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

Survey results of the 12th NB survey (MDR/IVDR) with data status 31 October 2024

(small, medium and large dataset)

8 May 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.
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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

CIVIC CONSULTING

European Commission

Acknowledgements

The study team would like to sincerely thank the following institutions and people for the support in the 12th NB survey:

- All **51 notified bodies** designated under MDR and/or IVDR as of 6 November 2024 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**.

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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
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

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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

European Commission

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

About

NB surveys already conducted by the study team

NB survey	Survey period (survey launch – survey closure)	Requested dataset* SD = small dataset MD = medium dataset LD = large dataset TE = targeted evaluation	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 30/08/2024	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%)**

Survey results included in the published dashboard

12th NB survey results (except for TE) are presented in this PowerPoint presentation

* 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**.
- The **targeted evaluation** is a set of questions asked **only once** on behalf of DG SANTE.

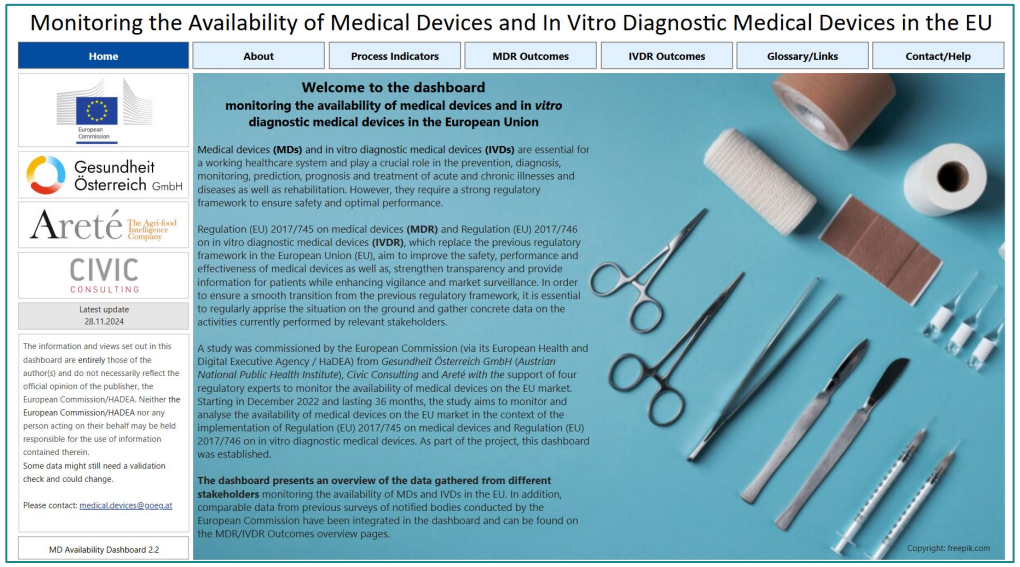
** **About the targeted evaluation:** Evaluations conducted by the European Commission assess how well a specific policy intervention has performed (or is performing) and whether it is still relevant and justified. Evaluations are a key component of the lifecycle of any policy intervention. For the MDR 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 NB survey** (conducted in the framework of the 'Study supporting the monitoring of the availability of medical devices on the EU market') was used to ask NBs questions that are relevant for the Targeted Evaluation.

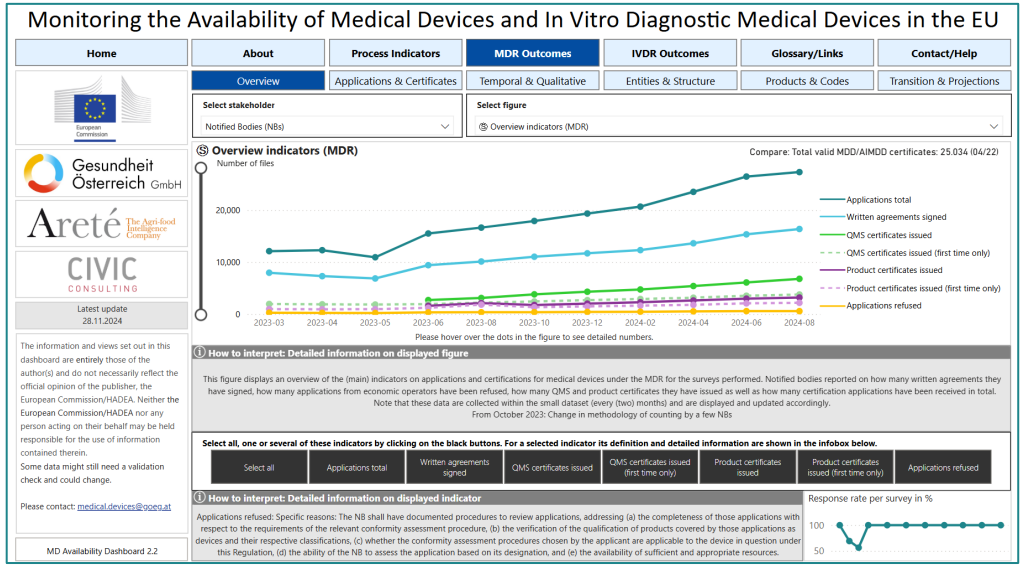
European Commission

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 **12th NB survey conducted at the beginning of November 2024** with **requested data** from notified bodies designated under MDR and/or IVDR **until 31 October 2024**.
  - These survey results are also compared with previous survey data (see data sources).

- **Data sources:**
  - Data collected between April 2023 and November 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, medium and large datasets collected in November 2024.

Ⓢ 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.

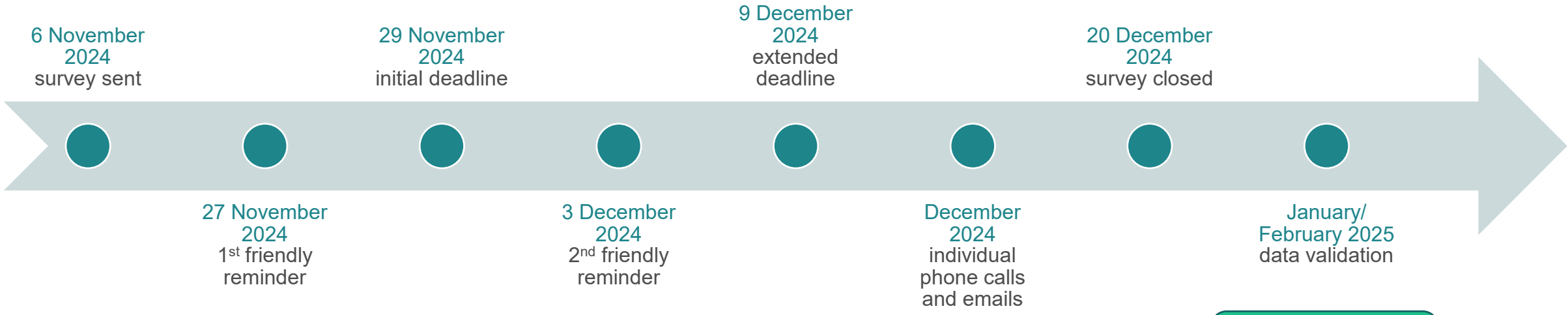
Ⓛ The **large dataset** contains additional data asked to notified bodies **once a year**.

Timeline for the 12th NB survey

(conducted in November 2024 with requested data from designation up to 31/10/2024)

About

51 notified bodies designated under MDR and/or IVDR
(data status: 6 November 2024)



Note: *Out of 51 notified bodies,* ***38 NBs*** *are designated under the* ***MDR*** *only,* ***12 NBs*** *are designated under* ***both the MDR and IVDR****, and* ***1 NB is*** *designated under the* ***IVDR only****.*

Final result
51 responses
(100% response rate)

European Commission

Response rate for the 12th NB survey

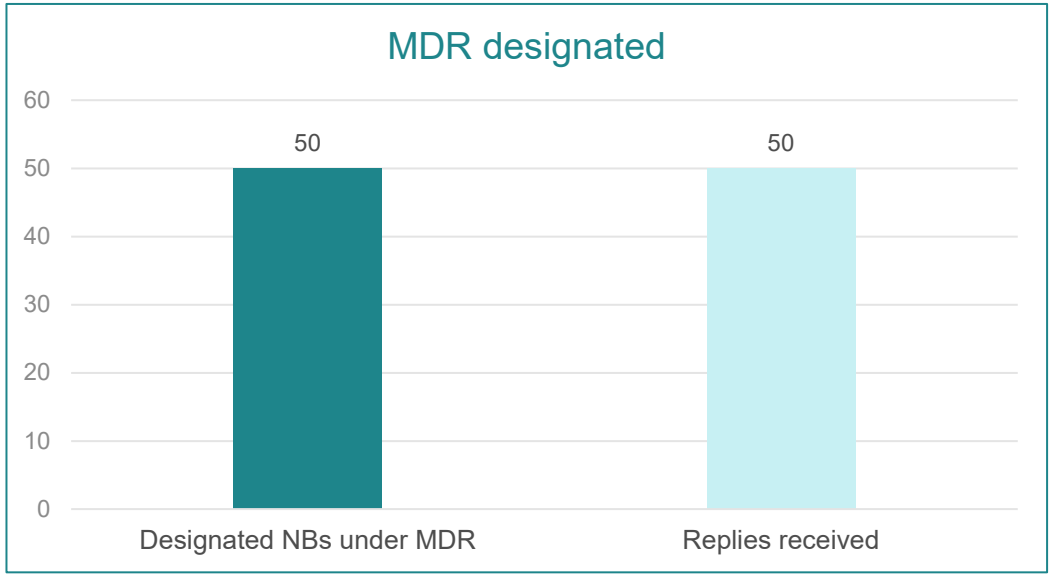
(conducted in November 2024 with requested data from designation up to 31/10/2024)

About

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

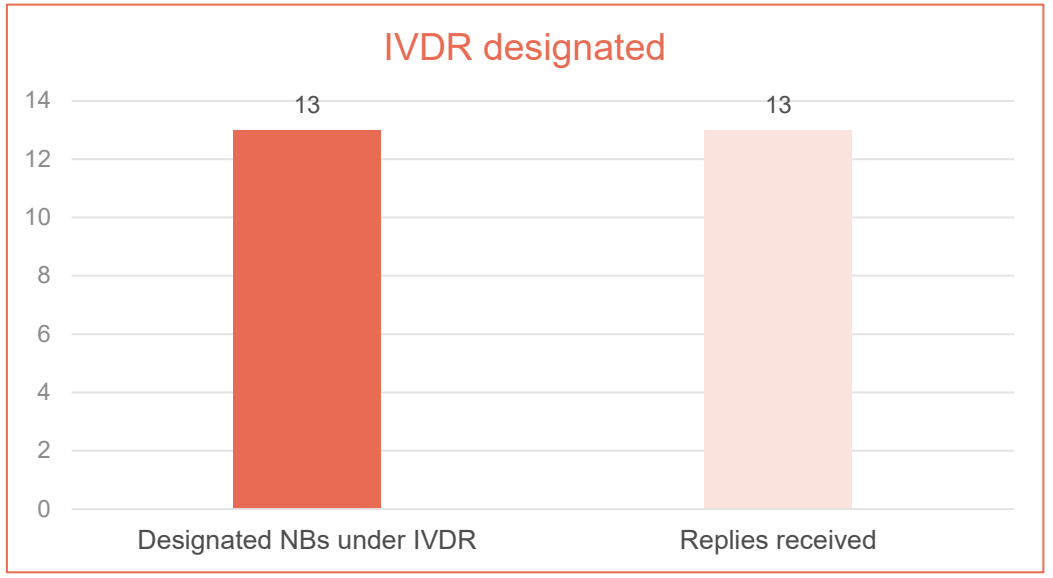
Note: *Out of 51 notified bodies,* ***38 NBs*** *are designated under the* ***MDR*** *only,* ***12 NBs*** *are designated under* ***both the MDR and IVDR****, and* ***1 NB is designated under the IVDR only****.*

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.**

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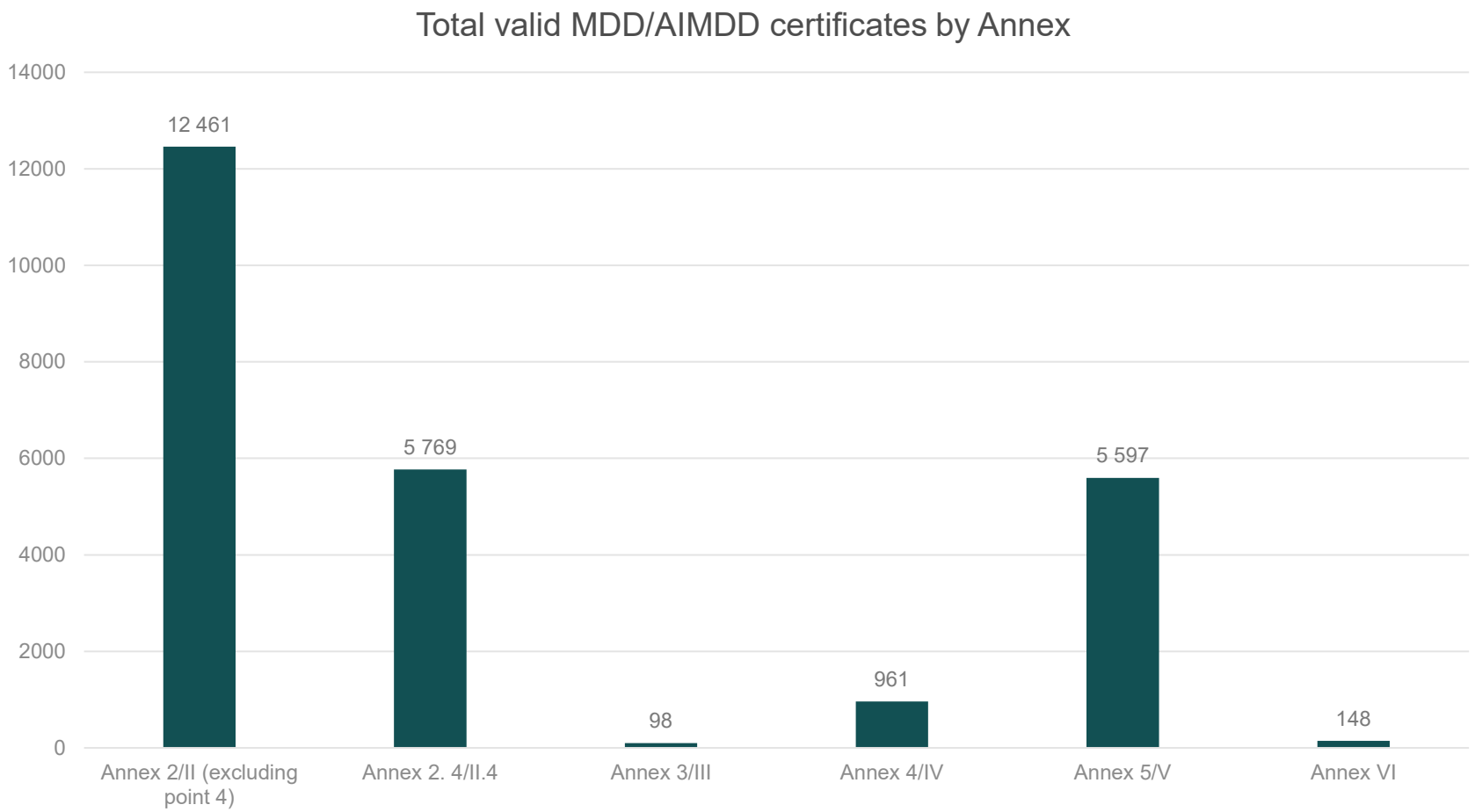
MDD/AIMDD Certificates by Annex (data status: April 2022)

MD

CAVEAT:
Not part of this 12th NB survey, but included for comparison.

MDD/AIMDD Data

Total: 25.034



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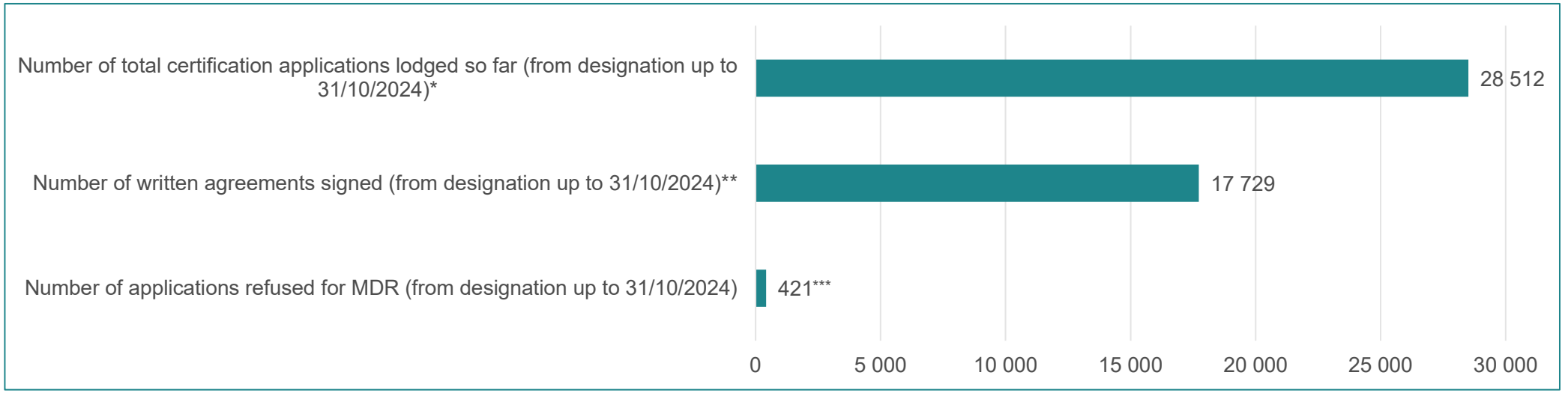
MD

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

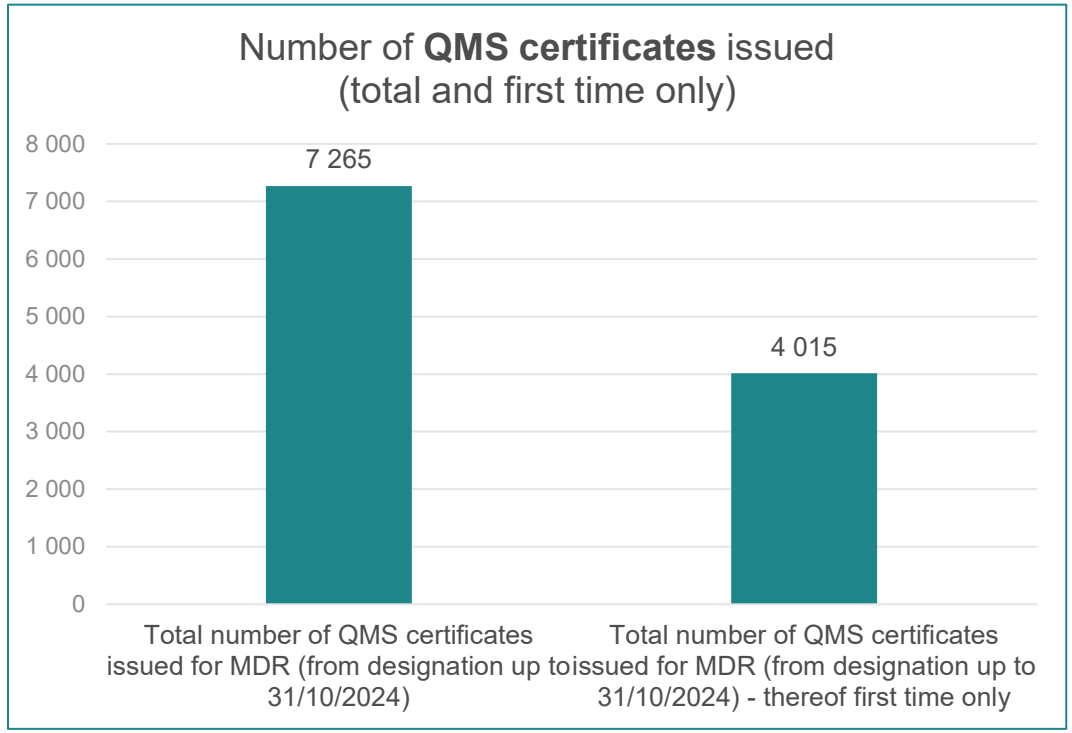


Notes:

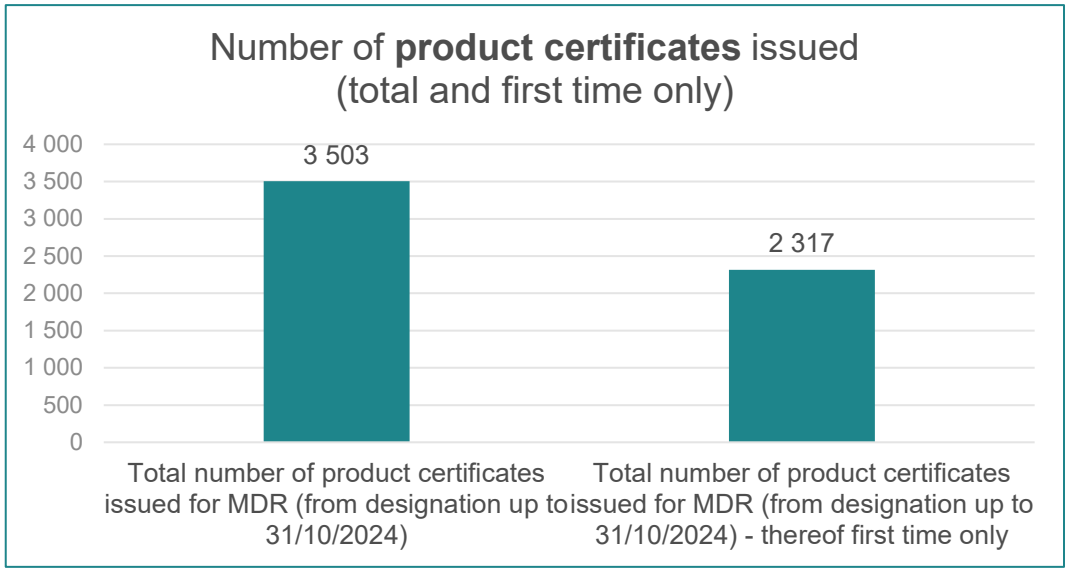
- **Designated NBs for MD: 50**
- *** Applications lodged**: This number includes **all applications lodged (syn. filed) so far** according to MDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 31/10/2024), 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.
- *** Number of applications refused is lower than in the previous dataset as there was a change in methodology of counting by some NBs

European Commission

MDR number of QMS / product certificates issued



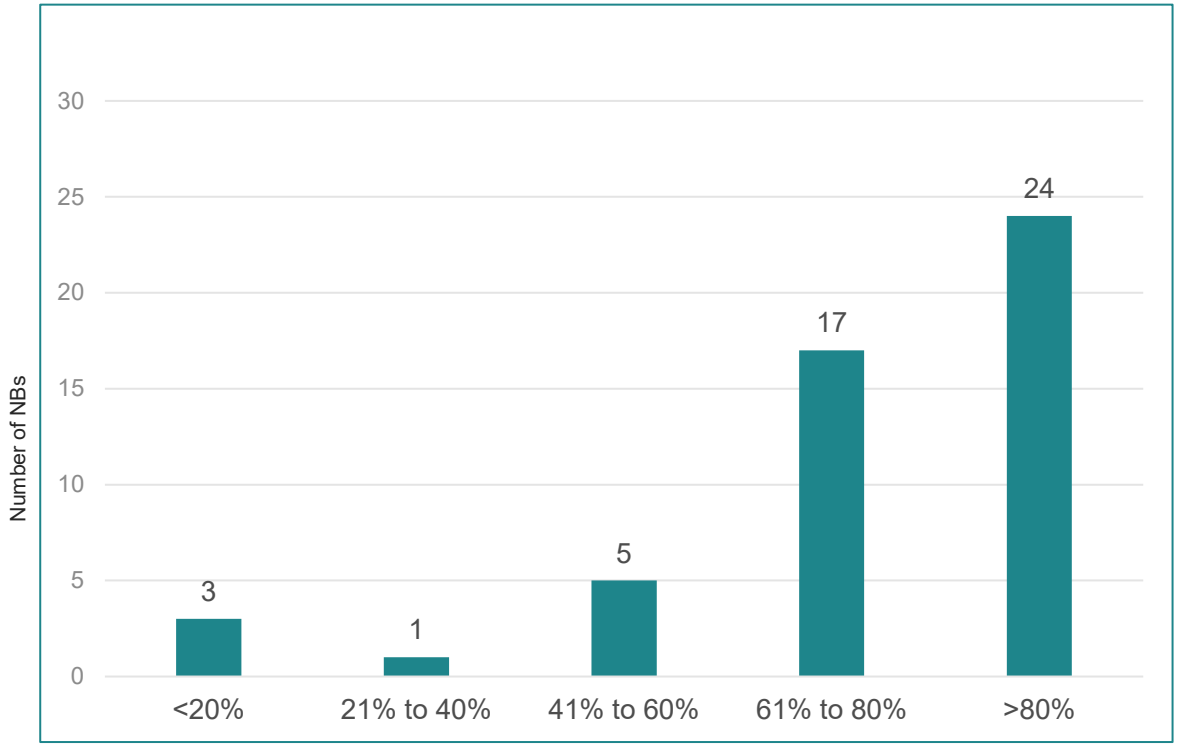
Note QMS Certificates: This relates to Annex IX Chapter I or Annex XI Part A according to MDR.



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

European Commission

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



- **17 out of 50 NBs (34%)** reported that **61-80%** of the MDR applications cover the scope of (AI)MDD certificates
- **41 out of 50 NBs (82%)** indicated that MDR applications **cover more than 60%** of the scope of (AI)MDD certificates.

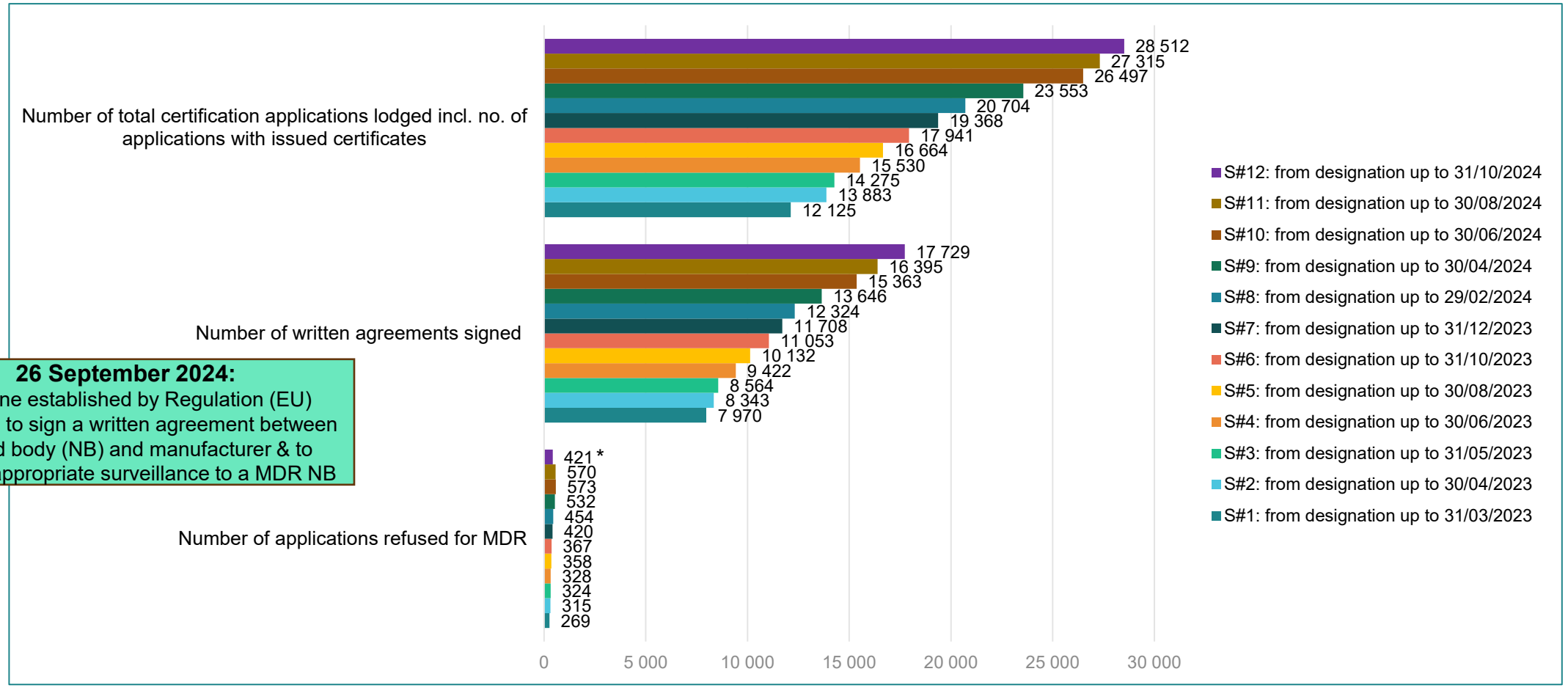
Calculation:
- meaning of scope coverage: MDD certificate covers 100 products, MDR application covers 50 products then coverage of the MDR = 50% of the MDD cert

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%

European Commission

Survey comparison – March 2023 to October 2024

MD



26 September 2024:
Deadline established by Regulation (EU) 2023/607 to sign a written agreement between notified body (NB) and manufacturer & to transfer appropriate surveillance to a MDR NB

S = Survey; # = number

Notes:
- Survey **#12:** 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 of methodology of counting by some NBs.

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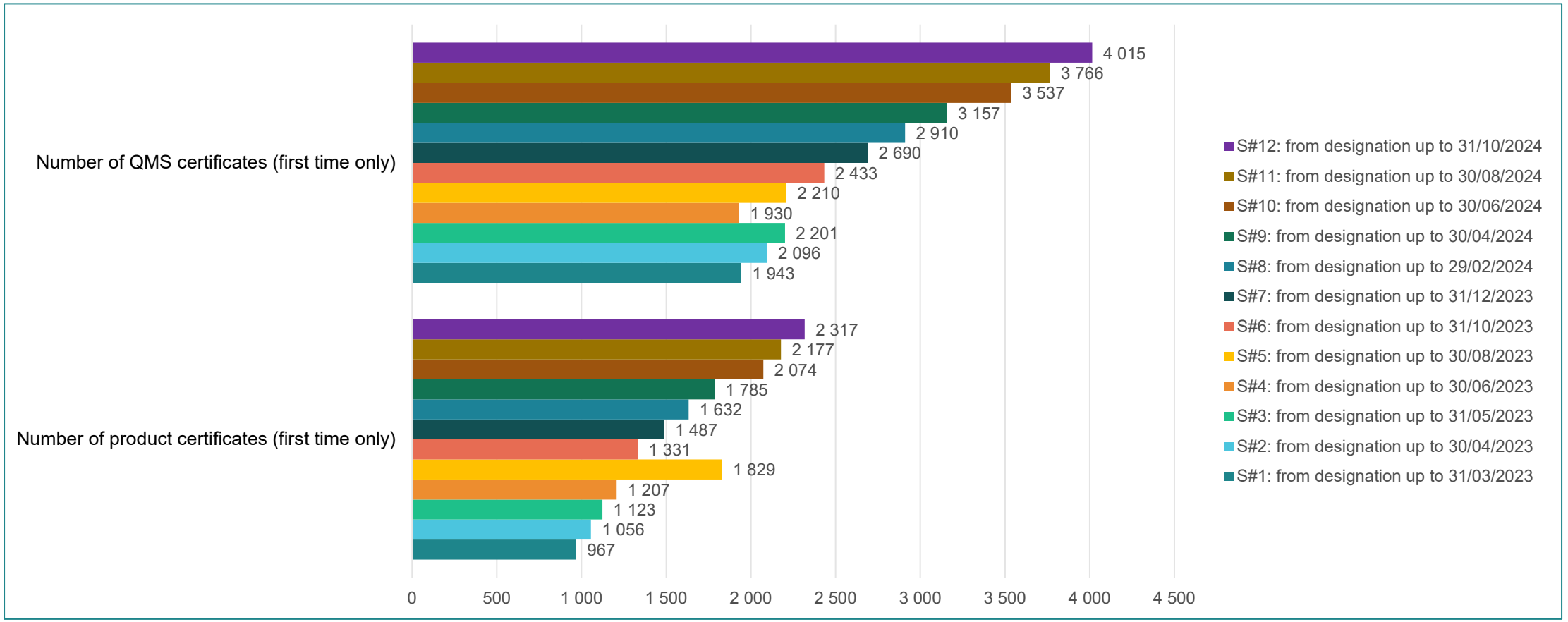
Survey comparison – March 2023 to October 2024

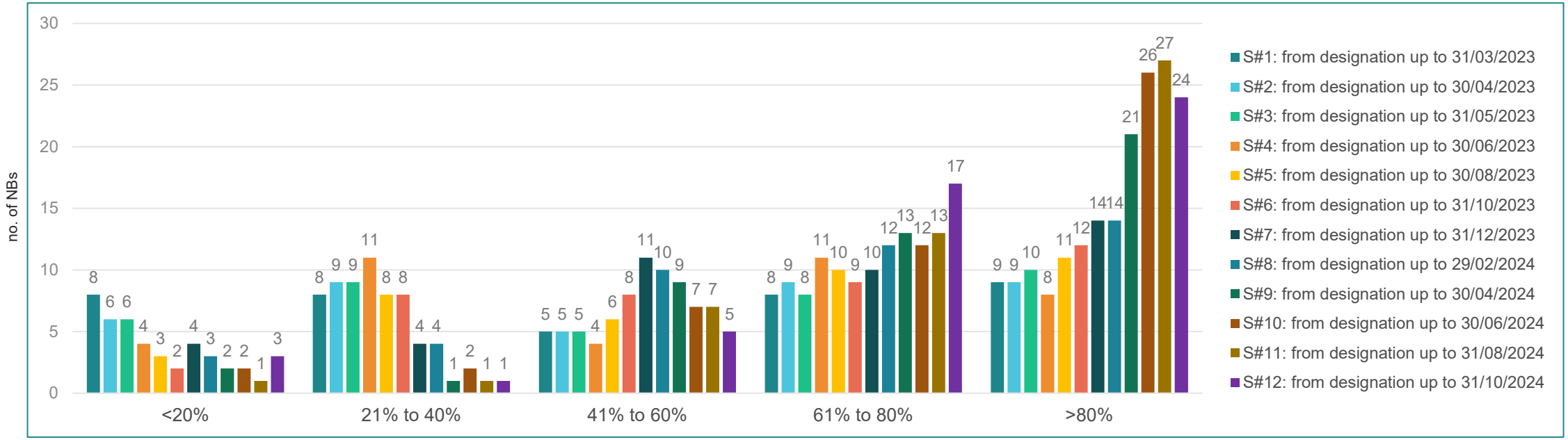


S = Survey; # = number

Notes:

- Survey **#12:** 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 and #5.

Survey comparison – March 2023 to October 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 **#12:** 50 designated NBs for MD

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

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)

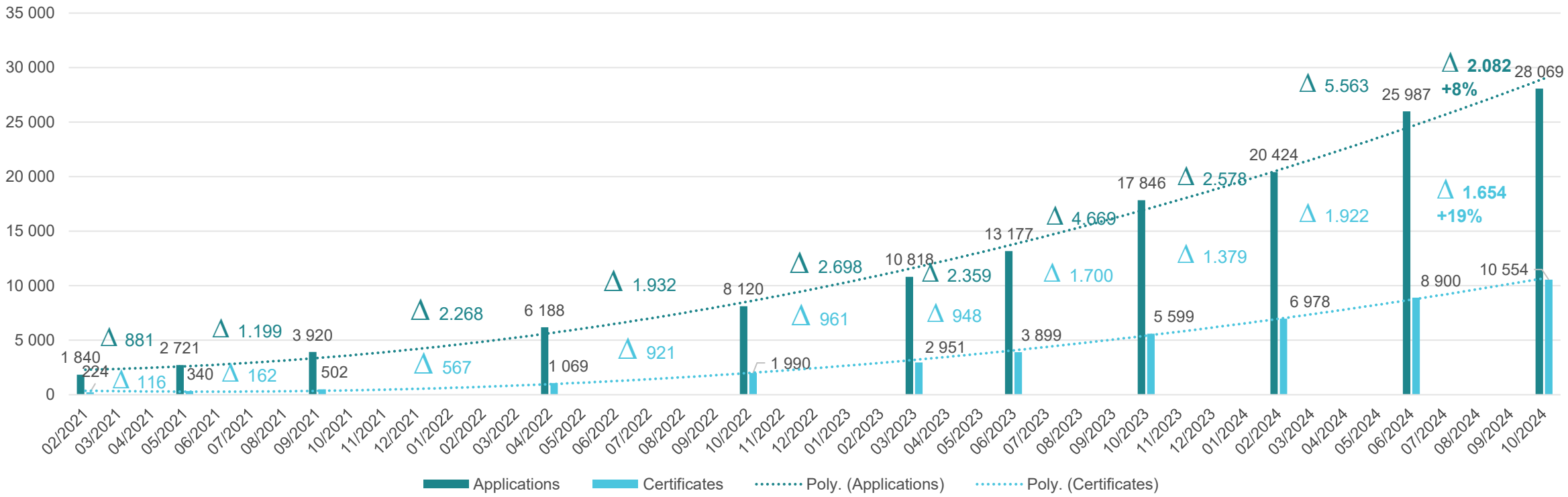
MD

Ⓜ

October 2024

MDR Applications:
Total number of applications filed by Annex Ⓜ: 28.069*

MDR Certificates:
Total number of certificates by Annex Ⓜ: 10.554

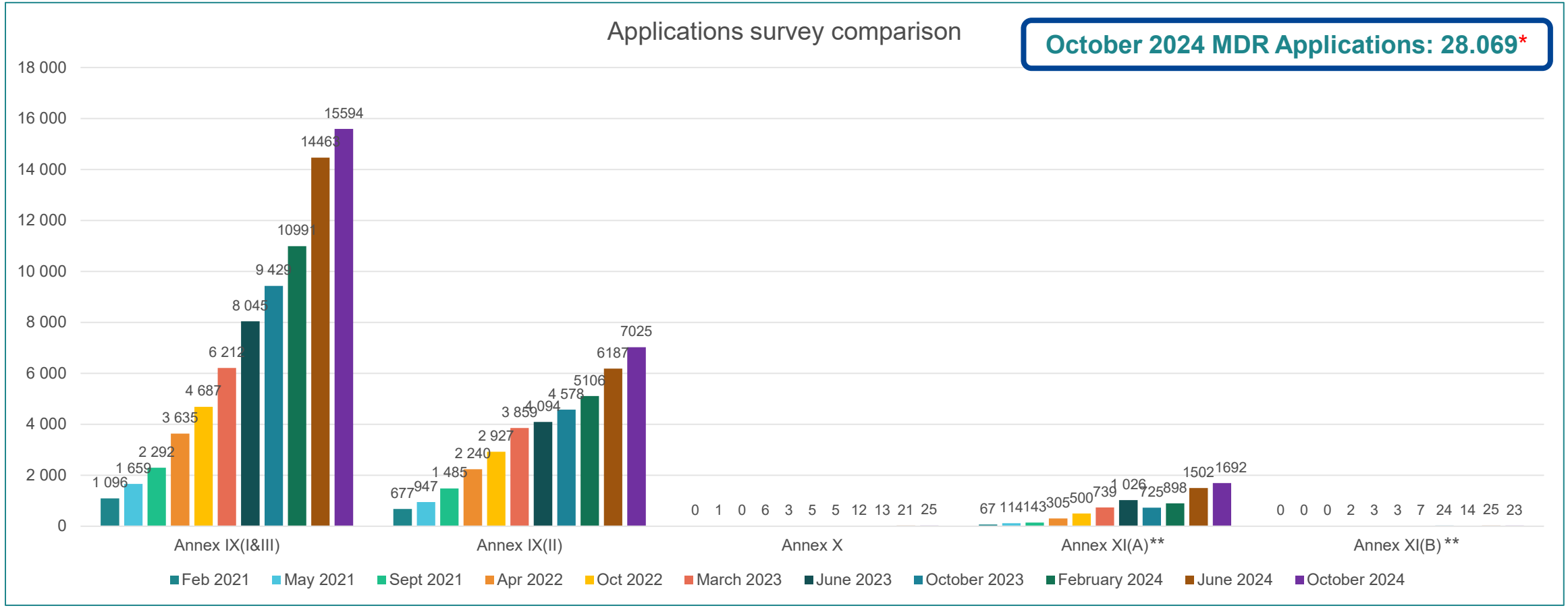


Notes: Designated NBs for MD: 50

* 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 31/10/2024), 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 31/10/2024) under the MDR.
- The dotted line shows the polynomial trend line (grade 2).

MDR applications by annex – survey comparison



Notes:

- Designated NBs for MD: 50; NBs that included Annex XVI products in the numbers provided: 26
- * 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 31/10/2024), 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.

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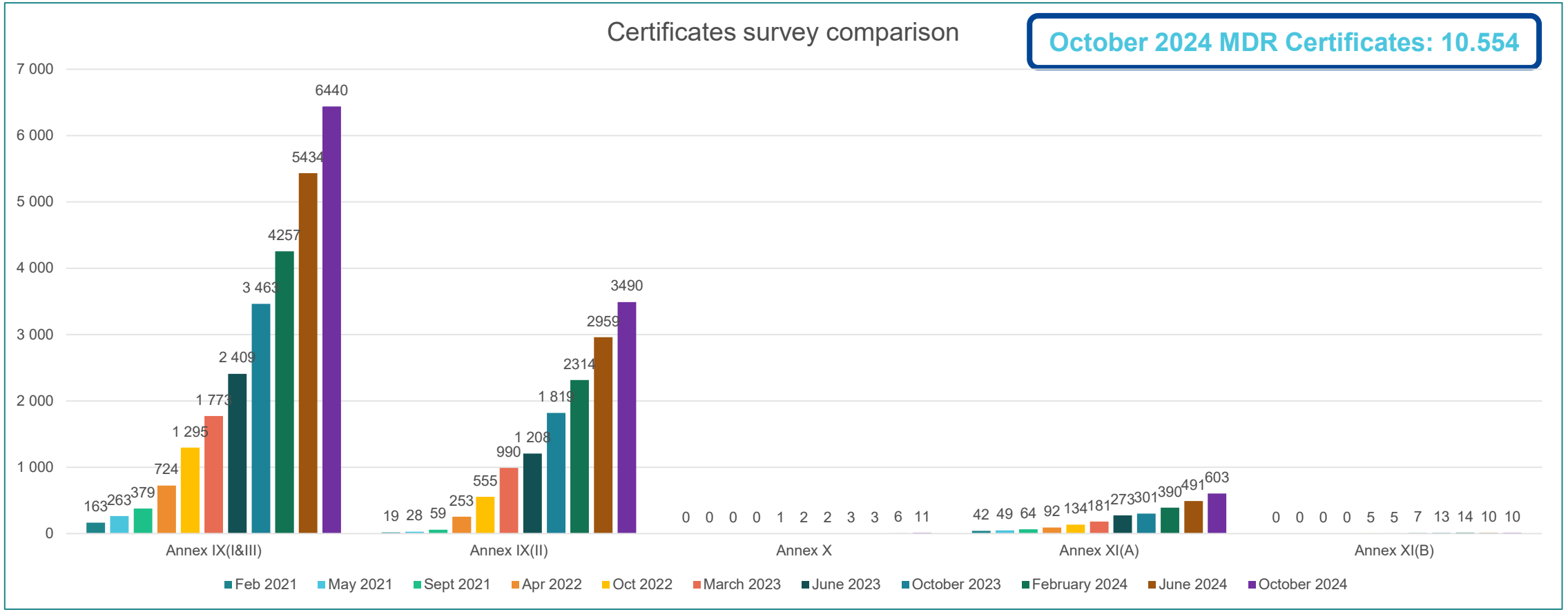
MDR certificates by annex - survey comparison



Notes:

- Designated NBs for MD: 50; NBs that included Annex XVI products in the numbers provided: 26
- * The data shown comes from the medium data set
- ** Change in methodology of counting by a few NBs, leading to decreases.
- **Certificates issued by annex:** This number includes **certificates issued so far** (from designation up to 31/10/2024) under the MDR **by annex**.

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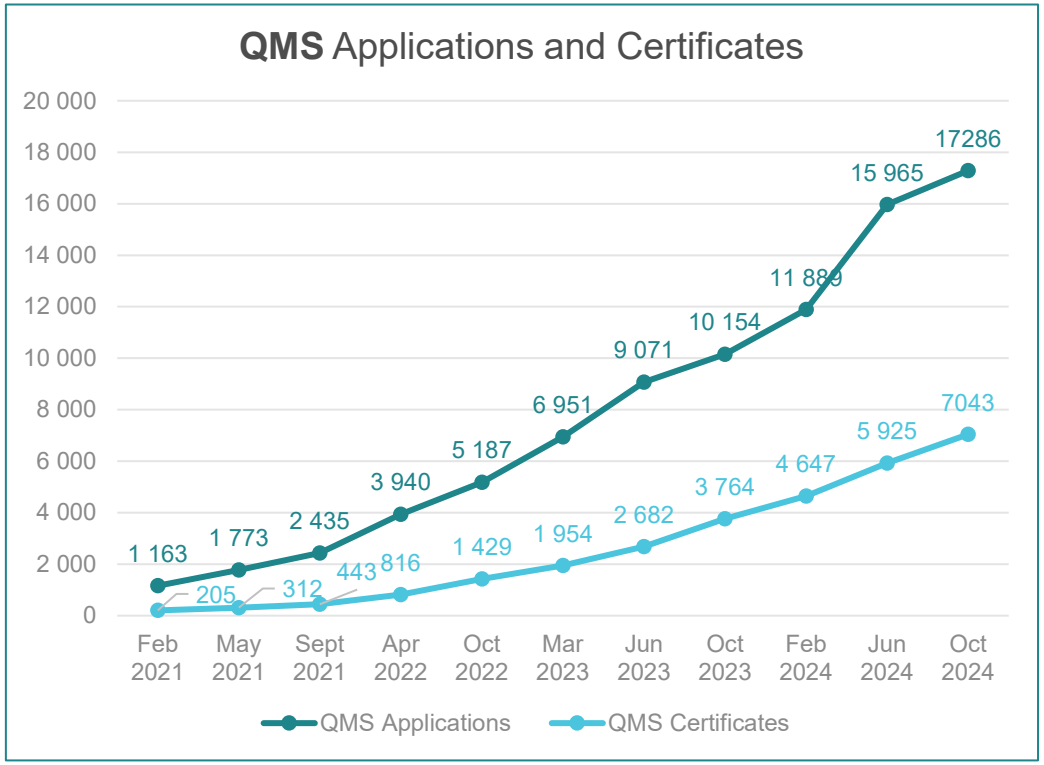
MDR applications and certificates by type (QMS vs Product) – survey comparison

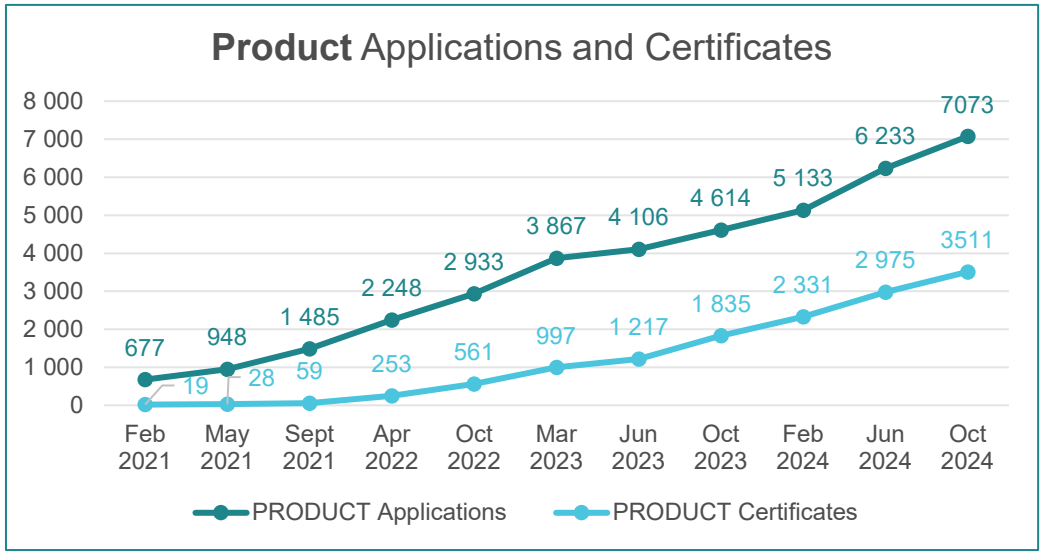
MD

October 2024
MDR Applications: 28.069*
MDR Certificates: 10.554

* 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: 4.572
Note: This number is included in the total number of applications.

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Specific additional procedures according to Annex IX (II)

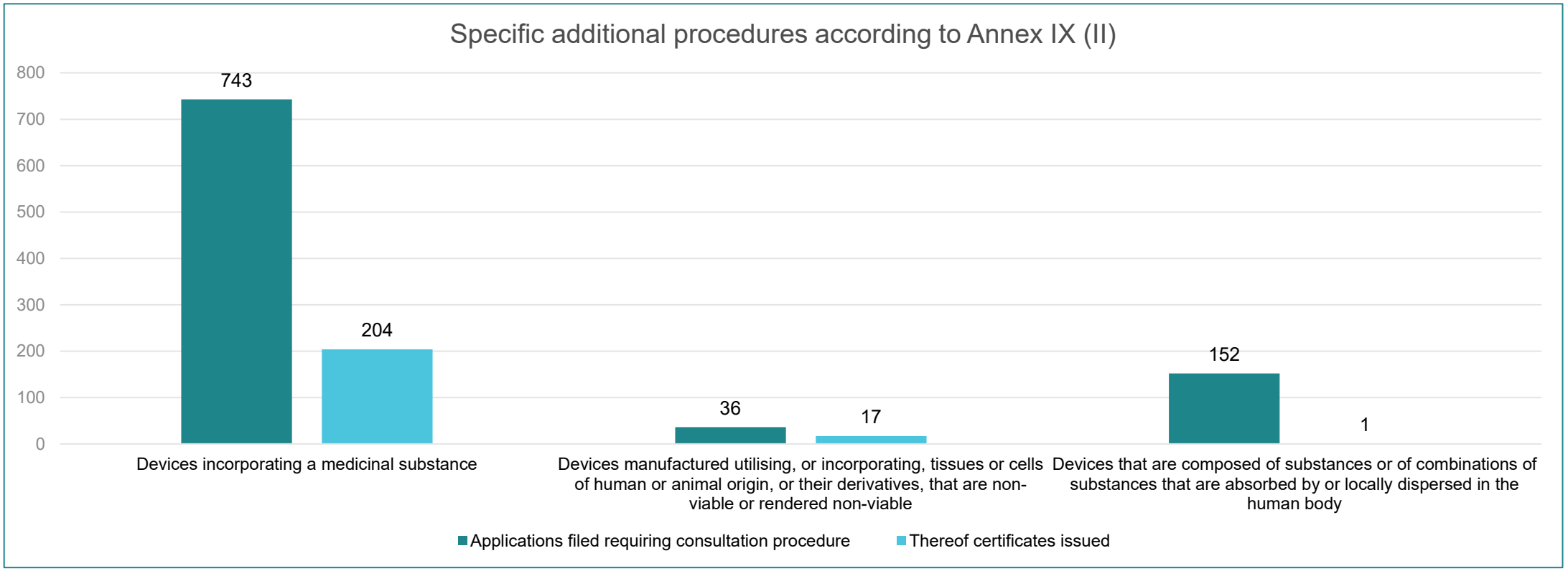
MD

Ⓜ

October 2024

MDR Applications:
Total number of applications filed by Annex Ⓜ: 28.069*

MDR Certificates:
Total number of certificates by Annex Ⓜ: 10.554



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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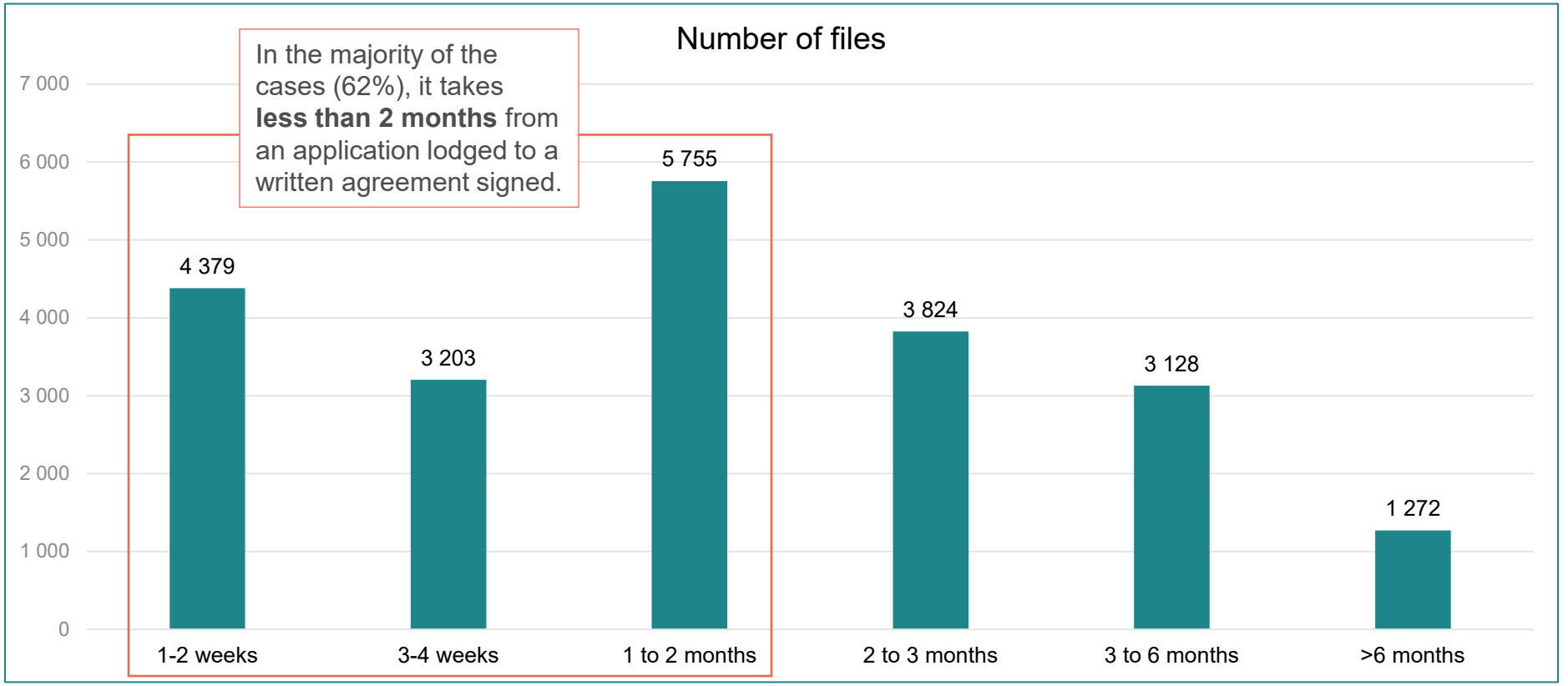
Average timeframe to written agreement signed

MD

Average timeframe between application lodged and written agreement signed:



Note: Data of 50 notified bodies designated under MDR

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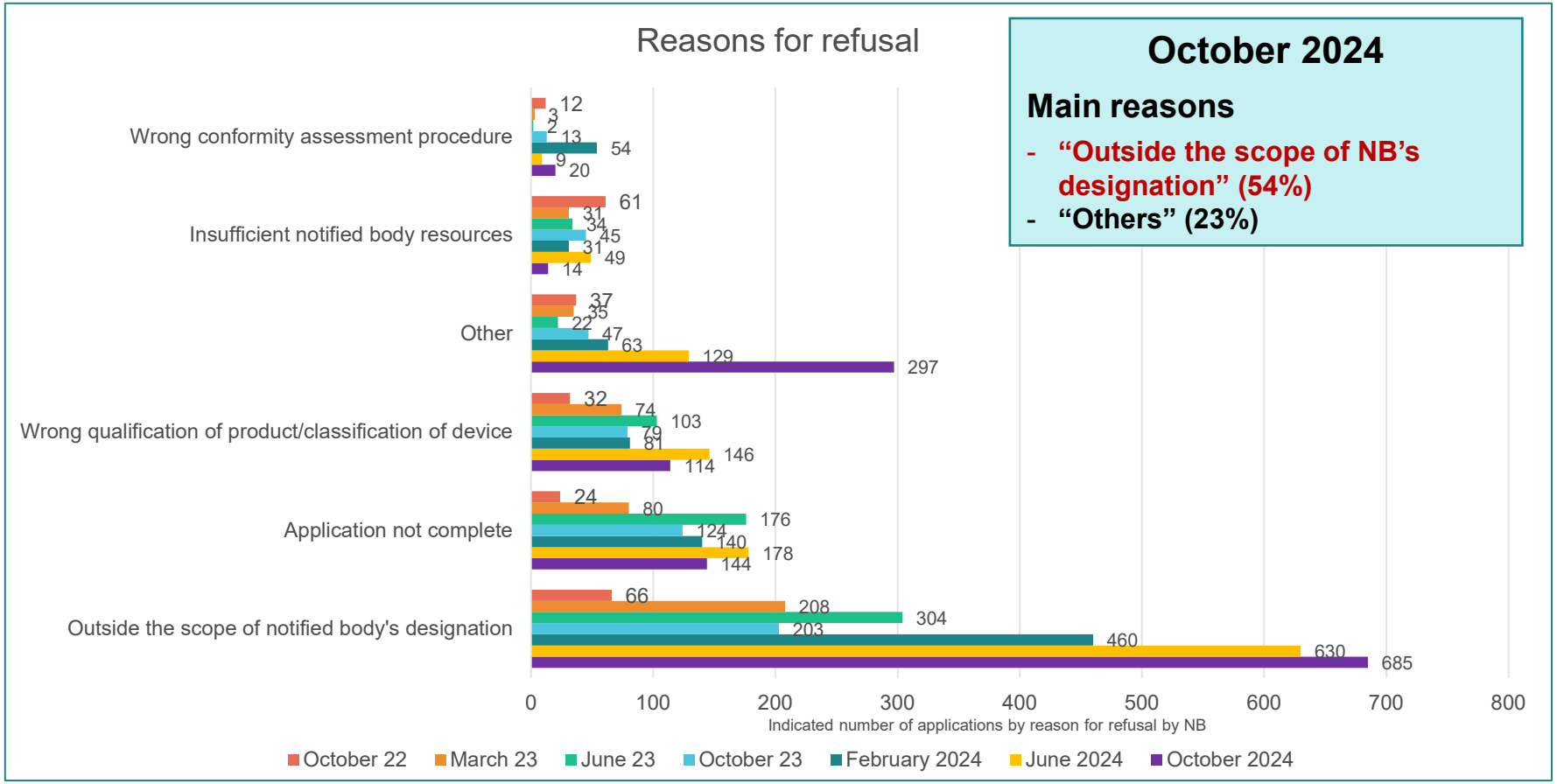
MDR applications - reasons for refusal



October 2024

Main reasons

- **"Outside the scope of NB's designation" (54%)**
- **"Others" (23%)**

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: 28.512*

* 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.

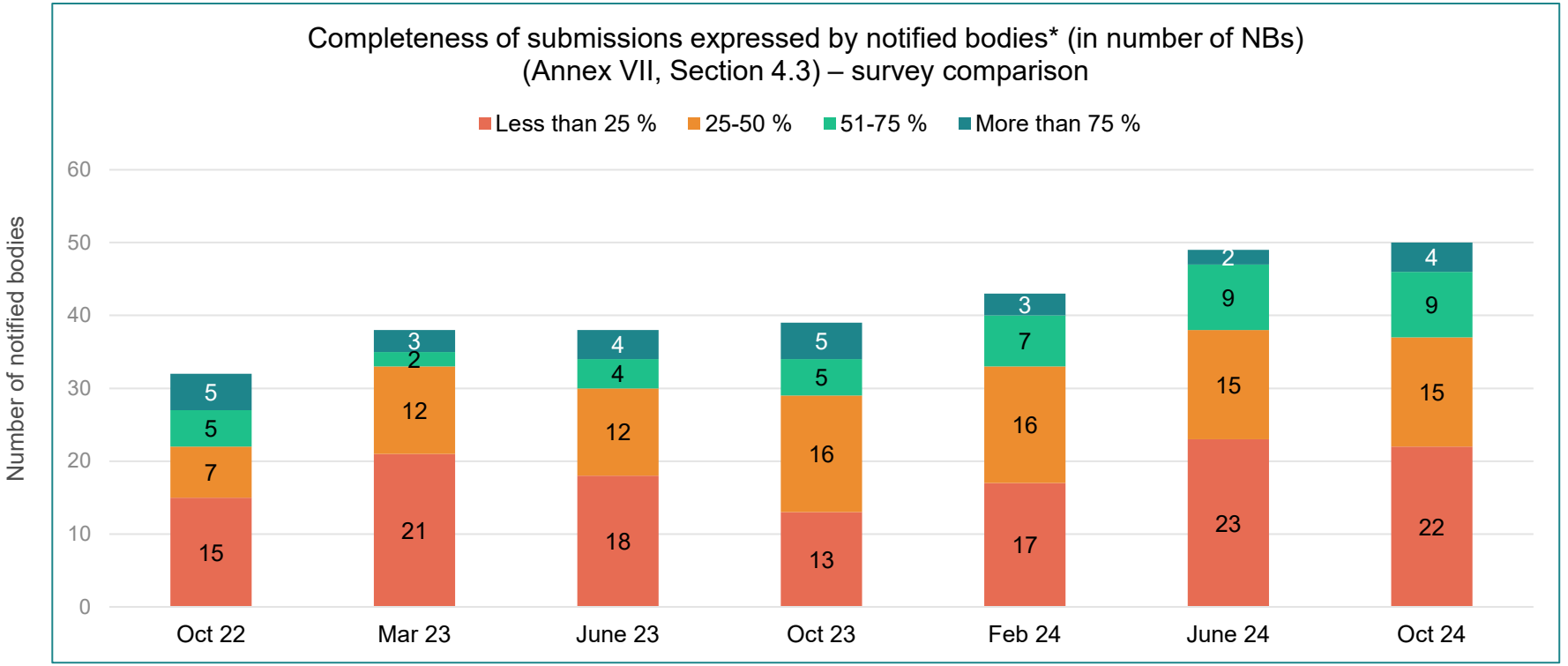
Number of application refusals:**

October 2022: 232
March 2023: 269
June 2023: 328
October 2023: 367
February 2024: 454
June 2024: 620
October 2024: 421

Notes:

- Comparison of reasons for refusal in October 2022, March 2023, June 2023, October 2023, February 2024, June 2024 and October 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.
- October 2024: data of 30 NBs; some stated "other" reasons in October 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:

13 out of 50 NBs designated under MDR in October 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

European Commission

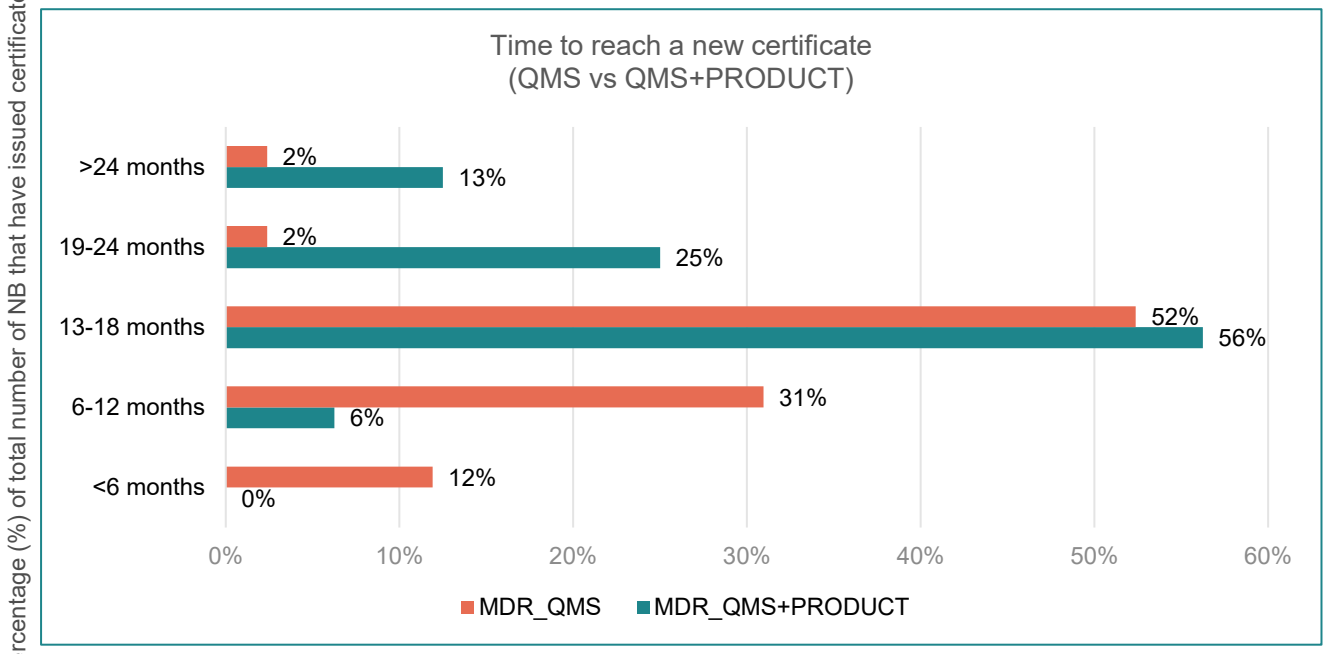
Time to reach a new certificate (QMS vs QMS+PRODUCT)

MD

Ⓜ

October 2024
MDR Applications: 28.069*
MDR Certificates: 10.554

* 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



MDR QMS certificates

- 52% of NBs: 13-18 months to issue a new QMS certificate
- 31% of NBs: 6-12 months

MDR QMS+PRODUCT certificates: longer time

- 56% of NBs: 13-18 months
- 25% of NBs: 19-24 months

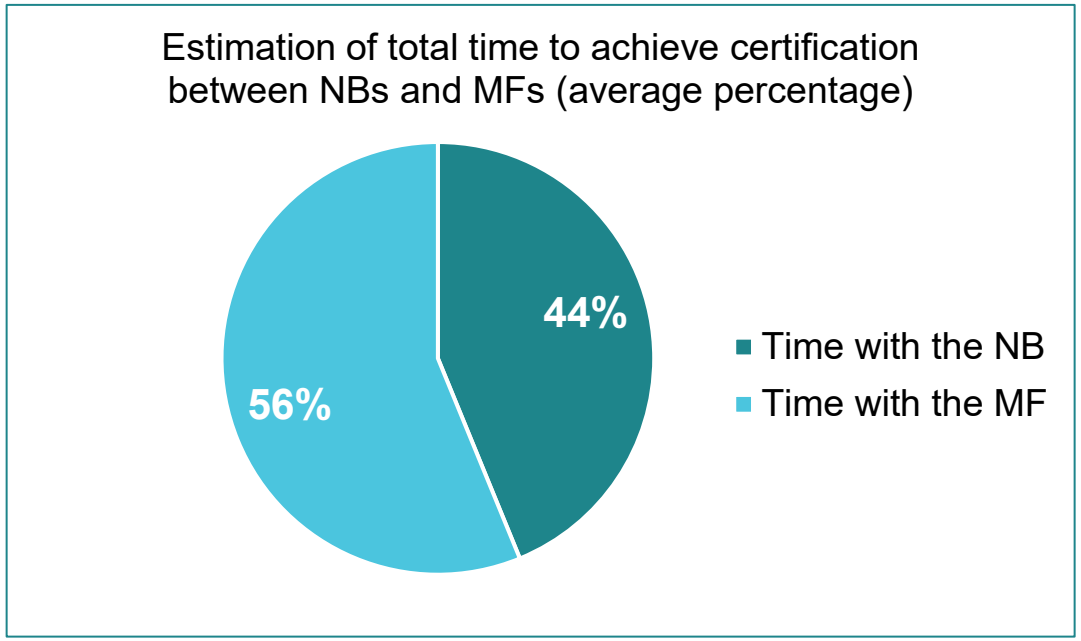
Notes:
QMS+PRODUCT: Data of 32 NBs designated under MDR
QMS: Data of 42 NBs designated under MDR

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

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

- **17** out of 32 NBs (53%) indicated >50% of the time with the MF
- **7** out of 32 NBs (22%) indicated that the time is equally divided (50:50) between NB and MF
- **8** out of 32 NBs (25%) indicated >50% of the time with the NB

Time with the notified body

- Minimum value: 20%
- Maximum value: 70%

Time with the manufacturer

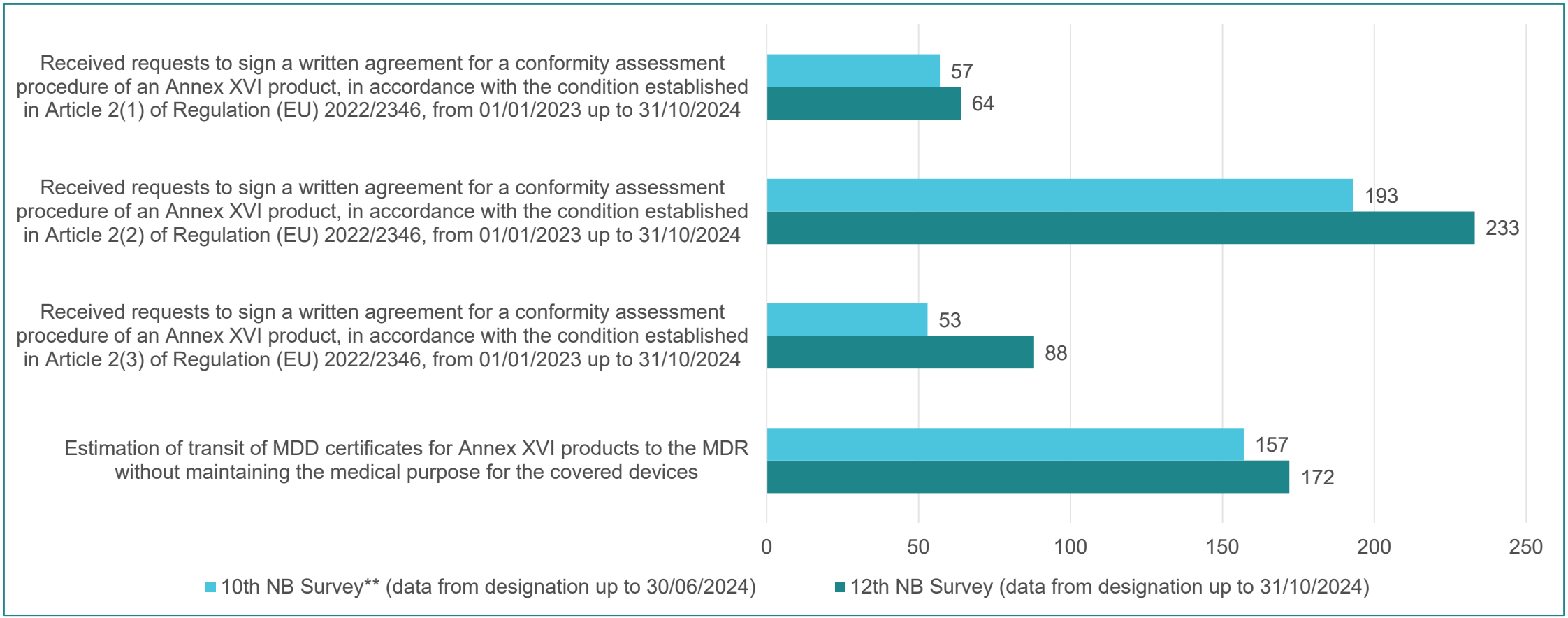
- Minimum value: 30%
- Maximum value: 80%

Notes:

- Data of 32 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)



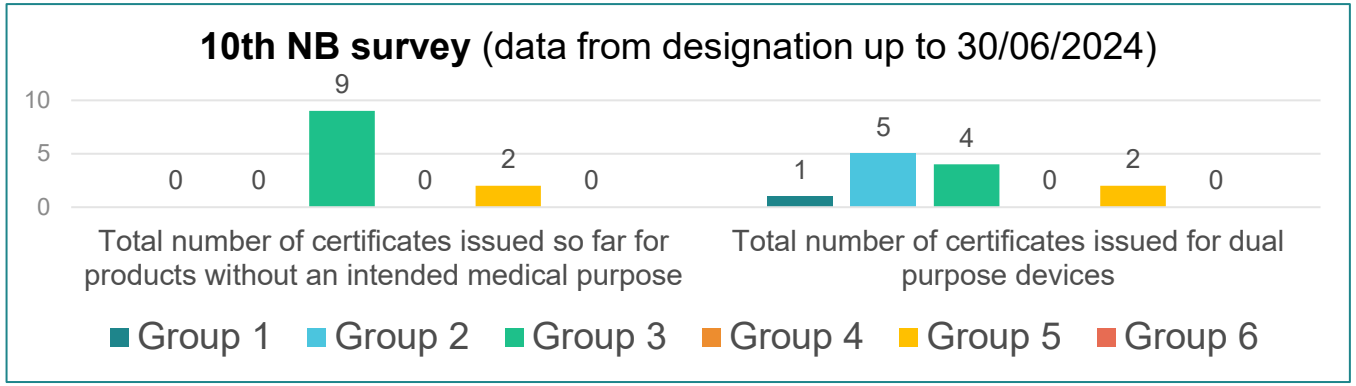
Notes:
10th NB survey: 24 out of 49 NBs entered "0" for all questions relating to Annex XVI products
** Within the data validation for the 12th NB survey, retrospective changes were reported for the 10th NB survey, which were considered in this chart.
12th NB survey: 23 out of 50 NBs entered "0" for all questions relating to Annex XVI products.

European Commission

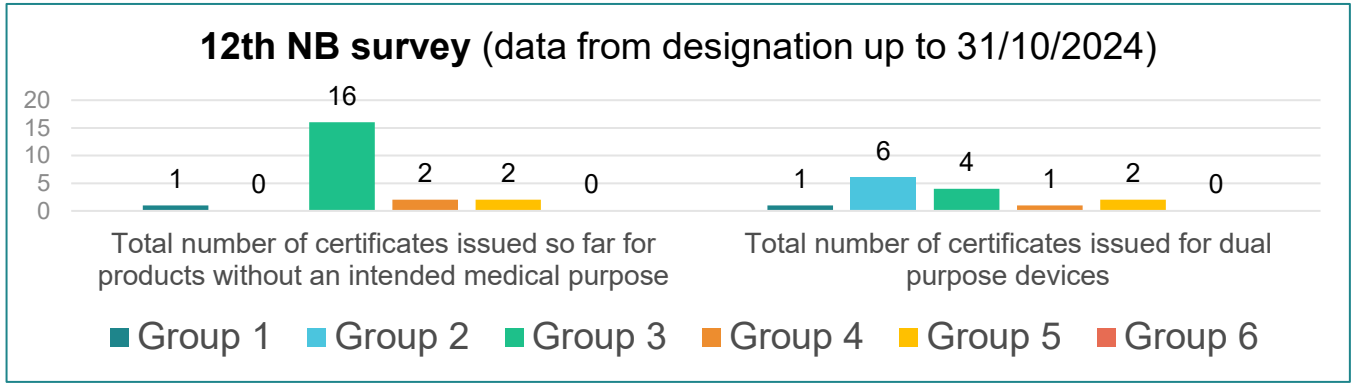
Certificates issued for products without an intended medical purpose* and for dual purpose devices**

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 4 NBs; 45 out of 49 NBs entered "0" for all groups



Notes: Data of 6 NBs; 44 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.

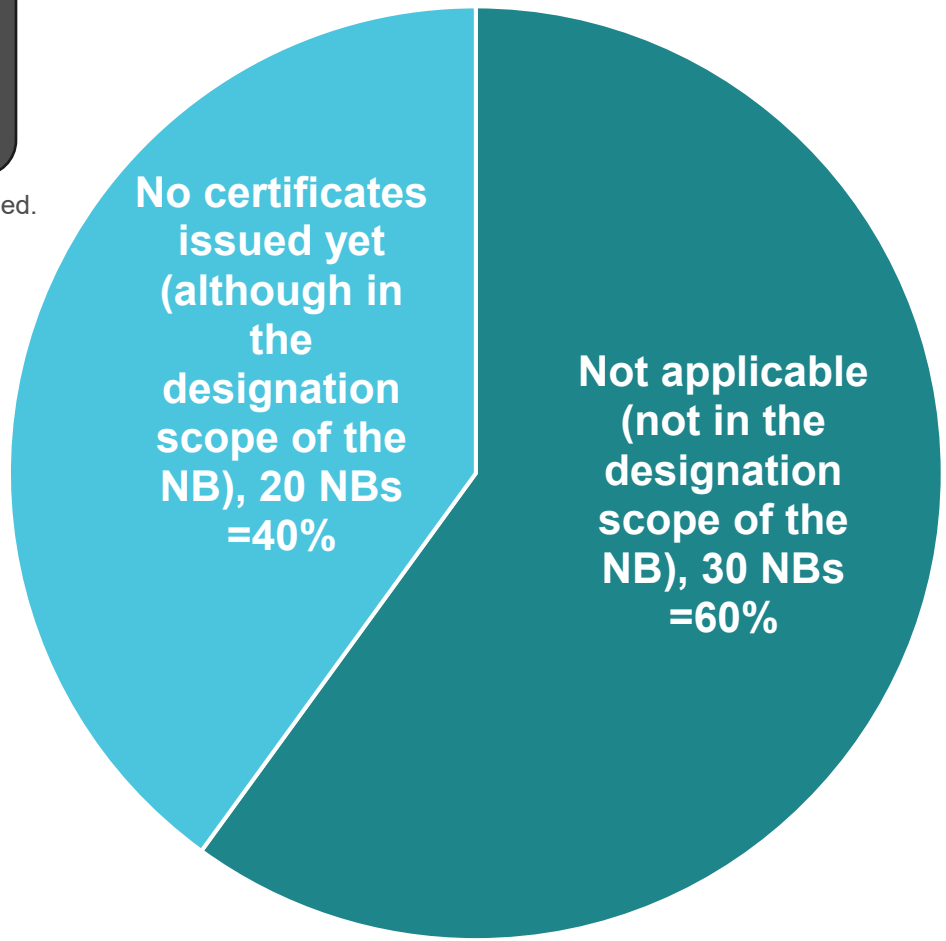
European Commission

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

MD

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

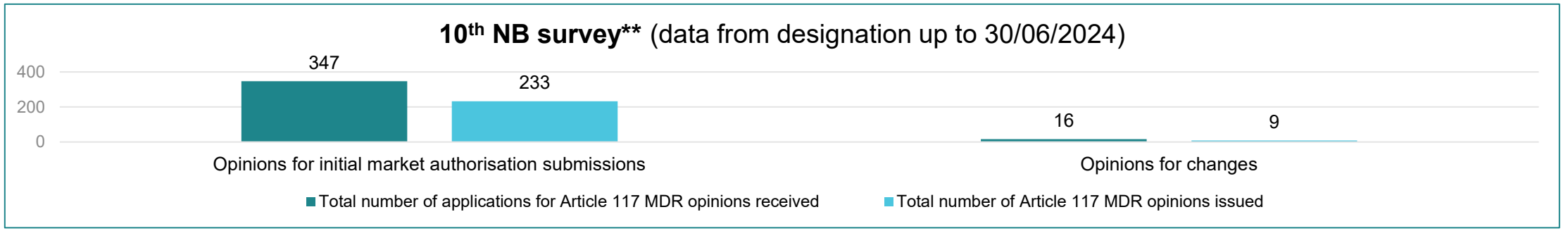
Note: No information available on applications lodged.



Data of 50 NBs designated under MDR

European Commission

Article 117 MDR opinions* - requests received and opinions issued



Notes 10th NB survey:
- 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

** Within the data validation for the 12th NB survey, retrospective changes were reported for the 10th NB survey, which were considered in this chart.

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

*** 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.*

European Commission

MD

Large dataset Ⓛ

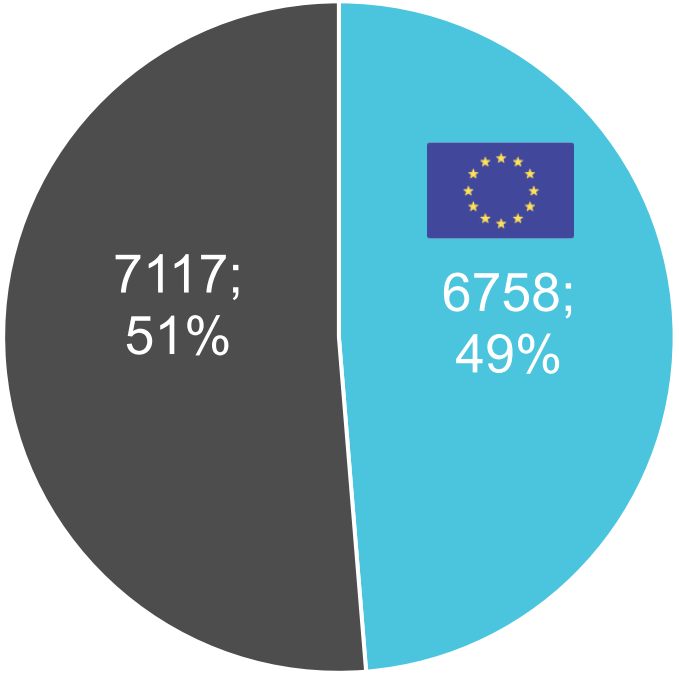
The **large dataset** contains additional data asked to notified bodies once a year.

European Commission

Number of clients for MDR

October 2024
Total number of clients for MDR: 13.875

Number of clients based **outside the EU**



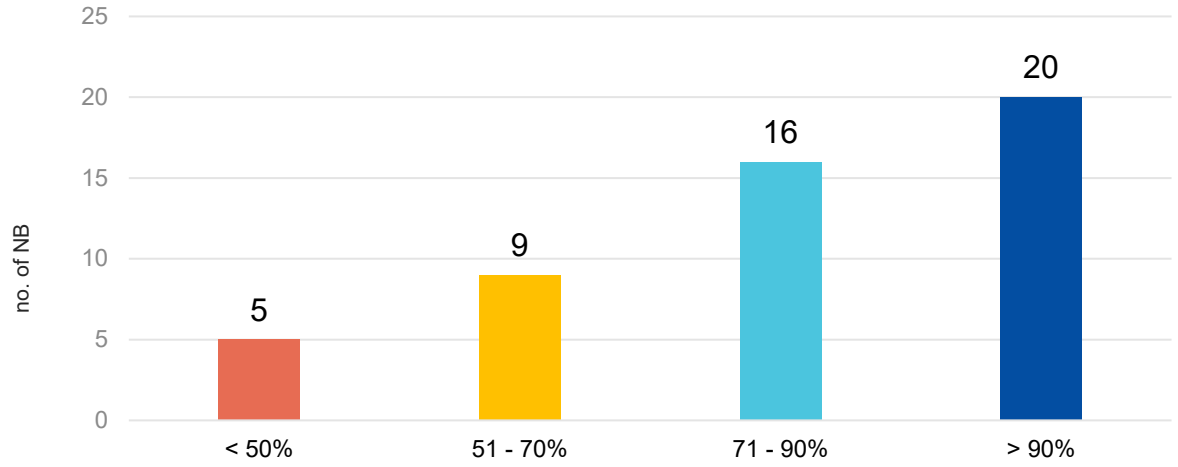
Number of clients based **in the EU**

Data of 50 NBs designated under MDR
Photo credit EU flag: Flaticon.com

MD

How many of the clients are SMEs*?

October 2024
Total number of clients for MDR: 13.875



Almost all NBs have SMEs as their main clients:

- Only 5 NBs (10%) indicated that less than 50% of their clients are SMEs
- 9 NBs (18%) indicated that between 51 and 70% of their clients are SMEs
- 16 NBs (32%) indicated that between 71 and 90% of their clients are SMEs
- 20 NBs (40%) indicated that they almost only have SMEs as clients (>90%)

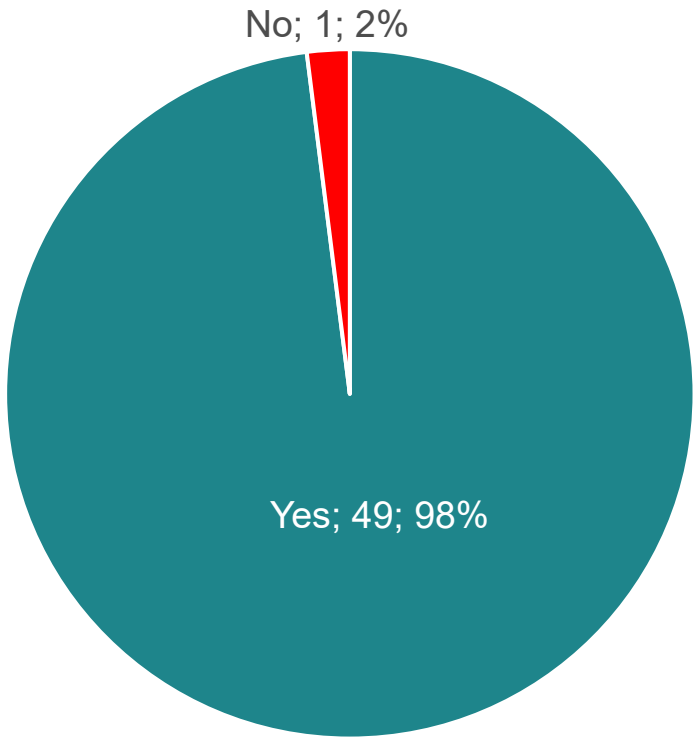
Notes:
Data of 50 NBs designated under MDR

*__Definition SME:__ The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.' (Source: Extract of Article 2 of the annex to Recommendation 2003/361/EC)

European Commission

MD

Does your NB take on new clients for MDR?



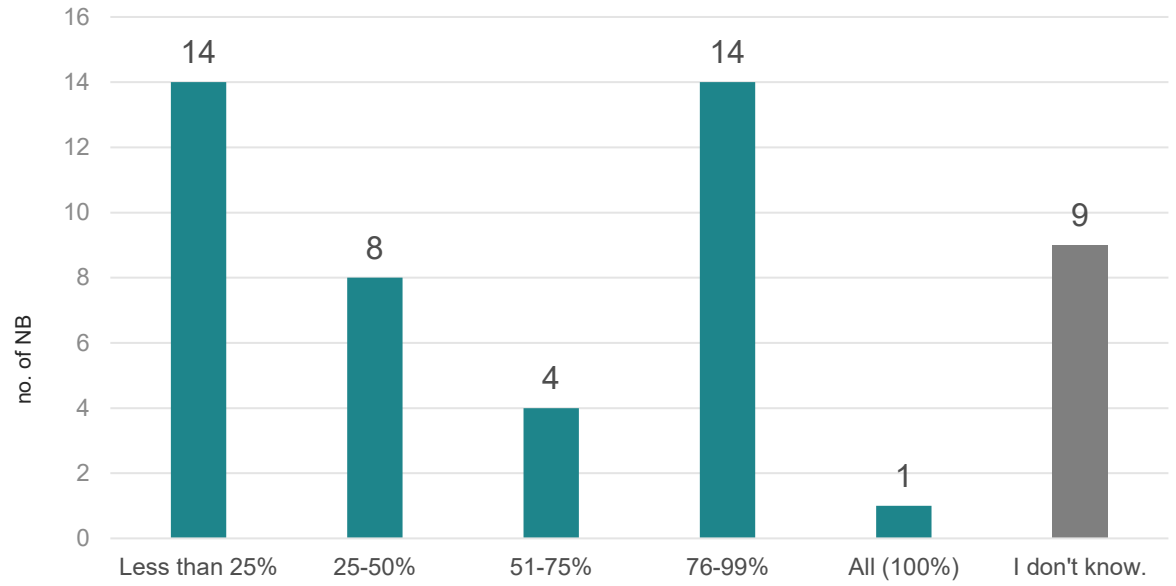
Data of 50 NBs designated under MDR

European Commission

To MDR: How many of the clients with certificates under the Directives completed the transfer of all devices intended to be certificated?

MD

October 2024
Total number of clients for MDR: 13.875



Data of 50 NBs designated under MDR

- 14 NBs (28%) indicated that less than 25% of their clients with certificates under the Directives have completed the transfer to MDR of all devices intended to be certificated
- 14 NBs (28%) indicated that between 76 and 99% of their clients with certificates under the Directives have completed the transfer to MDR of all devices intended to be certificated
- For 1 NB all clients have completed the transfer of all devices intended to be certificated.

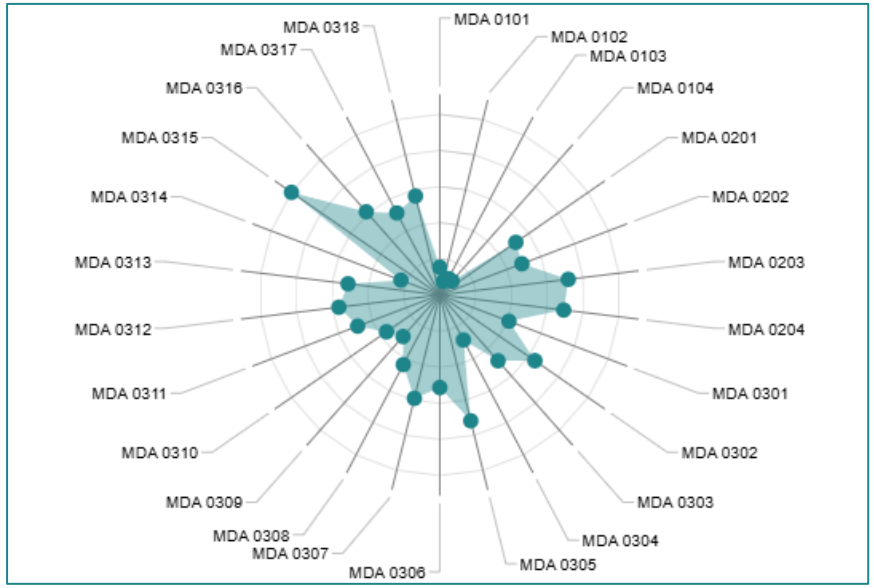
European Commission

Which MDA codes are covered by MDR certificates?

MD

I: Codes reflecting the design and intended purpose of the device

MDA = Active devices



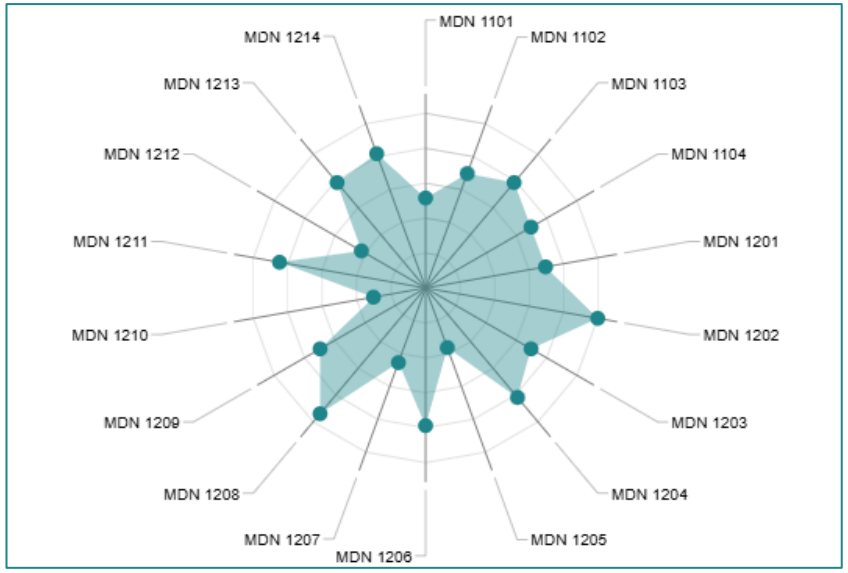
	Number of NBs indicating devices/categories
MDA 0315 Software	39
MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	28
MDA 0305 Active non-implantable devices for stimulation or inhibition	28
MDA 0204 Other active non-implantable devices for monitoring and / or diagnosis	27
MDA 0302 Active non-implantable devices utilising non-ionizing radiation	25
MDA 0316 Medical gas supply systems and parts thereof	24
MDA 0307 Active non-implantable respiratory devices	23
MDA 0312 Other active non-implantable surgical devices	22
MDA 0318 Other active non-implantable devices	22
MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	20
MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	20
MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	20
MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	20
MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	19
MDA 0303 Active non-implantable devices utilising hyperthermia / hypothermia	19
MDA 0311 Active non-implantable dental devices	19
MDA 0308 Active non-implantable devices for wound and skin care	17
MDA 0301 Active non-implantable devices utilising ionizing radiation	16
MDA 0310 Active non-implantable devices for ear, nose and throat	14
MDA 0309 Active non-implantable ophthalmologic devices	12
MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)	11
MDA 0314 Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	9
MDA 0101 Active implantable devices for stimulation / inhibition / monitoring	6
MDA 0103 Active implantable devices supporting or replacing organ functions	4
MDA 0104 Active implantable devices utilising radiation and other active implantable devices	4
MDA 0102 Active implantable devices delivering drugs or other substances	3

European Commission

Which MDN codes are covered by MDR certificates?

I: Codes reflecting the design and intended purpose of the device

MDN = Non-active devices



	Number of NBs indicating devices/categories
MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	33
MDN 1208 Non-active non-implantable instruments	31
MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	28
MDN 1204 Non-active non-implantable devices for wound and skin care	27
MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	27
MDN 1103 Non-active dental implants and dental materials	26
MDN 1206 Non-active non-implantable ophthalmologic devices	26
MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	26
MDN 1102 Non-active osteo- and orthopaedic implants	23
MDN 1104 Non-active soft tissue and other implants	23
MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	23
MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	23
MDN 1209 Non-active non-implantable dental materials	23
MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	17
MDN 1207 Non-active non-implantable diagnostic devices	15
MDN 1212 Non-active non-implantable devices for processing and pre-servation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	14
MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	12
MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	10

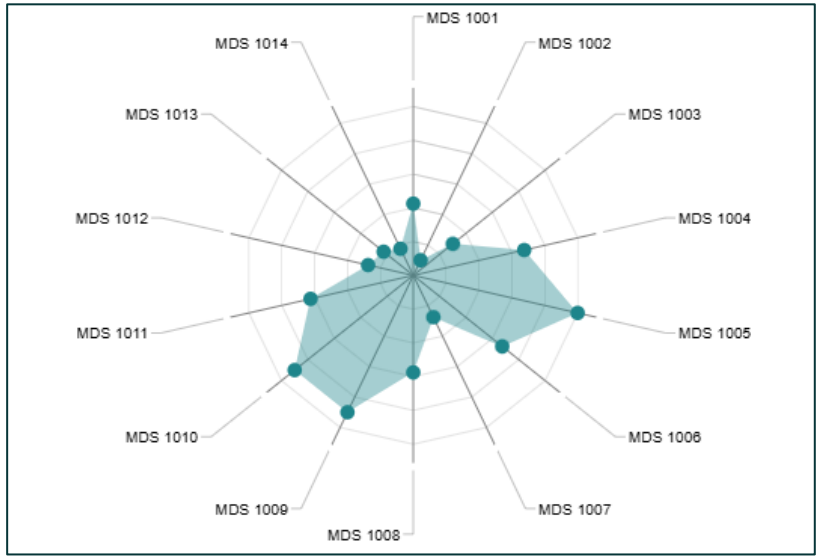
European Commission

Which MDS codes are covered by MDR certificates?

MD

II Horizontal codes

MDS = Devices with specific characteristics



	Number of NBs indicating devices/categories
MDS 1005 Devices in sterile condition	40
MDS 1009 Devices incorporating software / utilising software / controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices	36
MDS 1010 Devices with a measuring function	36
MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council	27
MDS 1006 Reusable surgical instruments	27
MDS 1011 Devices in systems or procedure packs	25
MDS 1008 Devices utilising biologically active coatings and / or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body	23
MDS 1001 Devices incorporating medicinal substances	17
MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives	12
MDS 1007 Devices incorporating or consisting of nanomaterial	11
MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745	11
MDS 1013 Class III custom-made implantable devices	9
MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device	7
MDS 1002 Devices manufactured utilising tissues or cells of human origin, or their derivatives	4

European Commission

Which MDT codes are covered by MDR certificates?

MD

II Horizontal codes

MDT = Devices for which specific technologies or processes are used

	Number of NBs indicating devices/categories
MDT 2011 Devices which require packaging, including labelling	43
MDT 2008 Devices manufactured in clean rooms and associated controlled environments	41
MDT 2001 Devices manufactured using metal processing	39
MDT 2002 Devices manufactured using plastic processing	38
MDT 2010 Devices manufactured using electronic components including communication devices	37
MDT 2012 Devices which require installation, refurbishment	36
MDT 2006 Devices manufactured using chemical processing	30
MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)	28
MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)	25
MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals	19
MDT 2005 Devices manufactured using biotechnology	17
MDT 2013 Devices which have undergone reprocessing	16
MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin	15

European Commission

Which kinds of devices/categories of devices are covered by MDR certificates?

MD

A more detailed analysis can be found in the dashboard!

OVERVIEW

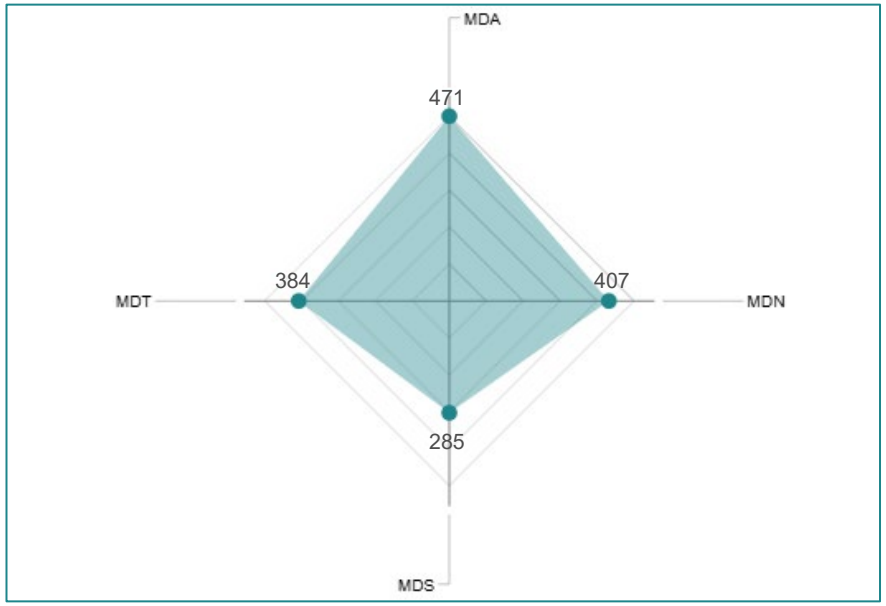
Number of NBs indicating this devices/categories:

I: Codes reflecting the design and intended purpose of the device

- Active devices (MDA): **471**
- Non-active devices (MDN): **407**

II: Horizontal codes

- Devices with specific characteristics (MDT): **384**
- Devices for which specific technologies or processes are used (MDS): **285**



European Commission

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:

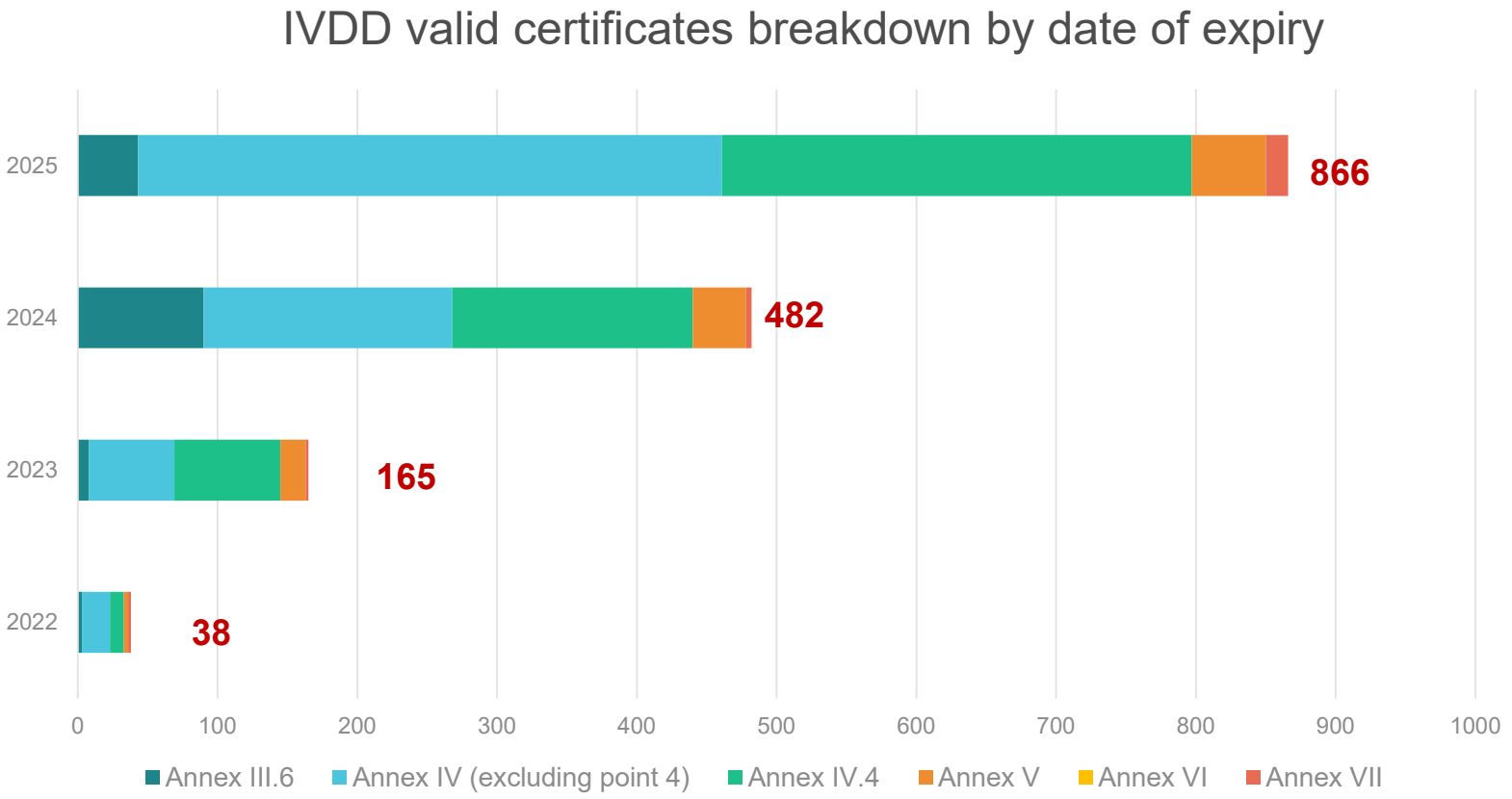
  Ⓢ The **small dataset** is a small set of questions asked to notified bodies **every two months.**
  Note: From April to July 2023, it was asked monthly.
  Ⓜ The **medium dataset** is a set of questions asked to notified bodies **every four months** concerning the activities they have been performing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

European Commission

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

IVD

CAVEAT:
Not part of this 12th NB survey, but included for comparison.



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

IVD

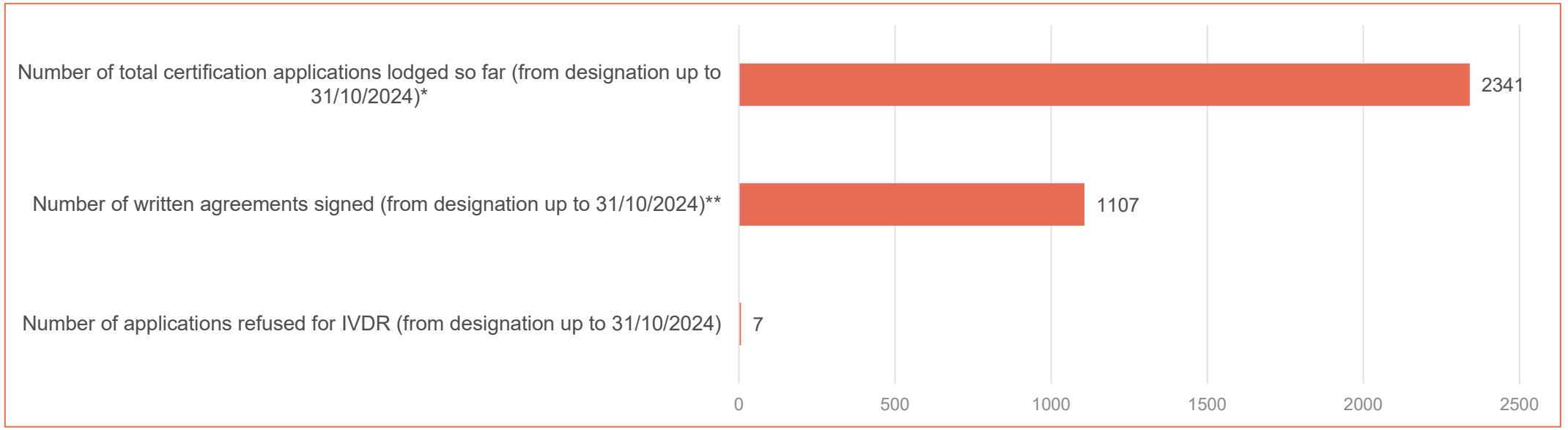
Small dataset Ⓢ

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.

IVDR applications filed and refused, written agreements signed

IVD



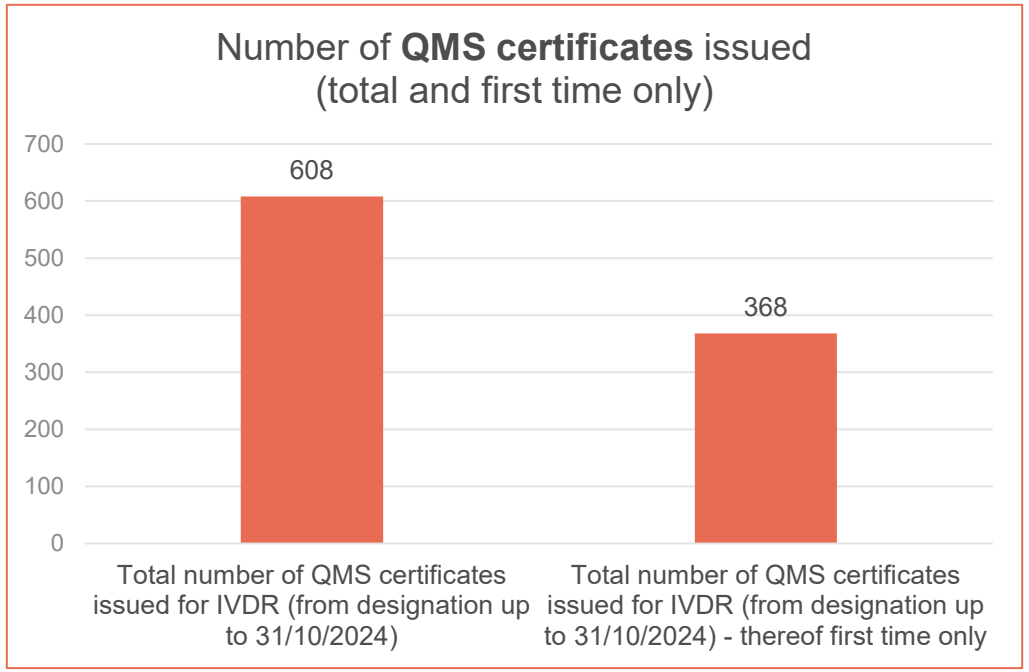
Notes:

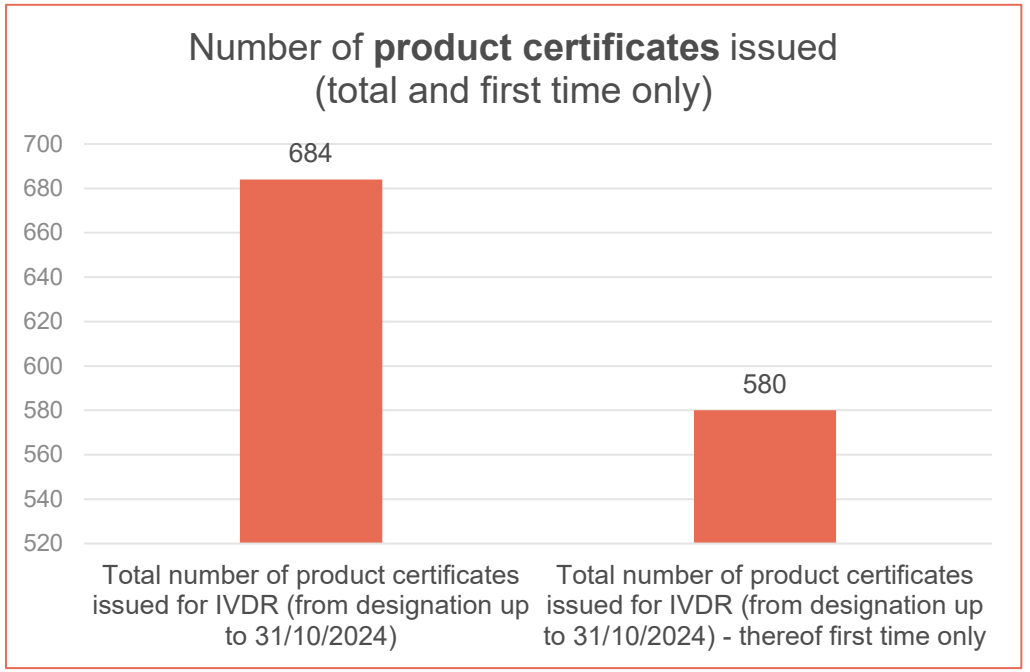
- **Designated NBs for IVD:** 13
- *** Applications lodged**: This number includes **all applications lodged (syn. filed) so far** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 31/10/2024), 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





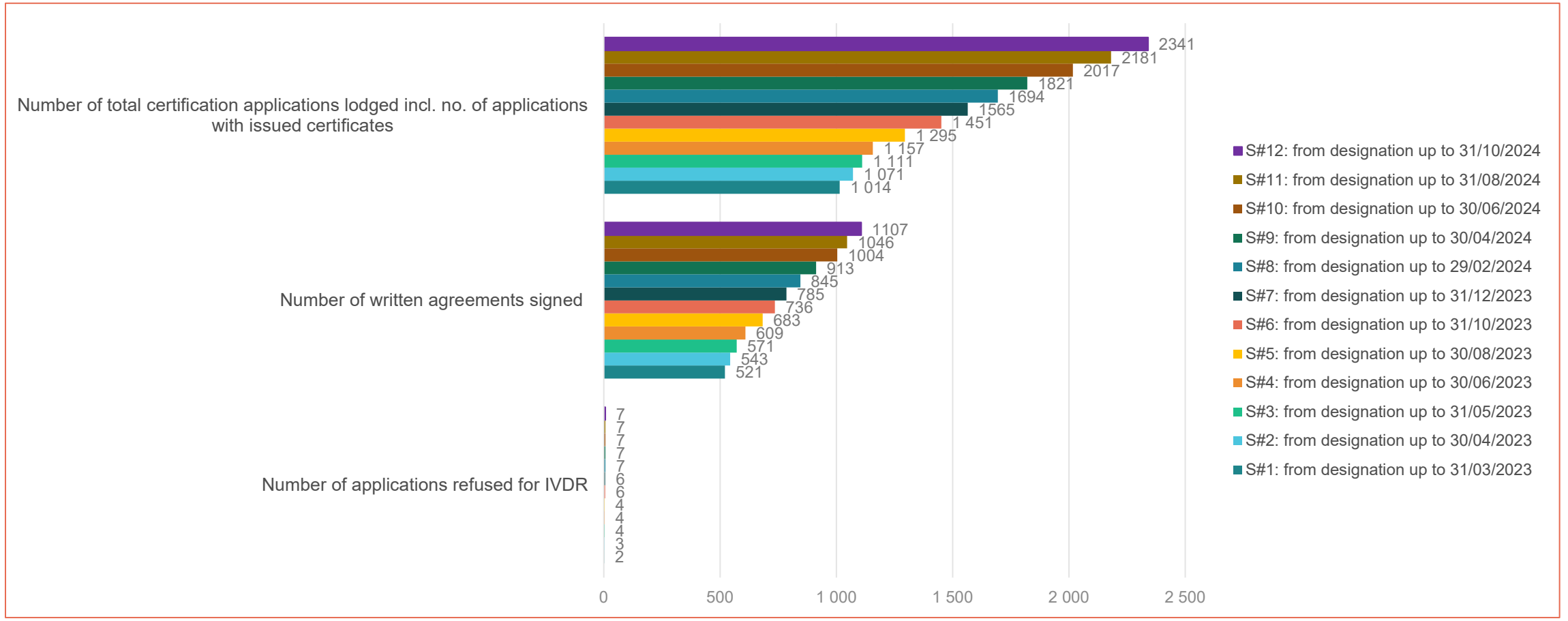
Note QMS Certificates: This relates to Annex IX Chapter I or Annex XI according to IVDR.

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

European Commission

Survey comparison – March 2023 to October 2024

IVD



S = Survey; # = number

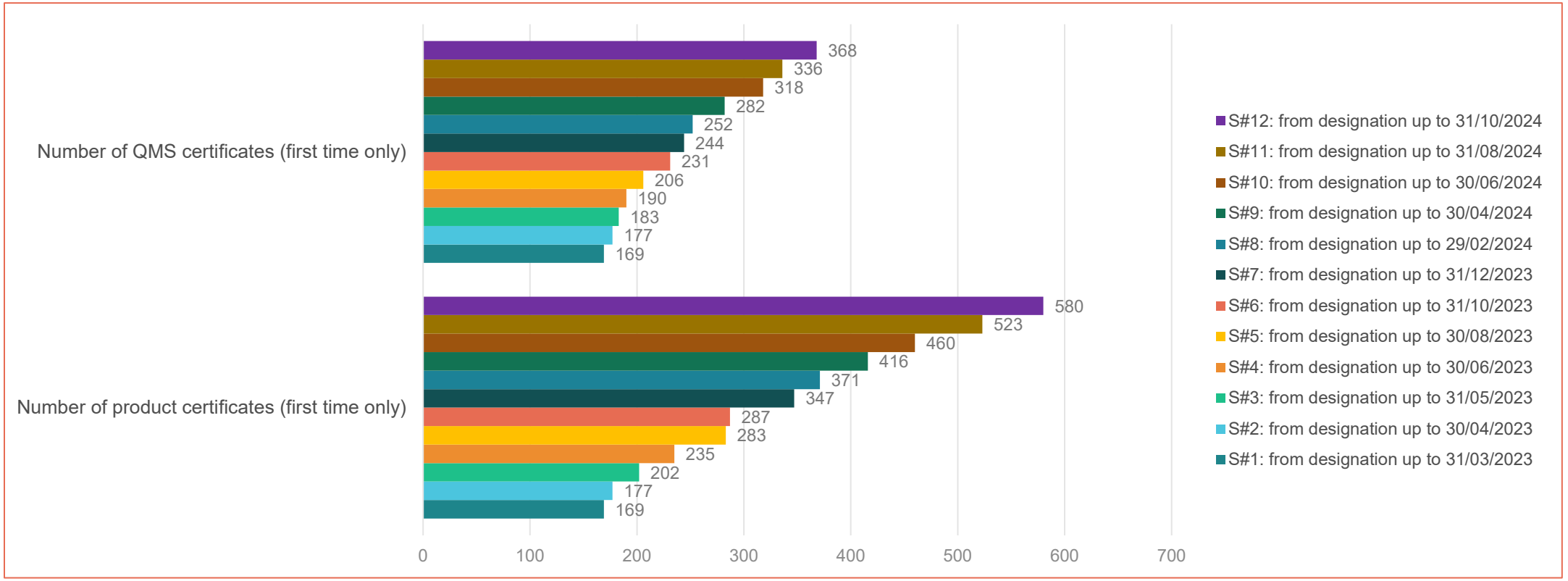
Notes:

- Designated NBs for IVDs: S#1 to S#5: 10; S#6 to S#10: 12, S#12: 13
- 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 October 2024



S = Survey; # = number

Notes:

- Designated NBs for IVDs: S#1 to S#5: 10; S#6 to S#10: 12; S#12: 13
- 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

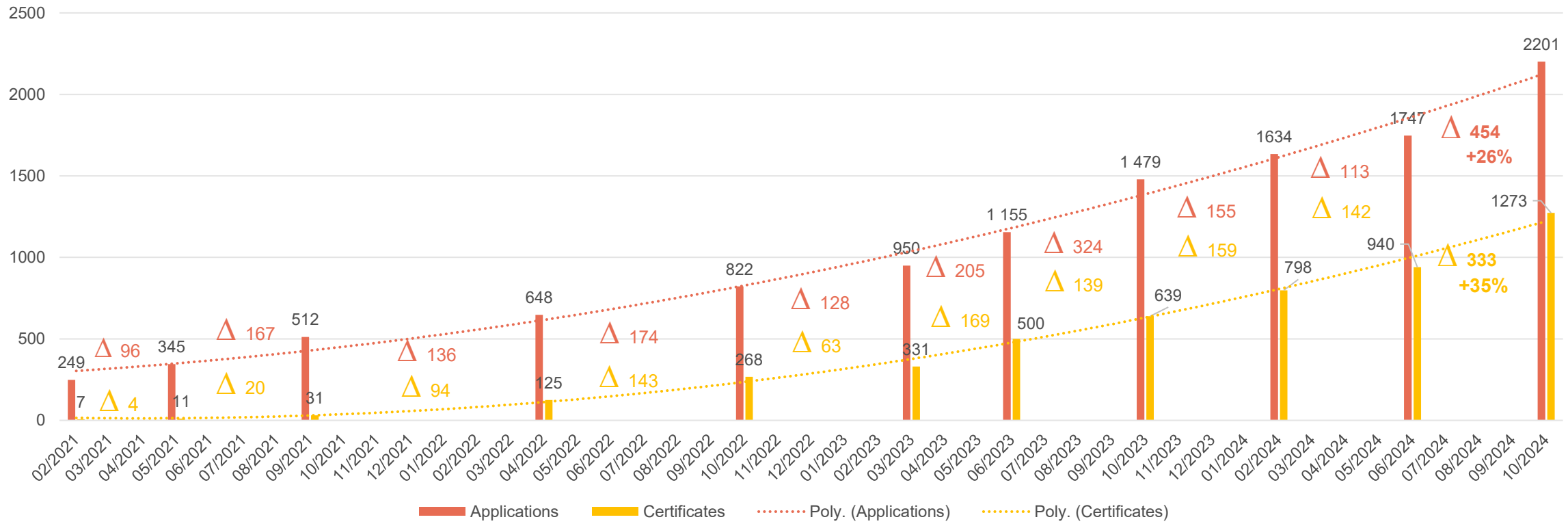
Medium dataset Ⓜ

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

October 2024
IVDR Applications: 2.201
IVDR Certificates: 1.273

IVD



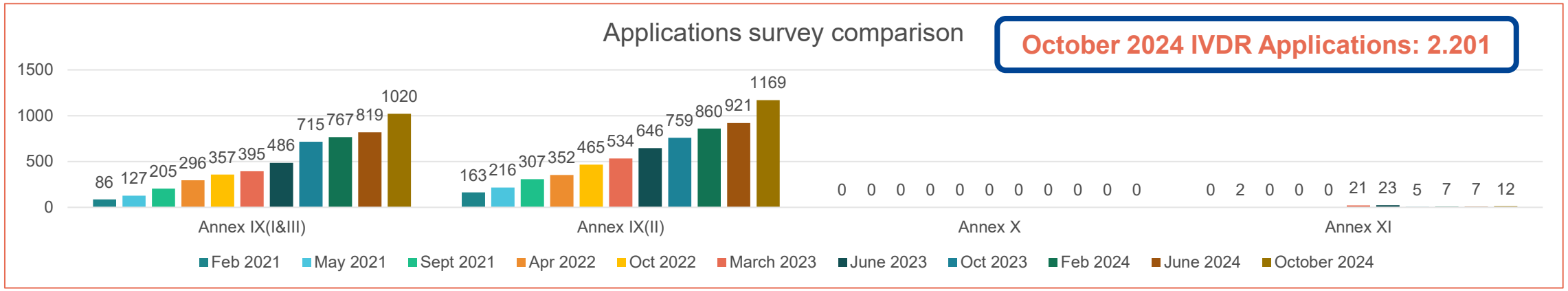
Notes: Designated NBs for IVDR: 13

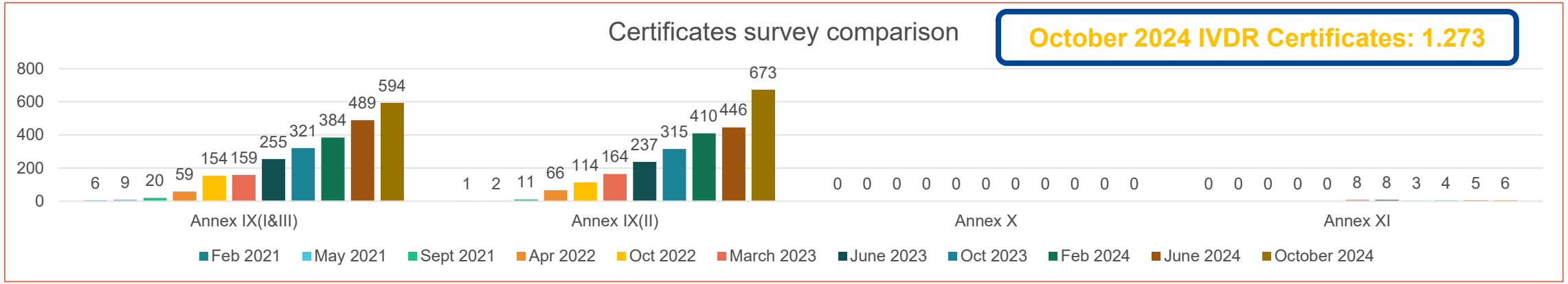
- Δ (Delta) = Difference in IVDR Applications / IVDR Certificates from one survey to the next one
- **Applications lodged**: This number includes **all applications lodged (syn. filed) so far** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 31/10/2024), 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 31/10/2024) 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:

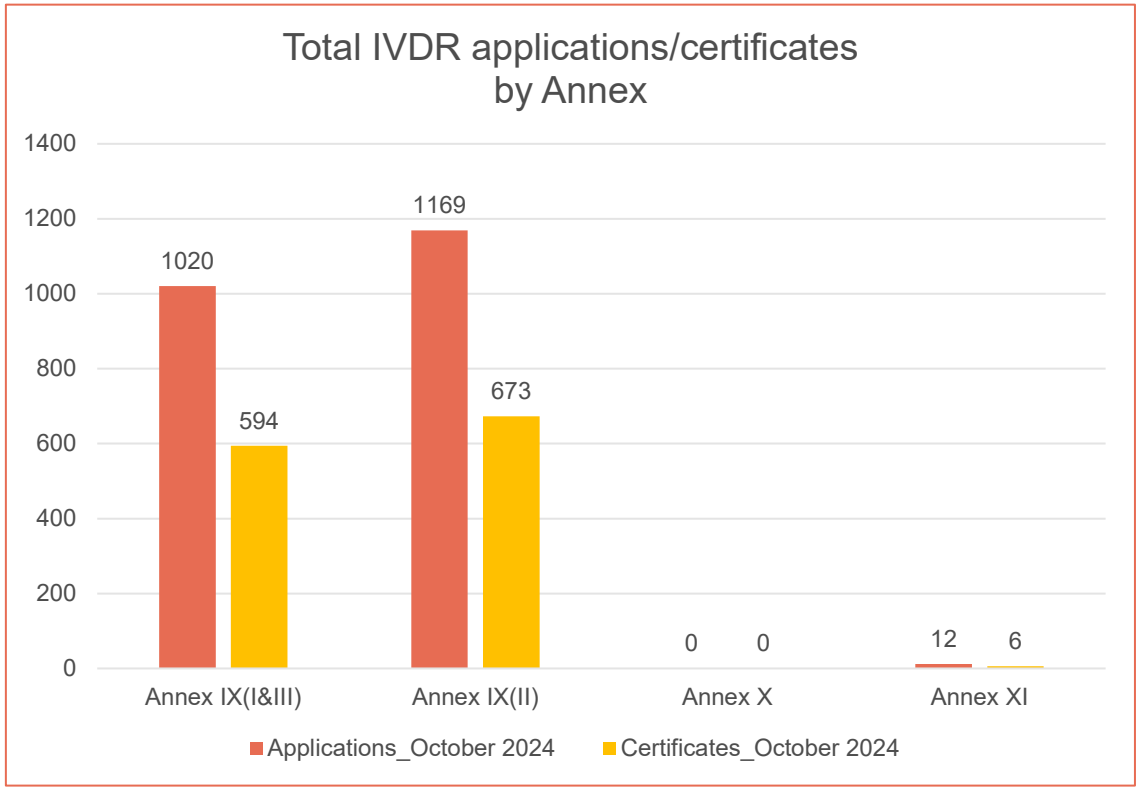
- **Applications lodged by annex**: This number includes **all applications lodged (syn. filed) by annex** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 31/10/2024), 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 31/10/2024) under the IVDR **by annex**.

European Commission

IVDR applications and certificates by annex

IVD

October 2024
IVDR Applications: 2.201
IVDR Certificates: 1.273



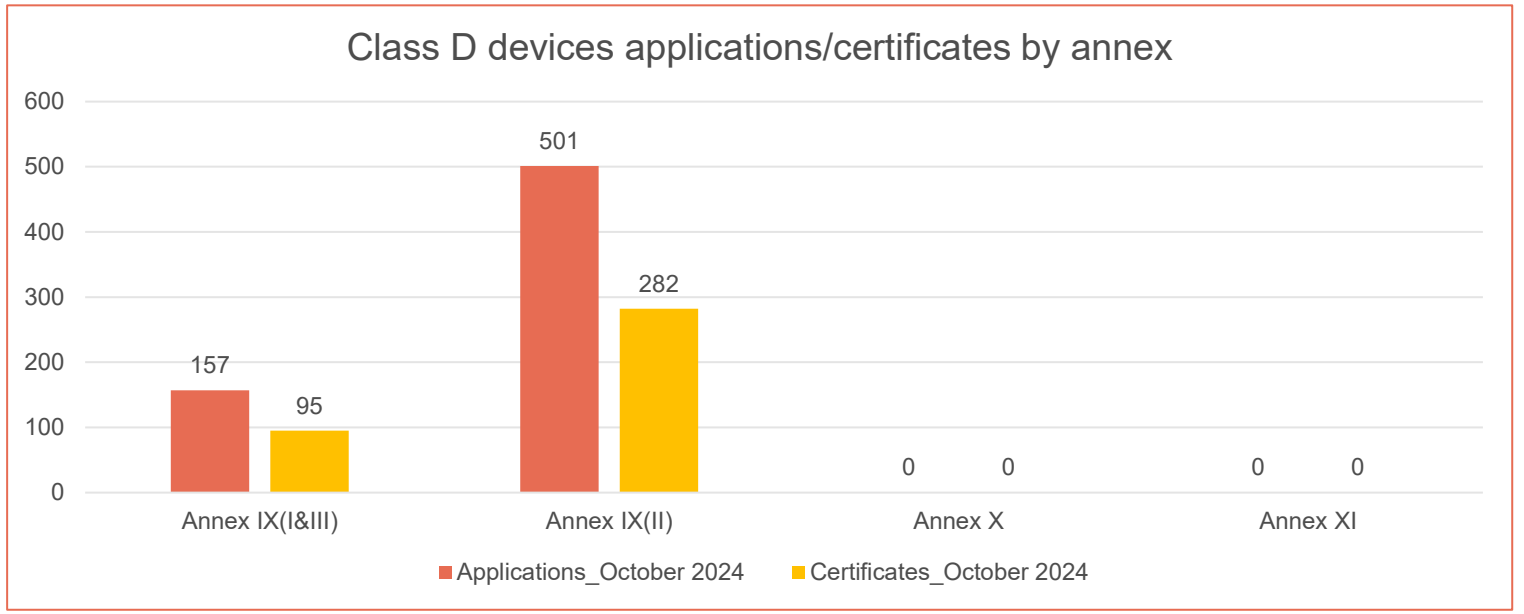
Notes:

- **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 31/10/2024), 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 31/10/2024) 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



October 2024
IVDR Applications: 2.201
IVDR Certificates: 1.273

October 2024:
Class D devices Applications: 658
Class D devices Certificates: 377

Notes:

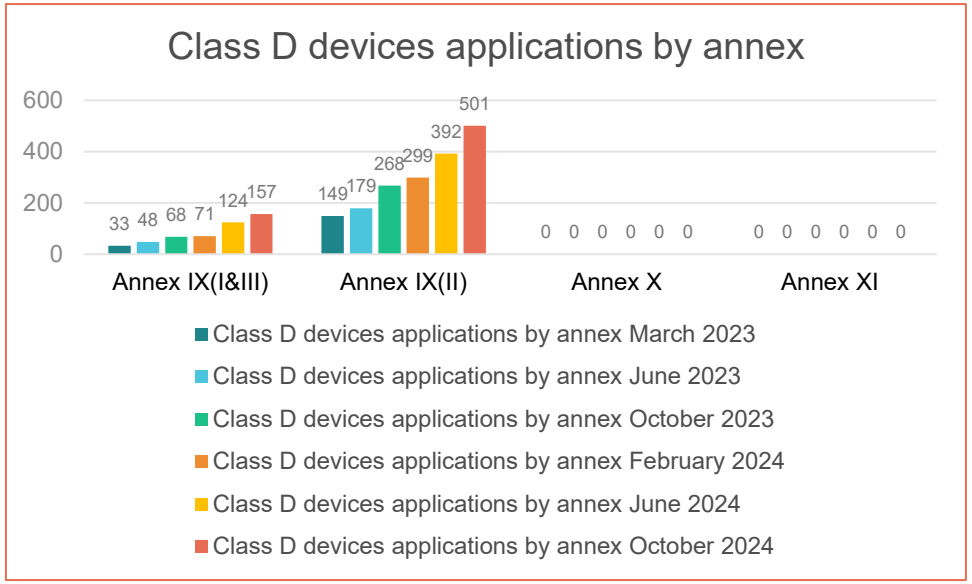
- **Applications lodged by annex:** This number includes all applications lodged (syn. filed) by annex according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 31/10/2024), 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 31/10/2024) 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.

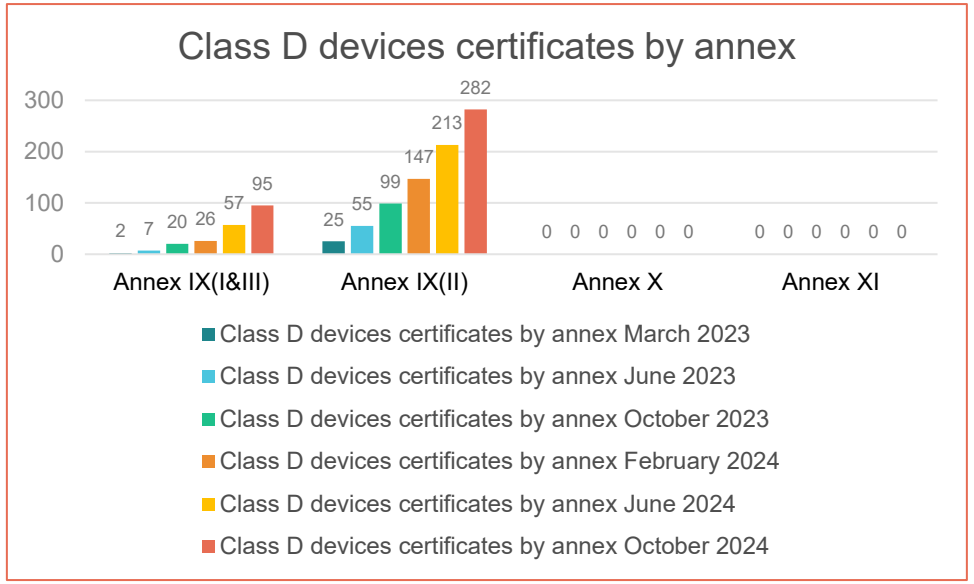
European Commission

Class D IVDs applications and certificates development

IVD

October 2024:
Class D devices applications up to now: 658
Class D devices certificates up to now: 377





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 **31/10/2024**), 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 **31/10/2024**) under the IVDR by annex.

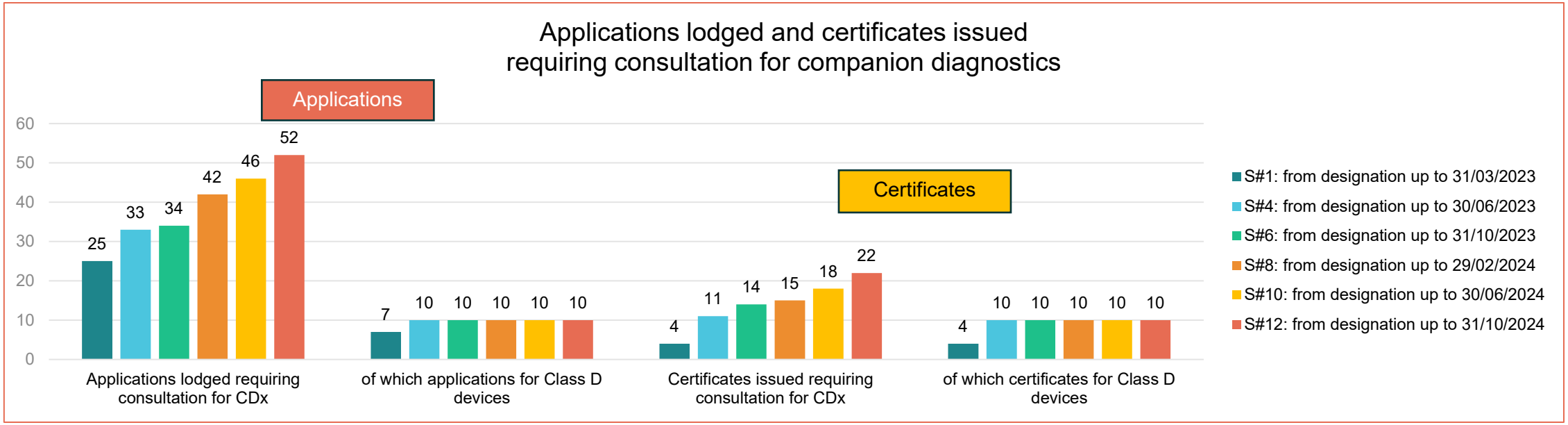
European Commission

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

IVD

October 2024:
Class D devices Applications: 658
Class D devices Certificates: 377

October 2024
IVDR Applications: 2.201
IVDR Certificates: 1.273

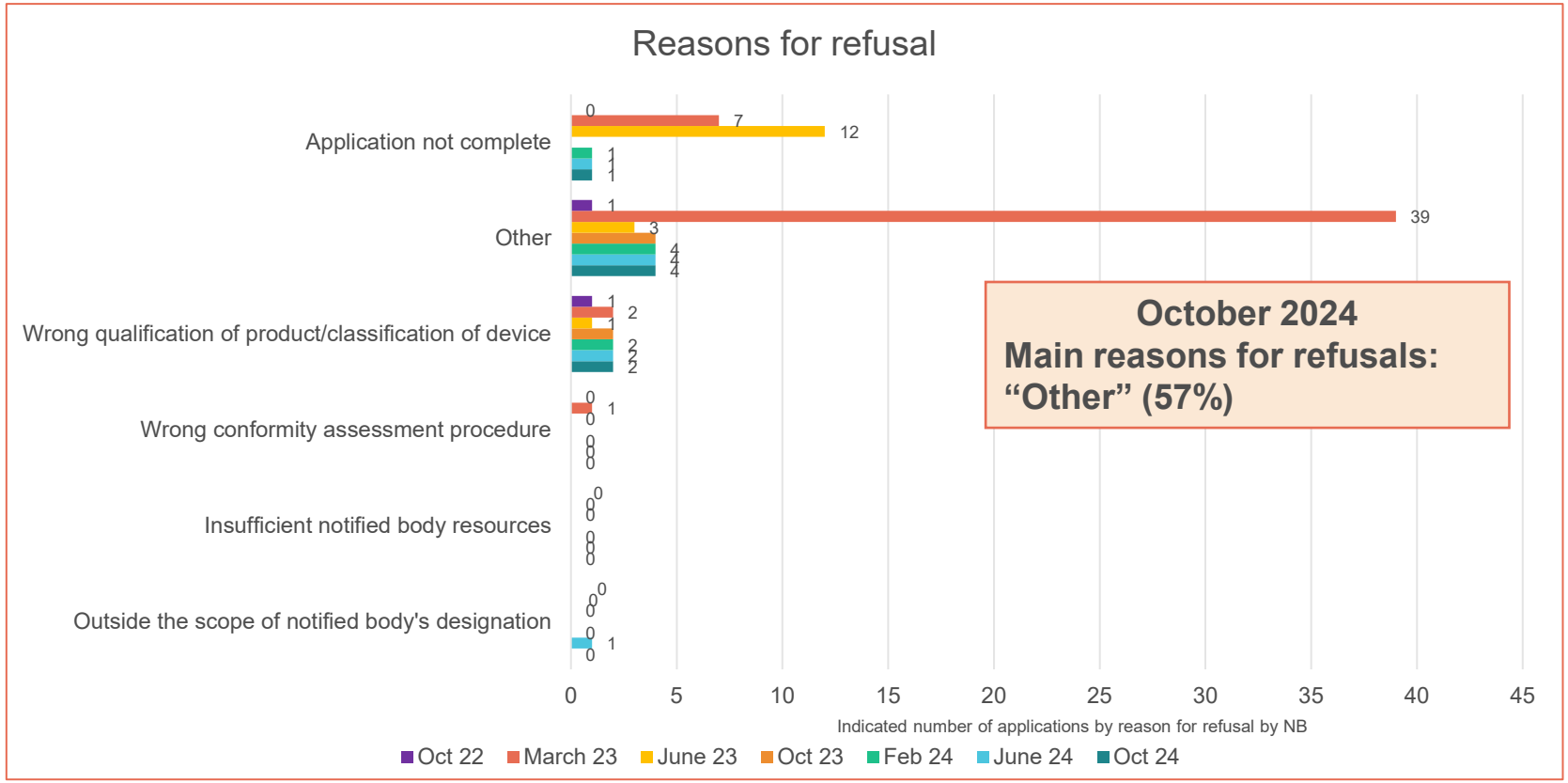


* According to Article 2 (7) IVDR, a companion diagnostic means a *device which is essential for the safe and effective use of a corresponding medicinal product to:*
(a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or
(b)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

IVD

IVDR applications - reason for refusal



October 2024
IVDR Applications: 2.201
IVDR Certificates: 1.273

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

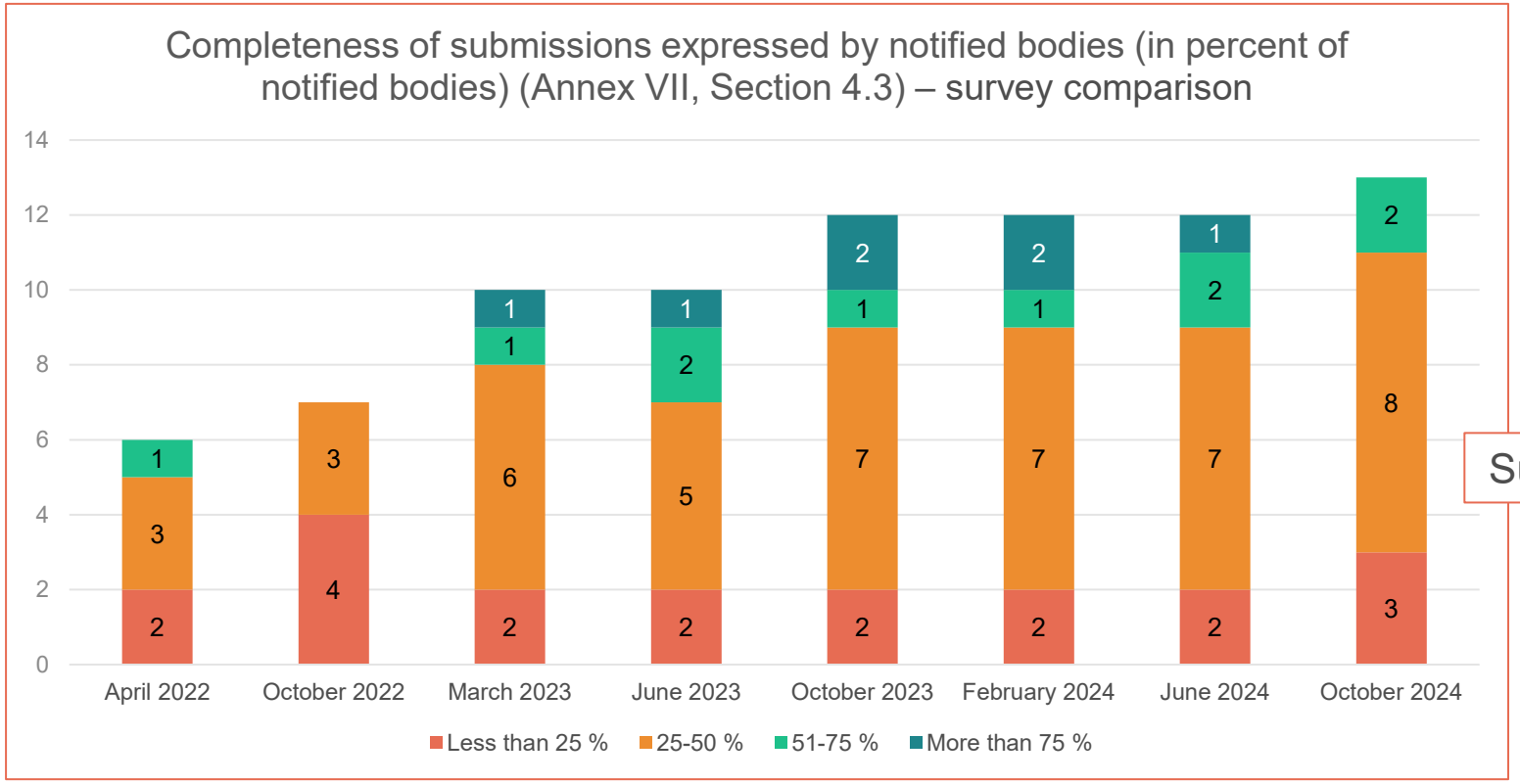
Notes:

- 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 and October 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"
- October 2024: Reasons were indicated by **one** NB only. "Other" reasons: "assessment resulted in negative outcome".

European Commission

IVD

Completeness of submissions



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

2 out of 13 NBs in October 2024

Submissions largely incomplete*

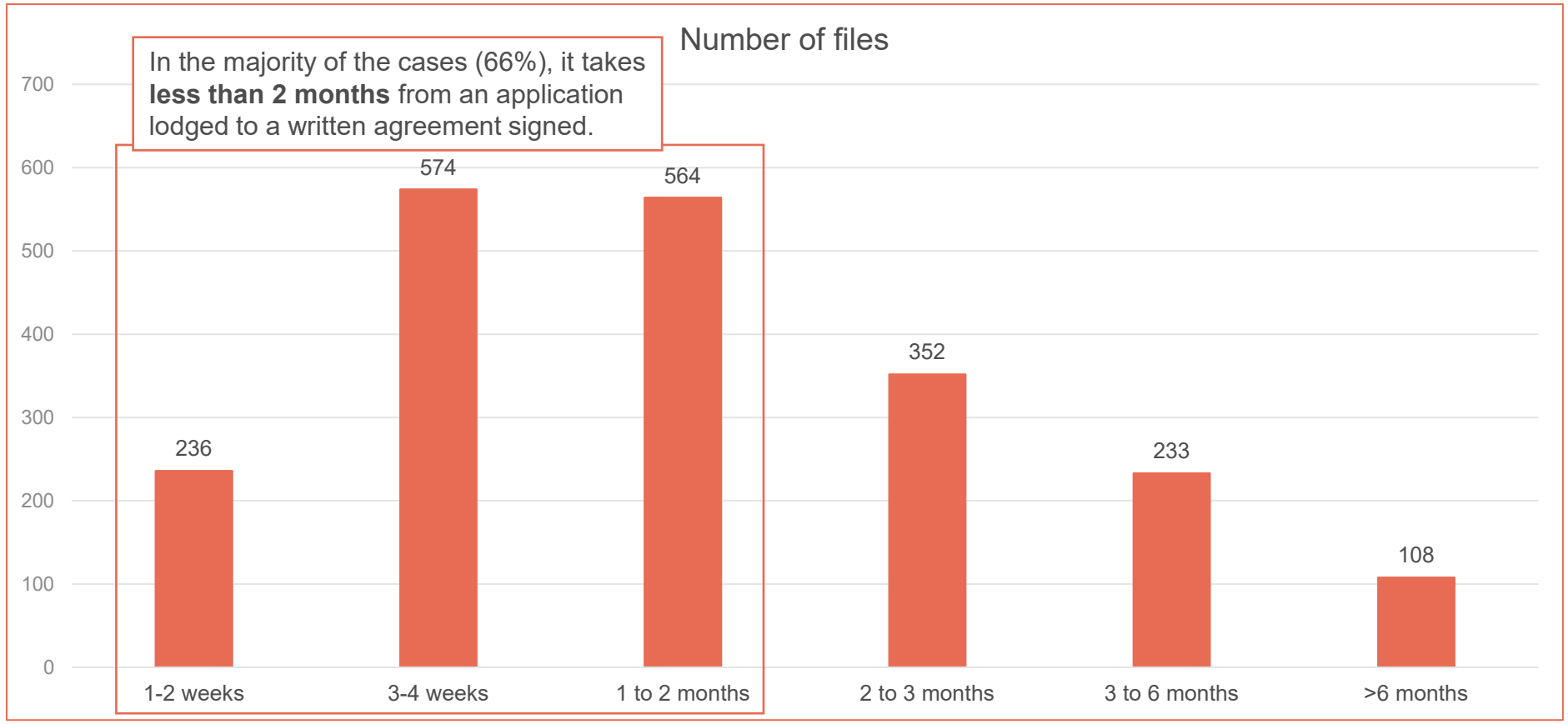
* Estimated percentage of submissions which were deemed satisfactory in terms of documentation provided (before undertaking the review of its content) without requesting for any additional information

European Commission

IVD

Average timeframe to written agreement signed

Average timeframe between application lodged and written agreement signed

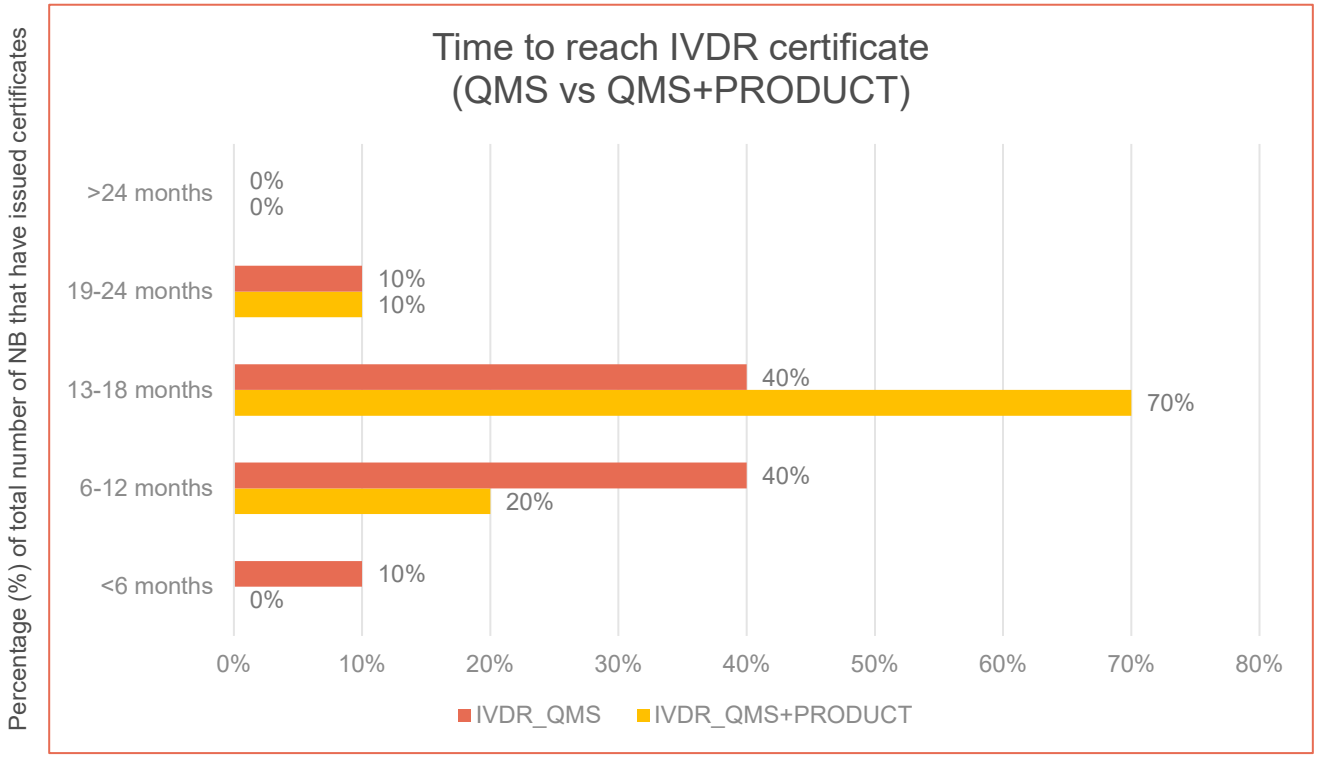


Note: Data of 13 notified bodies designated under IVDR

European Commission

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

IVD



October 2024
IVDR Applications: 2.201
IVDR Certificates: 1.273

IVDR QMS certificates

- For 40% of NBs: 6-12 months to issue a new QMS certificate
- 40% of NBs: 13-18 months

IVDR QMS+PRODUCT certificates: longer time

- 70% of NBs: 13-18 months
- 10% of NBs: 19-24 months

Notes:

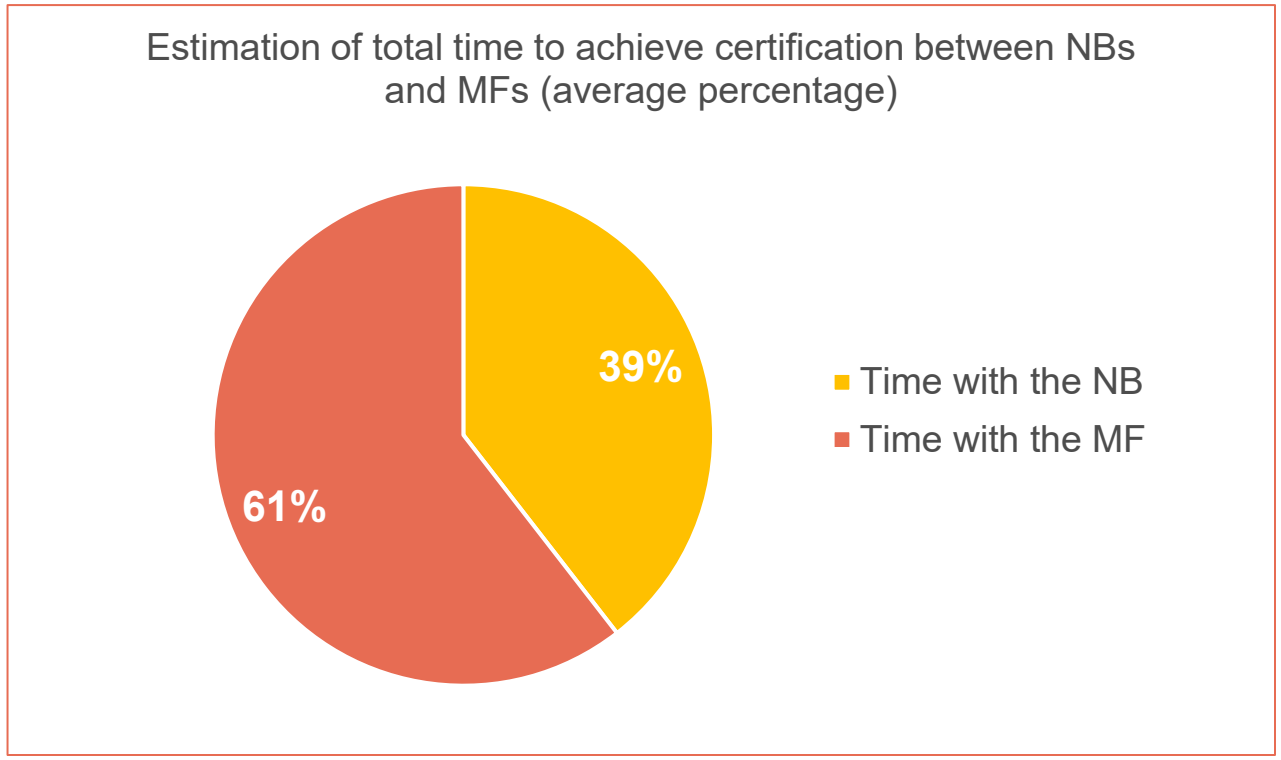
- Data of 10 NBs
- This indicator shows the time to reach issuance of a new EC certificate (from written agreement signed to issuance) under IVDR.
- 3 out of 13 NBs who are designated under the IVDR have not issued certificates yet.

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 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: 70%

Time with the manufacturer

- Minimum value: 30%
- Maximum value: 80%

Notes:

- Data of 10 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.

European Commission

IVD

Large dataset Ⓛ

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

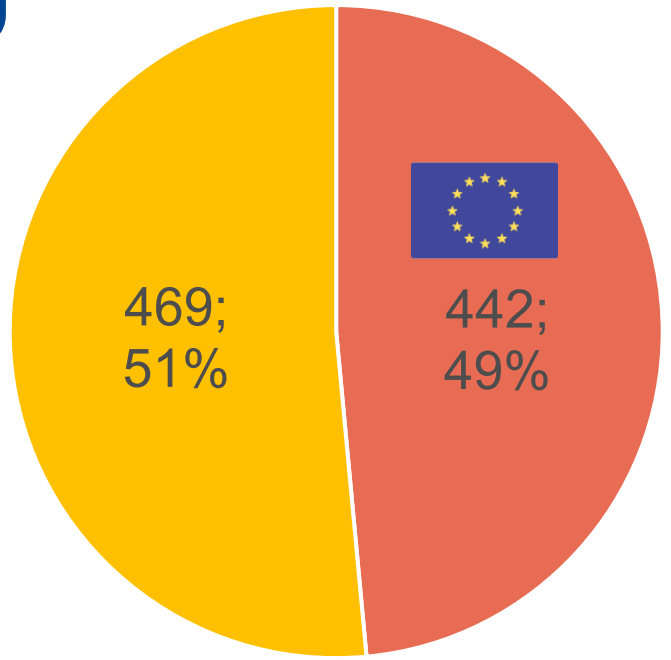
European Commission

IVD

Number of clients for IVDR

October 2024
Total number of clients: 911

Number of clients based **outside the EU**



Number of clients based **in the EU**

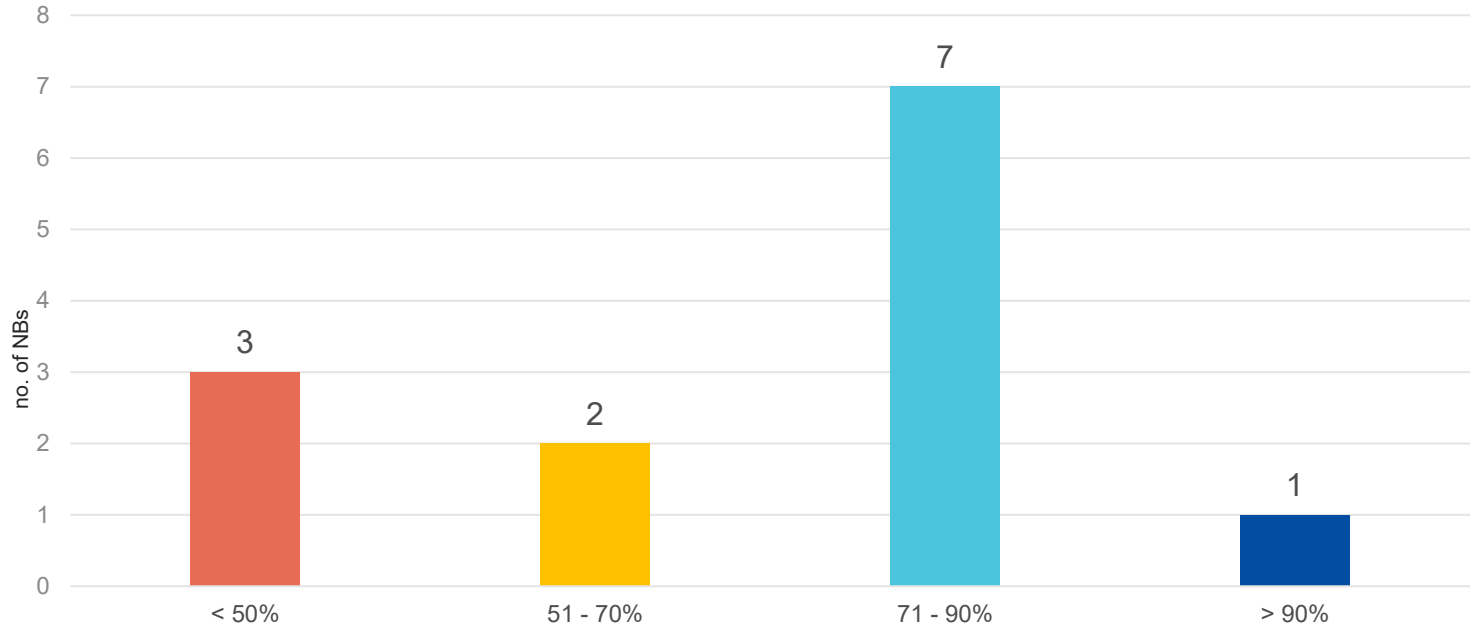
Data of 13 NBs designated under IVDR
Photo credit EU flag: Flaticon.com

European Commission

IVD

How many of the clients are SMEs*?

October 2024
Total number of clients: 911



Almost all NBs have SMEs as their main clients:

- 3 NBs (23%) indicated that less than 50% of their clients are SMEs
- 2 NBs (15%) indicated that between 51 and 70% of their clients are SMEs
- 7 NBs (54%) indicated that between 71 and 90% of their clients are SMEs
- Only 1 NB (8%) indicated that it almost only has SMEs as clients

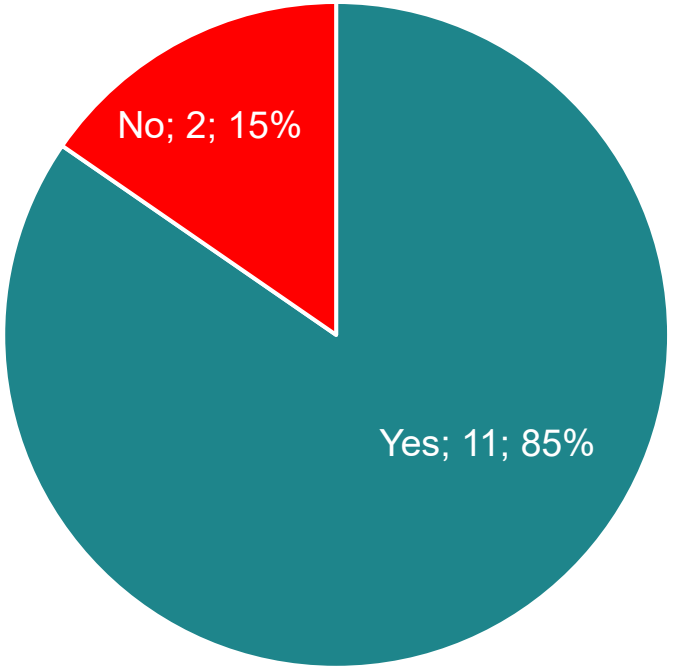
Notes:
Data of 13 NBs designated under IVDR

*Definition SME: The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.' (Source: Extract of Article 2 of the annex to Recommendation 2003/361/EC)

European Commission

IVD

Does your NB take on new clients for IVDR?



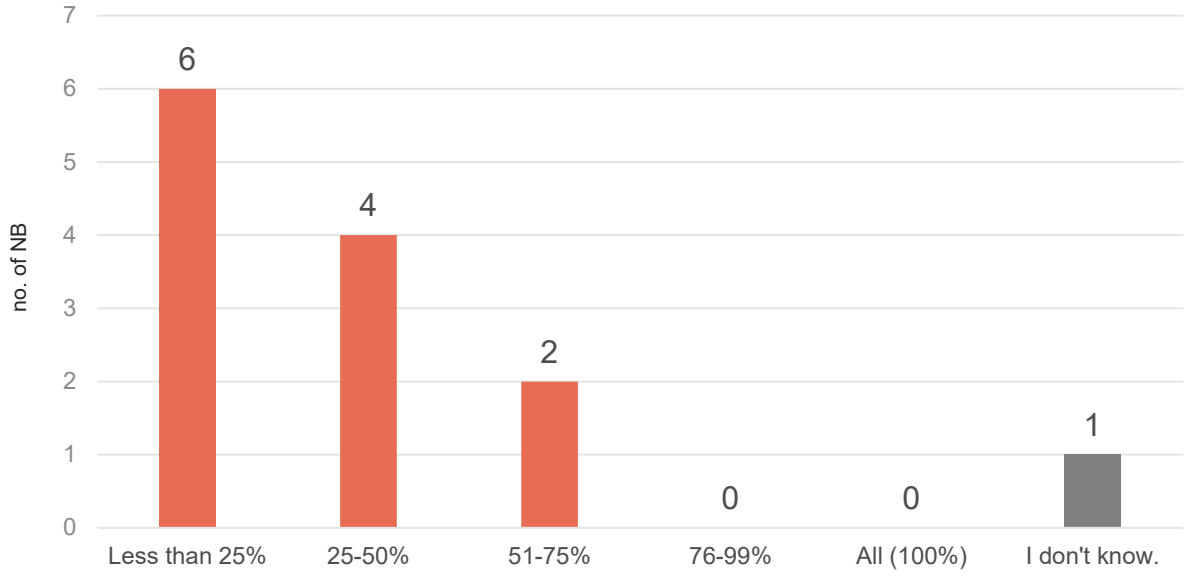
Data of 13 NBs designated under IVDR

European Commission

To IVDR: How many of the clients with certificates under the Directive completed the transfer of all devices intended to be certificated?

IVD

October 2024
Total number of clients: 911



Data of 13 NBs designated under IVDR

- About half of the NBs (6; 46%) indicated that less than 25 % of their clients with certificates under the Directive have completed the transfer to IVDR of all devices intended to be certificated
- Only 2 NBs (15%) indicated that > 50% of their clients have completed the transfer
- No NB indicated that 76-100% of their clients have completed the transfer

European Commission

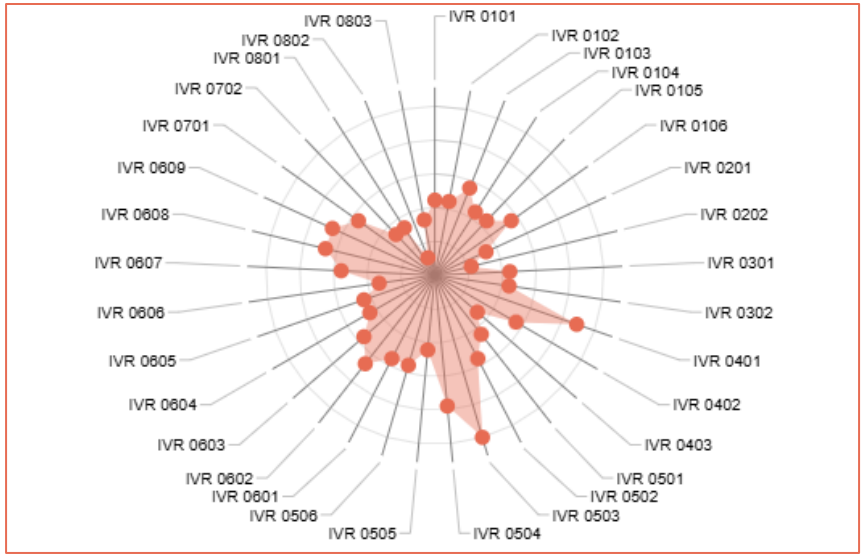
Which IVR codes are covered by IVDR certificates?

IVD

I: Codes reflecting the design and intended purpose of the device

IVR

Devices for blood grouping, tissue typing, determination of markers of cancer and non-malignant tumours, human genetic testing, determination of markers of infection/immune status, non-infectious diseases, physiological markers, disorders/impairments (exept human genetic testing) and therapeutic measures, control materials without an assigned quantitative or qualitative value, class A devices in sterile condition



	Number of NBs indicating devices/categories
IVR 0503 Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents	9
IVR 0401 Devices intended to be used in screening/confirmation of congenital/inherited disorders	8
IVR 0504 Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging	7
IVR 0602 Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease	6
IVR 0608 Devices intended to be used for screening, determination or monitoring of physiological markers	6
IVR 0609 Other devices intended to be used to define or monitor physiological status and therapeutic measures	6
IVR 0103 Devices intended to determine markers of the Kell system [Kell (K)]	5
IVR 0106 Other devices intended to be used for blood grouping	5
IVR 0402 Devices intended to be used to predict genetic disease/disorder risk and prognosis	5
IVR 0502 Devices intended to be used to detect the presence of, or exposure to transmissible agents in blood, blood components, cells, tissues or organs, or in any of their derivatives, to assess their suitability for transfusion, transplantation or cell administration	5

Note: Top 10 only; for more details see dashboard

European Commission

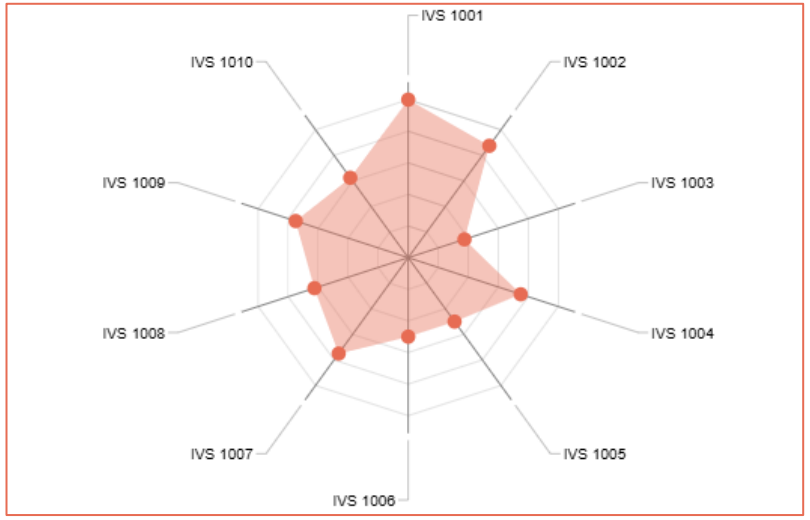
Which IVS codes are covered by IVDR certificates?

IVD

II: Horizontal codes

IVS

In vitro diagnostic devices with specific characteristics



	Number of NBs indicating devices/categories
IVS 1001 Devices intended to be used for near-patient testing	8
IVS 1002 Devices intended to be used for self-testing	7
IVS 1004 Devices manufactured utilising tissues or cells of human origin, or their derivatives	6
IVS 1007 Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes (point 1.6 of Annex VIII to Regulation (EU) 2017/746)	6
IVS 1009 Software that are devices in themselves including software apps, software for data analysis, and for defining or monitoring therapeutic measures	6
IVS 1008 Instruments, equipment, systems or apparatus	5
IVS 1010 Devices incorporating software/utilising software/controlled by software	5
IVS 1005 Devices in sterile condition	4
IVS 1006 Calibrators (point 1.5 of Annex VIII to Regulation (EU) 2017/746)	4
IVS 1003 Devices intended to be used as companion diagnostics	3

European Commission

Which IVT codes are covered by IVDR certificates?

IVD

II: Horizontal codes

IVT

In vitro diagnostic devices
for which specific technologies are used

	Number of NBs indicating devices/categories
IVT 2005 In vitro diagnostic devices manufactured using biotechnology	10
IVT 2009 In vitro diagnostic devices manufactured using processing of materials of human, animal or microbial origin	10
IVT 2011 In vitro diagnostic devices which require packaging, including labelling	10
IVT 2006 In vitro diagnostic devices manufactured using chemical processing	9
IVT 2008 In vitro diagnostic devices manufactured in clean rooms and associated controlled environments	8
IVT 2010 In vitro diagnostic devices manufactured using electronic components including communication devices	6
IVT 2002 In vitro diagnostic devices manufactured using plastic processing	5
IVT 2003 In vitro diagnostic devices manufactured using non-metal mineral processing (e.g. glass, ceramics)	2
IVT 2001 In vitro diagnostic devices manufactured using metal processing	1
IVT 2004 In vitro diagnostic devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)	1
IVT 2007 In vitro diagnostic devices which require knowledge regarding the production of pharmaceuticals	1

European Commission

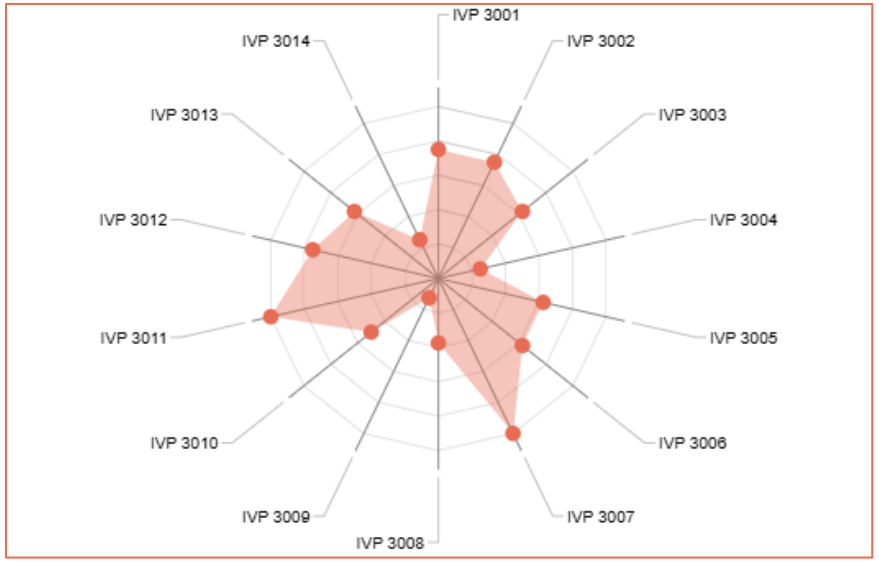
Which IVP codes are covered by IVDR certificates?

IVD

II: Horizontal codes

IVP

In vitro diagnostic devices
which require specific knowledge in examination
procedures for the purpose of product verification



	Number of NBs indicating devices/categories
IVP 3007 In vitro diagnostic devices which require knowledge regarding immunoassays	8
IVP 3011 In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	8
IVP 3001 In vitro diagnostic devices which require knowledge regarding agglutination tests	6
IVP 3002 In vitro diagnostic devices which require knowledge regarding biochemistry	6
IVP 3012 In vitro diagnostic devices which require knowledge regarding physical chemistry including electrochemistry	6
IVP 3003 In vitro diagnostic devices which require knowledge regarding chromatography	5
IVP 3005 In vitro diagnostic devices which require knowledge regarding coagulometry	5
IVP 3006 In vitro diagnostic devices which require knowledge regarding flow cytometry	5
IVP 3013 In vitro diagnostic devices which require knowledge regarding spectroscopy	5
IVP 3010 In vitro diagnostic devices which require knowledge regarding microscopy	4
IVP 3008 In vitro diagnostic devices which require knowledge regarding lysis based testing	3
IVP 3004 In vitro diagnostic devices which require knowledge regarding chromosomal analysis	2
IVP 3014 In vitro diagnostic devices which require knowledge regarding tests of cell function	2
IVP 3009 In vitro diagnostic devices which require knowledge regarding measurement of radioactivity	1

European Commission

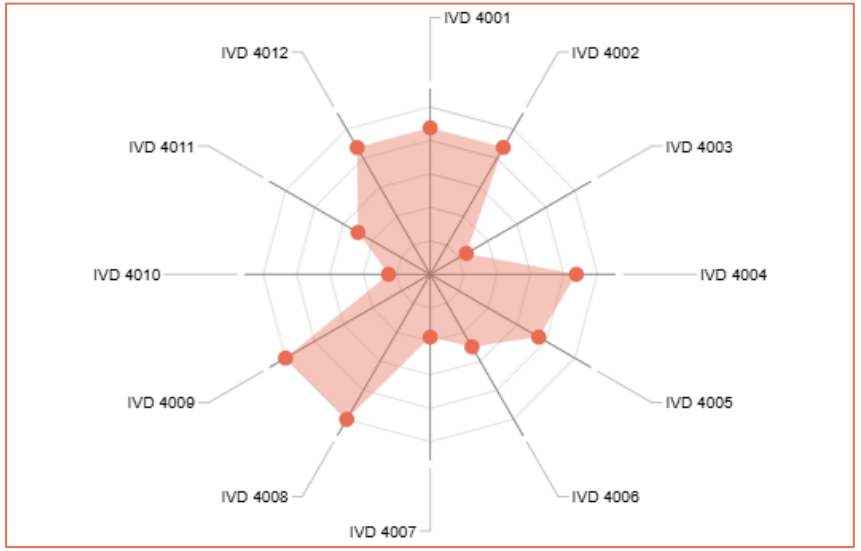
Which IVD codes are covered by IVDR certificates?

IVD

II: Horizontal codes

IVD

In vitro diagnostic devices which require specific knowledge in laboratory and clinical disciplines for the purpose of product verification



	Number of NBs indicating devices/categories
IVD 4008 In vitro diagnostic devices which require knowledge regarding immunology	8
IVD 4009 In vitro diagnostic devices which require knowledge regarding molecular biology/diagnostics	8
IVD 4001 In vitro diagnostic devices which require knowledge regarding bacteriology	7
IVD 4002 In vitro diagnostic devices which require knowledge regarding clinical chemistry/biochemistry	7
IVD 4004 In vitro diagnostic devices which require knowledge regarding genetics	7
IVD 4012 In vitro diagnostic devices which require knowledge regarding virology	7
IVD 4005 In vitro diagnostic devices which require knowledge regarding haematology/haemostasis, including coagulation disorders	6
IVD 4006 In vitro diagnostic devices which require knowledge regarding histocompatibility and immunogenetics	4
IVD 4011 In vitro diagnostic devices which require knowledge regarding parasitology	4
IVD 4007 In vitro diagnostic devices which require knowledge regarding immunohistochemistry/histology	3
IVD 4003 In vitro diagnostic devices which require knowledge regarding detection of transmissible agents (without organisms or viruses)	2
IVD 4010 In vitro diagnostic devices which require knowledge regarding mycology	2

European Commission

Which kinds of devices/categories of devices are covered by IVDR certificates?

IVD

A more detailed analysis can be found in the dashboard!

OVERVIEW

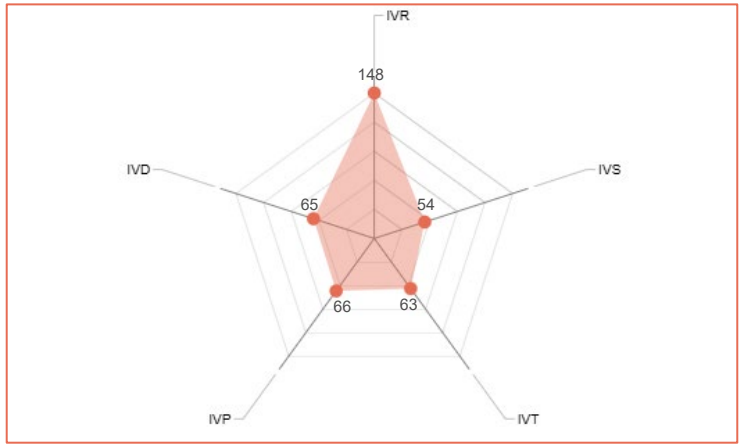
Number of NBs indicating this devices/categories:

I: Codes reflecting the design and intended purpose of the device

- Devices for blood grouping, tissue typing, determination of markers of cancer and non-malignant tumours, human genetic testing, determination of markers of infection/immune status, non-infectious diseases, physiological markers, disorders/impairments (exept human genetic testing) and therapeutic measures, control materials without an assigned quantitative or qualitative value, class A devices in sterile condition **(IVR): 148**

II: Horizontal codes

- In vitro diagnostic devices with specific characteristics **(IVS): 54**
- In vitro diagnostic devices for which specific technologies are used **(IVT): 63**
- In vitro diagnostic devices which require specific knowledge in examination procedures for the purpose of product verification **(IVP): 66**
- In vitro diagnostic devices which require specific knowledge in laboratory and clinical disciplines for the purpose of product verification **(IVD): 65**



European Commission

IVD

MD

4. Survey results regarding NB staff

Note:

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

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

Staff: Number of people employed by NBs in the field of medical devices (MDR & IVDR)

MD

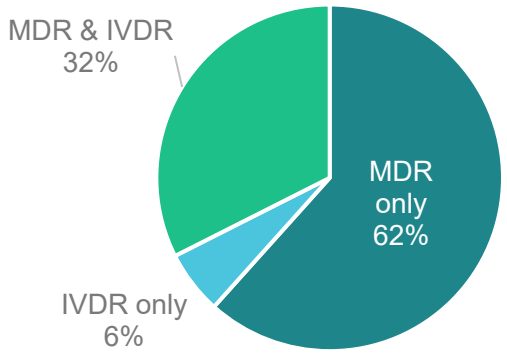
IVD

Note: Out of 51 notified bodies, **38 NBs** are designated under the **MDR** only, **12 NBs** are designated under **both the MDR and IVDR**, and **1 NB** is designated under the **IVDR only**.

October 2024
Total number of FTEs with conformity assessment activities and within administrative and supporting activities: **6.274,03** (internal staff and external contractors, data of 50 NBs)

- Thereof number of personnel with relevant clinical expertise: 922,31 FTEs (data of 48 NBs)

Staff working on …



Note: n=5.228,52 FTEs excl. staff with clinical expertise

Notes:
- Data status: 31/10/2024
- By employee type
- Counted in Full Time Equivalents (FTE)

Employees within conformity assessment activities: 4.615,77 (FTE)
- Internal: 3.506,51 FTEs
- External contractors: 1109,26 FTEs

Employees within administrative and supporting activities (in relation to Regulations): 1.658,26 (FTE)
- Internal: 1.637,26 FTEs
- External contractors: 21 FTEs

Employees within the conformity assessment activities is the personnel referred to in Sections from 3.2.3 to 3.2.7 of Annex VII MDR/IVDR in addition to the personnel referred to in Section 4.4, second paragraph, of Annex VII MDR/IVDR ([…individual responsible for ensuring that the assessment of that application is conducted in accordance with the relevant procedures and for ensuring that the appropriate resources including personnel are utilised for each of the tasks of the assessment…].
Other roles would fit under employees within "administrative and supporting activities", including e.g. commercial operations team, marketing team, sales team, training team etc.
Data of 50 NBs

European Commission

Thank you

Contact for questions: medical.devices@goeg.at

Austrian National Public Health Institute/ Gesundheit Österreich (GÖG)

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