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

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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.

Content

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

About

1. About the study, survey and datasets

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

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

About

- **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

European Commission

About

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
1st NB survey	03/04/2023 - 05/05/2023	SD1 + MD1	from designation up to 31/03/2023	39 out of 39 NBs** **100%**
2nd NB survey	12/05/2023 - 05/06/2023	SD2	from designation up to 30/04/2023	27 out of 39 NBs** **~ 70%**
3rd NB survey	05/06/2023 - 19/06/2023	SD3	from designation up to 31/05/2023	22 out of 39 NBs** **~ 56%**
4th NB survey	03/07/2023 - 28/07/2023	SD4 + MD2	from designation up to 30/06/2023	39 out of 39 NBs** **100%**
5th NB survey	01/09/2023 - 06/10/2023	SD5	from designation up to 31/08/2023	40 out of 40 NBs** **100%**
6th NB survey	03/11/2023 - 22/12/2023	SD6 + MD3 + LD1	from designation up to 31/10/2023	41 out of 41 NBs** **100%**

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

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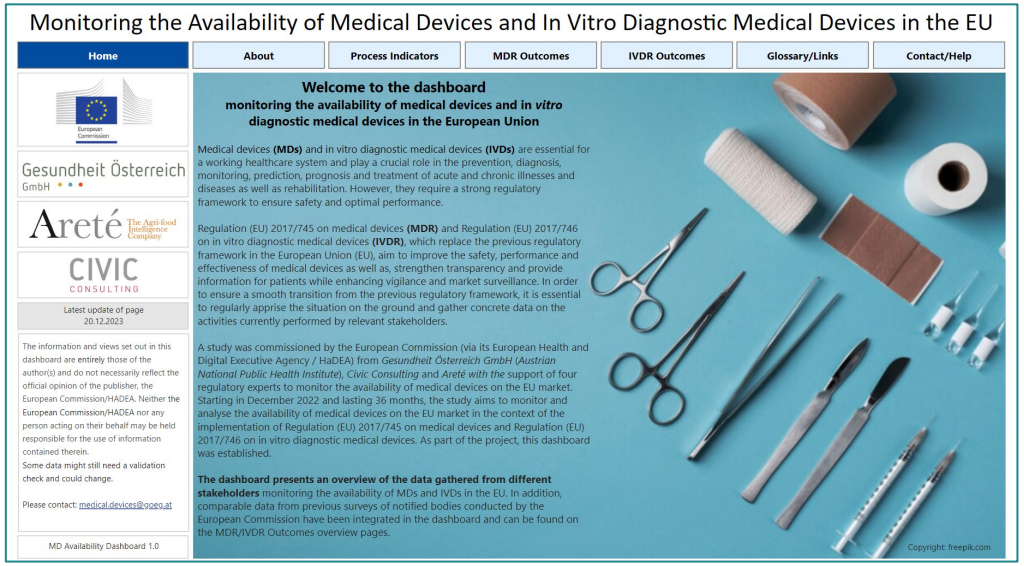
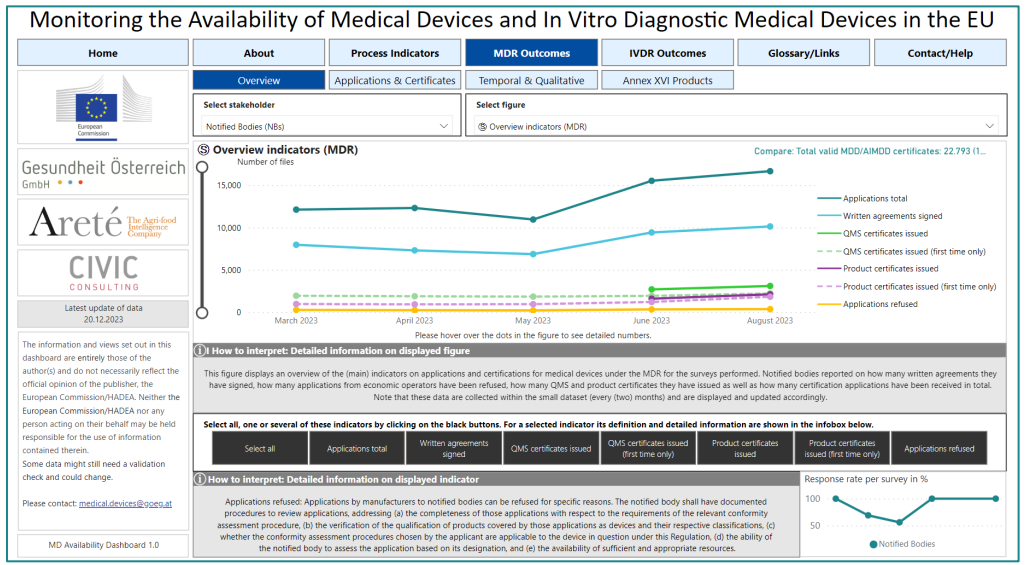
About

Dashboard

- NB survey results are presented in the study-related dashboard
- Available at: [Study supporting the monitoring of availability of medical devices on the EU market - European Commission (europa.eu)]





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About

Preliminary notes

- **Data content:**
  - The following slides show the results of the **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**.

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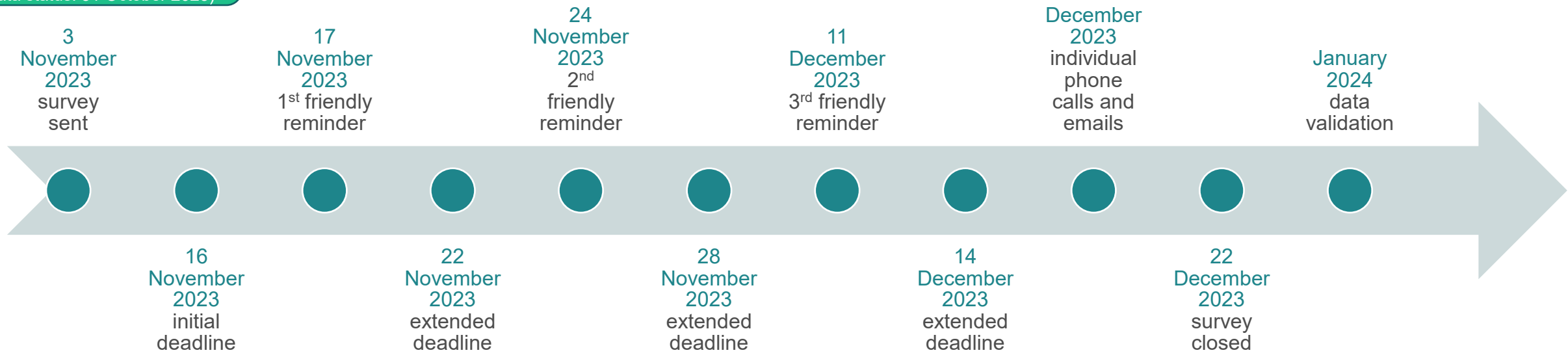
Timeline for the survey conducted in November 2023 (data was requested until 31 October 2023)

About

41 notified bodies designated under MDR and/or IVDR
(Data status: 31 October 2023)



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)

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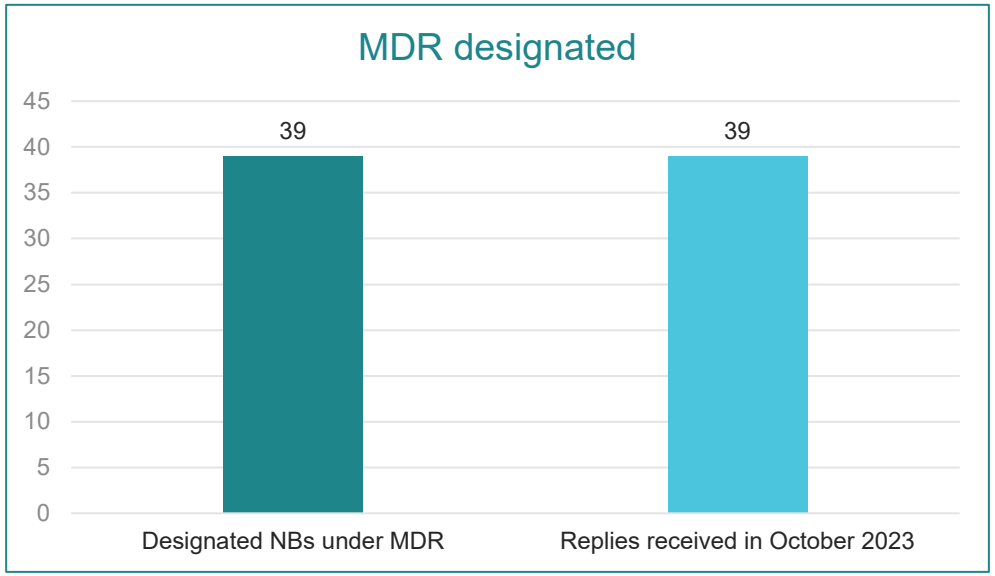
Response rate for the survey conducted in November 2023 (data was requested until 31 October 2023)

About

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

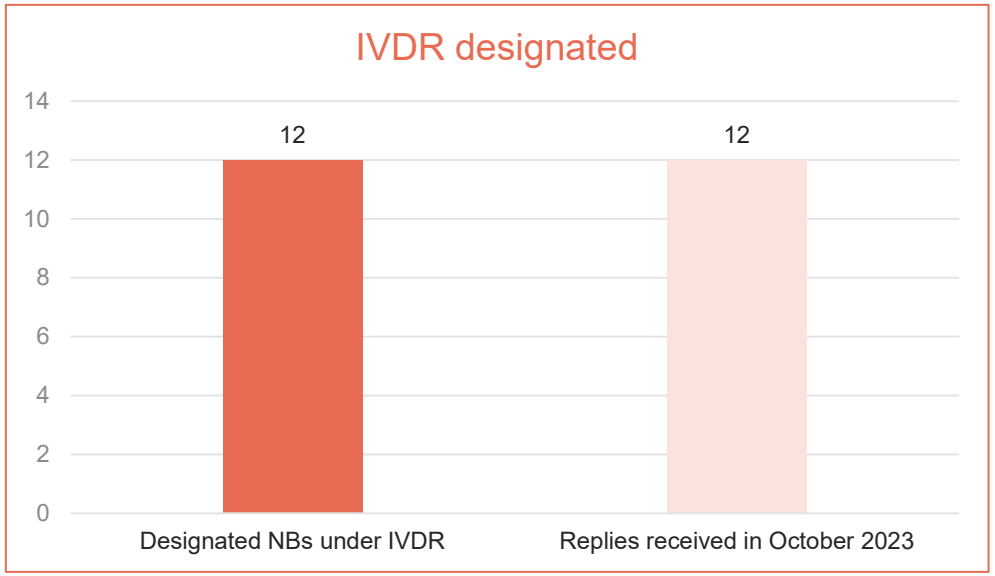
Note: *Out of 41 notified bodies,* ***29 NBs*** *are designated under the* ***MDR*** *only,* ***10 NBs*** *are designated under* ***both the MDR and IVDR****, and* ***two NBs*** *are designated under the* ***IVDR only****.*

MD



100% response rate

IVD



100% response rate

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MD

2. Survey results for medical devices

Note:

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

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

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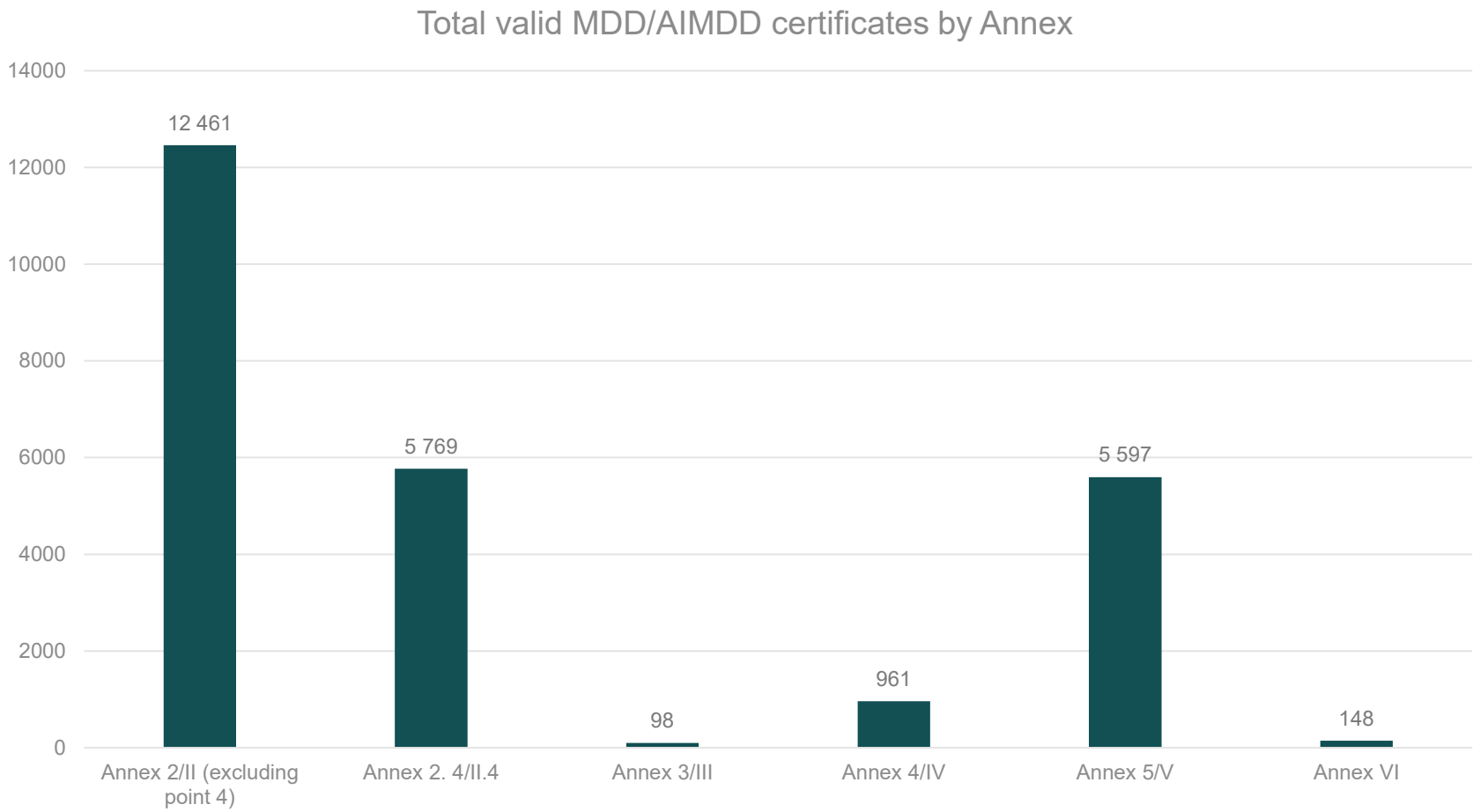
MDD/AIMDD Certificates by Annex (data status: April 2022)

MD

MDD/AIMDD Data



Total: 25.034

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MDR applications filed and certificates issued (sum of Annexes)

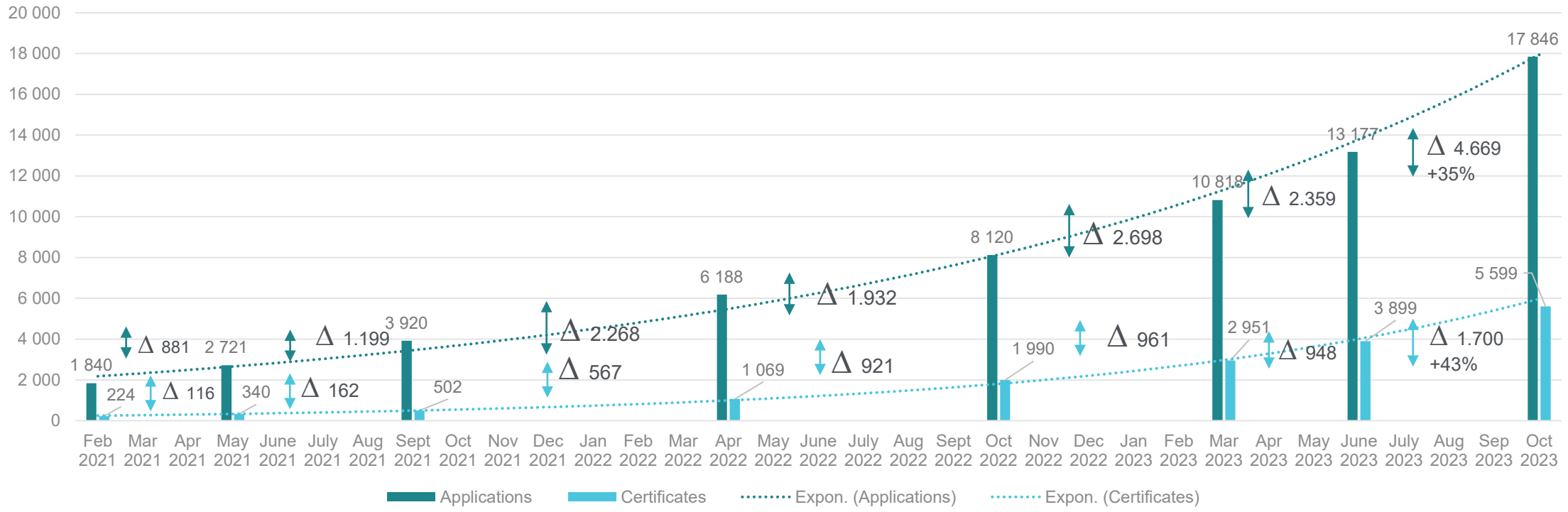
MD

Ⓜ

October 2023

MDR Applications:
Total number of applications filed by Annex Ⓜ: 17.846*

MDR Certificates:
Total number of certificates by Annex Ⓜ: 5.599



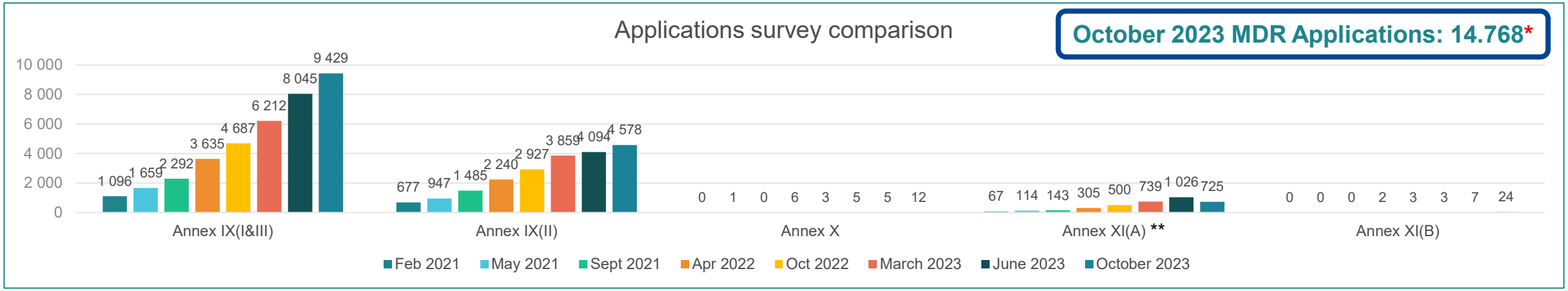
Notes: October 2023: Designated NBs for MD: 39; NBs that included Annex XVI products in the numbers provided: 15

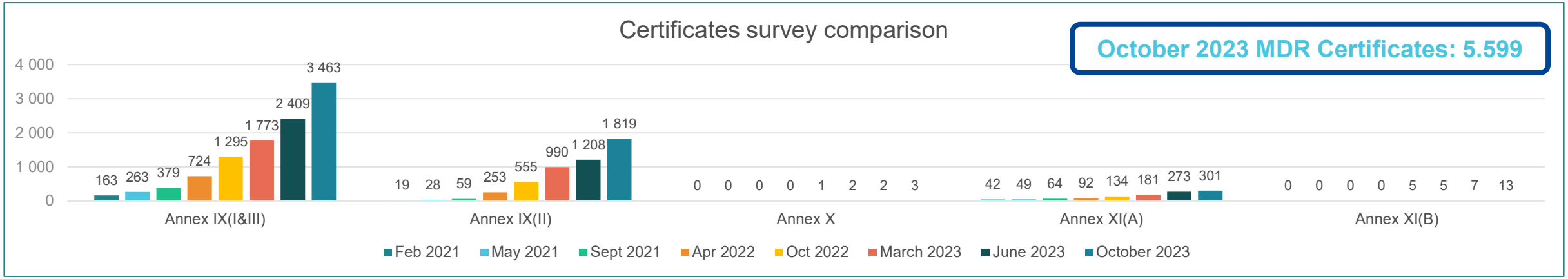
* The data shown comes from the medium data set Ⓜ – except for 2 NBs where the total number of applications filed was derived from the small data set Ⓢ since they could not provide the data per Annex.

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

MD





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.
- **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**.

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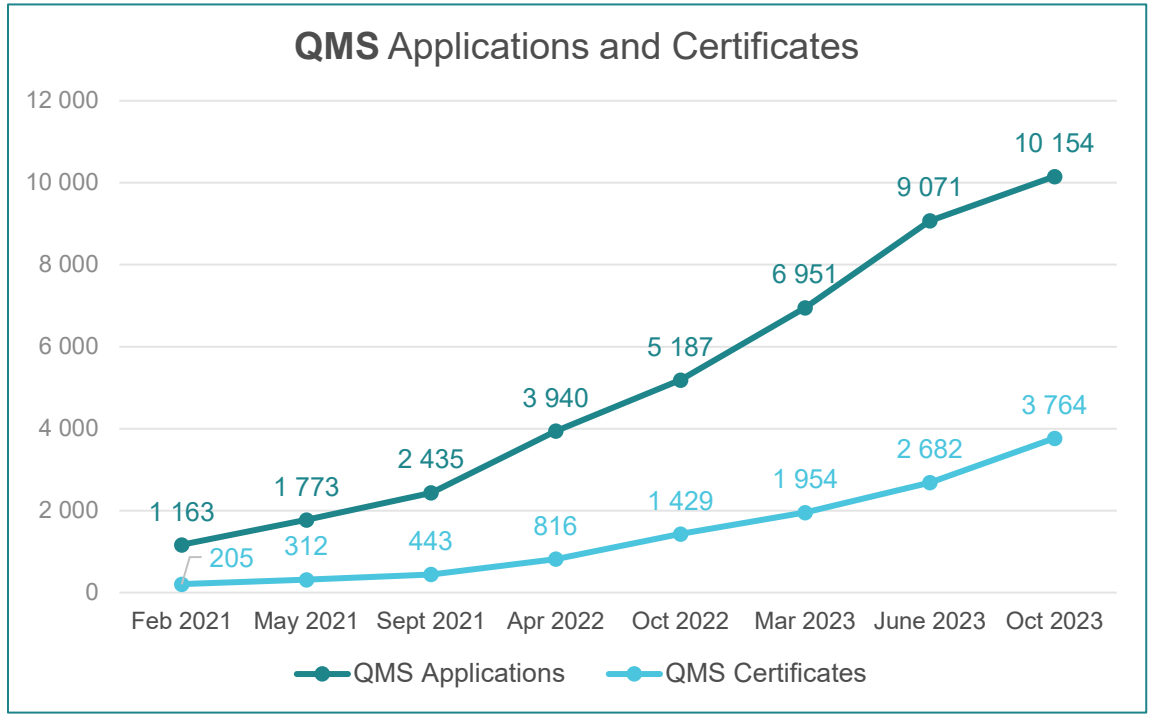
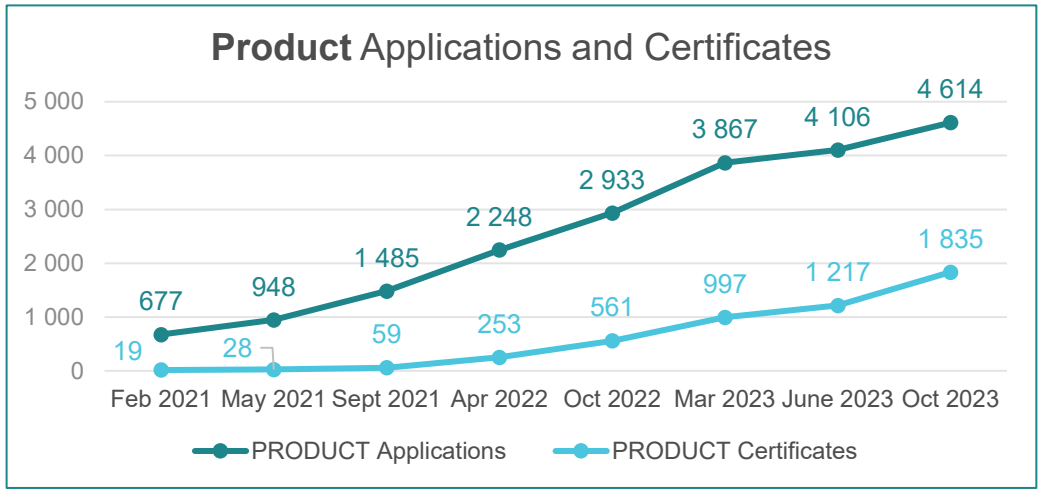
MDR applications and certificates by type (QMS vs Product) – survey comparison



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

* The data shown comes from the small data set. The data from the medium data set (applications and certificates by Annex) differs as 2 NBs could not provide the application information by Annex; hence the total number of applications is lower: 14.768)

Specific additional procedures according to Annex IX (II)

MD

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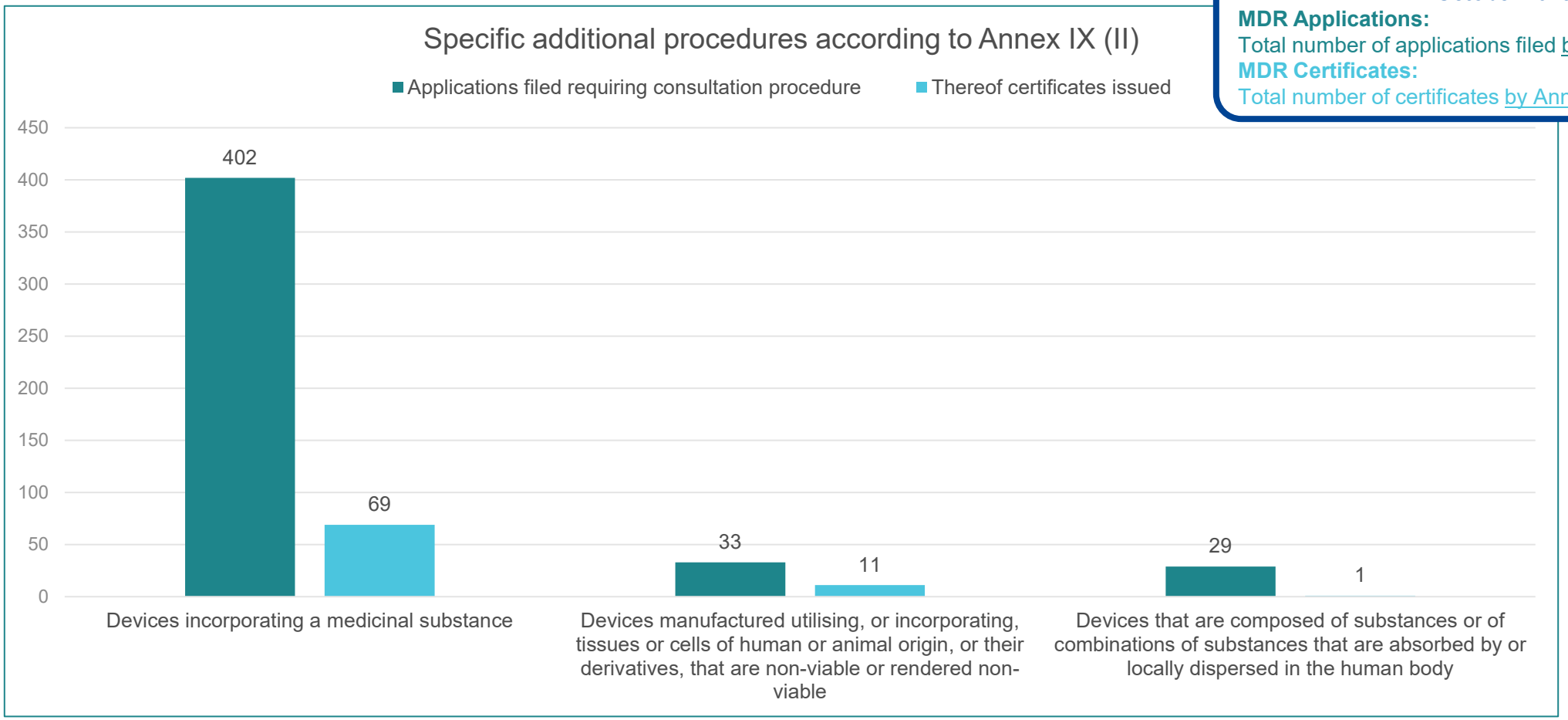
October 2023

MDR Applications:
Total number of applications filed by Annex Ⓜ: 17.846*

MDR Certificates:
Total number of certificates by Annex Ⓜ: 5.599



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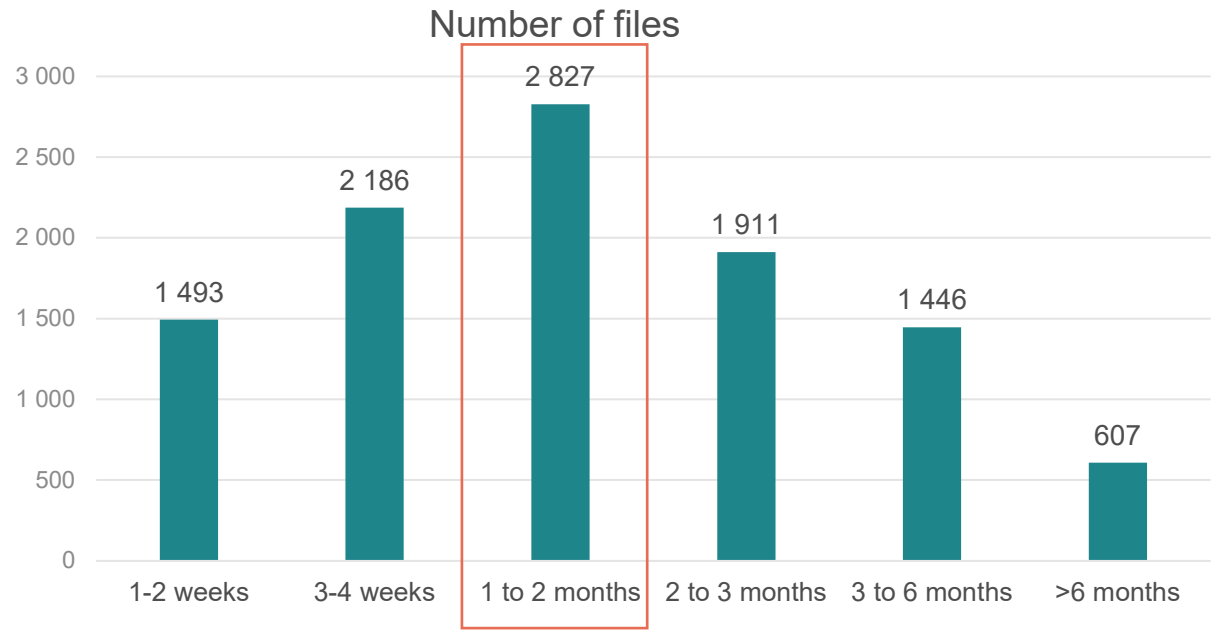
Average timeframe to written agreement signed

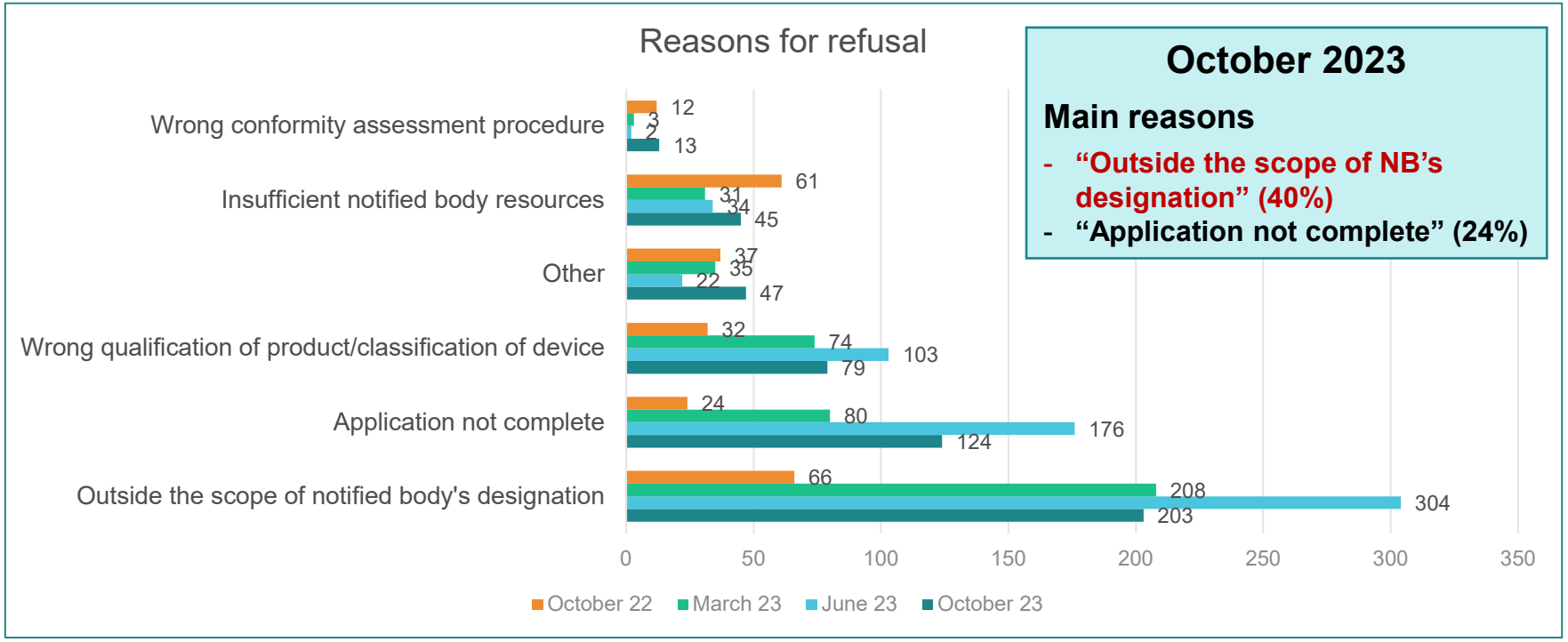
Average timeframe between application lodged and written agreement signed:



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

Note: Data of 39 notified bodies

MDR applications - reason for refusal



October 2023

Main reasons

- **"Outside the scope of NB's designation" (40%)**
- **"Application not complete" (24%)**

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

Application refusals:**

October 2022: 232

March 2023: 269

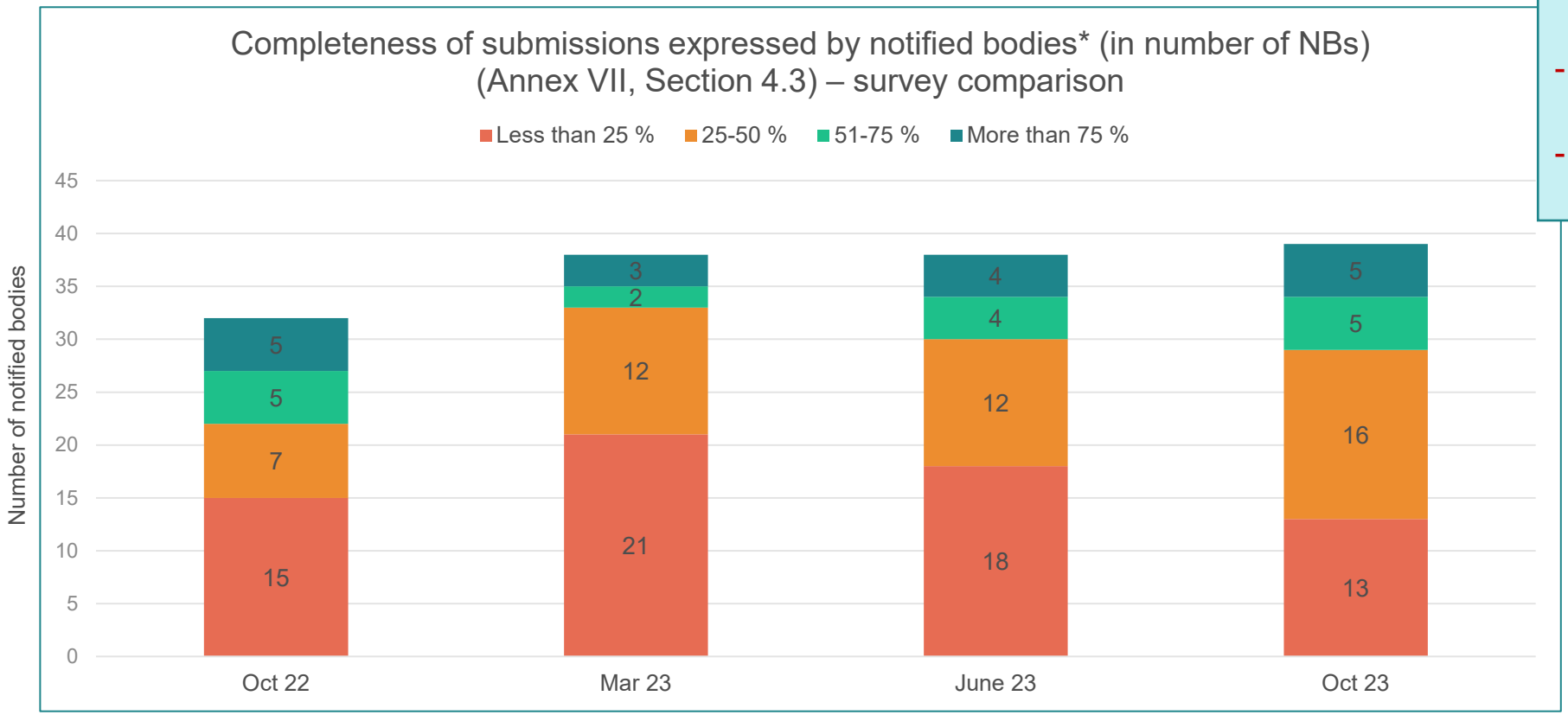
June 2023: 328

October 2023: 367

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 metabolical means by ingredients", "customer has voluntarily requested to cancel MDR application.", "product did not meet essential requirements despite comprehensive feeback 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 metabolical means by ingredients", "customer has voluntarily requested to cancel MDR application.", "product did not meet essential requirements despite comprehensive feeback 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 metabolical means by ingredients", "customer has voluntarily requested to cancel MDR application.", "product did not meet essential requirements despite comprehensive feeback 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

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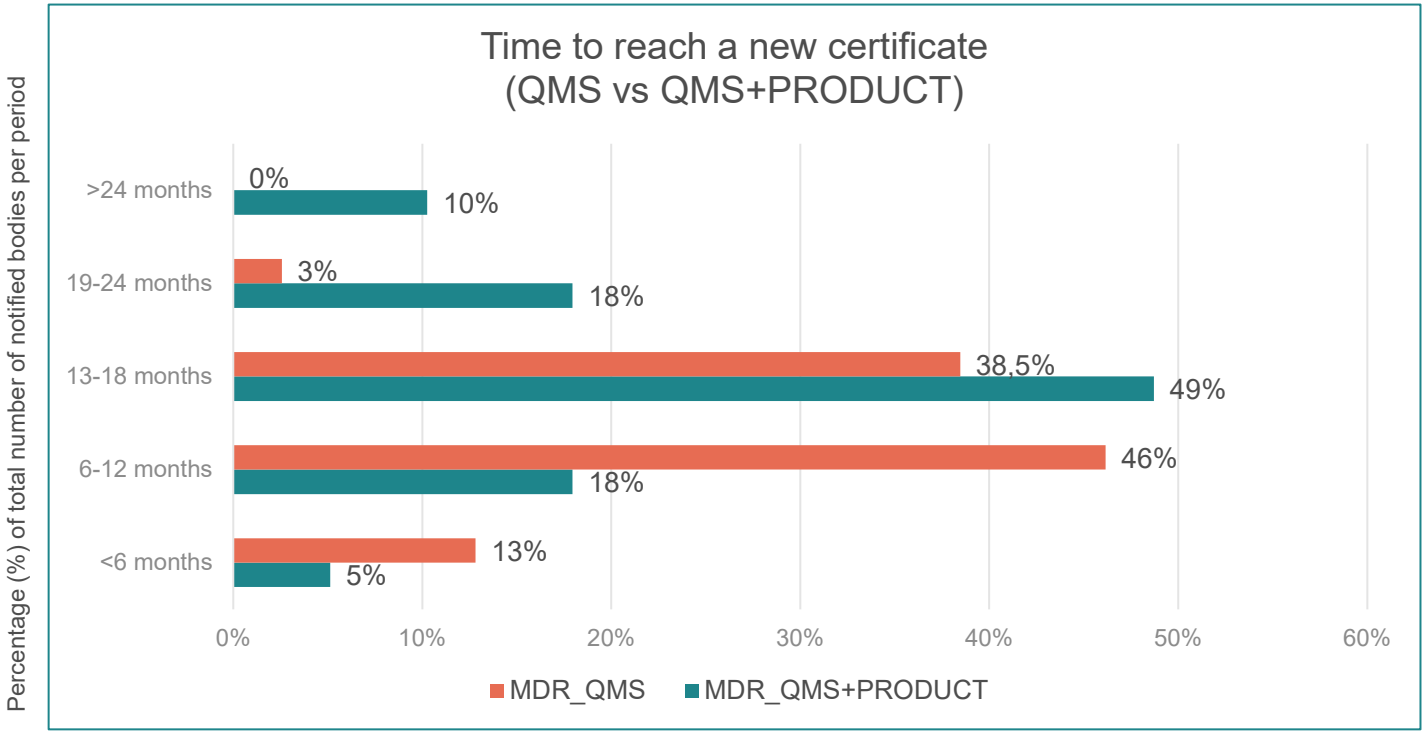
Time to reach a new certificate (QMS vs QMS+PRODUCT)

MD

Ⓜ

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

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

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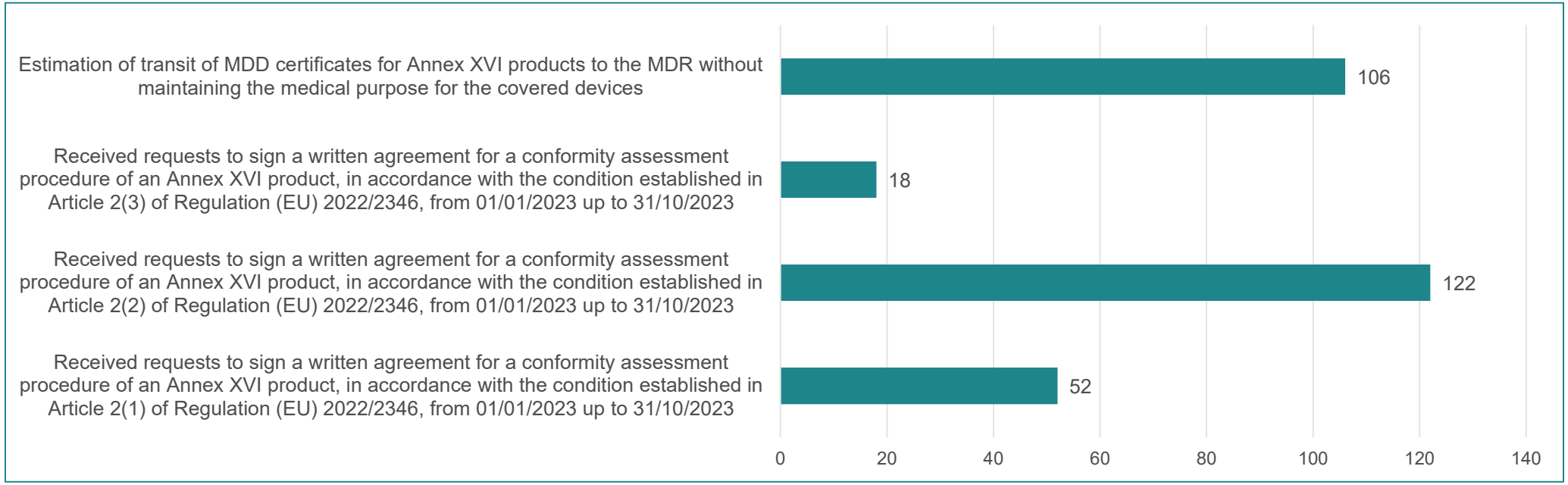
Questions on Annex XVI products

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



Notes:

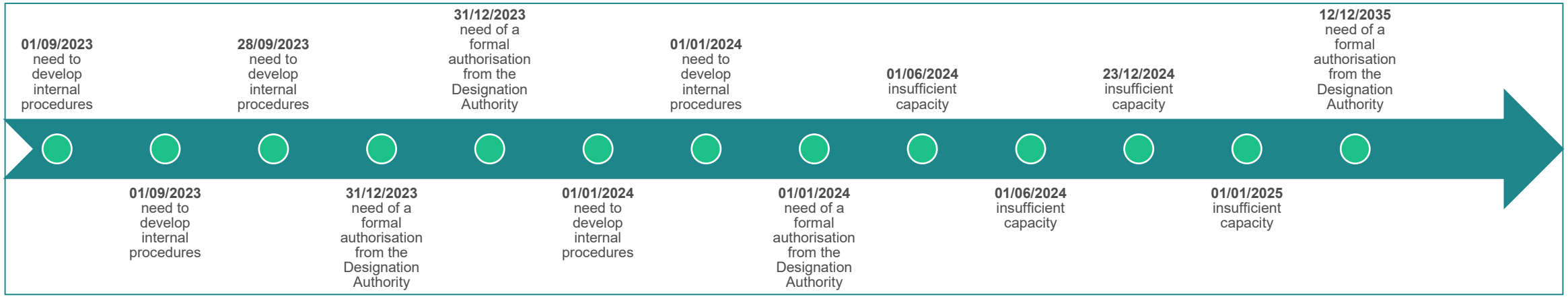
- 21 out of 39 NBs entered "0" for all questions relating to Annex XVI products
- As a result of further data validation activities, some figures have been adjusted slightly compared to the PPT previously published and dated 5 February 2024.

Questions on Annex XVI products

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

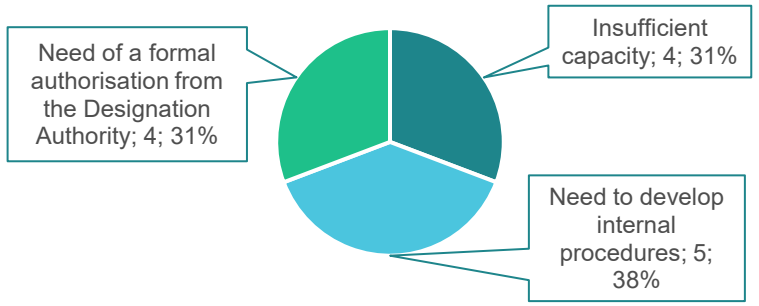
From which **date** can the NB work on Annex XVI products?

- **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



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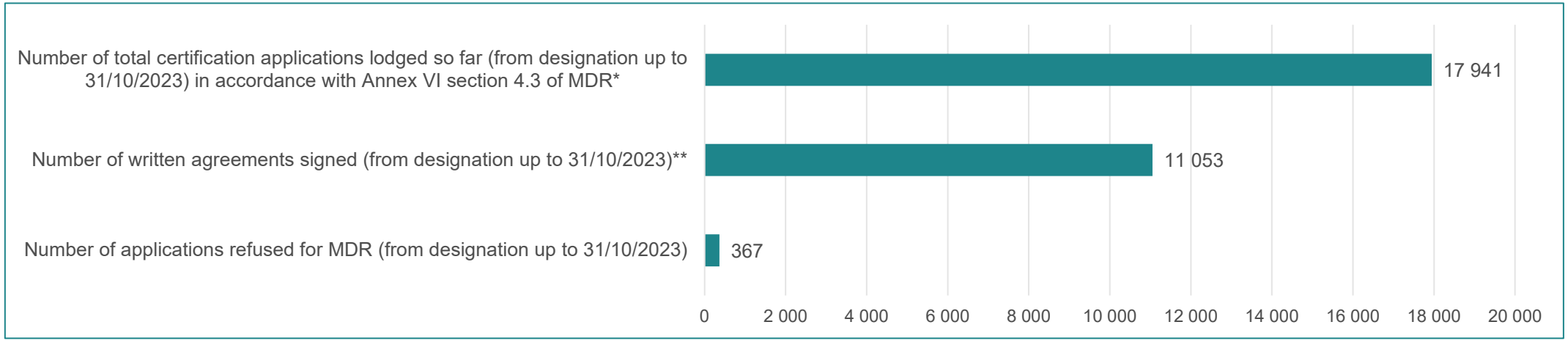
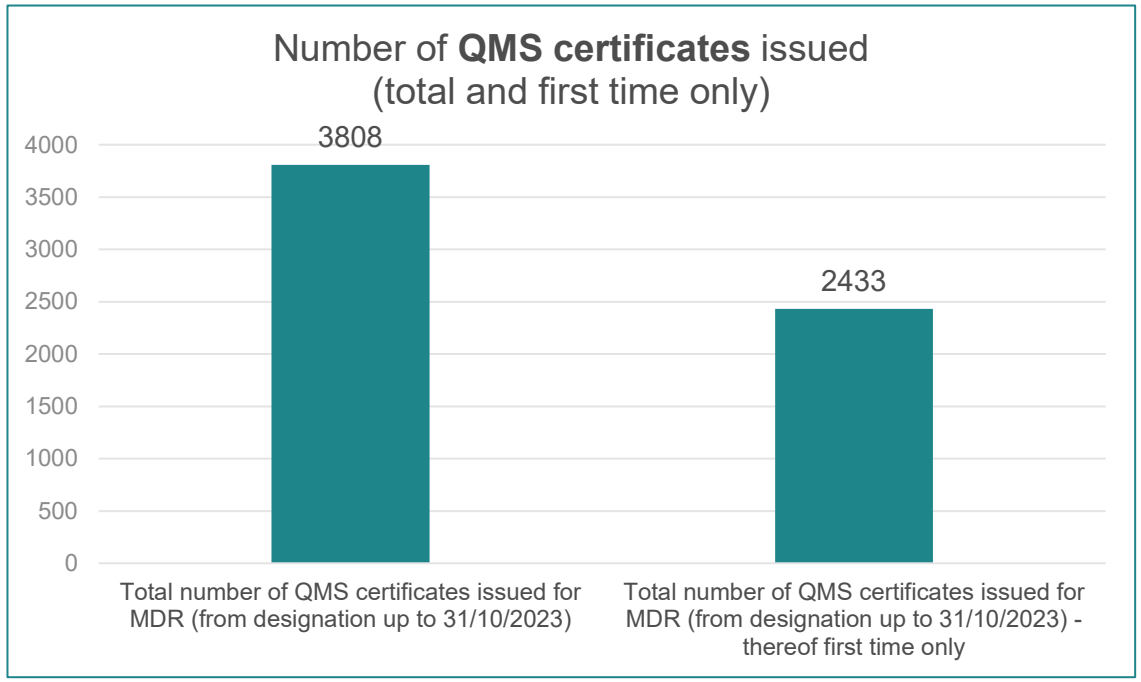
MDR applications filed and refused, written agreements signed



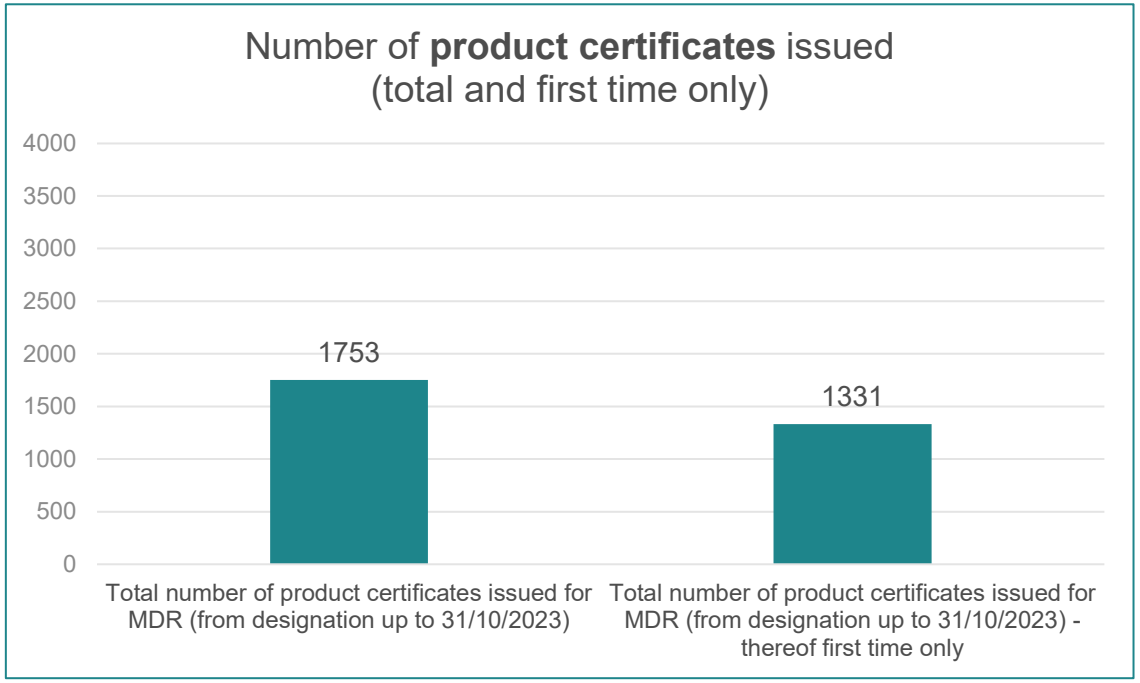
Notes:

- **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



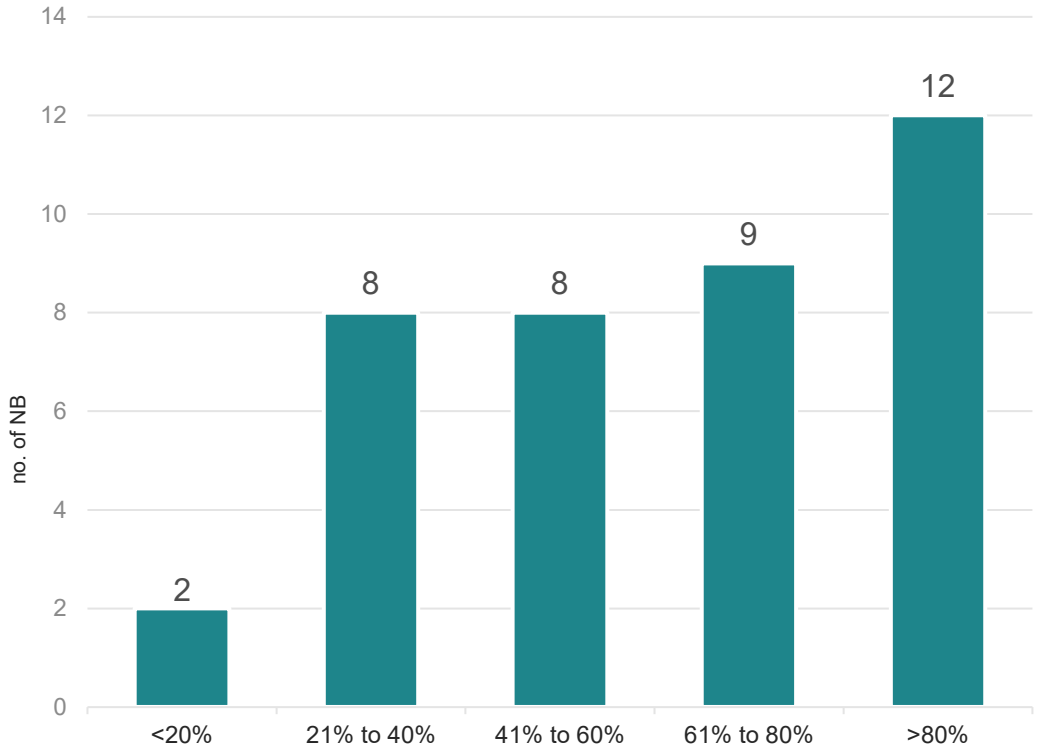
Note QMS Certificates: This relates to Annex IX Chapter I or Annex XI Part A according to MDR.



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)

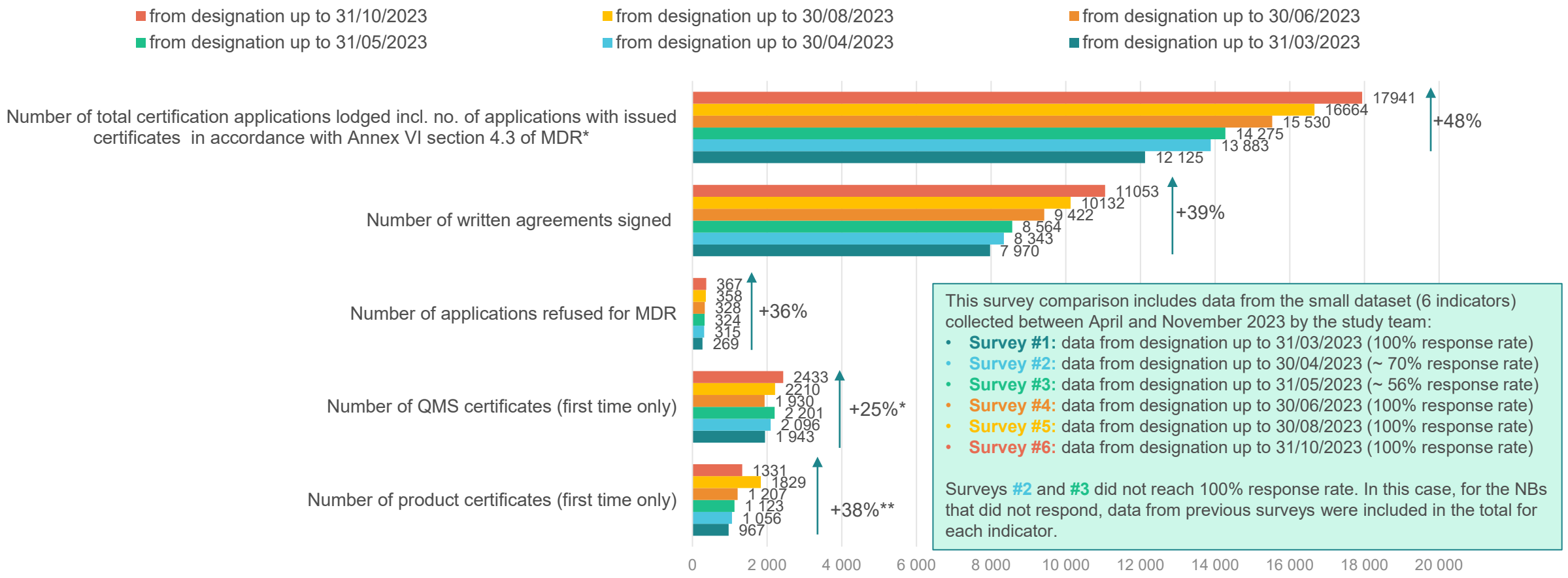


- **8 out of 39 NBs (20%)** reported that **21-40%** of the MDR applications cover the scope of (AI)MDD certificates
- **21 out of 39 NBs (more than 50%)** indicated that MDR applications **cover more than 60%** of the scope of (AI)MDD certificates.

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



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)

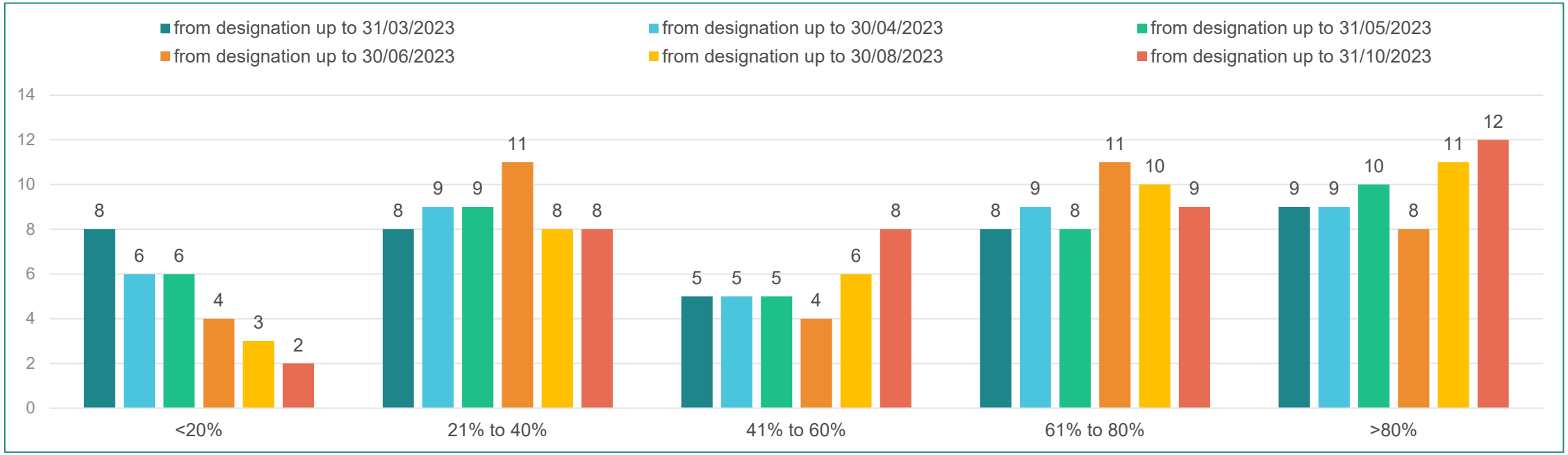
Surveys #2 and #3 did not reach 100% response rate. In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.

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

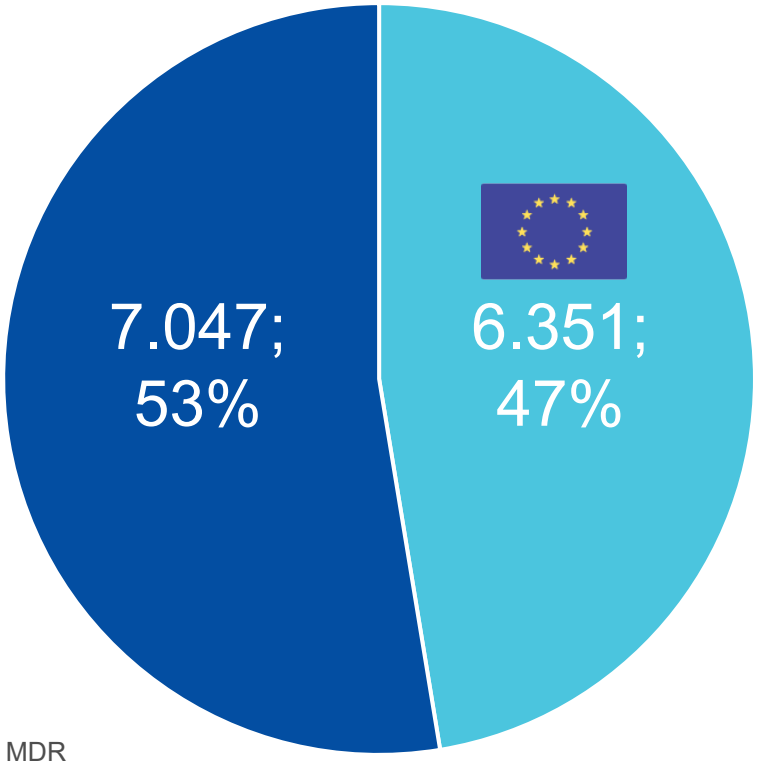
Meaning of average:

- 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

Number of clients based **outside the EU**



Number of clients based **in the EU**

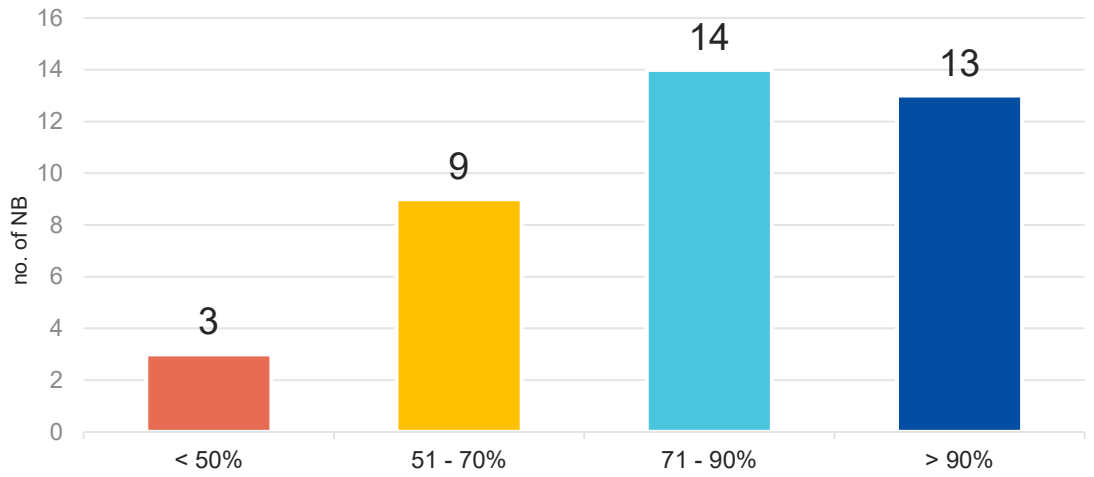
Data of 39 NBs designated under MDR
Photo credit: Flaticon.com

European Commission

MD

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

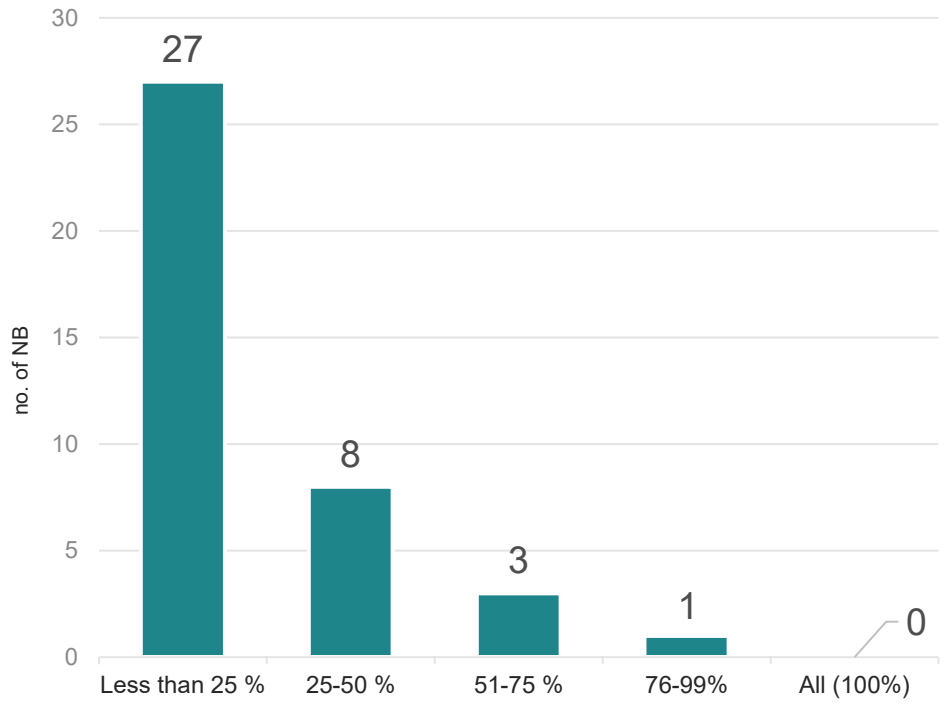
***Definition SME:** The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.' (Source: Extract of Article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

European Commission

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

MD

October 2023
Total number of clients: 13.398



- 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

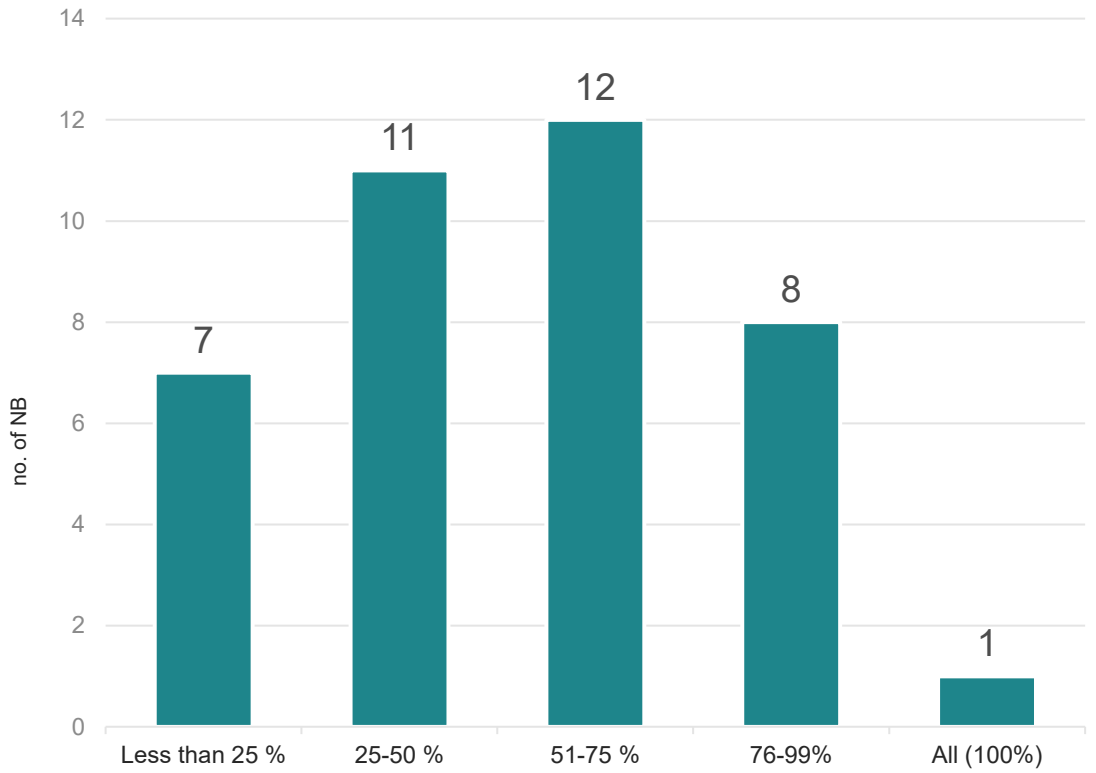
Data of 39 NBs designated under MDR

European Commission

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

MD

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

European Commission

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

MD

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

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

MD

Ⓛ

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 • MDT 2002 Devices manufactured using plastic processing • MDT 2010 Devices manufactured using electronic components including communication devices • MDT 2012 Devices which require installation, refurbishment	24
• MDS 1005 Devices in sterile condition • MDT 2001 Devices manufactured using metal processing	23

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

IVD

3. Survey results for in vitro diagnostic medical devices

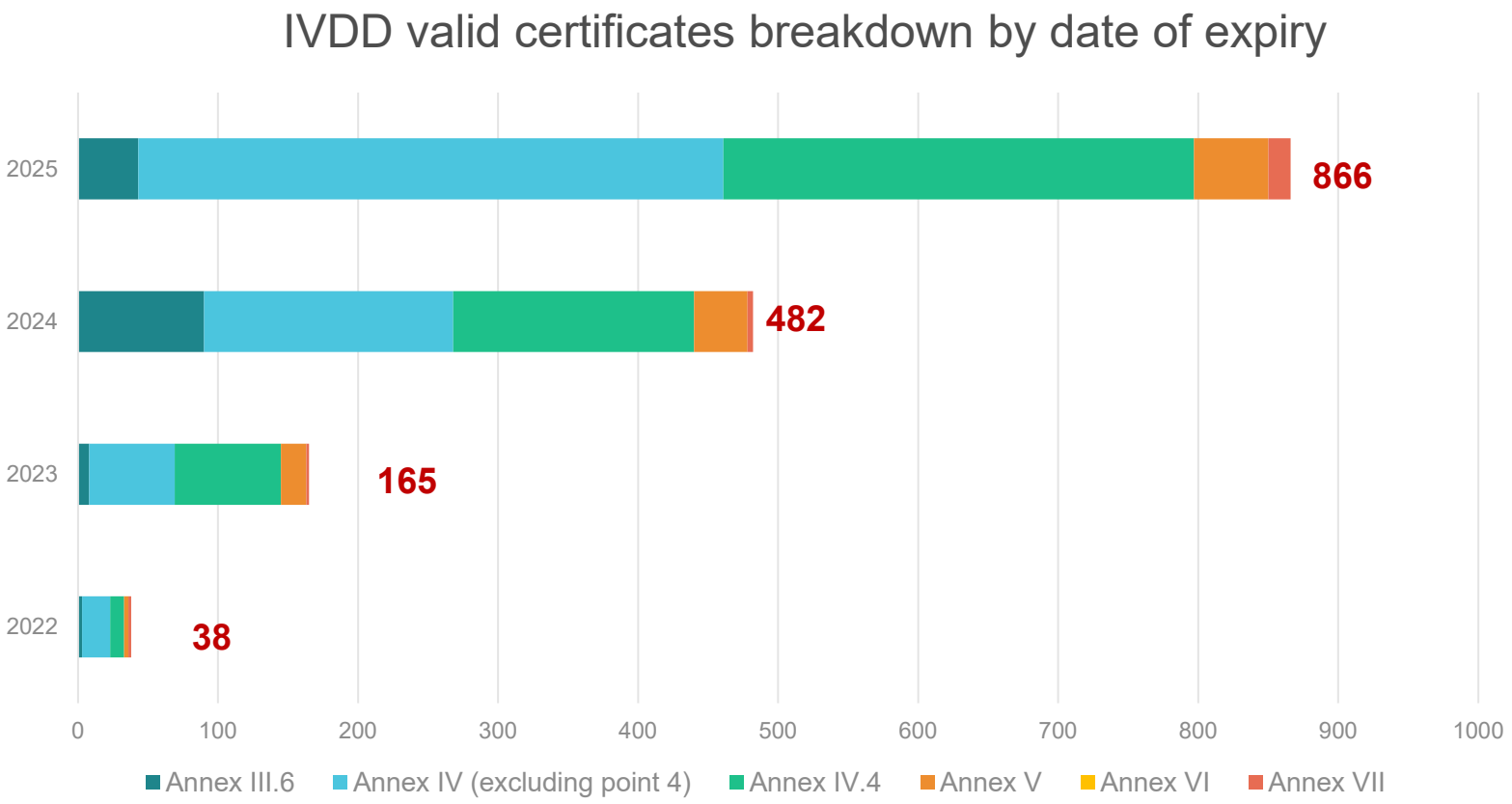
Note:

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

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

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

IVD



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

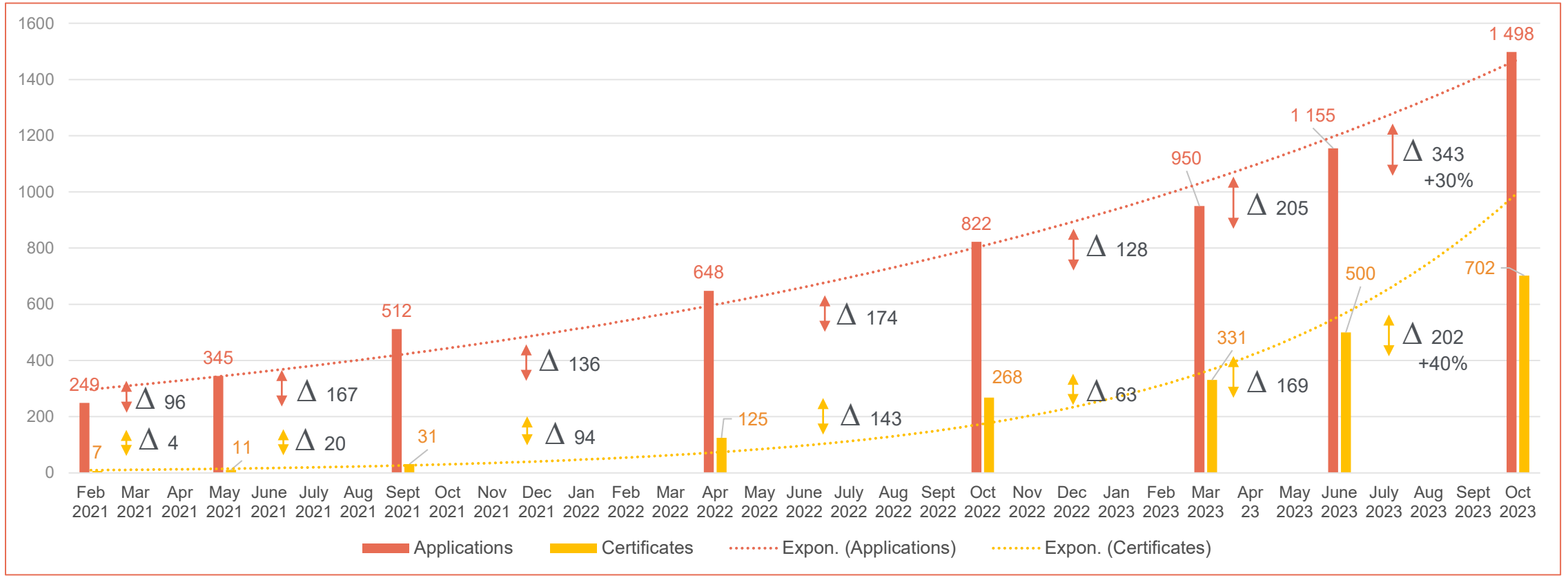
Tot. valid IVDD certificates 1.551

European Commission

IVDR applications lodged and certificates issued

IVD

October 2023
IVDR Applications: 1.498
IVDR Certificates: 702



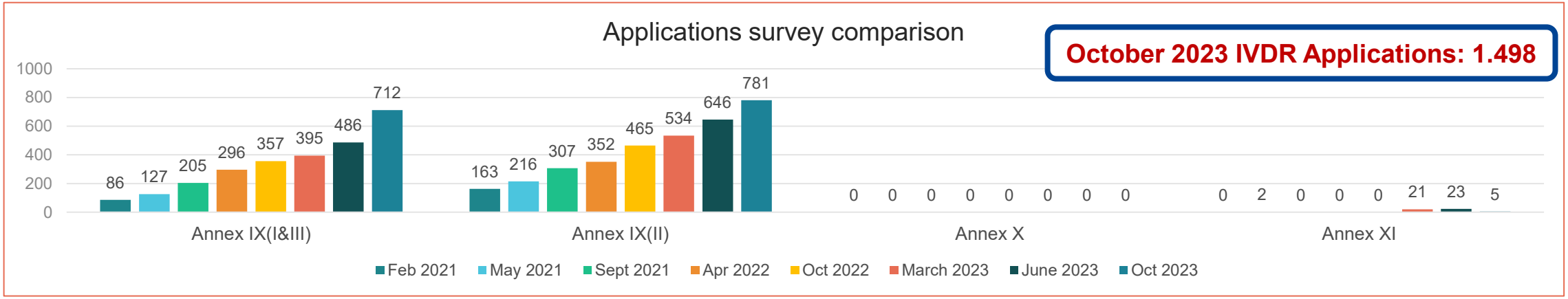
Notes:

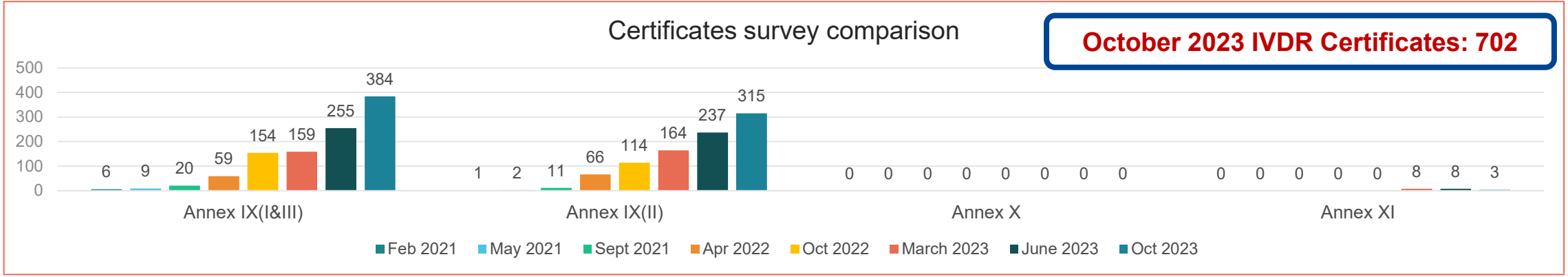
- Δ (Delta) = Difference in IVDR Applications / IVDR Certificates from one survey to the next one
- **Applications lodged**: This number includes **all applications lodged (syn. filed) so far** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after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

European Commission

IVDR applications and certificates by annex – surveys comparison

IVD





Notes:

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

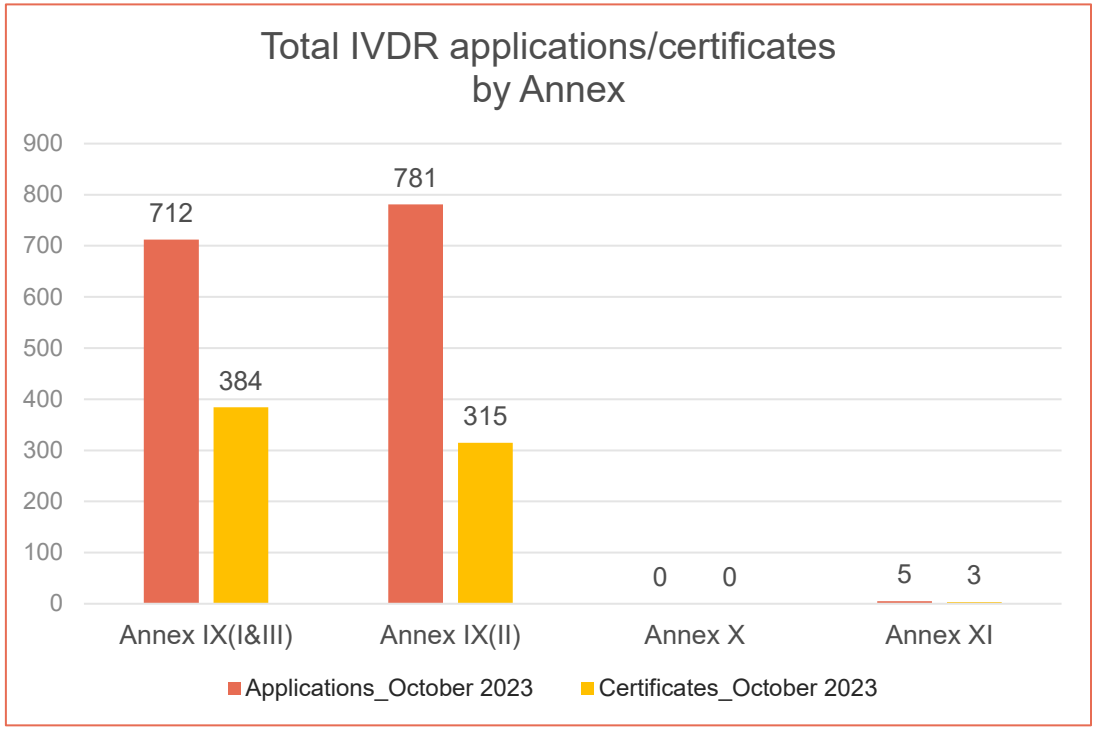
European Commission

IVDR applications and certificates by annex

IVD

Ⓜ

October 2023
IVDR Applications: 1.498
IVDR Certificates: 702



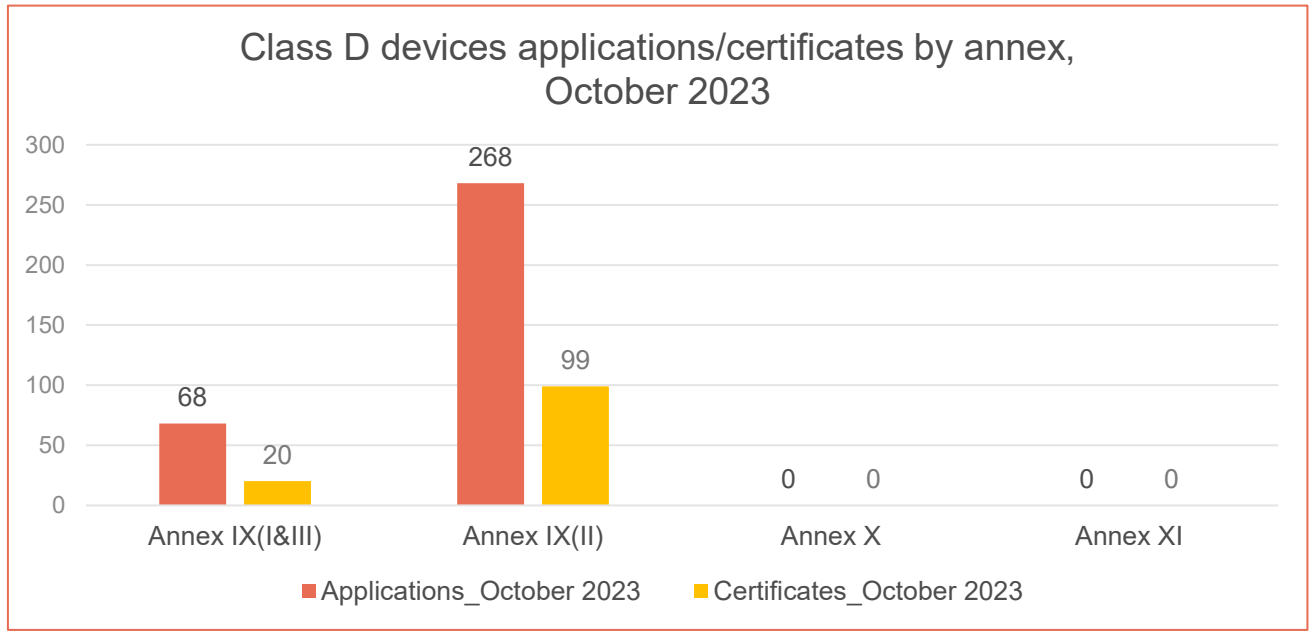
Notes:

- **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.

European Commission

Class D devices applications and certificates

IVD



October 2023
IVDR Applications: 1.498
IVDR Certificates: 702

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

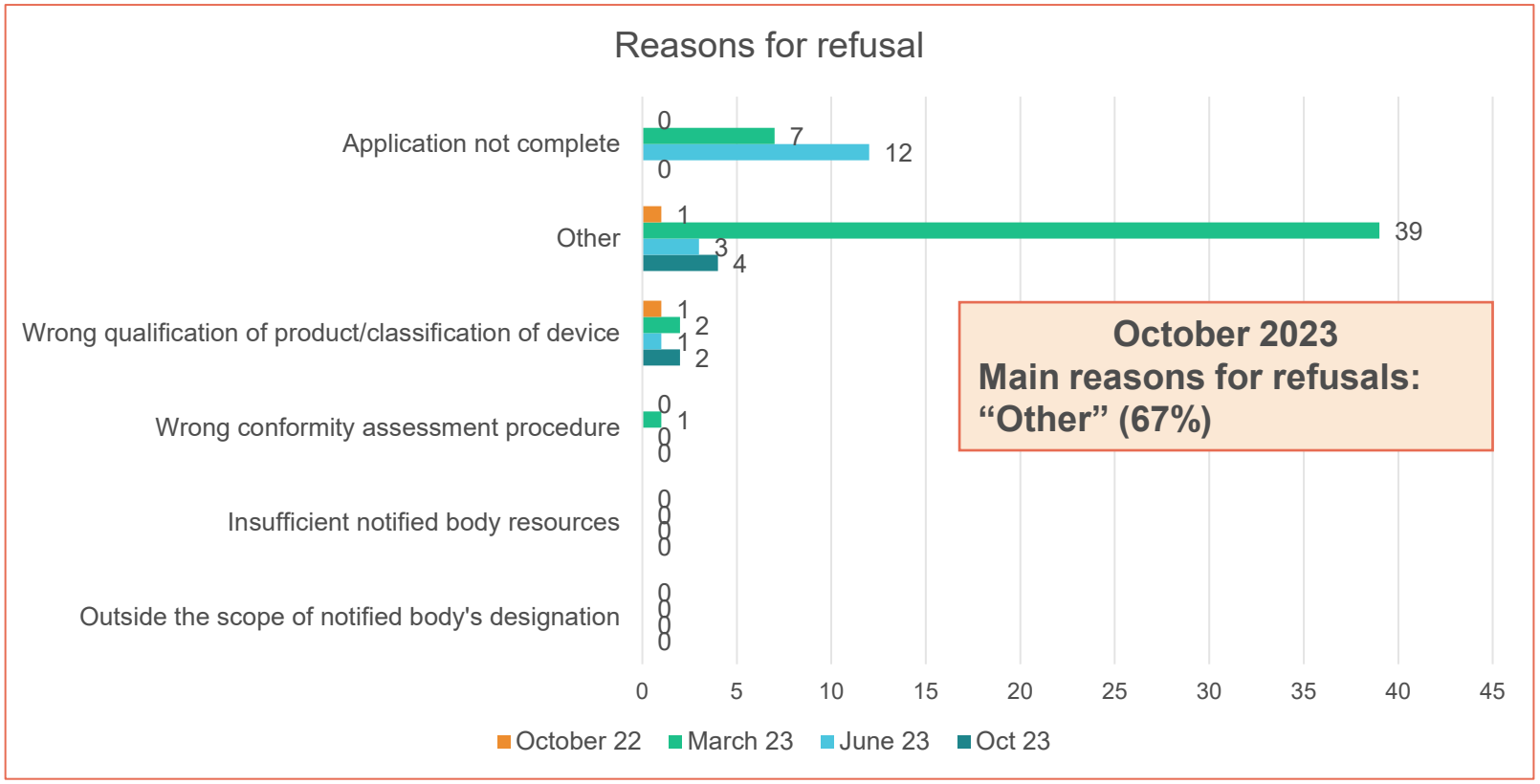
Notes:

- **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.

European Commission

IVD

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

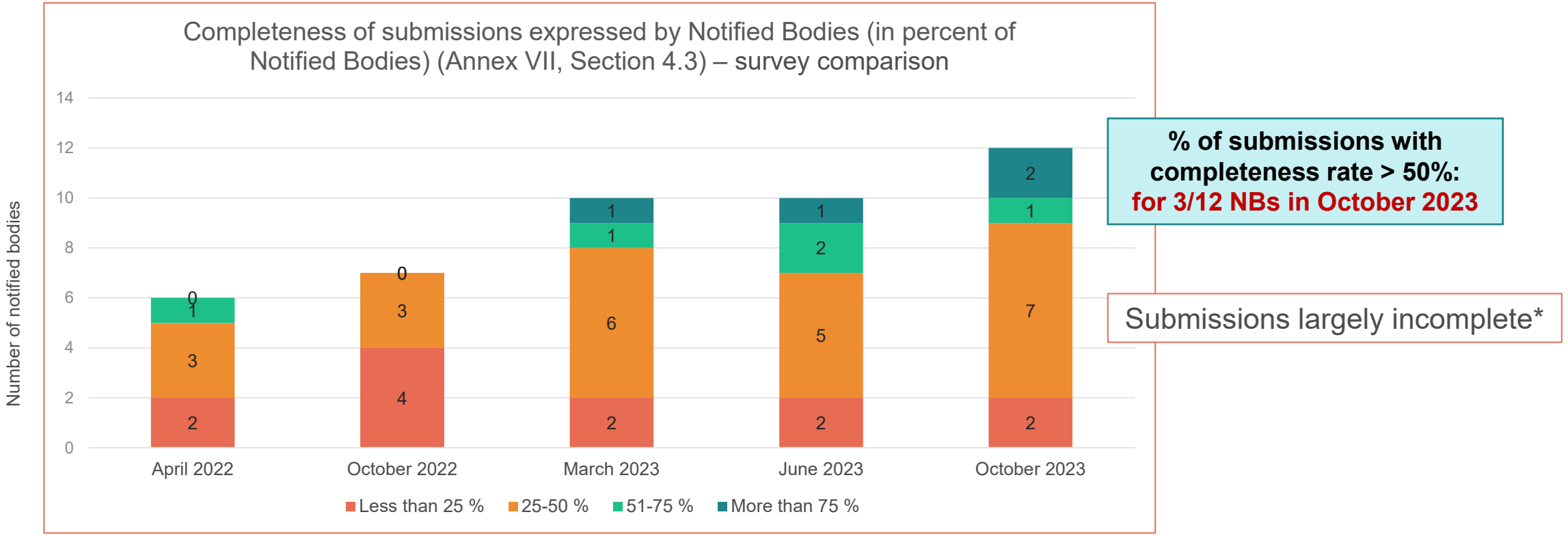
Notes:

- 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"

European Commission

IVD

Completeness of submissions



% of submissions with completeness rate > 50%:
for 3/12 NBs in October 2023

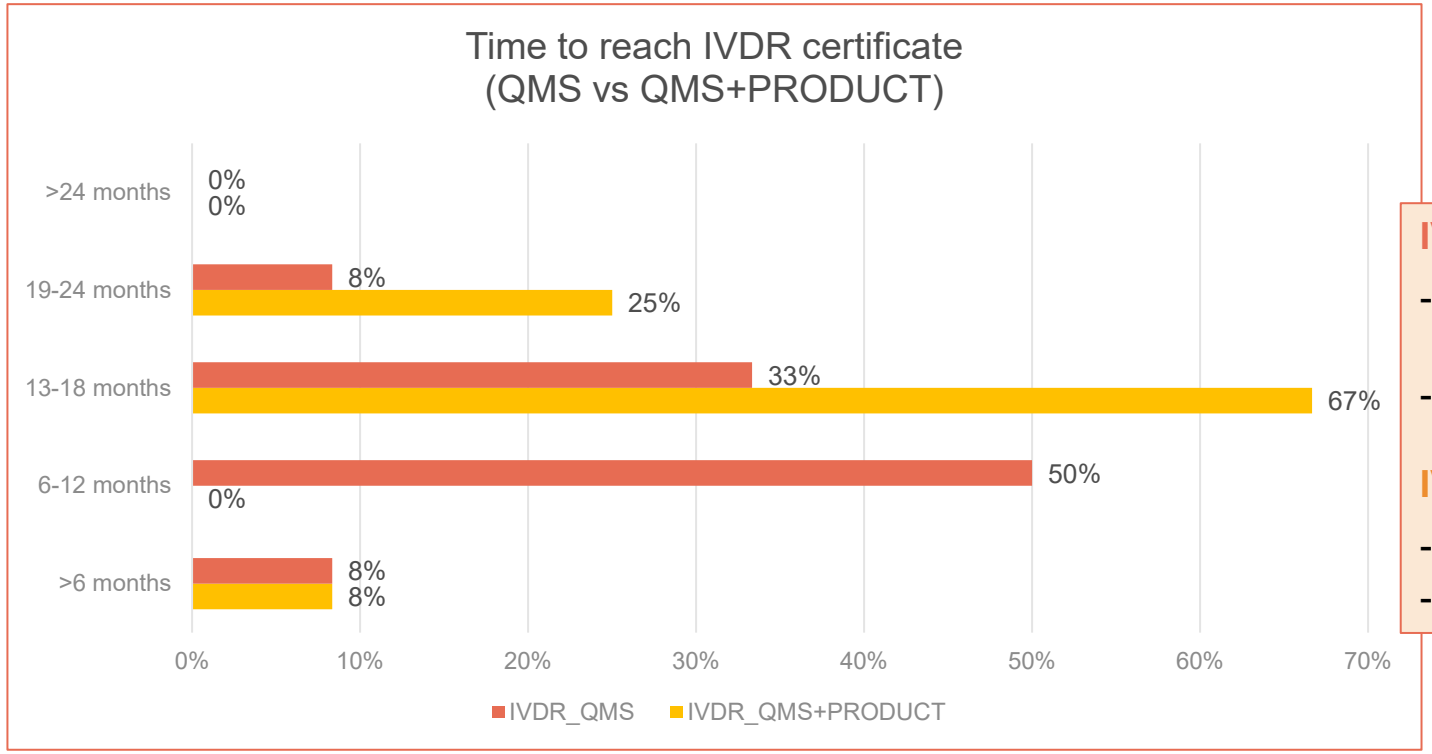
Submissions largely incomplete*

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

European Commission

Time to reach a certificate

IVD



October 2023
IVDR Applications: 1.498
IVDR Certificates: 702

IVDR QMS certificates

- For ≈ 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

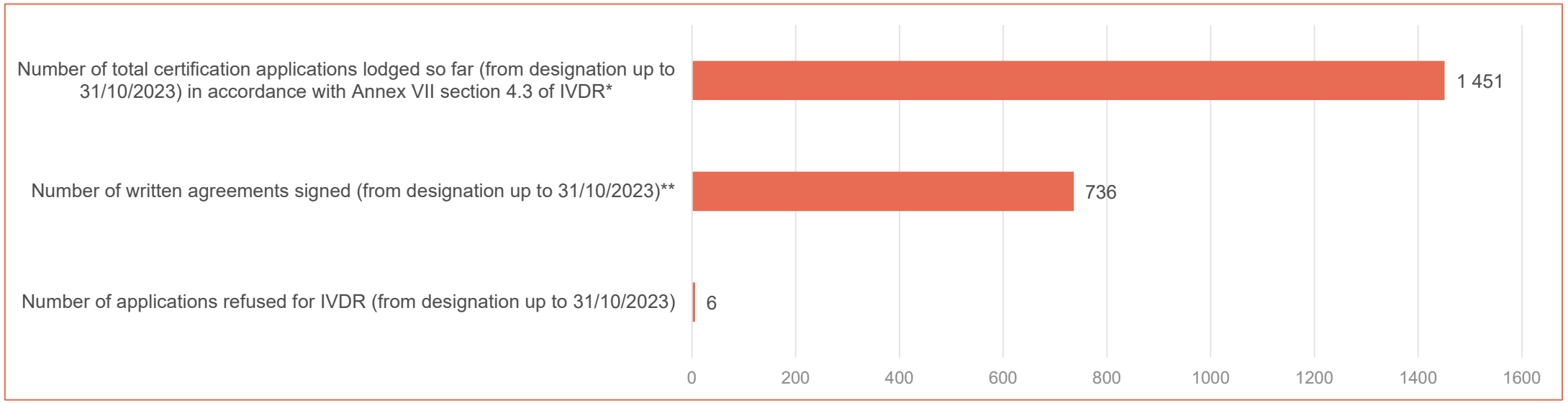
Notes:

- 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.

European Commission

IVDR applications filed and refused, written agreements signed

IVD



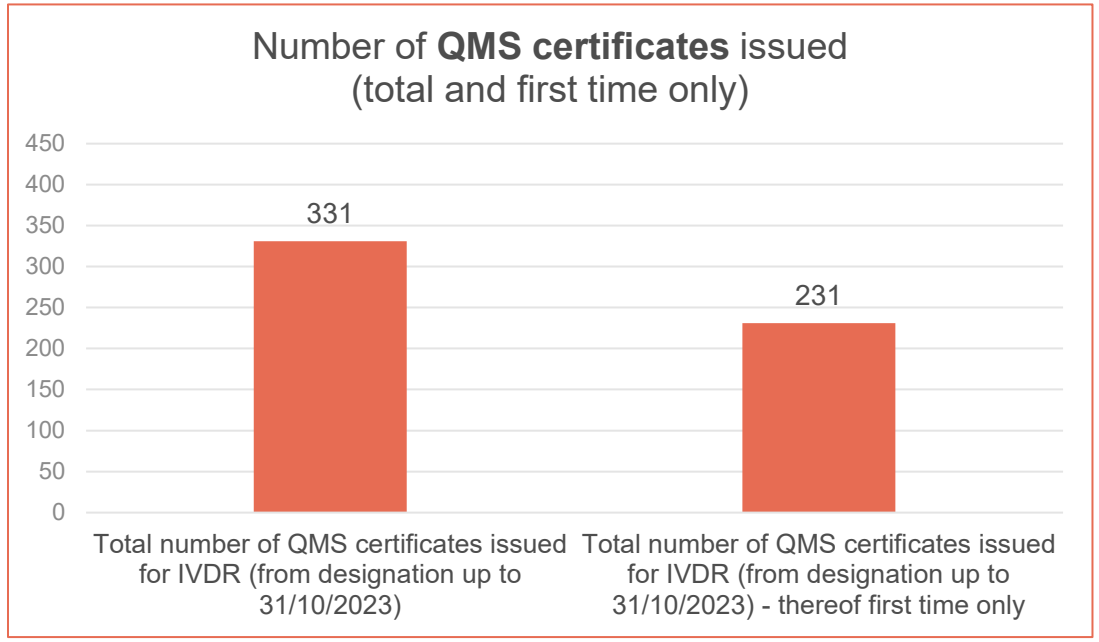
Notes:

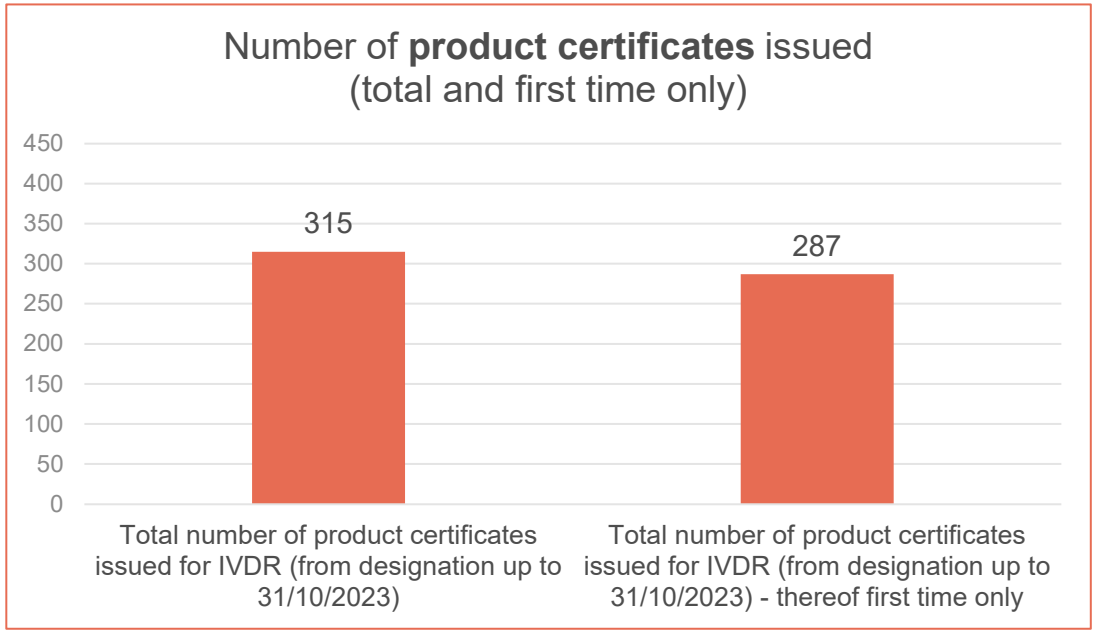
- **Designated NBs for IVD:** 12
- *** Applications lodged**: This number includes **all applications lodged (syn. filed) so far** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date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

European Commission

IVDR Number of QMS / product certificates issued

IVD





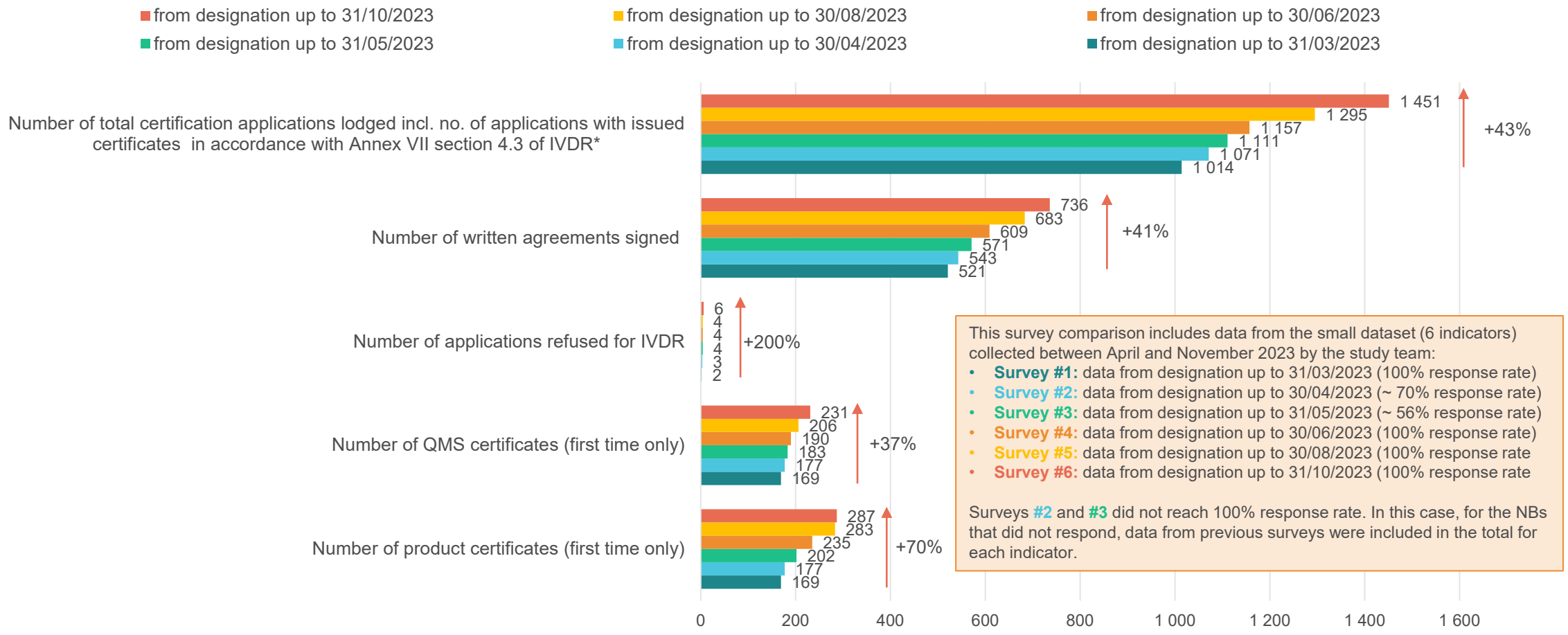
Note QMS Certificates: This relates to Annex IX Chapter I or Annex XI according to IVDR.
As a result of further data validation activities, some figures have been adjusted slightly compared to the PPT previously published and dated 5 February 2024.

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

European Commission

Survey comparison – March to October 2023
6 indicators

IVD



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

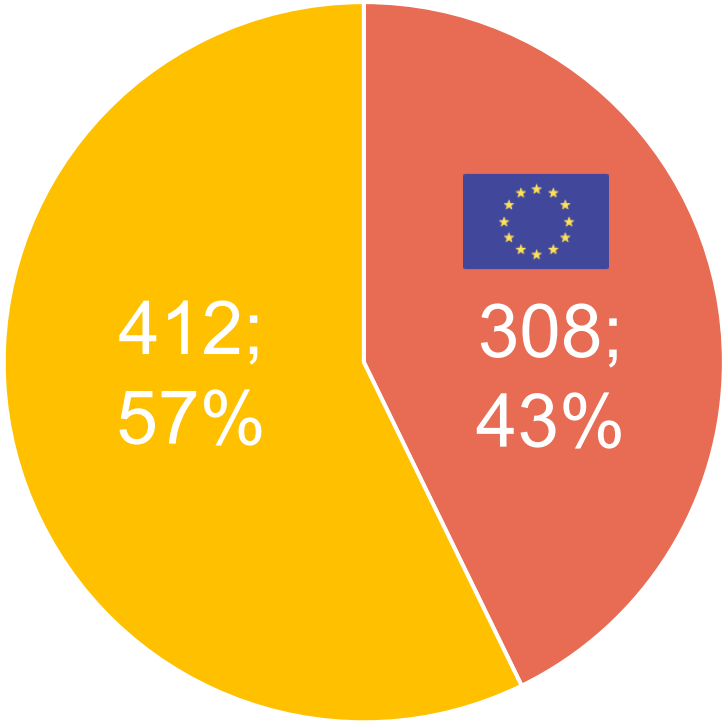
European Commission

IVD

Number of clients for IVDR/IVDD

October 2023
Total number of clients: 720

Number of clients based **outside the EU**



Number of clients based **in the EU**

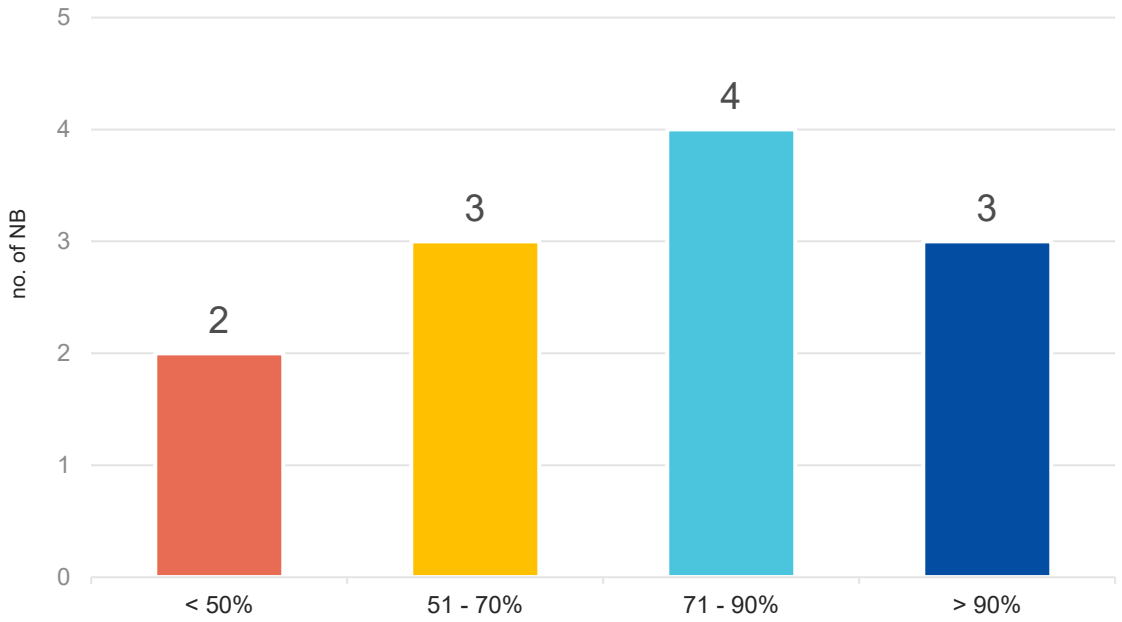
Data of 12 NBs designated under IVDR
Photo credit: Flaticon.com

European Commission

IVD

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

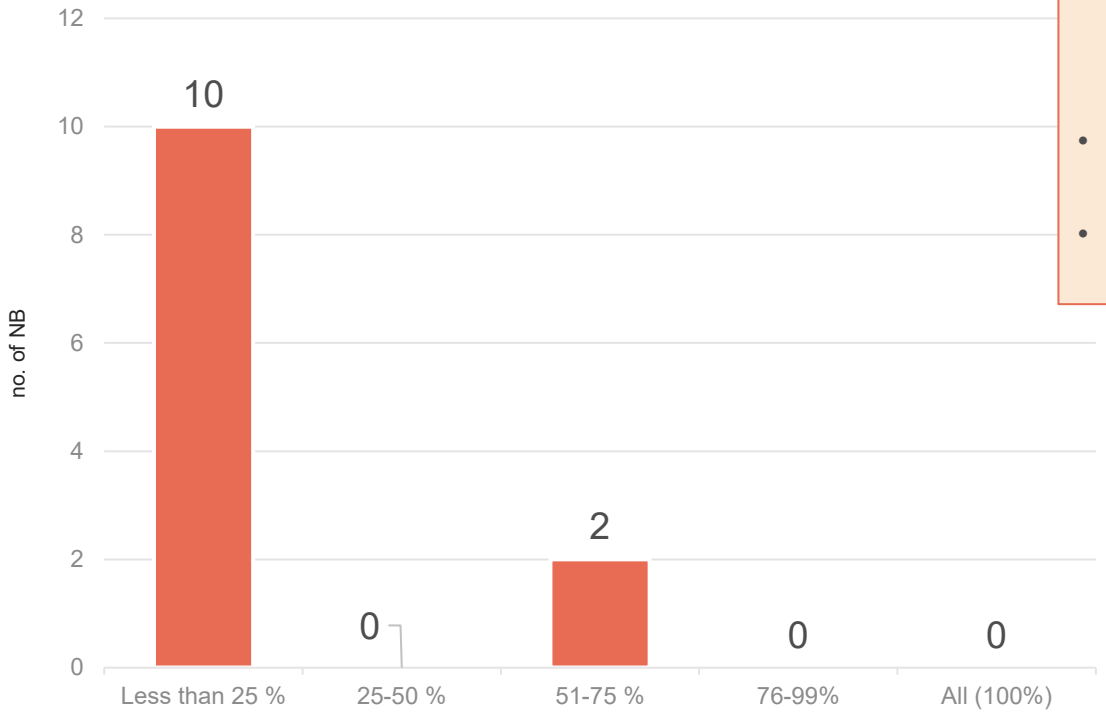
*Definition SME: The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.'
(Source: Extract of Article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

European Commission

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

IVD

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

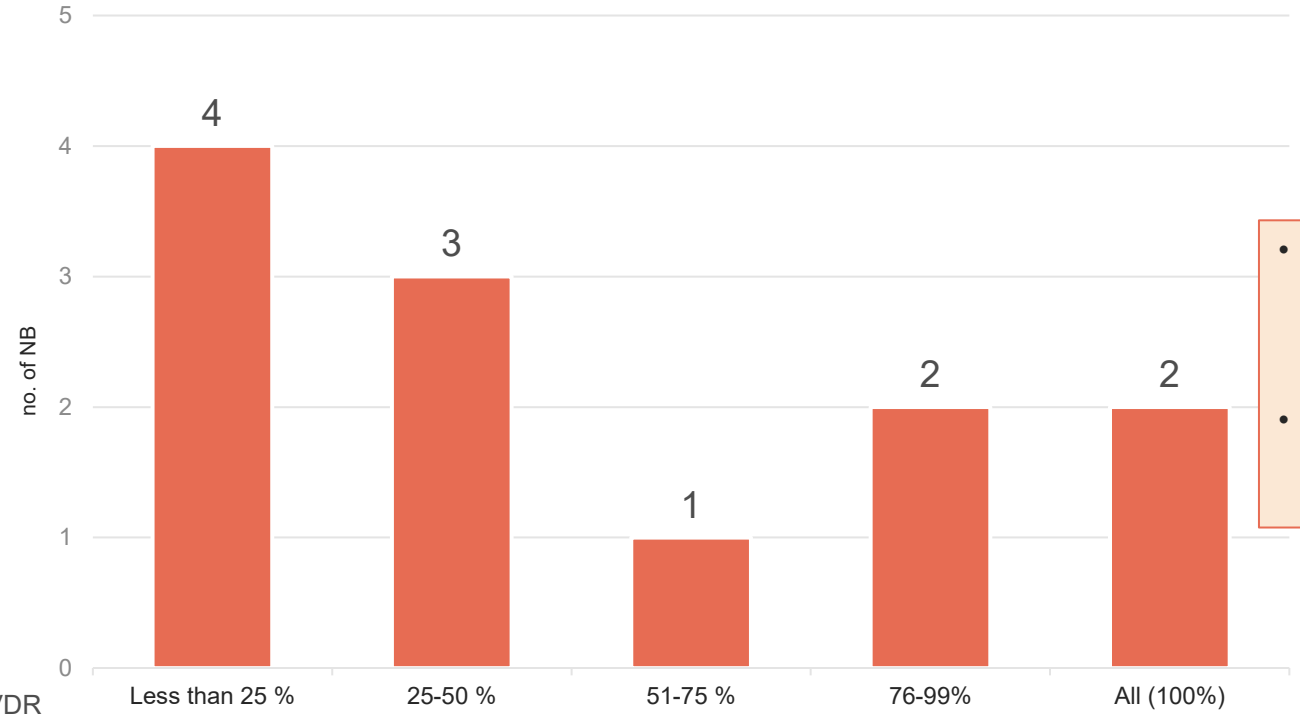
Data of 12 NBs designated under IVDR

European Commission

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

IVD

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

European Commission

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

IVD

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. IVR 0301 Devices intended to be used in screening, diagnosis, staging or monitoring of cancer, IVR 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

IVD

MD

4. Staff

Note:

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

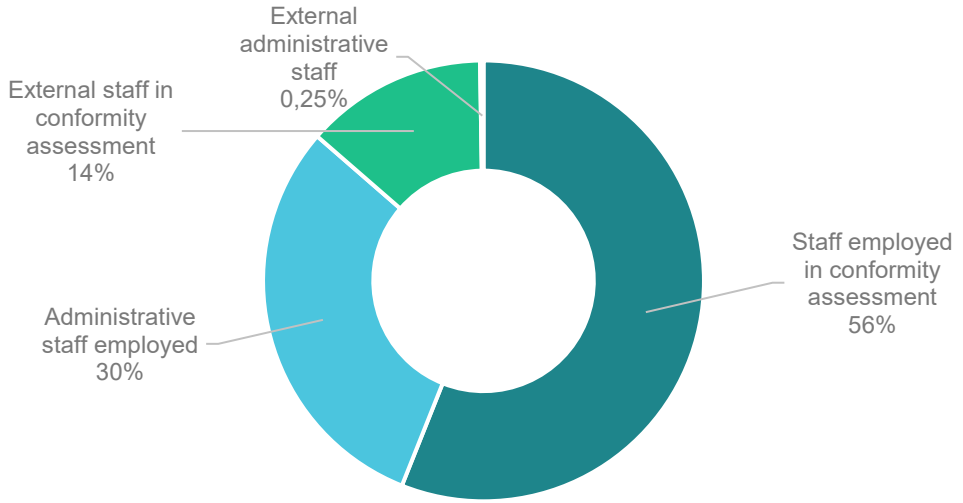
  Ⓢ The **small dataset** is a small set of questions (6 indicators) asked to notified bodies **every two months.**
  Note: From April to July 2023, it was asked monthly.
  Ⓜ The **medium dataset** is a set of questions asked to notified bodies **every four months** concerning the activities they have 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/AIMDD/MDD & IVDR/IVDD)

MD

IVD

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.

European Commission

Thank you

Contact for questions: medical.devices@goeg.at

European Commission