



Notified Bodies Survey on certifications and applications (MDR/IVDR)

Survey results of the 6th NB survey with data status 31 October 2023
(small, medium and large dataset)

11 March 2024 (revised version)

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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- As a result of further data validation activities, some figures have been adjusted slightly compared to the PPT previously published and dated 5 February 2024.

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MD

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List of abbreviations

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

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

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



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



Areté



Civic Consulting

Supported by experts from the medical devices sector

NB survey overview

NB surveys already conducted by the study team

| NB Survey | Survey period (survey launch – survey closure) | Requested dataset* SD = small dataset MD = medium dataset LD = large dataset | Requested data | Response rate |
|---------------------------|---|---|-----------------------------------|------------------------------------|
| 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% |

Survey results included in the published [dashboard](#)

6th NB survey results are presented in this PowerPoint presentation

* Datasets:

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

** designated under MDR and/or IVDR

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://study.supportingtheavailabilityofmedicaldevices.europa.eu)

Monitoring the Availability of Medical Devices and In Vitro Diagnostic Medical Devices in the EU

Home About Process Indicators MDR Outcomes IVDR Outcomes Glossary/Links Contact/Help

Welcome to the dashboard monitoring the availability of medical devices and in vitro diagnostic medical devices in the European Union

Medical devices (MDs) and in vitro diagnostic medical devices (IVDs) are essential for a working healthcare system and play a crucial role in the prevention, diagnosis, monitoring, prediction, prognosis and treatment of acute and chronic illnesses and diseases as well as rehabilitation. However, they require a strong regulatory framework to ensure safety and optimal performance.

Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), which replace the previous regulatory framework in the European Union (EU), aim to improve the safety, performance and effectiveness of medical devices as well as, strengthen transparency and provide information for patients while enhancing vigilance and market surveillance. In order to ensure a smooth transition from the previous regulatory framework, it is essential to regularly apprise the situation on the ground and gather concrete data on the activities currently performed by relevant stakeholders.

A study was commissioned by the European Commission (via its European Health and Digital Executive Agency / HADEA) from *Gesundheit Österreich GmbH (Austrian National Public Health Institute)*, *Civic Consulting* and *Areté* with the support of four regulatory experts to monitor the availability of medical devices on the EU market. Starting in December 2022 and lasting 36 months, the study aims to monitor and analyse the availability of medical devices on the EU market in the context of the implementation of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices. As part of the project, this dashboard was established.

The dashboard presents an overview of the data gathered from different stakeholders monitoring the availability of MDs and IVDRs in the EU. In addition, comparable data from previous surveys of notified bodies conducted by the European Commission have been integrated in the dashboard and can be found on the MDR/IVDR Outcomes overview pages.

Latest update of page 20.12.2023

Please contact: medical.devices@ec.europa.eu

MD Availability Dashboard 1.0

Monitoring the Availability of Medical Devices and In Vitro Diagnostic Medical Devices in the EU

Home About Process Indicators MDR Outcomes IVDR Outcomes Glossary/Links Contact/Help

Overview Applications & Certificates Temporal & Qualitative Annex XVI Products

Select stakeholder: Notified Bodies (NBs) Select figure: Overview indicators (MDR)

Overview indicators (MDR)

Number of files

Compare: Total valid MDD/AIMDD certificates: 22.793 (1..)

| Month | Applications total | Written agreements signed | QMS certificates issued | Product certificates issued | Applications refused |
|-------------|--------------------|---------------------------|-------------------------|-----------------------------|----------------------|
| March 2023 | ~12,000 | ~8,000 | ~2,000 | ~1,000 | ~1,000 |
| April 2023 | ~12,000 | ~8,000 | ~2,000 | ~1,000 | ~1,000 |
| May 2023 | ~12,000 | ~8,000 | ~2,000 | ~1,000 | ~1,000 |
| June 2023 | ~13,000 | ~9,000 | ~2,500 | ~1,500 | ~1,000 |
| August 2023 | ~14,000 | ~10,000 | ~3,000 | ~2,000 | ~1,000 |

Please hover over the dots in the figure to see detailed numbers.

How to interpret: Detailed information on displayed figure

This figure displays an overview of the (main) indicators on applications and certifications for medical devices under the MDR for the surveys performed. Notified bodies reported on how many written agreements they have signed, how many applications from economic operators have been refused, how many QMS and product certificates they have issued as well as how many certification applications have been received in total. Note that these data are collected within the small dataset (every two months) and are displayed and updated accordingly.

Select all, one or several of these indicators by clicking on the black buttons. For a selected indicator its definition and detailed information are shown in the infobox below.

| Select all | Applications total | Written agreements signed | QMS certificates issued | QMS certificates issued (first time only) | Product certificates issued | Product certificates issued (first time only) | Applications refused |
|--------------------------|--------------------------|---------------------------|--------------------------|---|-----------------------------|---|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

How to interpret: Detailed information on displayed indicator

Response rate per survey in %

100
50
0

Notified Bodies

Applications refused: Applications by manufacturers to notified bodies can be refused for specific reasons. The notified body shall have documented procedures to review applications, addressing (a) the completeness of those applications with respect to the requirements of the relevant conformity assessment procedure, (b) the verification of the qualification of products covered by those applications as devices and their respective classifications, (c) whether the conformity assessment procedures chosen by the applicant are applicable to the device in question under this Regulation, (d) the ability of the notified body to assess the application based on its designation, and (e) the availability of sufficient and appropriate resources.

Please contact: medical.devices@ec.europa.eu

MD Availability Dashboard 1.0

Preliminary notes

- **Data content:**

- The following slides show the results of the **6th NB survey conducted at the beginning of November 2023** with requested data from notified bodies designated under MDR and/or IVDR until 31 October 2023.
- These survey results are also compared with previous survey data (see data sources).

- **Data sources:**

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

- **Datasets:**

- This presentation contains the results of the small and medium datasets as well as the large dataset (for the first time) surveyed in November 2023.

Ⓢ 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**.

Timeline for the survey conducted in November 2023 (data was requested until 31 October 2023)

About

41 notified bodies designated under MDR and/or IVDR

(Data status: 31 October 2023)

3 November 2023 survey sent

17 November 2023 1st friendly reminder

24 November 2023 2nd friendly reminder

11 December 2023 3rd friendly reminder

December 2023 individual phone calls and emails

January 2024 data validation

16 November 2023 initial deadline

22 November 2023 extended deadline

28 November 2023 extended deadline

14 December 2023 extended deadline

22 December 2023 survey closed

Note: Out of 41 notified bodies, 29 NBs are designated under the MDR only, 10 NBs are designated under both the MDR and IVDR, and two NBs are designated under the IVDR only.

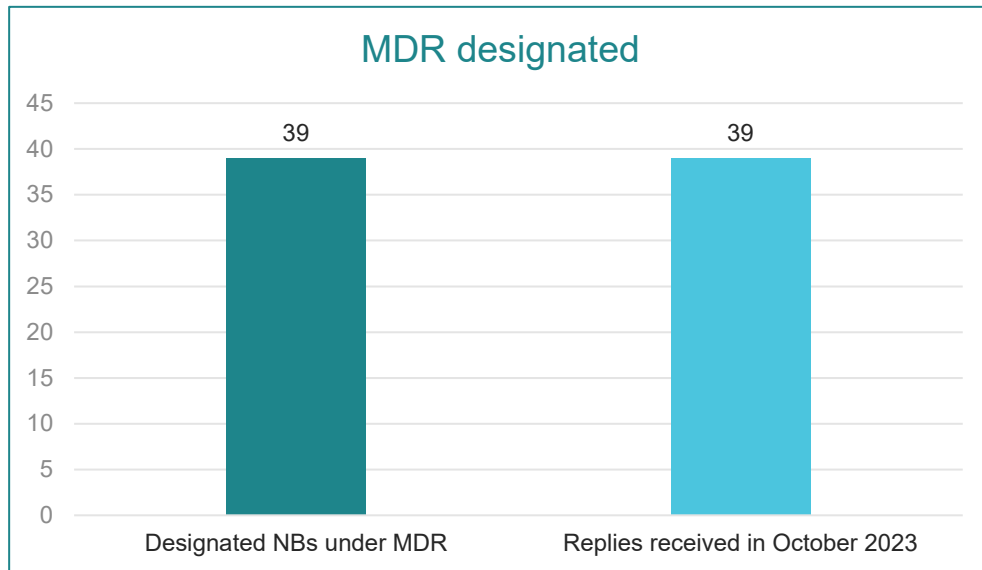
Final result
41 responses
(100% response rate)

Response rate for the survey conducted in November 2023 (data was requested until 31 October 2023)

41 out of 41 notified bodies replies received (100% response rate)

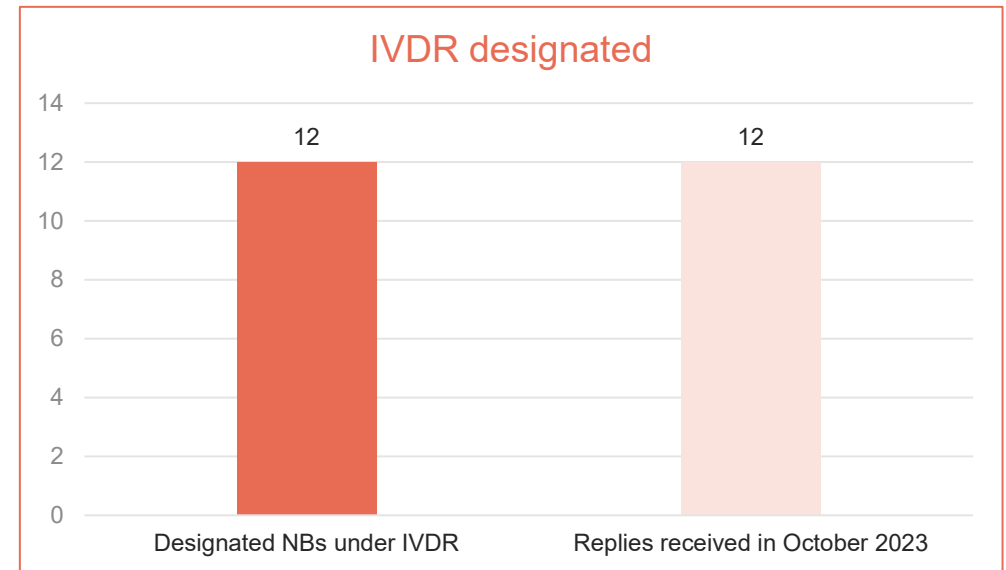
Note: Out of 41 notified bodies, 29 NBs are designated under the MDR only, 10 NBs are designated under both the MDR and IVDR, and two NBs are designated under the IVDR only.

MD



100% response rate

IVD



100% response rate

2. Survey results for medical devices

Note:

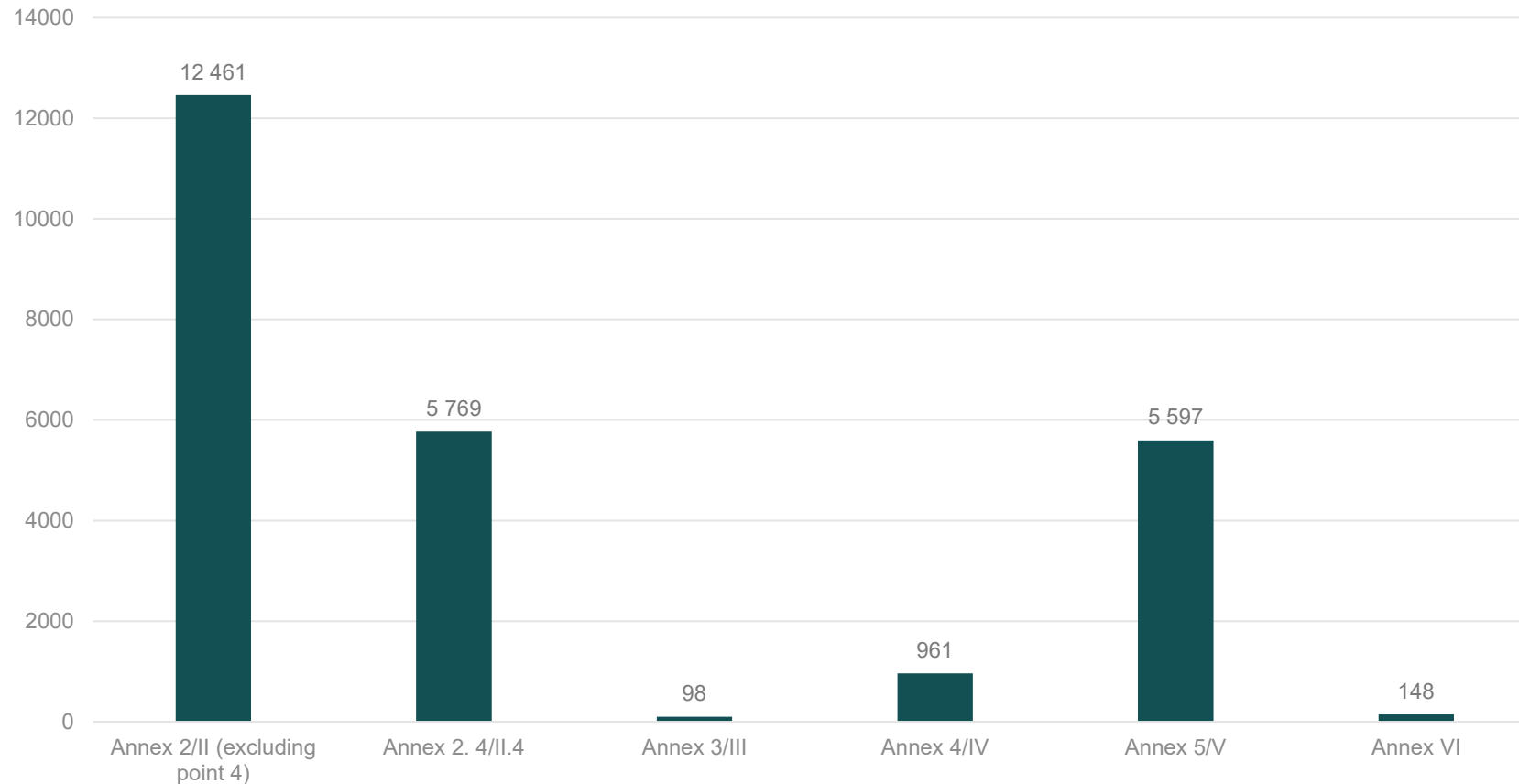
- Thousands separators are represented as dots or blank space (not comma) in the graphs.
- Datasets:
 - ① The **small dataset** is a small set of questions (6 indicators) asked to notified bodies **every two months**.
Note: From April to July 2023, it was asked monthly.
 - ② The **medium dataset** is 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**.

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

MD

MDD/AIMDD Data

Total valid MDD/AIMDD certificates by Annex

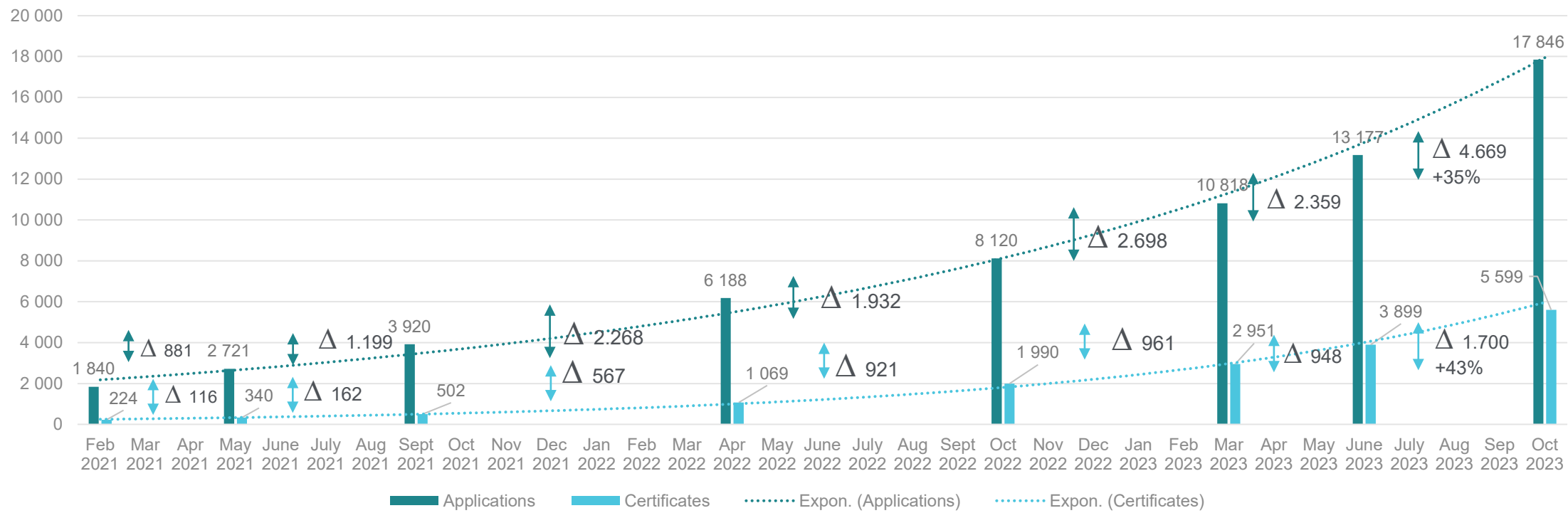


Total: 25.034

MDR applications filed and certificates issued (sum of Annexes)



October 2023
MDR Applications:
 Total number of applications filed by Annex (M): 17.846*
MDR Certificates:
 Total number of certificates by Annex (M): 5.599

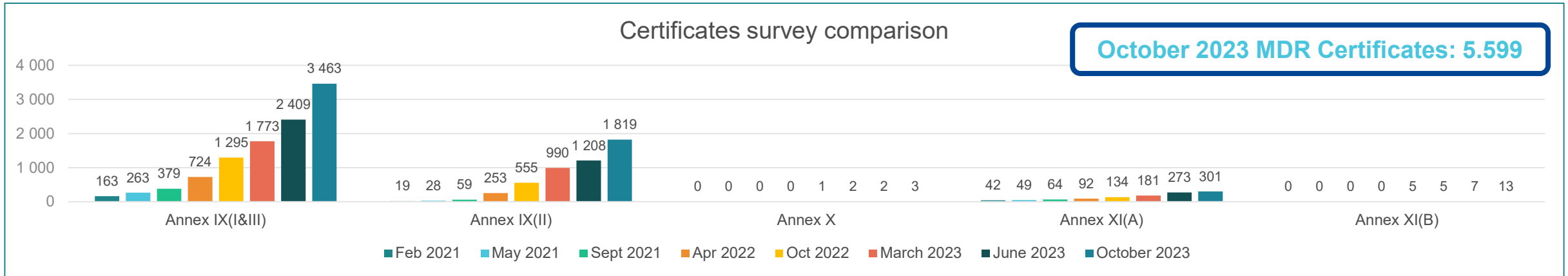
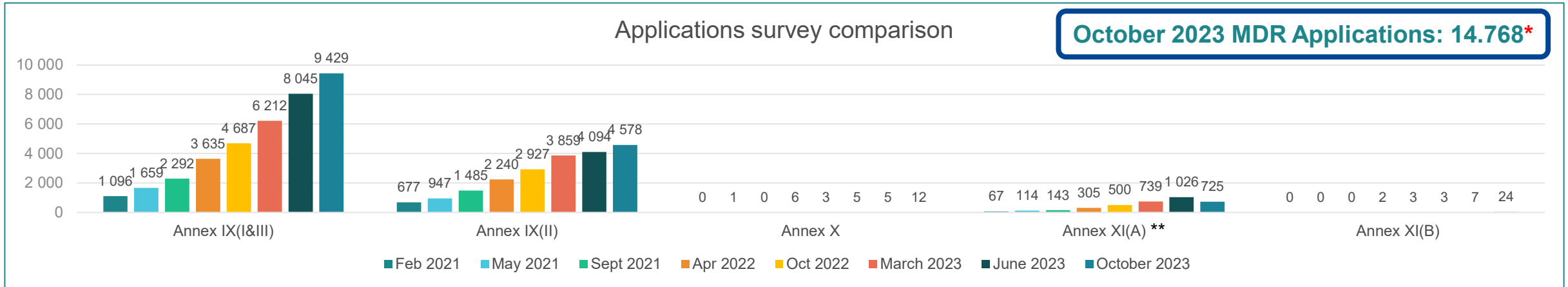


Notes: October 2023: Designated NBs for MD: 39; NBs that included Annex XVI products in the numbers provided: 15

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

- Δ (Delta) = Difference in MDR Applications / MDR Certificates from one survey to the next one
- **Applications filed:** This number includes **all applications filed (syn. lodged) so far** according to MDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the [Single Market Compliance Space](#) to the date of the survey up to 31/10/2023), 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 to 31/10/2023) under the MDR.

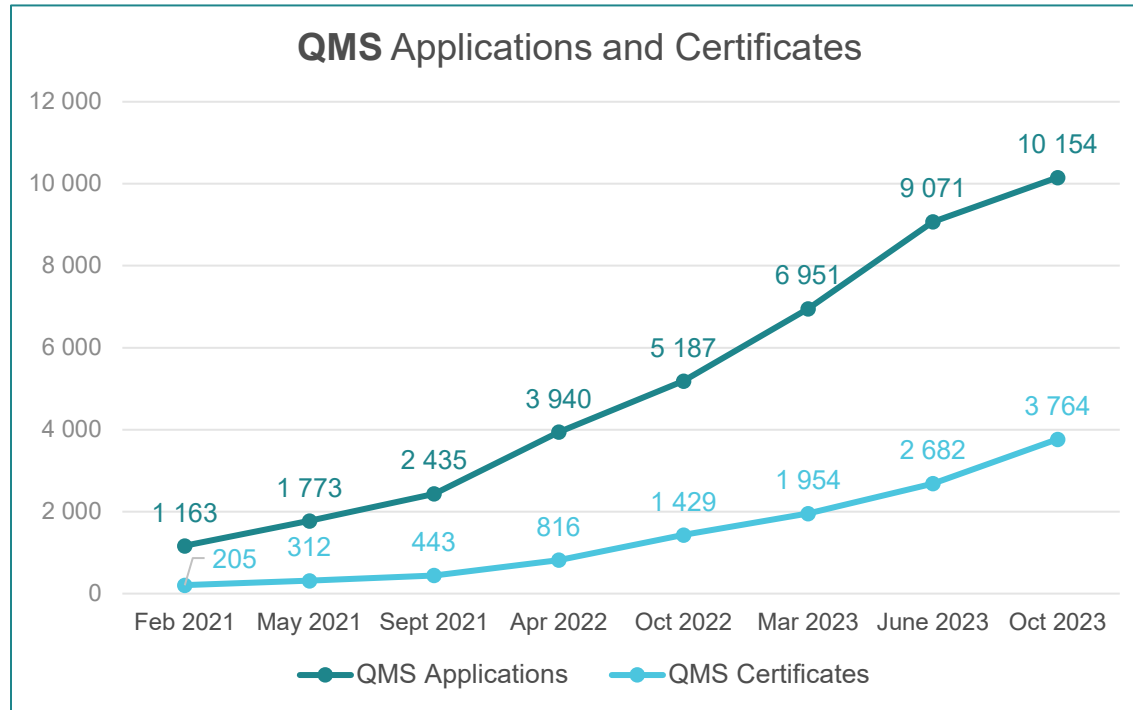
MDR applications and certificates by annex survey comparison



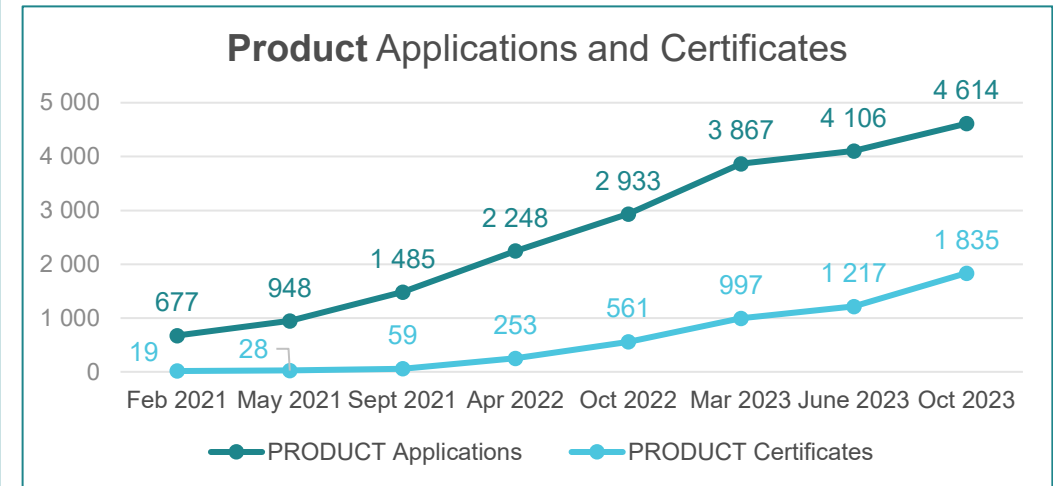
Notes:

- Designated NBs for MD: 39; NBs that included Annex XVI products in the numbers provided: 15
 - * The data shown comes from the medium data set (applications and certificates by Annex; 2 NBs could not provide the application information by Annex; hence the total number of applications is higher → see number in the small data set)
 - ** Change in methodology of counting by few NBs.
- 15 **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 31/10/2023), 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 31/10/2023) under the MDR by annex.

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



October 2023
MDR Applications: 14.768*
MDR Certificates: 5.599



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: 1.909

Specific additional procedures according to Annex IX (II)

October 2023

MDR Applications:

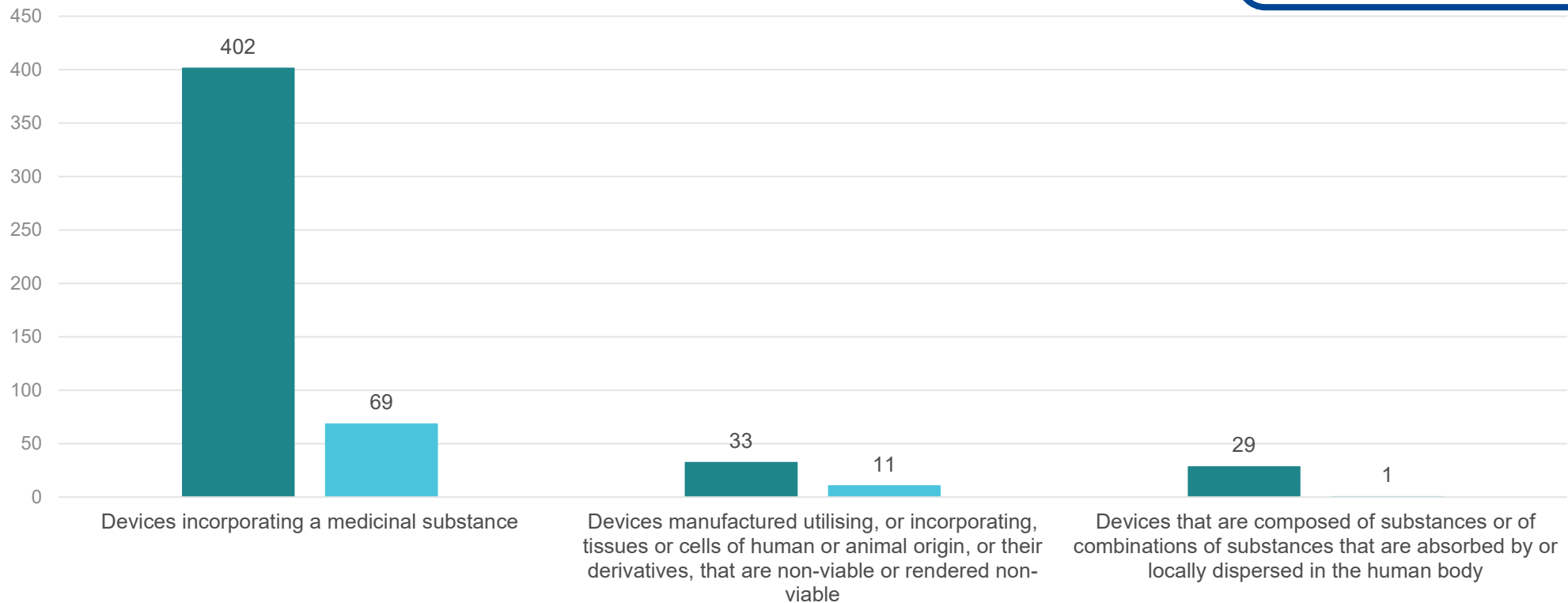
Total number of applications filed by Annex M: 17.846*

MDR Certificates:

Total number of certificates by Annex M: 5.599

Specific additional procedures according to Annex IX (II)

■ Applications filed requiring consultation procedure ■ Thereof certificates issued



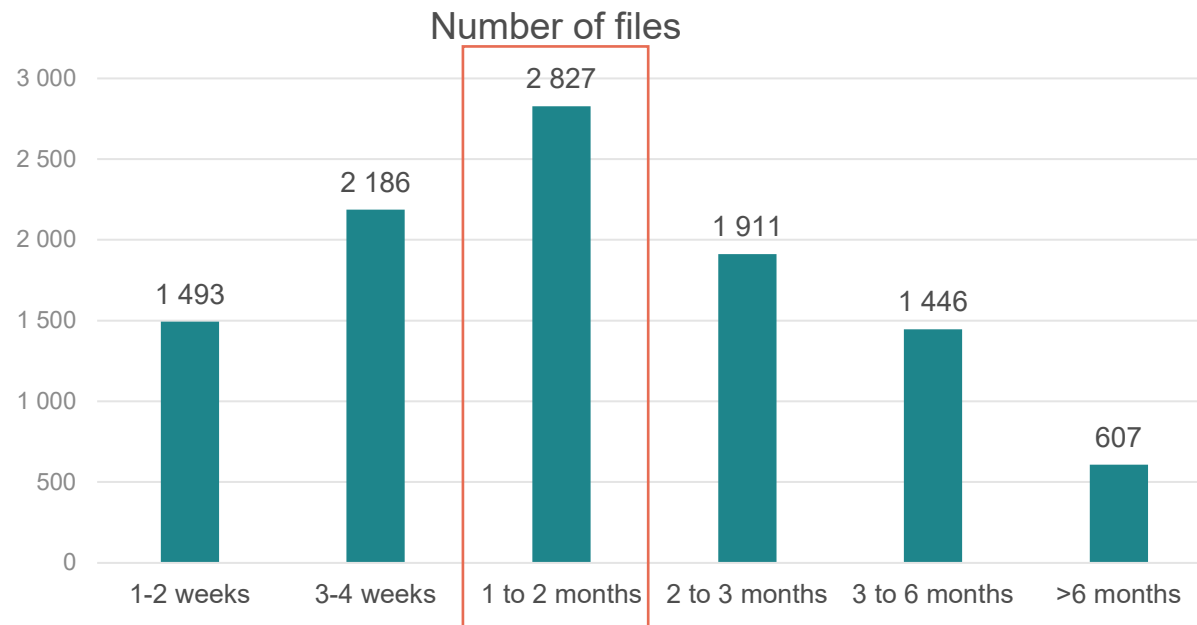
Notes:

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

As a result of further data validation activities, some figures have been adjusted slightly compared to the PPT previously published and dated 5 February 2024.

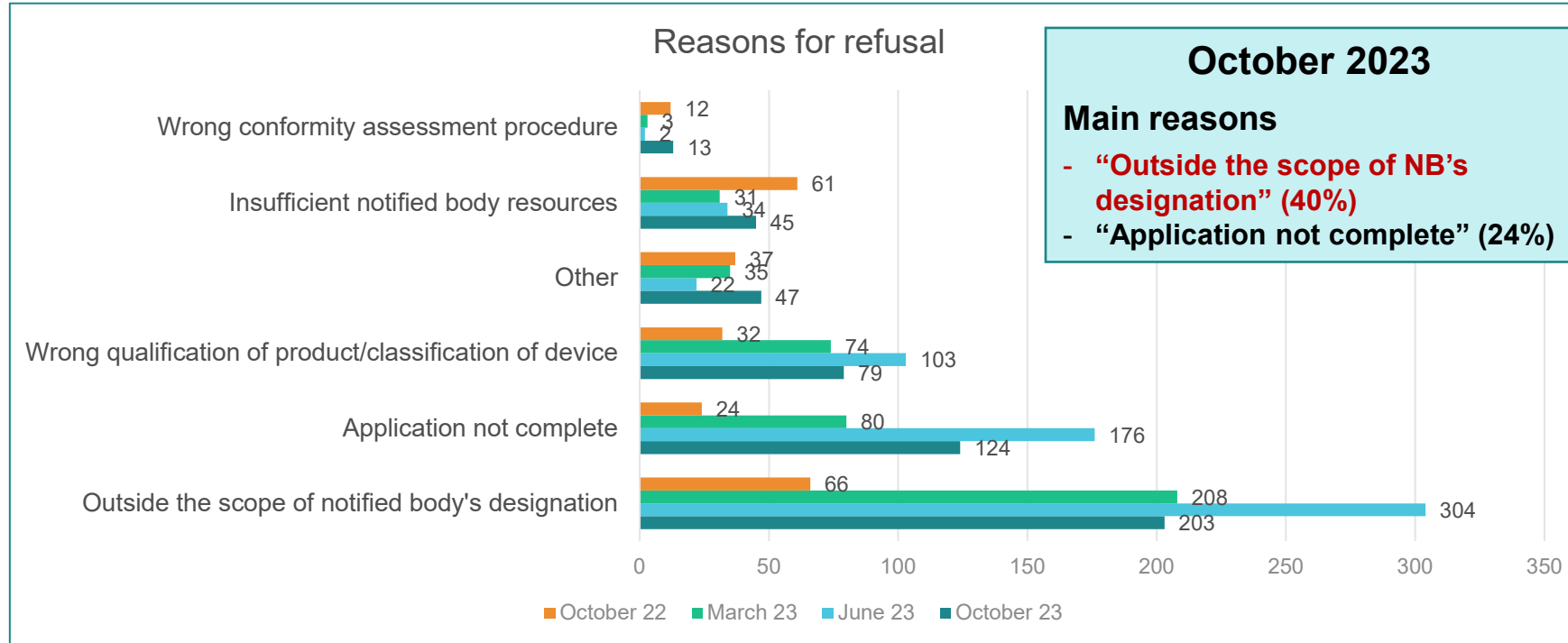
Average timeframe to written agreement signed

Average timeframe between application lodged and written agreement signed:



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

MDR applications - reason for refusal



Total number of MDR applications:

October 2022: 8120
 March 2023: 11.418
 June 2023: 13.177
 October 2023: 17.846*

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

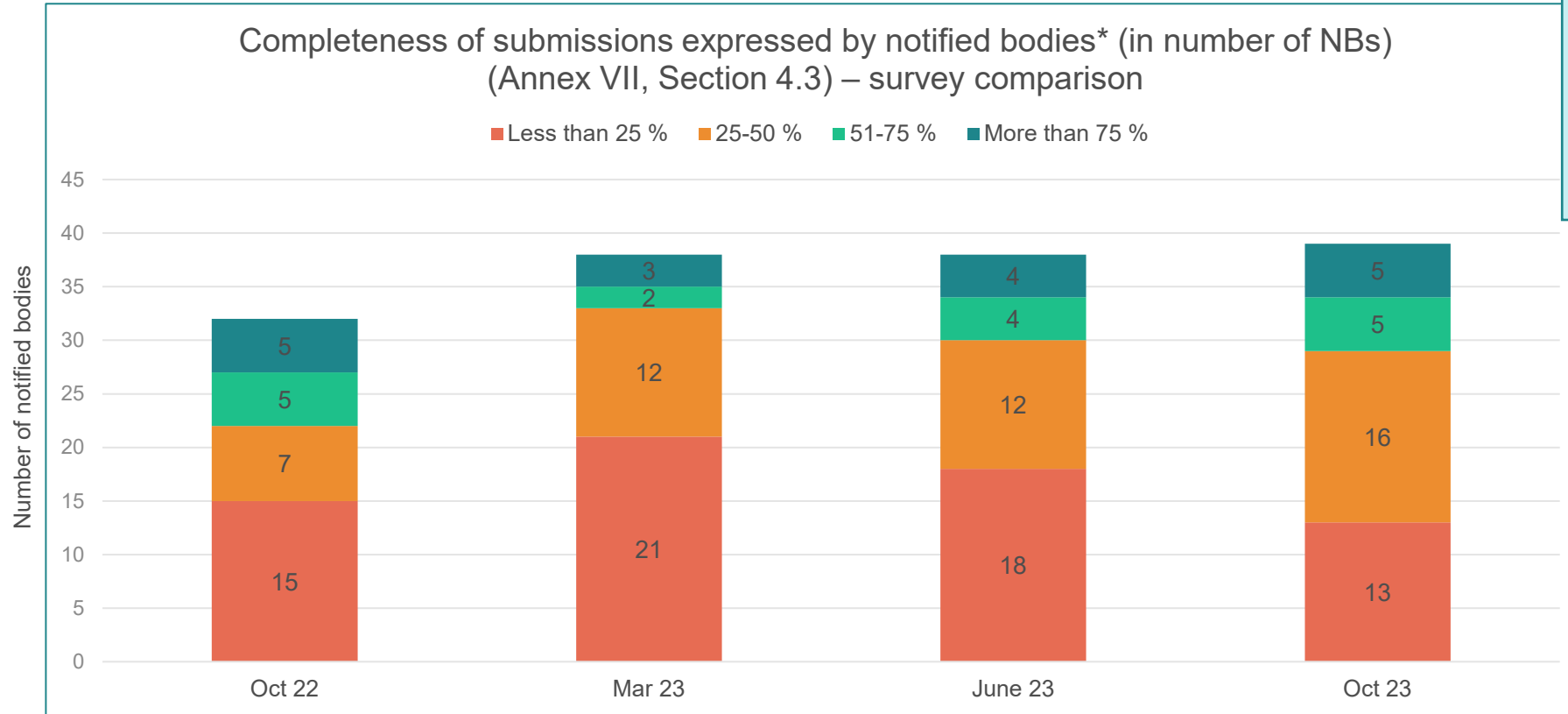
Application refusals**:

October 2022: 232
 March 2023: 269
 June 2023: 328
 October 2023: 367

Notes:

- Comparison of reasons for refusal in October 2022, March 2023, June 2023 and October 2023
- ** Applications can have multiple reasons for refusal; the number shown is derived from the small data set.
- October 2023: data of 24 NBs; some stated „other“ reasons in October 2023: “Withdrawal by the customer”, “Unresolved non-conformities”, “Customer refused audit”, “incorrect codes”, “not a medical device”, “PMS plan not at MDR level”, “client stopped communication”, “the client rejected the offer”, customer did not respond on e-mails and phone calls”, “manufacturer was unable to prove the given indication of use was achieved without pharmacological and metabolic means by ingredients”, “customer has voluntarily requested to cancel MDR application.”, “product did not meet essential requirements despite comprehensive feedback by the NB”
- June 2023: data of 24 NBs; some stated “other” reasons in June 2023: “Withdrawal by the customer”, “Unresolved non-conformities”, “PMS plan not at MDR level”, “customer did not respond on e-mails and phone calls”, “manufacturer was unable to prove the given indication of use was achieved without pharmacological and metabolic means by ingredients”, “customer has voluntarily requested to cancel MDR application.”, “product did not meet essential requirements despite comprehensive feedback by the NB”
- March 2023: data of 19 NBs; some stated “other” reasons in March 2023: “withdrawal of the application by the manufacturer - not ready for MDR, due to economic reasons, etc.”, “customer did not respond on e-mails and phone calls”, “manufacturer was unable to prove the given indication of use was achieved without pharmacological and metabolic means by ingredients”, “customer has voluntarily requested to cancel MDR application.”, “product did not meet essential requirements despite comprehensive feedback by the NB”, “PMS plan not at MDR level”
- As a result of further data validation activities, some figures have been adjusted slightly compared to the PPT previously published and dated 5 February 2024.

Completeness of submissions



% of submissions with completeness rate > 50%

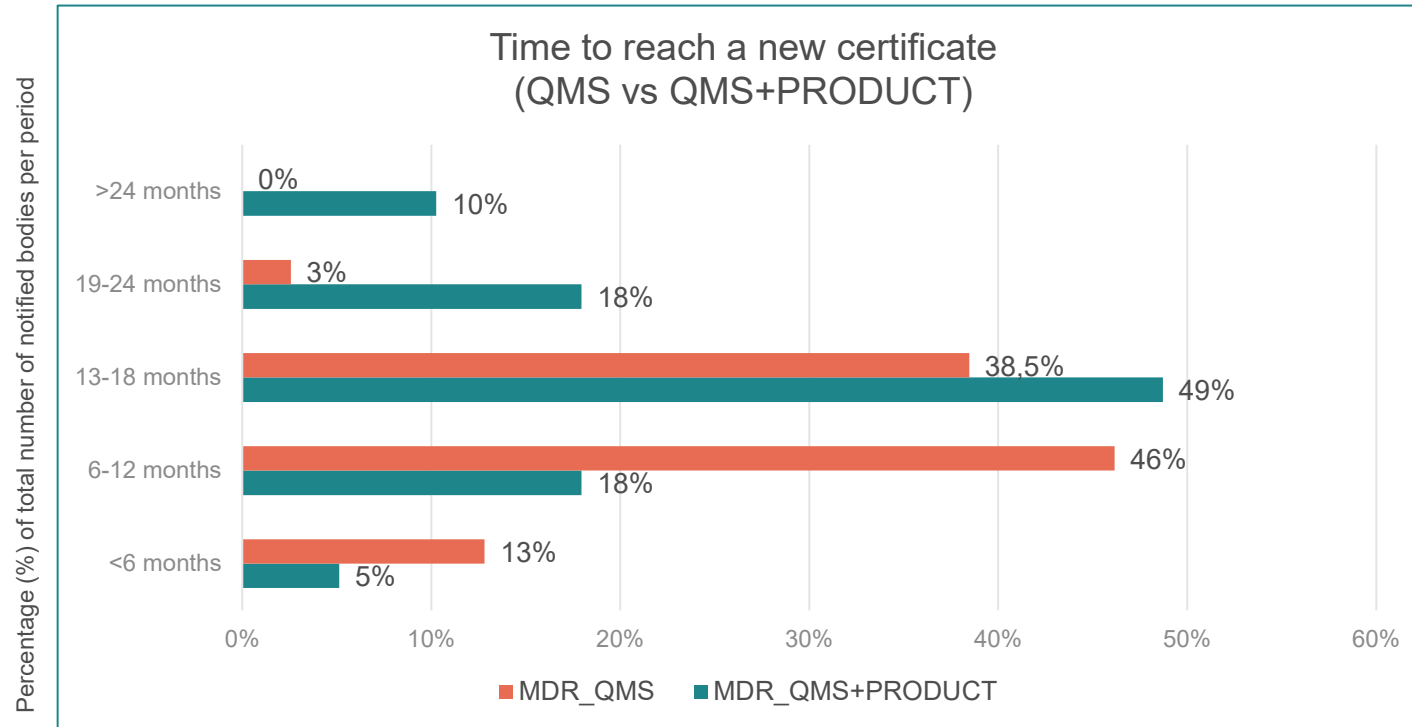
- **13% (of NBs) in March 2023**
- **26% (of NBs) in October 2023**

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)

October 2023
 MDR Applications: 17.846*
 MDR Certificates: 5.599



MDR QMS certificates:

- For ≈ 50% (46%) of NBs: **6-12 months** to issue a new QMS certificate
- For 41% of NBs: **≥ 13 months** (max: 24 months)

MDR QMS+PRODUCT certificates: longer time

- For ≈ 50% (49%) of NBs: **13-18 months** to issue a new product certificate
- For 77% of NBs: **≥ 13 months**

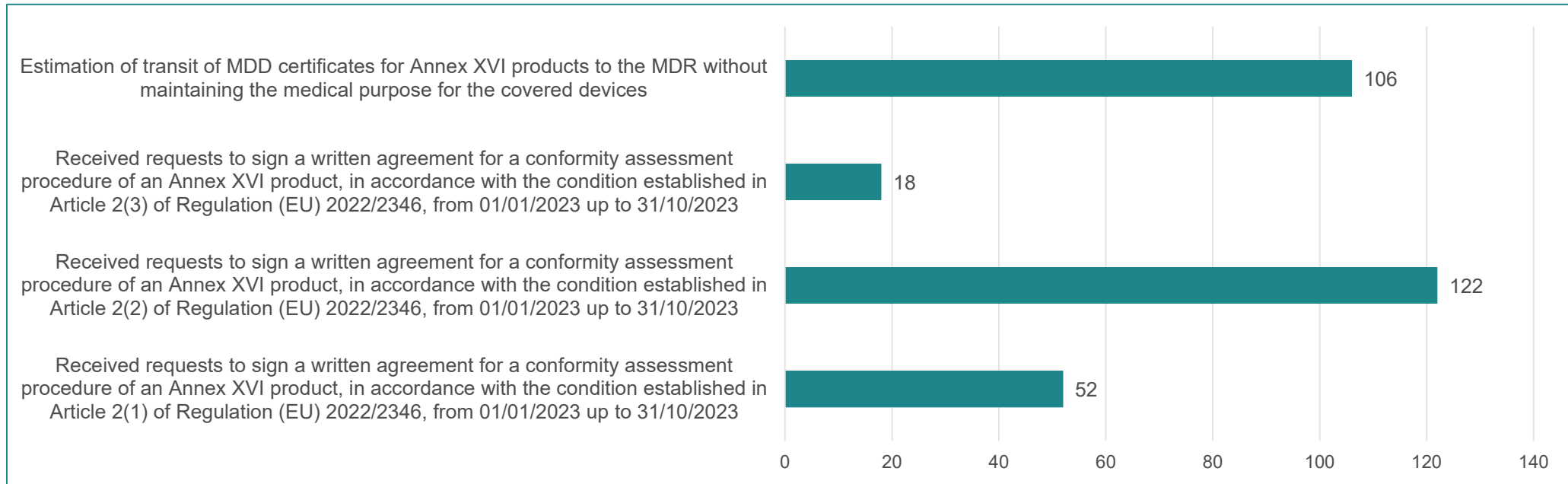
Notes:

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

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

Questions on Annex XVI products

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



Notes:

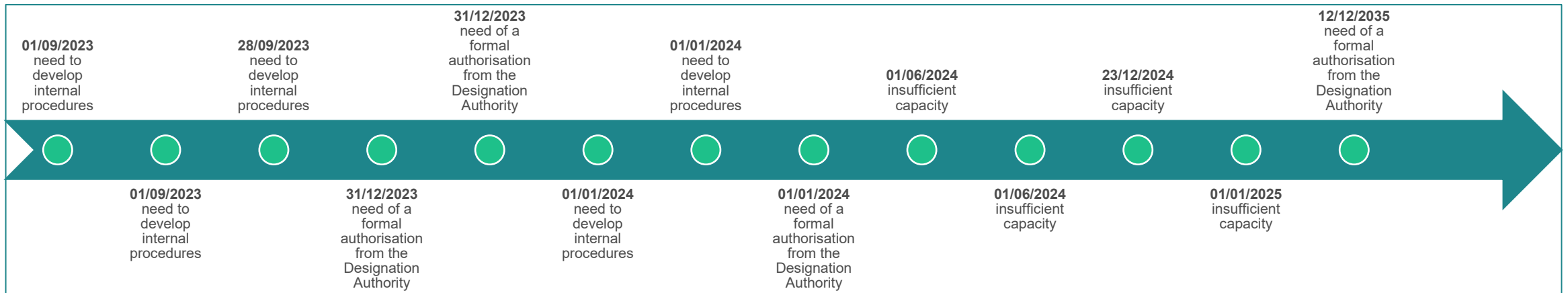
- 21 out of 39 NBs entered "0" for all questions relating to Annex XVI products
- As a result of further data validation activities, some figures have been adjusted slightly compared to the PPT previously published and dated 5 February 2024.

Questions on Annex XVI products

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

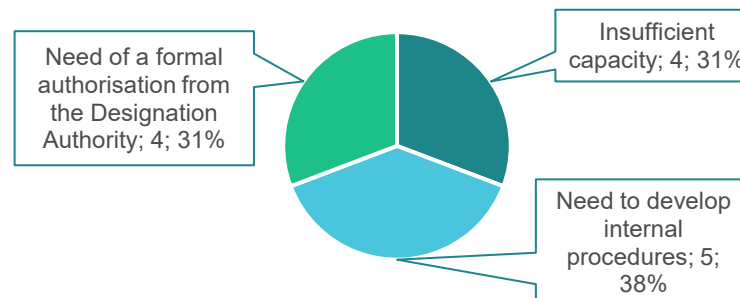
From which **date** can the NB work on Annex XVI products?

- **26 out of 39** notified bodies can already work on Annex XVI products from 22 June 2023 on
- **13 out of 39** notified bodies have stated **another date** and the reason for delay

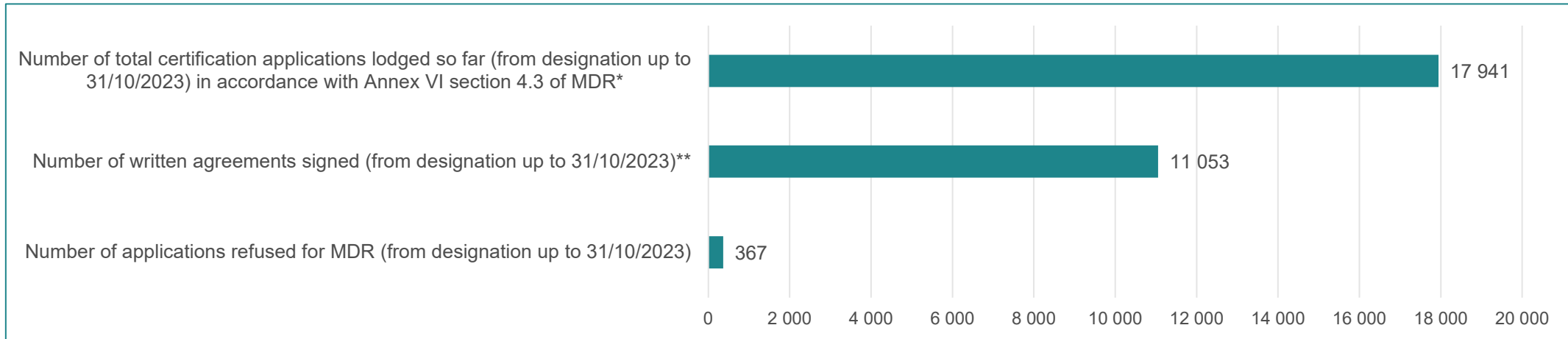


Data of 39 NBs designated under MDR

Reasons for delay



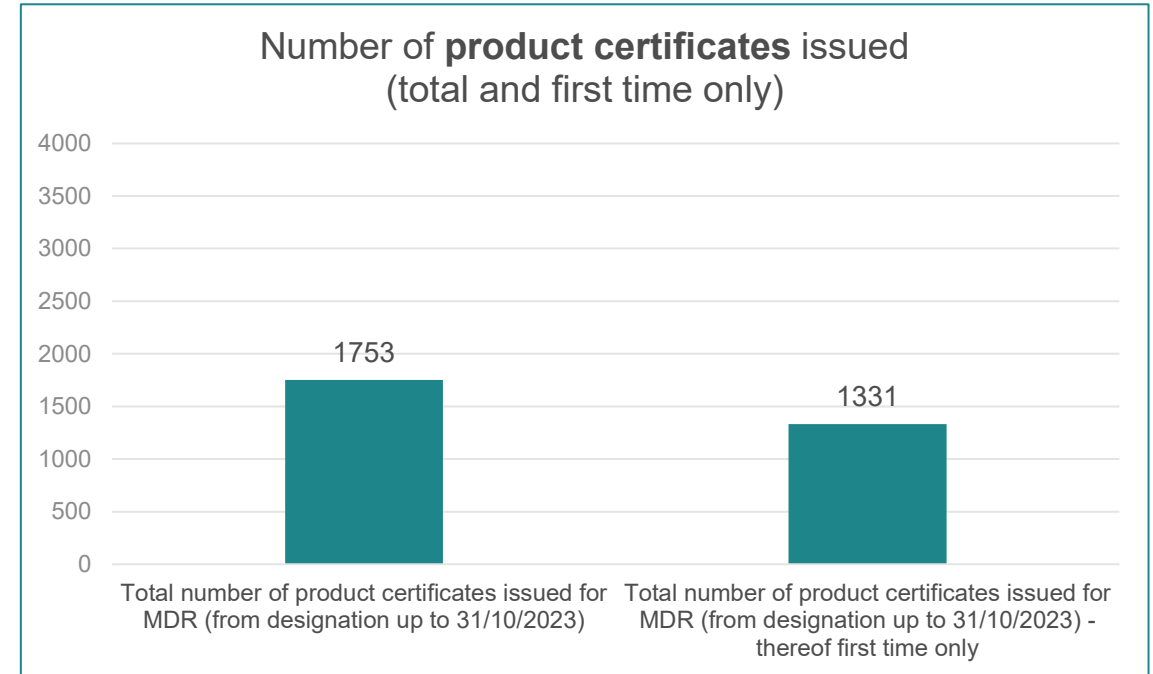
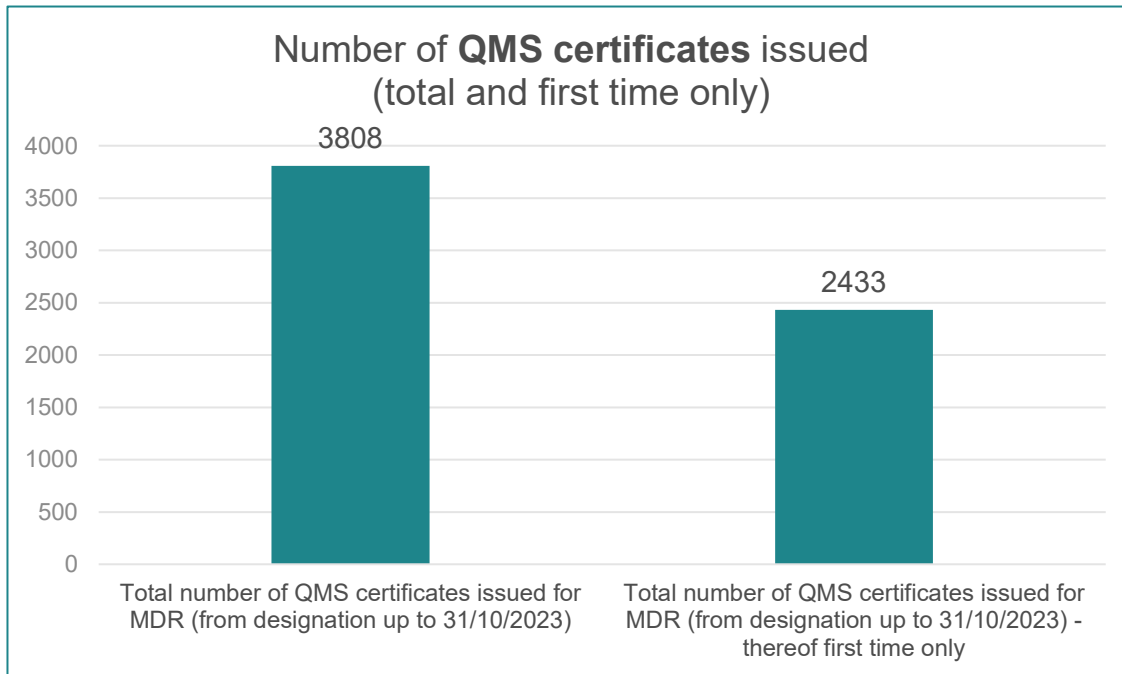
MDR applications filed and refused, written agreements signed



Notes:

- **Designated NBs for MD: 39**
- *** 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 31/10/2023), 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.
- As a result of further data validation activities, some figures have been adjusted slightly compared to the PPT previously published and dated 5 February 2024.

MDR number of QMS / product certificates issued

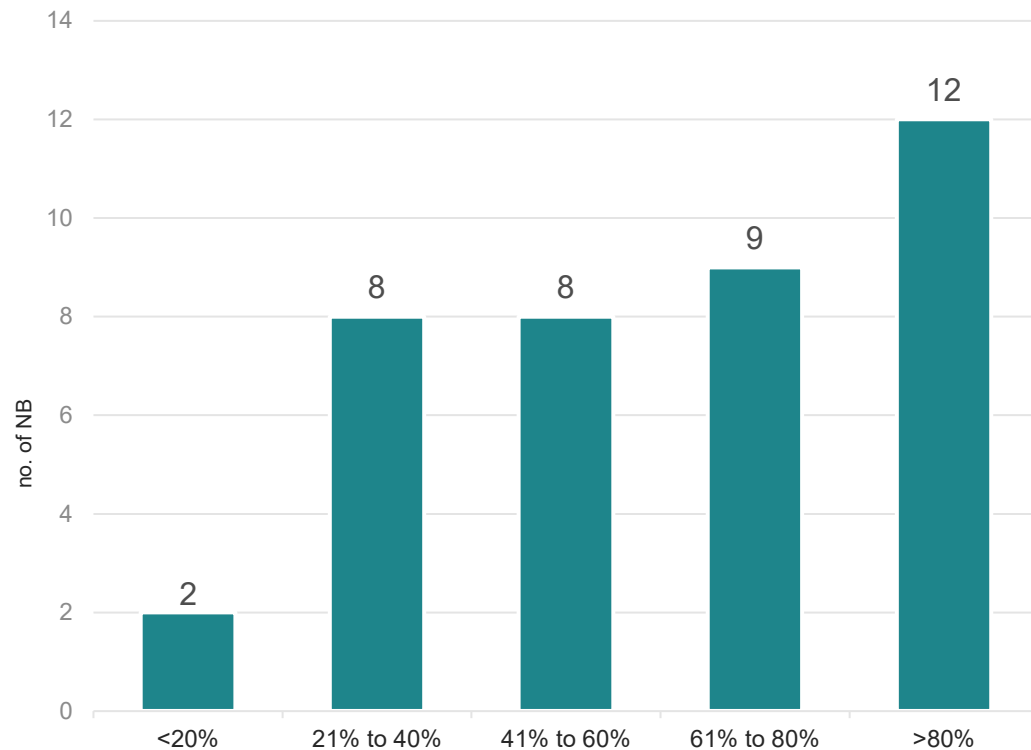


Note QMS Certificates: This relates to Annex IX Chapter I or Annex XI Part A according to MDR.

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

Change in methodology of counting by few NBs compared to previous surveys

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



- **8 out of 39 NBs (20%)** reported that **21-40%** of the MDR applications cover the scope of (AI)MDD certificates
- **21 out of 39 NBs (more than 50%)** indicated that MDR applications **cover more than 60%** of the scope of (AI)MDD certificates.

Calculation:

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

Meaning of average:

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

Survey comparison – March to October 2023

6 indicators

- from designation up to 31/10/2023
- from designation up to 30/08/2023
- from designation up to 30/06/2023
- from designation up to 31/05/2023
- from designation up to 30/04/2023
- from designation up to 31/03/2023

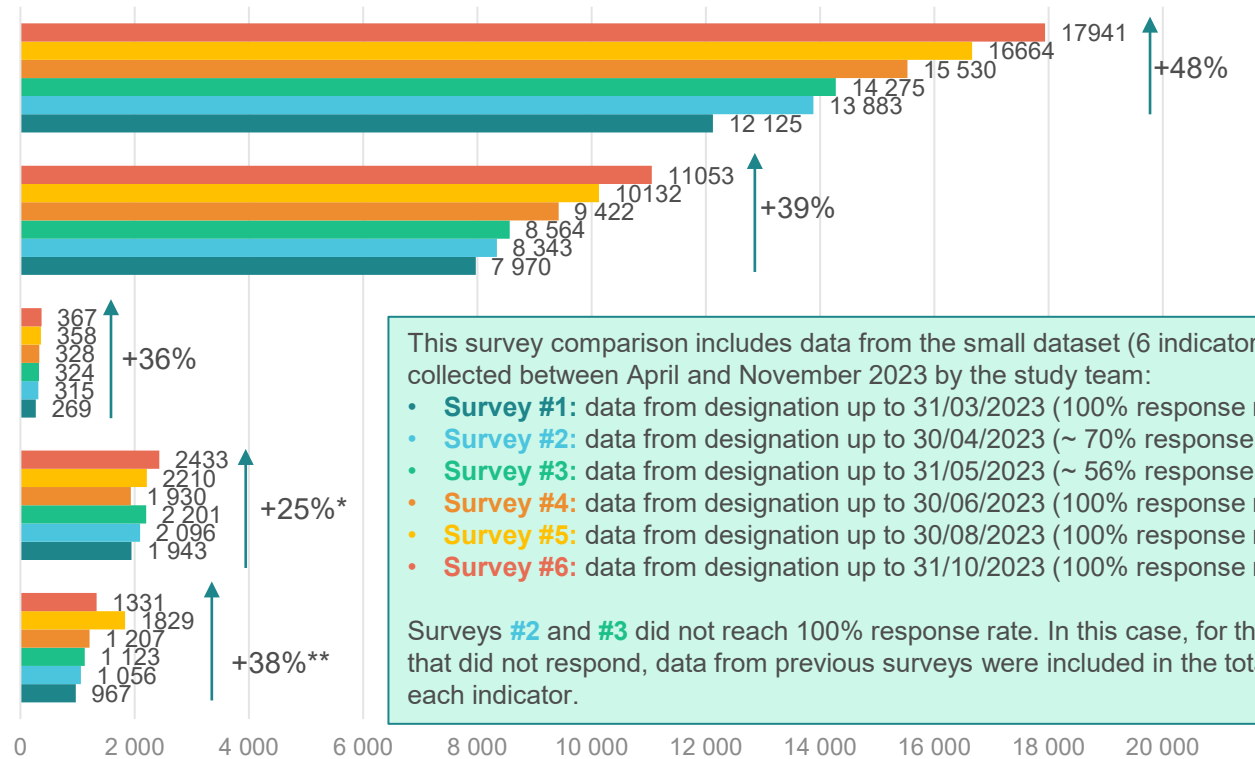
Number of total certification applications lodged incl. no. of applications with issued certificates in accordance with Annex VI section 4.3 of MDR*

Number of written agreements signed

Number of applications refused for MDR

Number of QMS certificates (first time only)

Number of product certificates (first time only)



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

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

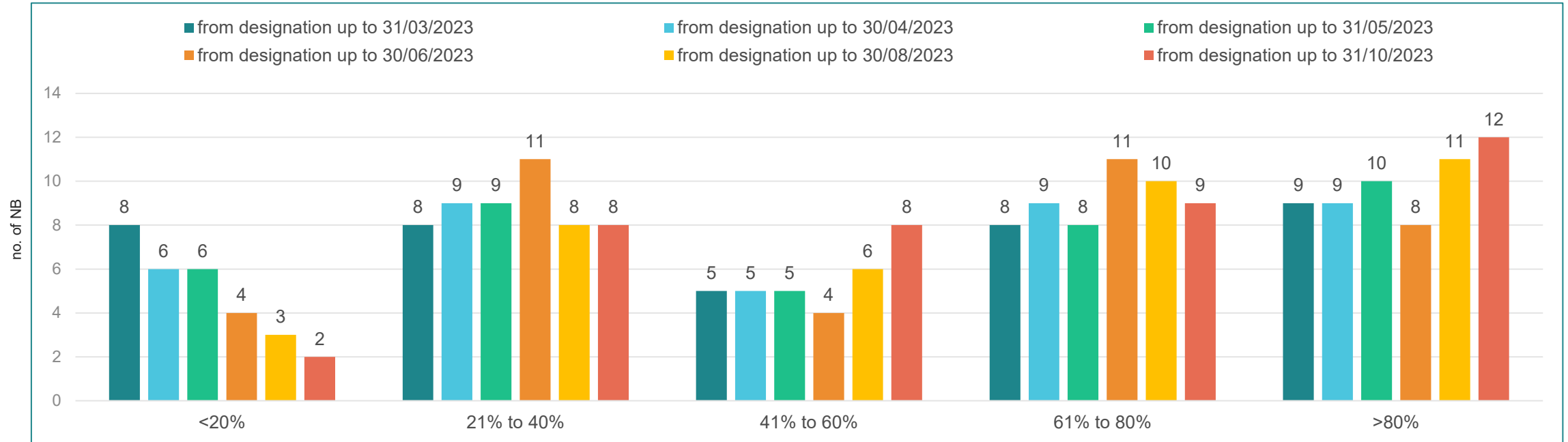
Surveys #2 and #3 did not reach 100% response rate. In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.

Notes:

- Designated NBs for MD for all survey rounds: 39; different response rates for each survey round (see info box above)
- * Increase of 13% from survey #1 to #3; In survey #4, the questionnaire was redesigned, and the question on "total number of certificates issued" (in addition to "first time only") was included in the small dataset. The redesign of the questionnaire helped the NBs to better assess the number of first-time only certificates. Therefore, the numbers of the previous surveys might be an overestimation.
- ** Change in methodology of counting by few NBs compared to previous surveys.
- As a result of further data validation activities, some figures have been adjusted slightly compared to the PPT previously published and dated 5 February 2024.

Survey comparison – March to October 2023

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



Calculation:

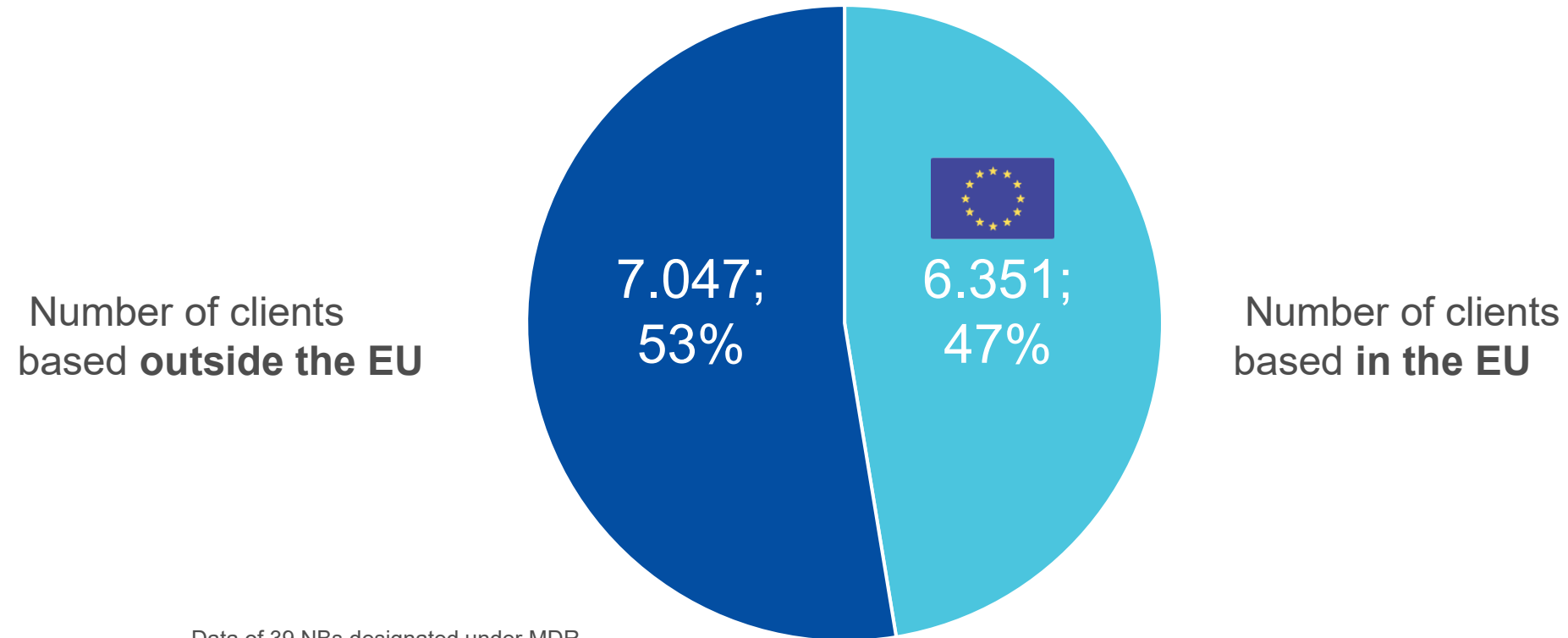
- meaning of scope coverage: MDD certificate covers 100 products, MDR application covers 50 products then coverage of the MDR = 50% of the MDD cert

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%

Number of clients for MDR/MDD/AIMDD

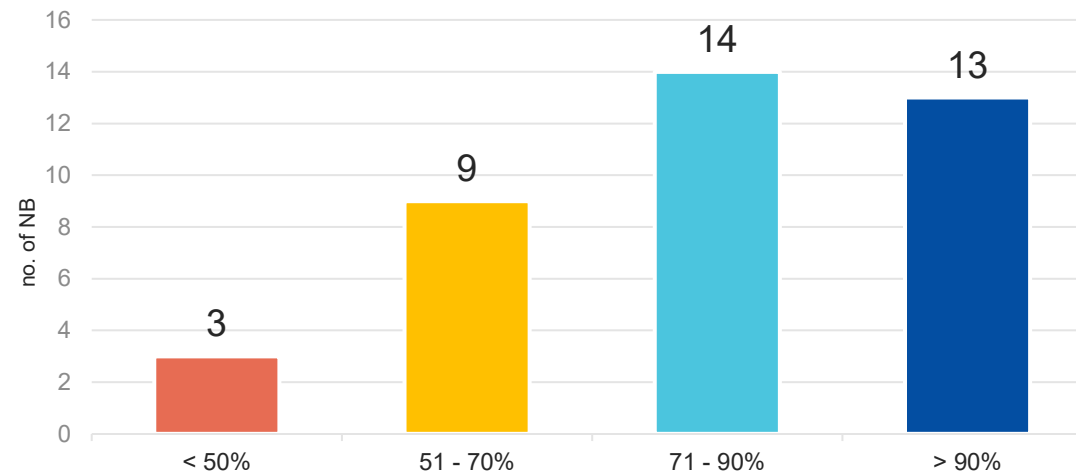
October 2023
Total number of clients: 13.398



Data of 39 NBs designated under MDR
Photo credit: [Flaticon.com](https://www.flaticon.com)

How many of the clients are SMEs*?

October 2023
Total number of clients: 13.398



Almost all NBs have SMEs as their main clients:

- Only 3 NBs indicated that less than 50% of their clients are SMEs
- 9 NBs (23%) indicated that between 51 and 70% of their clients are SMEs
- 14 NBs (36%) indicated that between 71 and 90% of their clients are SMEs
- 13 NBs (33%) indicated that they almost only have SMEs as clients (>90%)

Notes:

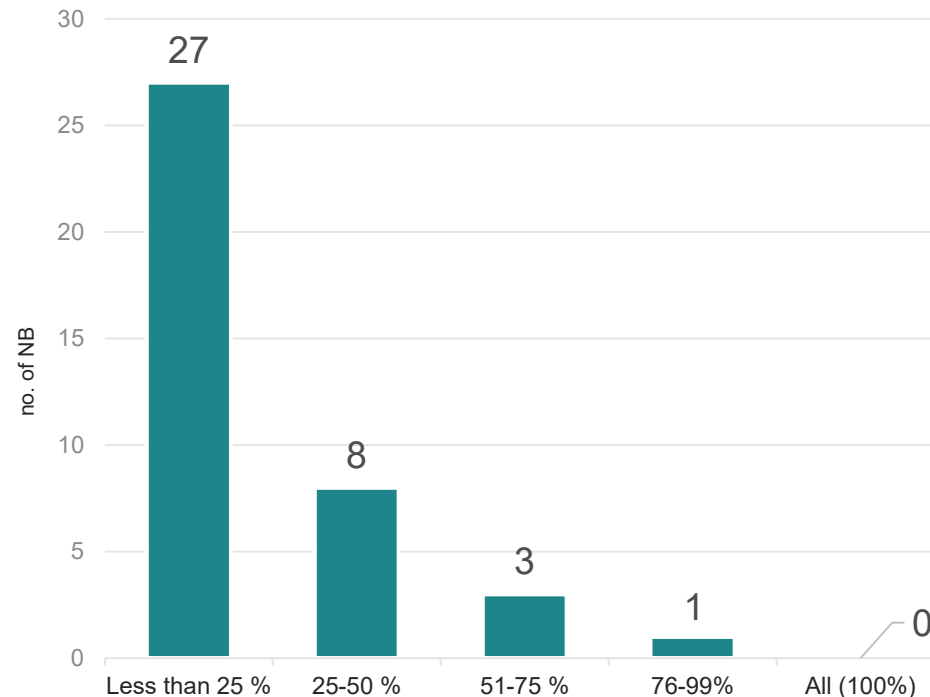
Data of 39 NBs designated under MDR

***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)

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

October 2023

Total number of clients: 13.398

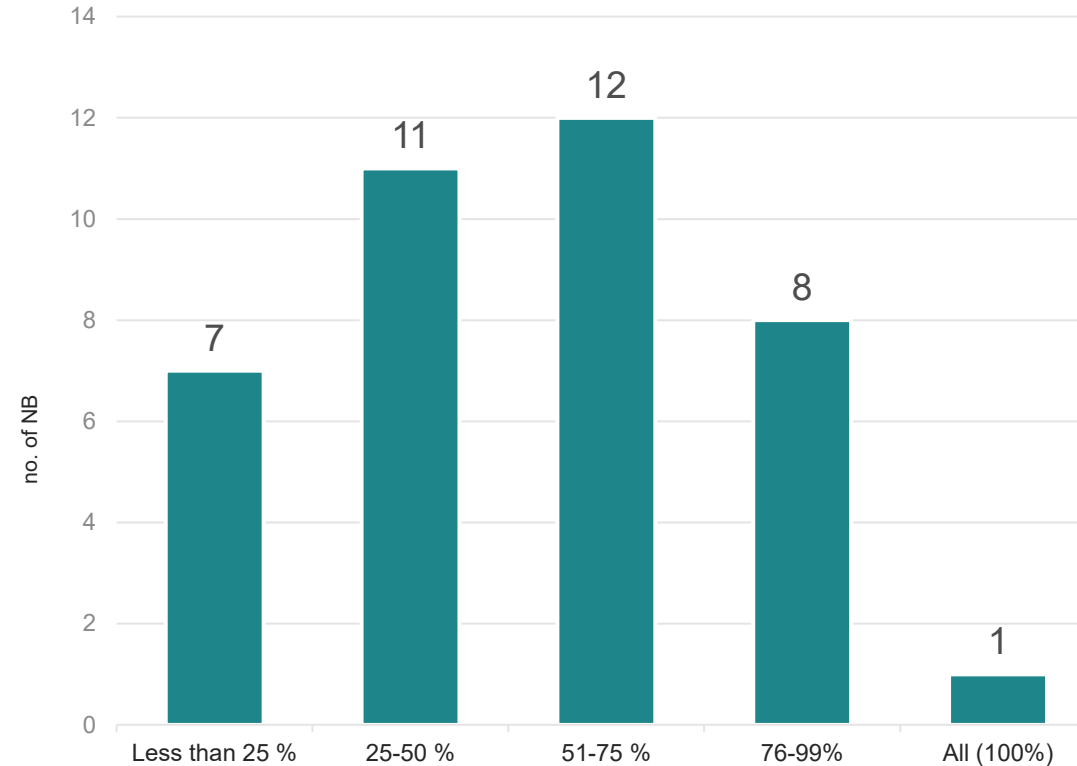


Data of 39 NBs designated under MDR

- The majority of the NBs (27; 69%) indicated that less than 25 % of their clients have completed the transfer to MDR of all devices intended to be certificated
- For no NB all clients have completed the transfer
- Only 4 NBs (11%) indicated that > 50% of their clients have completed the transfer

For how many clients is the transfer to MDR currently ongoing?

October 2023
Total number of clients: 13.398



- The majority of the NBs (21; 53%) indicated that for more than 50% of their clients the transfer is currently ongoing
- Only 1 NB indicated that for all clients the transfer to MDR is currently ongoing
- 7 NBs (18%) indicated that for less than 25% of their clients the transfer is currently ongoing

Data of 39 NBs designated under MDR

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

October 2023

MDR Applications: 17.846*

MDR Certificates: 5.599

A more detailed analysis will be shown in the [dashboard](#)!

Top 5

| I CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE | Indicated by.... NBs |
|---|----------------------|
| • MDA 0315 Software | 25 |
| • MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters | 22 |
| • MDN 1208 Non-active non-implantable instruments | 20 |
| • MDA 0305 Active non-implantable devices for stimulation or inhibition • MDA 0316 Medical gas supply systems and parts thereof • MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis • MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing | 19 |
| • MDN 1204 Non-active non-implantable devices for wound and skin care • 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 | 18 |

Notes:

• Data of 35 NBs designated under MDR; 4 NBs indicated that they don't have the information at hand

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

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

October 2023

MDR Applications: 17.846*

MDR Certificates: 5.599

A more detailed analysis will be shown in the [dashboard!](#)

Top 5

| II HORIZONTAL CODES | Indicated by.... NBs |
|---|----------------------|
| • MDT 2011 Devices which require packaging, including labelling | 28 |
| • MDS 1010 Devices with a measuring function | 26 |
| • MDT 2008 Devices manufactured in clean rooms and associated controlled environments | 25 |
| • 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 | 24 |
| • MDT 2002 Devices manufactured using plastic processing | |
| • MDT 2010 Devices manufactured using electronic components including communication devices | |
| • MDT 2012 Devices which require installation, refurbishment | |
| • MDS 1005 Devices in sterile condition | 23 |
| • MDT 2001 Devices manufactured using metal processing | |

Notes:

• Data of 35 NBs designated under MDR; 4 NBs indicated that they don't have the information at hand

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

3. Survey results for in vitro diagnostic medical devices

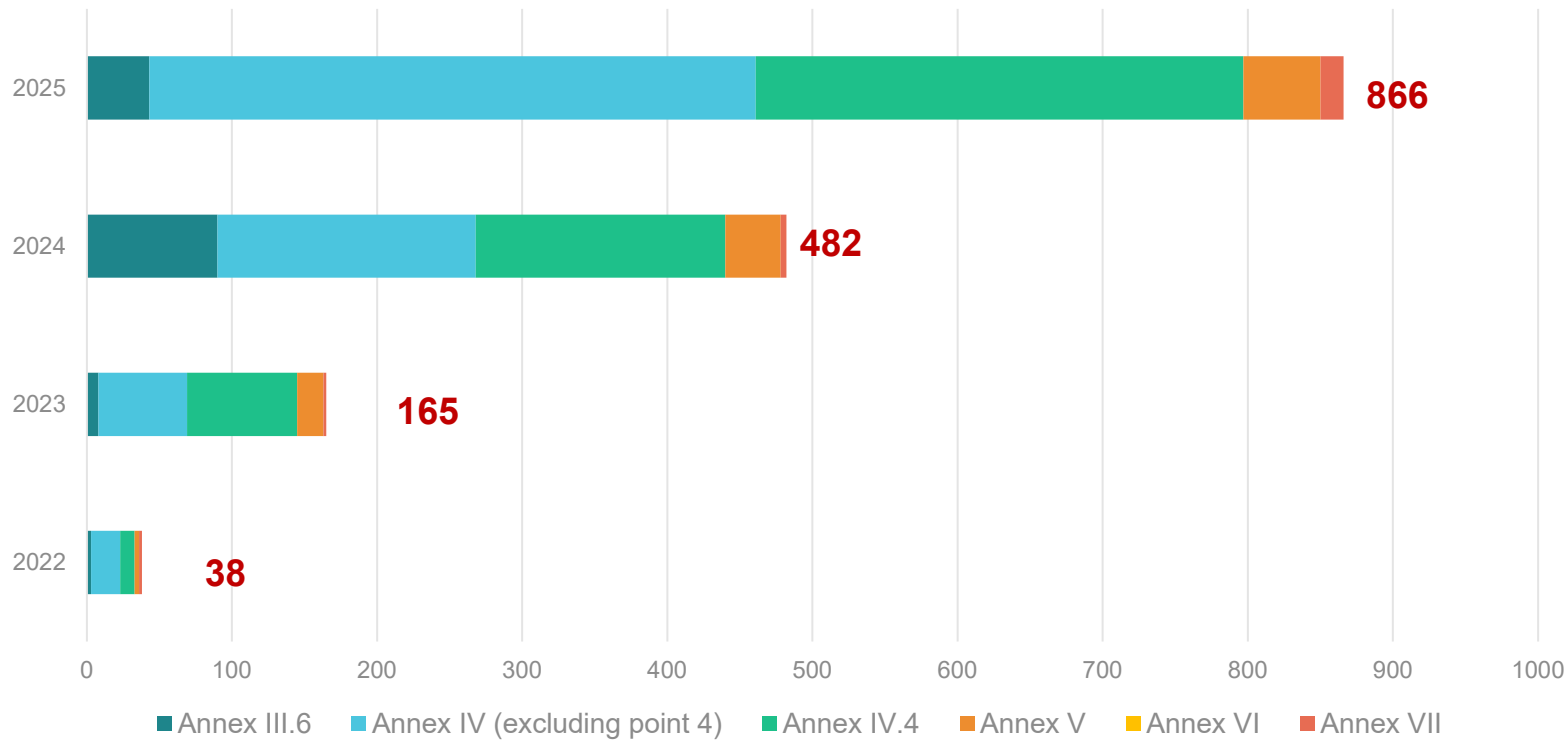
Note:

- Thousands separators are represented as dots or blank space (not comma) in the graphs.
- Datasets:
 - Ⓢ The **small dataset** is a small set of questions (6 indicators) asked to notified bodies **every two months**.
Note: From April to July 2023, it was asked monthly.
 - Ⓜ The **medium dataset** is a set of questions asked to notified bodies **every four months** concerning the activities they have been performing since their designation.
 - Ⓛ The **large dataset** contains additional data asked to notified bodies **once a year**.

IVDD Certificates by date of expiry

(data status: October 2022)

IVDD valid certificates breakdown by date of expiry

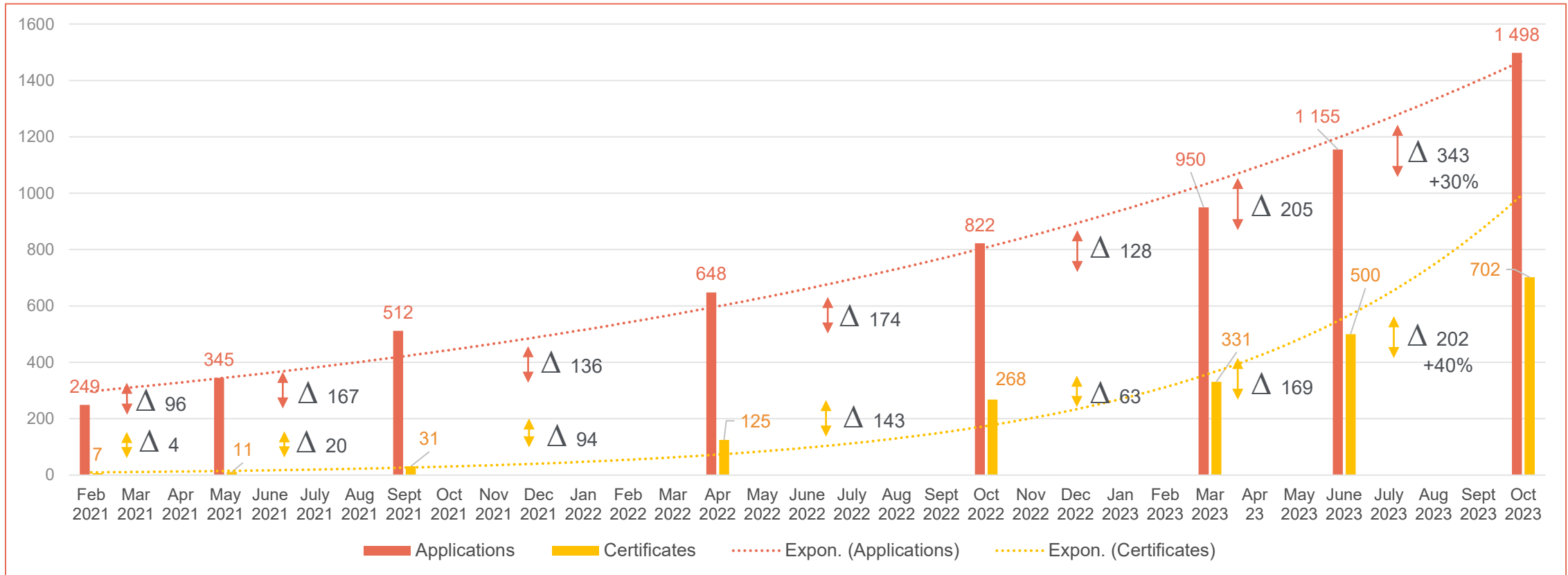


IVDD Data
Data from survey of October 2022
(20 out of 21 replies received from NB designated under IVDD)

Tot. valid IVDD certificates 1.551

IVDR applications lodged and certificates issued

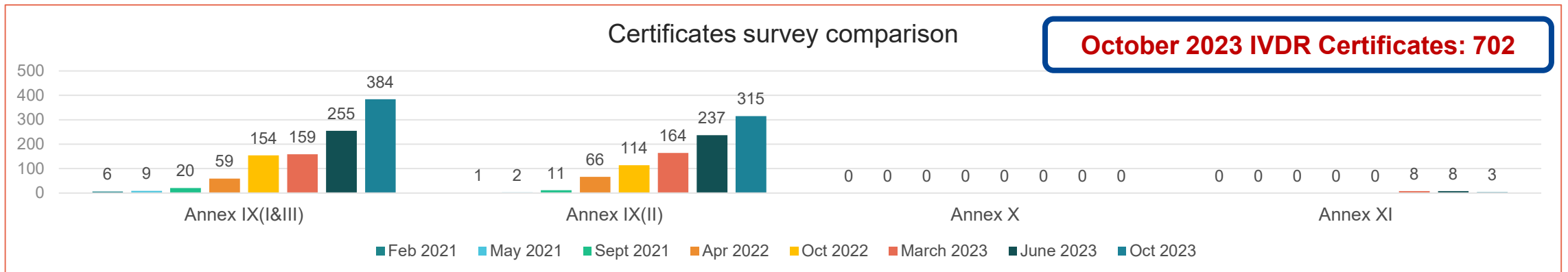
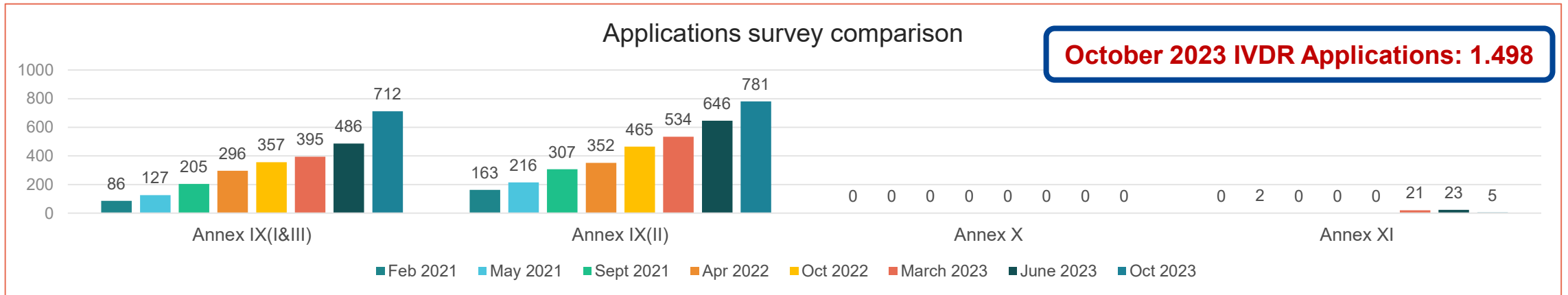
October 2023
IVDR Applications: 1.498
IVDR Certificates: 702



Notes:

- 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 31/10/2023), 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 31/10/2023) under the IVDR.

IVDR applications and certificates by annex – surveys comparison



Notes:

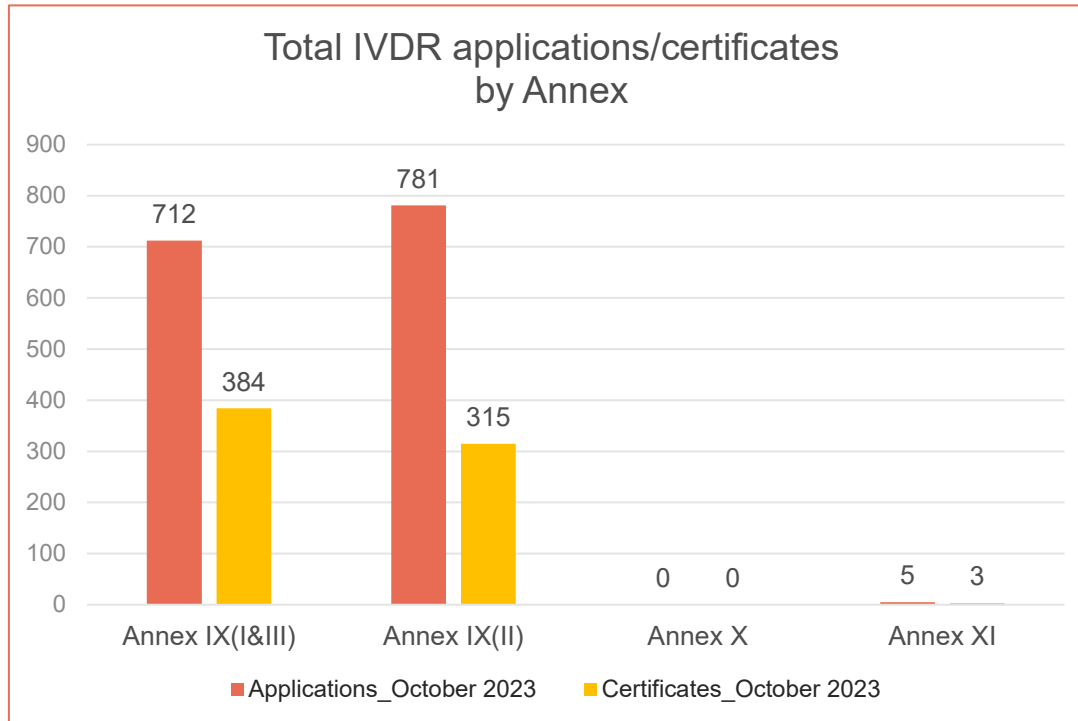
- **Applications lodged by annex:** This number includes **all applications lodged (syn. filed) by annex** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the [Single Market Compliance Space](#) to the date of the survey up to 31/10/2023), 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 31/10/2023) under the IVDR **by annex**.

IVDR applications and certificates by annex

IVD



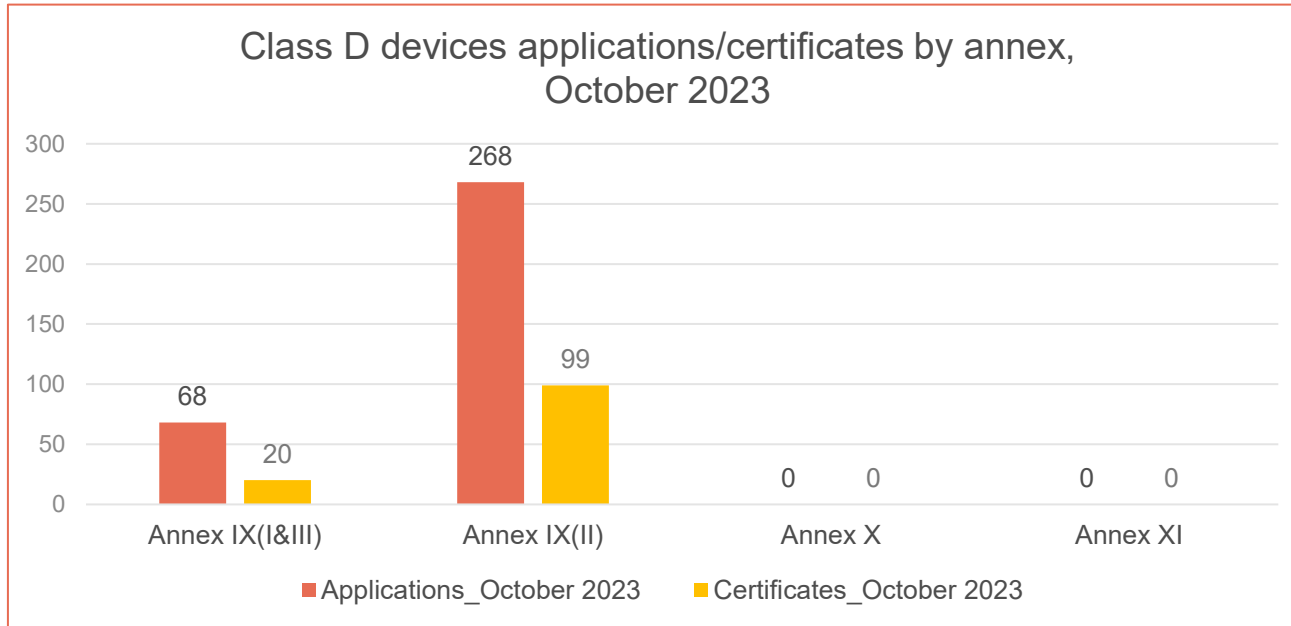
October 2023
IVDR Applications: 1.498
IVDR Certificates: 702



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 31/10/2023), 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 31/10/2023) under the IVDR by annex.
- **Class D devices are included** in the total number of applications/certificates.

Class D devices applications and certificates



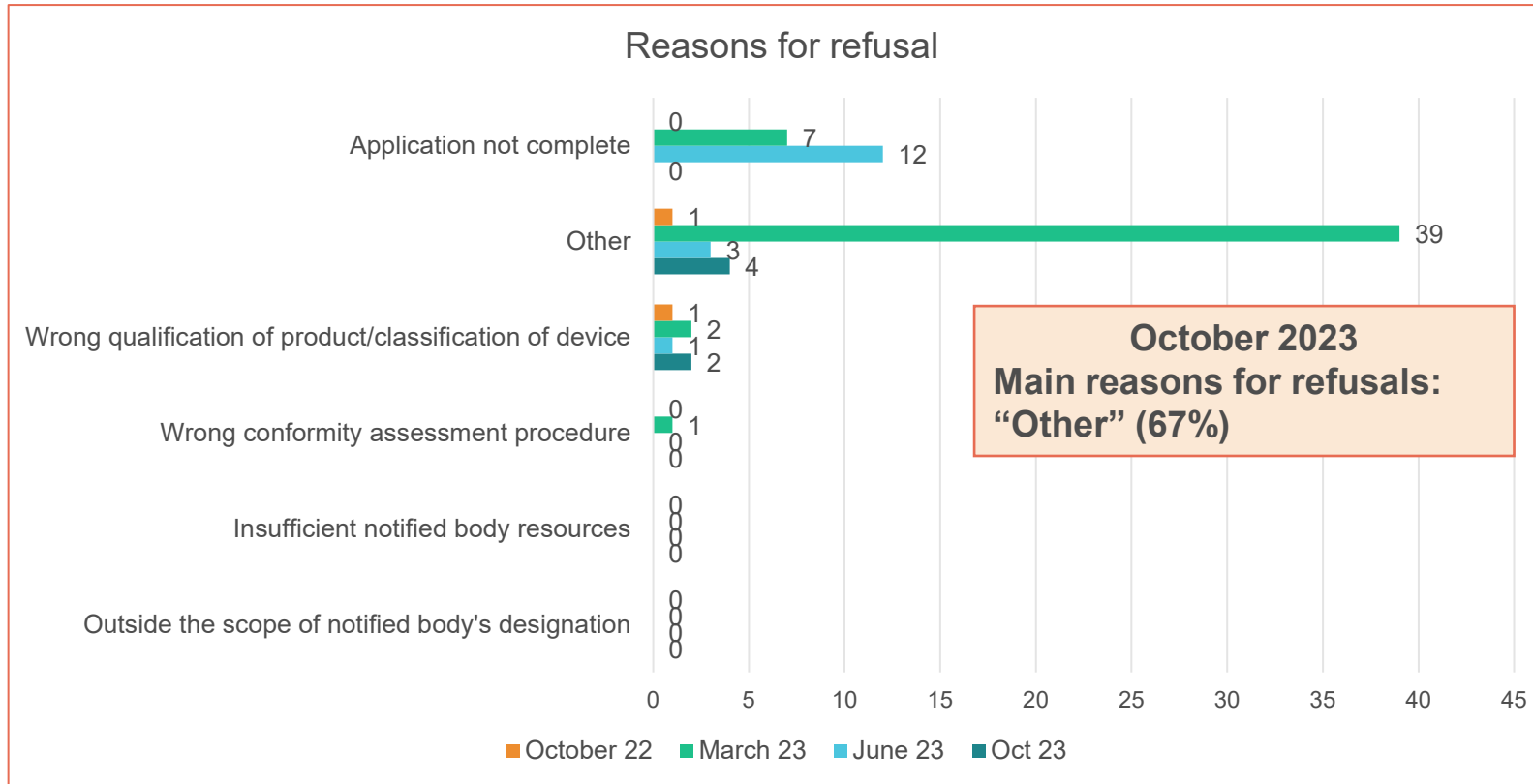
October 2023
IVDR Applications: 1.498
IVDR Certificates: 702

October 2023:
Class D devices Applications: 336
Class D devices Certificates: 119

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 31/10/2023), 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 31/10/2023) 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.

IVDR applications - reason for refusal



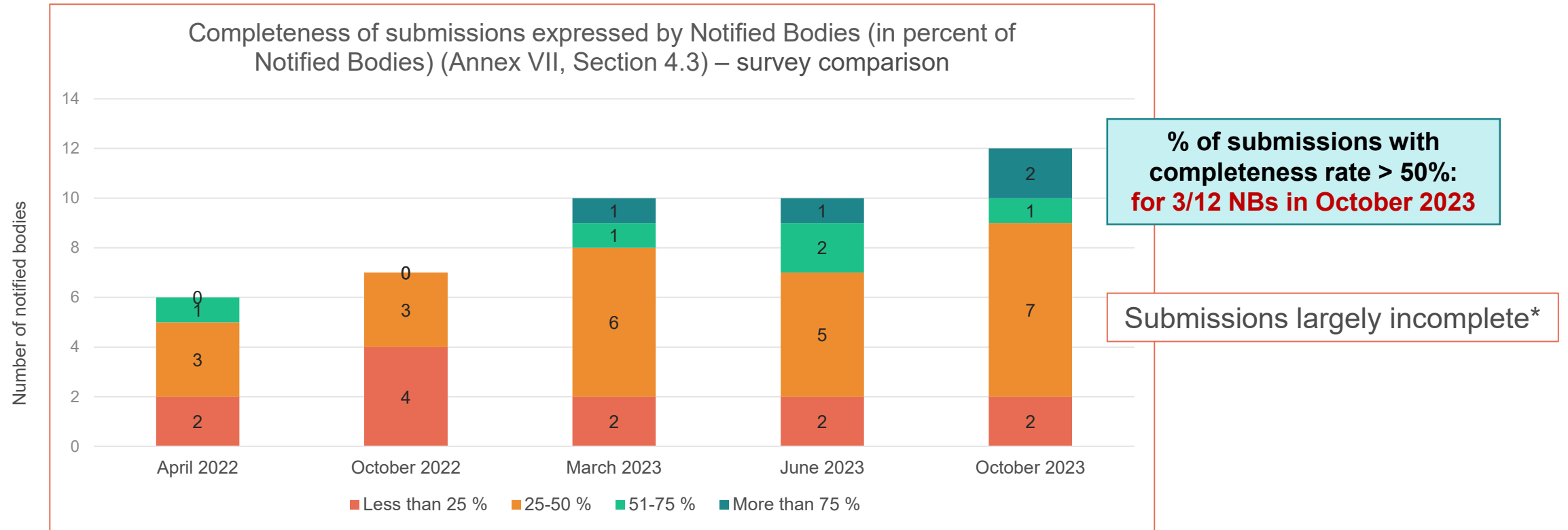
October 2023
IVDR Applications: 1.498
IVDR Certificates: 702

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

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 and October 2023.
- 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"

Completeness of submissions



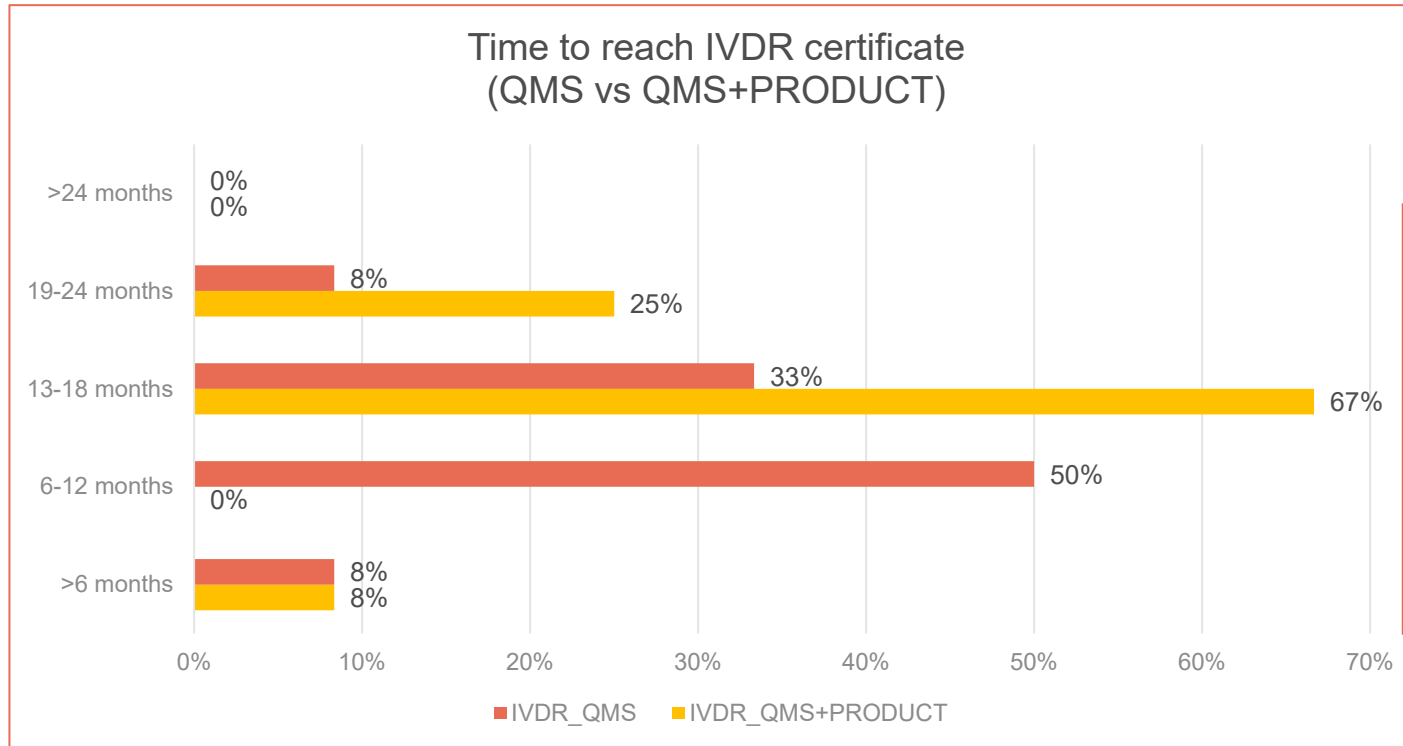
* Estimated percentage of submissions which were deemed satisfactory in terms of documentation provided (before undertaking the review of its content) without requesting for any additional information

Time to reach a certificate

October 2023

IVDR Applications: 1.498

IVDR Certificates: 702



IVDR QMS certificates

- For \approx 50% of NBs: 6-12 months to issue a new QMS certificate
- 33% of NBs: 13-18 months

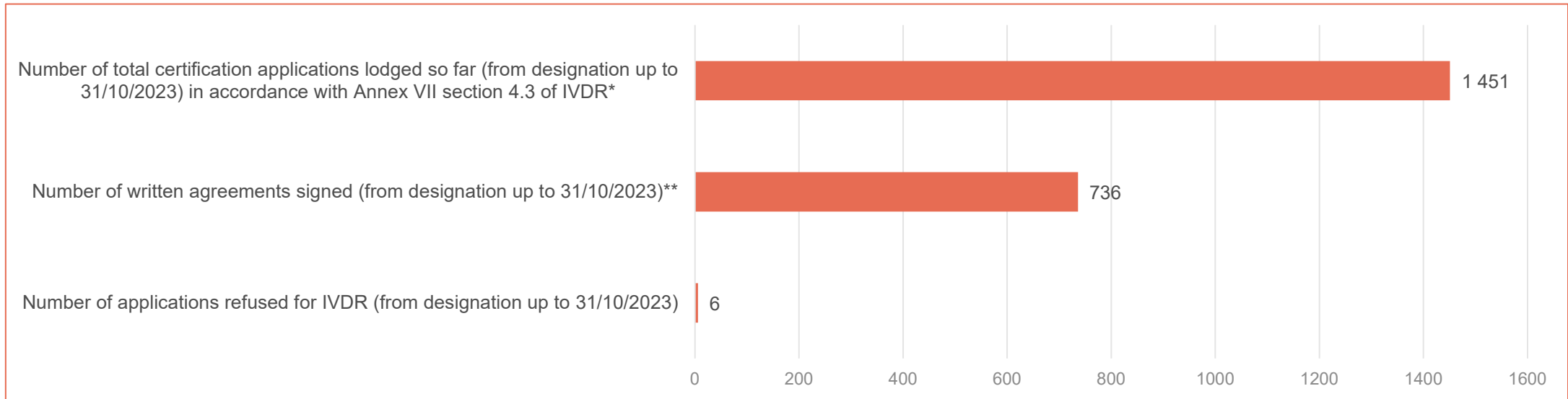
IVDR QMS+PRODUCT certificates: longer time

- 67% of the NBs: 13-18 months
- 25% of NBs: 9-24 months

Notes:

- This indicator shows the time to reach issuance of a new EC certificate (from written agreement signed to issuance) under IVDR.
- One NB stated that it expects the required time for IVDR certification to go down over time.
- One NB has currently no certificates issued.
- Three NBs have specifically pointed out that this is an estimate.

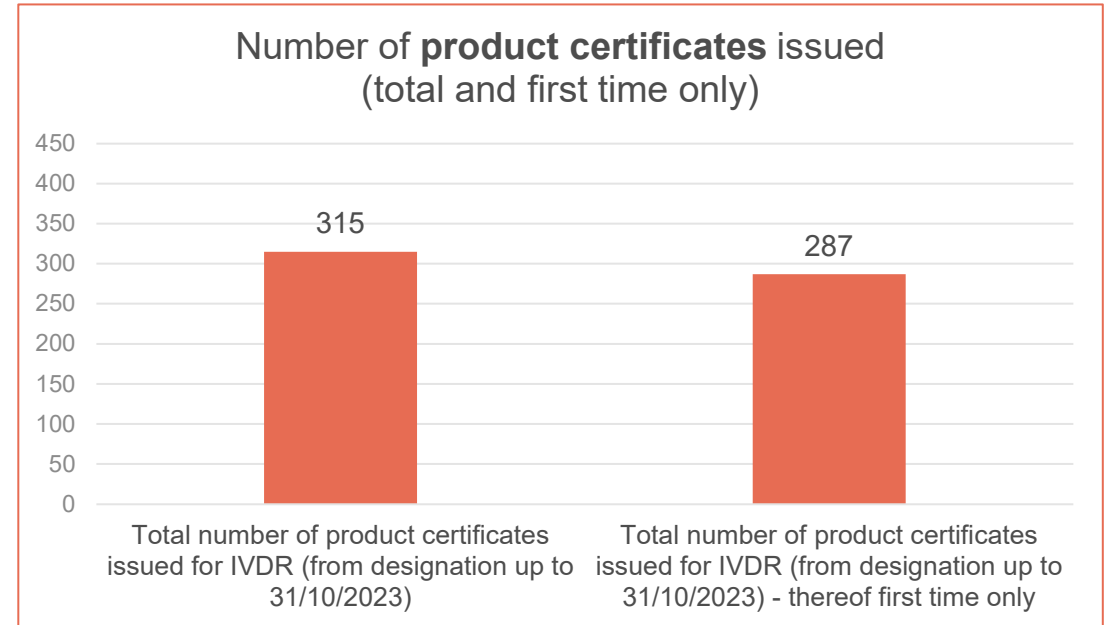
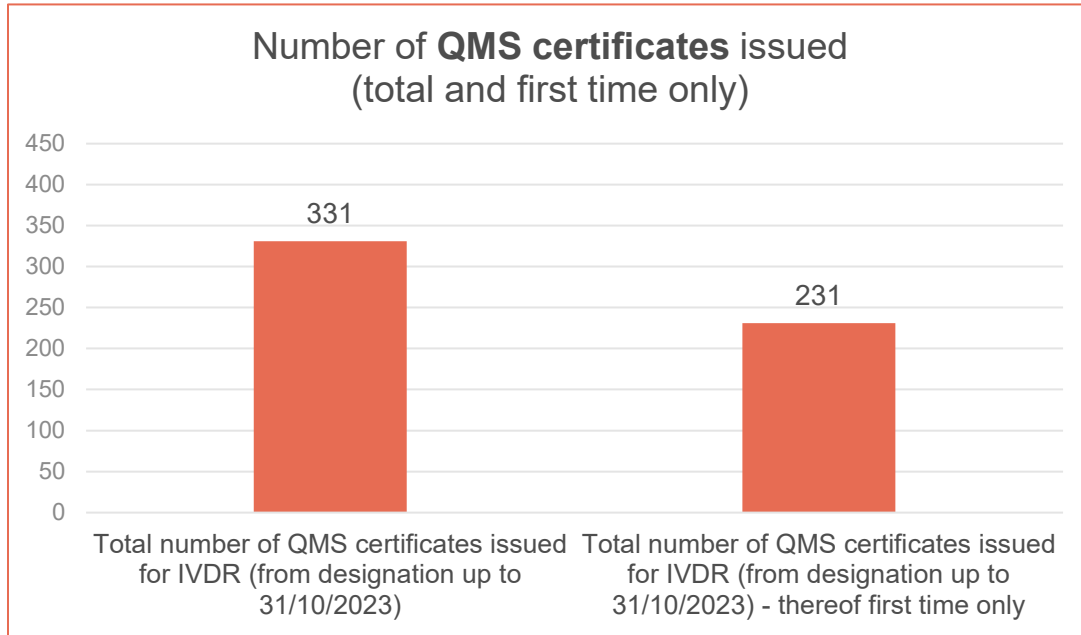
IVDR applications filed and refused, written agreements signed



Notes:

- **Designated NBs for IVD:** 12
- * **Applications lodged:** This number includes **all applications lodged (syn. filed) so far** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the [Single Market Compliance Space](#) to the date of the survey up to 31/10/2023), 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

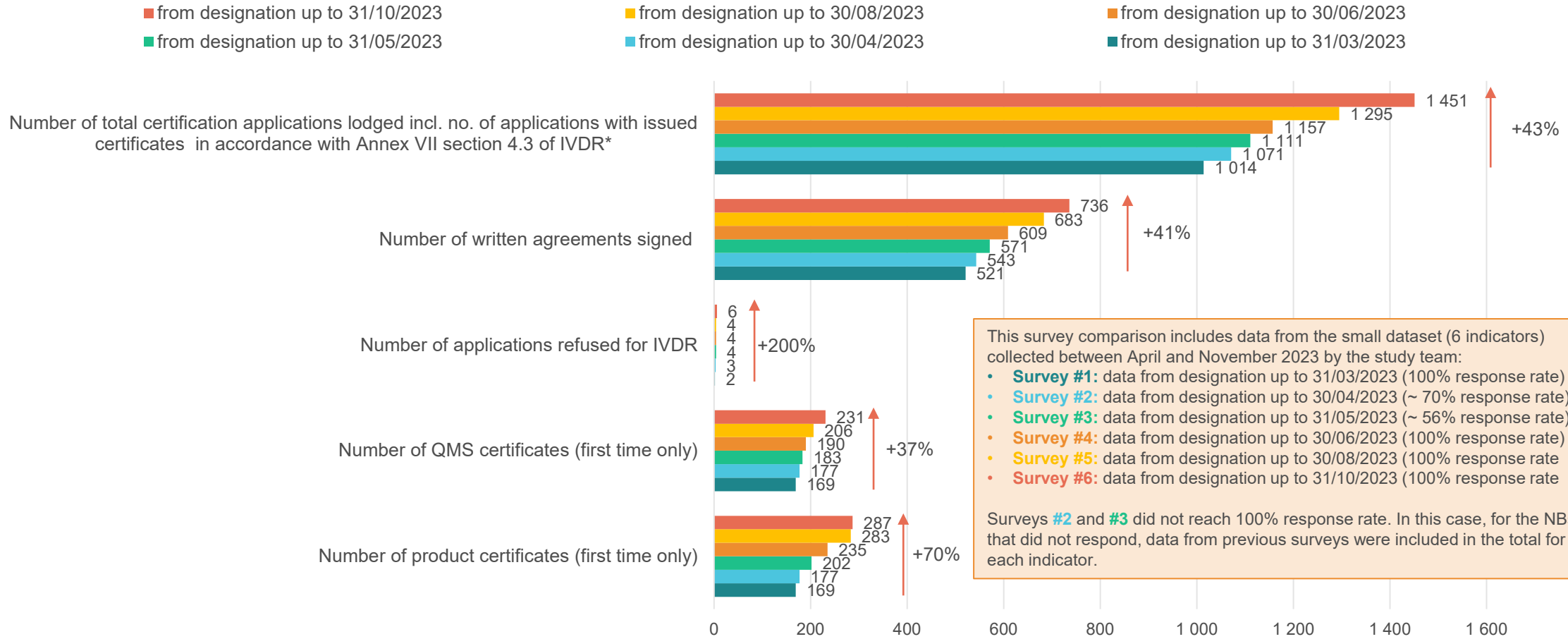


Note QMS Certificates: This relates to Annex IX Chapter I or Annex XI according to IVDR. As a result of further data validation activities, some figures have been adjusted slightly compared to the PPT previously published and dated 5 February 2024.

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

Survey comparison – March to October 2023

6 indicators



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

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

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

Notes:

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

Number of clients for IVDR/IVDD

October 2023

Total number of clients: 720

Number of clients
based **outside the EU**

412;
57%



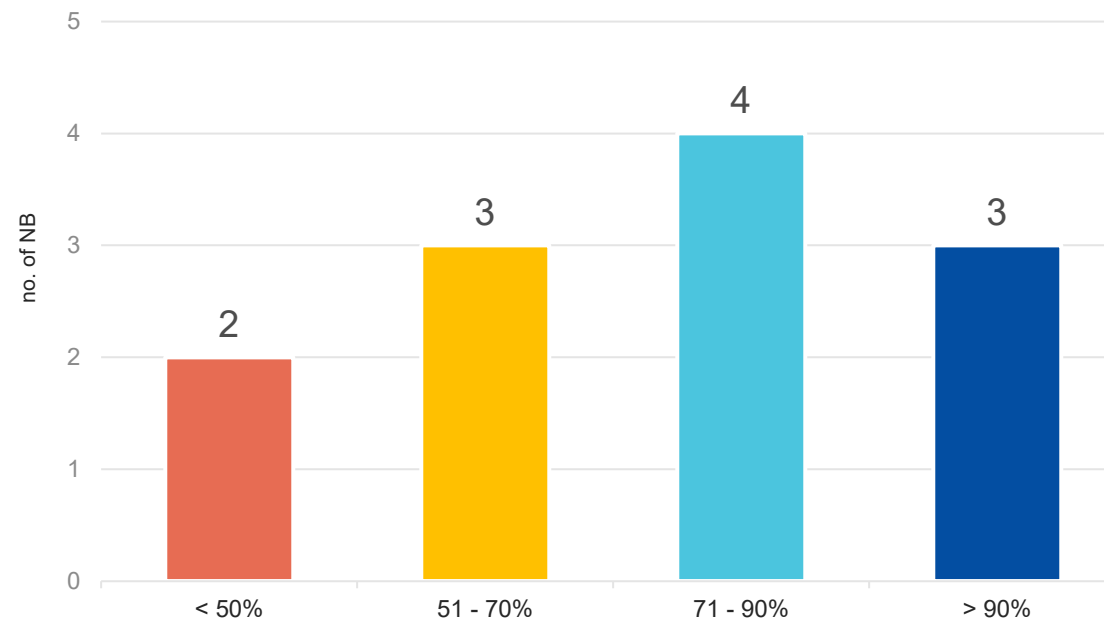
308;
43%

Number of clients
based **in the EU**

Data of 12 NBs designated under IVDR
Photo credit: [Flaticon.com](https://www.flaticon.com)

How many of the clients are SMEs*?

October 2023
Total number of clients: 720



Almost all NBs have SMEs as their main clients:

- 10 NBs indicated that > 50% of their clients are SMEs
- Only 2 NBs indicated that less than 50% of their clients are SMEs

Data of 12 NBs designated under IVDR

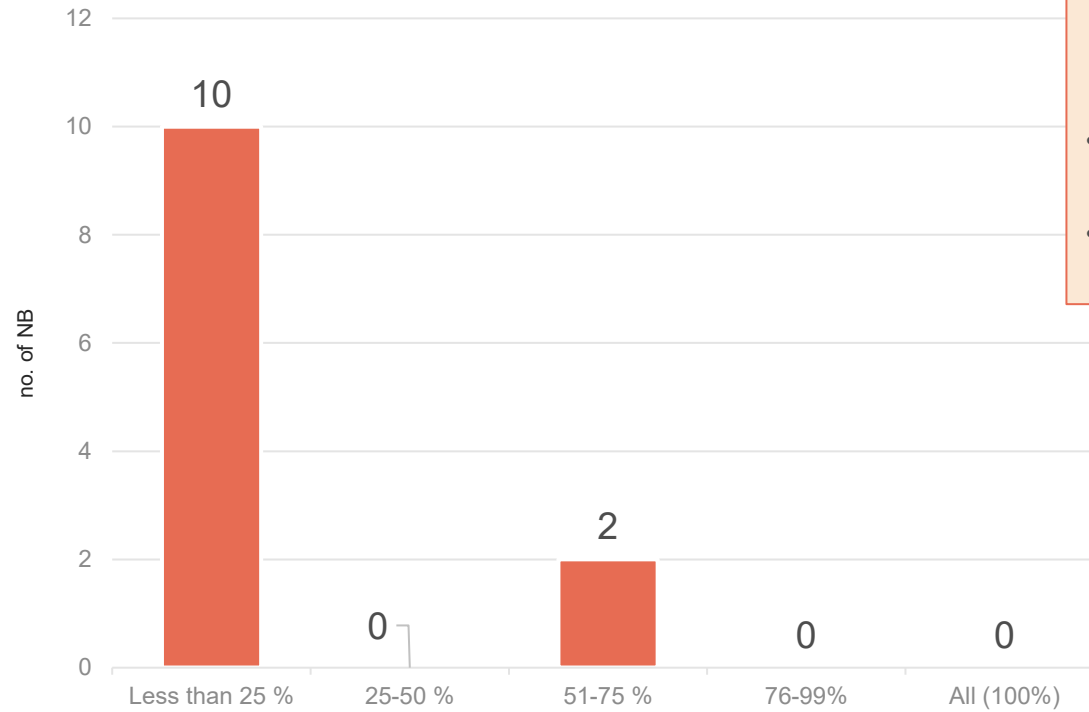
*Definition SME: The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.'

(Source: Extract of Article 2 of the annex to Recommendation 2003/361/EC)

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

October 2023

Total number of clients: 720



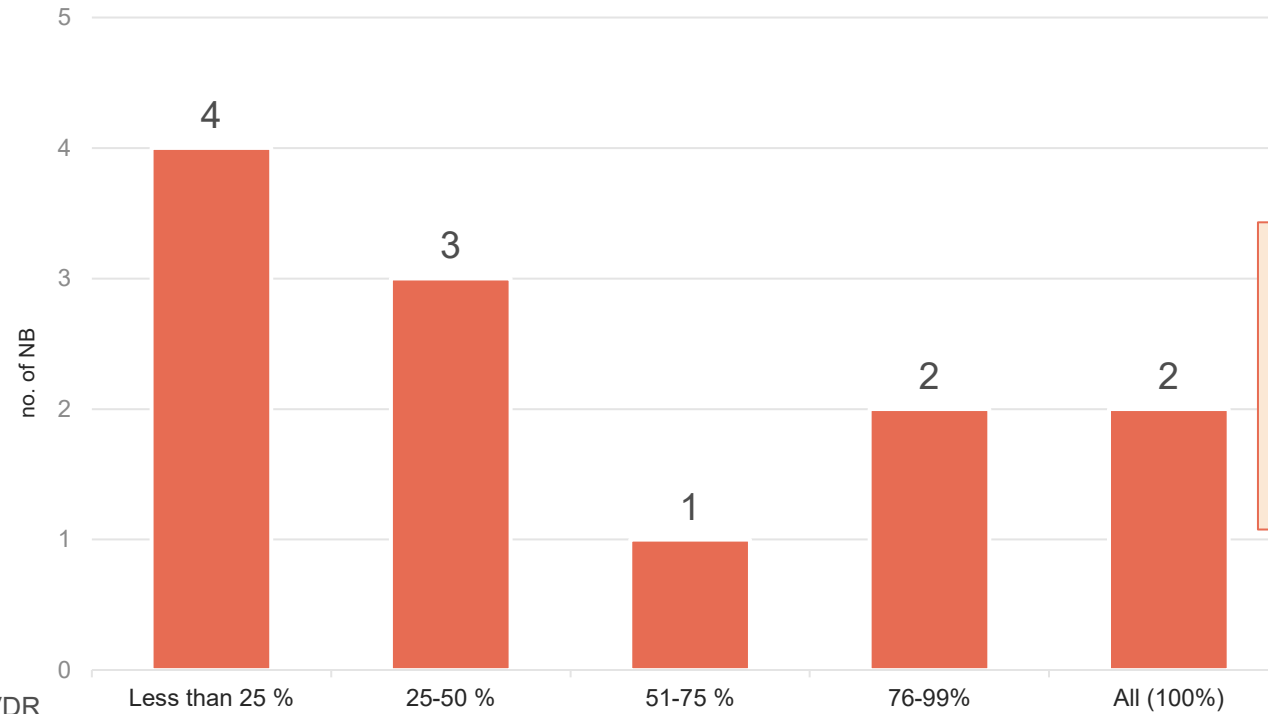
- Almost all NBs (10; 83%) indicated that less than 25 % of their clients have completed the transfer to IVDR of all devices intended to be certificated
- No NB indicated that 100% of their clients have completed the transfer
- Only 2 NBs (17%) indicated that > 50% of their clients have completed the transfer

Data of 12 NBs designated under IVDR

For how many of the clients is the transfer to IVDR currently ongoing?

October 2023

Total number of clients: 720



- The majority of the NBs (7; 58%) indicated that for less than 50% of their clients the transfer to IVDR is currently ongoing
- Only 2 NBs (17%) indicated that for all of their clients the transfer to IVDR is currently ongoing

Data of 12 NBs designated under IVDR

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

October 2023

IVDR Applications: 1.451

IVDR Certificates: 702

A more detailed analysis will be shown in the [dashboard!](#)

- 61 different categories mentioned by 3 NBs – e.g. IVD 0301 Devices intended to be used in screening, diagnosis, staging or monitoring of cancer, IVD 0608 Devices intended to be used for screening, determination or monitoring of physiological markers, etc.
- 13 different categories mentioned by 2 NBs
- 5 different categories mentioned by 1 NB

Notes:

- Data of 12 NBs designated under IVDR:
- 4 NBs indicated that they don't have the information at hand
- 5 NBs indicated that they have no certificates issued yet

4. Staff

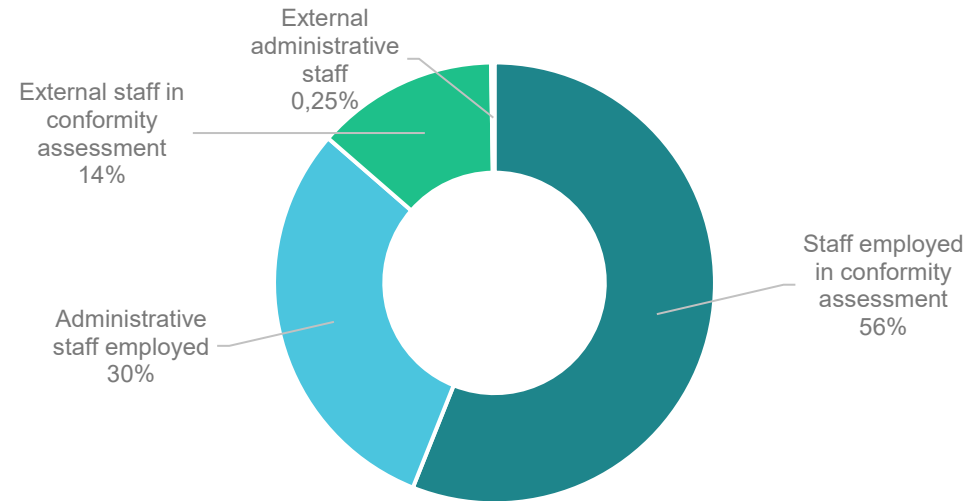
Note:

- Thousands separators are represented as dots or blank space (not comma) in the graphs.
- Datasets:
 - ③ 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.
 - 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.
 - ⑤ 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/AIMDD/MDD & IVDR/IVDD)

October 2023

Total number of FTEs with conformity assessment activities and within administrative and supporting activities: **4.932,41**



Notes:

- Data status: 31/10/2023
- By employee type
- Counted in Full Time Equivalents (FTE)

Employees within administrative and supporting activities (in relation to Regulations/Directives): 1.509,45 (FTE)

- Internal: 1.496,95 FTEs (data of 39 NBs)
- Externalised contractors: 12,5 FTEs (data of 38 NBs)

Employees within conformity assessment activities: 3.422,96 (FTE)

- Internal: 2.764,13 FTEs (data of 38 NBs)
- Externalised contractors: 658,83 FTEs (data of 37 NBs)

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 in addition to the personnel referred to in Section 4.4, second paragraph, of Annex VII MDR ([...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.

Thank you

Contact for questions: medical.devices@goeg.at



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