



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

Survey results of the 16th NB survey (MDR/IVDR)
with data status 30 June 2025
(small, medium and large dataset)

25 March 2026

Disclaimer

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

Acknowledgements

The study team would like to sincerely thank the following institutions and people for the support in the 16th NB survey:

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

Content

About

1. About the study, survey and datasets

MD

2. Survey results for medical devices

IVD

3. Survey results for in vitro diagnostic medical devices

MD

IVD

4. Survey results regarding NB staff

MD

IVD

5. Medical device single audit program

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List of abbreviations (1)

Abbreviation	Meaning
AIMDD	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
CE	Conformité Européenne
DG SANTE	Directorate-General for Health and Food Safety
EC	European Commission
EU	European Union
EURLs	EU reference laboratories
FTE	Full Time Equivalent
FWC	Framework contract
GÖG	Gesundheit Österreich GmbH / Austrian National Public Health Institute
HaDEA	European Health and Digital Executive Agency
IVDs	In-vitro diagnostic medical device(s)
IVDD	Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices
IVDR	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 (In Vitro Diagnostic Medical Device Regulation)
LD	Large dataset

List of abbreviations (2)

Abbreviation	Meaning
MD	Medium dataset
MDCG	Medical Device Coordination Group
MDs	Medical device(s)
MDD	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (Medical Device Regulation)
MDSAP	Medical device single audit program
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

1. About the study, survey and datasets

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

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

- **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 June 2026 (42 months*)
* Study amendment from 2 December 2025 – 1 June 2026
- **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

Preliminary notes

- **Data content:**

- The following slides show the results of the **16th NB survey conducted at the beginning of July 2025** with **requested data** from notified bodies designated under MDR and/or IVDR **until 30 June 2025**.
- These survey results are also compared with previous survey data (see data sources).

- **Data sources:**

- Data collected between April 2023 and July 2025 by the study team
- Data collected between February 2021 and October 2022 by the European Commission

- **Datasets:**

- This presentation contains the results of the small, medium and large datasets collected in July 2025.
 - Ⓢ The **small dataset** is a small set of questions asked to notified bodies **every two months**.
Note: From April to July 2023, it was asked monthly.
 - Ⓜ The **medium dataset** is a set of questions asked to notified bodies **every four months** concerning the activities they have been performing since their designation.
 - Ⓛ The **large dataset** contains additional data asked to notified bodies **once a year**.

NB survey overview

NB survey	Survey period (survey launch – survey closure)	Requested dataset* SD = small dataset MD = medium dataset LD = large dataset	Requested data	Response rate (only NBs designated under MDR and/or IVDR)
1 st NB survey	03/04/2023 - 05/05/2023	SD1 + MD1	from designation up to 31/03/2023	39 out of 39 NBs (100%)
2 nd NB survey	12/05/2023 - 05/06/2023	SD2	from designation up to 30/04/2023	27 out of 39 NBs (~70%)
3 rd NB survey	05/06/2023 - 19/06/2023	SD3	from designation up to 31/05/2023	22 out of 39 NBs (~56%)
4 th NB survey	03/07/2023 - 28/07/2023	SD4 + MD2	from designation up to 30/06/2023	39 out of 39 NBs (100%)
5 th NB survey	01/09/2023 - 06/10/2023	SD5	from designation up to 31/08/2023	40 out of 40 NBs (100%)
6 th NB survey	03/11/2023 - 22/12/2023	SD6 + MD3 + LD1	from designation up to 31/10/2023	41 out of 41 NBs (100%)
7 th NB survey	08/01/2024 - 05/02/2024	SD7	from designation up to 31/12/2023	45 out of 45 NBs (100%)
8 th NB survey	04/03/2024 - 20/03/2024	SD8 + MD4	from designation up to 29/02/2024	45 out of 45 NBs (100%)
9 th NB survey	02/05/2024 - 21/06/2024	SD9	from designation up to 30/04/2024	48 out of 48 NBs (100%)
10 th NB survey	01/07/2024 - 06/08/2024	SD10 + MD5	from designation up to 30/06/2024	50 out of 50 NBs (100%)
11 th NB survey	02/09/2024 - 17/10/2024	SD11	from designation up to 31/08/2024	50 out of 50 NBs (100%)
12 th 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%)
13 th NB survey	21/01/2025 – 27/02/2025	SD13 + TE2**	from designation up to 31/12/2024	51 out of 51 NBs (100%)
14 th NB survey	03/03/2025 – 08/04/2025	SD14 + MD7	from designation up to 28/02/2025	51 out of 51 NBs (100%)
15 th NB survey	05/05/2025 – 23/05/2025	SD15	from designation up to 30/04/2025	51 out of 51 NBs (100%)
16 th NB survey	01/07/2025 – 02/09/2025	SD16 + MD8 + LD3	from designation up to 30/06/2025	51 out of 51 NBs (100%)

16th NB survey results are presented in this PowerPoint presentation

* **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 and 13th NB survey** (conducted in the framework of the 'Study supporting the monitoring of the availability of medical devices on the EU market') were used to ask NBs questions that are relevant for the Targeted Evaluation.

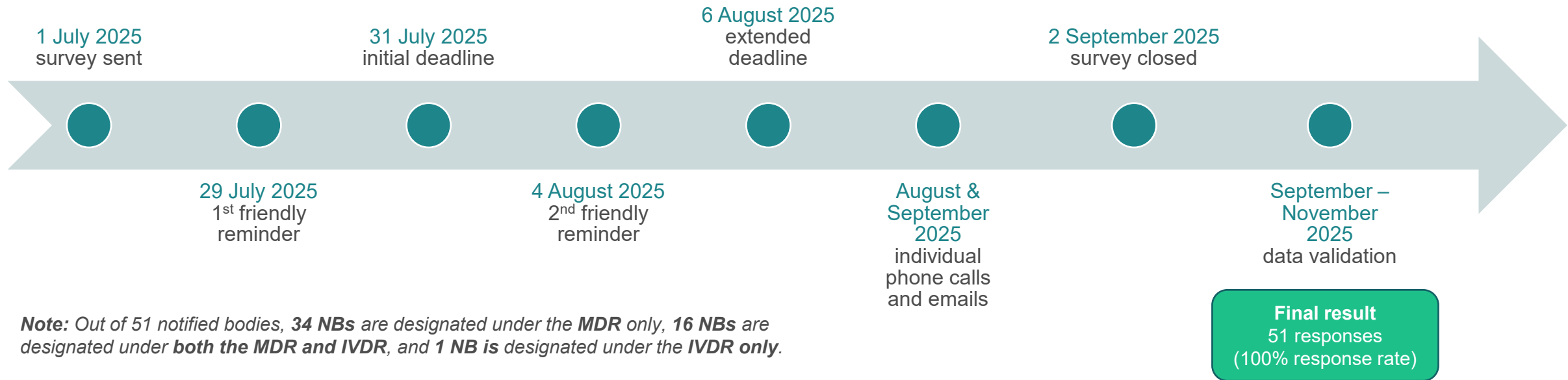
Dashboard

- 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 \(europa.eu\)](https://ec.europa.eu/evidence_centre/studies/monitoring-medical-devices)
- [Instructions for use for the dashboard](#)

Timeline for the 16th NB survey

(conducted in July 2025 with requested data from designation up to 30/06/2025)

51 notified bodies designated under MDR and/or IVDR (data status: 27 June 2025)



Note: Out of 51 notified bodies, 34 NBs are designated under the MDR only, 16 NBs are designated under both the MDR and IVDR, and 1 NB is designated under the IVDR only.

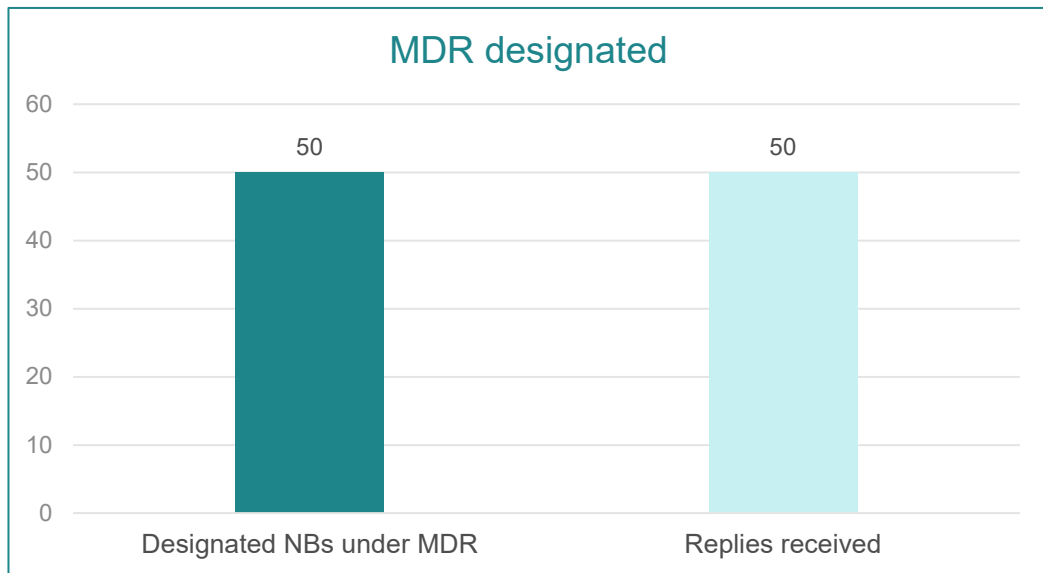
Response rate for the 16th NB survey

(conducted in July 2025 with requested data from designation up to 30/06/2025)

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

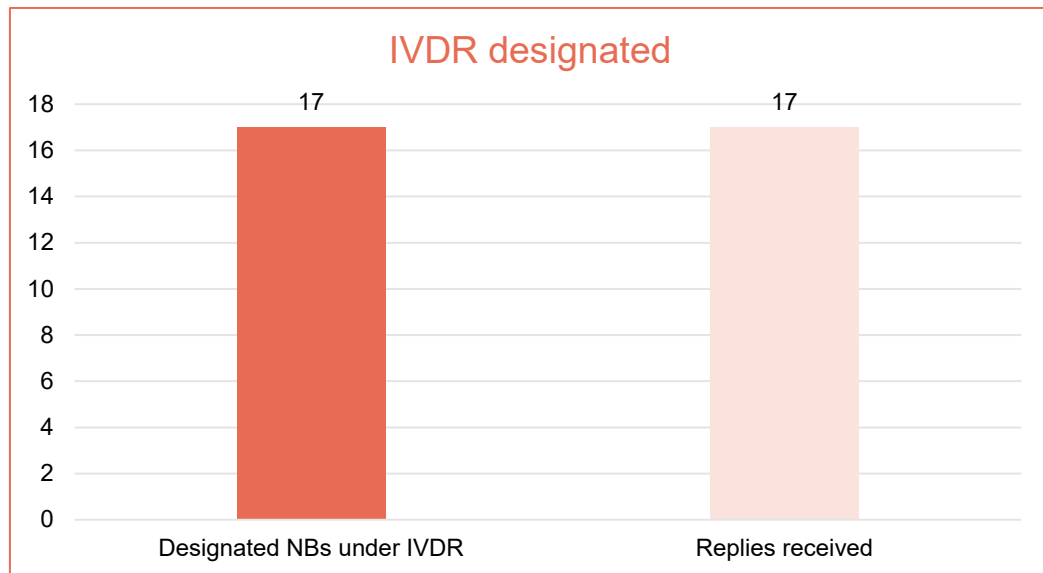
Note: Out of 51 notified bodies, 34 NBs are designated under the MDR only, 16 NBs are designated under both the MDR and IVDR, and 1 NB is designated under the IVDR only.

MD



100% response rate

IVD



100% response rate

2. Survey results for medical devices

Note:

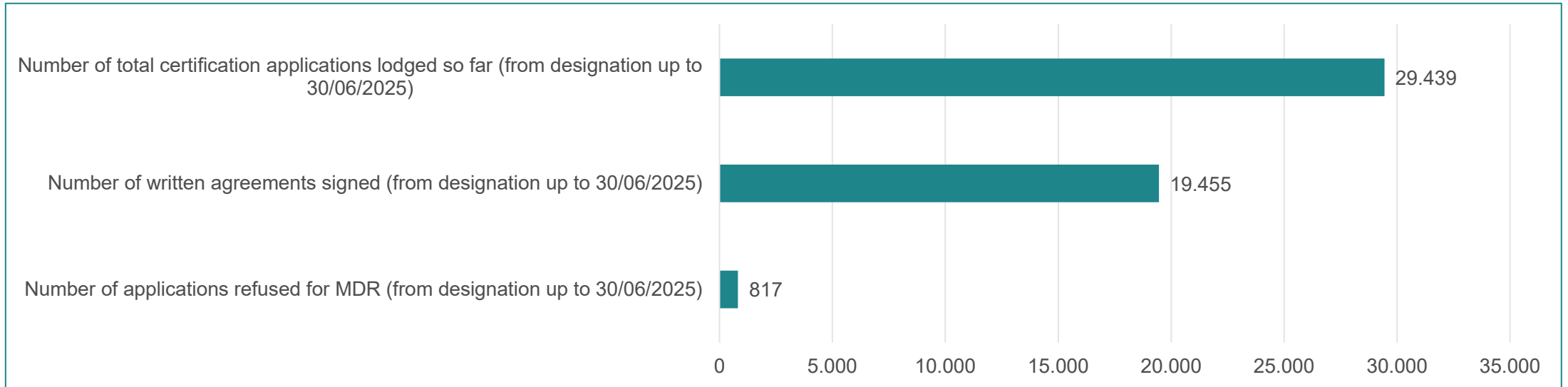
- Thousands separators are represented as dots or blank space (not comma) in the graphs.
- Datasets:
 - ⑤ The **small dataset** is a small set of questions asked to notified bodies **every two months**.
Note: From April to July 2023, it was asked monthly.
 - ④ The **medium dataset** is a set of questions asked to notified bodies **every four months** concerning the activities they have been performing since their designation.
 - ③ The **large dataset** contains additional data asked to notified bodies **once a year**.

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.

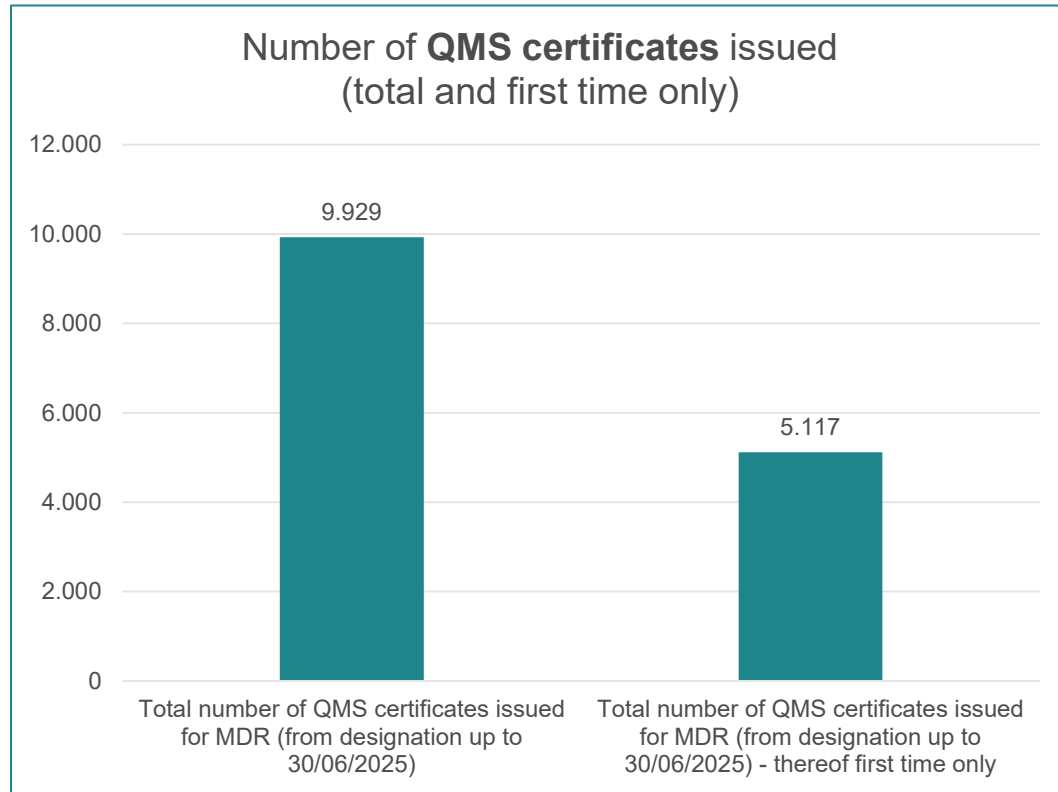
MDR applications filed and refused, written agreements signed



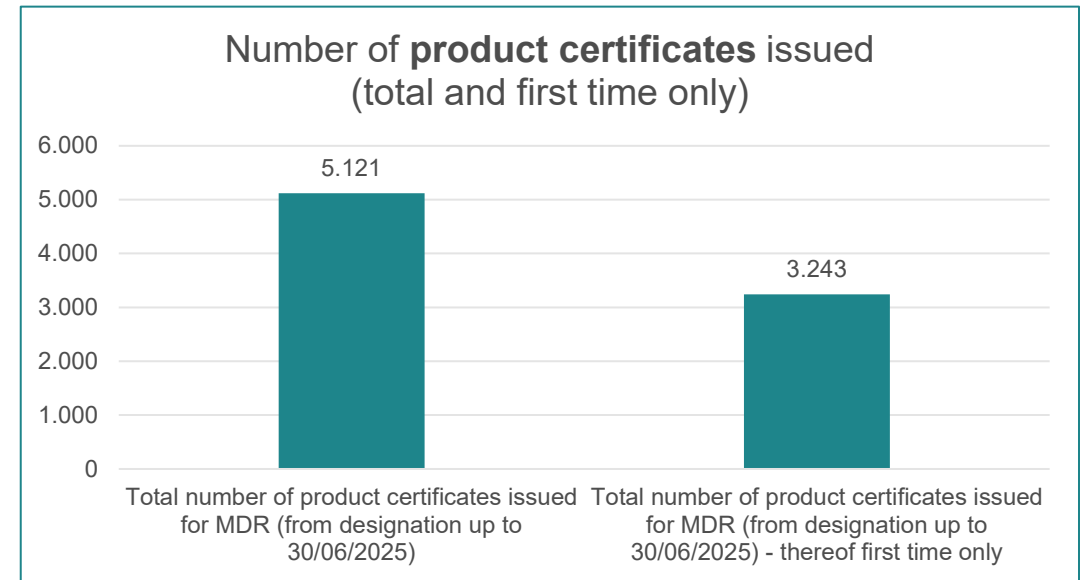
Notes:

- **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 30/06/2025), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included.
- **Written agreements signed:** This refers to the number of written agreements (contracts) between a NB and a manufacturer signed by both parties.

MDR number of QMS / product certificates issued

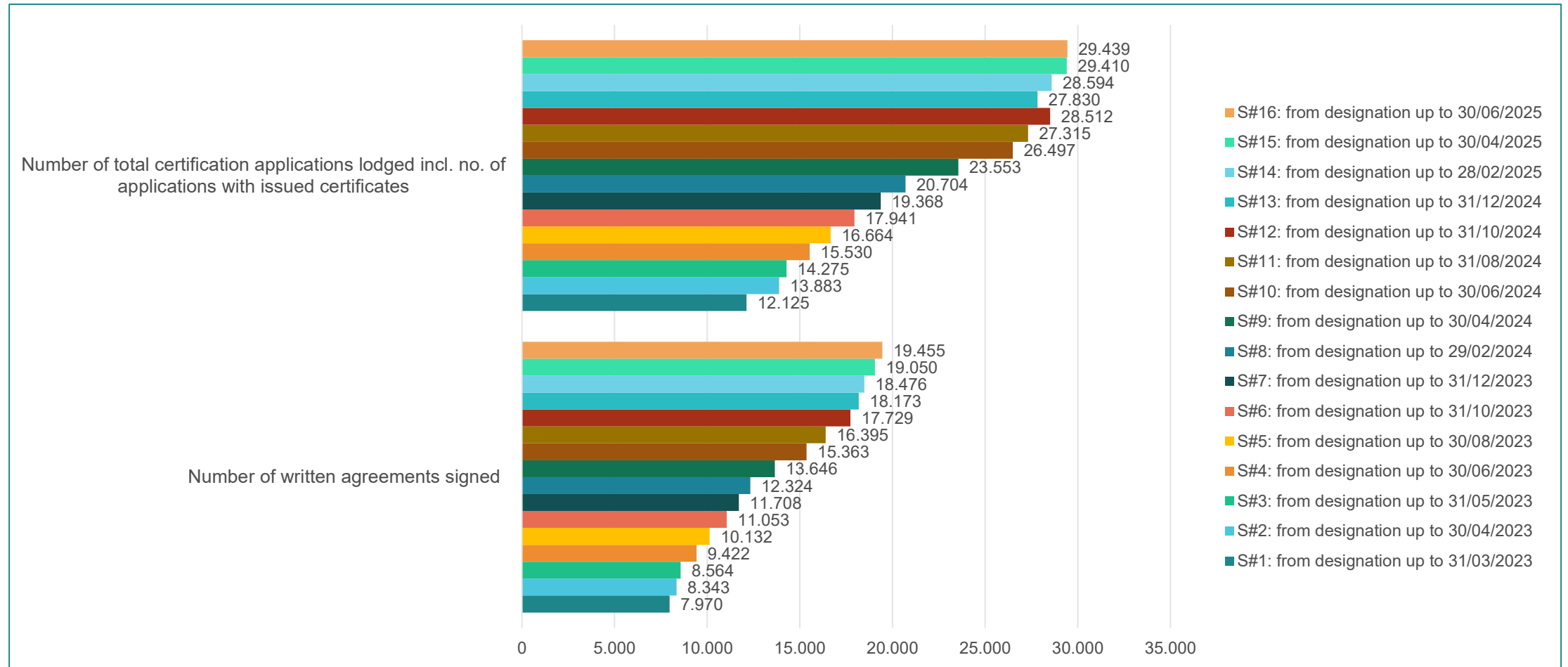


Note QMS Certificates: This relates to Annex IX Chapter I or Annex XI Part A according to MDR.



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

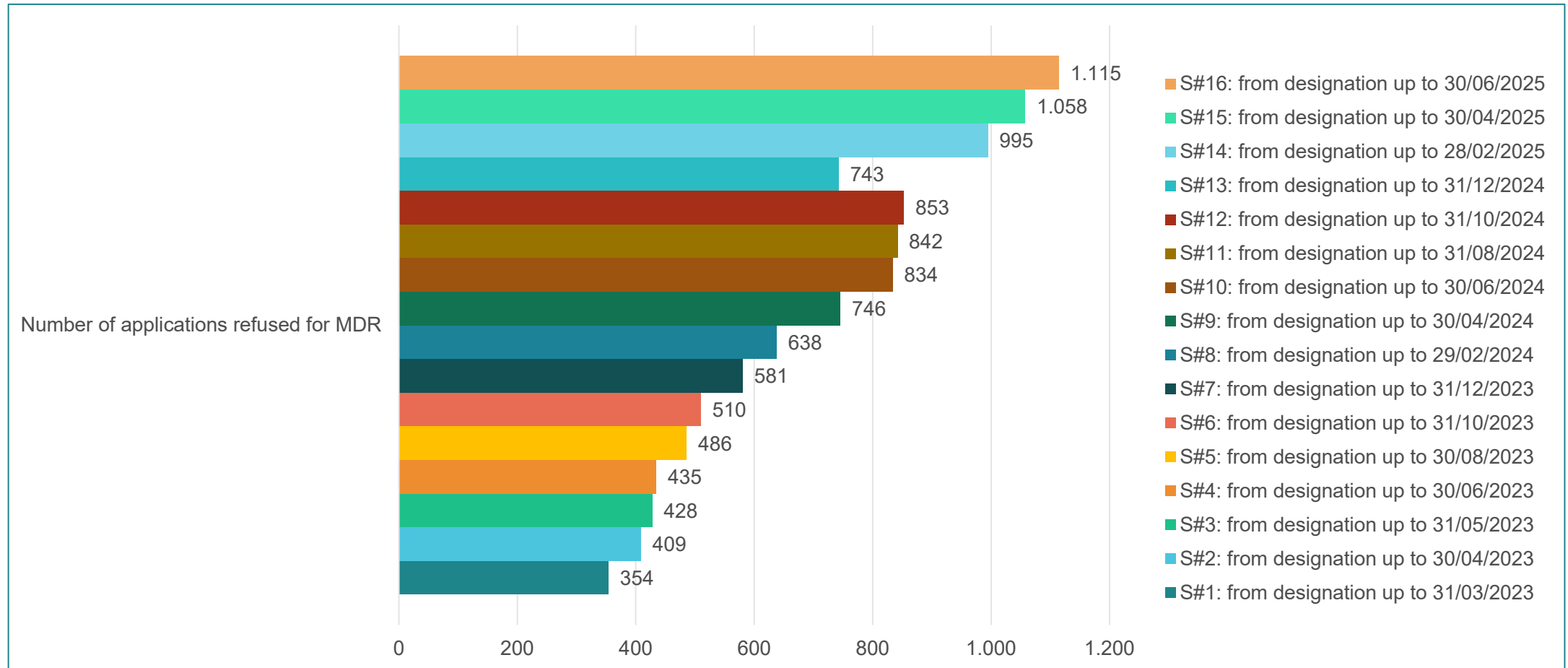
Survey comparison – March 2023 to June 2025



Notes:

- S = Survey; # = number
- Survey **#16**: 50 designated NBs for MD
- Surveys **#2** and **#3** did not reach 100% response rate (#2: ~70%; #3: 56%). In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.
- Change in methodology of counting applications by one NB in survey #13
- Change in methodology of counting refused applications compared to previous surveys by NBs in survey #11, #12 and #13

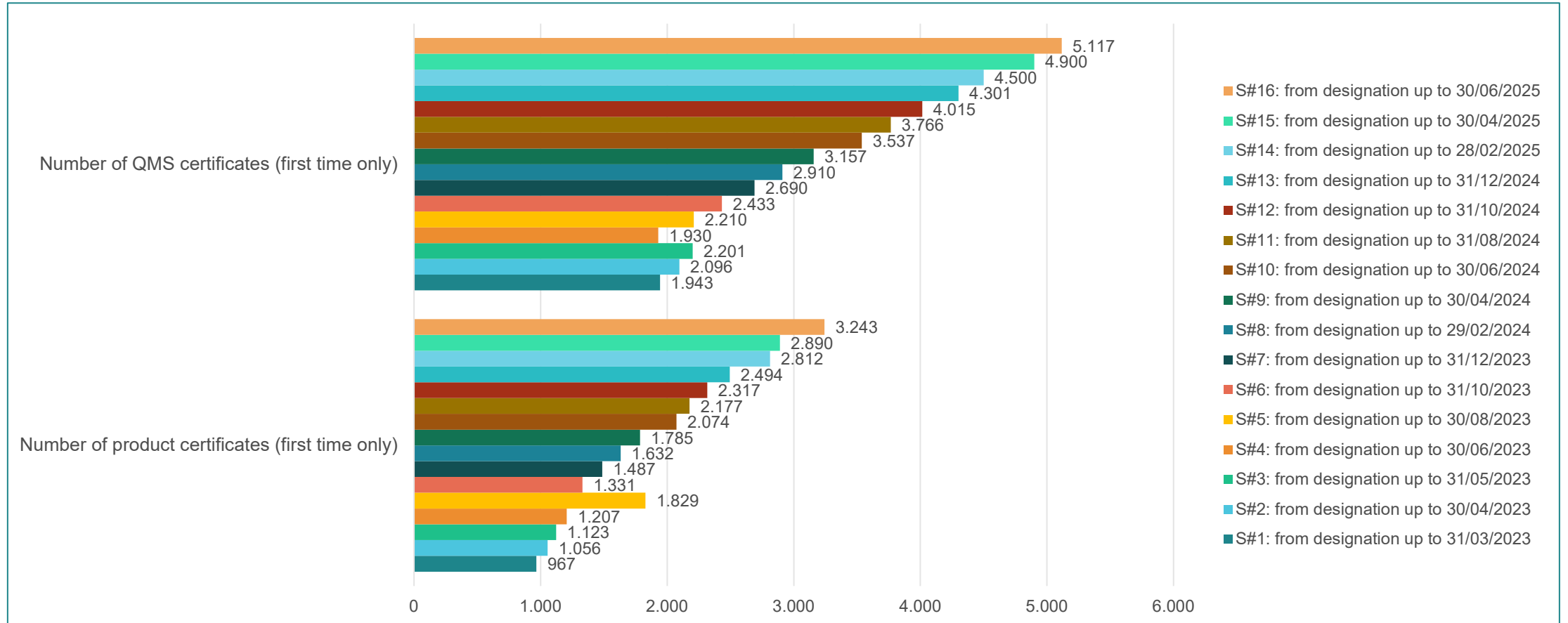
Survey comparison – March 2023 to June 2025



Notes:

- S = Survey; # = number
- Survey **#16**: 50 designated NBs for MD
- Surveys **#2** and **#3** did not reach 100% response rate (#2: ~70%; #3: 56%). In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.
- Change in methodology of counting refused applications compared to previous surveys by NBs in survey #11, #12 and #13.
- Retrospective data provided by one NB (starting from S#1) have been incorporated into this graph from this presentation onward.

Survey comparison – March 2023 to June 2025



S = Survey; # = number

Notes:

20

- Survey #16: 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.

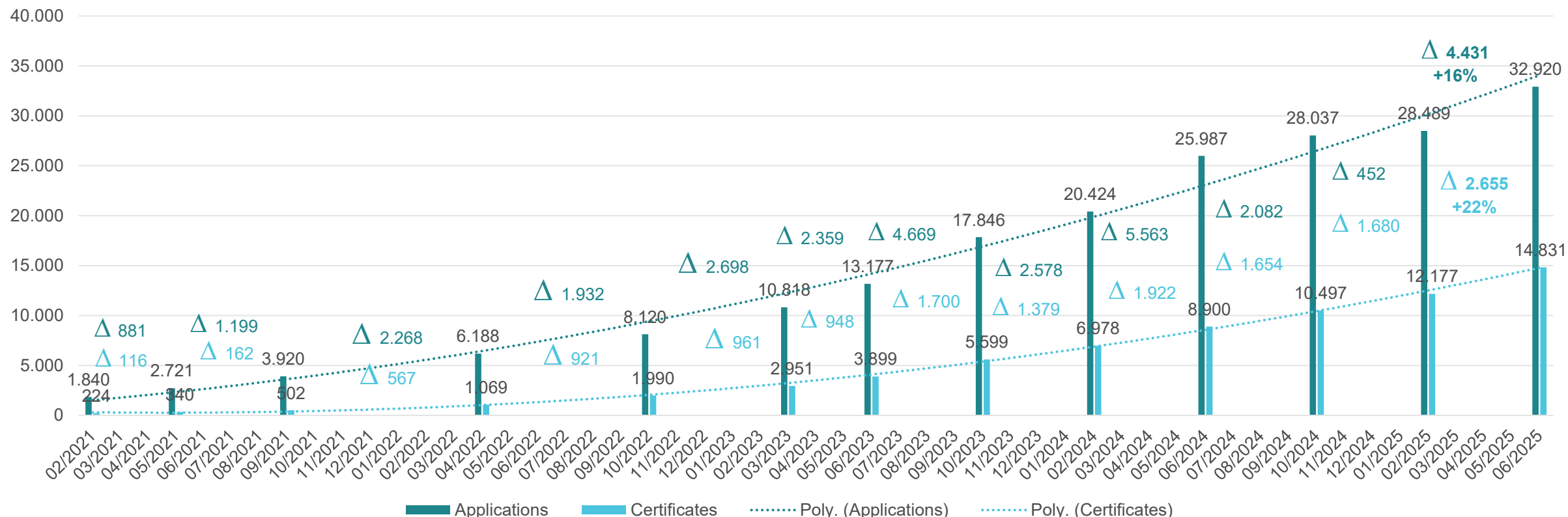
Medium dataset

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)



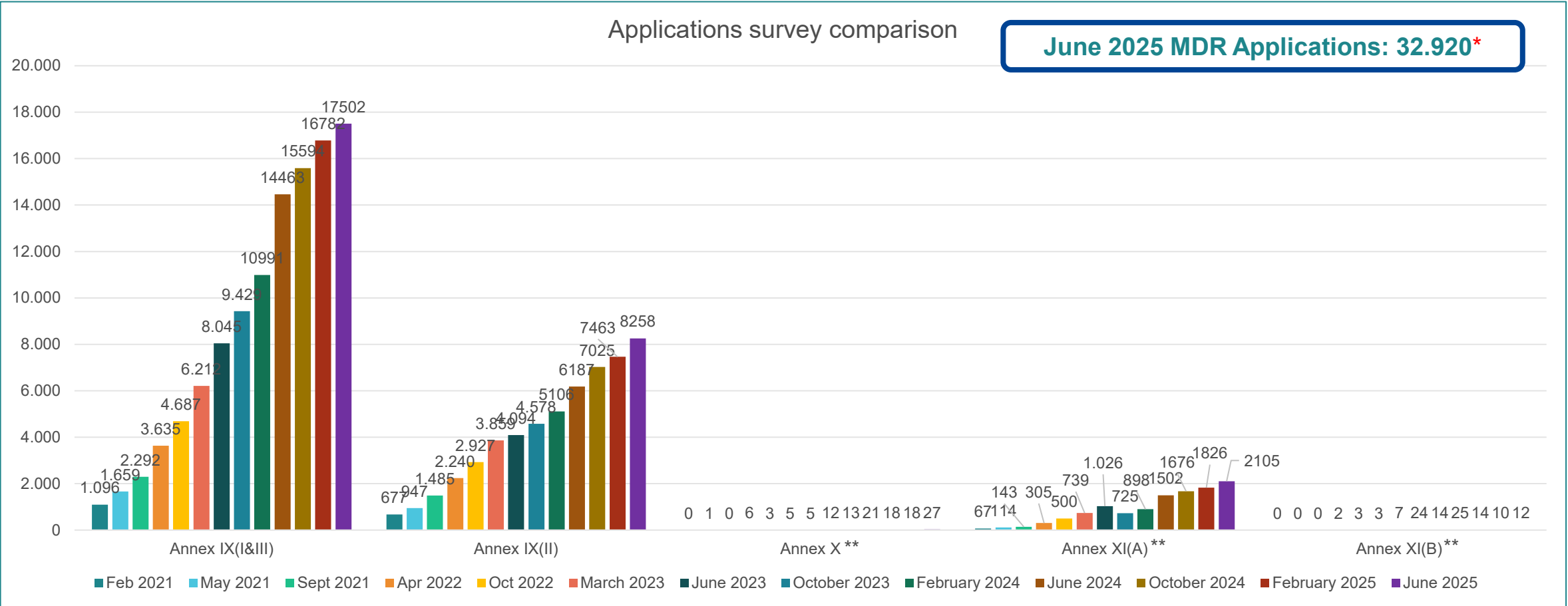
June 2025
MDR Applications:
 Total number of applications filed by Annex [Ⓜ]: 32.920*
MDR Certificates:
 Total number of certificates by Annex [Ⓜ]: 14.831



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 30/06/2025), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
- **Certificates issued:** This number includes **certificates issued so far** (from designation up 30/06/2025) under the MDR.
- The dotted line shows the polynomial trend line (grade 2).

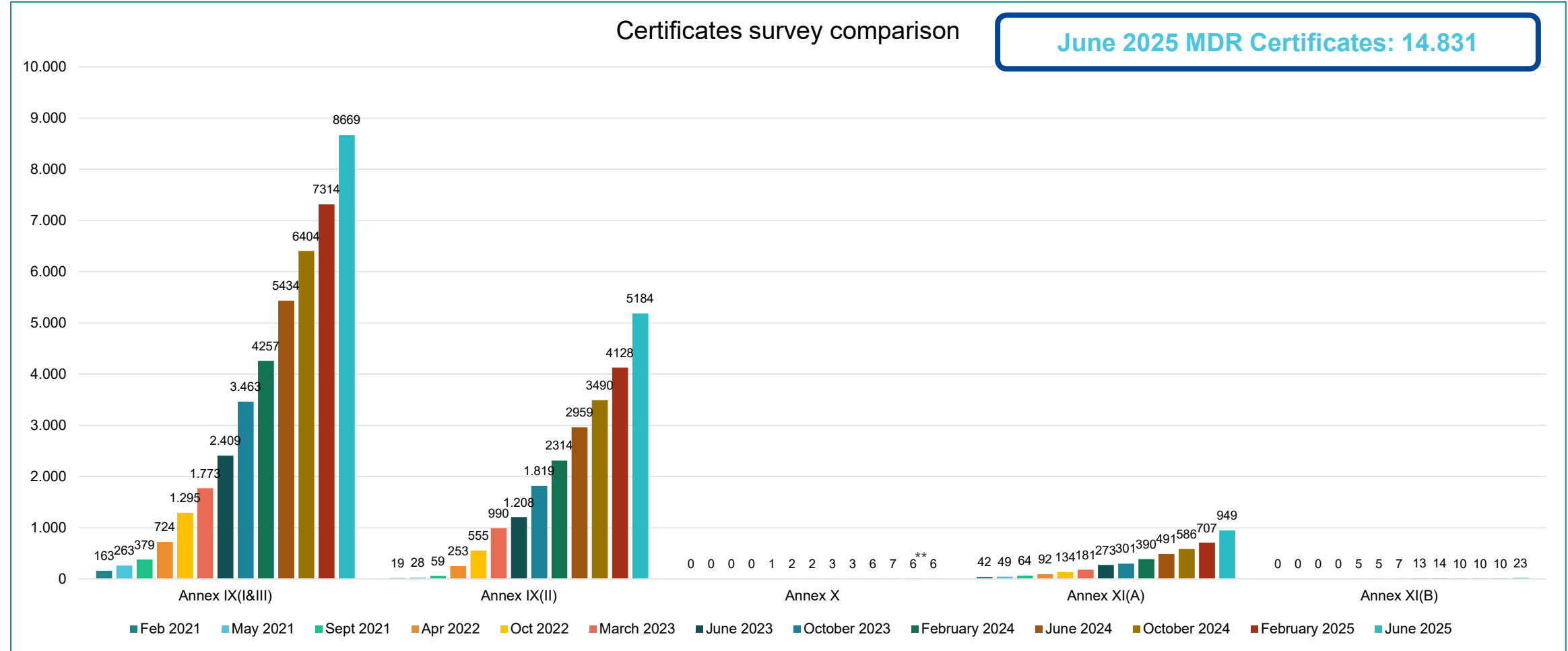
MDR applications by annex – survey comparison



Notes:

- Designated NBs for MD: 50; NBs that included Annex XVI products in the numbers provided: 29
- * 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 30/06/2025), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.

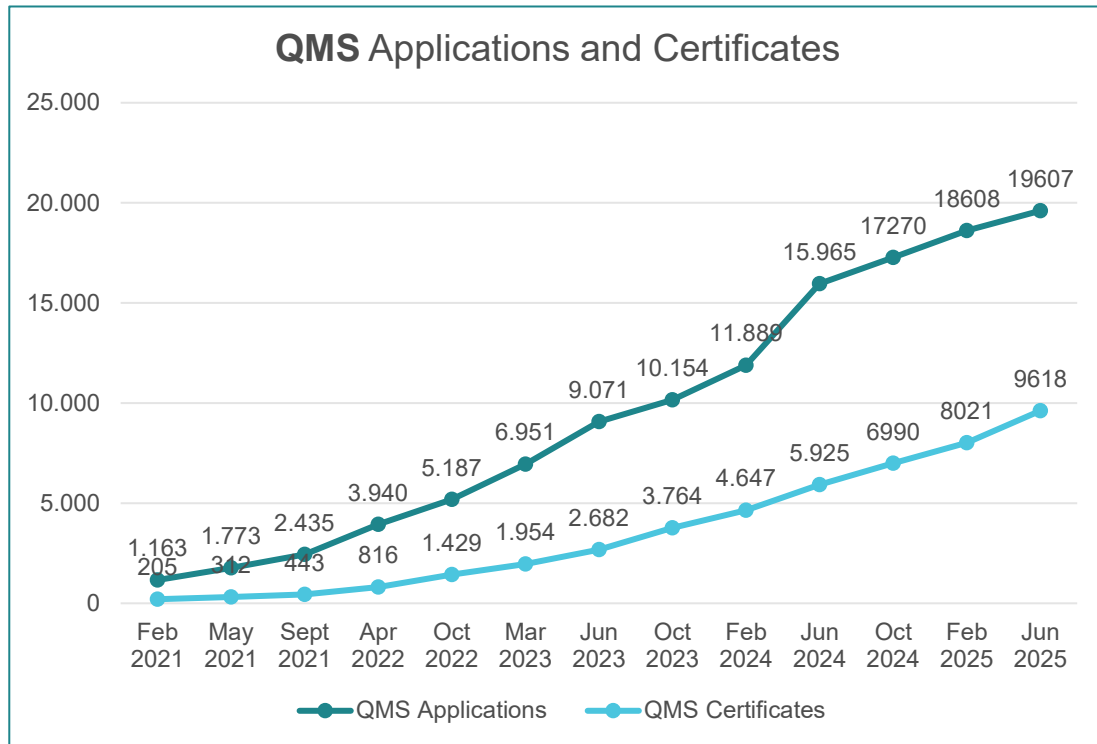
MDR certificates by annex - survey comparison



Notes:

- Designated NBs for MD: 50; NBs that included Annex XVI products in the numbers provided: 29
- * The data shown comes from the medium data set
- ** Change in methodology of counting by one NB leading to a decrease
- **Certificates issued by annex:** This number includes certificates issued so far (from designation up to 30/06/2025) under the MDR by annex.

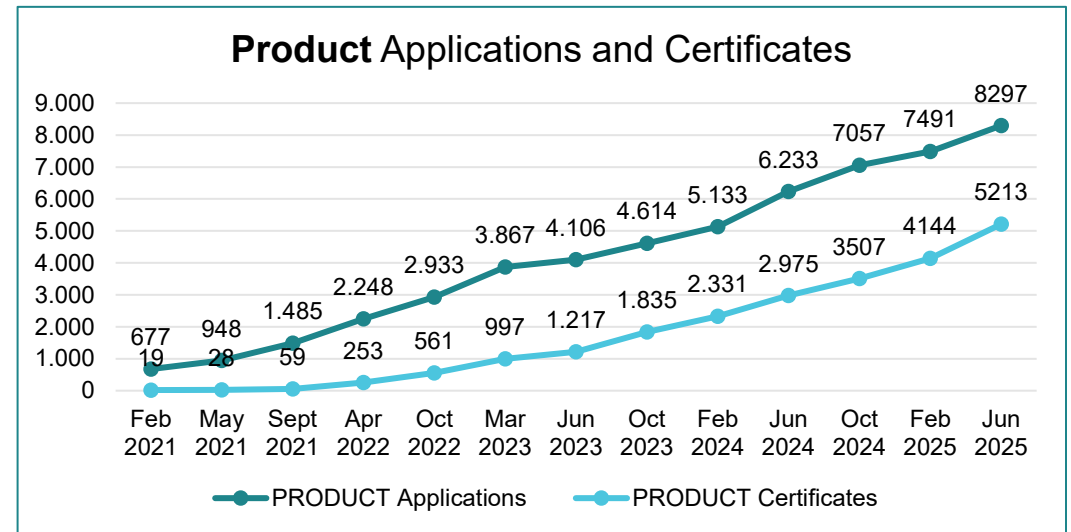
MDR applications and certificates by type (QMS vs Product) – survey comparison



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

June 2025
MDR Applications: 32.920*
MDR Certificates: 14.831

* 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.



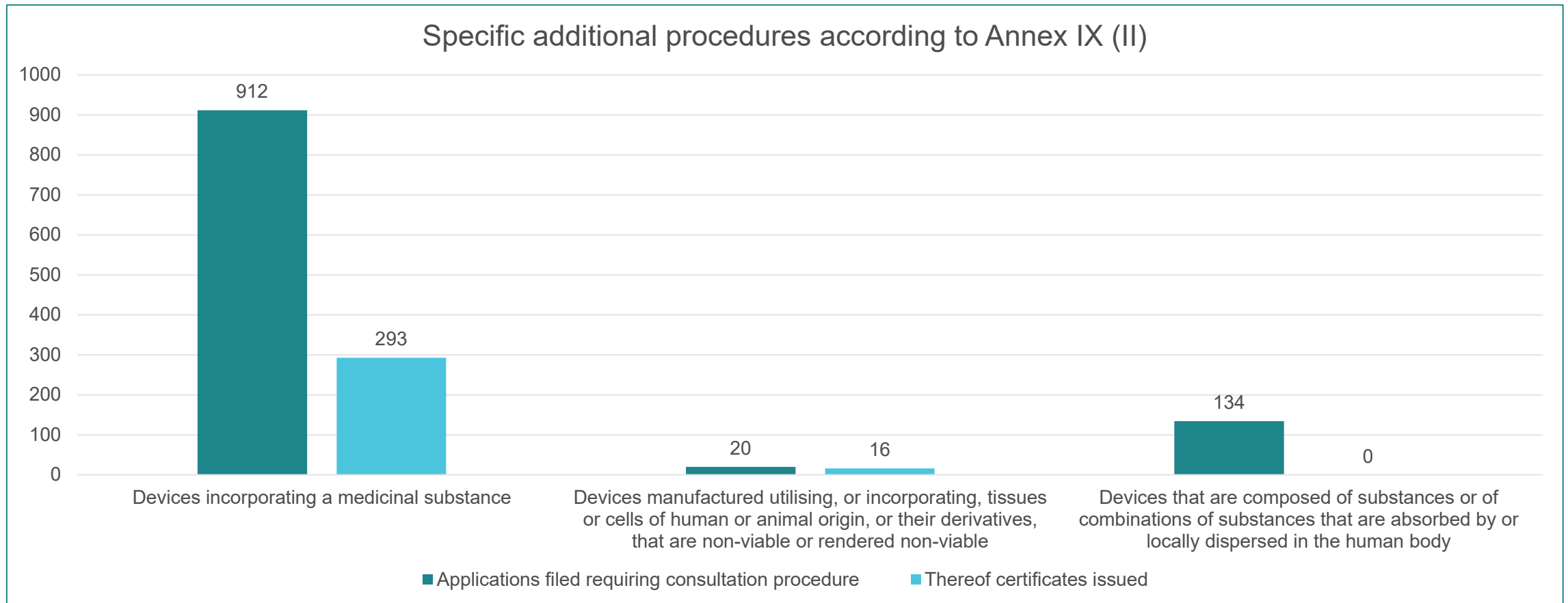
Note PRODUCT Applications and Certificates: This relates to Annex IX Chapter II, Annex X or Annex XI Part B according to MDR.

Total number of applications lodged for changes received for already MDR issued certificates: 6.243

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

Specific additional procedures according to Annex IX (II)

June 2025

MDR Applications:Total number of applications filed by Annex [Ⓜ]: 32.920***MDR Certificates:**Total number of certificates by Annex [Ⓜ]: 14.831**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.

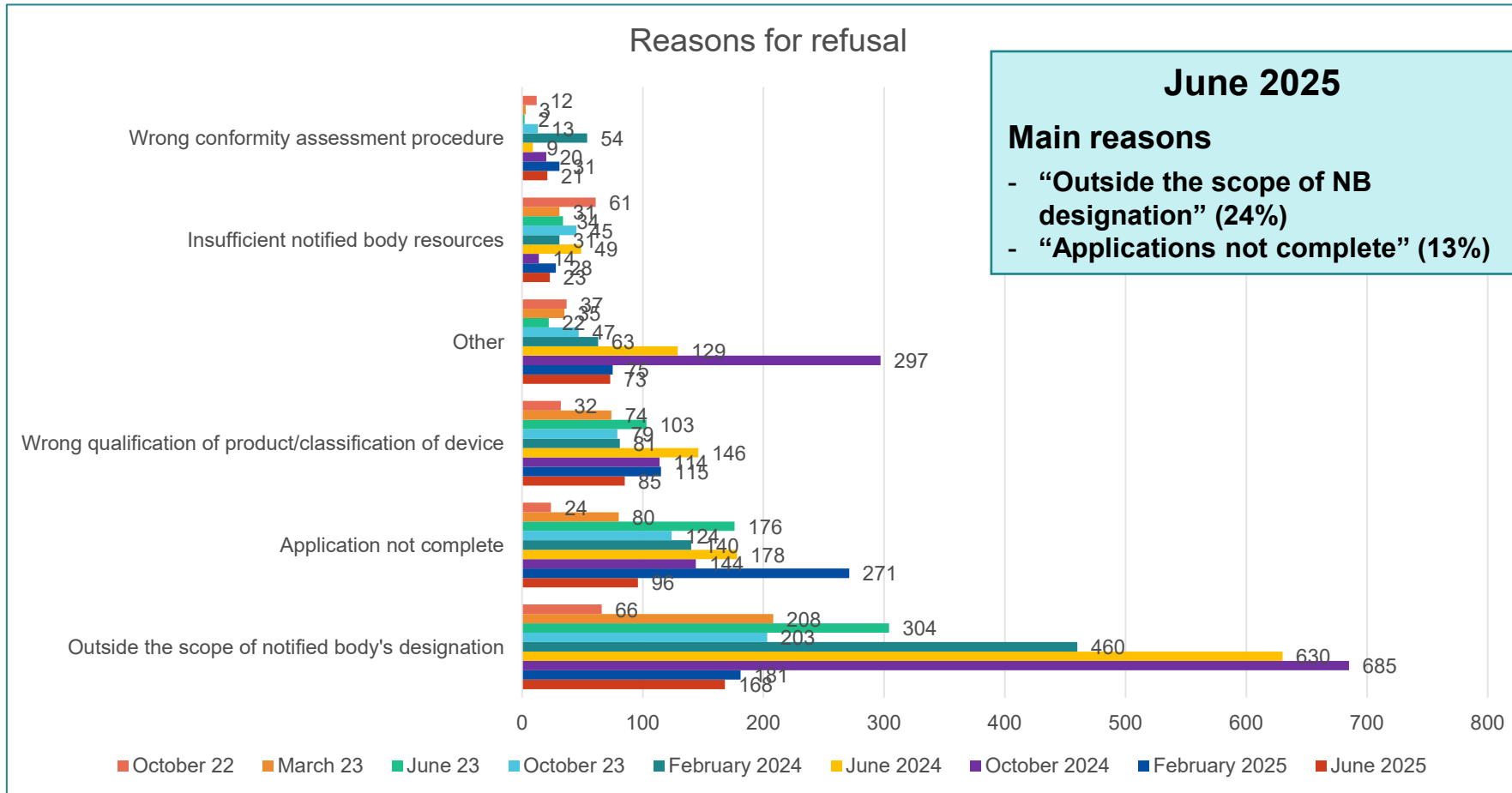
Average timeframe to written agreement signed

Average timeframe between application lodged and written agreement signed:





MDR applications - reasons for refusal



Total number of MDR applications:

- October 2022: 8120
- March 2023: 11.418
- June 2023: 13.177
- October 2023: 17.846*
- February 2024: 20.424*
- June 2024: 26.185*
- October 2024: 28.069*
- February 2025: 28.489*
- June 2025: 32.920*

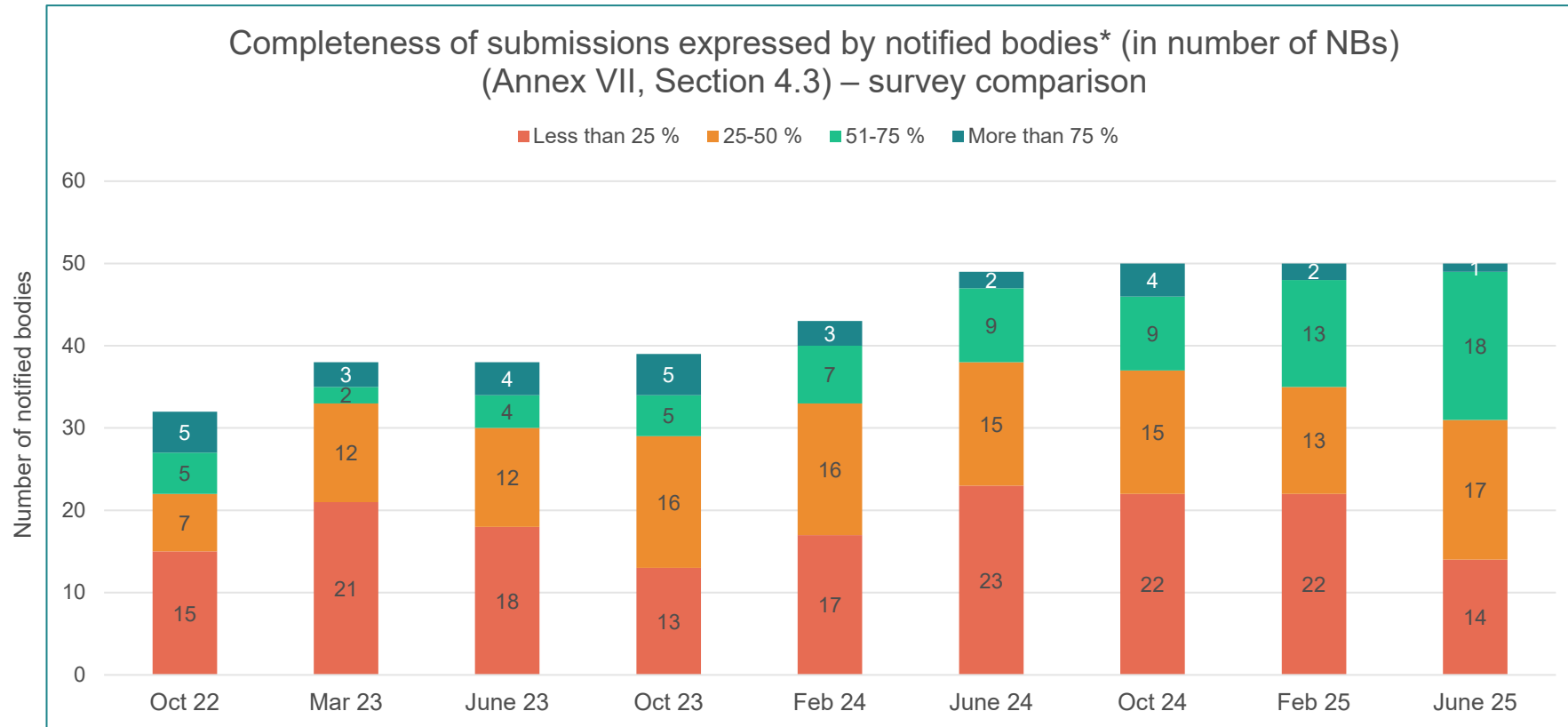
* The total number comes from the medium data set (M) – except for a few NBs where the total number of applications filed was derived from the small data set (S) since they could not provide complete data per Annex.

Number of application refusals:**

- October 2022: 232
- March 2023: 269
- June 2023: 328
- October 2023: 367
- February 2024: 454
- June 2024: 620
- October 2024: 562
- February 2025: 650
- June 2025: 701

- Notes:**
- Comparison of reasons for refusal in October 2022, March 2023, June 2023, October 2023, February 2024, June 2024, October 2024, February 2025 and June 2025.
 - ** Applications can have multiple reasons for refusal; the total number shown is derived from the small data set and differ from the figures in the medium data set indicated on the graph on this slide.
 - June 2025: some stated “other” reasons in June 2025: “cancellation/withdrawal by the customer”, “requirements not met”; “concerns about violation of Article 7 and/or prejudice; “wrong qualification/classification”, “client stopped communication”, “unresolved non-conformities”, “language requirements”.

Completeness of submissions



Number of notified bodies which report that > 50% of submissions are considered complete:
19 out of 50 NBs designated under MDR in June 2025

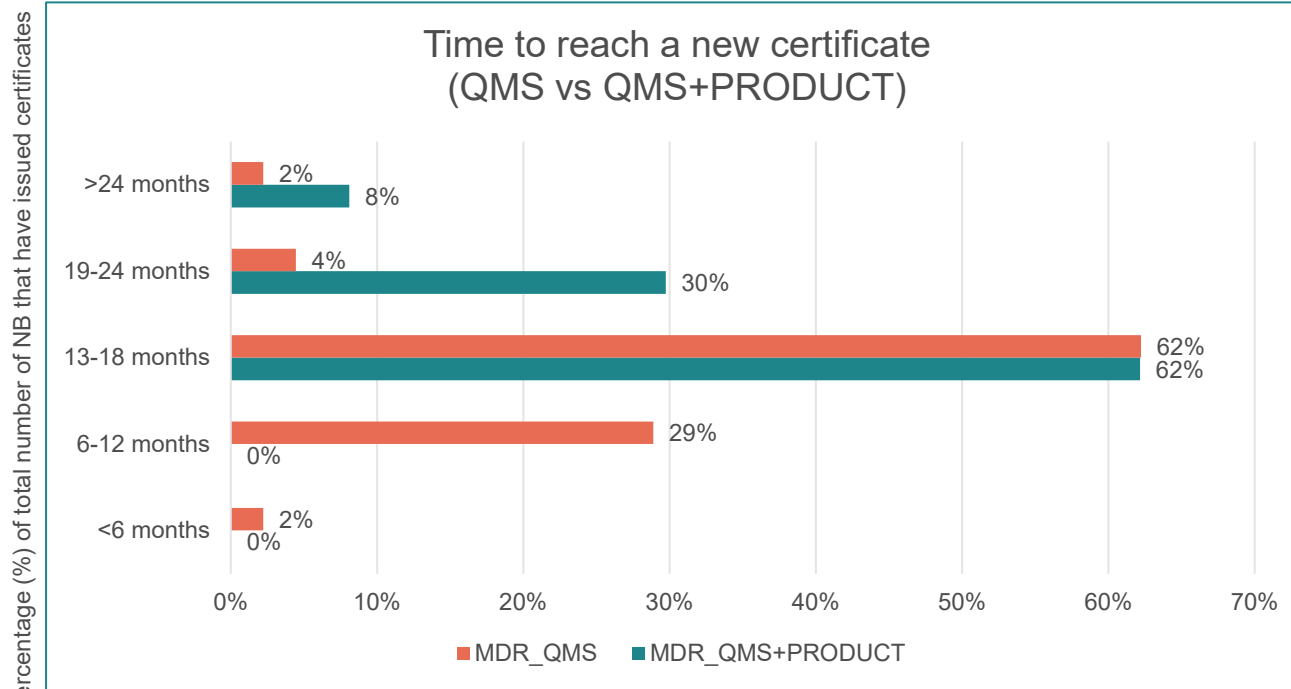
Incomplete submissions remain high*

*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

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

June 2025
 MDR Applications: 32.920*
 MDR Certificates: 14.831

* The total number comes from the medium data set
 M – 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

- 62% of NBs: 13-18 months to issue a new QMS certificate
- 29% of NBs: 6-12 months

MDR QMS+PRODUCT certificates: longer time

- 62% of NBs: 13-18 months
- 30% of NBs: 19-24 months

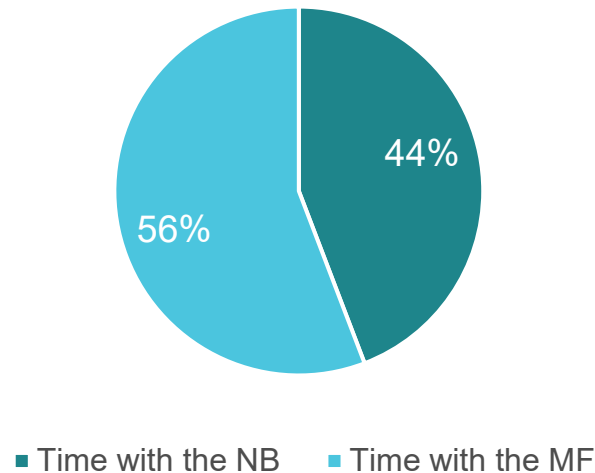
Notes:

- This indicator shows the time to reach issuance of a new EC certificate (from written agreement signed to issuance) under MDR
- QMS+PRODUCT: Data of 37 NBs designated under MDR; 13 NBs indicated that no QMS+PRODUCT certificate was issued yet
- QMS: Data of 45 NBs designated under MDR; 5 NBs indicated that no QMS certificate was issued yet

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

* from written agreement signed to issuance of a new certificate

Estimation of total time to achieve certification between NBs and MFs (average percentage)



More time with the manufacturer

- 26 out of 46 NBs (59%) indicated >50% of the time with the MF
- 11 out of 46 NBs (24%) indicated that the time is equally divided (50:50) between NB and MF
- 9 out of 46 NBs (20%) indicated >50% of the time with the NB

Time with the notified body

- Minimum value: 20%
- Maximum value: 90%

Time with the manufacturer

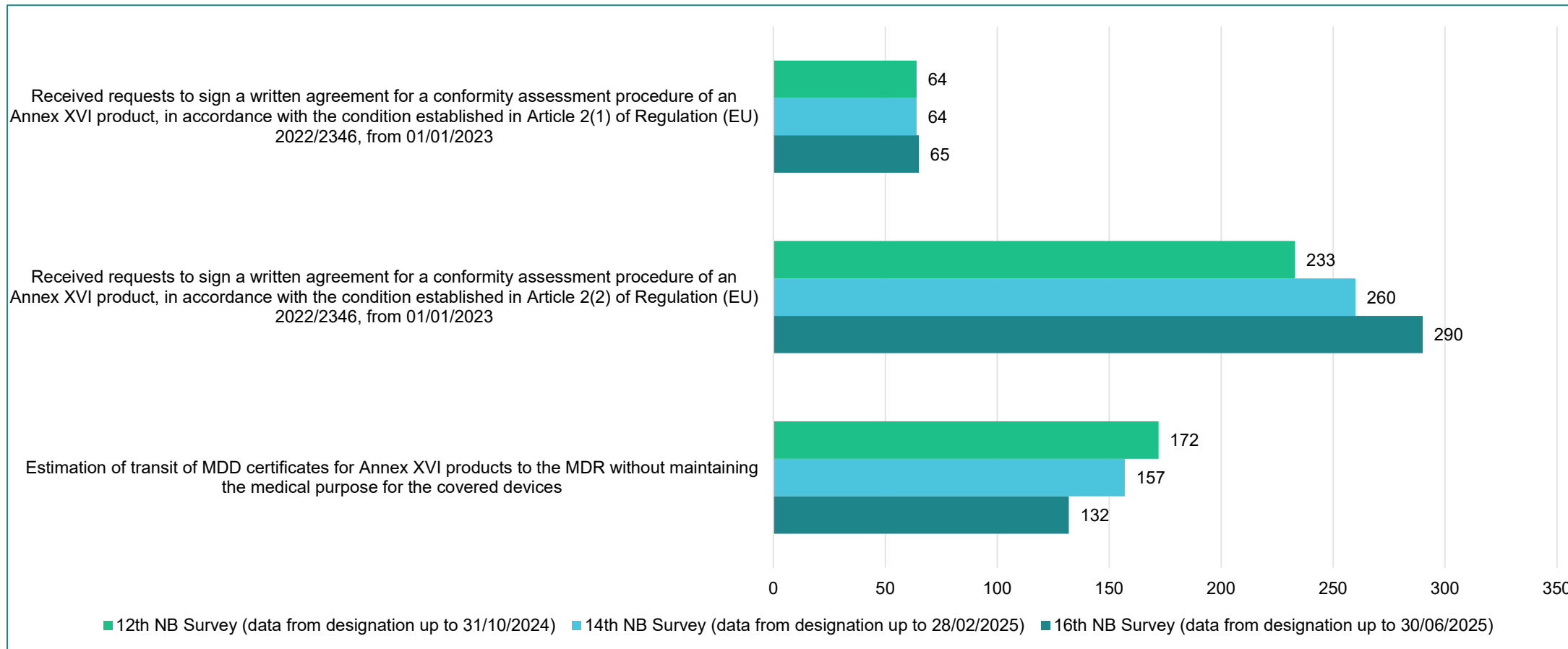
- Minimum value: 10%
- Maximum value: 80%

Notes:

- Data of 46 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:

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

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

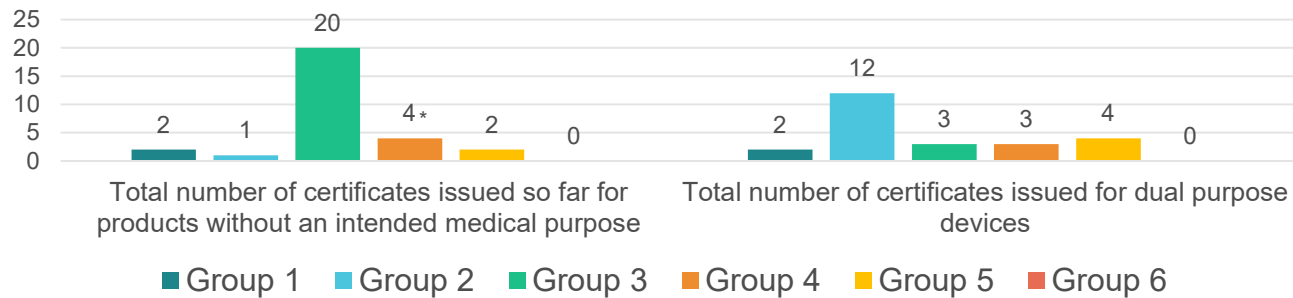
16th NB survey: 22 out of 50 NBs entered "0" for all questions relating to Annex XVI products

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

* 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.

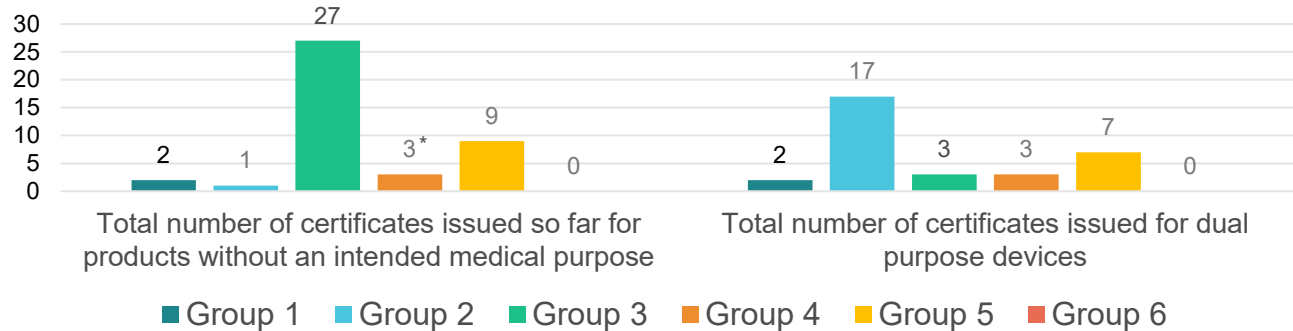
** **Dual purpose devices**: products having both a medical and a non-medical intended purpose

14th NB Survey (data from designation up to 28/02/2025)



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

16th NB Survey (data from designation up to 30/06/2025)



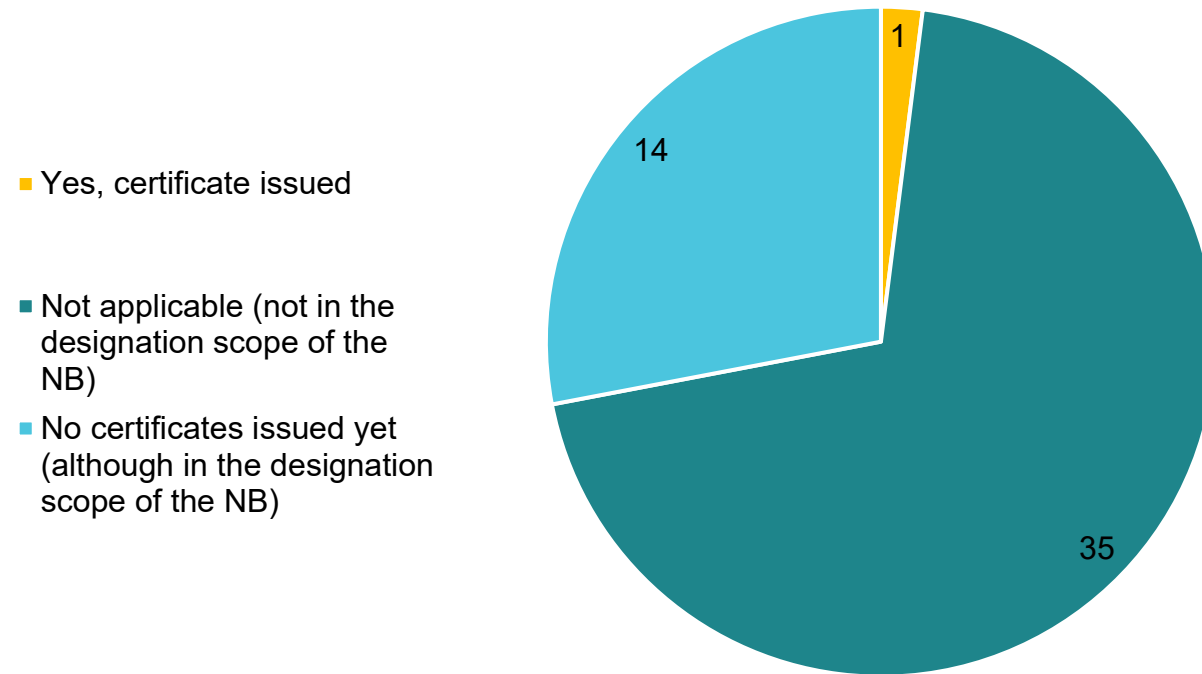
Notes: Data of 15 NBs; 35 out of 50 NBs entered "0" for all groups.

***Group 4**: For one certificate for products without an intended medical purpose, the indication was changed from 14th NB survey to the 16th NB survey according to the respective NB.

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.

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

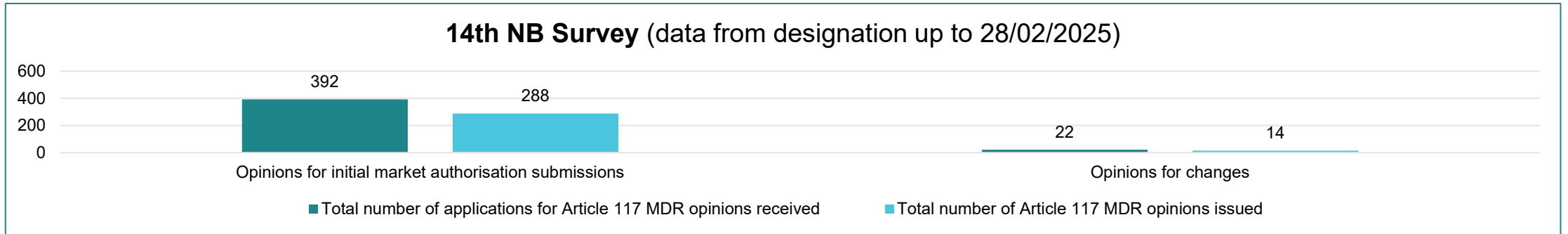


Data of 50 NBs designated under MDR

One NB indicated issuance of certificates:

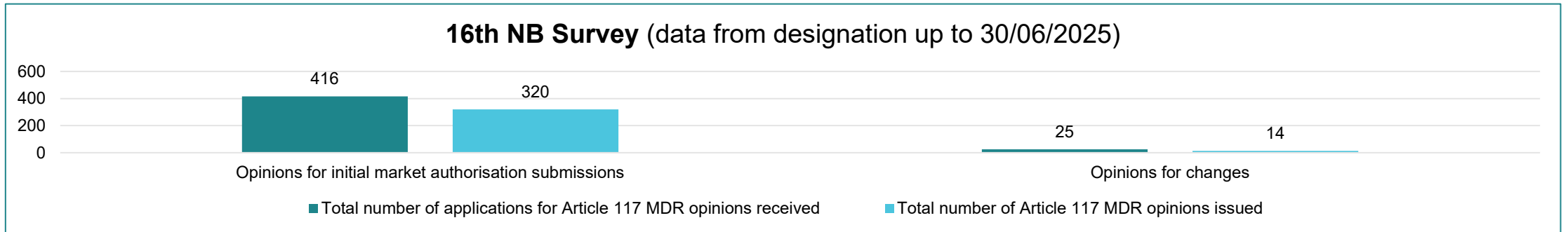
- **4 certificates** issued in accordance with Art. 17(2)
- **No certificates** issued in accordance with Art. 17(5)

Article 117 MDR opinions* - requests received and opinions issued



Notes 14th NB survey:

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



Notes 16th NB survey:

- Total number of requests for Article 117 MDR opinions for initial market authorization submissions received: data of 22 NBs
- Total number of requests for Article 117 MDR opinions for changes received: data of 6 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.

Large dataset

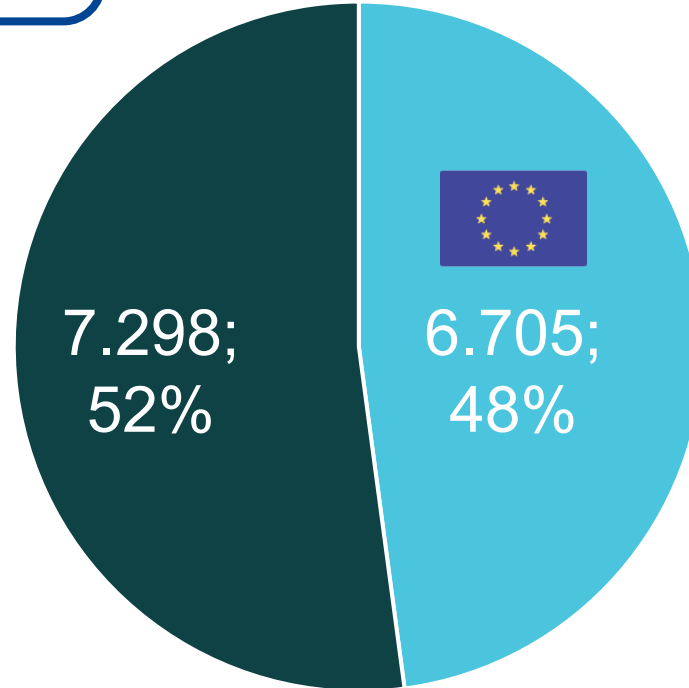
The **large dataset** contains additional data asked to notified bodies once a year.

Number of clients for MDR

June 2025

Total number of clients for MDR: 14.003
(October 2024: 13.875)

Number of clients based
outside the EU

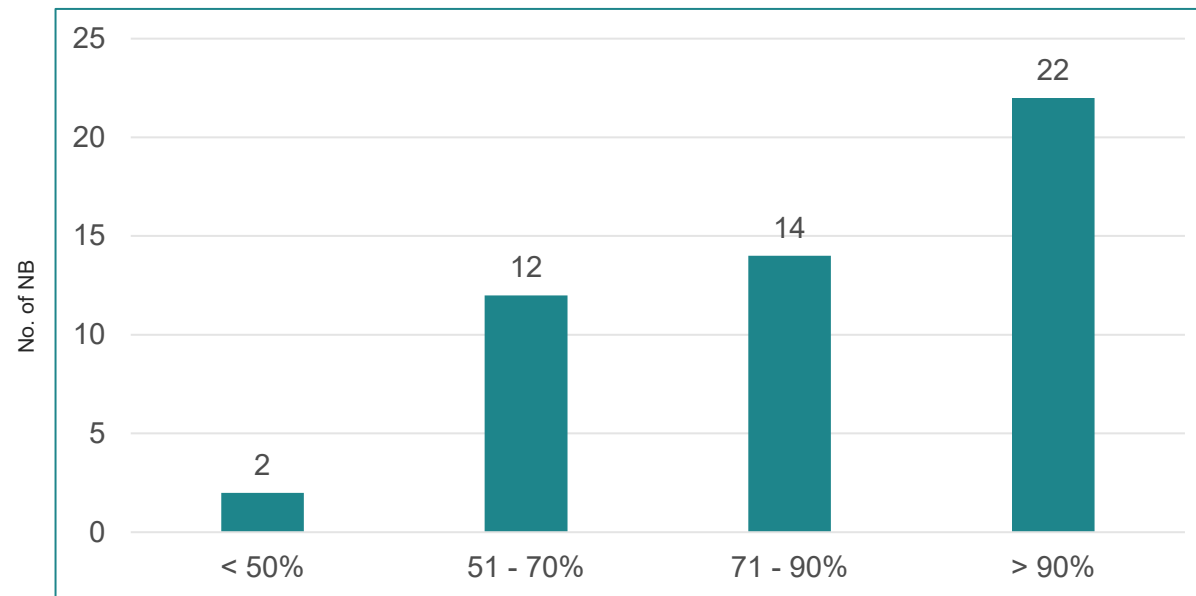


Number of clients based
in the EU

How many of the clients are SMEs*?

June 2025

Total number of clients for MDR: 14.003



Almost all NBs have SMEs as their main clients:

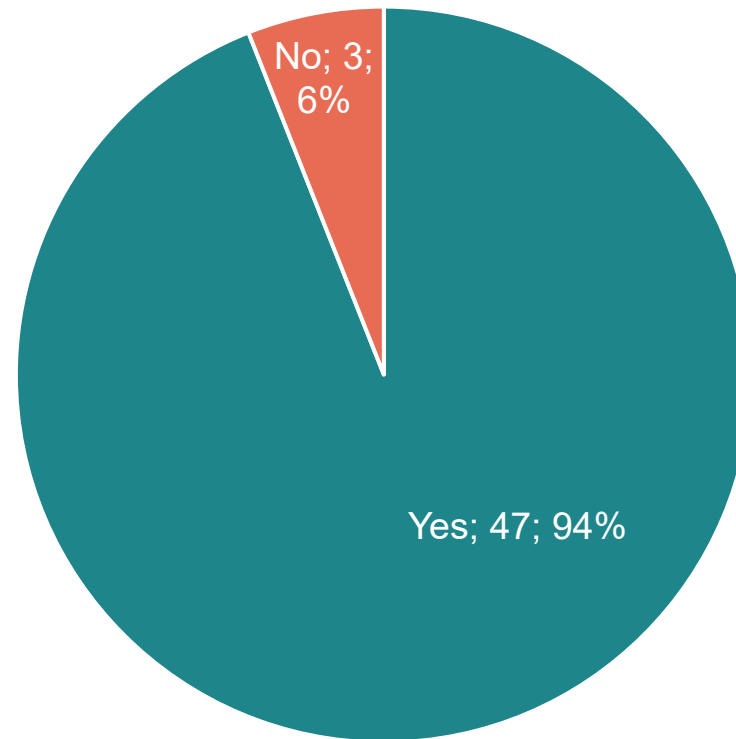
- Only 2 NBs (4%) indicated that less than 50% of their clients are SMEs
- 12 NBs (24%) indicated that between 51 and 70% of their clients are SMEs
- 14 NBs (28%) indicated that between 71 and 90% of their clients are SMEs
- 22 NBs (44%) indicated that they almost only have SMEs as clients (>90%)

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)

Does your NB take on new clients for MDR?

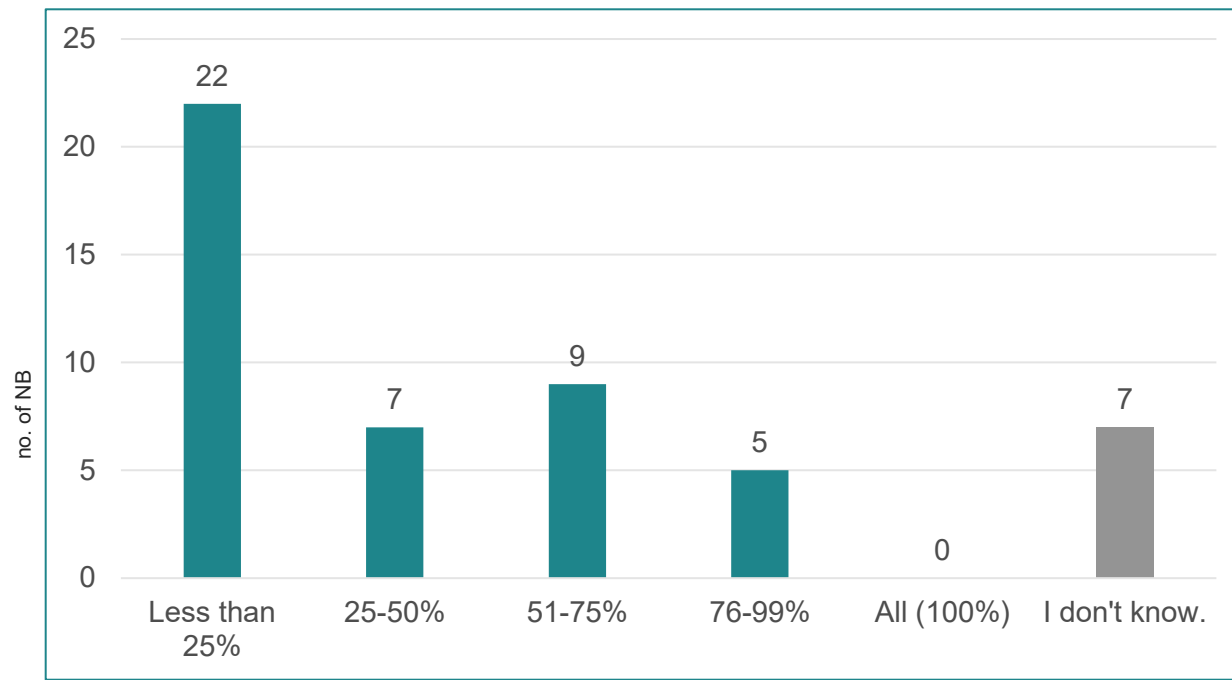


Data of 50 NBs designated under MDR

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

June 2025

Total number of clients for MDR: 14.003



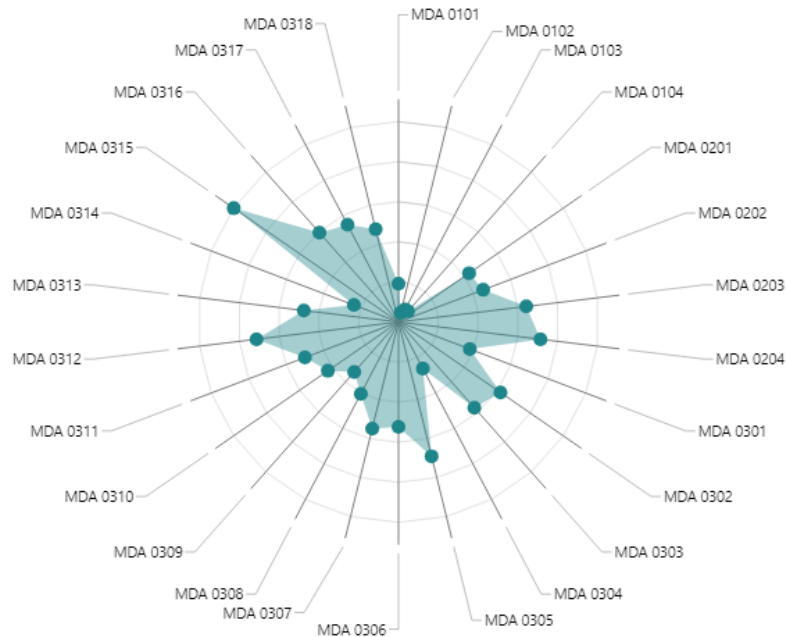
Data of 50 NBs designated under MDR

- 22 NBs (44%) 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
- 5 NBs (10%) 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
- No NB indicated that all clients have completed the transfer of all devices intended to be certificated.

Which MDA codes are covered by MDR certificates?

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

MDA = Active devices



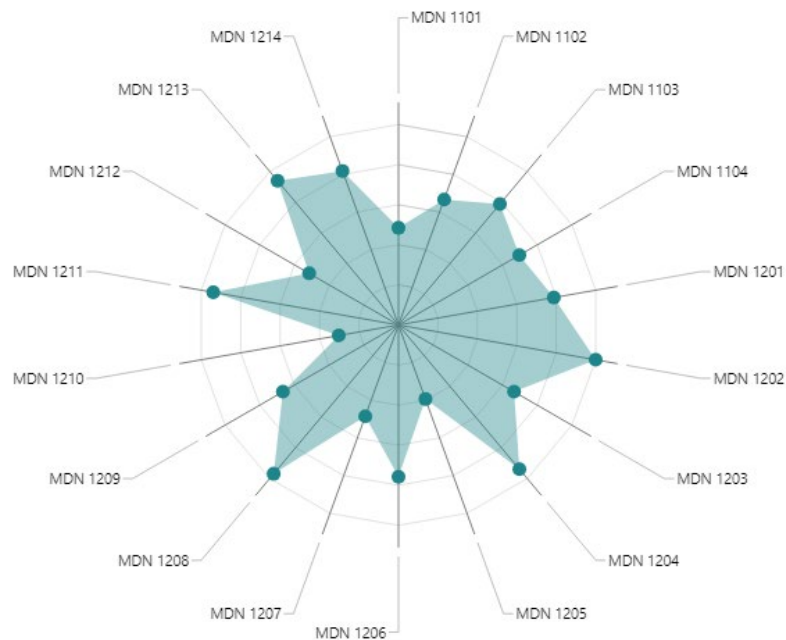
Number of NBs
indicating devices/categories

MDA 0315 Software	42
MDA 0204 Other active non-implantable devices for monitoring and / or diagnosis	30
MDA 0312 Other active non-implantable surgical devices	30
MDA 0305 Active non-implantable devices for stimulation or inhibition	29
MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	27
MDA 0302 Active non-implantable devices utilising non-ionizing radiation	26
MDA 0316 Medical gas supply systems and parts thereof	25
MDA 0303 Active non-implantable devices utilising hyperthermia / hypothermia	24
MDA 0307 Active non-implantable respiratory devices	23
MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	23
MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	22
MDA 0311 Active non-implantable dental devices	21
MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	20
MDA 0318 Other active non-implantable devices	20
MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	19
MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	18
MDA 0310 Active non-implantable devices for ear, nose and throat	18
MDA 0308 Active non-implantable devices for wound and skin care	17
MDA 0301 Active non-implantable devices utilising ionizing radiation	16
MDA 0309 Active non-implantable ophthalmologic devices	14
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)	10
MDA 0101 Active implantable devices for stimulation / inhibition / monitoring	8
MDA 0103 Active implantable devices supporting or replacing organ functions	3
MDA 0104 Active implantable devices utilising radiation and other active implantable devices	3
MDA 0102 Active implantable devices delivering drugs or other substances	2

Which MDN codes are covered by MDR certificates?

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

MDN = Non-active devices

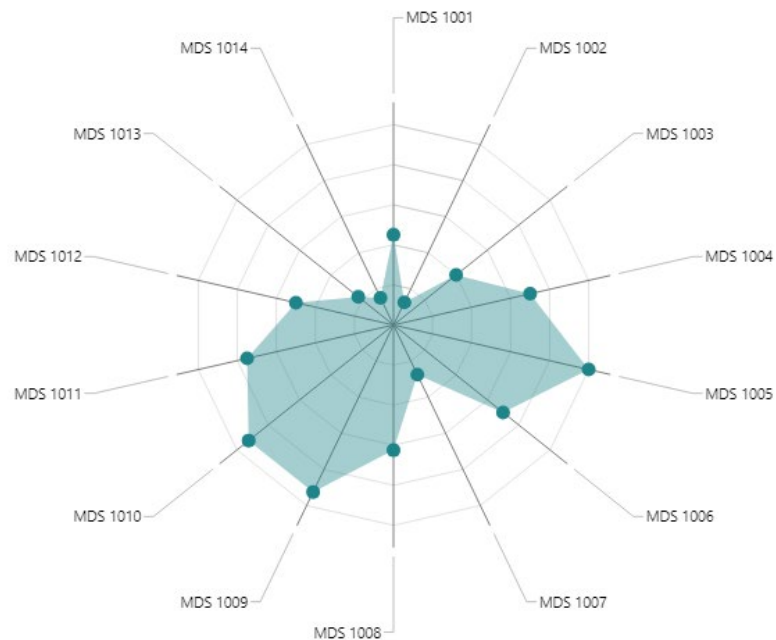


	Number of NBs indicating devices/categories
MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	33
MDN 1208 Non-active non-implantable instruments	32
MDN 1204 Non-active non-implantable devices for wound and skin care	31
MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	31
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	31
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 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	26
MDN 1206 Non-active non-implantable ophthalmologic devices	25
MDN 1104 Non-active soft tissue and other implants	23
MDN 1102 Non-active osteo- and orthopaedic implants	22
MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	22
MDN 1209 Non-active non-implantable dental materials	22
MDN 1212 Non-active non-implantable devices for processing and pre-preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	17
MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	16
MDN 1207 Non-active non-implantable diagnostic devices	16
MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	13
MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	10

Which MDS codes are covered by MDR certificates?

II Horizontal codes

MDS = Devices with specific characteristics



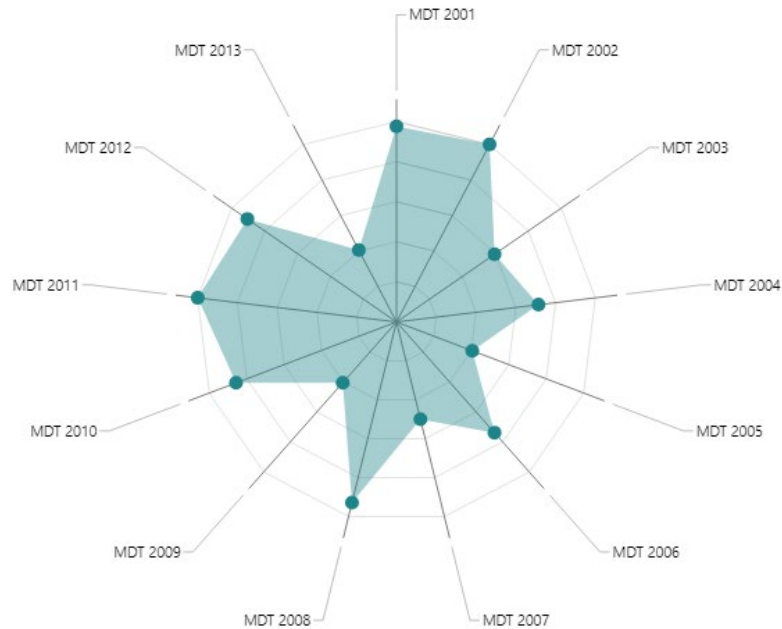
Number of NBs
indicating devices/categories

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	37
MDS 1010 Devices with a measuring function	37
MDS 1011 Devices in systems or procedure packs	30
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	28
MDS 1006 Reusable surgical instruments	28
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	25
MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745	20
MDS 1001 Devices incorporating medicinal substances	18
MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives	16
MDS 1007 Devices incorporating or consisting of nanomaterial	11
MDS 1013 Class III custom-made implantable devices	9
MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device	6
MDS 1002 Devices manufactured utilising tissues or cells of human origin, or their derivatives	5

Which MDT codes are covered by MDR certificates?

II Horizontal codes

MDT = Devices for which specific technologies or processes are used

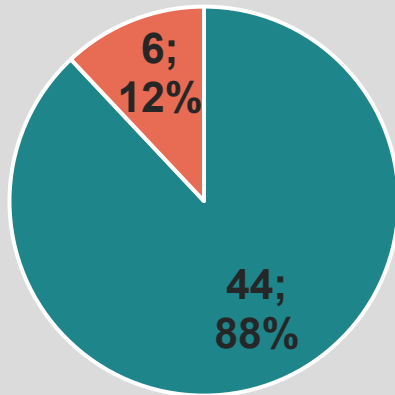


Number of NBs
indicating devices/categories

MDT 2002 Devices manufactured using plastic processing	42
MDT 2011 Devices which require packaging, including labelling	42
MDT 2001 Devices manufactured using metal processing	41
MDT 2008 Devices manufactured in clean rooms and associated controlled environments	39
MDT 2012 Devices which require installation, refurbishment	38
MDT 2010 Devices manufactured using electronic components including communication devices	36
MDT 2006 Devices manufactured using chemical processing	31
MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)	30
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	21
MDT 2005 Devices manufactured using biotechnology	17
MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin	17
MDT 2013 Devices which have undergone reprocessing	17

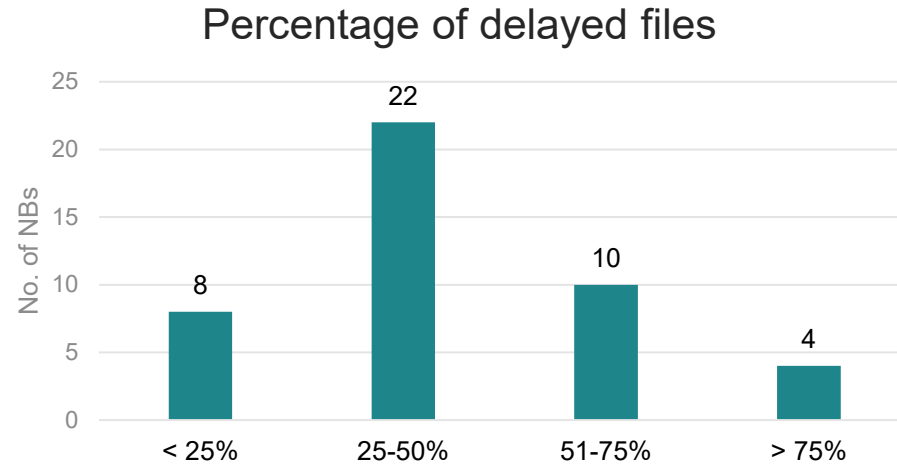
Technical documentation (TD) – shifting of submission from NBs' perspective

Do you experience MFs requesting the delay of the submission of the TD to be reviewed (in comparison to possible timelines previously agreed)?

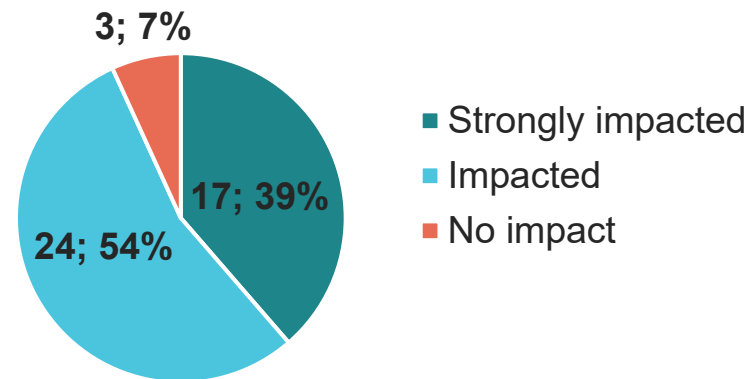


■ Yes ■ No

If yes
(44/50 NBs)



Impact on the schedule of NB's activities

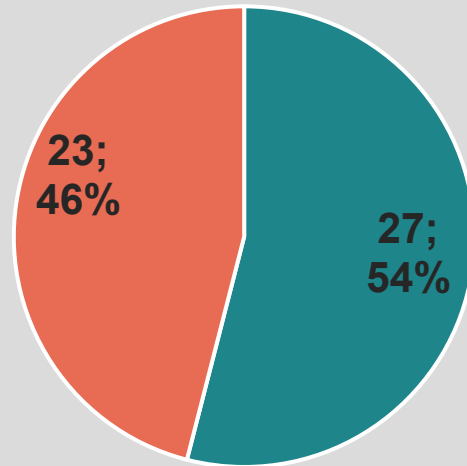


MDR designated NBs: 50

Shifting of QMS audits from NBs' perspective



Do you experience MFs requesting the delay of the submission of the QMS audits that cover the requirements of MDR?

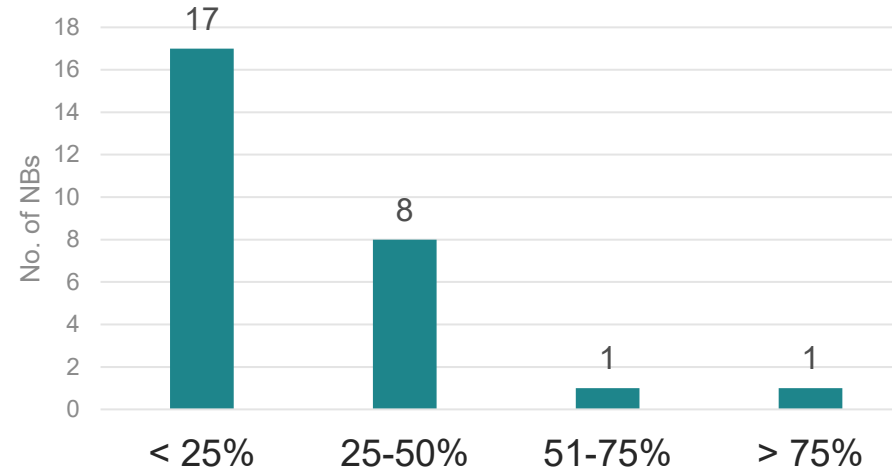


■ Yes ■ No

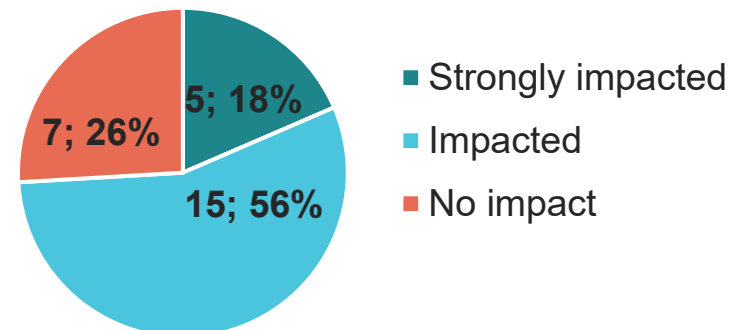
MDR designated NBs: 50

If yes
(27/50 NBs)

Percentage of delayed QMS audits



Impact on the schedule of NB's activities



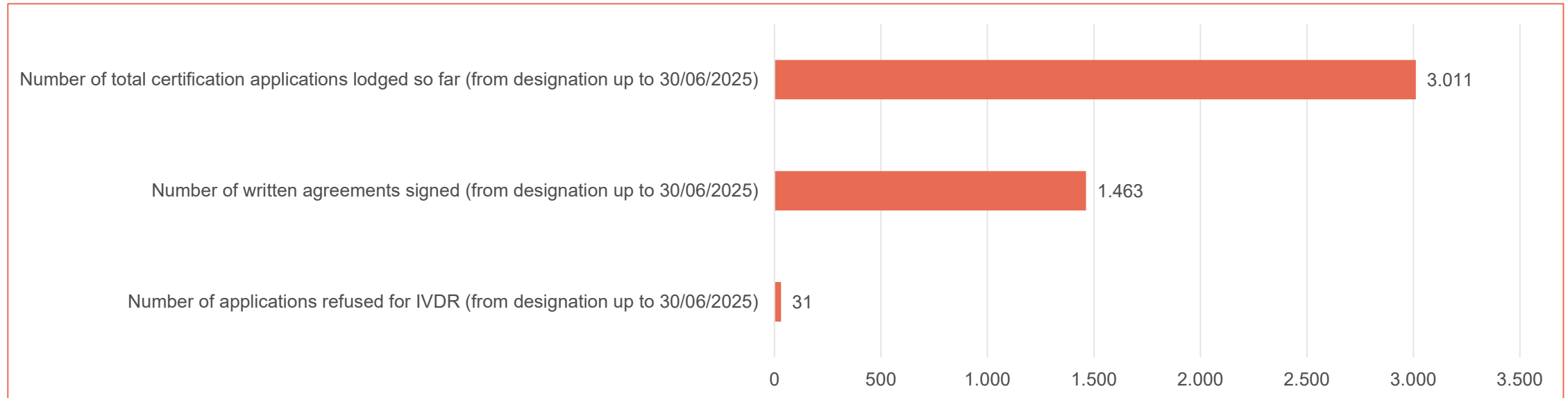
■ Strongly impacted
■ Impacted
■ No impact

3. Survey results for in vitro diagnostic medical devices

Note:

- Thousands separators are represented as dots or blank space (not comma) in the graphs.
- Datasets:
 - Ⓢ The **small dataset** is a small set of questions asked to notified bodies **every two months**.
Note: From April to July 2023, it was asked monthly.
 - Ⓜ The **medium dataset** is a set of questions asked to notified bodies **every four months** concerning the activities they have been performing since their designation.
 - Ⓛ The **large dataset** contains additional data asked to notified bodies **once a year**.

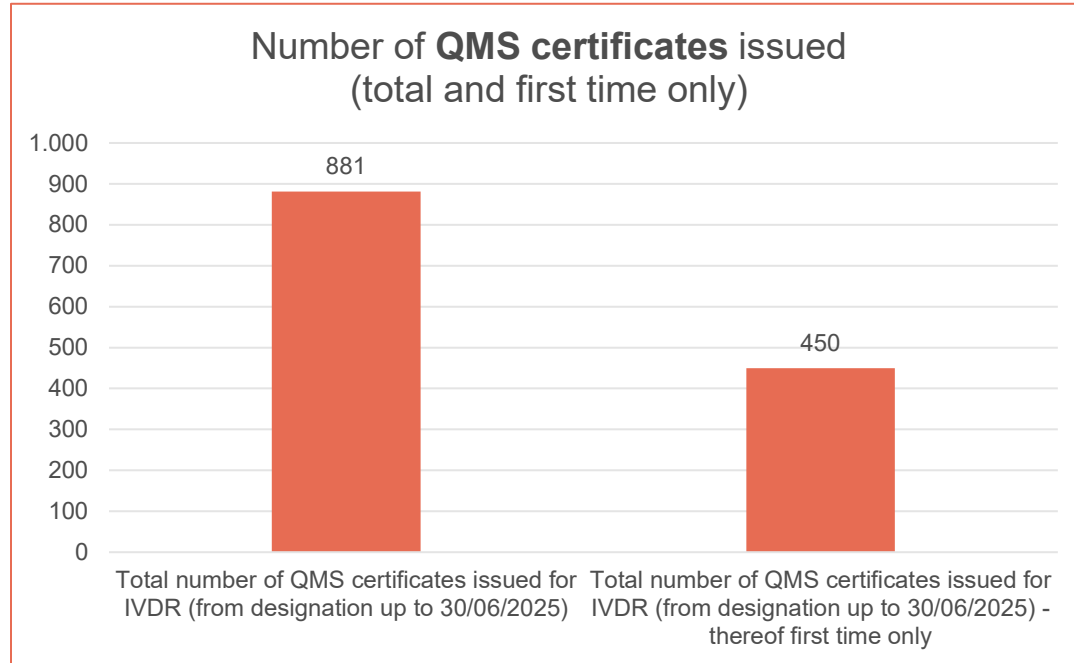
IVDR applications filed and refused, written agreements signed



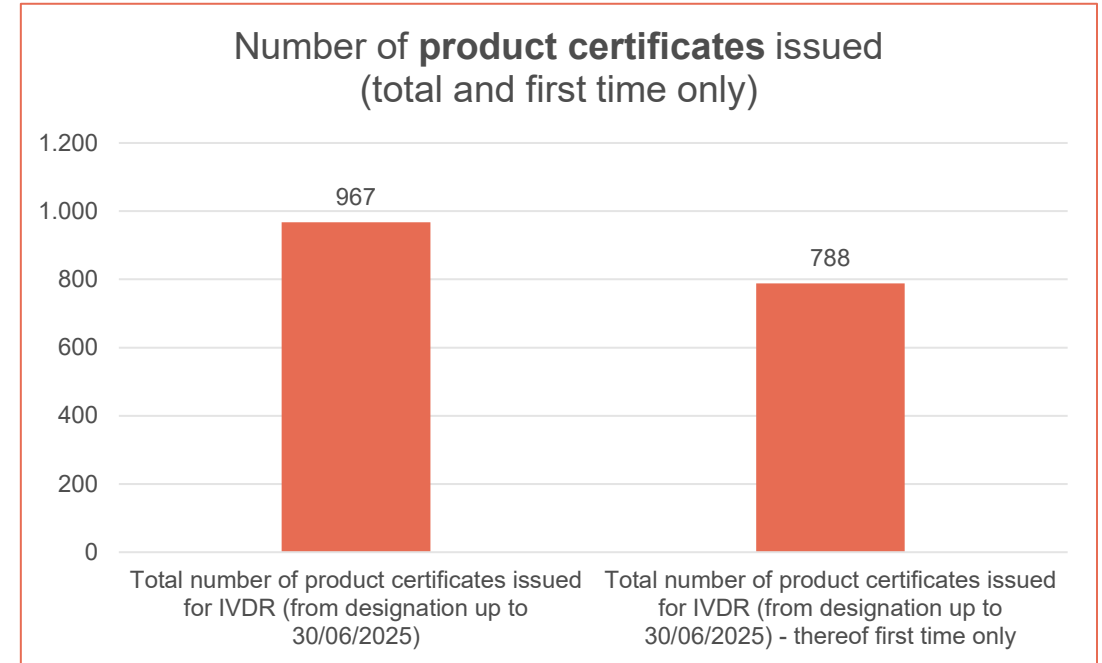
Notes:

- **Designated NBs for IVD:** 17
- **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 30/06/2025), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included.
- **Written agreements signed:** This refers to the number of written agreements (contracts) between a NB and a manufacturer signed by both parties.

IVDR Number of QMS / product certificates issued

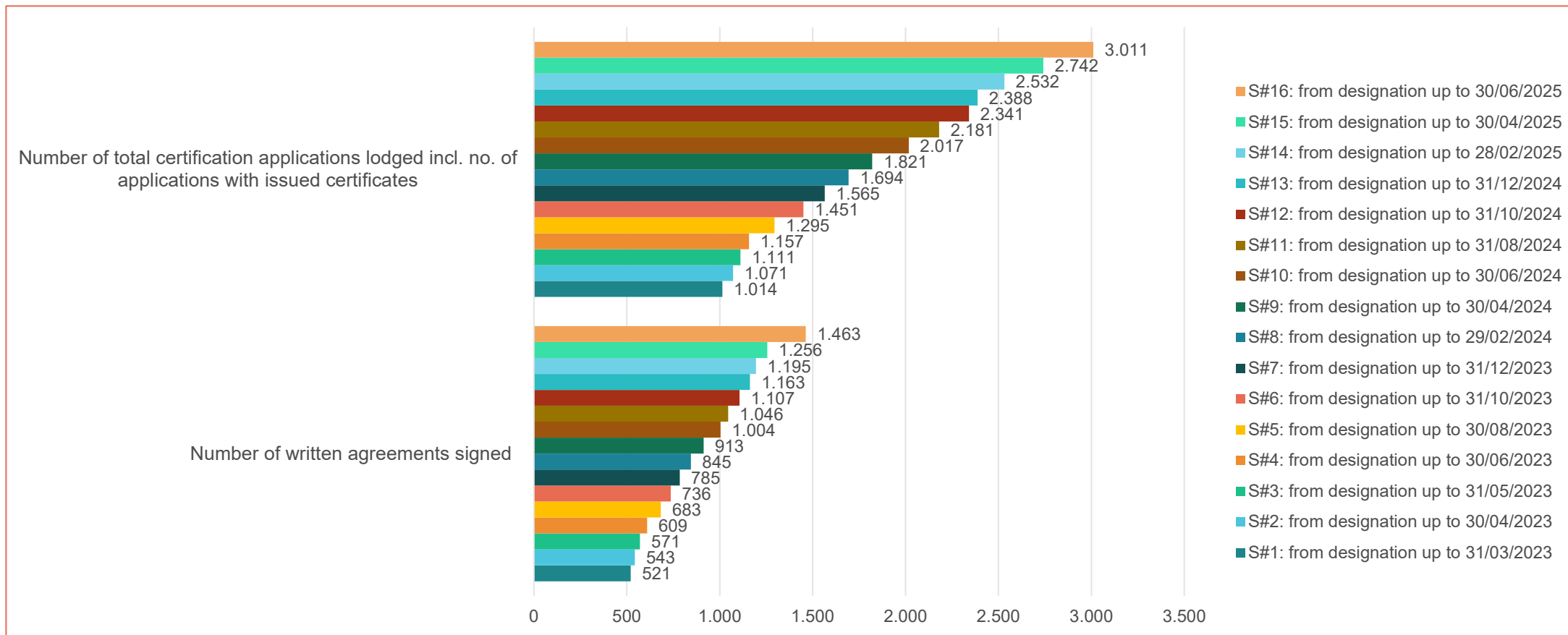


Note QMS Certificates: This relates to Annex IX Chapter I or Annex XI according to IVDR.



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

Survey comparison – March 2023 to June 2025

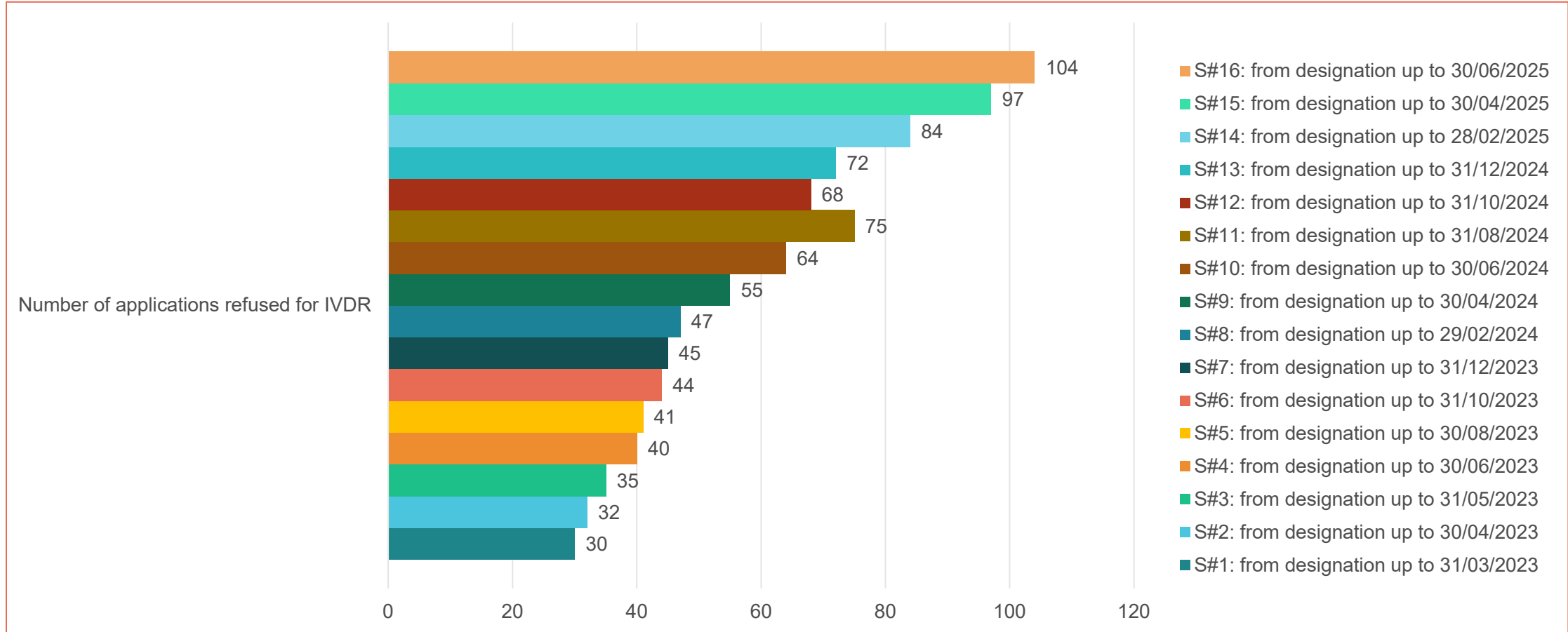


S = Survey; # = number

Notes:

- Designated NBs for IVDs: S#1 to S#5: 10; S#6 to S#11: 12; S#12 to S#13: 13; S#14: 14; S#15: 16, S#16: 17
- 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.

Survey comparison – March 2023 to June 2025

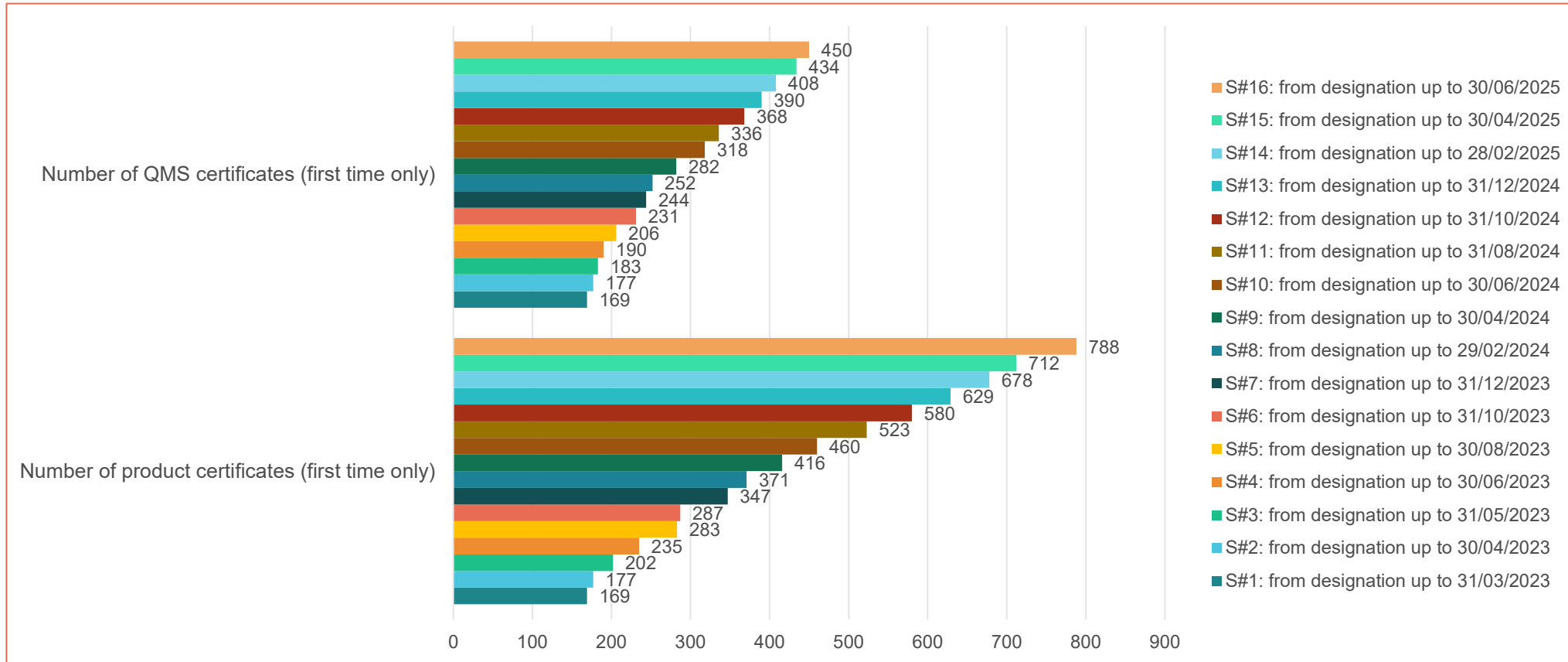


S = Survey; # = number

Notes:

- Designated NBs for IVDs: S#1 to S#5: 10; S#6 to S#11: 12; S#12 to S#13: 13; S#14: 14; S#15: 16, S#16: 17
- 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.
- Change in methodology of counting applications refused compared to previous surveys by NBs in S#12.
- Retrospective data provided by one NB (starting from S#1) have been incorporated into this graph from this presentation onward.

Survey comparison – March 2023 to June 2025



S = Survey; # = number

Notes:

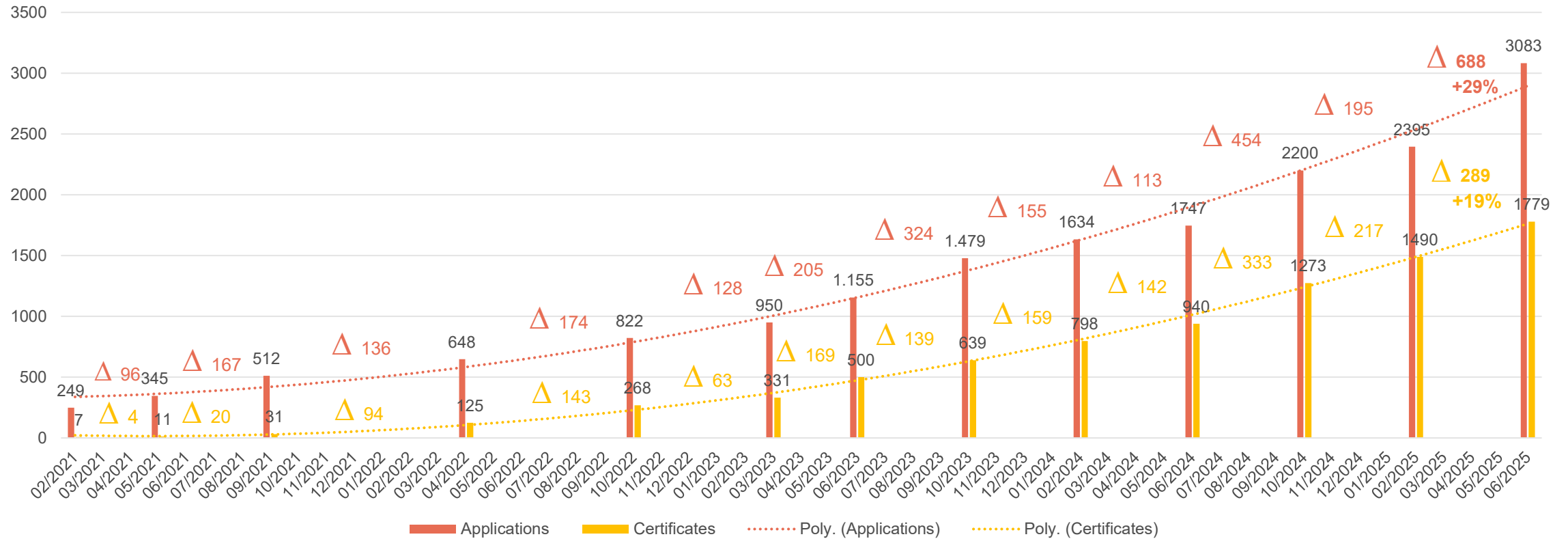
- Designated NBs for IVDs: S#1 to S#5: 10; S#6 to S#11: 12; S#12 to S#13: 13; S#14: 14; S#15: 16; S#16: 17
- Surveys #2 and #3 did not reach 100% response rate (S#2: ~70%; S#3: 56%). In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.

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

June 2025
IVDR Applications: 3.083
IVDR Certificates: 1.779



Notes: Designated NBs for IVDR in June 2025: 17

- 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 30/06/2025), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing IVDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
- **Certificates issued:** This number includes **certificates issued so far** (from designation up to 30/06/2025) under the IVDR.
- The dotted line shows the polynomial trend line (grade 2).

IVDR applications and certificates by annex

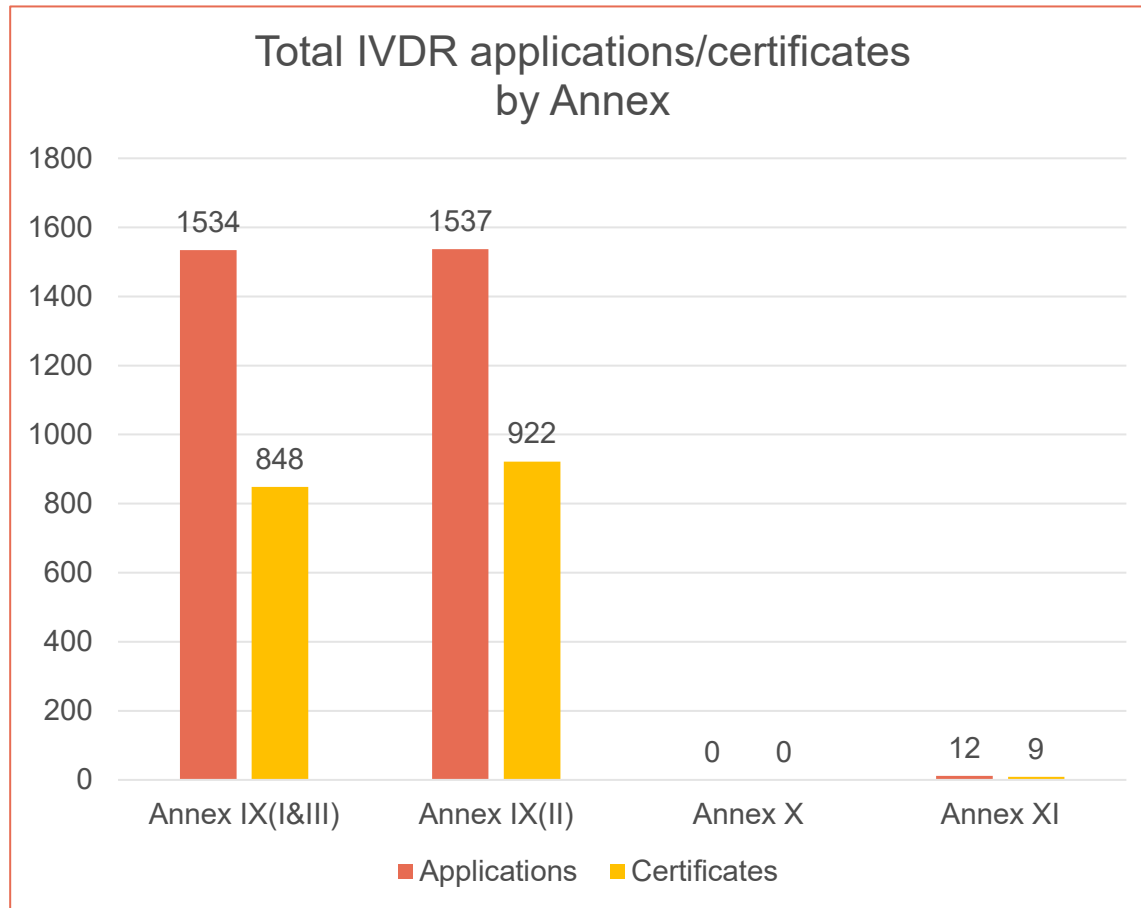
IVD



June 2025

IVDR Applications: 3.083

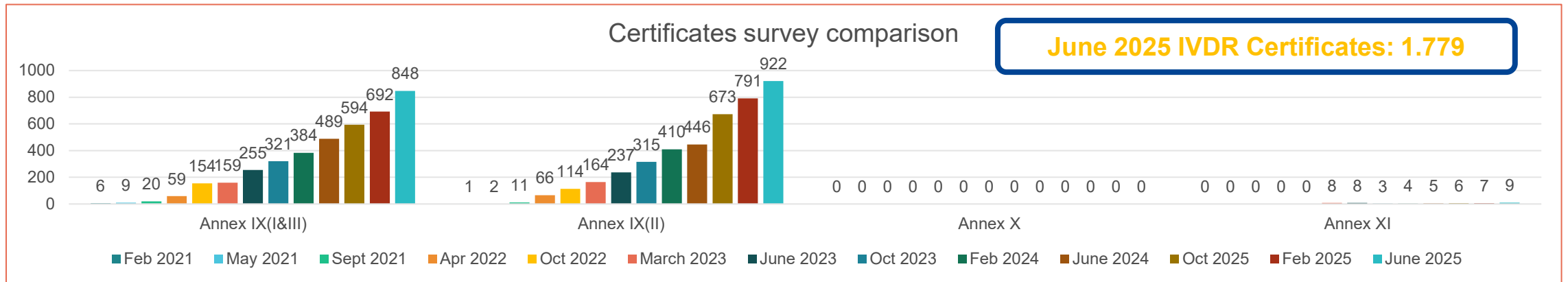
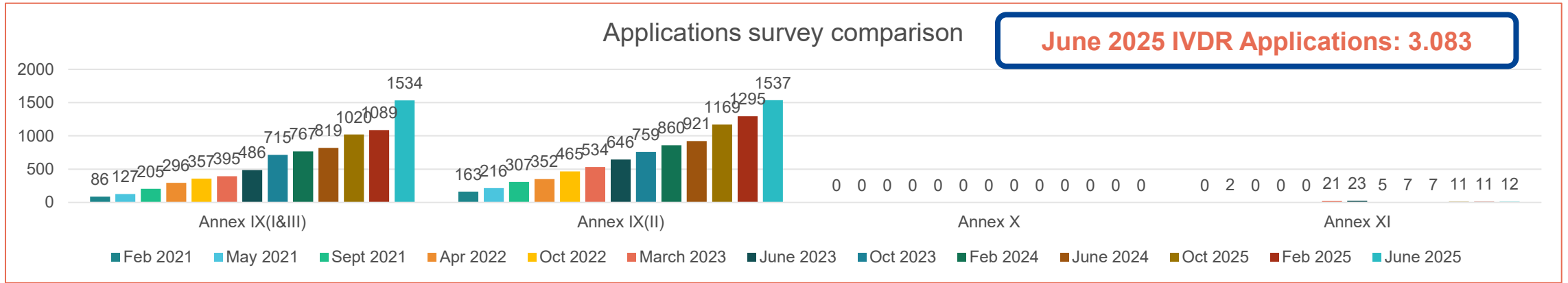
IVDR Certificates: 1.779



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 30/06/2025), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
- **Certificates issued by annex:** This number includes certificates issued so far (from designation up to 30/06/2025) under the IVDR by annex.
- **Class D devices are included** in the total number of applications/certificates.

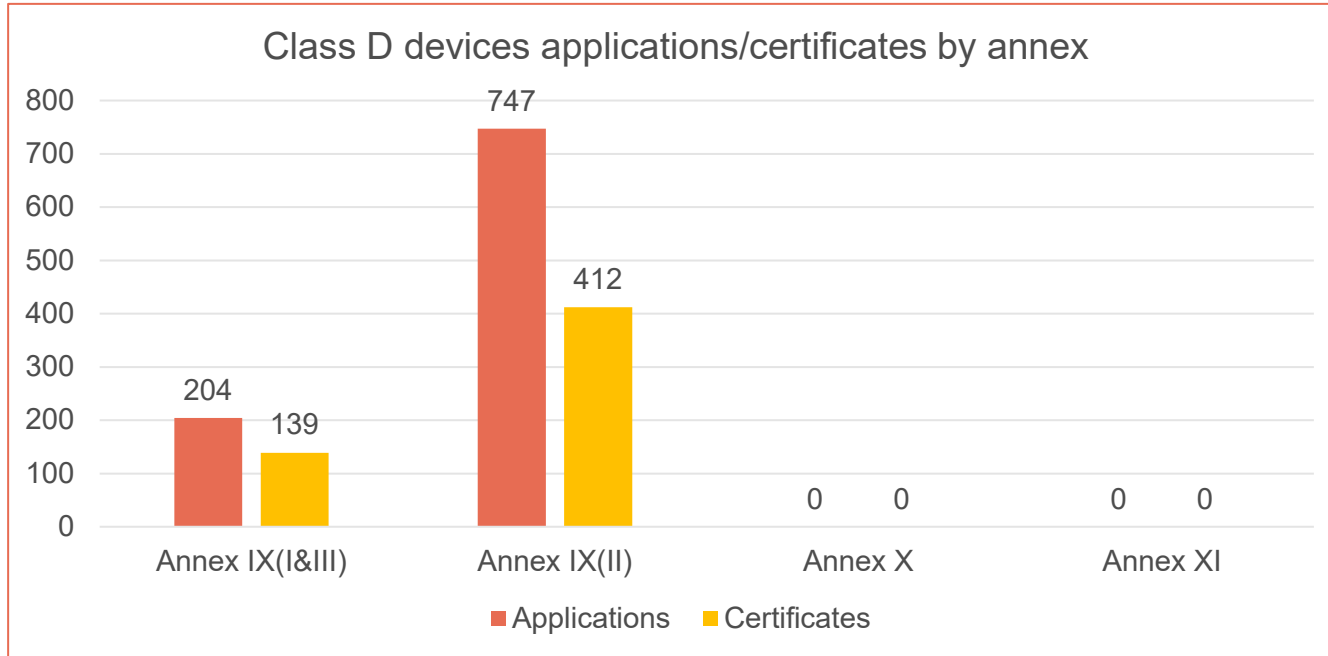
IVDR applications and certificates by annex – surveys comparison



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 30/06/2025), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing IVDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
- **Certificates issued by annex:** This number includes **certificates issued so far** (from designation up to 30/06/2025) under the IVDR by annex.

Class D devices applications and certificates



June 2025
IVDR Applications: 3.083
IVDR Certificates: 1.779

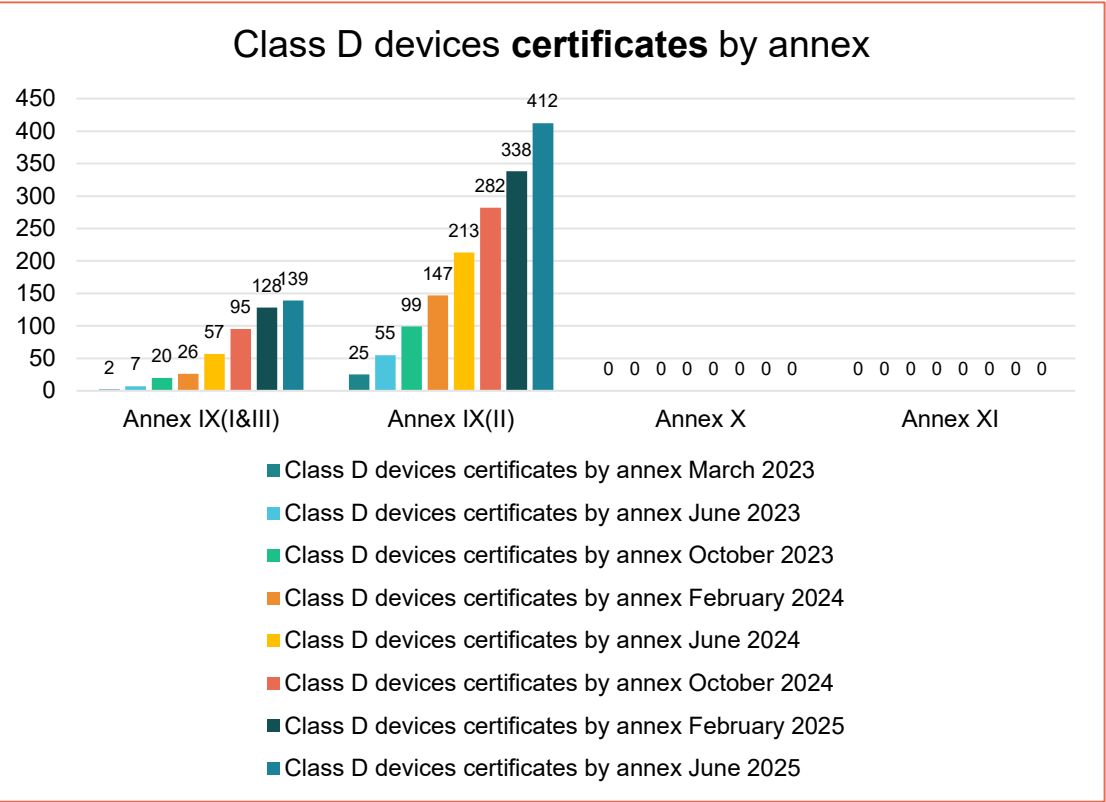
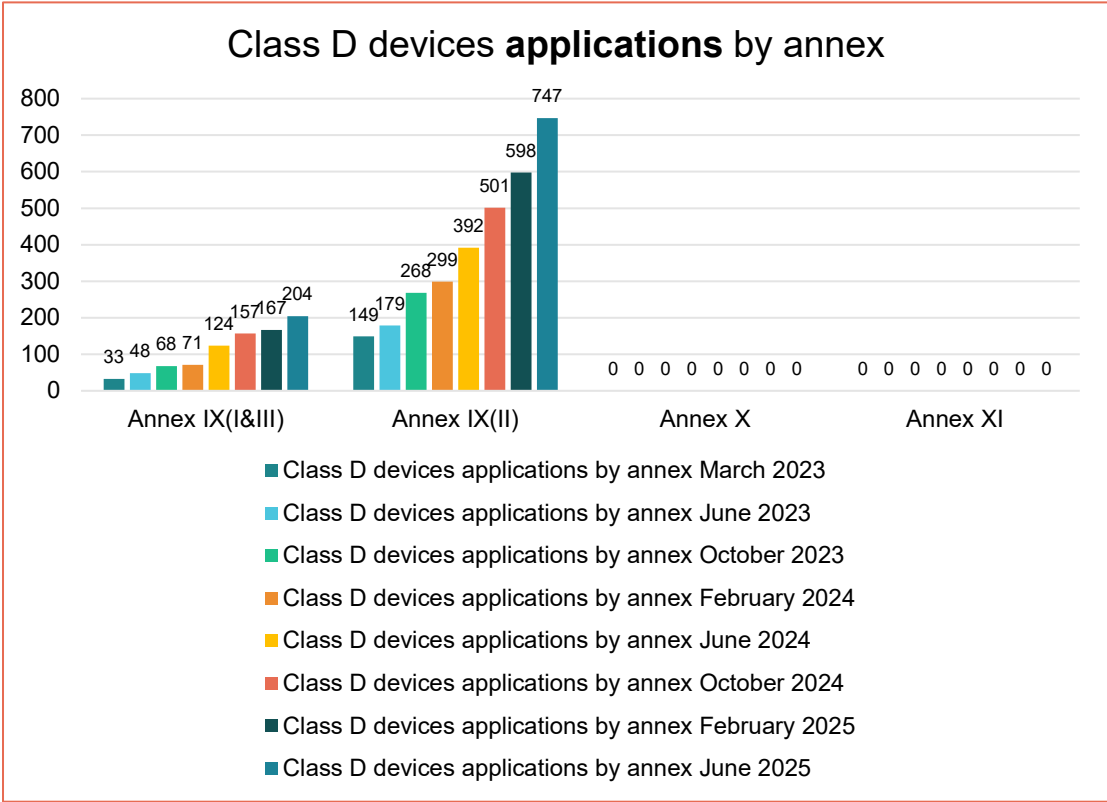
June 2025:
Total number of Class D devices Applications: 951
Total number of Class D devices Certificates: 551

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 30/06/2025), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing IVDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
- **Certificates issued by annex:** This number includes certificates issued so far (from designation up to 30/06/2025) under the IVDR by annex.
- Data for Annex XI has changed compared to previous surveys because of a change in methodology of counting by NBs.

Class D IVDs applications and certificates development

June 2025:
 Total number of Class D devices **Applications:** 951
 Total number of Class D devices **Certificates:** 551



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 **30/06/2025**), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.

Note:
Certificates issued by annex: This number includes certificates issued so far (from designation up to **30/06/2025**) under the IVDR by annex.

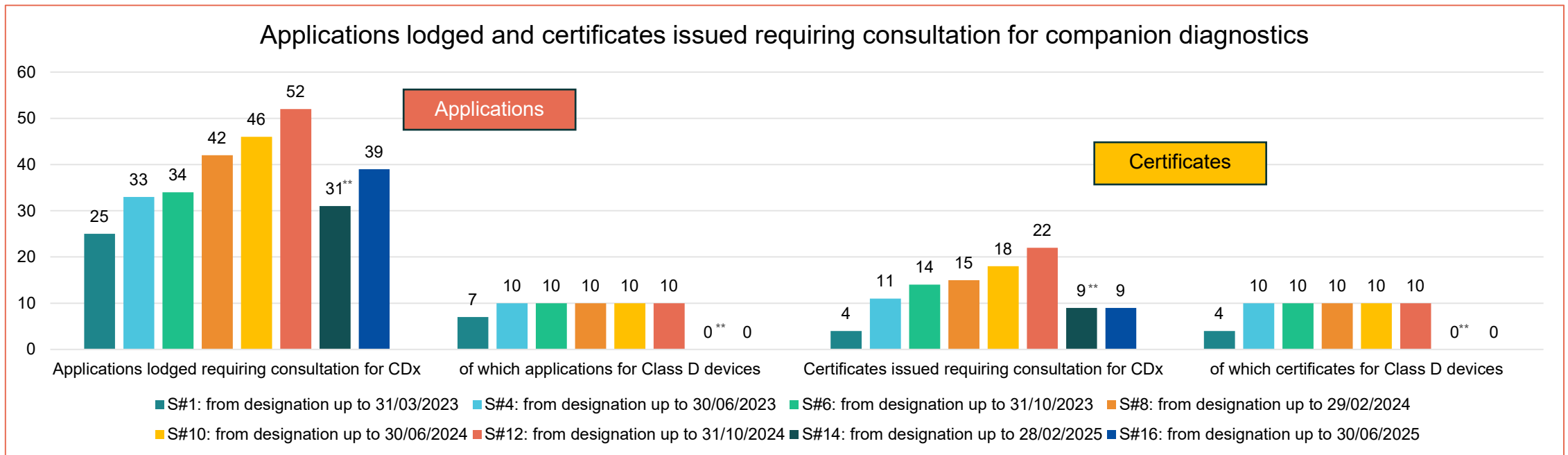
Applications and certificates requiring consultation for companion diagnostics (CDx)*

IVD



June 2025:
 Class D devices Applications: 951
 Class D devices Certificates: 551

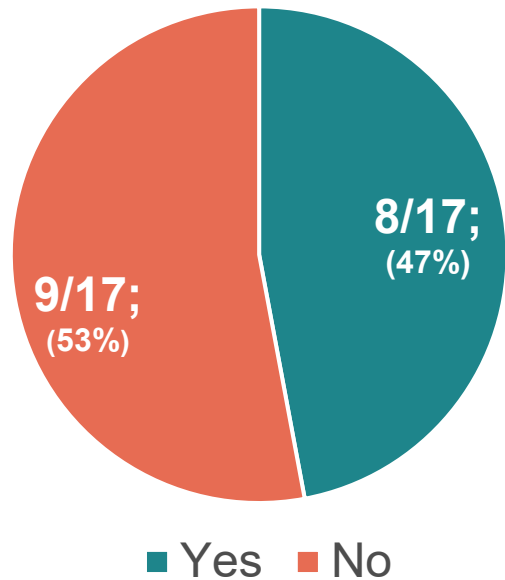
June 2025
 IVDR Applications: 3.083
 IVDR Certificates: 1.779



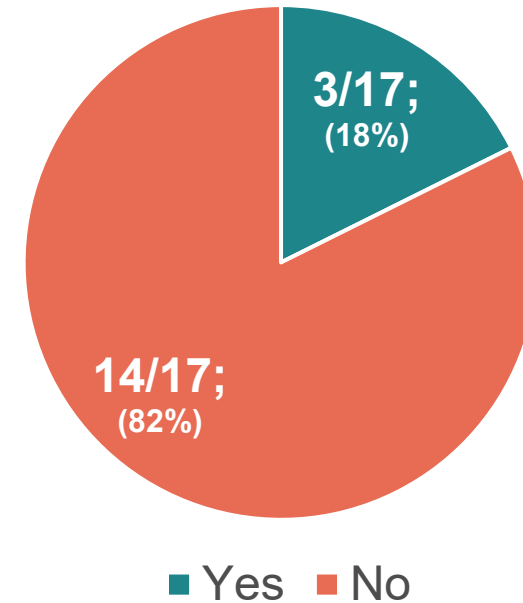
* According to [Article 2 \(7\) IVDR](#), a companion diagnostic means a device which is essential for the safe and effective use of a corresponding medicinal product to:
 (a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or
 (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.
 ** Change in methodology of counting by one NB from the 14th NB Survey onwards.

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

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



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



Data of 17 NBs designated under IVDR

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

IVD



Class D applications

	Hepatitis and retrovirus	Respiratory viruses	Bacterial pathogens	Herpes virus	TOTAL
Total number of class D devices (covered by an application lodged [from 01/10/2024 up to 30/06/2025]) that fall in the categories of currently designated EURLs	66	10	39	9	124
Number of devices covered by a signed master services agreement with an EURL for performance verification (EURL task in IVDR Article 100(2)(a)) [as of 30/06/2025]	365	13	9	10	397
Number of devices covered by a signed statement of work with an EURL for performance verification (EURL task in IVDR Article 100(2)(a)) [as of 30/06/2025]	14	0	0	0	14
Number of devices for which performance verification by EURLs has been scheduled or completed [as of 30/06/2025]	14	0	0	0	14

Data of 8 NBs designated under IVDR

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

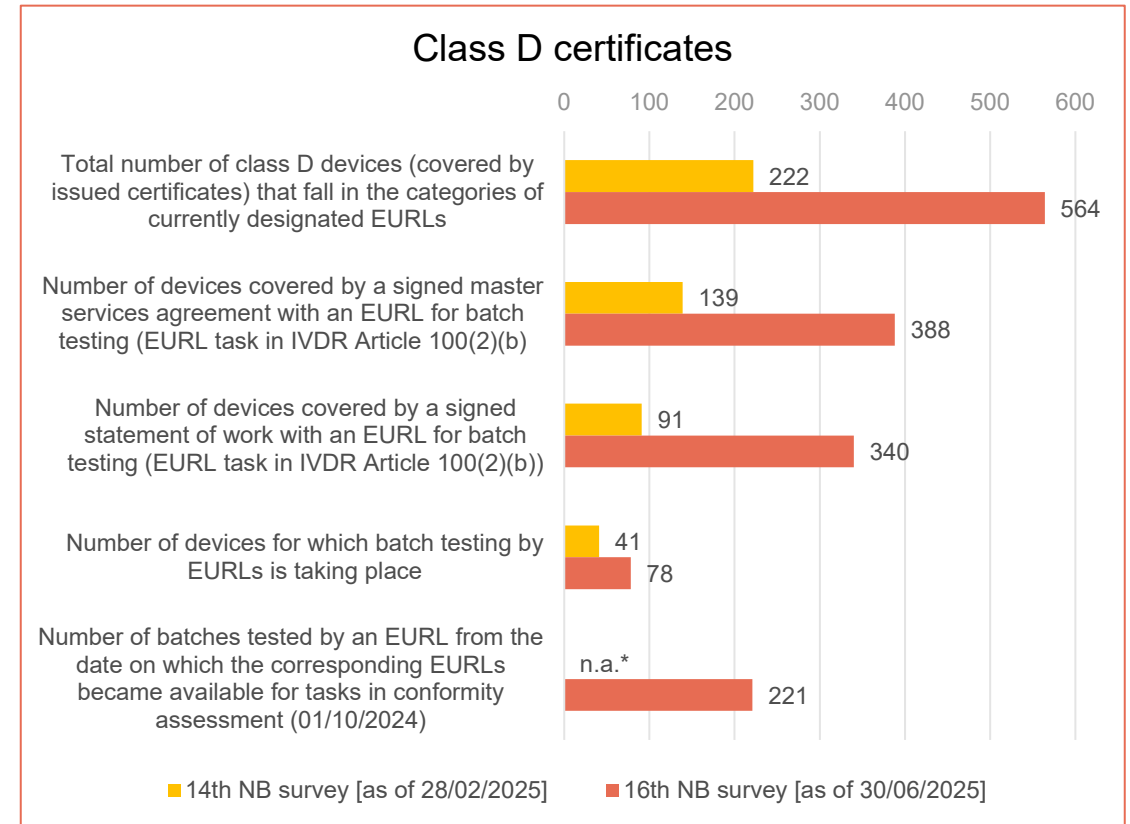
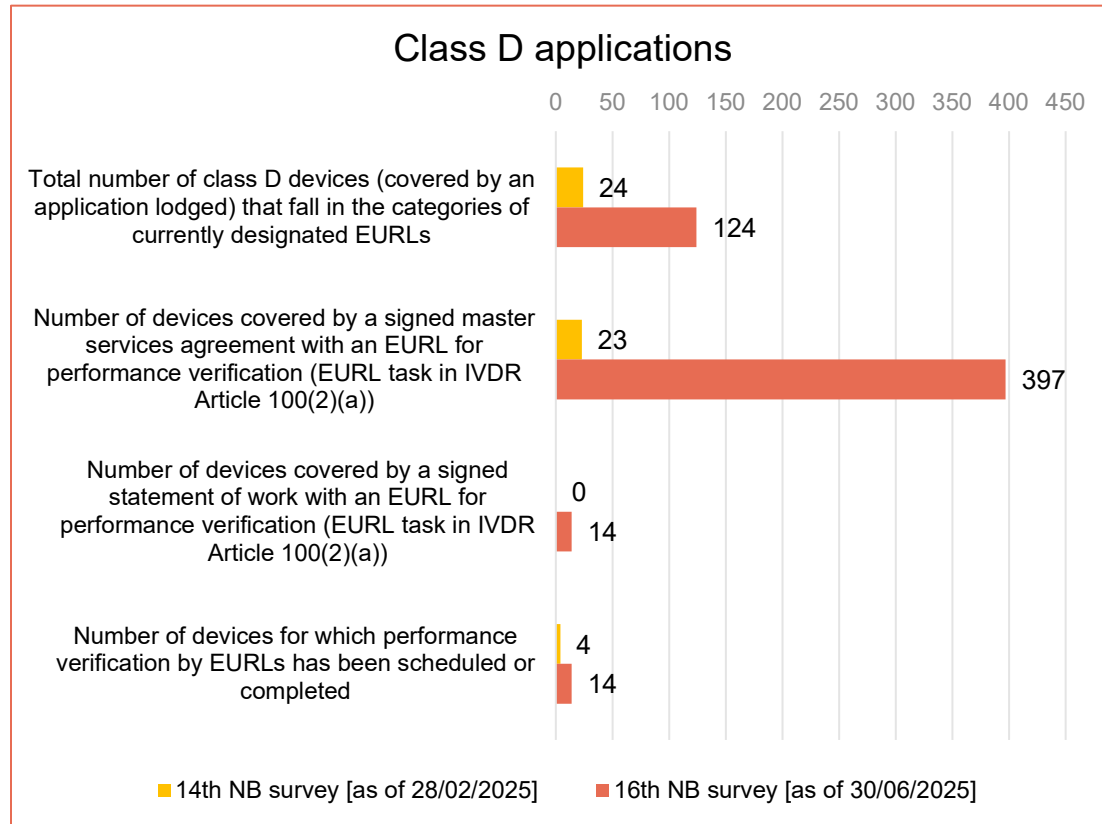
Class D certificates

	Hepatitis and retrovirus	Respiratory viruses	Bacterial pathogens	Herpes virus	TOTAL
Total number of class D devices (covered by issued certificates [as of 30/06/2025]) that fall in the categories of currently designated EURLs	440	52	31	41	564
Number of devices covered by a signed master services agreement with an EURL for batch testing (EURL task in IVDR Article 100(2)(b) [as of 30/06/2025])	351	19	8	10	388
Number of devices covered by a signed statement of work with an EURL for batch testing (EURL task in IVDR Article 100(2)(b)) [as of 30/06/2025]	333	7	0	0	340
Number of devices for which batch testing by EURLs is taking place [as of 30/06/2025]	76	2	0	0	78
Number of batches tested [as of 30/06/2025]* Note: sum across devices in category	221	0	0	0	221

Data of 3 NBs designated under IVDR

*This question was asked in the 16th NB survey for the first time.

Comparison of EURLs results of the 14th and 16th NB survey



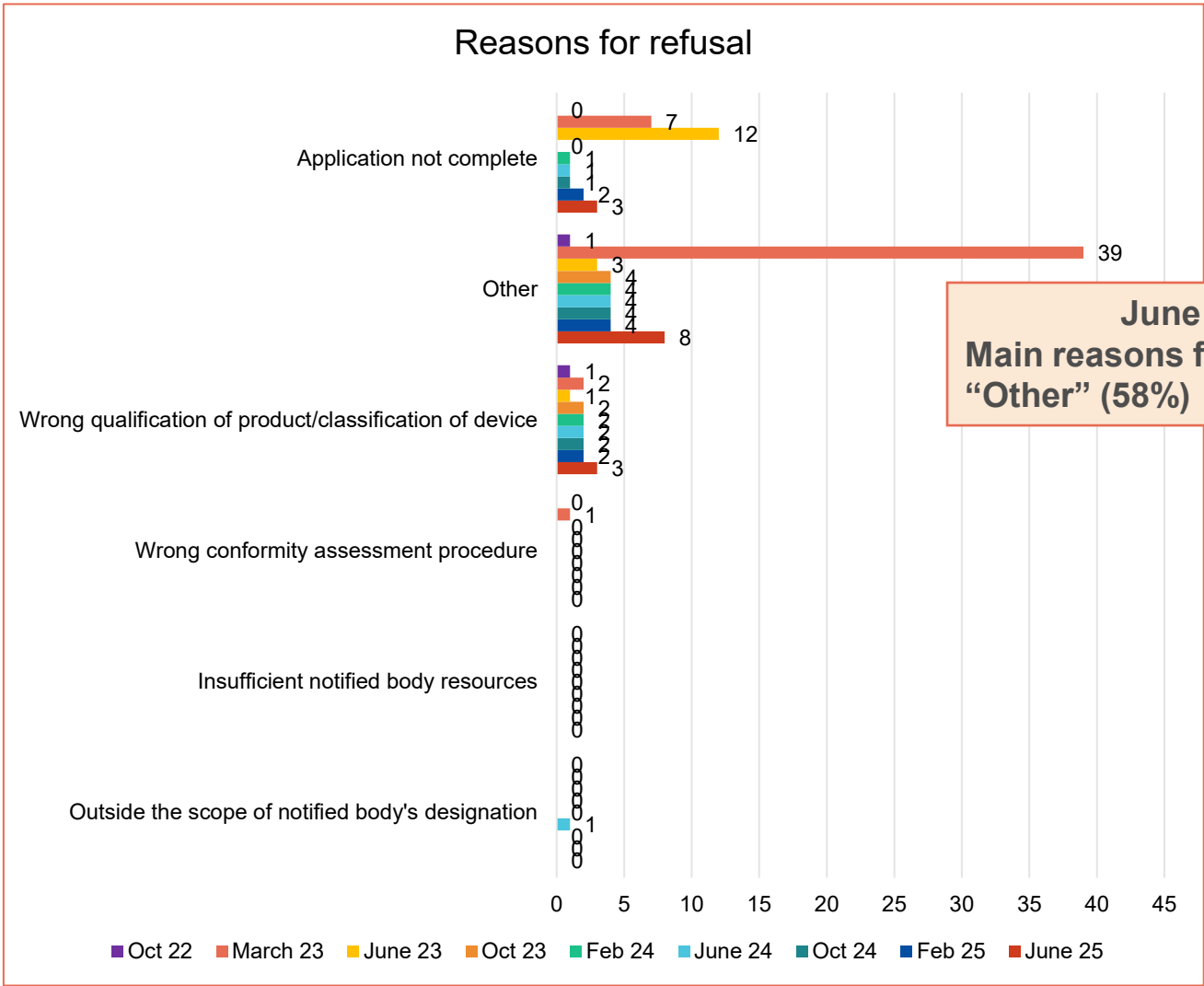
n.a. = not available

* This question was asked in the 16th NB survey for the first time.

IVDR applications - reason for refusal

June 2025
IVDR Applications: 3.083
IVDR Certificates: 1.779

Total number of IVDR application refusals*:
October 2022: 2
March 2023: 49
June 2023: 16
October 2023: 6
February 2024: 7
June 2024: 7
October 2024: 7
February 2025: 12
June 2025: 14

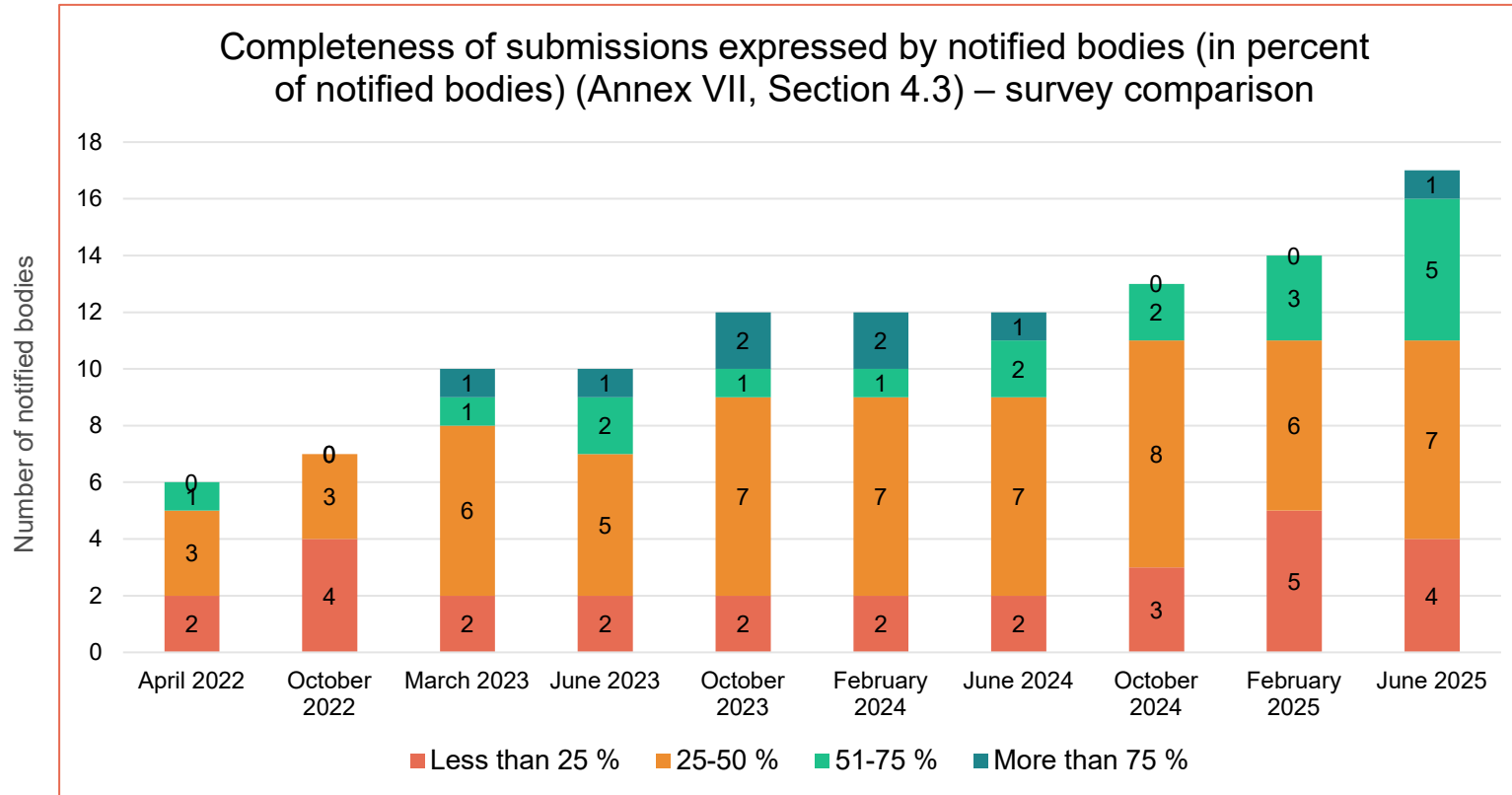


June 2025
Main reasons for refusals:
“Other” (58%)

Notes:

- This graph compares the total number of applications that have been refused under IVDR by reason of refusal in October 2022, March 2023, June 2023, October 2023, February 2024, June 2024, October 2024, February 2025 and June 2025.
- * Applications can have multiple reasons for refusal; the total number shown is derived from the small data set and differ from the figures in the medium data set indicated on the graph on this slide.
- June 2025: Reasons were indicated by **two** NBs. "Other" reasons: "nonconformities not solved", "refusal of client", "assessment resulted in negative outcome", "client stopped communication"

Completeness of submissions



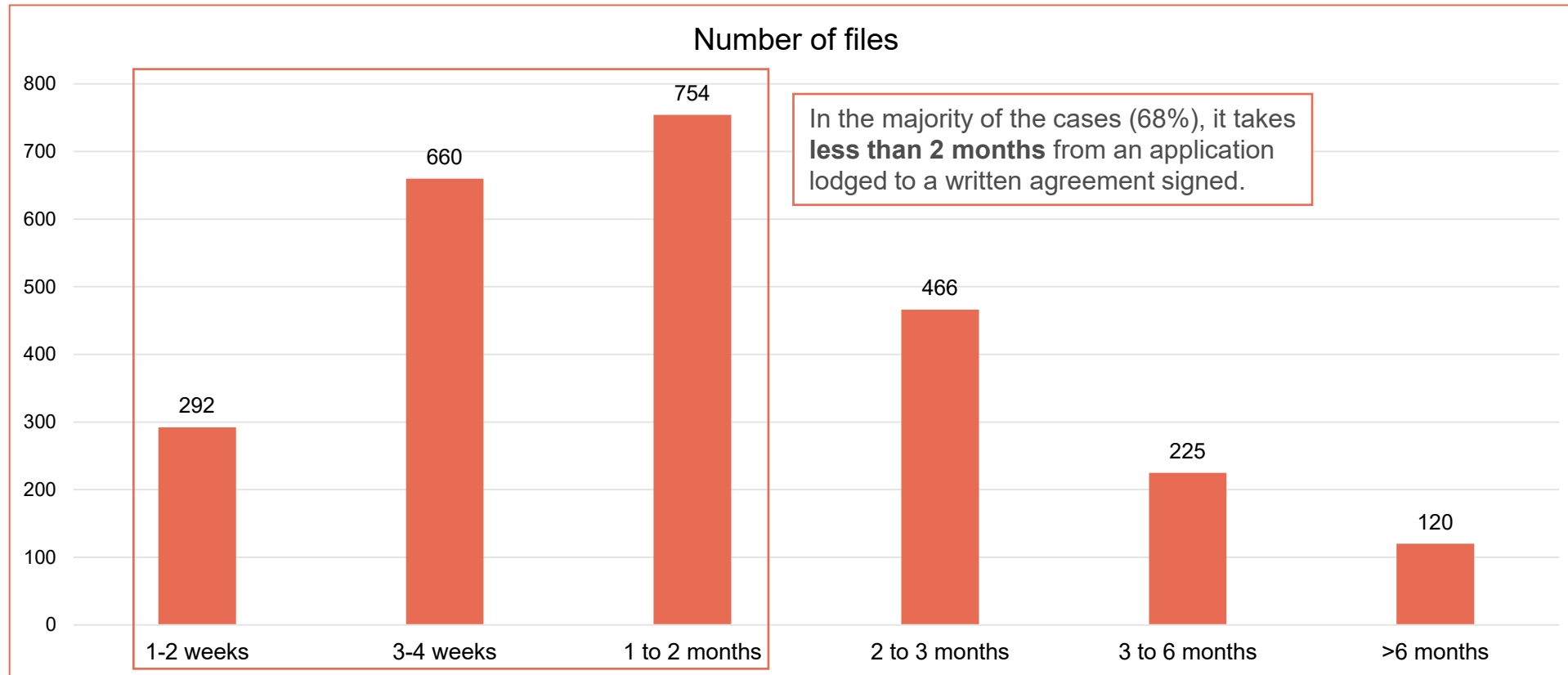
Number of notified bodies which report that > 50% of submissions are considered complete:
6 out of 17 NBs in June 2025

Submissions remain 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

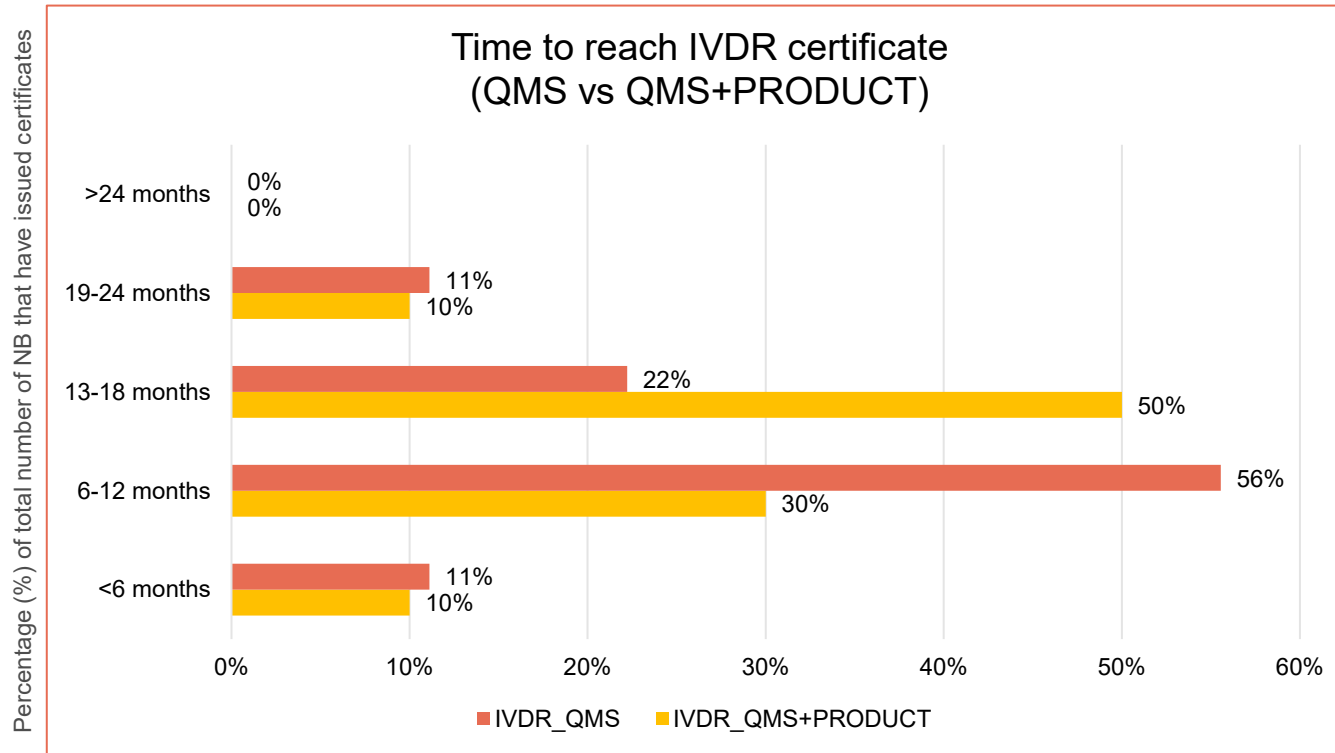
Average timeframe to written agreement signed

Average timeframe between application lodged and written agreement signed



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

June 2025
 IVDR Applications: 3.083
 IVDR Certificates: 1.779



IVDR QMS certificates

- For 56% of NBs: 6-12 months to issue a new QMS certificate
- 22% of NBs: 13-18 months

IVDR QMS+PRODUCT certificates: longer time

- 50% of NBs: 13-18 months
- 10% of NBs: 19-24 months

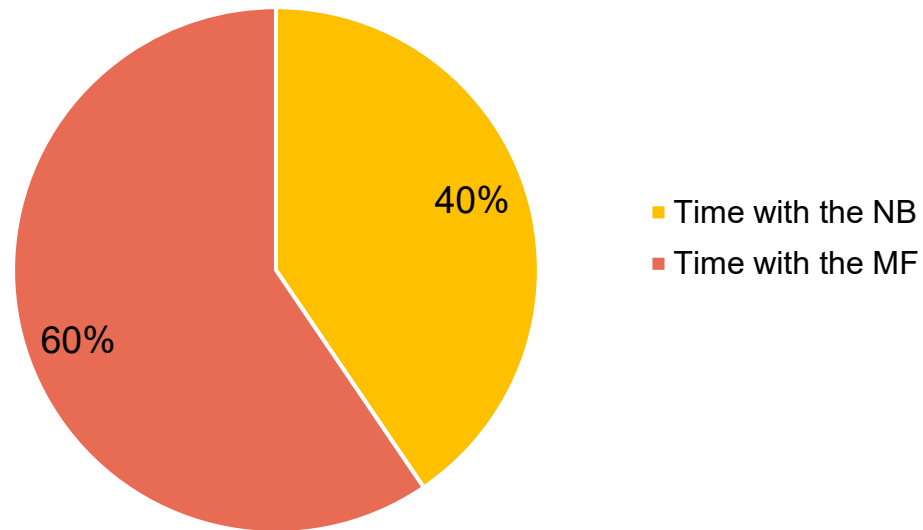
Notes:

- This indicator shows the time to reach issuance of a new EC certificate (from written agreement signed to issuance) under IVDR.
- QMS+PRODUCT: Data of 10 NBs designated under IVDR
- QMS: Data of 9 NBs designated under IVDR

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

* from written agreement signed to issuance of a new certificate

Estimation of total time to achieve certification between NBs and MFs (average percentage)



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.

Large dataset

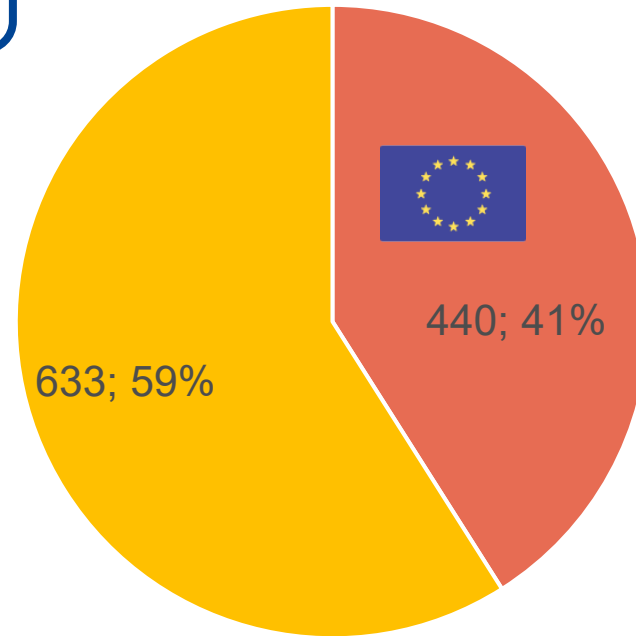
The **large dataset** contains additional data asked to notified bodies once a year.

Number of clients for IVDR

June 2025

Total number of clients: 1.073
(October 2024: 911)

Number of clients based
outside the EU



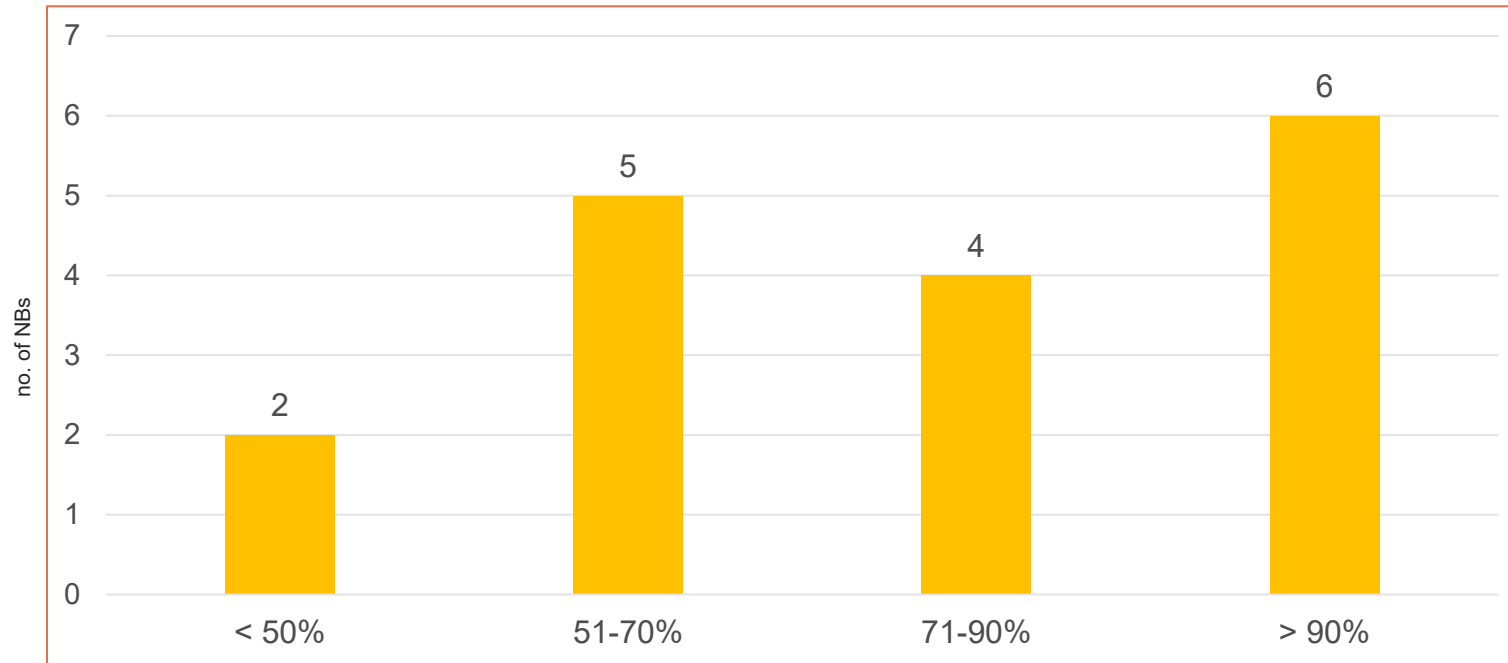
Number of clients based
in the EU

Data of 17 NBs designated under IVDR
Photo credit EU flag: [Flaticon.com](https://www.flaticon.com)

How many of the clients are SMEs*?

June 2025

Total number of clients: 1.073



Almost all NBs have SMEs as their main clients:

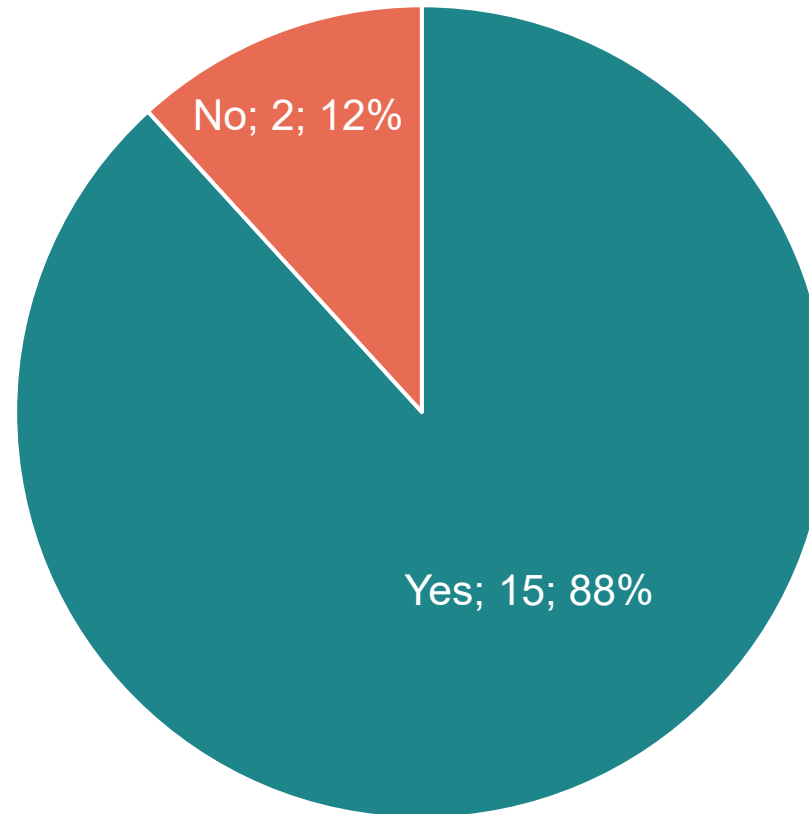
- 2 NBs (12%) indicated that less than 50% of their clients are SMEs
- 5 NBs (29%) indicated that between 51 and 70% of their clients are SMEs
- 4 NBs (24%) indicated that between 71 and 90% of their clients are SMEs
- 6 NB (35%) indicated that they almost only have SMEs as clients

Notes:

Data of 17 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)

Does your NB take on new clients for IVDR?

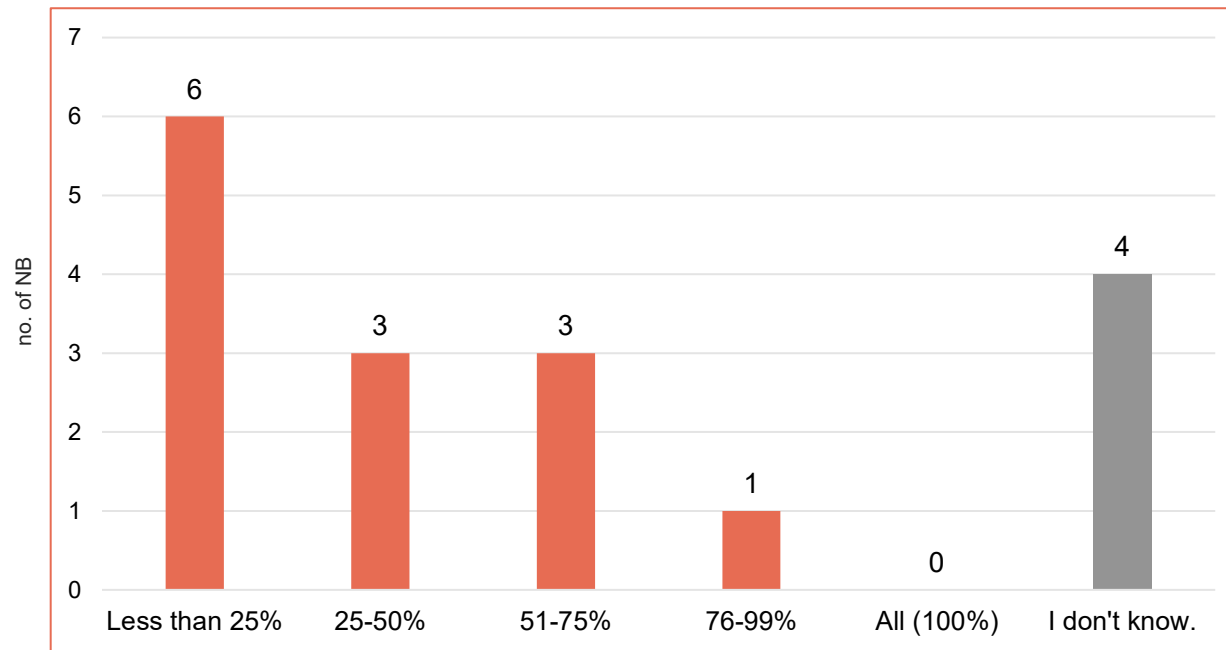


Data of 17 NBs designated under IVDR

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

June 2025

Total number of clients: 1073



Data of 17 NBs designated under IVDR

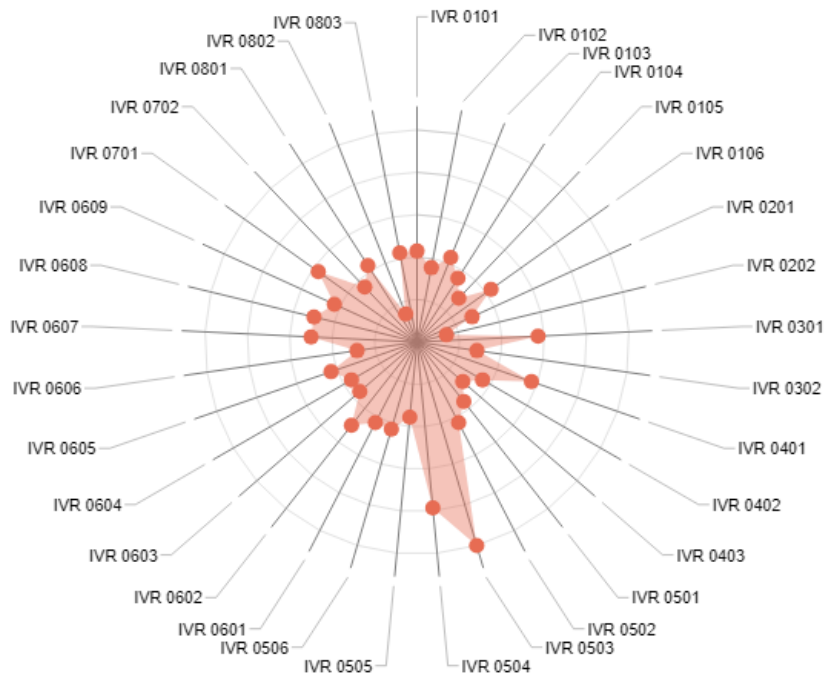
- 6 NBs (35%) indicated that less than 25 % of their clients with certificates under the Directive have completed the transfer to IVDR of all devices intended to be certificated
- 4 NBs (24%) indicated that > 50% of their clients have completed the transfer
- Only one NB indicated that 76-99% of their clients have completed the transfer

Which IVR codes are covered by IVDR certificates?

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 (except human genetic testing) and therapeutic measures, control materials without an assigned quantitative or qualitative value, class A devices in sterile condition

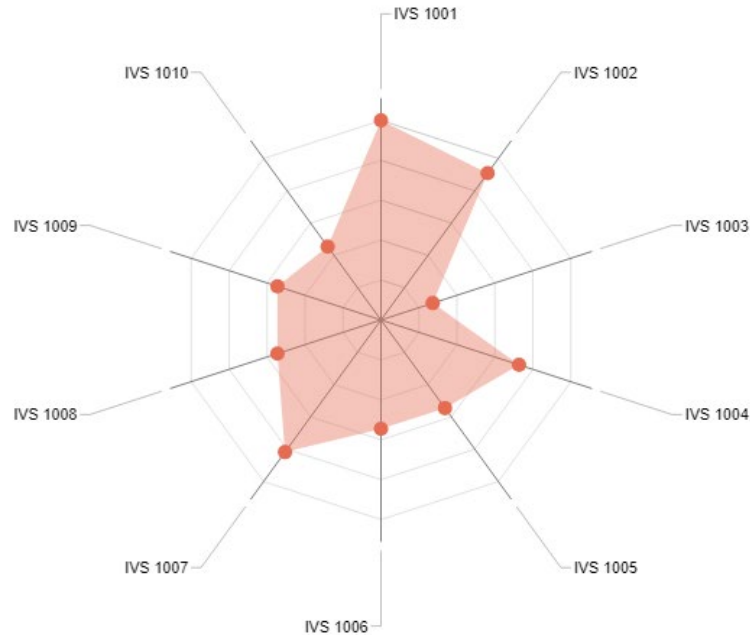


	Number of NBs indicating devices/categories		Number of NBs indicating devices/categories
IVR 0503 Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents	14	IVR 0801 Devices referred to in point 2.5 (rule 5), under a), of Annex VIII to Regulation (EU) 2017/746	6
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	11	IVR 0803 Specimen receptacles referred to in point 2.5 (rule 5), under c), of Annex VIII to Regulation (EU) 2017/746	6
IVR 0301 Devices intended to be used in screening, diagnosis, staging or monitoring of cancer	8	IVR 0102 Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]	5
IVR 0401 Devices intended to be used in screening/confirmation of congenital/inherited disorders	8	IVR 0104 Devices intended to determine markers of the Kidd system [JK1 (Jka), JK2 (Jkb)]	5
IVR 0701 Devices which are controls without a quantitative assigned value	8	IVR 0402 Devices intended to be used to predict genetic disease/disorder risk and prognosis	5
IVR 0602 Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease	7	IVR 0501 Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents	5
IVR 0607 Devices intended to be used for detection of pregnancy or fertility testing	7	IVR 0505 Devices intended to be used to grow/isolate/identify and handle infectious agents	5
IVR 0608 Devices intended to be used for screening, determination or monitoring of physiological markers	7	IVR 0603 Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances	5
IVR 0101 Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)]	6	IVR 0604 Other devices intended to be used for a specific disease	5
IVR 0103 Devices intended to determine markers of the Kell system [Kel1 (K)]	6	IVR 0702 Devices which are controls without a qualitative assigned value	5
IVR 0106 Other devices intended to be used for blood grouping	6	IVR 0105 Devices intended to determine markers of the Duffy system [FY1 (Fya), FY2 (Fyb)]	4
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	6	IVR 0201 Devices intended to be used for tissue typing (HLA A, B, DR) to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration	4
IVR 0506 Other devices intended to be used to determine markers of infections/immune status	6	IVR 0302 Other devices intended to be used for markers of cancer and non-malignant tumours	4
IVR 0601 Devices intended to be used for screening/confirmation of specific disorders/impairment	6	IVR 0403 Other devices intended to be used for human genetic testing	4
IVR 0605 Devices intended to be used for monitoring of levels of medicinal products, substances or biological components	6	IVR 0606 Devices intended to be used for non-infectious disease staging	4
IVR 0609 Other devices intended to be used to define or monitor physiological status	6	IVR 0202 Other devices intended to be used for tissue typing	2
		IVR 0802 Instruments intended specifically to be used for in vitro diagnostic procedures referred to in point 2.5 (rule 5), under b), of Annex VIII to Regulation (EU)	2

Which IVS codes are covered by IVDR certificates?

II: Horizontal codes IVS

In vitro diagnostic devices with specific characteristics



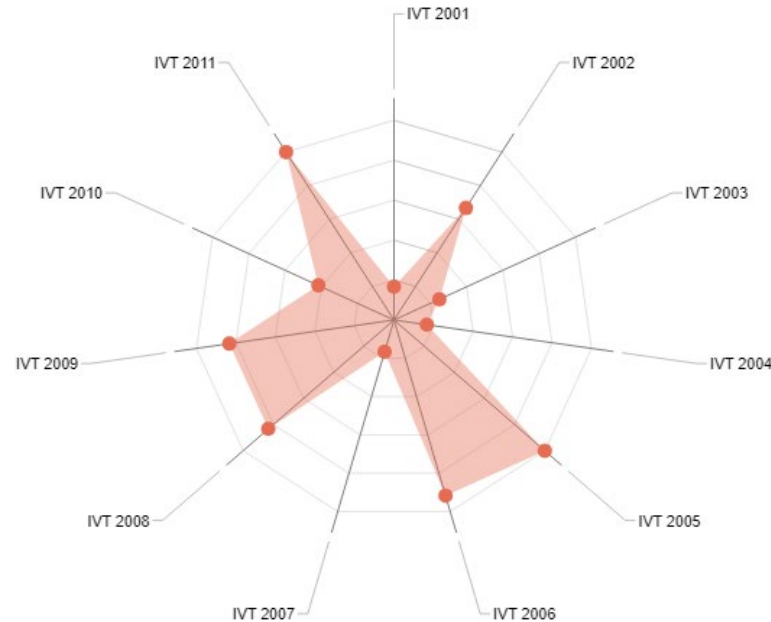
	Number of NBs indicating devices/categories
IVS 1001 Devices intended to be used for near-patient testing	11
IVS 1002 Devices intended to be used for self-testing	10
IVS 1007 Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes (point 1.6 of Annex VIII to Regulation (EU) 2017/746)	9
IVS 1004 Devices manufactured utilising tissues or cells of human origin, or their derivatives	8
IVS 1005 Devices in sterile condition	6
IVS 1006 Calibrators (point 1.5 of Annex VIII to Regulation (EU) 2017/746)	6
IVS 1008 Instruments, equipment, systems or apparatus	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 1010 Devices incorporating software/utilising software/controlled by software	5
IVS 1003 Devices intended to be used as companion diagnostics	3

Which IVT codes are covered by IVDR certificates?

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	12
IVT 2011 In vitro diagnostic devices which require packaging, including labelling	12
IVT 2006 In vitro diagnostic devices manufactured using chemical processing	11
IVT 2008 In vitro diagnostic devices manufactured in clean rooms and associated controlled environments	10
IVT 2009 In vitro diagnostic devices manufactured using processing of materials of human, animal or microbial origin	10
IVT 2002 In vitro diagnostic devices manufactured using plastic processing	8
IVT 2010 In vitro diagnostic devices manufactured using electronic components including communication devices	5
IVT 2003 In vitro diagnostic devices manufactured using non-metal mineral processing (e.g. glass, ceramics)	3
IVT 2001 In vitro diagnostic devices manufactured using metal processing	2
IVT 2004 In vitro diagnostic devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)	2
IVT 2007 In vitro diagnostic devices which require knowledge regarding the production of pharmaceuticals	2

Which IVP codes are covered by IVDR certificates?

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

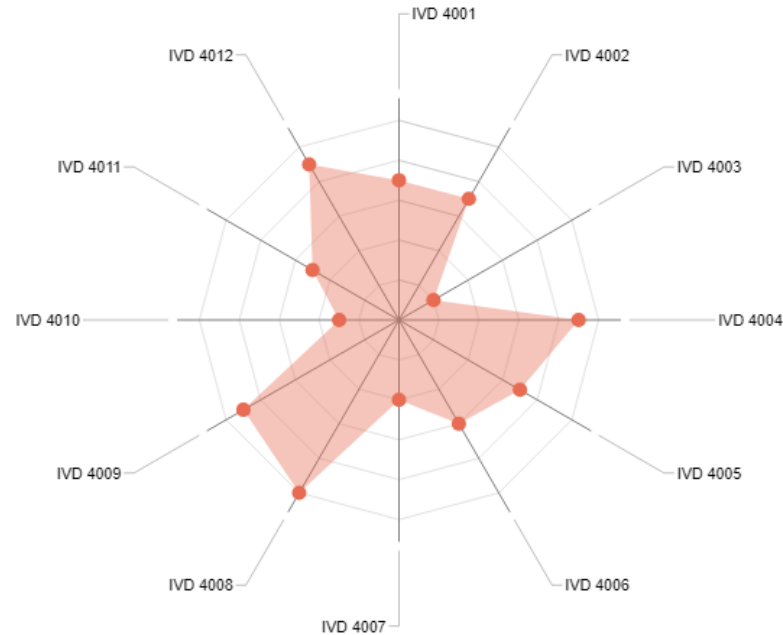
IVP 3007 In vitro diagnostic devices which require knowledge regarding immunoassays	11
IVP 3011 In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	10
IVP 3002 In vitro diagnostic devices which require knowledge regarding biochemistry	8
IVP 3001 In vitro diagnostic devices which require knowledge regarding agglutination tests	7
IVP 3005 In vitro diagnostic devices which require knowledge regarding coagulometry	6
IVP 3008 In vitro diagnostic devices which require knowledge regarding lysis based testing	6
IVP 3010 In vitro diagnostic devices which require knowledge regarding microscopy	6
IVP 3012 In vitro diagnostic devices which require knowledge regarding physical chemistry including electrochemistry	6
IVP 3013 In vitro diagnostic devices which require knowledge regarding spectroscopy	6
IVP 3003 In vitro diagnostic devices which require knowledge regarding chromatography	5
IVP 3006 In vitro diagnostic devices which require knowledge regarding flow cytometry	5
IVP 3014 In vitro diagnostic devices which require knowledge regarding tests of cell function	4
IVP 3004 In vitro diagnostic devices which require knowledge regarding chromosomal analysis	3
IVP 3009 In vitro diagnostic devices which require knowledge regarding measurement of radioactivity	2

Which IVD codes are covered by IVDR certificates?

II: Horizontal codes

IVD

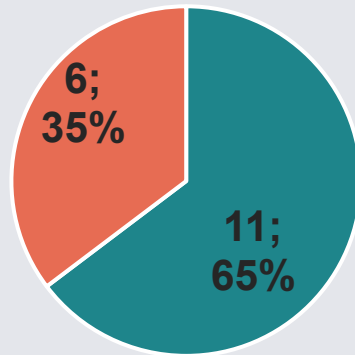
In vitro diagnostic devices which require specific knowledge in laboratory and clinical disciplines for the purpose of product verification



	Number of NBs indicating devices/categories
IVD 4008 In vitro diagnostic devices which require knowledge regarding immunology	10
IVD 4004 In vitro diagnostic devices which require knowledge regarding genetics	9
IVD 4009 In vitro diagnostic devices which require knowledge regarding molecular biology/diagnostics	9
IVD 4012 In vitro diagnostic devices which require knowledge regarding virology	9
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 4005 In vitro diagnostic devices which require knowledge regarding haematology/haemostasis, including coagulation disorders	7
IVD 4006 In vitro diagnostic devices which require knowledge regarding histocompatibility and immunogenetics	6
IVD 4011 In vitro diagnostic devices which require knowledge regarding parasitology	5
IVD 4007 In vitro diagnostic devices which require knowledge regarding immunohistochemistry/histology	4
IVD 4010 In vitro diagnostic devices which require knowledge regarding mycology	3
IVD 4003 In vitro diagnostic devices which require knowledge regarding detection of transmissible agents (without organisms or viruses)	2

Technical documentation (TD) – shifting of submission from NBs' perspective

Do you experience MFs requesting the delay of the submission of the TD to be reviewed (in comparison to possible timelines previously agreed)?

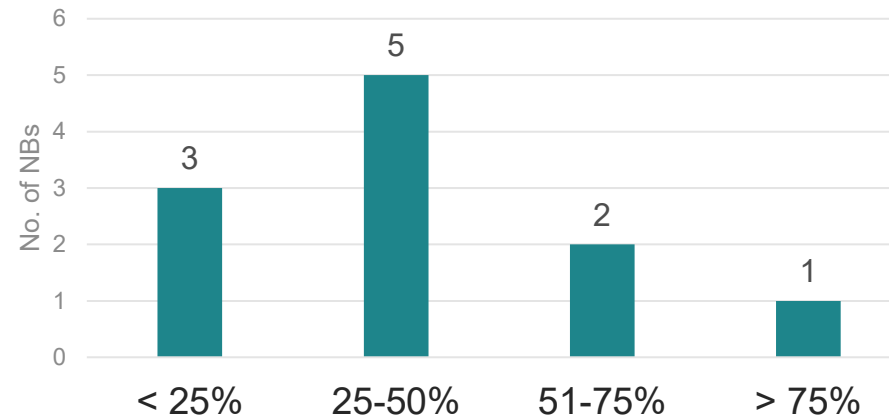


■ Yes ■ No

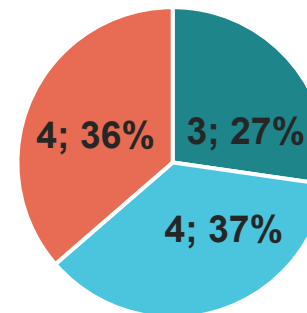
IVDR designated NBs: 17



Percentage of delayed files

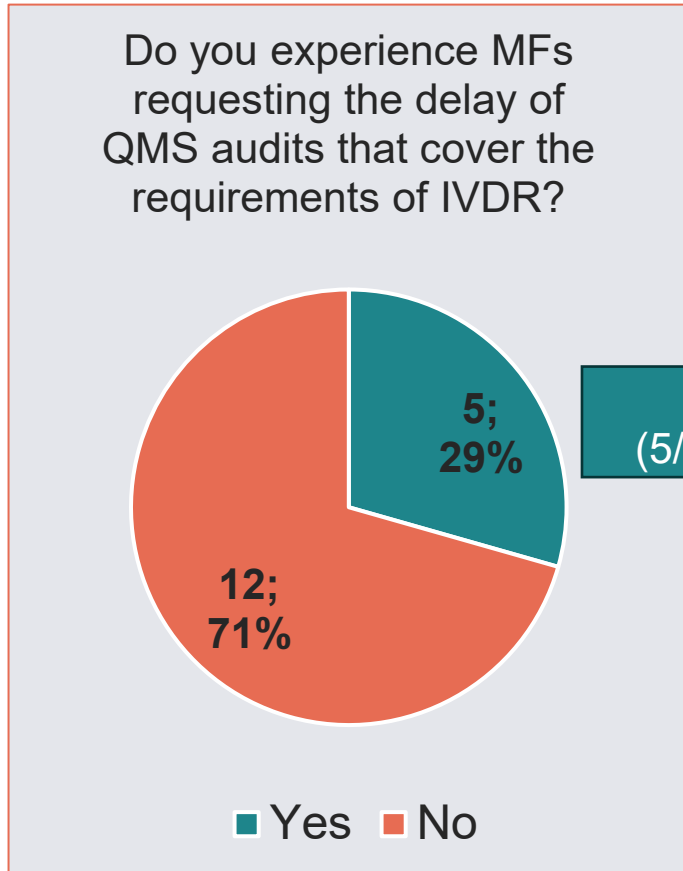


Impact on the schedule of NB's activities



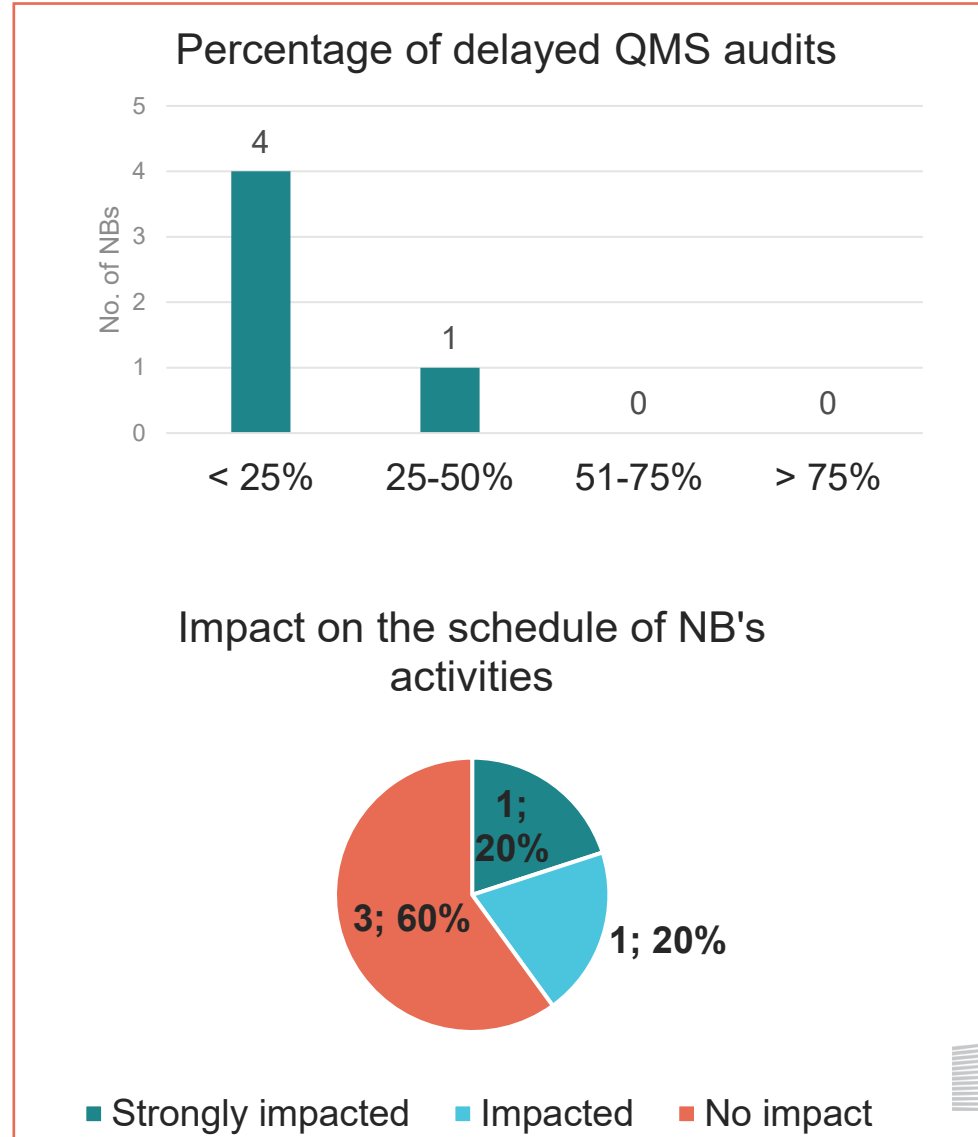
■ Strongly impacted ■ Impacted ■ No impact

Shifting of QMS audits from NBs' perspective



If yes
(5/17 NBs)

IVDR designated NBs: 17



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)

Note: Out of 51 notified bodies, 34 NBs are designated under the MDR only, 16 NBs are designated under both the MDR and IVDR, and 1 NB is designated under the IVDR only.

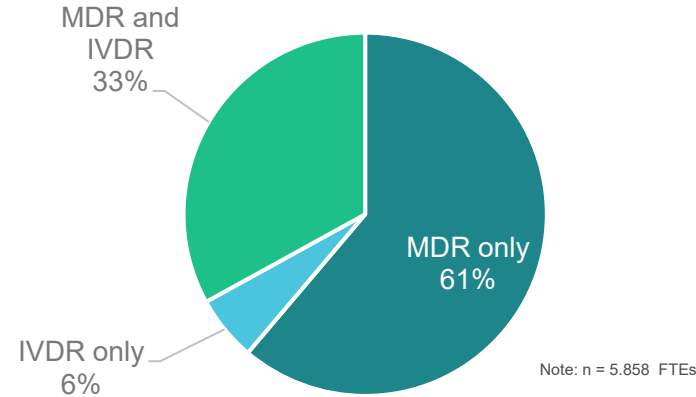


June 2025

Total number of FTEs with conformity assessment activities and within administrative and supporting activities: **6.290** (internal staff and external contractors, data of 51 NBs*)

- Thereof number of personnel with relevant clinical expertise: 992 FTEs

Staff working on ...



Notes:

- Data status: 30/06/2025
- By employee type
- Counted in Full Time Equivalents (FTE)

Employees within conformity assessment activities: 4.888 (FTE)

- Internal: 3.611 FTEs
- External contractors: 1.277 FTEs

Employees within administrative and supporting activities (in relation to Regulations): 1.402 (FTE)

- Internal: 1.320 FTEs
- External contractors: 82 FTEs

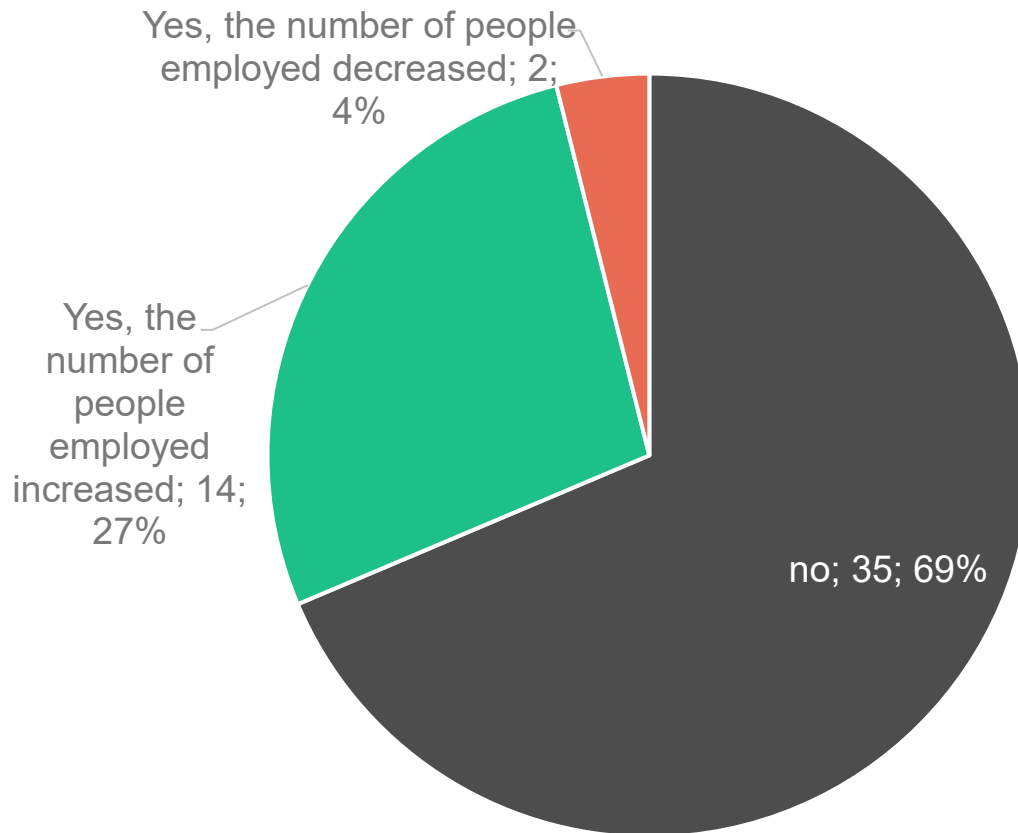
Employees within the conformity assessment activities is the personnel referred to in Sections from 3.2.3 to 3.2.7 of Annex VII MDR/IVDR in addition to the personnel referred to in Section 4.4, second paragraph, of Annex VII MDR/IVDR [...individual responsible for ensuring that the assessment of that 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 51 NBs

* For two NBs the data of the 12th NB survey (October 2024) was taken.

Staff: Was there a significant change in the number of people employed in 2025 (from 01/01/2025 up to 30/06/2025)?



Data of 51 NBs designated under MDR / IVDR

Reasons for increase:

- Increased resources needed to serve manufacturers adequately (7x)
- To fulfill competency requirements (3x)
- Designated for new codes (2x)
- IVDR designation (2x)

Reasons for decrease:

- Workers who left, decided to seek employment in another business (1x).
- Although the total number of FTE decreased, the overall number of staff conducting conformity assessment activities has increased. The number of administrative staff currently employed by the company has decreased following an internal reorganization (1x).



5. Medical device single audit program and monitoring

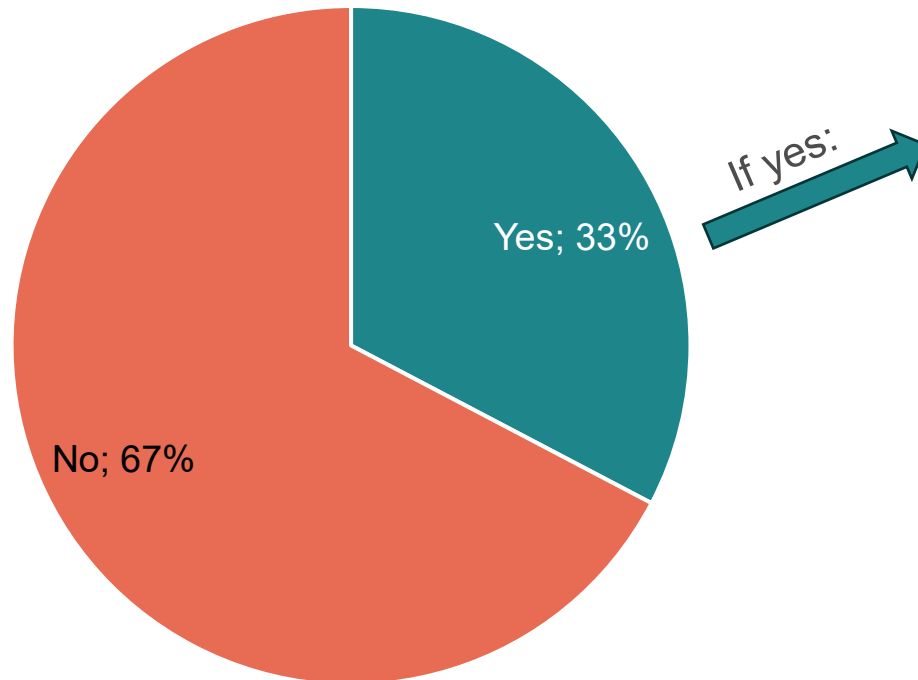
The **large dataset** contains additional data asked to notified bodies once/twice a year.

Is your organization or a sister company a Medical Device Single Audit Program (MDSAP) auditing organisation?

MD

IVD

MDSAP auditing organisation



**1131 MDR certificates and
120 IVDR certificates**
have already been issued on the
basis of the MDSAP/MDR-IVDR
combined audit

Notes:

- MDR: Data from 15 NBs (thereof 4 NBs indicated „0“)
- IVDR: Data from 9 NBs (thereof 4 NBs indicated „0“)

Data of 51 NBs designated under MDR and/or IVDR

Thank you

Contact for questions: medical.devices@goeg.at

Austrian National Public Health Institute/ Gesundheit Österreich (GÖG)



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