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

Survey results of the 13th NB survey (MDR/IVDR)
with data status 31 December 2024
(small dataset)

8 May 2025

Disclaimer

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- This presentation includes data and knowledge available at the time of the publication. The study-related dashboard contains the latest information und updates (e.g. further insights, retrospective corrections reported by stakeholders). Data discrepancies between this presentation and the regularly updated dashboard are therefore possible.

Gesundheit Österreich GmbH

Areté The Agri-food Intelligence Company

CIVIC CONSULTING

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Acknowledgements

The study team would like to sincerely thank the following institutions and people for the support in the 13th NB survey:

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

Content

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List of abbreviations

About

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
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
QMS	Quality Management System

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

- **Commissioned by:** The European Commission's Directorate-General for Health and Food Safety (DG SANTE) via the European Health and Digital Executive Agency (HaDEA)
- **Aim:** To support monitoring and analyzing the availability of medical devices on the EU market in the context of the implementation of medical devices and in vitro diagnostic medical devices Regulations from the perspectives of key stakeholders
- **Duration:** 2 December 2022 – 1 December 2025 (36 months)
- **Study team** (contact: medical.devices@goeg.at):

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

Areté The Agri-food Intelligence Company — Areté

CIVIC CONSULTING — Civic Consulting

Supported by experts from the medical devices sector

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NB survey overview

About

NB survey	Survey period (survey launch – survey closure)	Requested dataset* SD = small dataset MD = medium dataset LD = large dataset	Requested data	Response rate (only NBs designated under MDR and/or IVDR)
1st NB survey	03/04/2023 - 05/05/2023	SD1 + MD1	from designation up to 31/03/2023	39 out of 39 NBs **(100%)**
2nd NB survey	12/05/2023 - 05/06/2023	SD2	from designation up to 30/04/2023	27 out of 39 NBs **(~70%)**
3rd NB survey	05/06/2023 - 19/06/2023	SD3	from designation up to 31/05/2023	22 out of 39 NBs **(~56%)**
4th NB survey	03/07/2023 - 28/07/2023	SD4 + MD2	from designation up to 30/06/2023	39 out of 39 NBs **(100%)**
5th NB survey	01/09/2023 - 06/10/2023	SD5	from designation up to 31/08/2023	40 out of 40 NBs **(100%)**
6th NB survey	03/11/2023 - 22/12/2023	SD6 + MD3 + LD1	from designation up to 31/10/2023	41 out of 41 NBs **(100%)**
7th NB survey	08/01/2024 - 05/02/2024	SD7	from designation up to 31/12/2023	45 out of 45 NBs **(100%)**
8th NB survey	04/03/2024 - 20/03/2024	SD8 + MD4	from designation up to 29/02/2024	45 out of 45 NBs **(100%)**
9th NB survey	02/05/2024 - 21/06/2024	SD9	from designation up to 30/04/2024	48 out of 48 NBs **(100%)**
10th NB survey	01/07/2024 - 06/08/2024	SD10 + MD5	from designation up to 30/06/2024	50 out of 50 NBs **(100%)**
11th NB survey	02/09/2024 - 17/10/2024	SD11	from designation up to 31/08/2024	50 out of 50 NBs **(100%)**
12th NB survey	06/11/2024 – 20/12/2024	SD12 + MD6 + LD2 + TE1**	from designation up to 31/10/2024	51 out of 51 NBs **(100%)**
13th NB survey	21/01/2025 – 27/02/2025	SD13 + TE2**	from designation up to 31/12/2024	51 out of 51 NBs **(100%)**

Survey results included in the published dashboard

13th NB survey results (except the results of the targeted evaluation) 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**.
- The questions asked as part of the **targeted evaluation** are requested only once on behalf of DG SANTE.

** **About the targeted evaluation:** Evaluations conducted by the European Commission assess how well a specific policy intervention has performed (or is performing) and whether it is still relevant and justified. Evaluations are a key component of the lifecycle of any policy intervention. For the MDR and IVDR, the Commission has a legal obligation to conduct an evaluation of the Regulations by May 2027 (Article 121 MDR/Article 111 IVDR). The Commission has decided to launch a targeted evaluation of the Regulations in 2024. The **12th and 13th NB survey** (conducted in the framework of the 'Study supporting the monitoring of the availability of medical devices on the EU market') were used to ask NBs questions that are relevant for the Targeted Evaluation.

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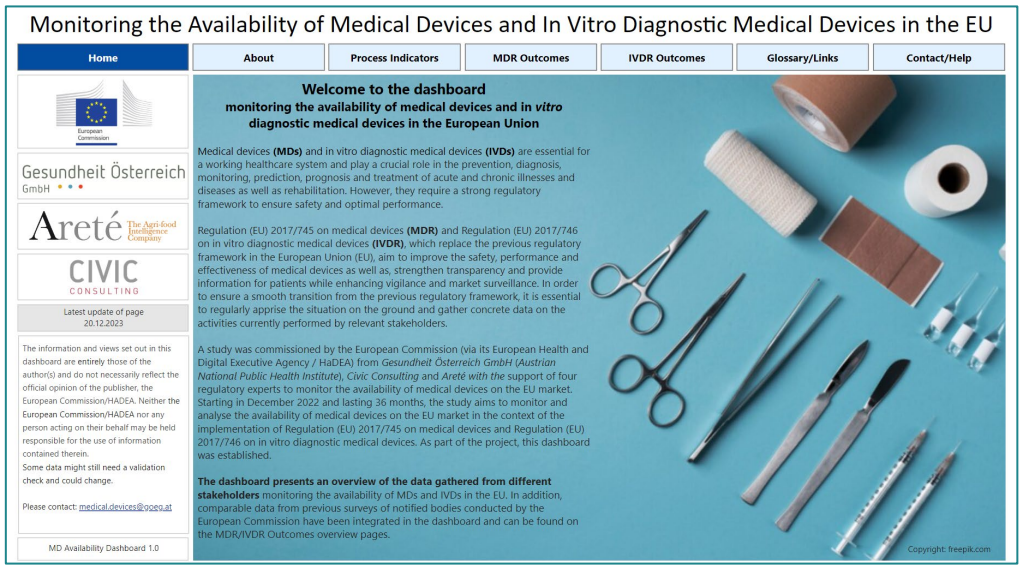
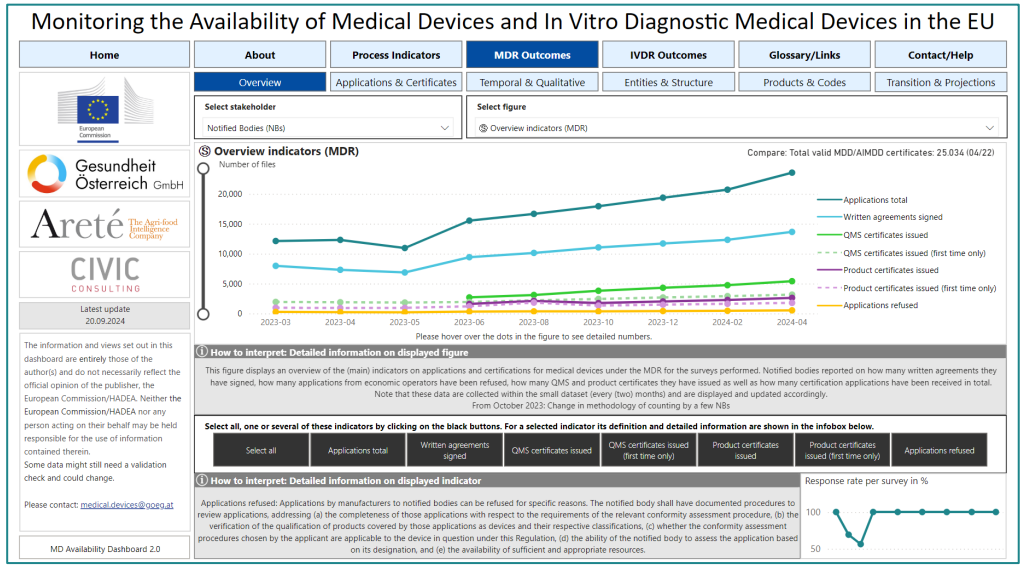
Dashboard

- 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

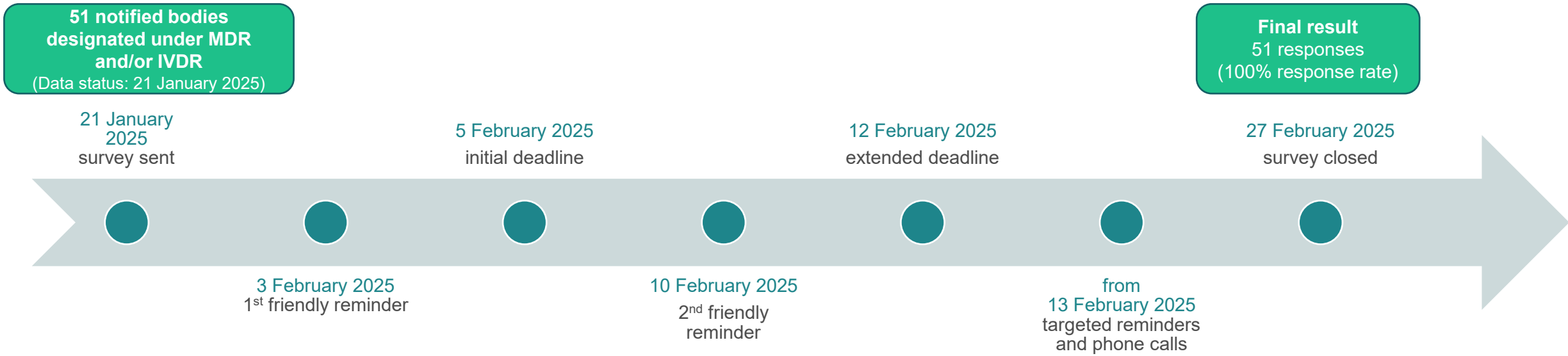
Preliminary notes on the survey

- **Data content:**
  - The following slides show the results of the survey containing a small dataset **conducted in January/February 2025** with **requested data** from notified bodies designated under MDR/IVDR **until 31 December 2024** and include a **survey comparison of thirteen surveys** conducted between April 2023 and February 2025.
  - The small dataset is a **small set of questions** asked to notified bodies concerning the activities they have been performing since their designation.
- **Data sources:**
  - Data collected between March 2023 and February 2025 by the study team

Timeline for the 13th NB survey

(conducted in January/February 2025 with requested data from designation until 31 December 2024)

About



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

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Response rate for the 13th NB survey

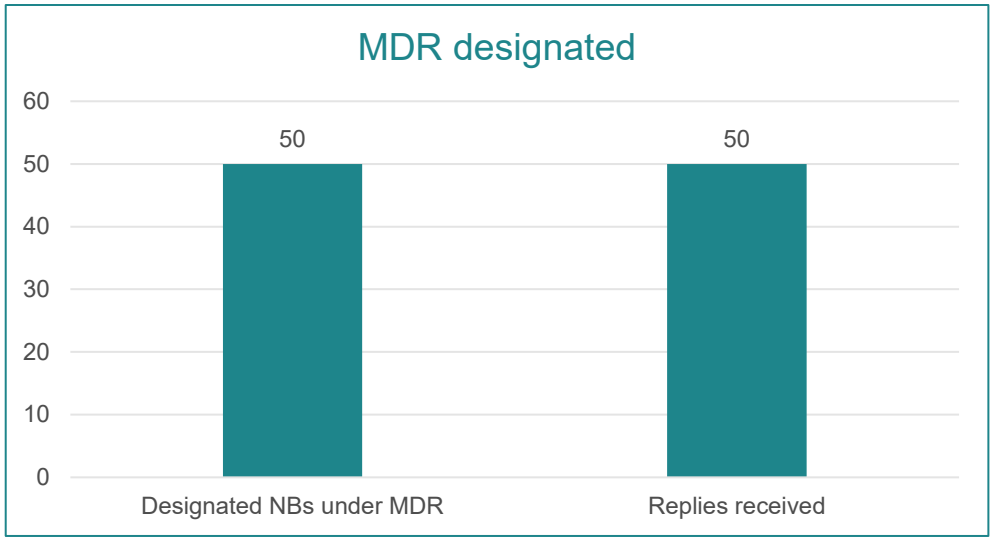
(conducted in January/February 2025 with requested data from designation until 31 December 2024)

About

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

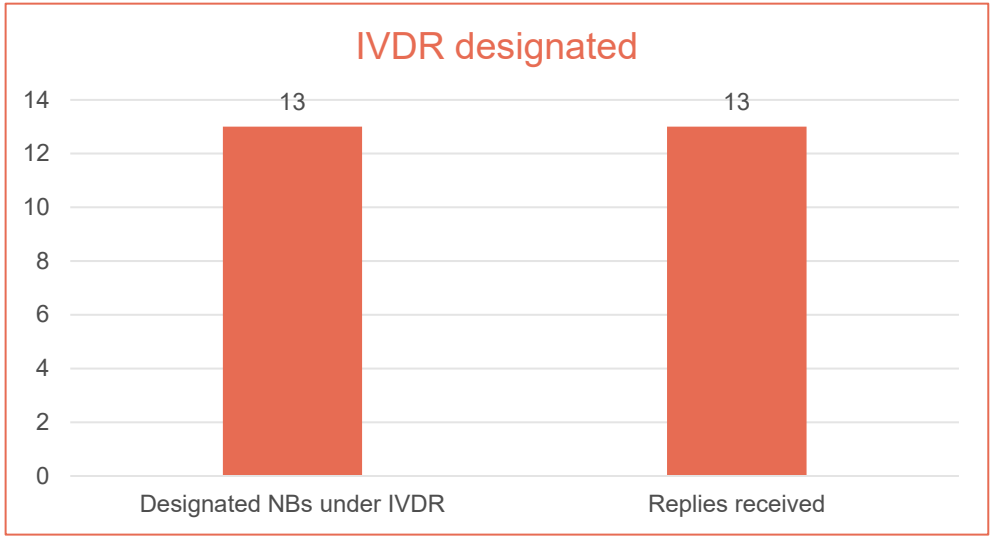
Note: *Out of 51 notified bodies,* ***38 NBs*** *are designated under the* ***MDR only****,* ***12 NBs*** *are designated under* ***both the MDR and IVDR****, and* ***one NB*** *is designated under the* ***IVDR only****.*

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.
- Datasets:

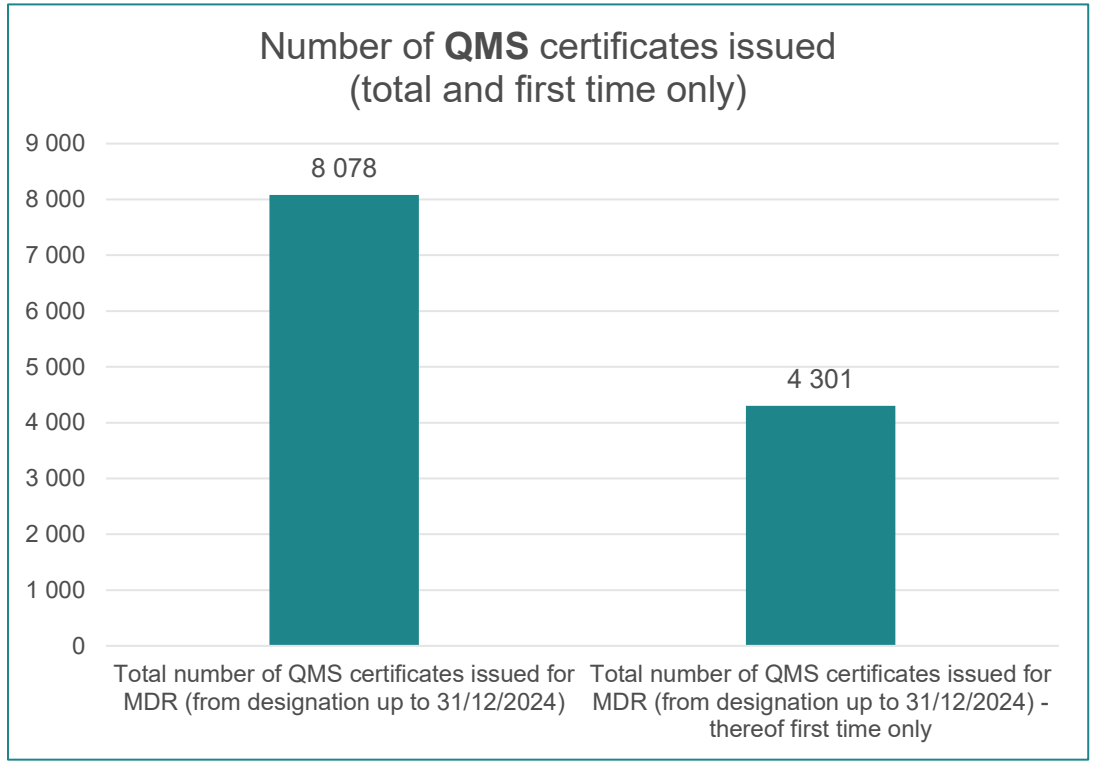
  Ⓢ The **small dataset** is a small set of questions asked to notified bodies **every two months.**
  Note: From April to July 2023, it was asked monthly.
  Ⓜ The **medium dataset** (not surveyed in the 13th NB survey) is a set of questions asked to notified bodies **every four months** concerning the activities they have been performing since their designation.
  Ⓛ The **large dataset** (not surveyed in the 13th NB survey) contains additional data asked to notified bodies **once a year.**

MDR applications filed and refused, written agreements signed

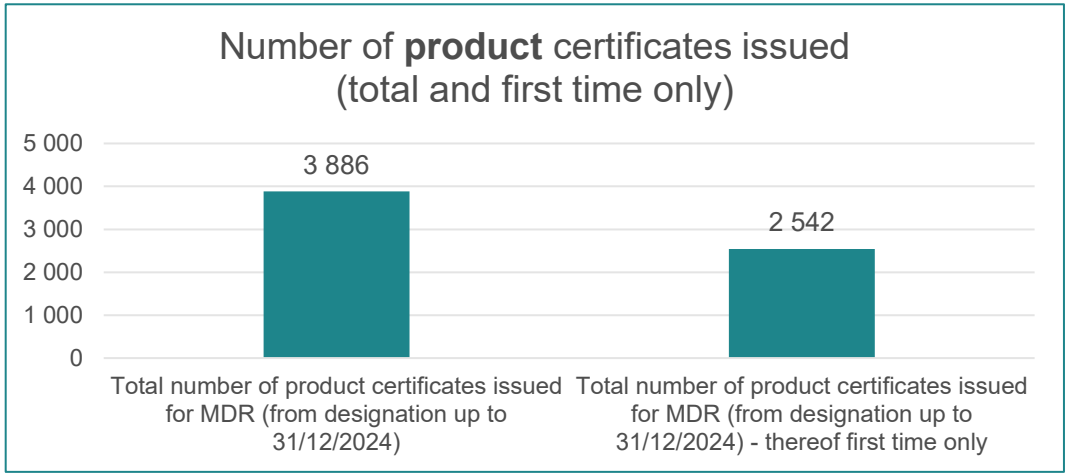
Notes:

- **Designated NBs for MD: 50**
- *** Applications lodged**: This number includes **all applications lodged (syn. filed) so far** according to MDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 31/12/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included.
- **** Written agreements signed:** This refers to the number of written agreements (contracts) between a NB and a manufacturer signed by both parties.
- ***Change in methodology of counting applications by one NB

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.

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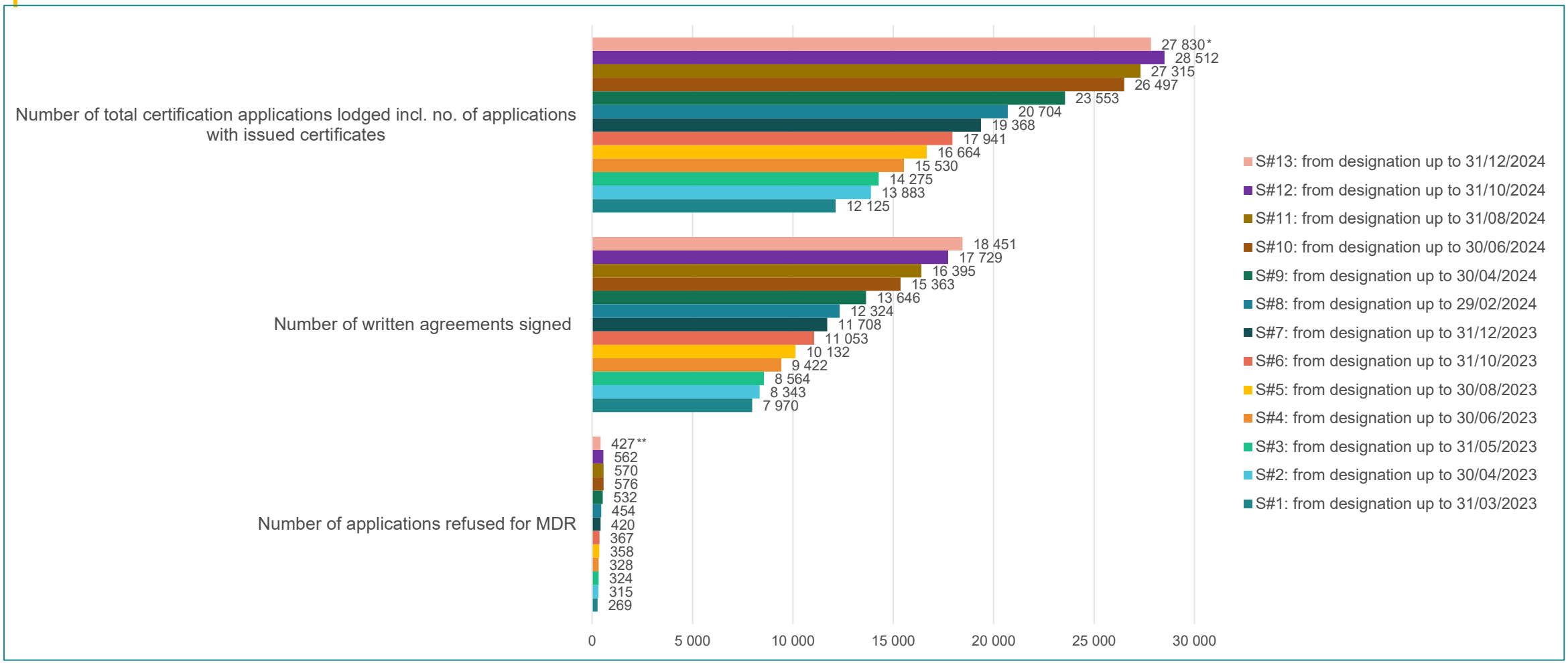
MD

Survey comparison – March 2023 to December 2024



Notes:

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

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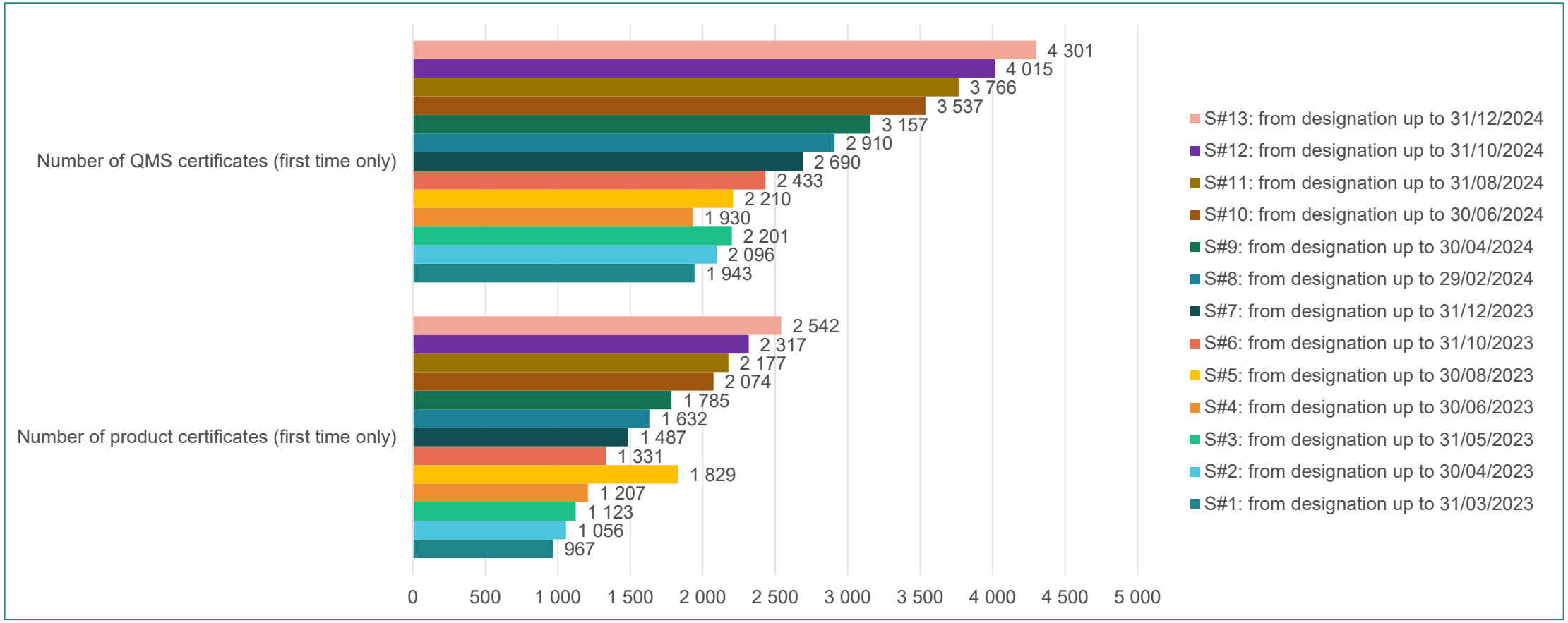
MD

Survey comparison – March 2023 to December 2024



S = Survey; # = number

Notes:

- Survey **#13:** 50 designated NBs for MD
- Surveys **#2** and **#3** did not reach 100% response rate (#2: ~70%; #3: 56%). In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.
- Increase from survey #1 to #3; in survey #4, the questionnaire was redesigned, and the question on "total number of certificates issued" (in addition to "first time only") was included in the small dataset. The redesign of the questionnaire helped the NBs to better assess the number of first-time only certificates. Therefore, the numbers of the previous surveys might be an overestimation.
- Change in methodology of counting by a few NBs compared to previous surveys in survey #4 and #5.

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IVD

3. Survey results for in vitro diagnostic medical devices

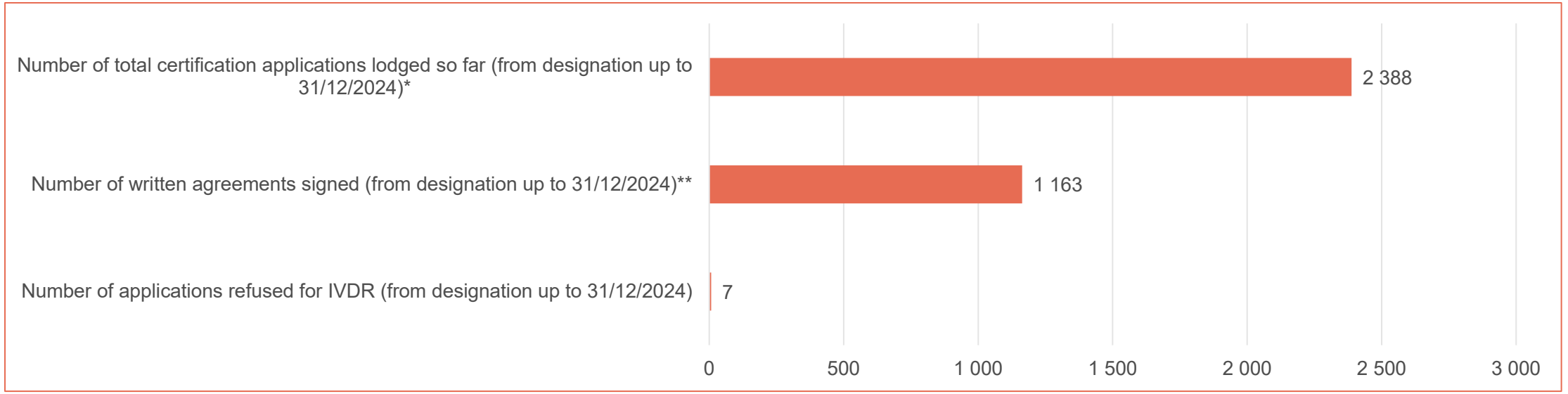
Note:

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

  Ⓢ The **small dataset** is a small set of questions asked to notified bodies **every two months.**
  Note: From April to July 2023, it was asked monthly.
  Ⓜ The **medium dataset** (not surveyed in the 13th NB survey) 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** (not surveyed in the 13th NB survey) contains additional data asked to notified bodies **once a year**.

IVDR applications filed and refused, written agreements signed

IVD



Notes:

- **Designated NBs for IVD:** 13
- *** Applications lodged**: This number includes **all applications lodged (syn. filed) so far** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 31/12/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included.
- **** Written agreements signed:** This refers to the number of written agreements (contracts) between a NB and a manufacturer signed by both parties.

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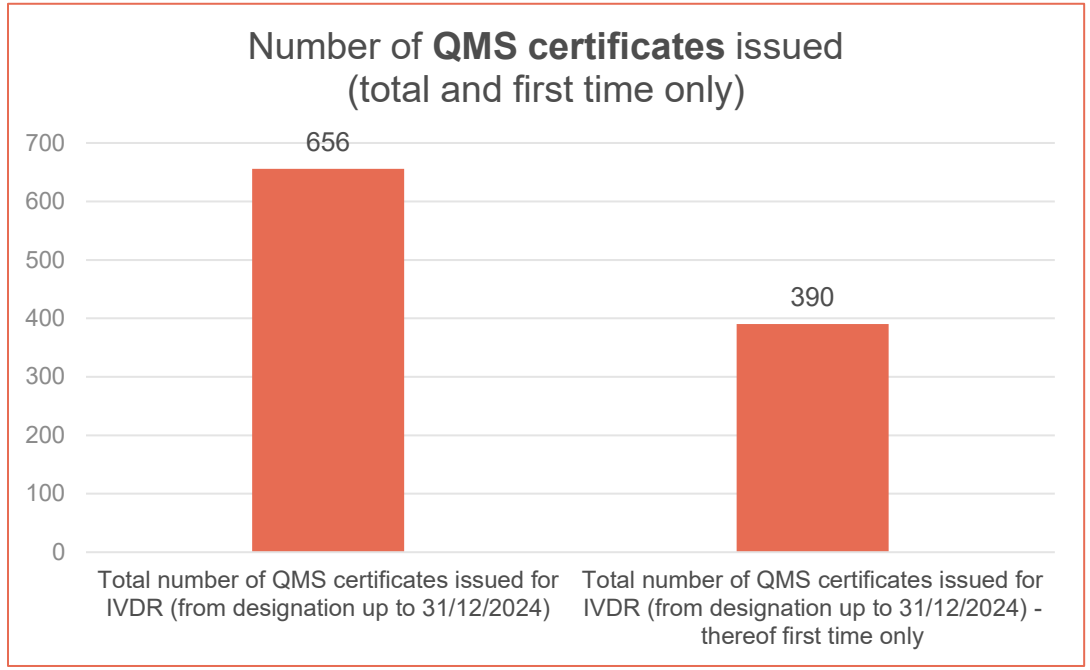
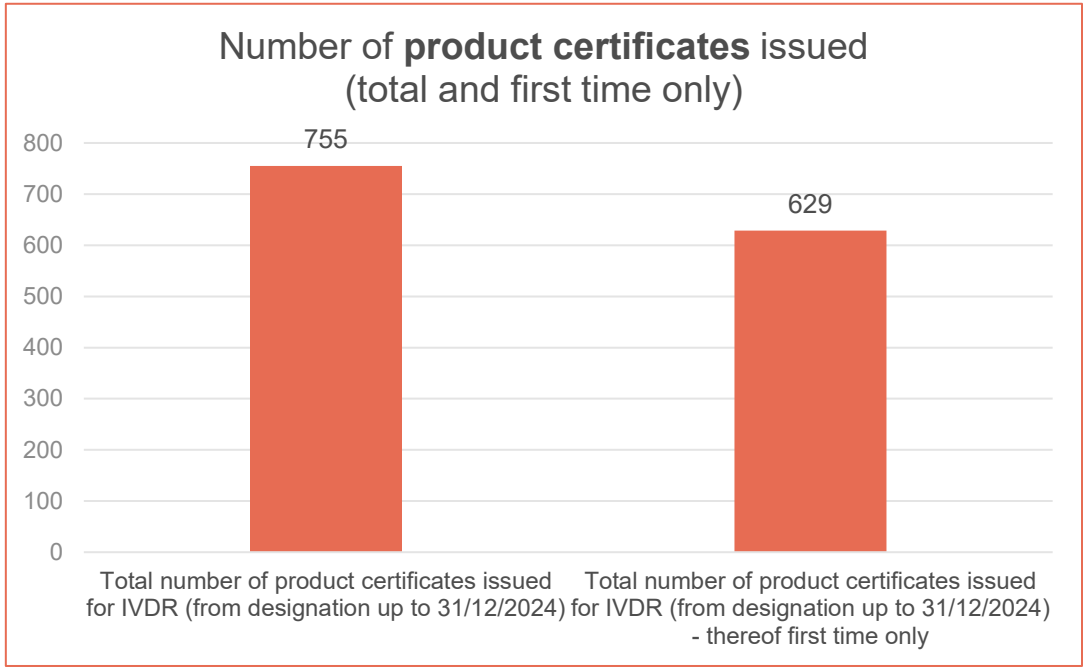
IVDR Number of QMS / product certificates issued

IVD





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

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

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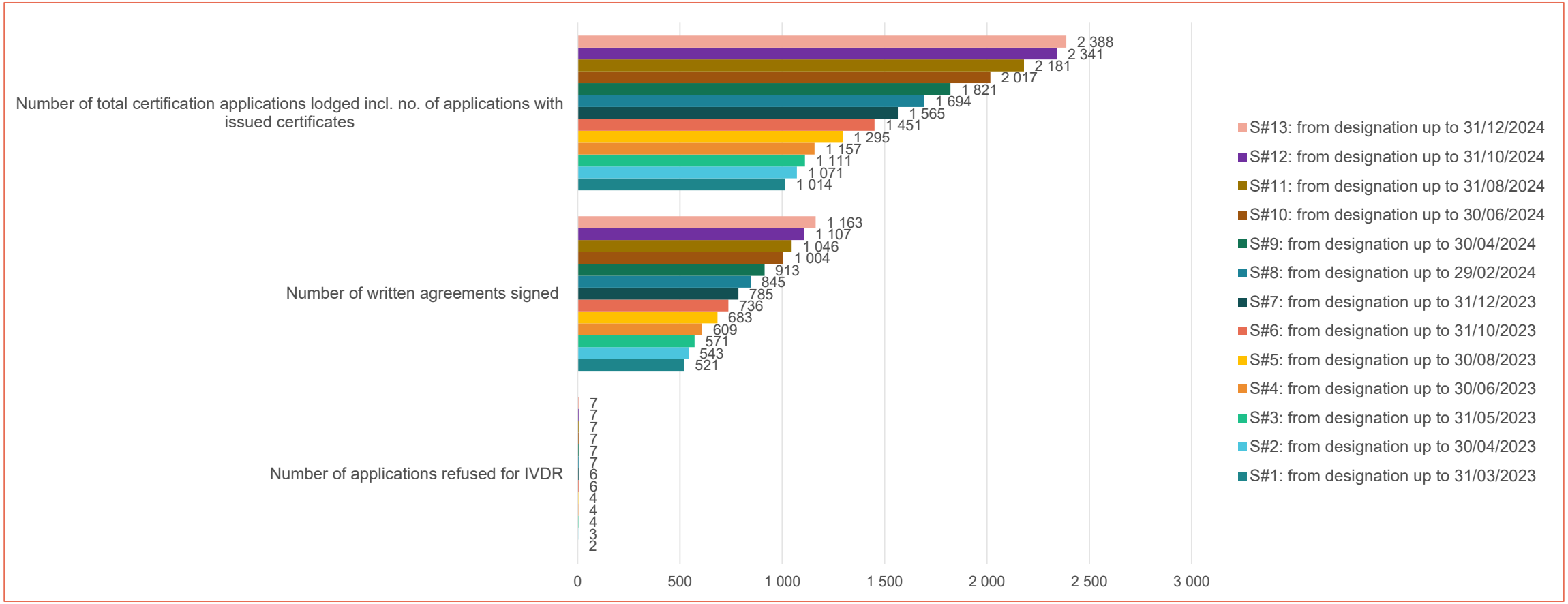
IVD

Survey comparison – March 2023 to December 2024



S = Survey; # = number

Notes:

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

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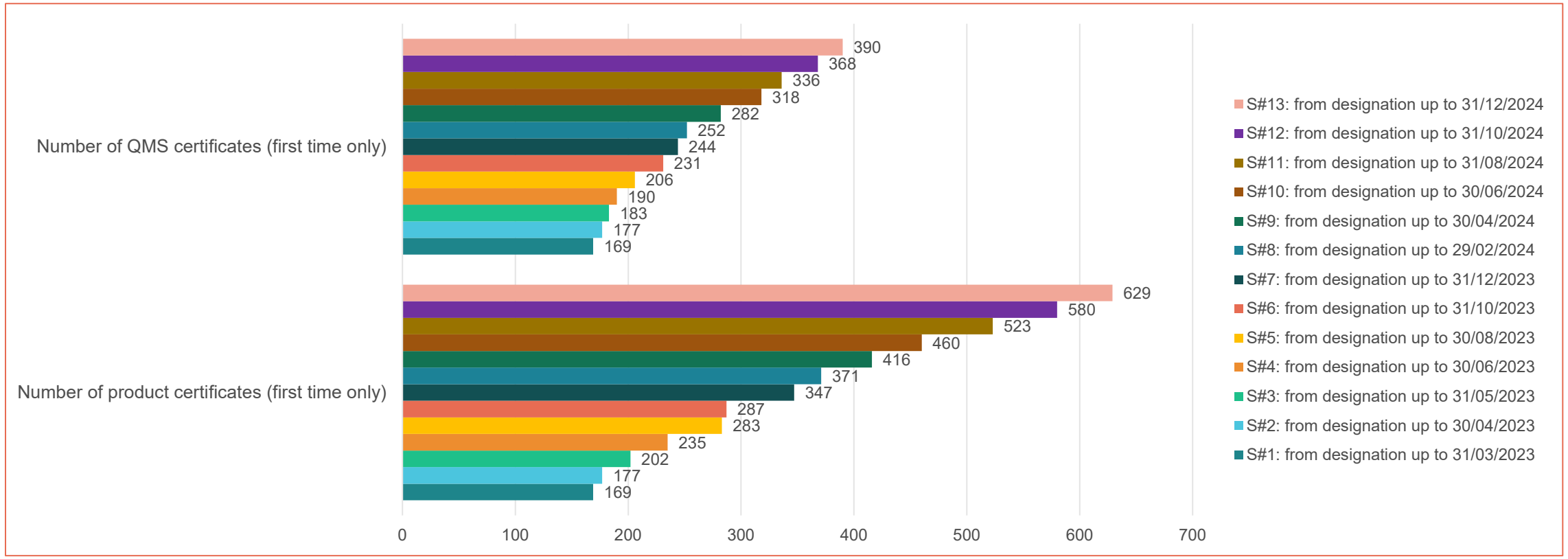
IVD

Survey comparison – March 2023 to December 2024



S = Survey; # = number

Notes:

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

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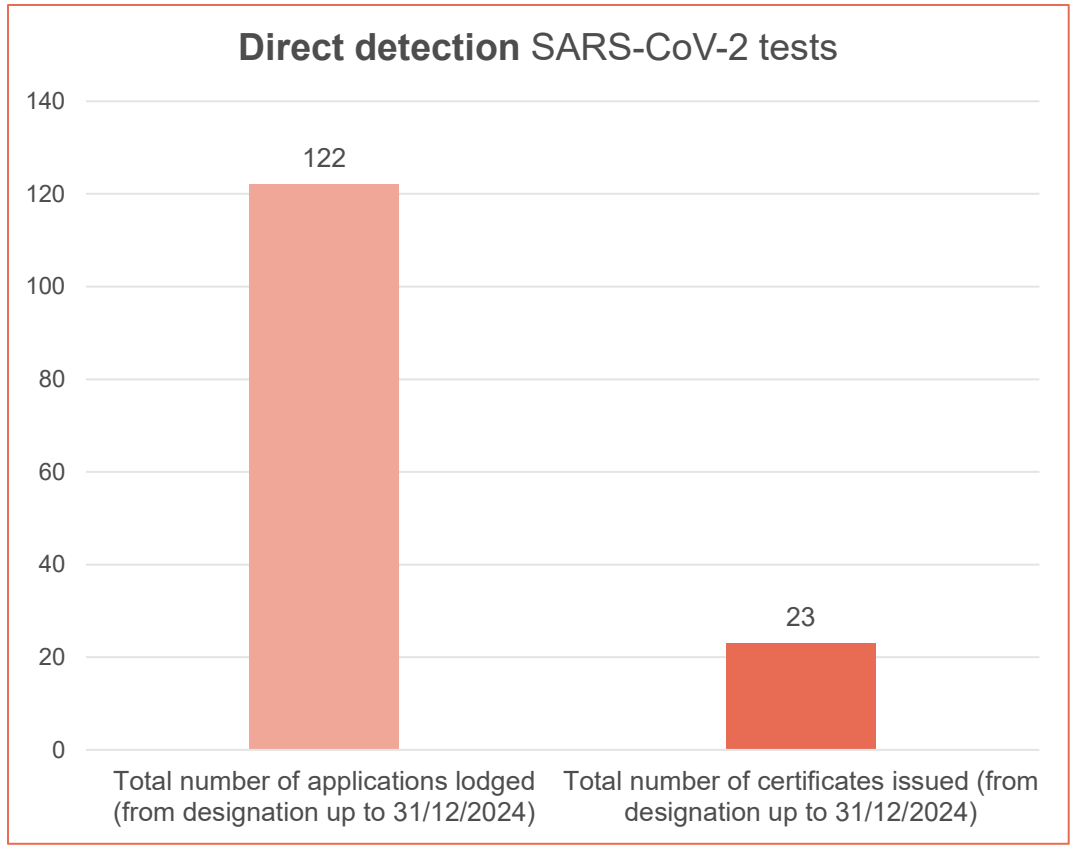
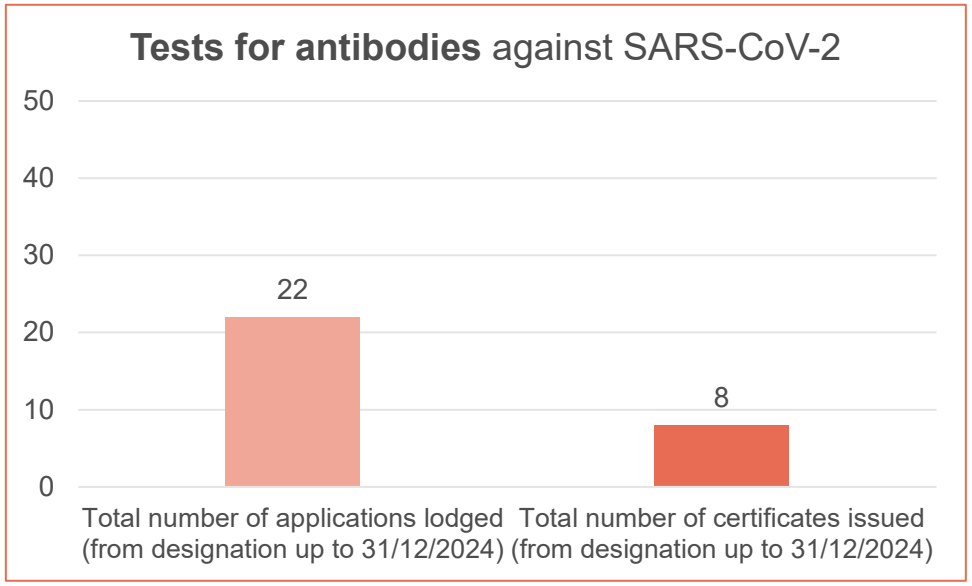
SARS-CoV-2 tests*: applications lodged and certificates issued

IVD





Notes:

- *devices intended for detection or quantification of markers of SARS-CoV-2 (Severe acute respiratory syndrome coronavirus 2) infection
- This question is only included once in the IVD part of the small dataset.

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Thank you

Contact for questions: medical.devices@goeg.at

Austrian National Public Health Institute/ Gesundheit Österreich GmbH (GÖG)

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