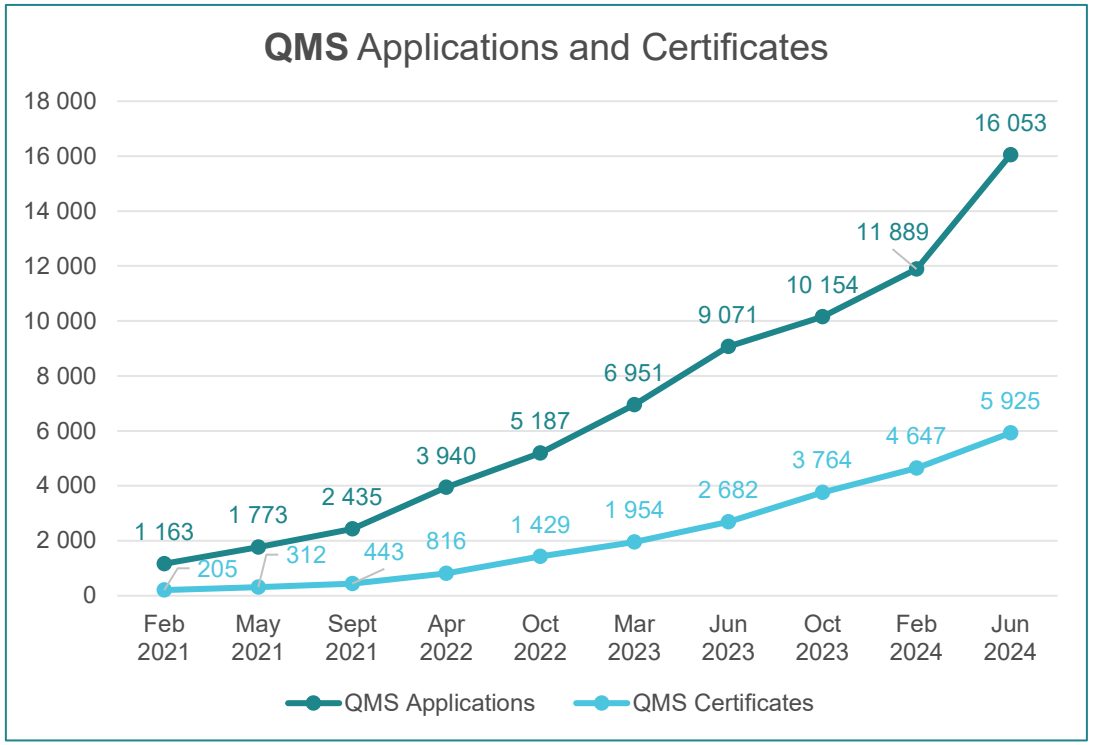
MDR applications and certificates by type (QMS vs Product) – survey comparison

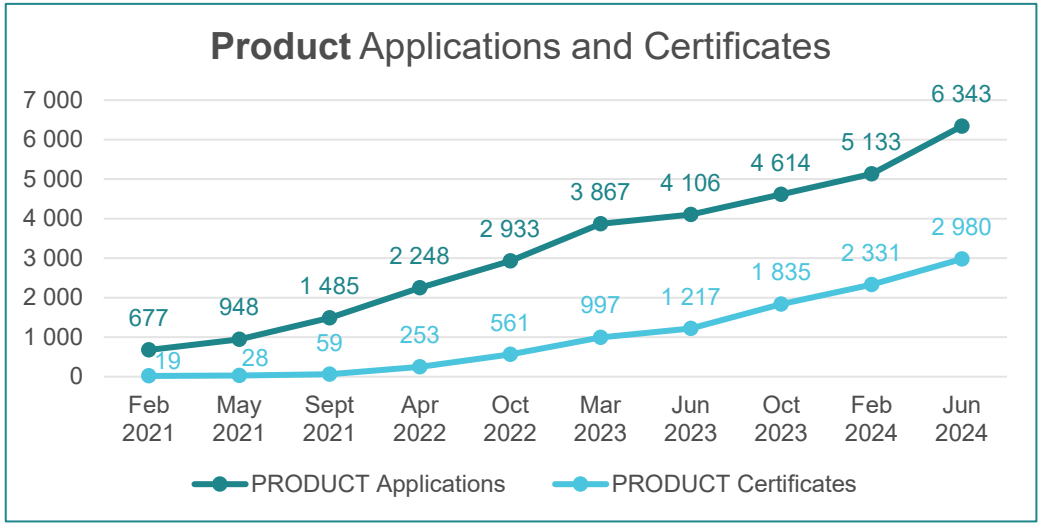
MD

June 2024
MDR Applications: 26.185*
MDR Certificates: 8.905

* 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: 3.696
Note: This number is included in the total number of applications.

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Specific additional procedures according to Annex IX (II)

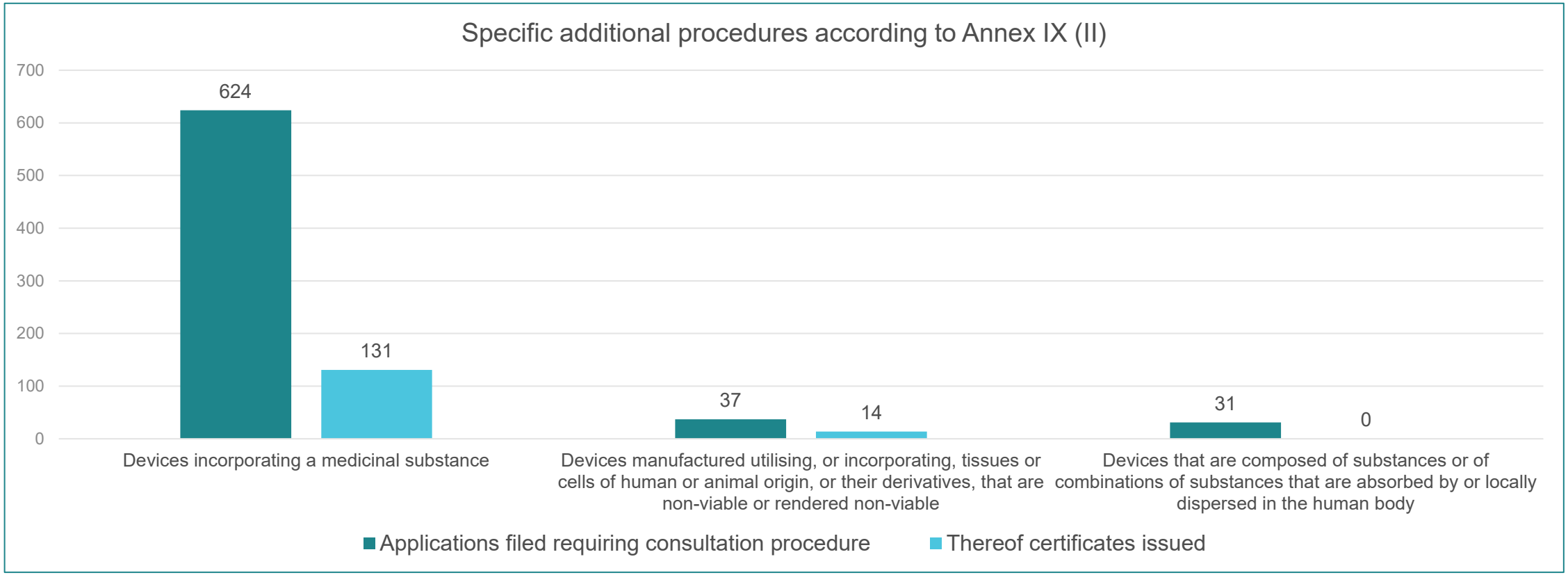
MD

Ⓜ

June 2024

MDR Applications:
Total number of applications filed by Annex Ⓜ: 26.185*

MDR Certificates:
Total number of certificates by Annex Ⓜ: 8.905



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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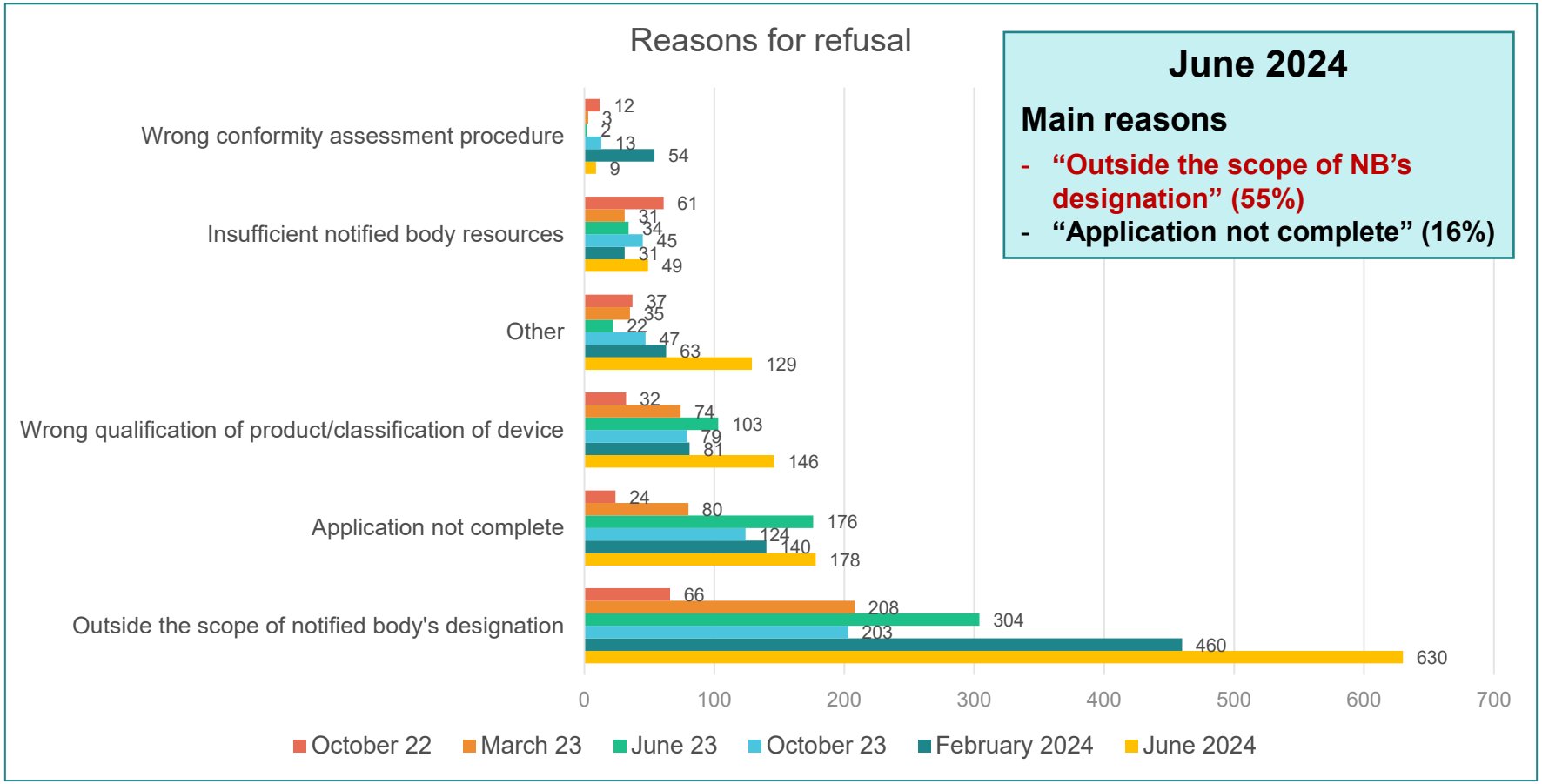
Average timeframe to written agreement signed

Average timeframe between application lodged and written agreement signed:

In the majority of the cases (67%), it takes **less than 2 months** from an application lodged to a written agreement signed.

Note: Data of 49 notified bodies

MDR applications - reasons for refusal



June 2024

Main reasons

- **"Outside the scope of NB's designation" (55%)**
- **"Application not complete" (16%)**

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*

* 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.

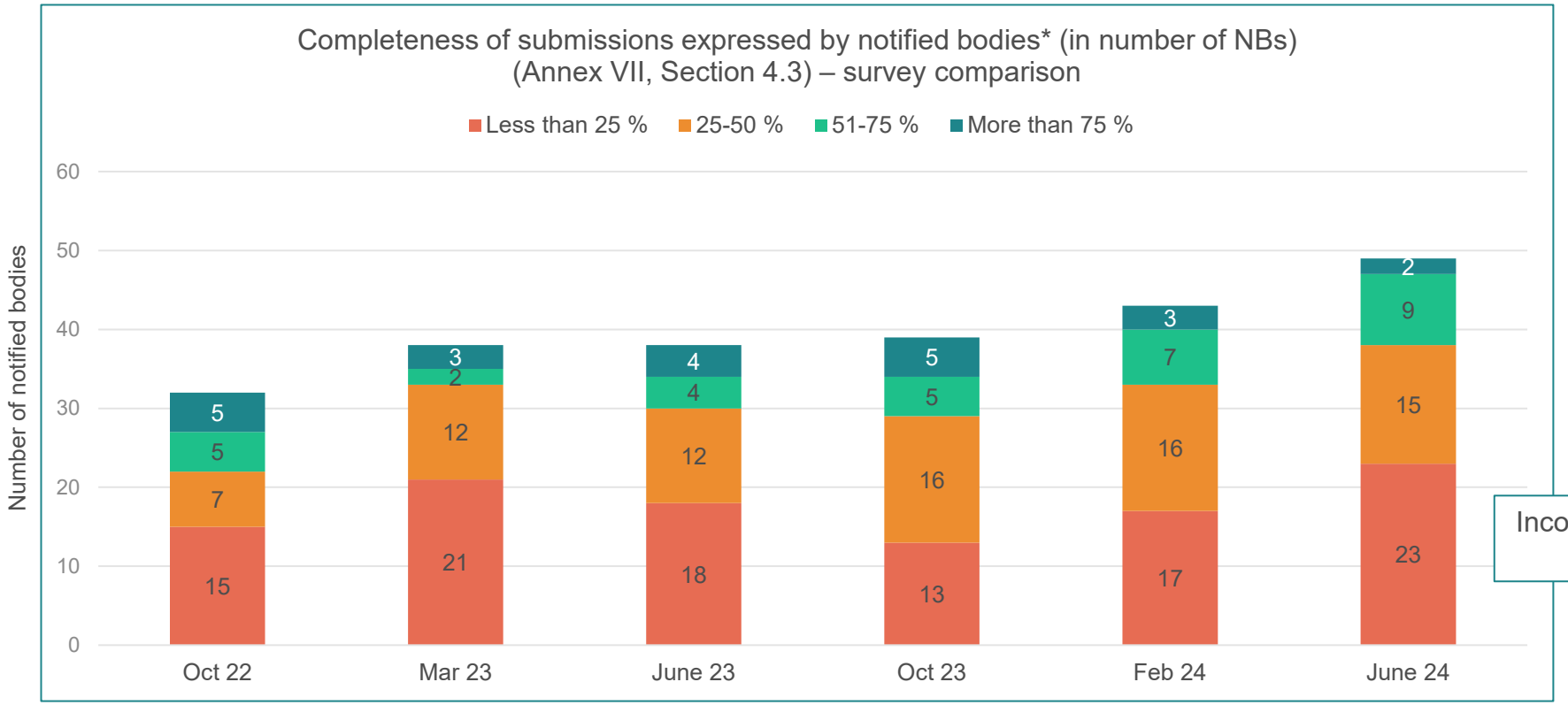
Application refusals:**

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

Notes:

- Comparison of reasons for refusal in October 2022, March 2023, June 2023, October 2023, February 2024 and June 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.
- June 2024: data of 30 NBs; some stated "other" reasons in June 2024: "withdrawal by the customer", "concerns about violation of Article 7 and/or prejudice!; "wrong qualification/classification", "client stopped communication", "Unresolved non-conformities; Customer refused audit", "language requirement not met"

Completeness of submissions



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

11 out of 49 NBs in June 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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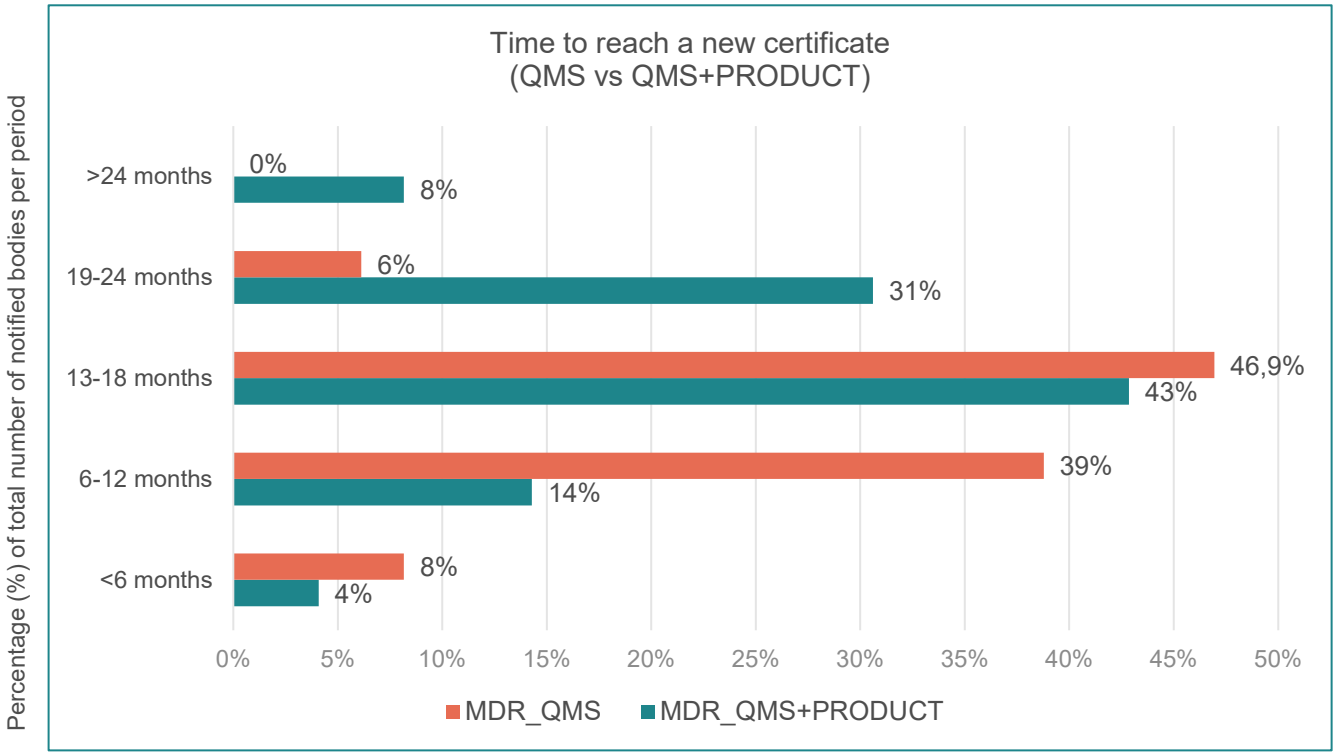
Time to reach a new certificate (QMS vs QMS+PRODUCT)

MD



June 2024
MDR Applications: 26.185*
MDR Certificates: 8.905

MDR QMS certificates:

- For 39% of NBs: 6-12 months to issue a new QMS certificate
- For 53% of NBs: ≥ 13 months (max: 24 months)

MDR QMS+PRODUCT certificates: longer time

- For 43% of NBs: 13-18 months to issue a new product certificate
- For 82% 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.
- Two NBs stated that time from agreement to certificate varies a lot.
- One NB expects the timelines to increase due to the extension of the timelines for providing technical documentation.

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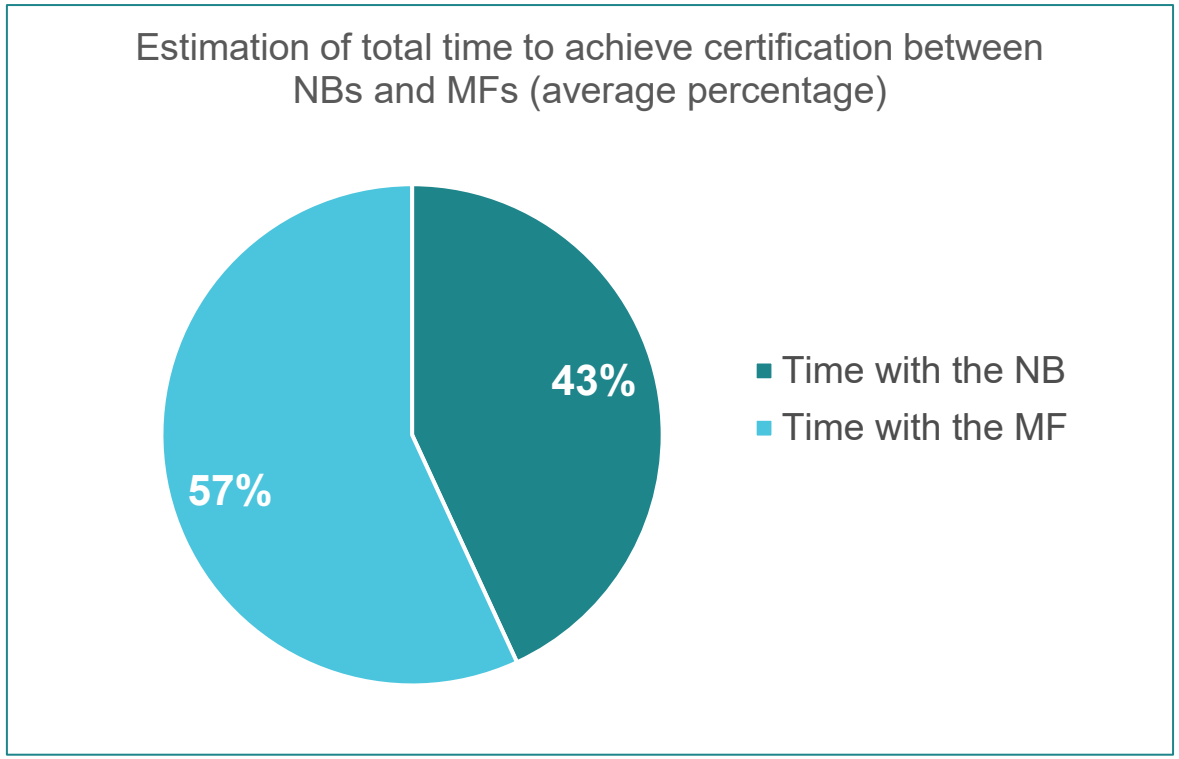
Estimation of the total time* to achieve certification between NBs and MFs

* from written agreement signed to issuance of a new certificate



More time with the manufacturer

- **23** out of 41 NBs (56%) indicated >50% of the time with the MF
- **12** out of 41 NBs (29%) indicated that the time is equally divided (50:50) between NB and MF
- **6** out of 41 NBs (15%) indicated >50% of the time with the NB

Time with the notified body

- Minimum value: 20%
- Maximum value: 80%

Time with the manufacturer

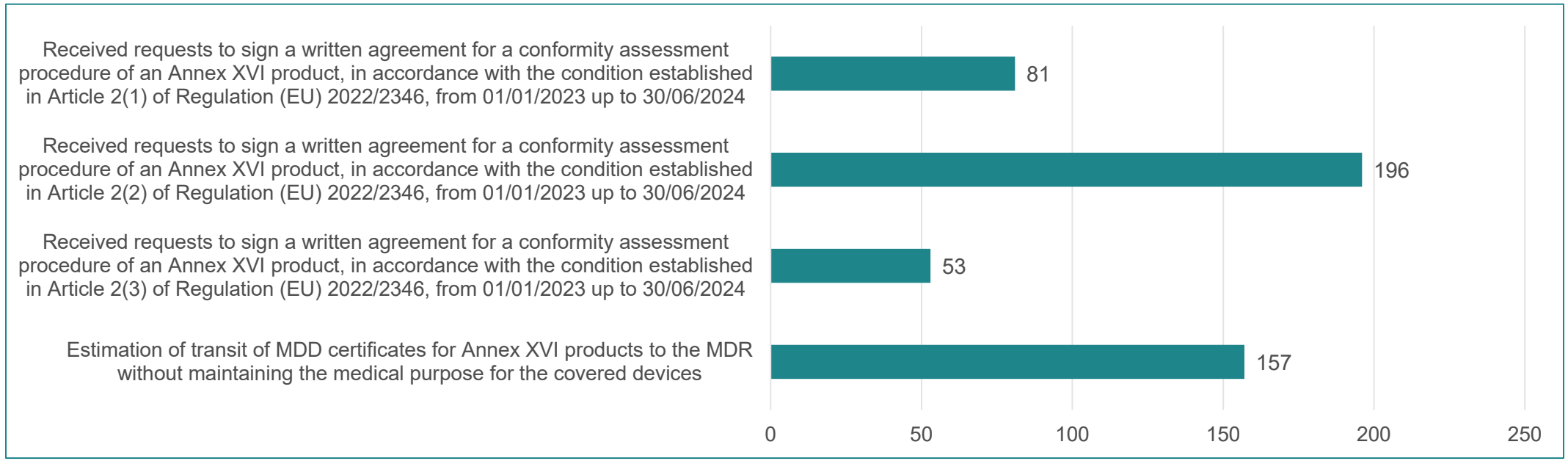
- Minimum value: 20%
- Maximum value: 80%

Notes:

- Data of 41 NBs (data of NBs that have not yet issued certificates were excluded)
- 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.

Questions on Annex XVI products

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

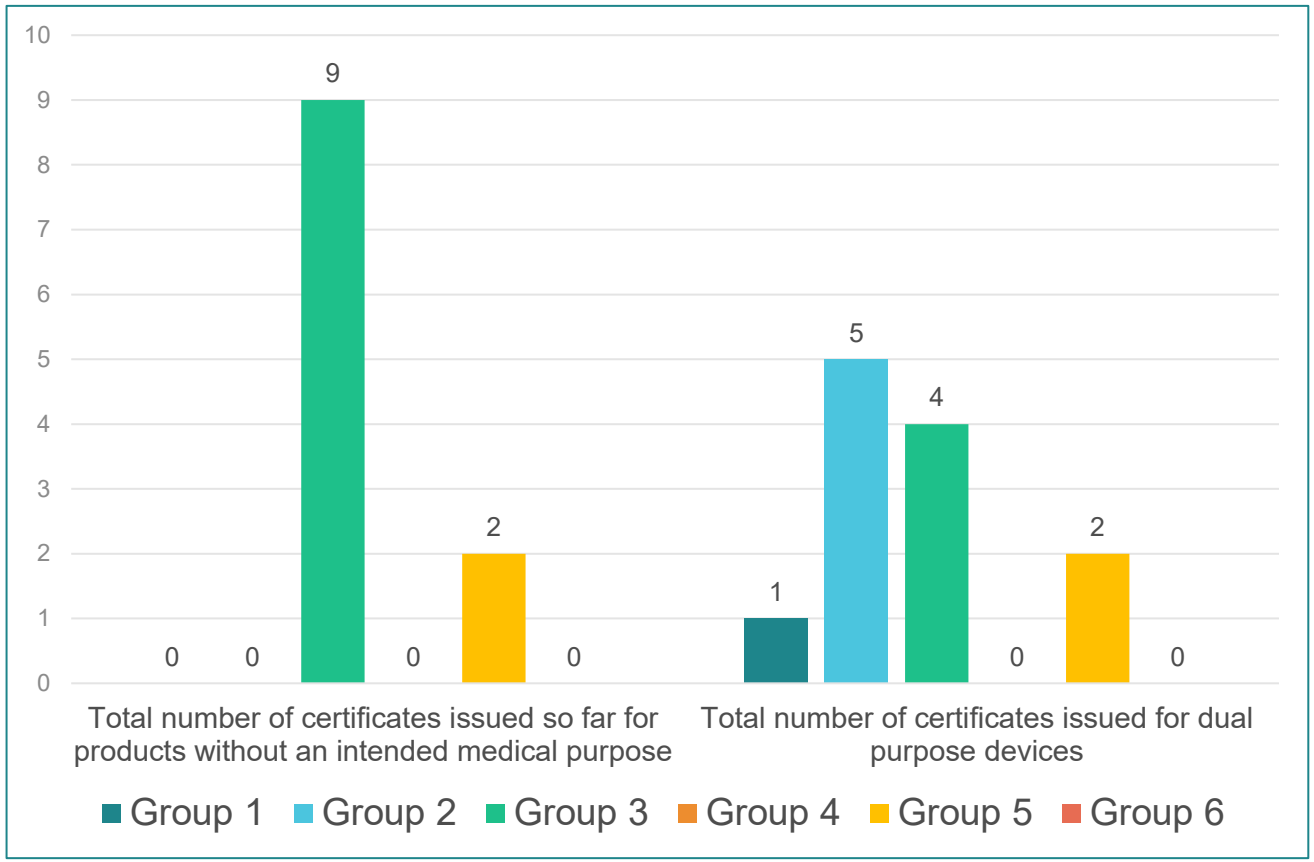


Notes:

- 24 out of 49 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*

*products having both a medical and a non-medical intended purpose



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.

Notes:

- Data of 4 NBs; 45 out of 49 NBs entered "0“ for all groups
- 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.

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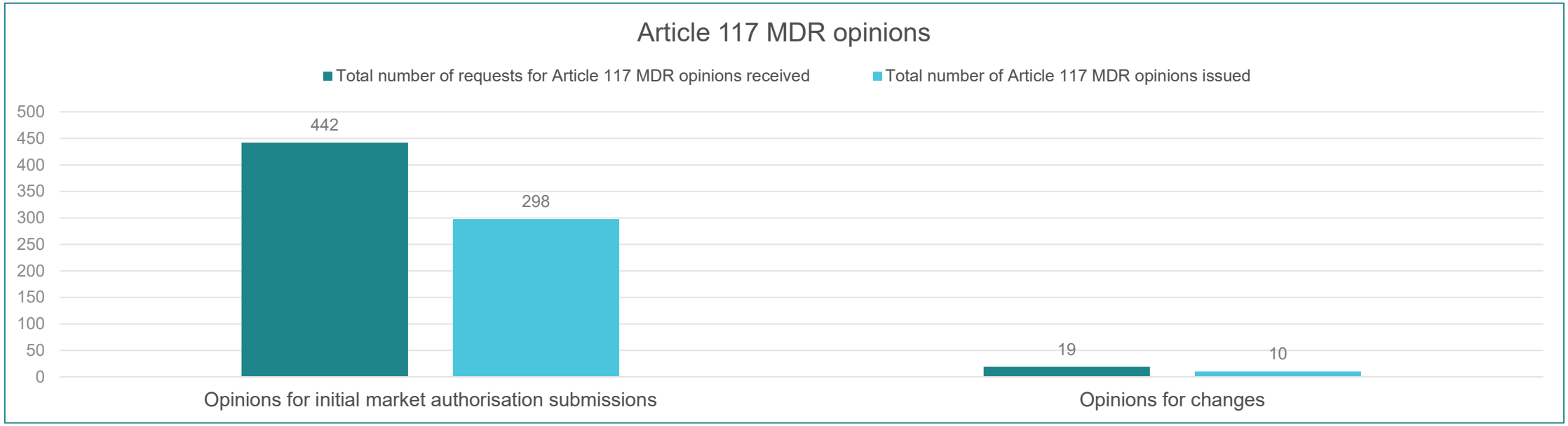
Article 117 MDR opinions* - requests received and opinions issued

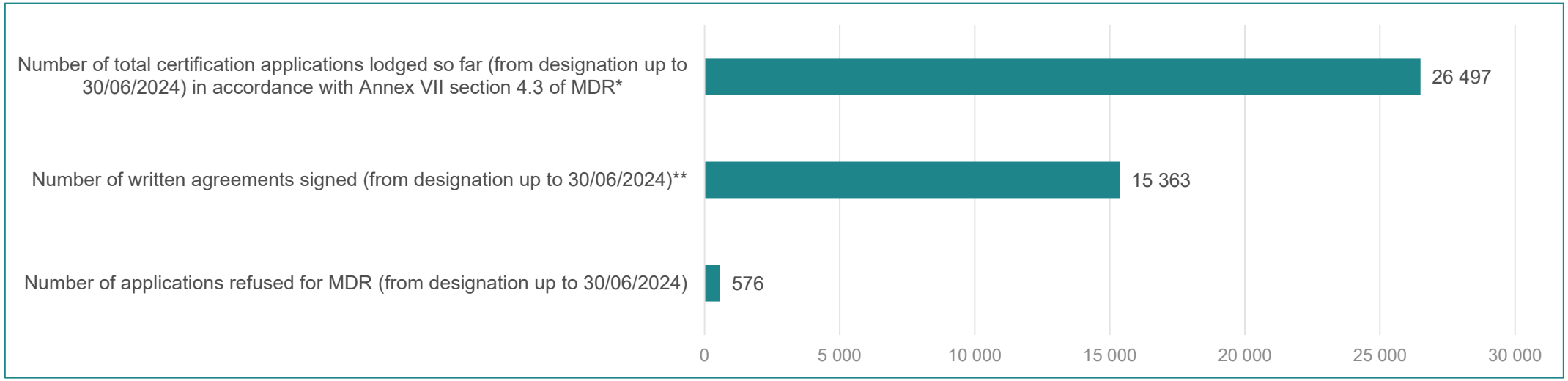


Notes:

- Total number of requests for Article 117 MDR opinions for initial market authorization submissions received: data of 16 NBs
- Total number of requests for Article 117 MDR opinions for changes received: data of 4 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.

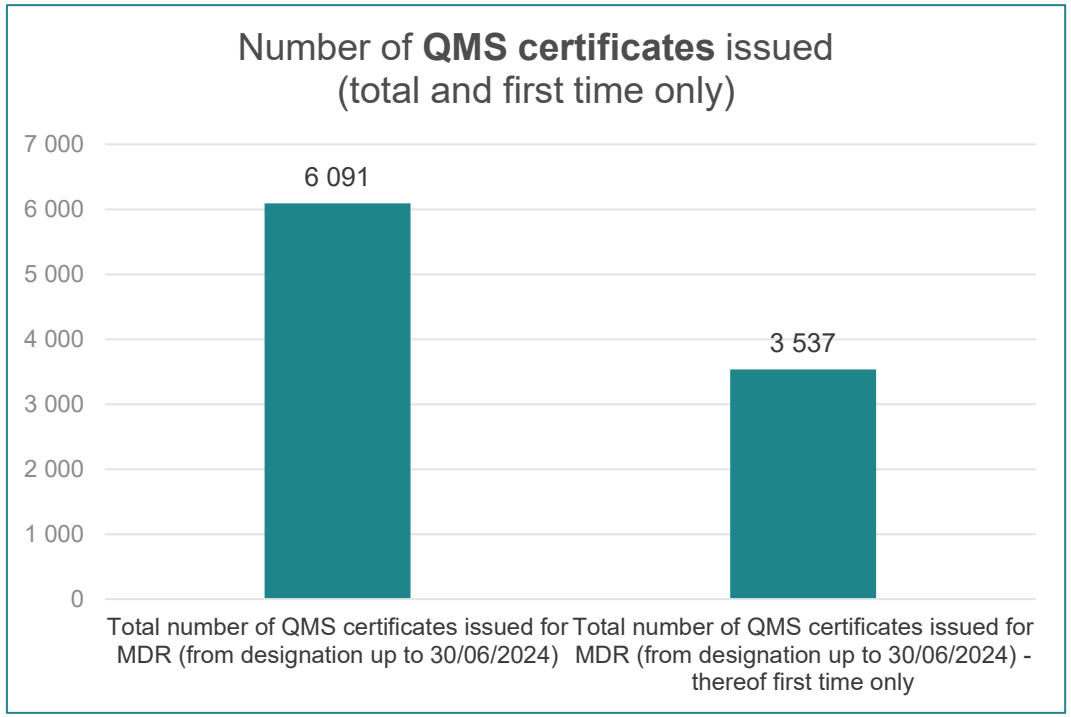
MDR applications filed and refused, written agreements signed



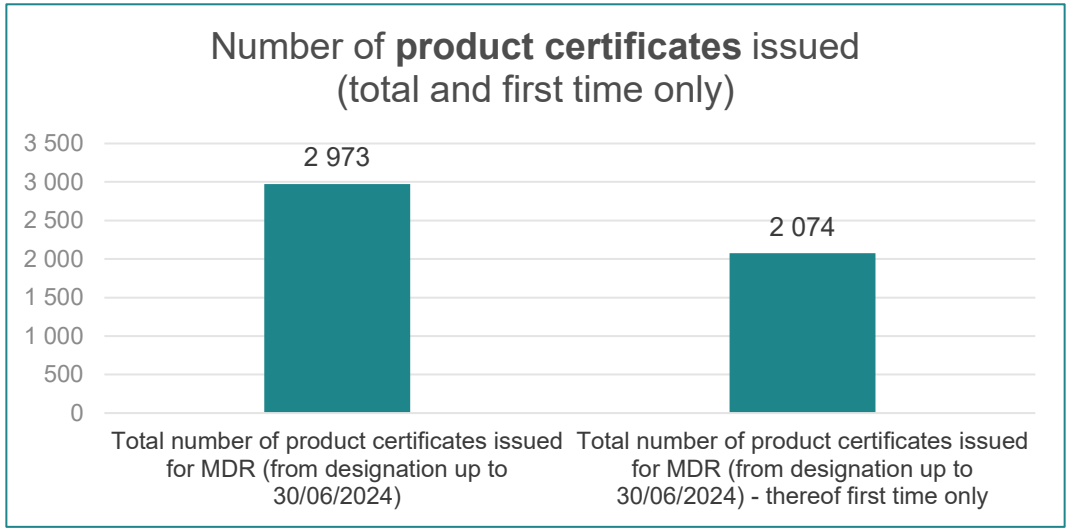
Notes:

- **Designated NBs for MD: 49**
- *** 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 30/06/2024), 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

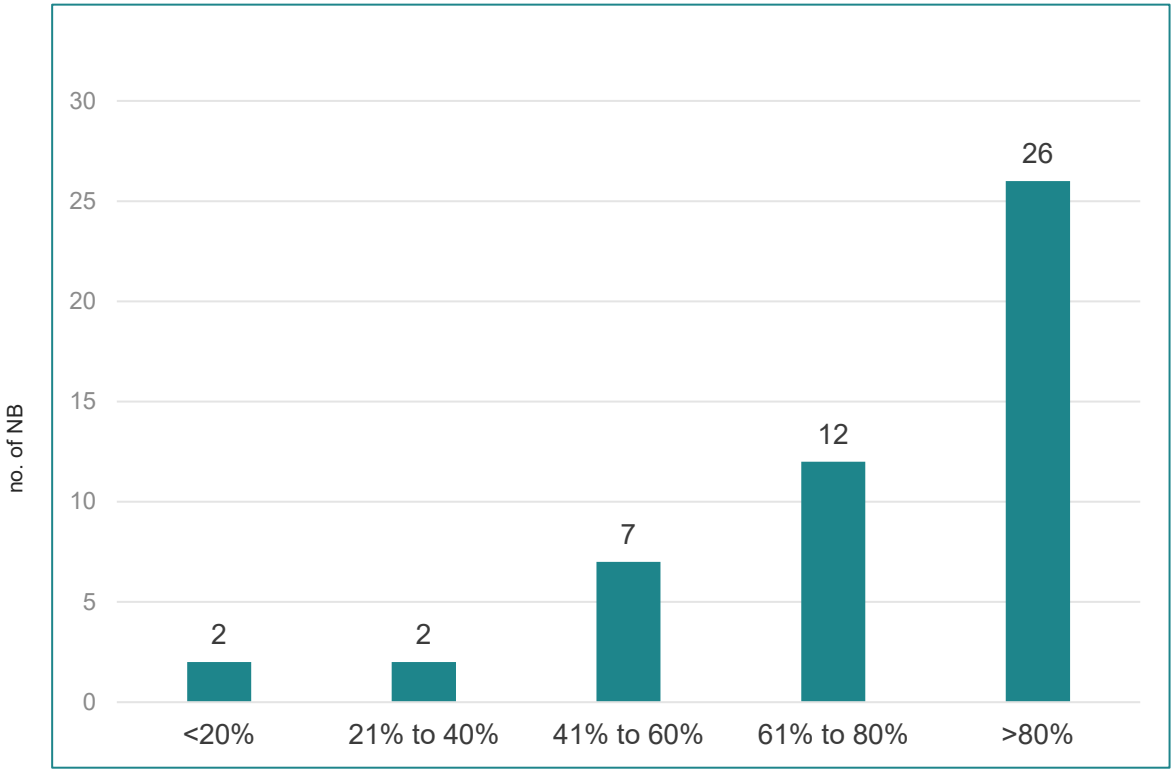


Note QMS Certificates: This relates to Annex IX Chapter I or Annex XI Part A according to MDR.



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)



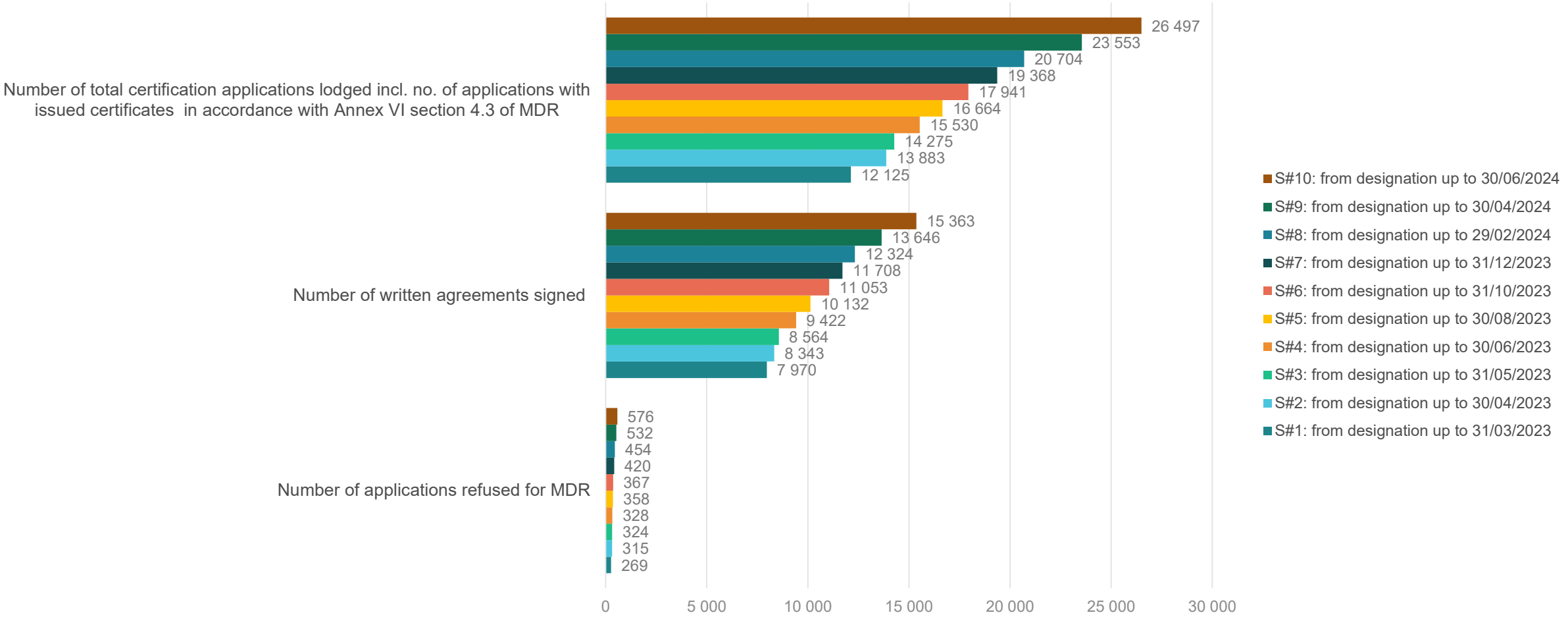
- **7 out of 49 NBs (14%)** reported that **41-60%** of the MDR applications cover the scope of (AI)MDD certificates
- **38 out of 49 NBs (78%)** indicated that MDR applications **cover more than 60%** of the scope of (AI)MDD certificates.

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 June 2024

MD



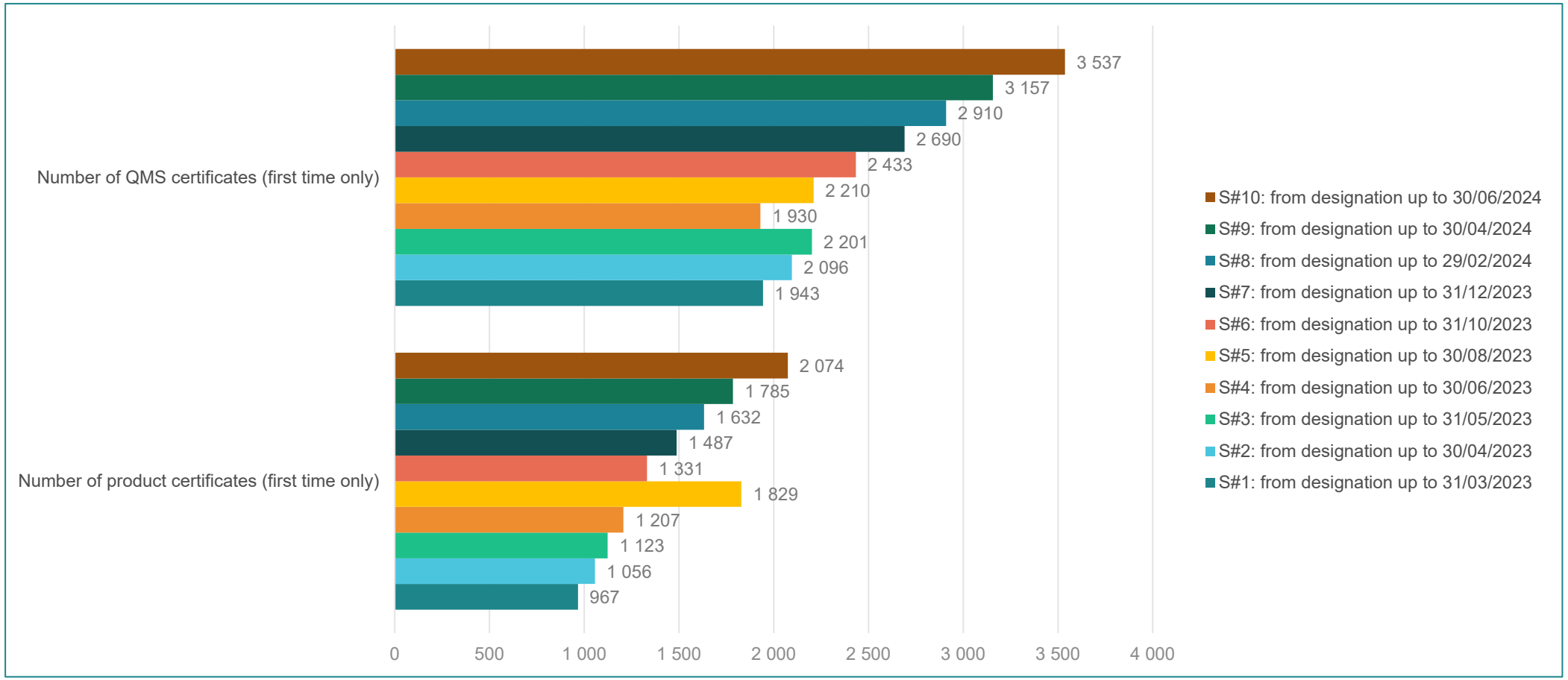
S = Survey; # = number

Notes:

- Survey **#10:** 49 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.

European Commission

Survey comparison – March 2023 to June 2024

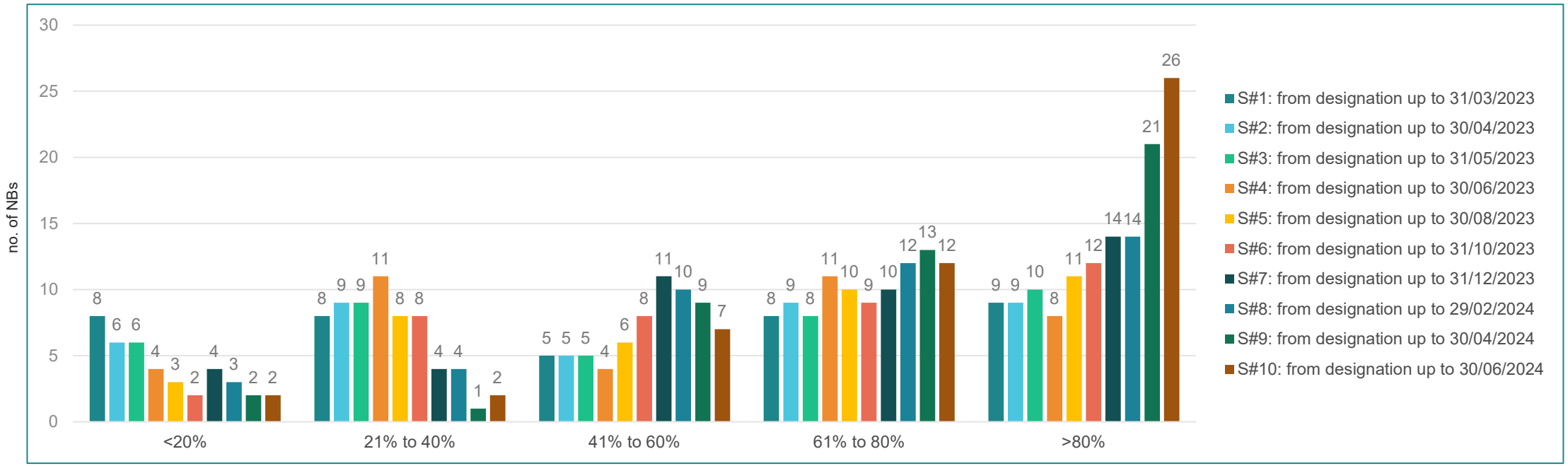


S = Survey; # = number

Notes:

- Survey **#10:** 49 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.

Survey comparison – March 2023 to June 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%

Survey **#10:** 49 designated NBs for MD

NBs = notified bodies; S = Survey; # = number

IVD

3. Survey results for in vitro diagnostic medical devices

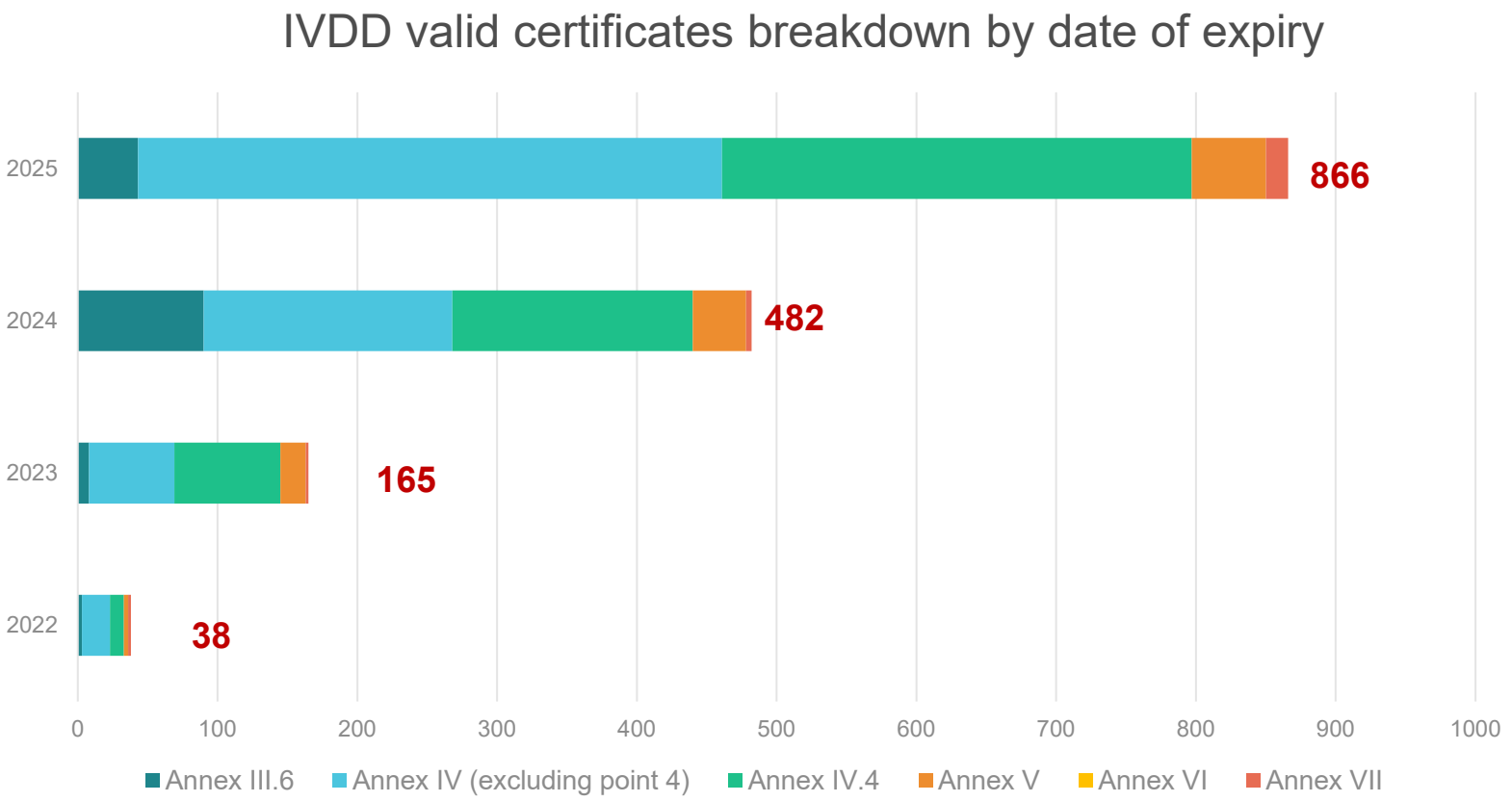
Note:

- 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** (not surveyed in the 10th NB survey) 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)

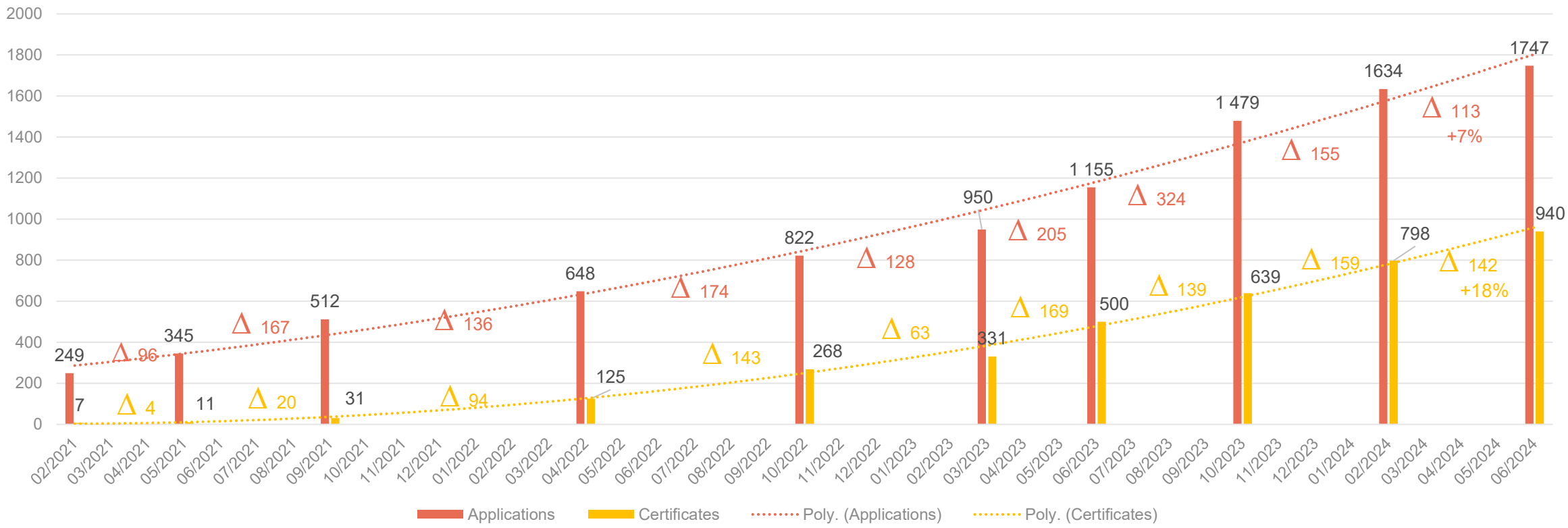
Tot. valid IVDD certificates 1.551

European Commission

IVDR applications lodged and certificates issued

IVD

June 2024
IVDR Applications: 1.747
IVDR Certificates: 940



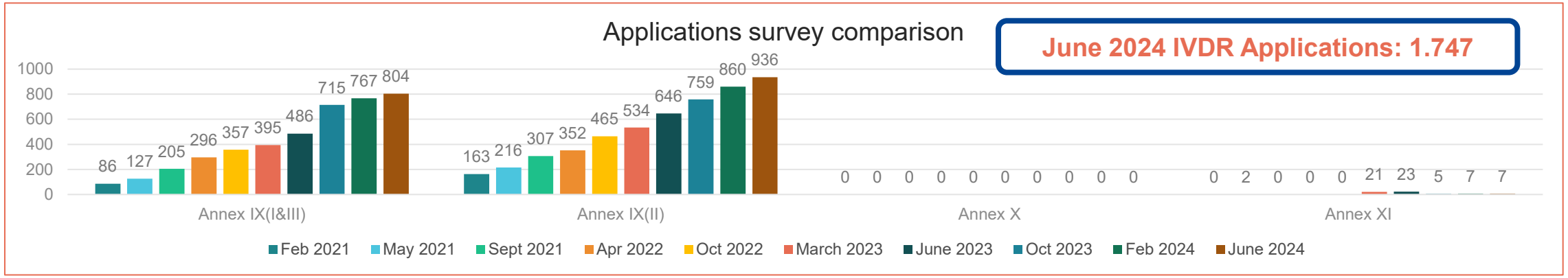
Notes: Designated NBs for IVDR: 12

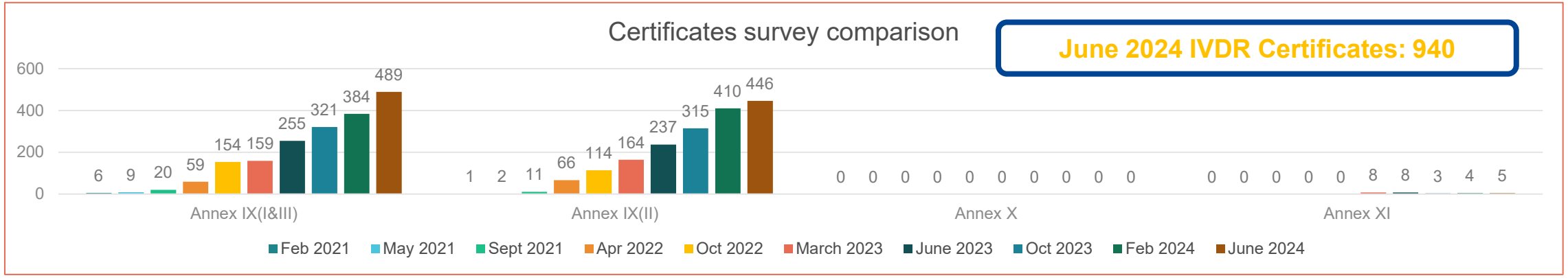
- Δ (Delta) = Difference in IVDR Applications / IVDR Certificates from one survey to the next one
- **Applications lodged**: This number includes **all applications lodged (syn. filed) so far** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 30/06/2024), 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 30/06/2024) under the IVDR.
- The dotted line shows the polynomial trend line (grade 2).

European Commission

IVD

IVDR applications and certificates by annex – surveys comparison





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 30/06/2024), 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 30/06/2024) under the IVDR **by annex**.

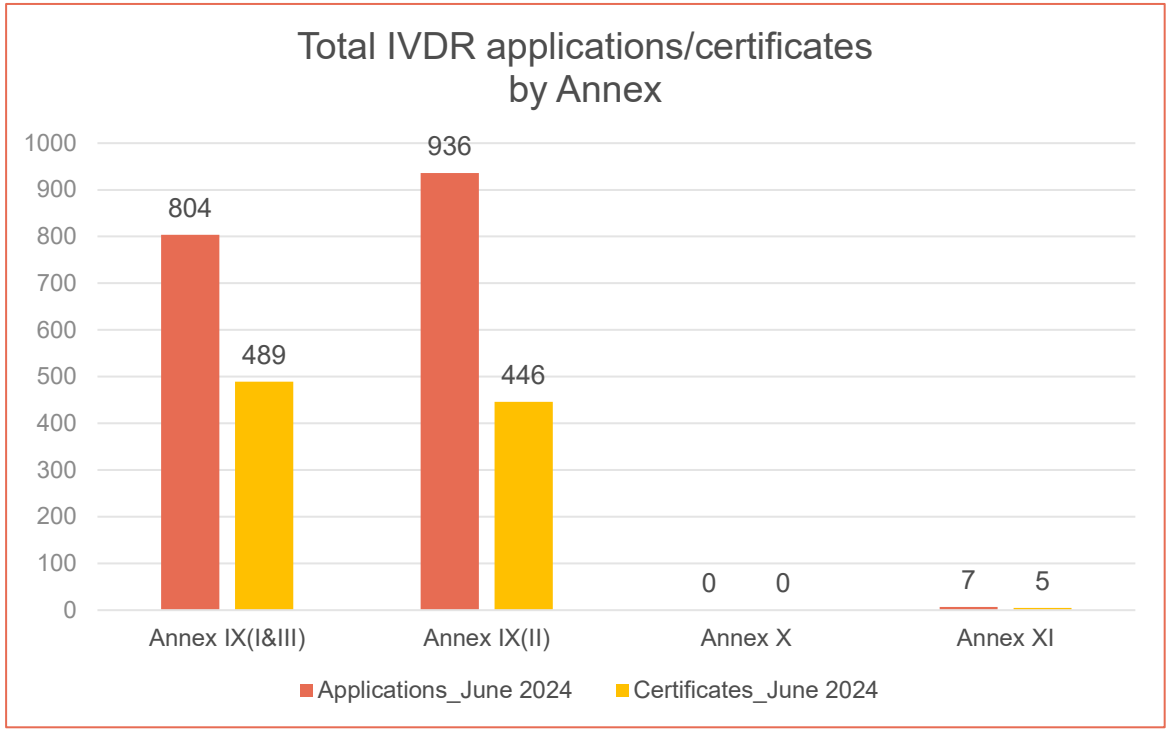
European Commission

IVDR applications and certificates by annex

IVD

Ⓜ

June 2024
IVDR Applications: 1.747
IVDR Certificates: 940



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 30/06/2024), 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 30/06/2024) under the IVDR by annex.
- **Class D devices** are **included** in the total number of applications/certificates.

European Commission

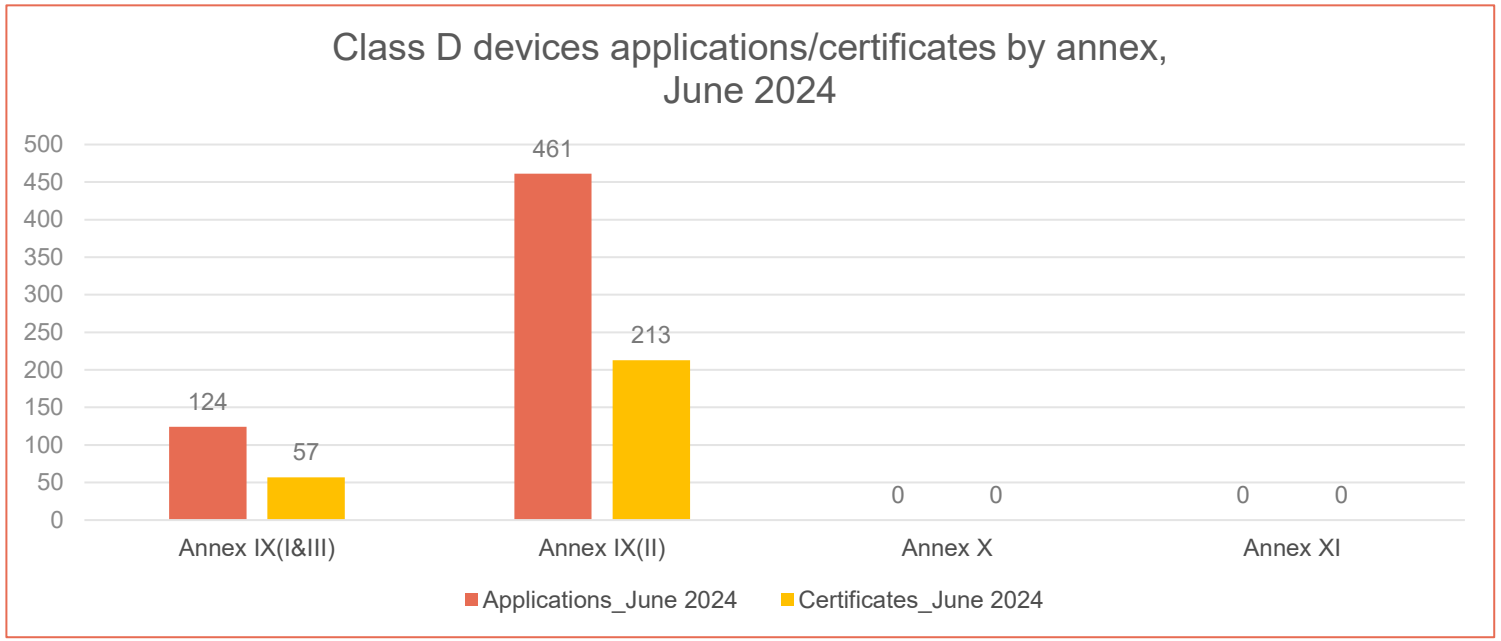
Class D devices applications and certificates

IVD

Ⓜ

June 2024
IVDR Applications: 1.747
IVDR Certificates: 940

June 2024:
Class D devices Applications: 585
Class D devices Certificates: 270



Notes:

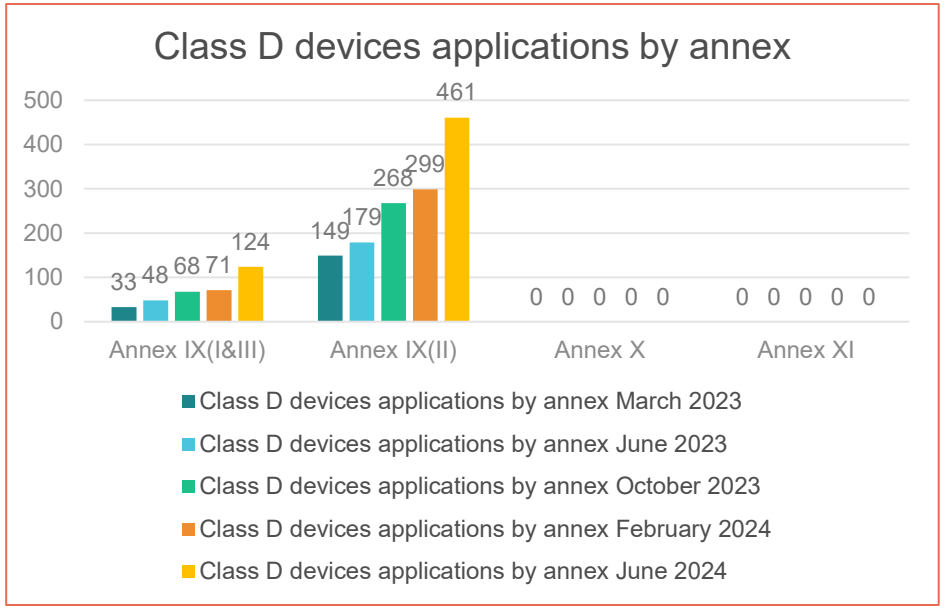
- **Applications lodged by annex:** This number includes all applications lodged (syn. filed) by annex according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 30/06/2024), 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 30/06/2024) 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.

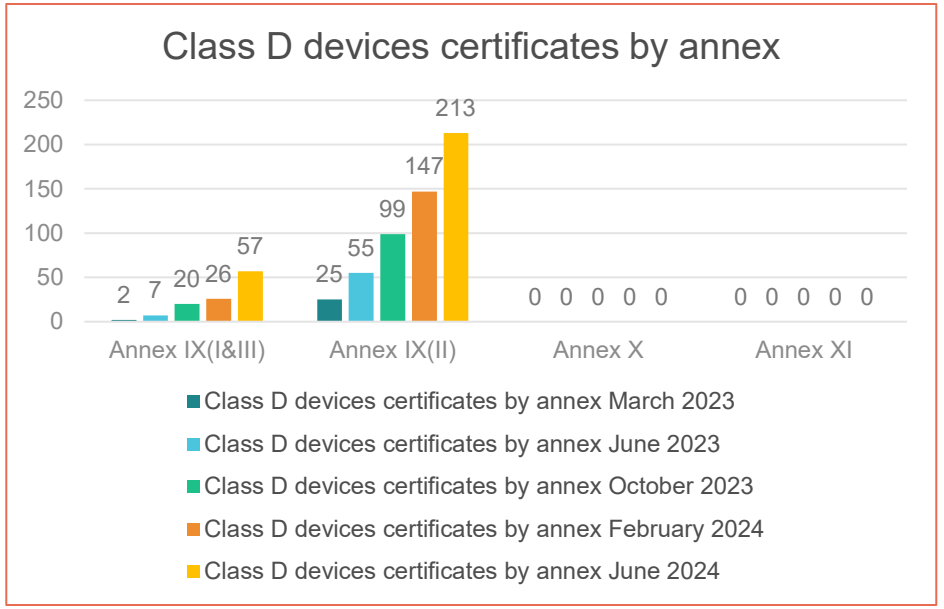
European Commission

Class D IVDs applications and certificates development

IVD

June 2024:
Class D devices Applications up to now: 585
Class D devices Certificates up to now: 270





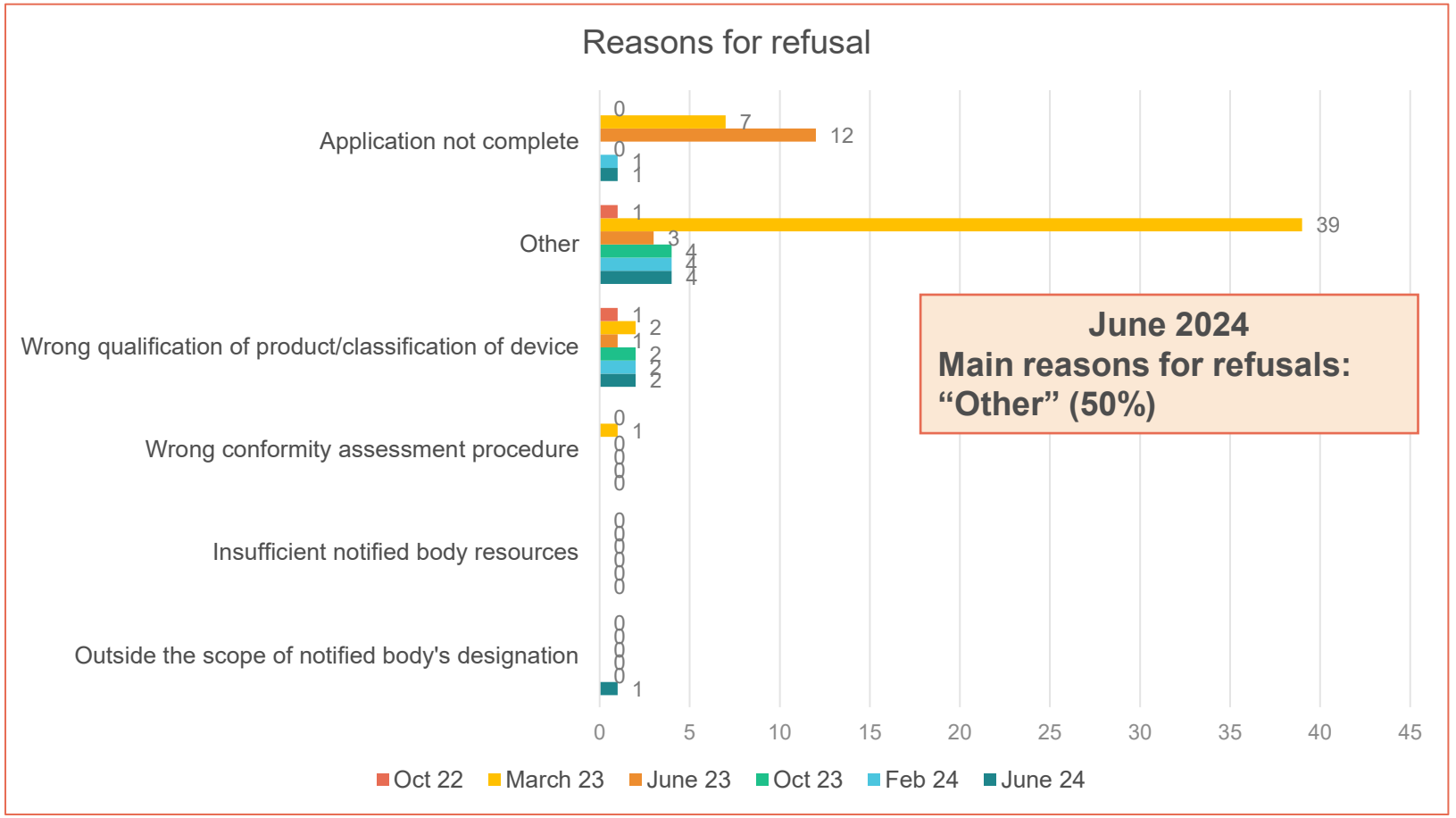
Note:
Applications lodged by annex: This number includes all applications lodged (syn. filed) by annex according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in NANDO to the date of the survey up to **30/06/2024**), i.e.: applications with 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.

Note:
Certificates issued by annex: This number includes certificates issued so far (from designation up to **30/06/2024**) under the IVDR by annex.

European Commission

IVD

IVDR applications - reason for refusal



June 2024
IVDR Applications: 1.747
IVDR Certificates: 940

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

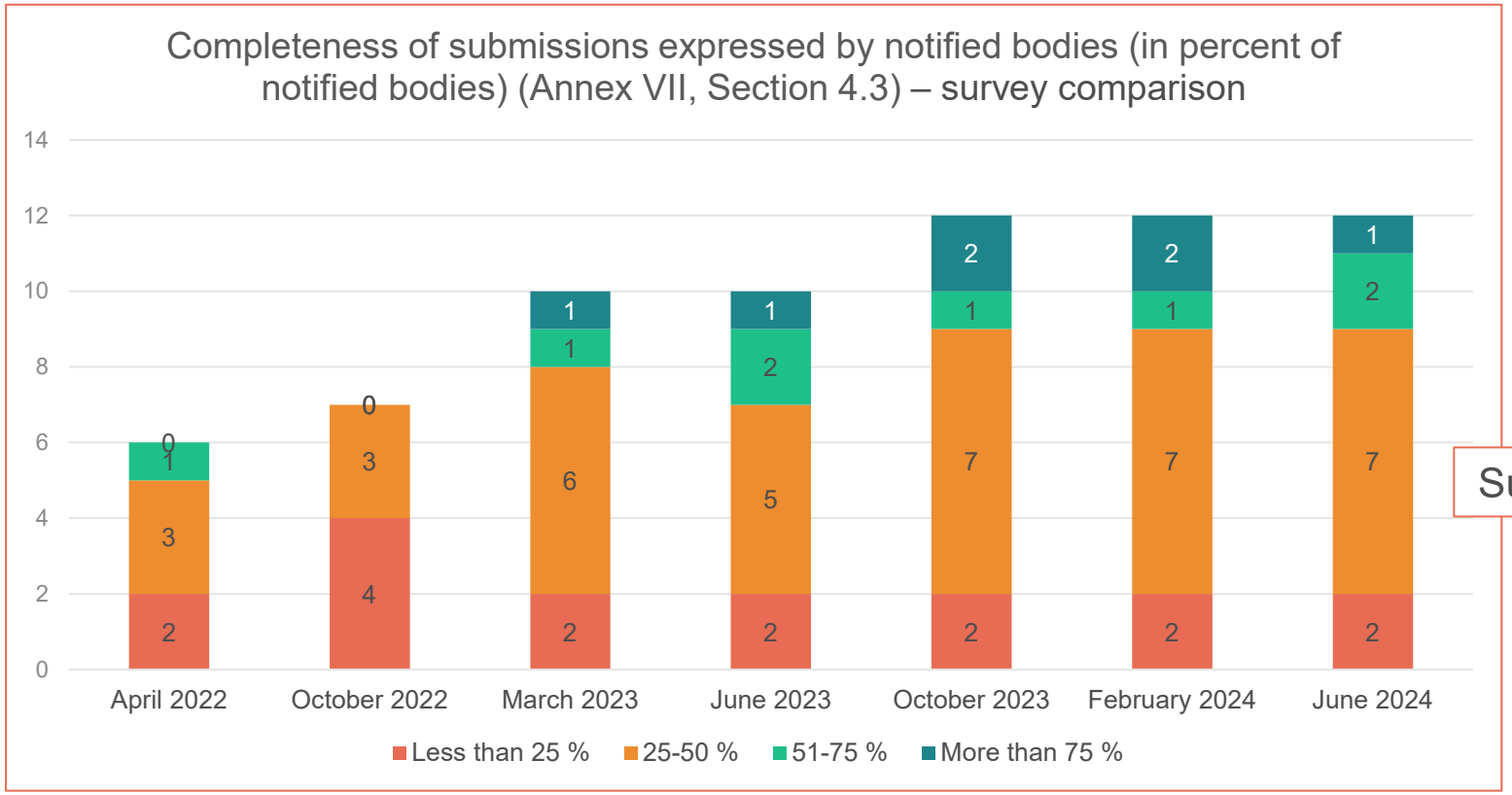
Notes:

- 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, February 2024 and June 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"
- June 2024: Reasons were indicated by **one** NB only. "Other" reasons: "nonconformities not solved", "withdrawal of client", "assessment resulted in negative outcome"

European Commission

IVD

Completeness of submissions



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

3 out of 12 NBs in June 2024

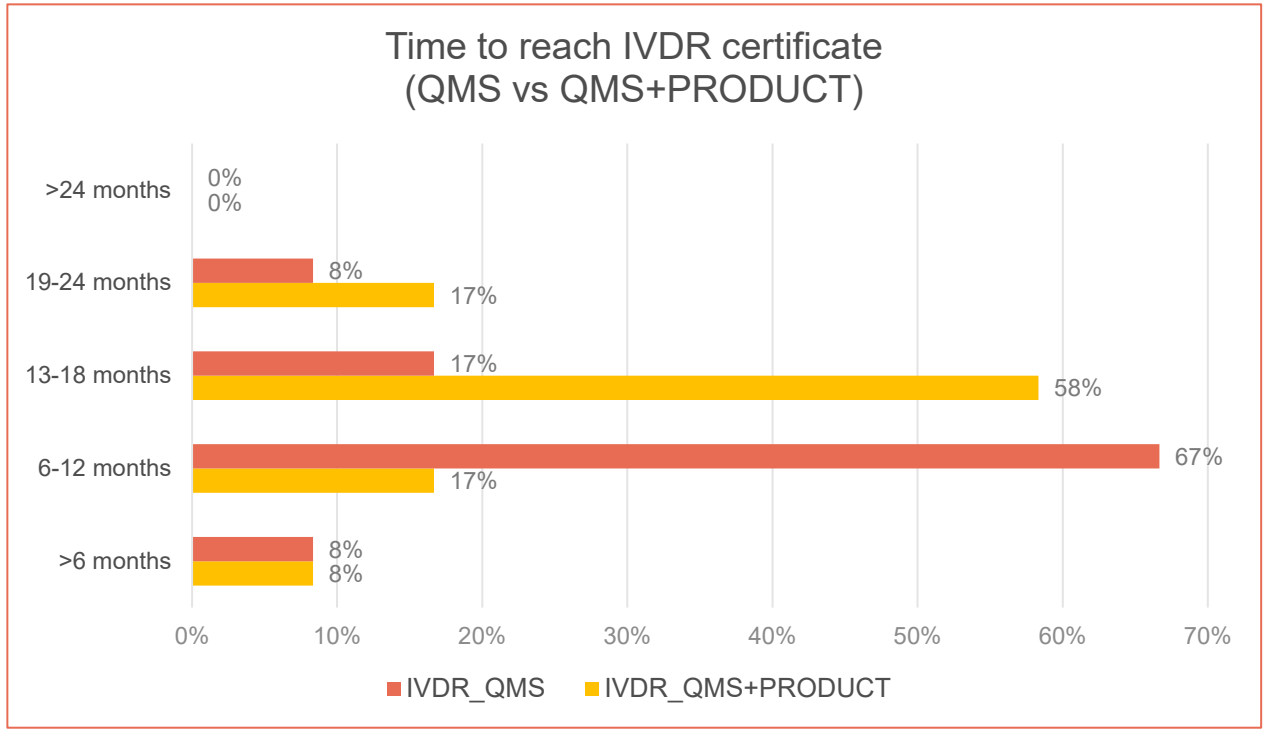
Submissions largely incomplete*

* 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



June 2024
IVDR Applications: 1.747
IVDR Certificates: 940

IVDR QMS certificates

- For 67% of NBs: 6-12 months to issue a new QMS certificate
- 17% of NBs: 13-18 months

IVDR QMS+PRODUCT certificates: longer time

- 58% of NBs: 13-18 months
- 17% of NBs: 19-24 months

Notes:

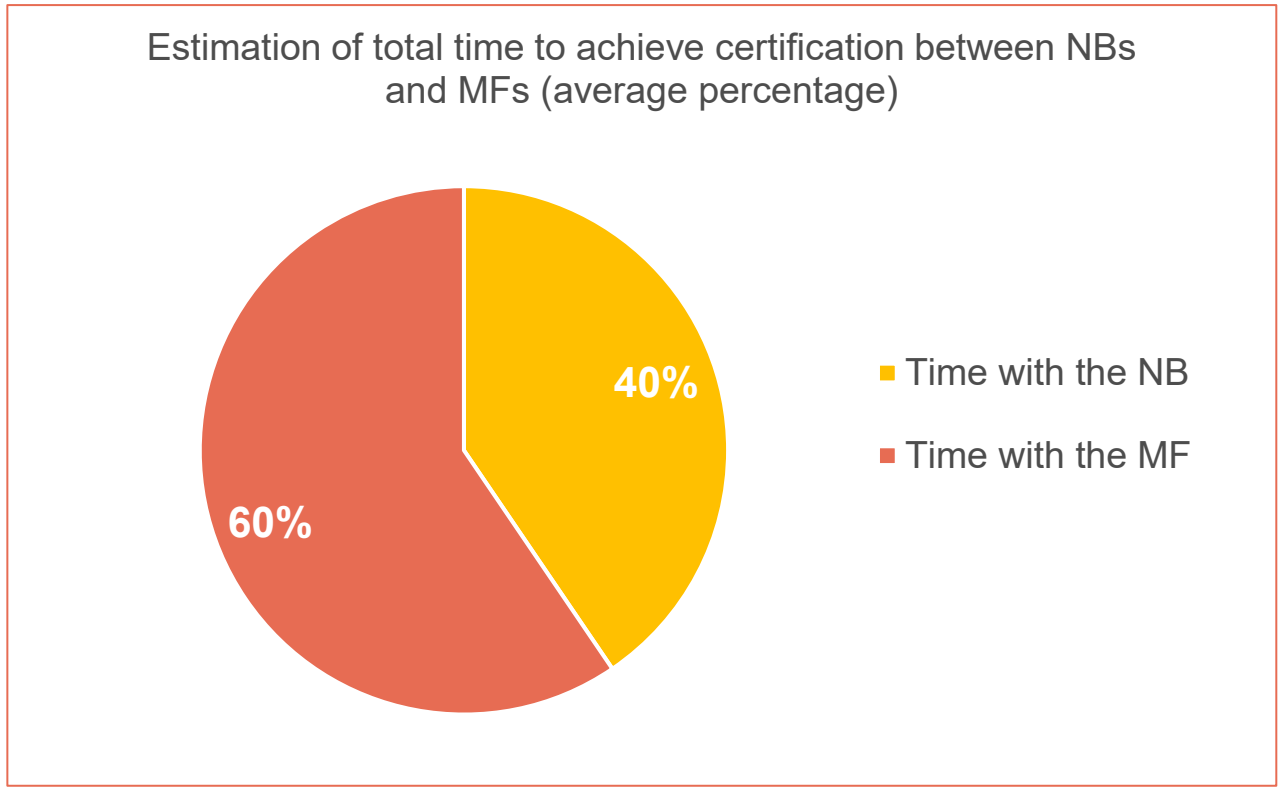
- Data of 12 NBs
- This indicator shows the time to reach issuance of a new EC certificate (from written agreement signed to issuance) under IVDR.
- One NB specifically pointed out that this is an estimate as they have not issued certificates yet.

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 10 NBs indicated >50% of the time with the MF
- **2** out of 10 NBs indicated >50% of the time with the NB
- **1** out of 10 NBs indicated that the time is equally divided (50:50) between NB and MF

Time with the notified body

- Minimum value: 20%
- Maximum value: 75%

Time with the manufacturer

- Minimum value: 25%
- Maximum value: 80%

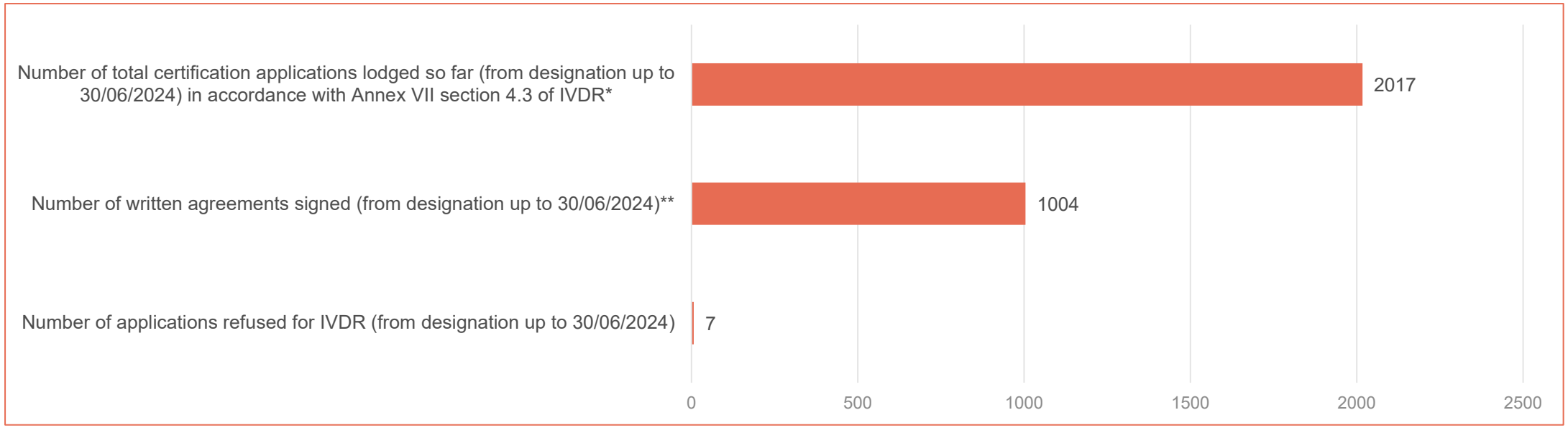
Notes:

- Data of 10 NBs (data of NBs that have not yet issued certificates were excluded)
- 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.

European Commission

IVDR applications filed and refused, written agreements signed

IVD



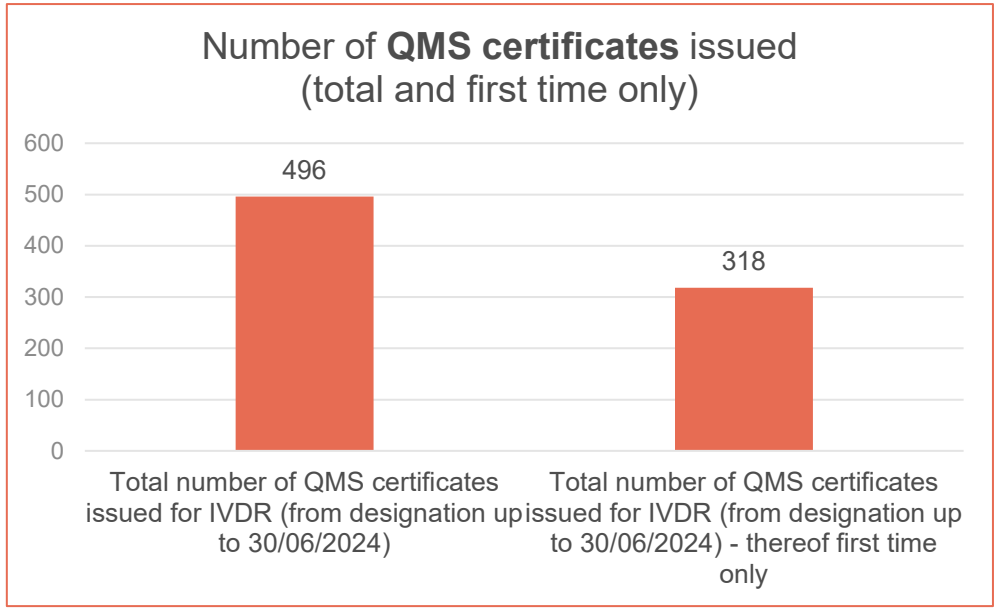
Notes:

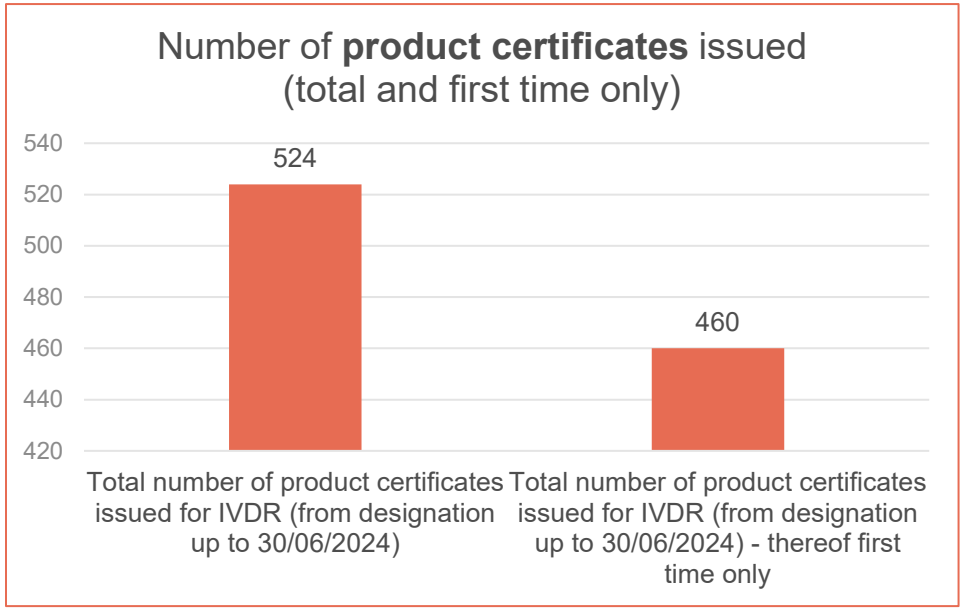
- **Designated NBs for IVD:** 12
- *** Applications lodged**: This number includes **all applications lodged (syn. filed) so far** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 30/06/2024), 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.

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.

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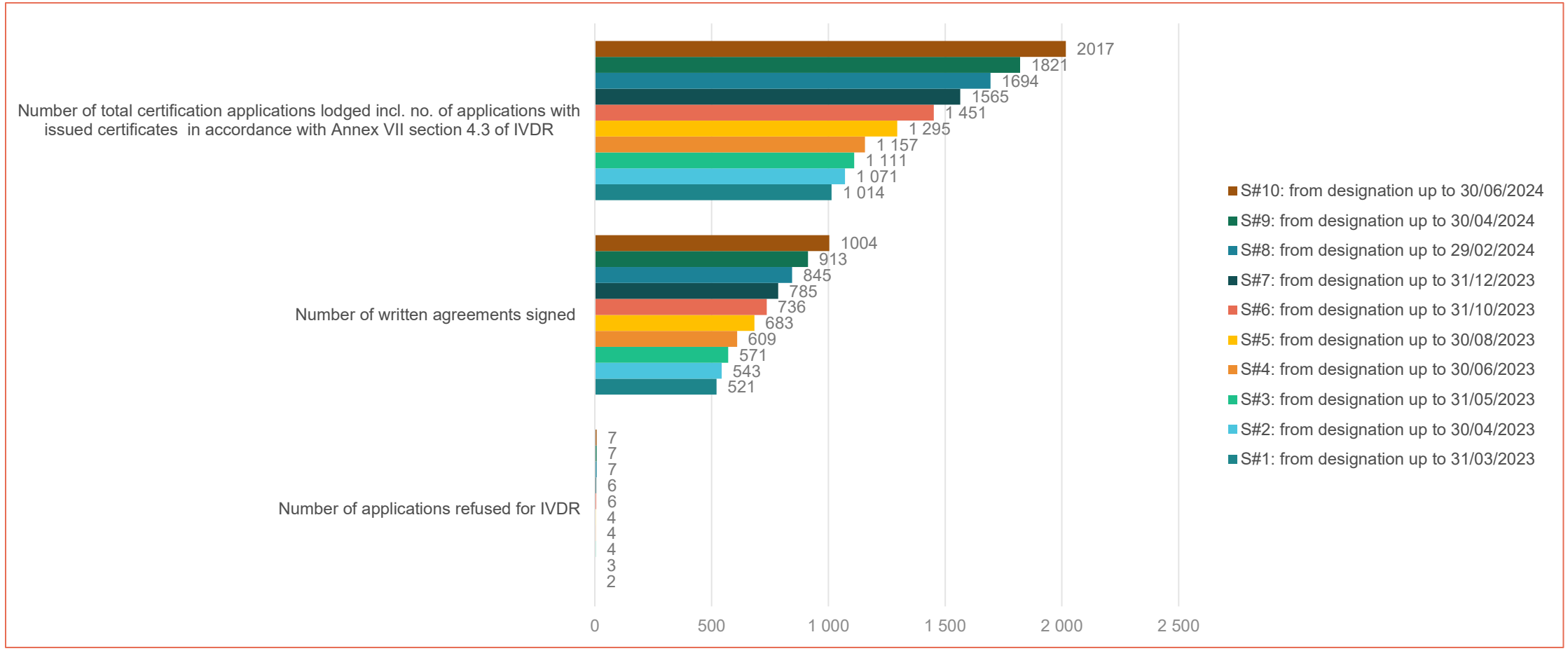
Survey comparison – March 2023 to June 2024



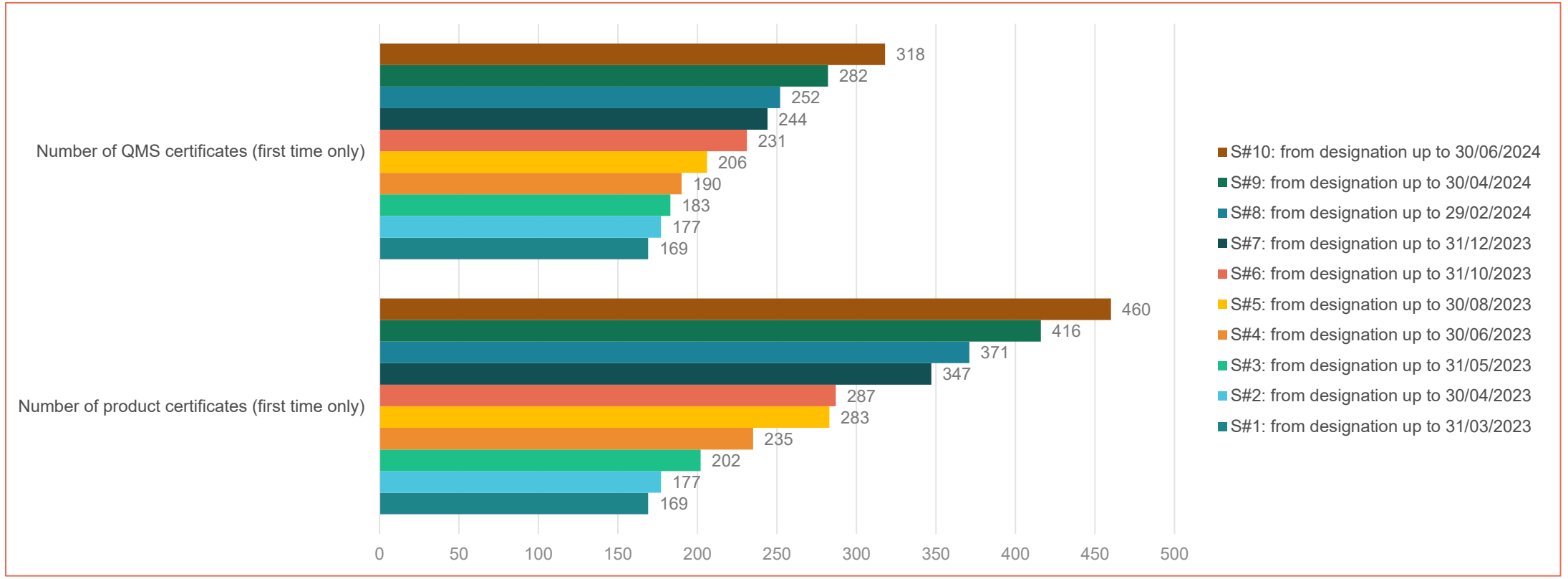
S = Survey; # = number

Notes:

- Designated NBs for IVDs: S#1 to S#5: 10; S#6 to S#10: 12
- 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.

IVD

Survey comparison – March 2023 to June 2024



S = Survey; # = number

Notes:

- Designated NBs for IVDs: S#1 to S#5: 10; S#6 to S#10: 12
- 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.

Thank you

Contact for questions: medical.devices@goeg.at

European Commission