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

Survey results with data status 30 June 2023 **(medium and small dataset)**

25 October 2023

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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- Some data may still need validation check and might change.

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* The **small dataset** is a small set of questions (6 indicators) asked to notified bodies every two months (from April to July 2023 it was asked monthly) and 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.

1. About the study and survey

- Study supporting the monitoring of availability of medical devices on the EU market
- List of abbreviations
- Preliminary notes on the survey
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- 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

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
IVD	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)
MD	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)
NB	Notified body
NANDO	New Approach Notified and Designated Organisations
QMS	Quality Management System

Preliminary notes on the survey conducted in July 2023

About

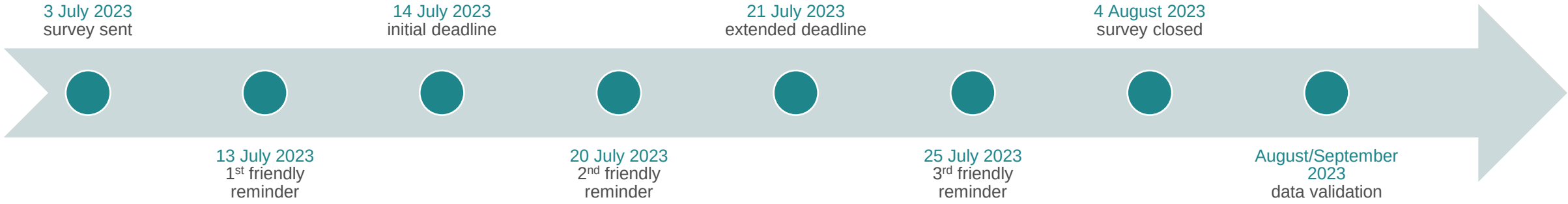
- **Data content:**
  - The following slides show the results of the survey **conducted at the beginning of July 2023** with **requested data** from notified bodies designated under MDR/IVDR **until 30 June 2023**.
  - These **survey results** are also **compared** with **previous survey data** (see data sources).
- **Data sources:**
  - Data collected between March and July 2023 by the study team
  - Data collected between February 2021 and October 2022 by the European Commission

Timeline for the survey conducted in July 2023 (data was requested until 30 June 2023)

About

39 notified bodies designated under MDR and/or IVDR
(Data status: 30 June 2023)

Final result
39 responses
(100% response rate)



Note: *Out of 39 notified bodies,* ***29 NBs*** *are designated under the* ***MDR****,* ***9 NBs*** *are designated under* ***both the MDR and IVDR****, and* ***one NB*** *is designated under the* ***IVDR only****.*

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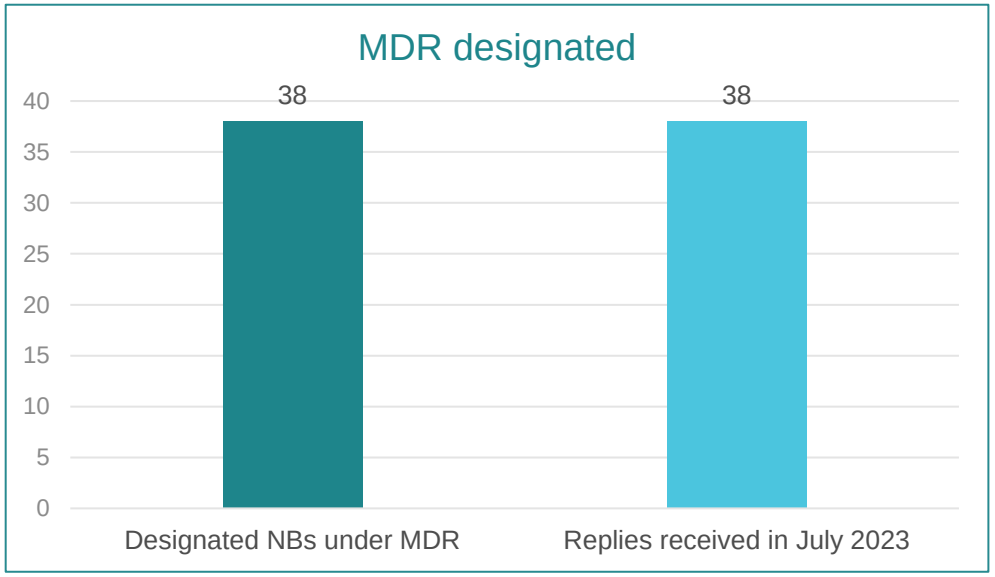
Response rate for the survey conducted in July 2023 (data was requested until 30 June 2023)

About

39 out of 39 notified bodies replies received (100% response rate)

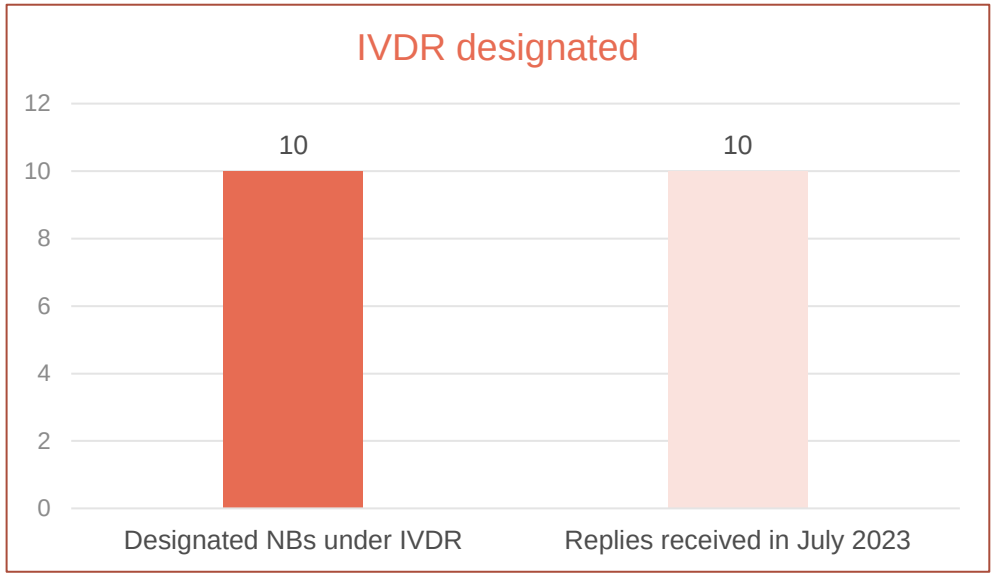
Note: *Out of 39 notified bodies,* ***29 NBs*** *are designated under the* ***MDR****,* ***9 NBs*** *are designated under* ***both the MDR and IVDR****, and* ***one NB*** *is designated under the* ***IVDR only****.*

MD



100% response rate

IVD



100% response rate

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MD

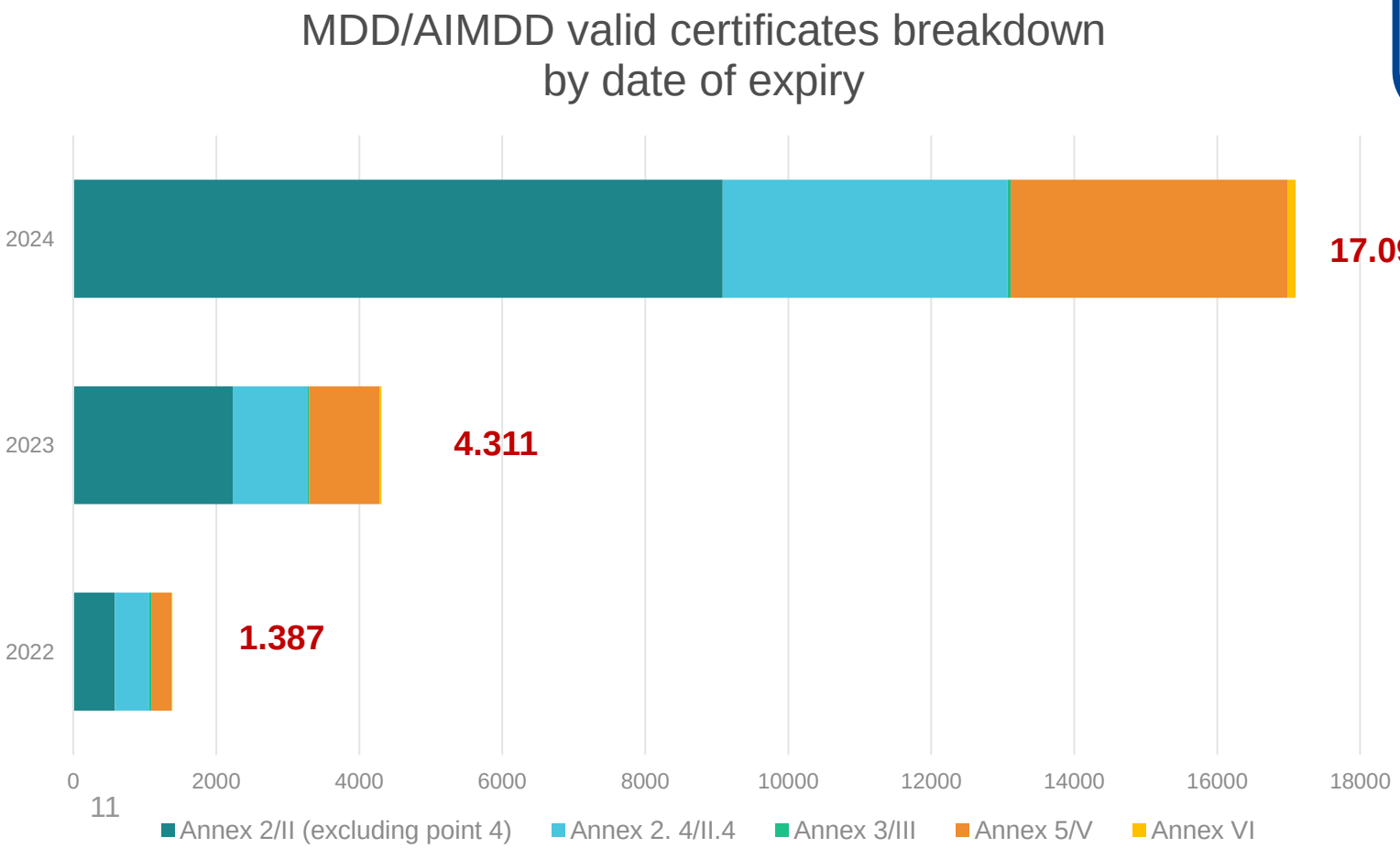
2. Survey results for medical devices

Note:

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

MDD/AIMDD Certificates
(data status: October 2022)

MD



MDD/AIMDD Data
Data from survey of October 2022

AIMDD designated	**16 replies out of 18 NBs**
MDD designated	**45 replies out of 49 NBs**

Total valid MDD/AIMDD certificates (*excluded Annex 4/IV): 22.793****

** Annex 4/IV certificates: 363*
*** 24.073 in April 2022*

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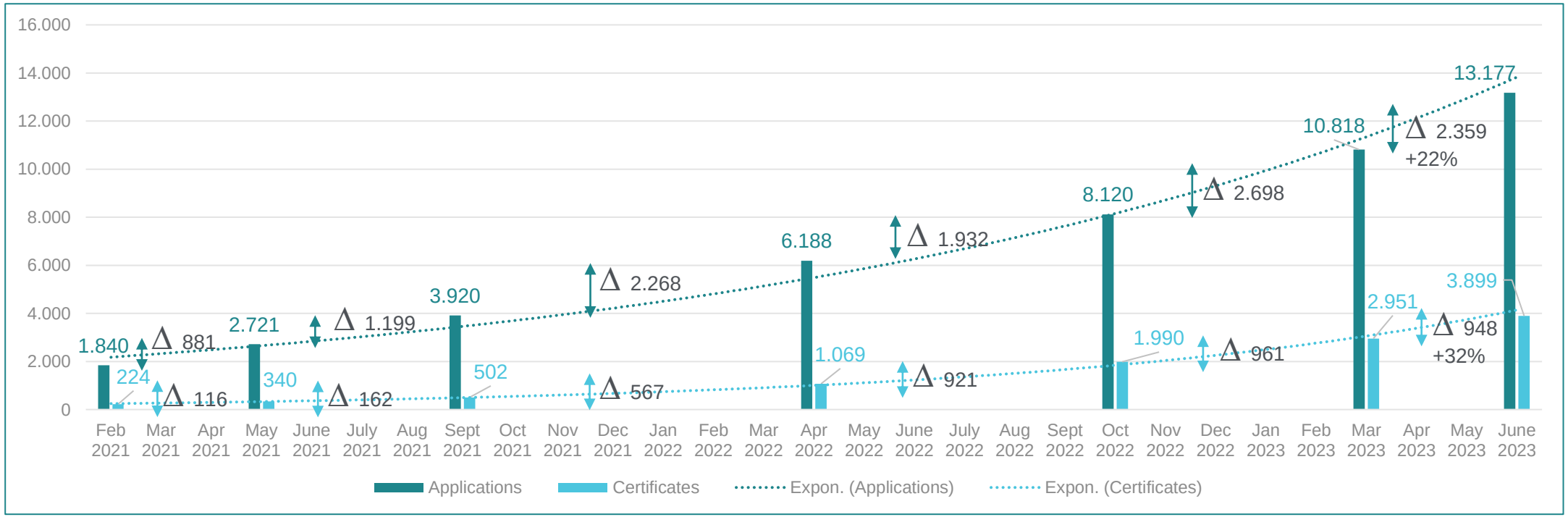
MDR applications filed and certificates issued

MD

Medium dataset

June 2023
MDR Applications: 13.177
MDR Certificates: 3.899



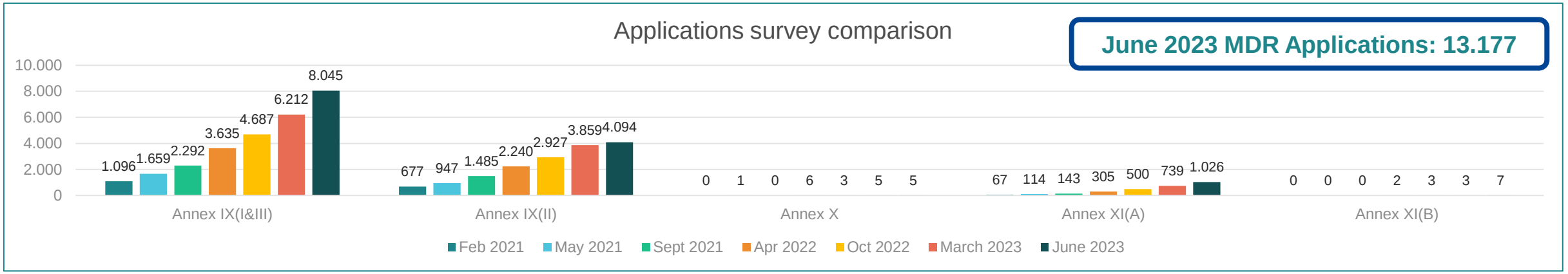
Notes: June 2023: Designated NBs for MD: 38; NBs that included Annex XVI products in the numbers provided: 9

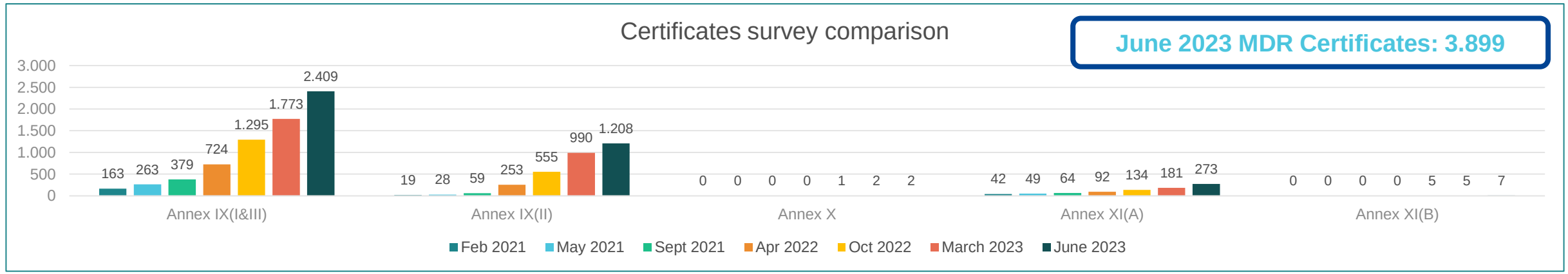
- Δ (Delta) = Difference in MDR Applications / MDR Certificates from one survey to the next one
- **Applications lodged**: This number includes **all applications lodged (syn. filed) so far** according to MDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in NANDO to the date of the survey up to 30/06/2023), 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 30/06/2023) under the MDR.

MDR applications and certificates by annex survey comparison

MD

Medium dataset





Notes:

- Designated NBs for MD: 38; NBs that included Annex XVI products in the numbers provided: 9
- **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 NANDO to the date of the survey up to 30/06/2023), 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 30/06/2023) under the MDR **by annex**.

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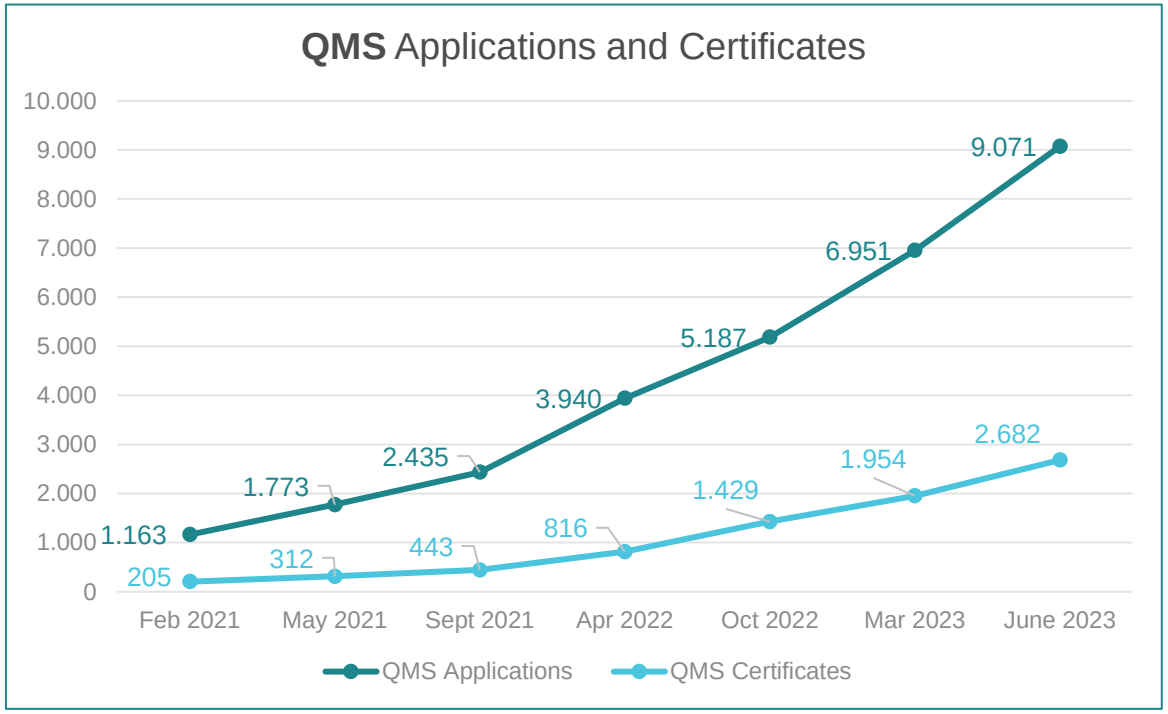
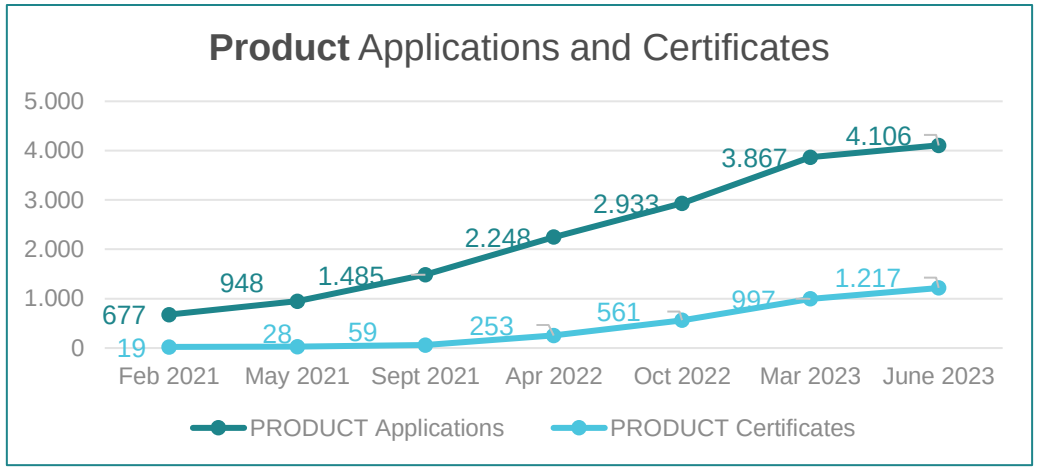
MDR applications and certificates by type (QMS vs Product) – survey comparison

MD

Medium dataset

June 2023
MDR Applications: 13.177
MDR Certificates: 3.899





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.

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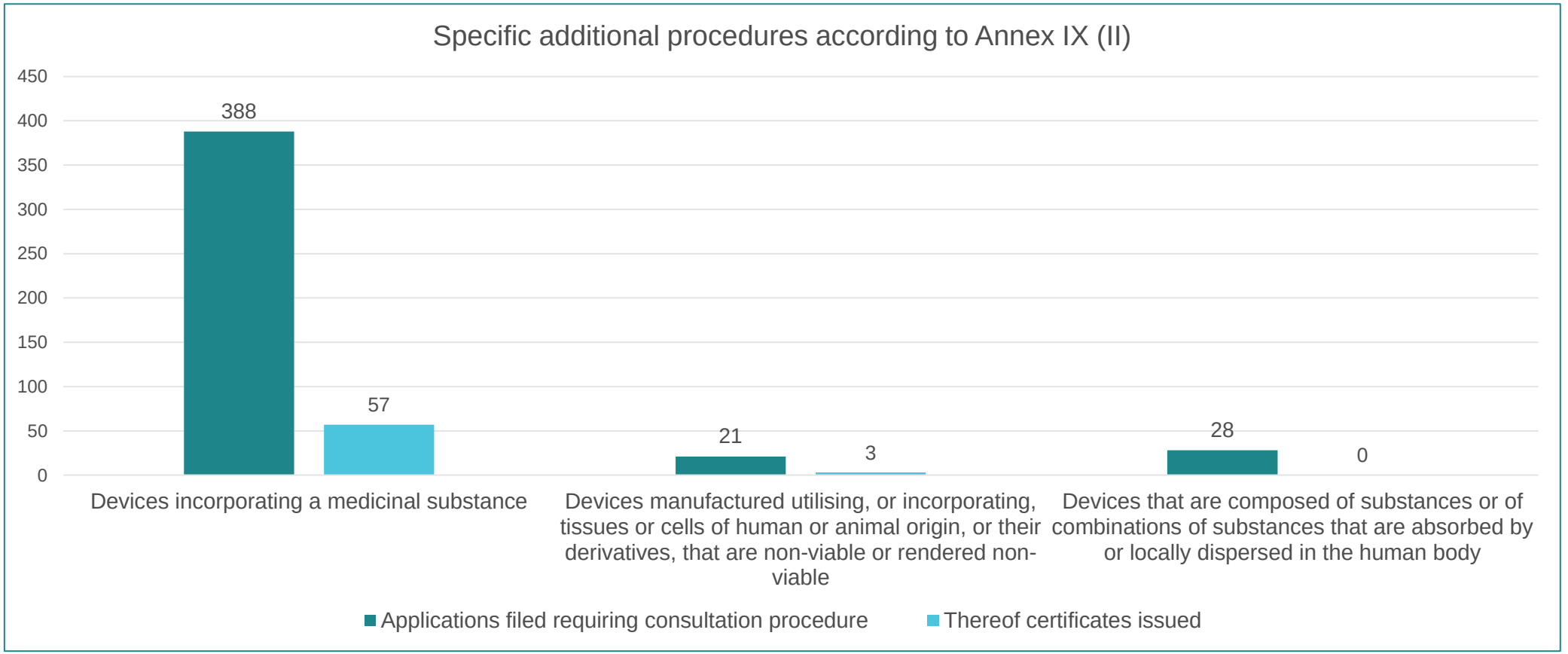
Specific additional procedures according to Annex IX (II)

MD

Medium dataset

June 2023
MDR Applications: 13.177
MDR Certificates: 3.899



European Commission

Total number of applications lodged for changes, average timeframe to written agreement signed

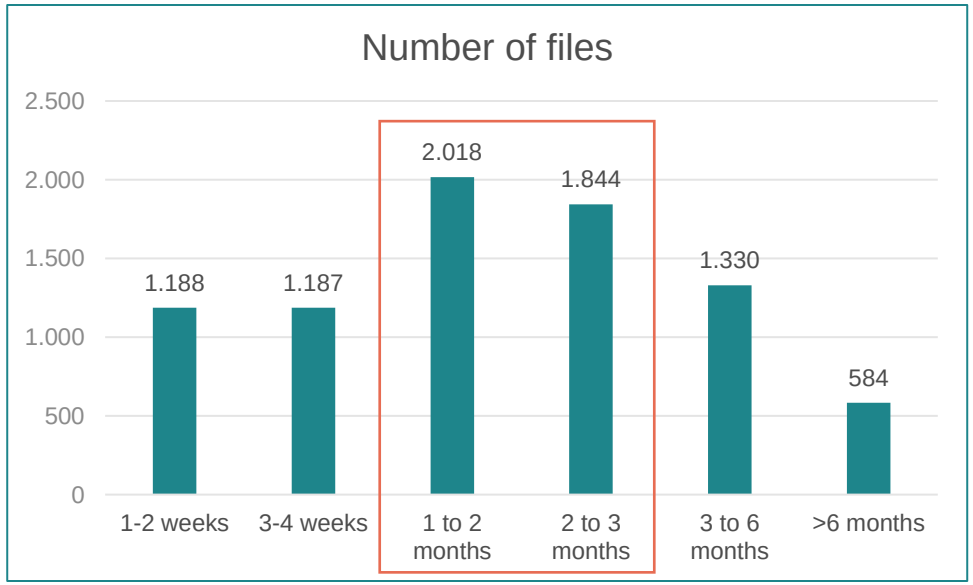
MD

Medium dataset

Total number of applications lodged for changes received for already MDR issued certificates: 1.208

June 2023 MDR Applications: 13.177

Average timeframe between application lodged and written agreement signed:



On average it takes **1 to 3 months** from an application lodged to a written agreement signed

Note: Data of 34 notified bodies

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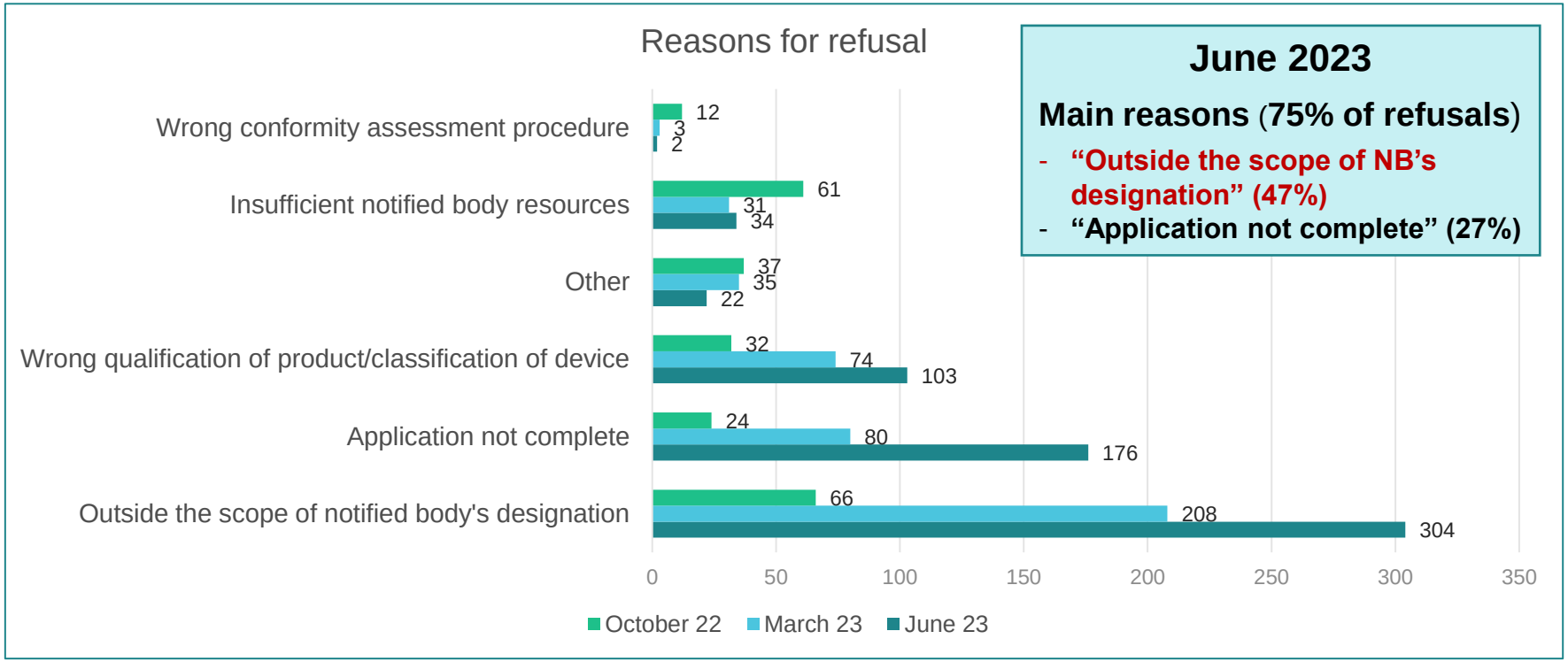
MDR applications - reason for refusal

MD

Medium dataset



June 2023

Main reasons (75% of refusals)

- **"Outside the scope of NB's designation" (47%)**
- **"Application not complete" (27%)**

Total number of MDR applications:
October 2022: 8120
March 2023: 11.418
June 2023: 13.177

Application refusals*:
October 2022: 232
March 2023: 431
June 2023: 641

Notes:

- Comparison of reasons for refusal in October 2022, March 2023 and June 2023
- * Applications can have multiple reasons for refusal
- 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"

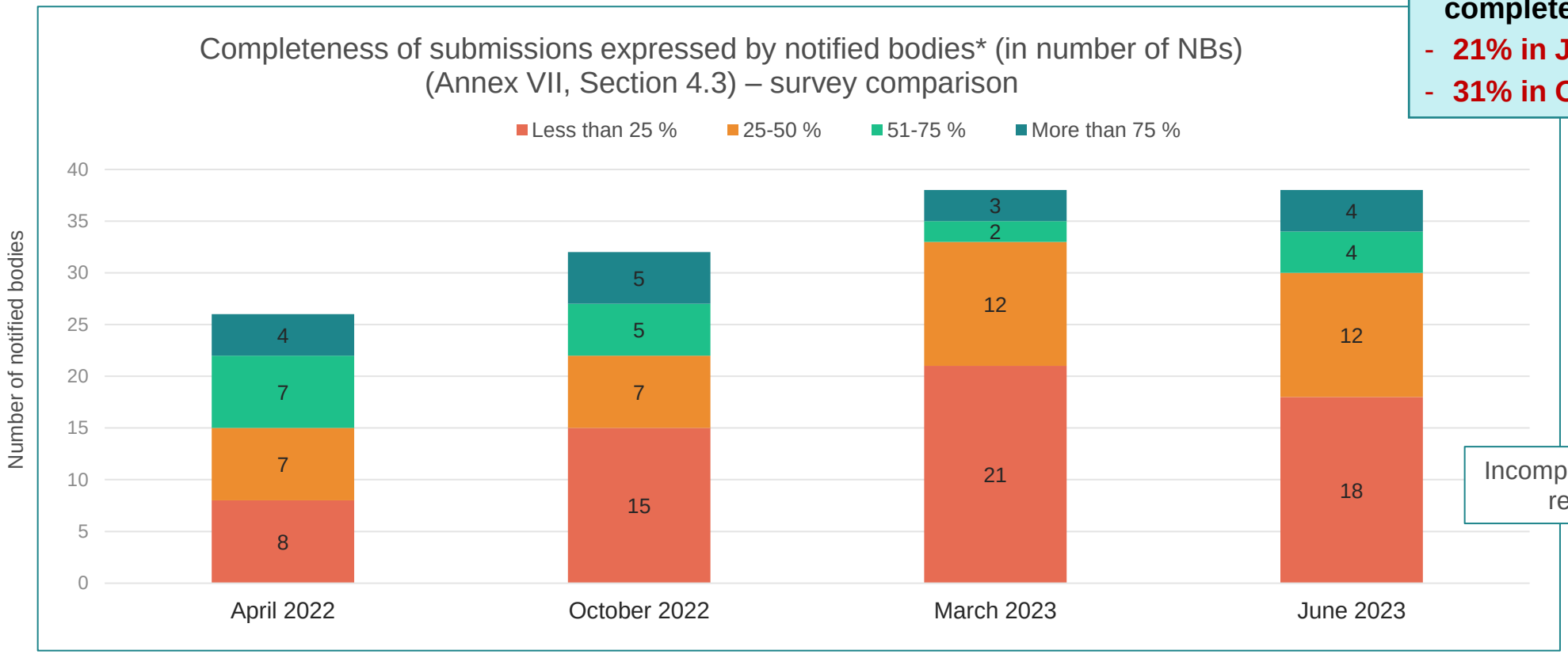
MD

Medium dataset

Completeness of submissions

% of submissions with completeness rate > 50%

- **21% in June 2023**
- **31% in October 2022**



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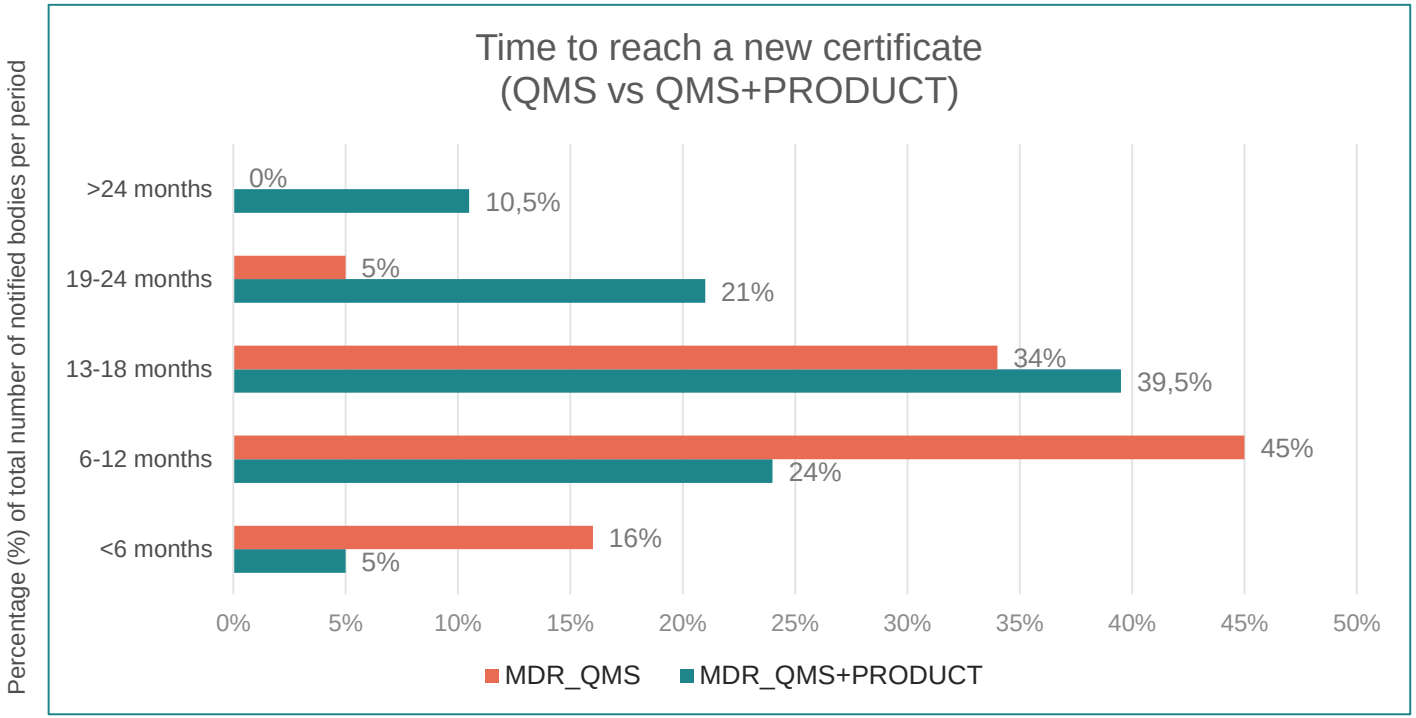
Time to reach a new certificate (QMS vs QMS+PRODUCT)

MD

Medium dataset

June 2023
MDR Applications: 13.177
MDR Certificates: 3.899



MDR QMS certificates:

- **For 45 % of NBs: 6-12 months to issue a new QMS certificate**
- **For 39 % of NBs: ≥ 13 months (max: 24 months)**

MDR QMS+PRODUCT certificates: longer time

- **For 40% of NBs: 13-18 months to issue a new product certificate**
- **For 71% of NBs: ≥ 13 months**

Notes:

- This indicator shows the time to reach issuance of a new EC certificate (from written agreement signed to issuance) under MDR.
- One NB stated that the learning curve leads to a slight reduction of time frames, another NB mentioned that the time is increasing.
- One NB mentioned that major impact comes from assessment postprocessing, CAPA closure, etc.
- 6 NBs mentioned that this question is not applicable for them and/or they have not issued a certificate yet; one out of these 6 NBs stated that estimates were indicated.
- One NB stated that for QMS-only certificates the usual timeframe is shifted towards the 12-month mark.

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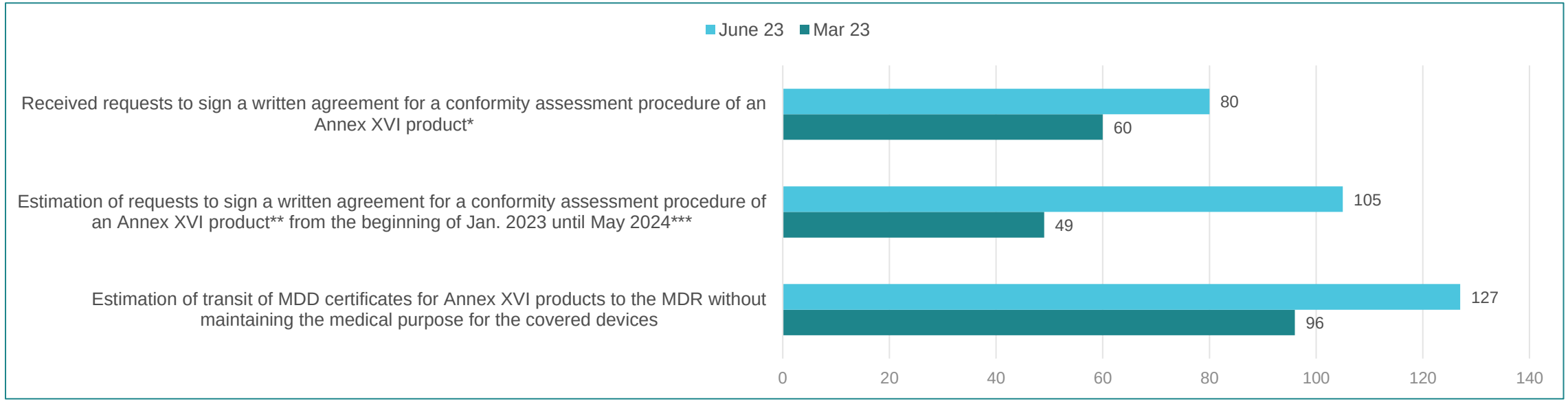
Questions on Annex XVI products

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

MD

Medium dataset



Notes:

* in accordance with the condition established in **Article 2(2) of Regulation (EU) 2022/2346**:
„A product for which the manufacturer does not intend to perform a clinical investigation, but in the conformity assessment of which a notified body has to be involved"

** in accordance with the condition established in **Article 2(1) of Regulation (EU) 2022/2346**:
"A product for which the manufacturer intends to perform, or is performing, a clinical investigation to generate clinical data for the clinical evaluation"

*** Regulation (EU) 2023/1194 amended the CS and the timeframes for the transitional periods have changed from 2024 to 2027.

- June 2023: 16 out of 38 NBs have "0" entered everywhere.

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Questions on Annex XVI products

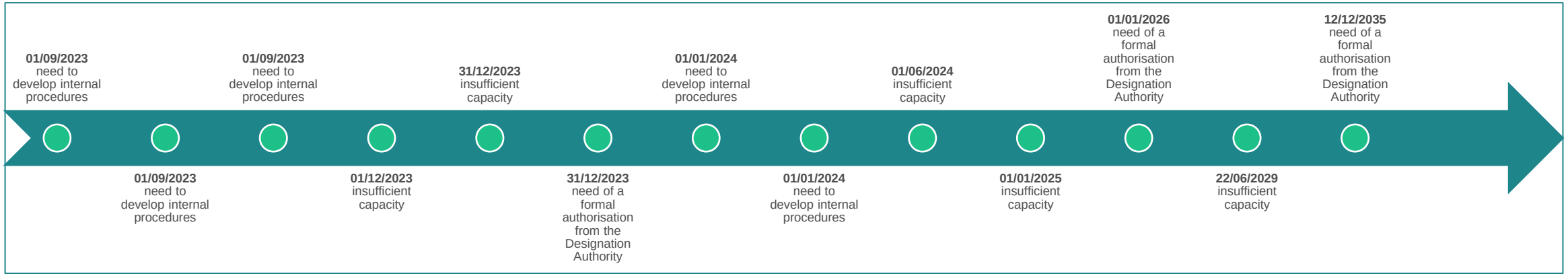
(products with no intended medical purpose that fall under the scope of the MDR)

MD

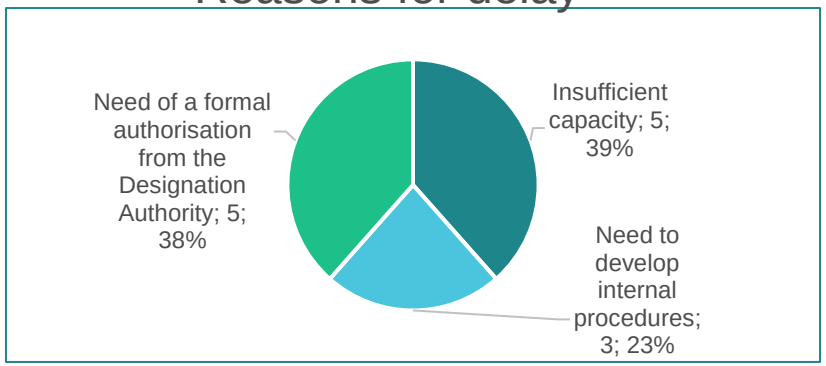
Medium dataset

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

- **25 out of 38** notified bodies can already work on Annex XVI products from 22 June 2023 on
- **13 out of 38** notified bodies have stated **another date** and the reason for delay



Reasons for delay



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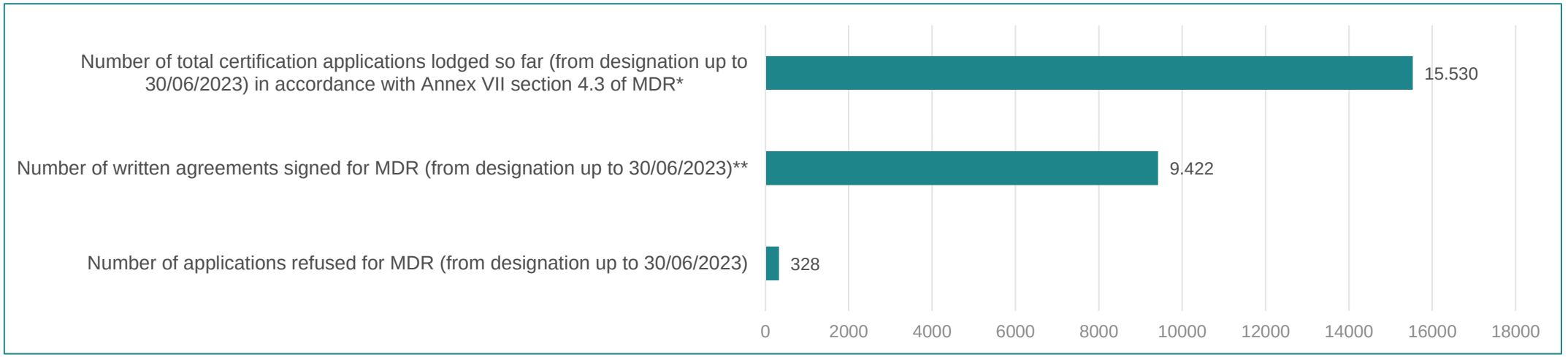
MDR applications filed and refused, written agreements signed

MD

Small dataset



Notes:

- **Designated NBs for MD:** 38
- *** 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 NANDO to the date of the survey up to 30/06/2023), 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.

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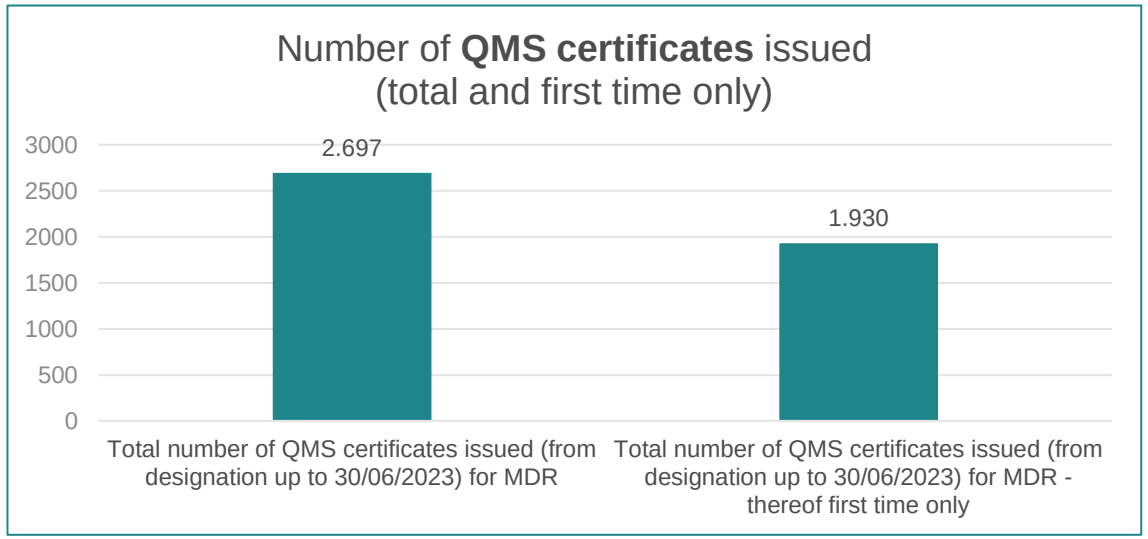
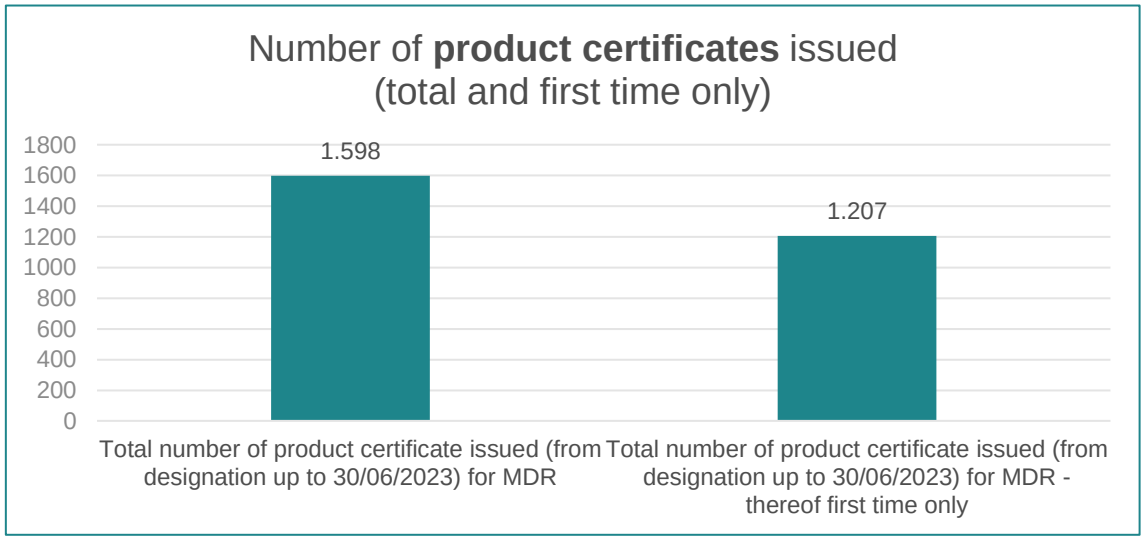
MDR number of QMS / product certificates issued

MD

Small dataset





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.

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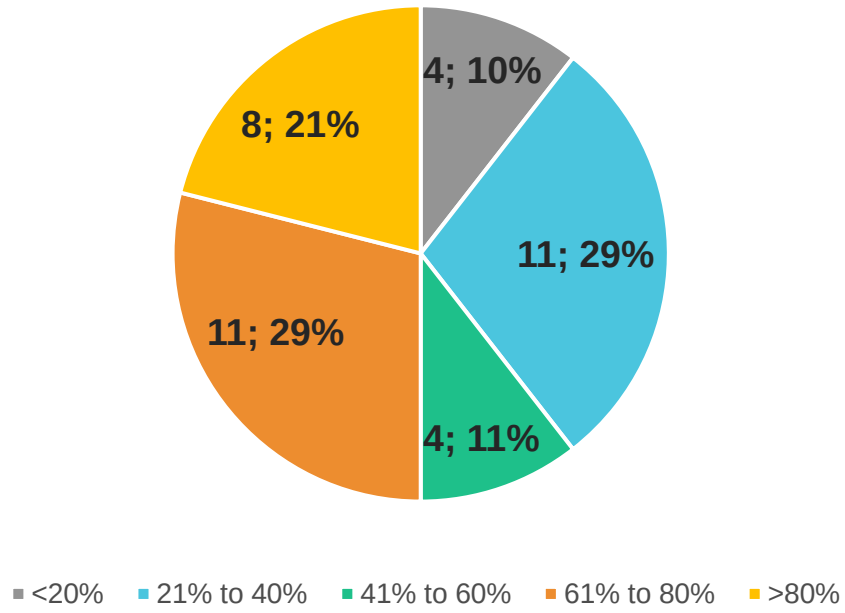
MD

Small dataset

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



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%

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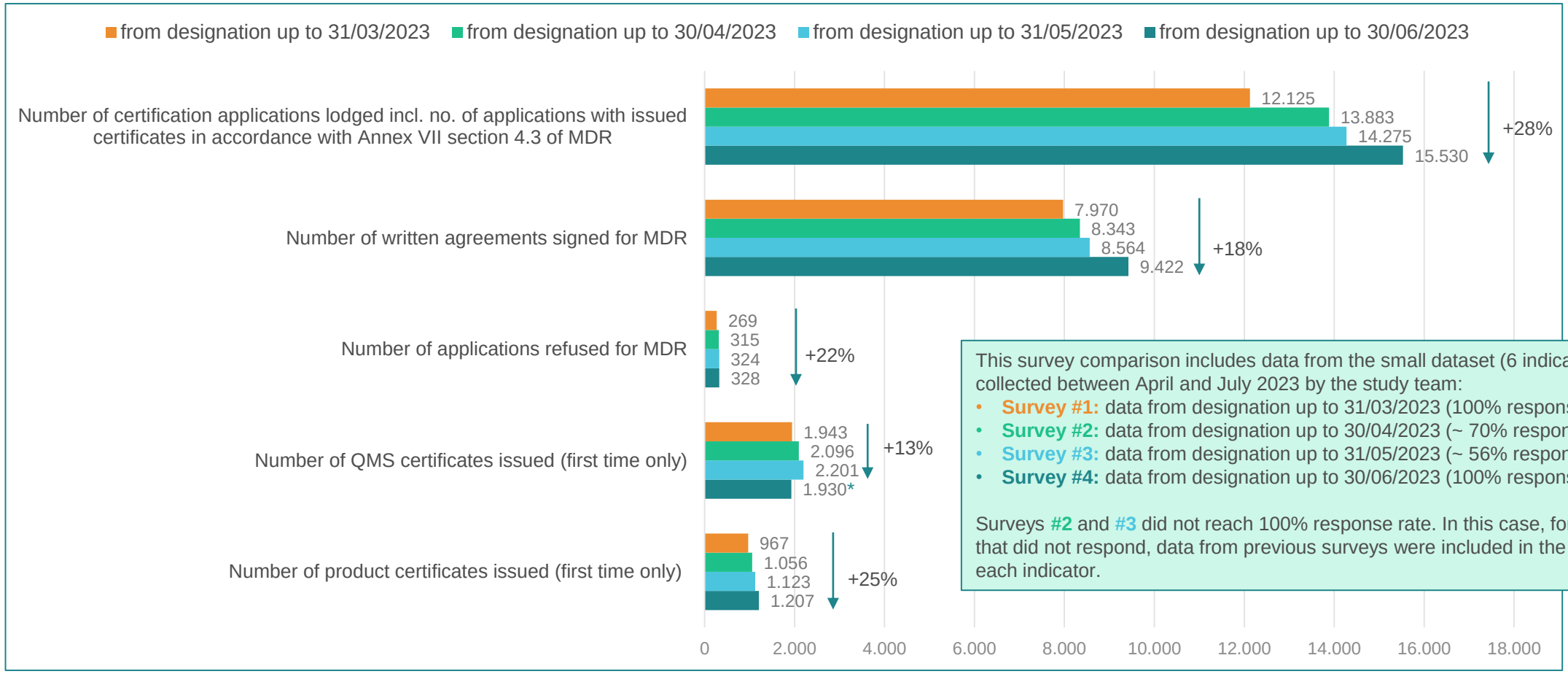
Survey comparison – March to June 2023
6 indicators

MD

Small dataset



This survey comparison includes data from the small dataset (6 indicators) collected between April and July 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)

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 four survey rounds: 38; 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.

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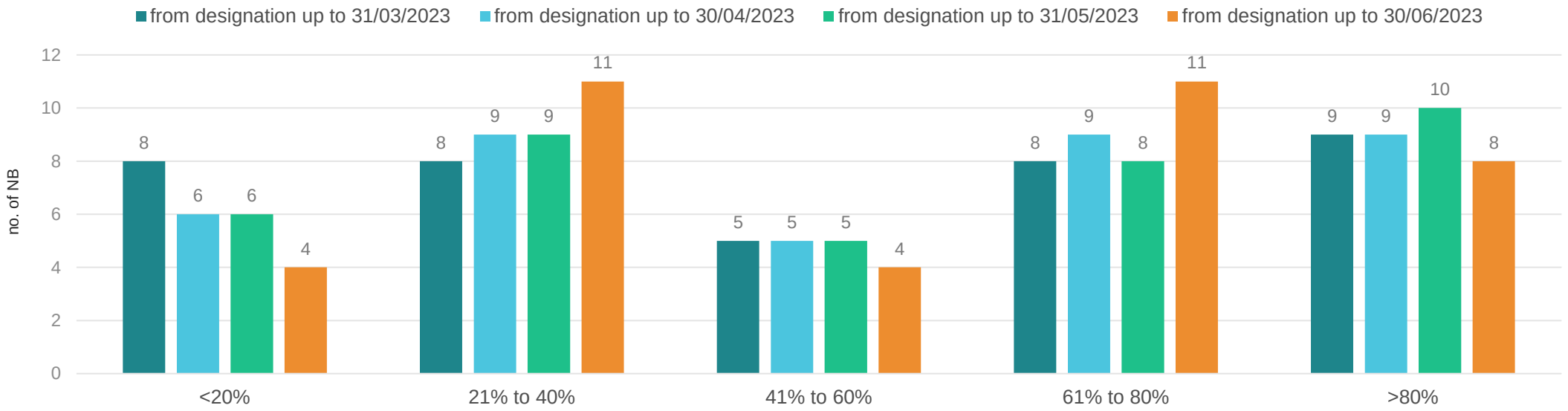
Survey comparison – March to June 2023
Estimation - Scope of the (AI)MDD certificates covered by MDR applications (on average)

MD

Small dataset



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=> so average % = 31% => between 21% and 40%

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IVD

3. Survey results for in vitro diagnostic medical devices

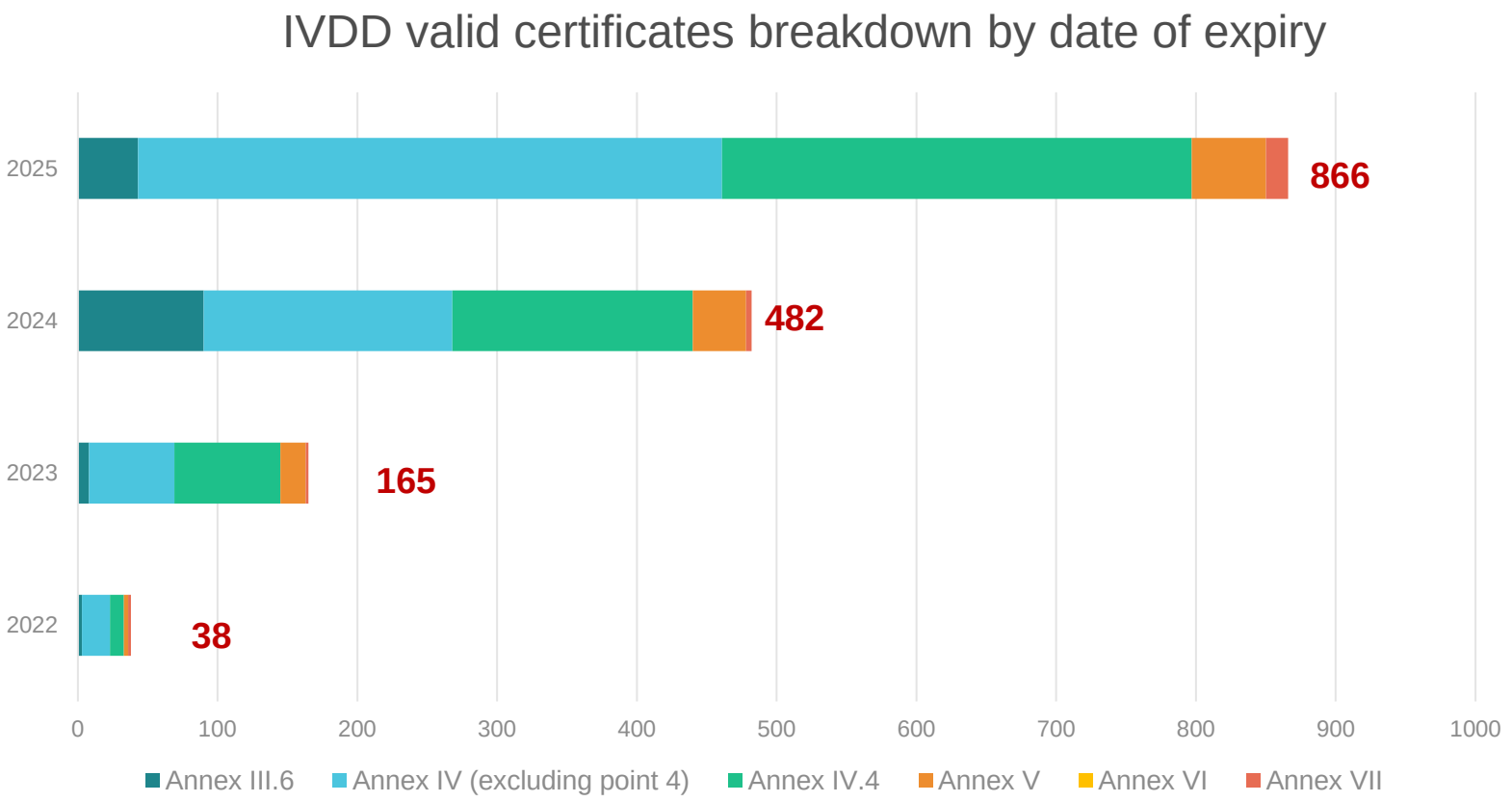
Note:

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

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

IVD

Medium dataset



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

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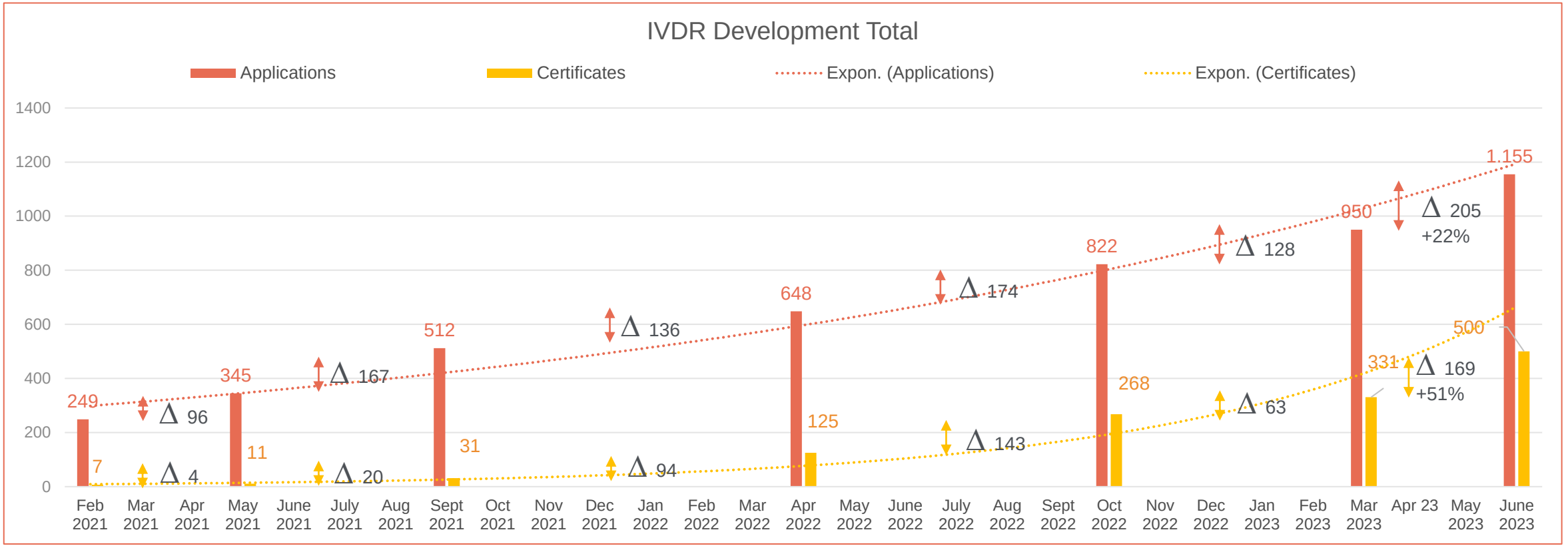
IVDR applications lodged and certificates issued

IVD

Medium dataset

June 2023
IVDR Applications: 1.155
IVDR Certificates: 500



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 NANDO to the date of the survey up to 30/06/2023), 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 30/06/2023) under the IVDR.

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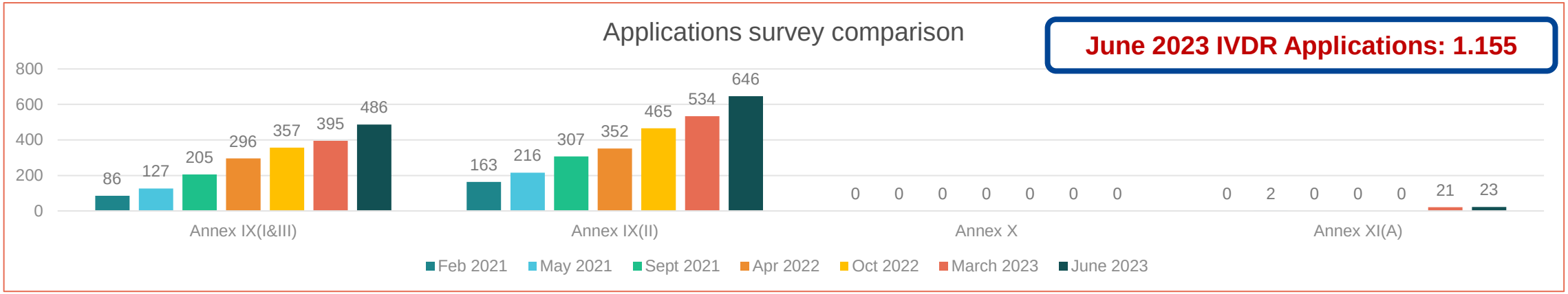
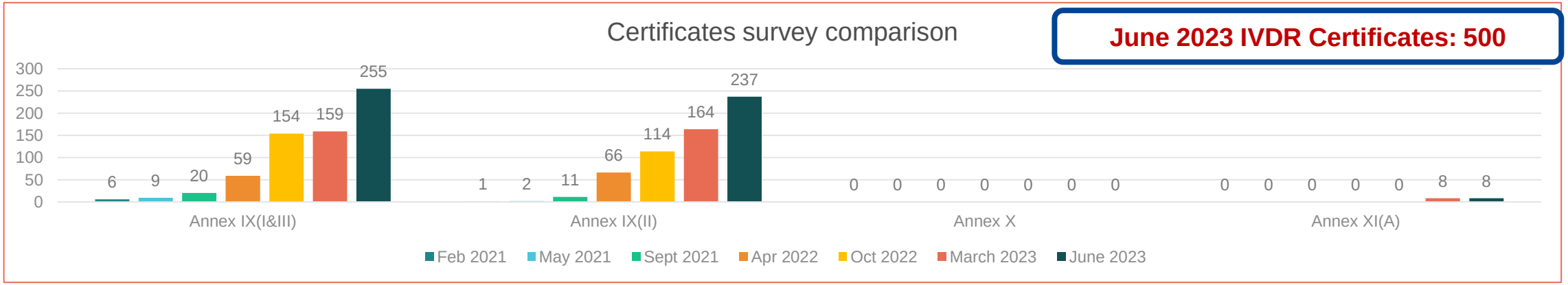
IVDR applications and certificates by annex surveys comparison

IVD

Medium dataset





Notes:

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- **Certificates issued by annex:** This number includes **certificates issued so far** (from designation up to 30/06/2023) under the IVDR **by annex**.

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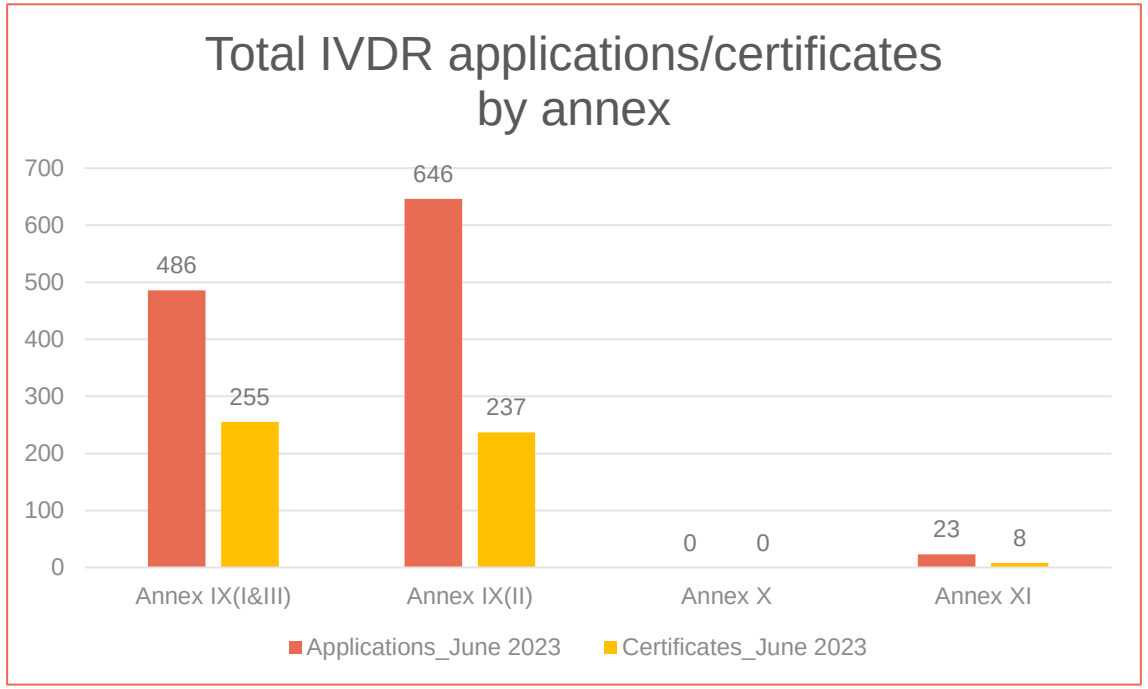
IVDR applications and certificates by annex

IVD

Medium dataset

June 2023
IVDR Applications: 1.155
IVDR Certificates: 500



Notes:

- **Applications lodged by annex:** This number includes all applications lodged (syn. filed) by annex according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in NANDO to the date of the survey up to 30/06/2023), 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 30/06/2023) under the IVDR by annex.
- **Class D devices** are **included** in the total number of applications/certificates.

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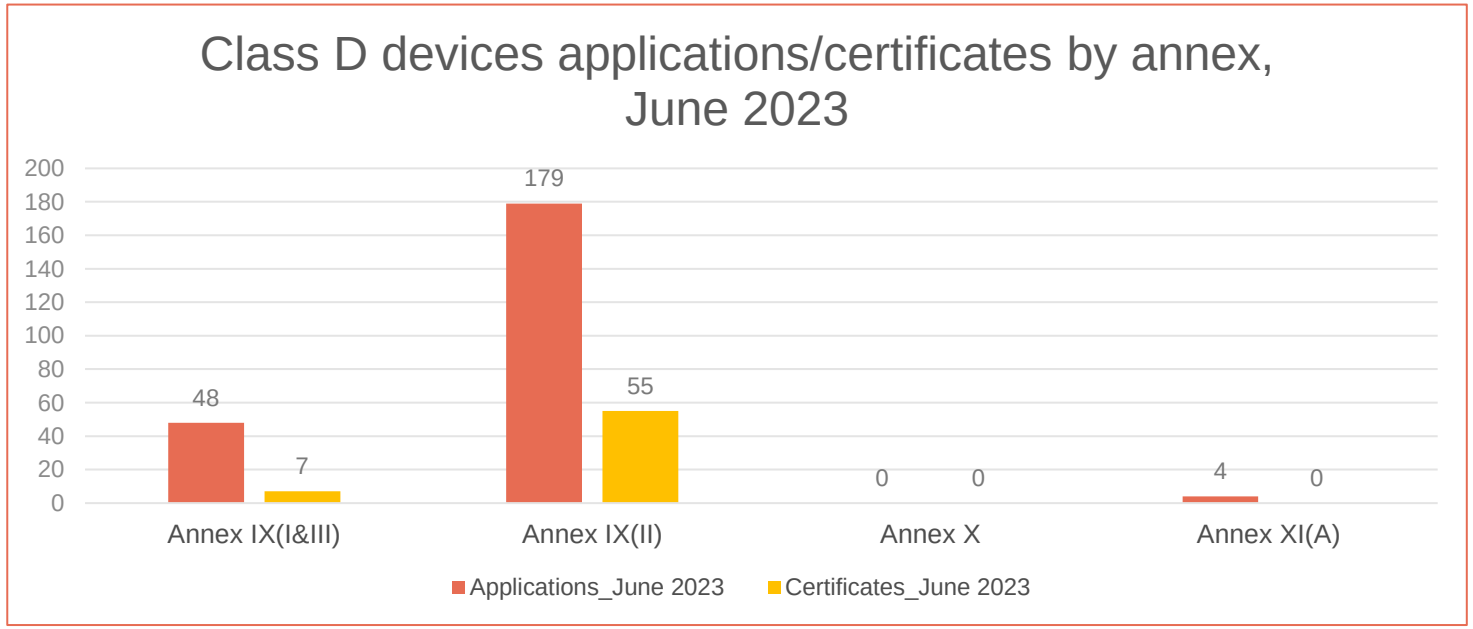
Class D devices applications and certificates

IVD

Medium dataset



June 2023
IVDR Applications: 1.155
IVDR Certificates: 500

June 2023:
Class D devices Applications: 231
Class D devices Certificates: 62

Notes:

- **Applications lodged by annex:** This number includes all applications lodged (syn. filed) by annex according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in NANDO to the date of the survey up to 30/06/2023), 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 30/06/2023) under the IVDR by annex.

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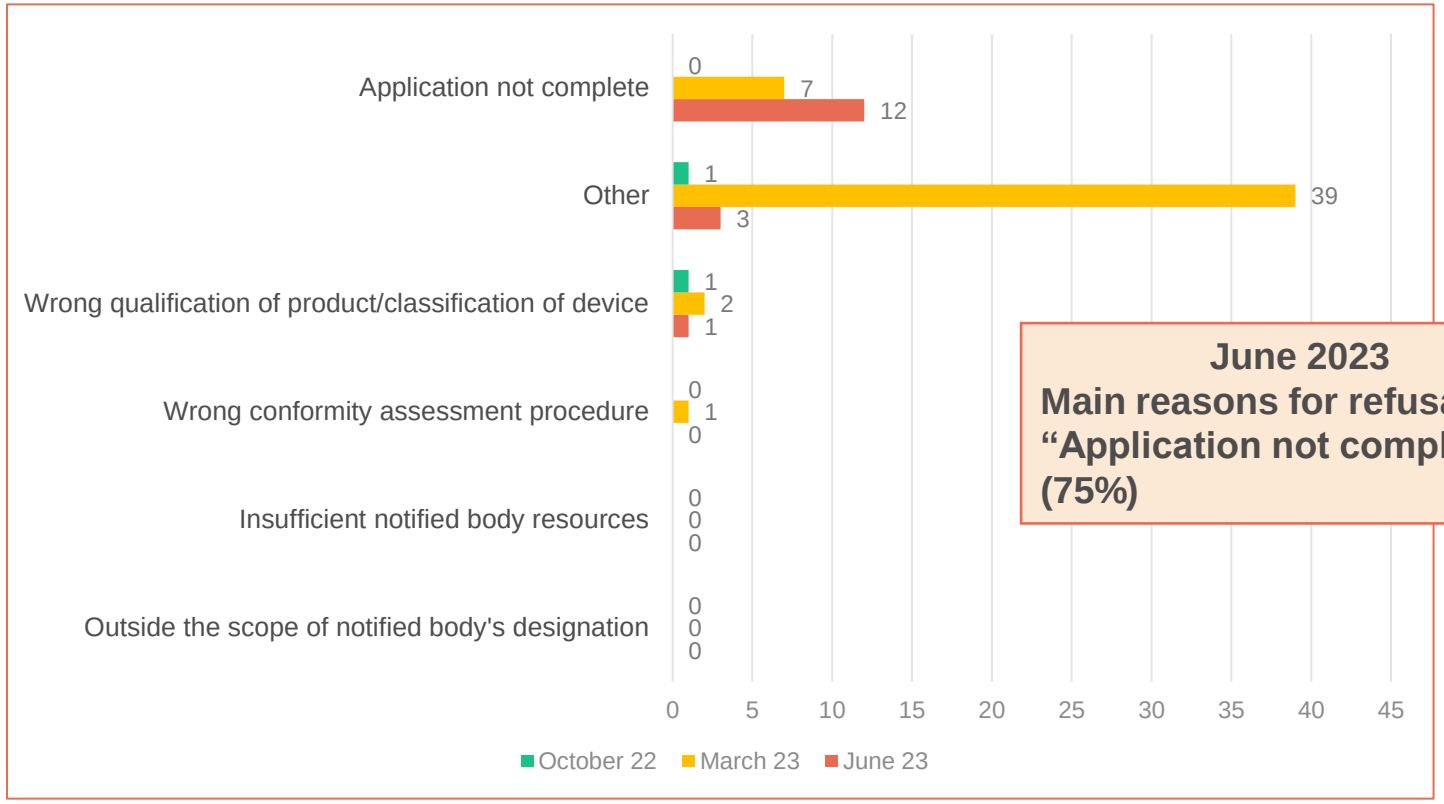
IVD

Medium dataset

IVDR applications - reason for refusal



June 2023
Main reasons for refusals: "Application not complete" (75%)

June 2023
IVDR Applications: 1.155
IVDR Certificates: 500

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

Notes:

- This graph compares the total number of applications that have been refused under IVDR by reason of refusal in October 2022, March 2023 and June 2023.
- Applications can have multiple reasons for refusal.
- March 2023:
  - Data were entered by **one** notified body only.
  - "Other" reasons: "application withdrawn by the manufacturer (not yet ready for the IVDR, due to economic reasons,…)"
- June 2023:
  - Data were entered by **two** notified bodies only.
  - "Other" reasons: "nonconformities not solved", "withdrawal of client", "assessment resulted in negative outcome"

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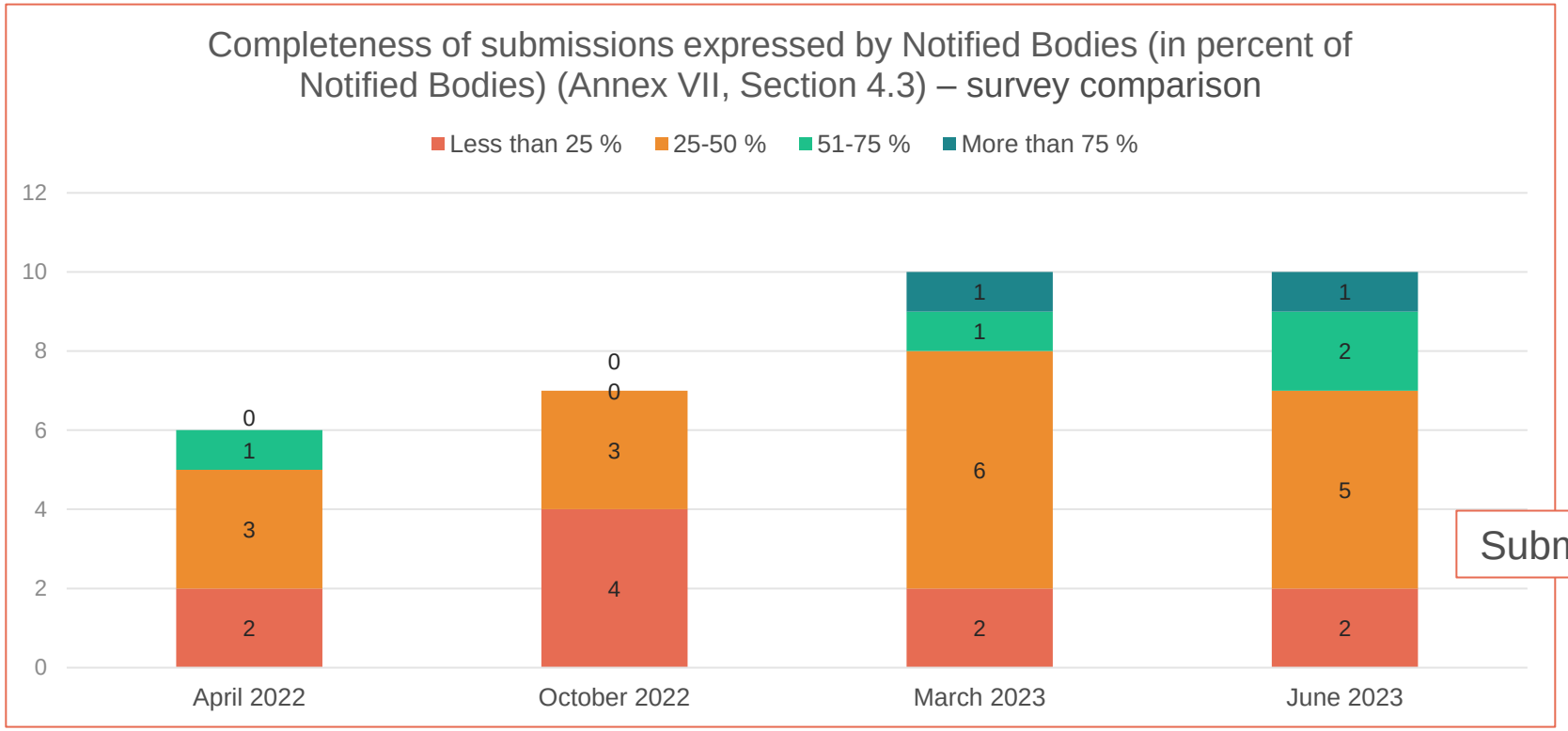
Completeness of submissions

IVD

Medium dataset



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

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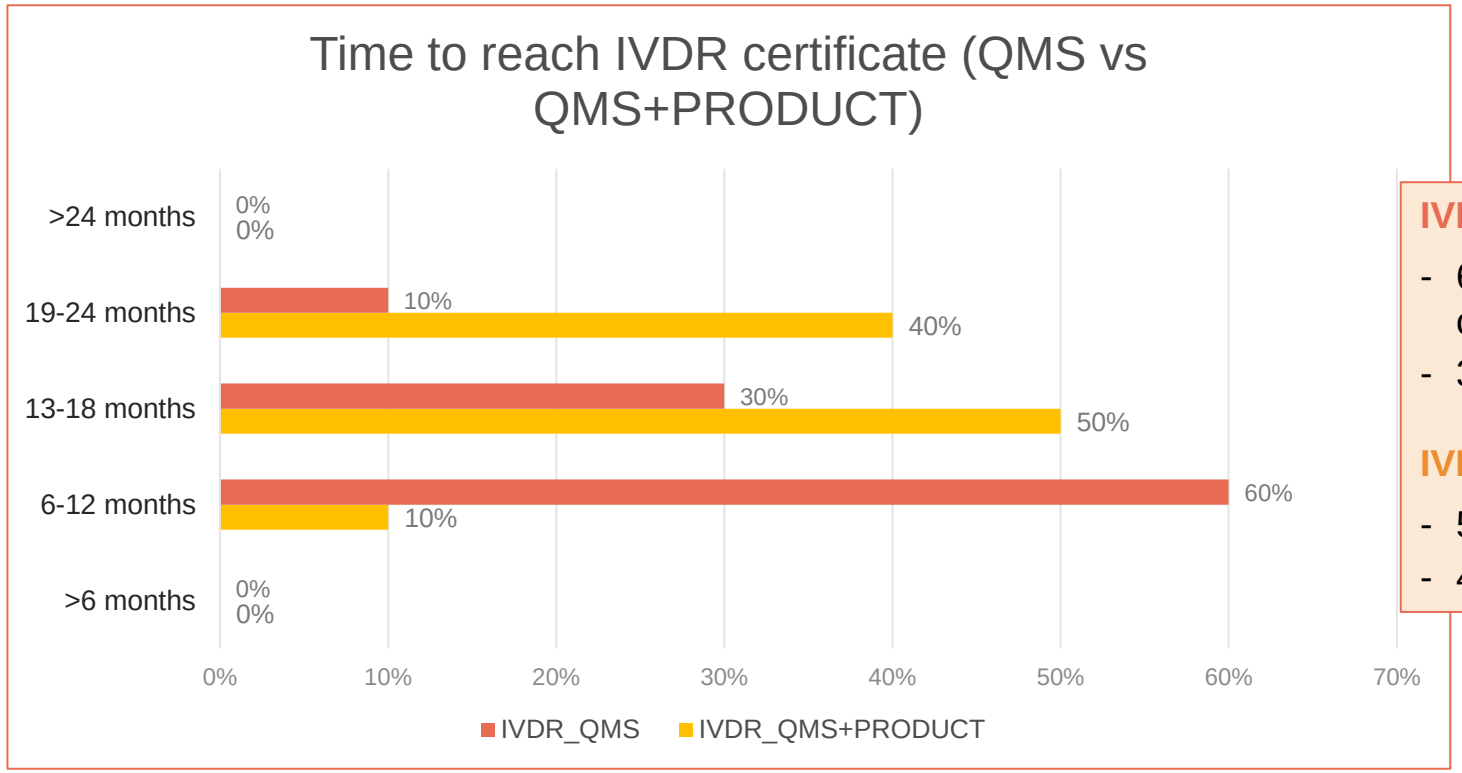
Time to reach a certificate

IVD

Medium dataset



June 2023
IVDR Applications: 1.155
IVDR Certificates: 500

IVDR QMS certificates

- 60% of NBs: 6-12 months to issue a new QMS certificate
- 30% of NBs: 13-18 months

IVDR QMS+PRODUCT certificates: longer time

- 50% of the NBs: 13-18 months
- 40% of NBs: 19-24 months

Notes:

- This indicator shows the time to reach issuance of a new EC certificate (from written agreement signed to issuance) under IVDR.
- One NB stated that it expects the required time for IVDR certification to go down over time.
- One NB mentioned that the time period depends on the quality of the file and there is a lot of variation in quality between the manufacturers.
- One NB has currently no certificates issued.

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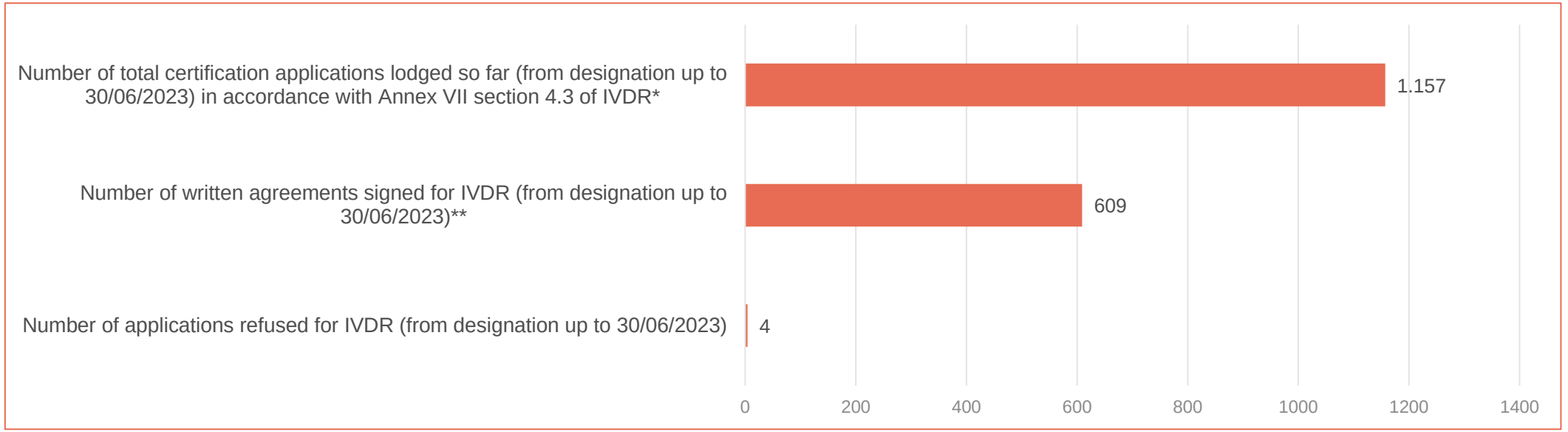
IVDR applications filed and refused, written agreements signed

IVD

Small dataset



Notes:

- **Designated NBs for IVD:** 10
- *** 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 NANDO to the date of the survey up to 30/06/2023), 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.

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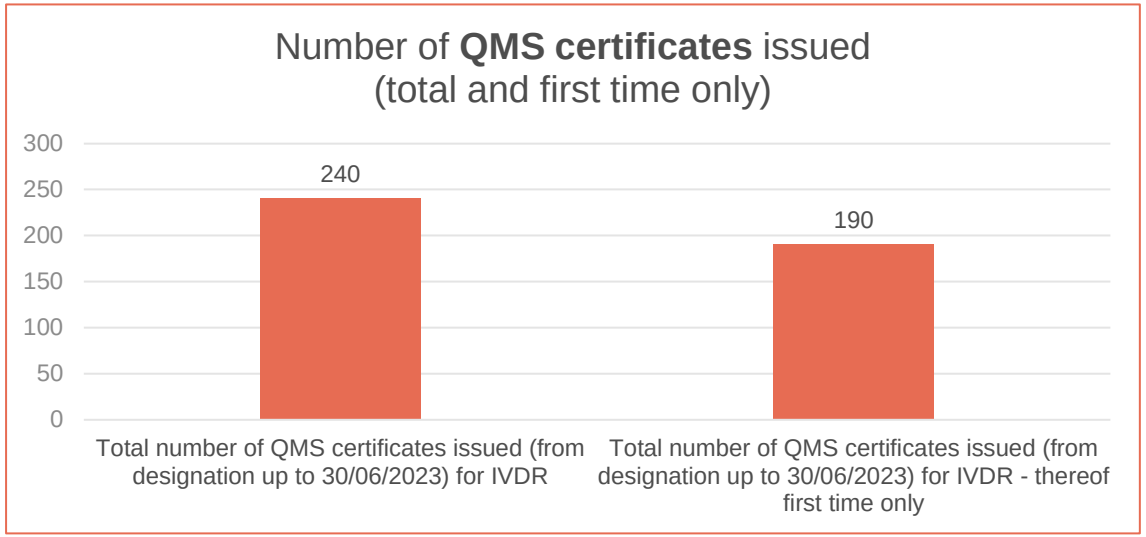
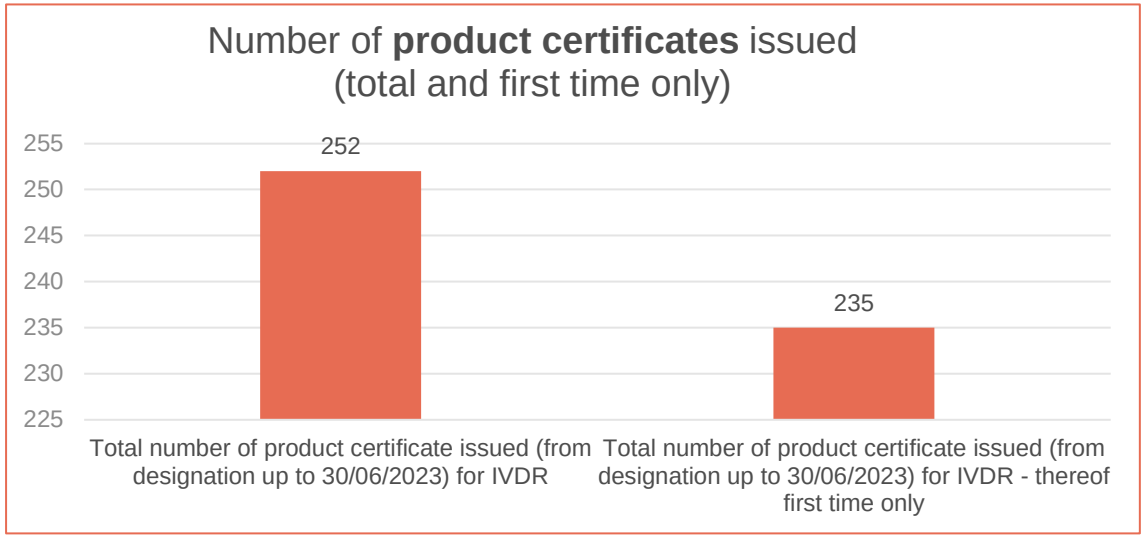
IVDR Number of QMS / product certificates issued

IVD

Small dataset





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

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

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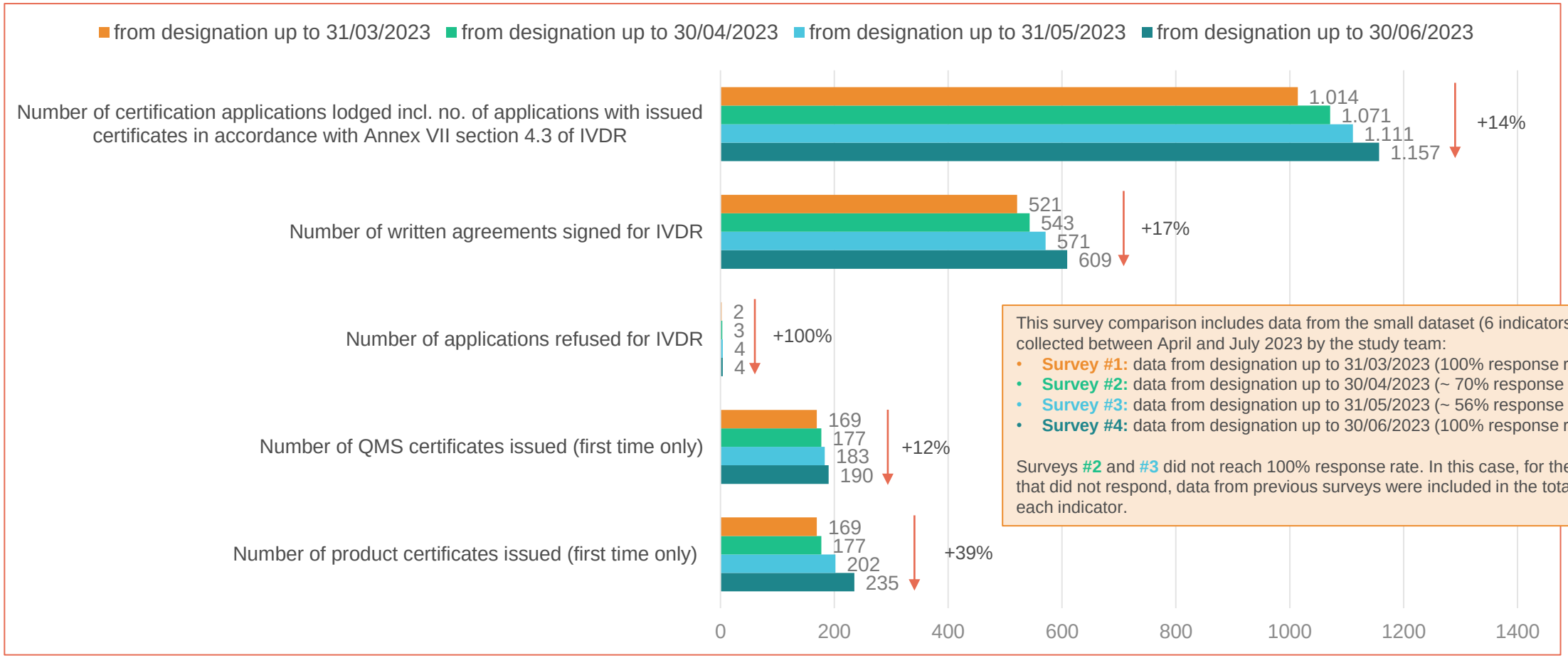
Survey comparison – March to June 2023
6 indicators

IVD

Small dataset



This survey comparison includes data from the small dataset (6 indicators) collected between April and July 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)

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 IVD for all four survey rounds: 10

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Thank you

Contact for questions: medical.devices@goeg.at

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