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

## **Survey results of the 19th NB survey (MDR/IVDR)**
with data status 31 December 2025
(small and large dataset)

*8 May 2026*

# Disclaimer

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



Gesundheit Österreich GmbH

Areté The Agri-food Intelligence Company

CIVIC CONSULTING

European Commission

# Acknowledgements

The study team would like to sincerely thank the following institutions and people for the support in the 19th NB survey:

- All **53 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




**Please cite as:** Austrian National Public Health Institute, Areté, Civic Consulting (2026). PowerPoint presentation containing a study overview and survey results of the 19th NB survey for the 'Study supporting the monitoring of availability of medical devices on the EU market'. Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG). Commissioned by the European Commission within the EU4Health Programme (under specific contract No 2021 P3 03 with the European Health and Digital Executive Agency, implementing framework contract No SANTE/2021/OP/0002).




European Commission

# List of abbreviations (1)

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

# List of abbreviations (2)

| Abbreviation | Meaning |
|---|---|
| MD | Medium dataset |
| MDCG | Medical Device Coordination Group |
| MDs | Medical device(s) |
| MDSAP | Medical device single audit program |
| 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) |
| MFs | Manufacturer(s) |
| NBs | Notified body / bodies |
| QMS | Quality Management System |
| SC | Special contract |
| SD | Small dataset |
| SMCS | Single Market Compliance Space |
| SMEs | Small and medium-sized enterprise(s) |
| TF | Task Force |

About

# 1. About the study, survey and datasets

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

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

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 June 2026 (42 months*)

  * Study amendment from 2 December 2025 – 1 June 2026
- **Study team** (contact: medical.devices@goeg.at):

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

Areté The Agri-food Intelligence Company — Areté

CIVIC CONSULTING — Civic Consulting

Supported by experts from the medical devices sector



European Commission

About

# Preliminary notes

- **Data content:**
  - The following slides show the results of the **19th NB survey conducted at the beginning of 2026** with **requested data** from notified bodies designated under MDR and/or IVDR **until 31 December 2025**.
  - These survey results are also compared with previous survey data (see data sources).

- **Data sources:**
  - Data collected between April 2023 and February 2026 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 large datasets collected in January/February 2026.
    - Ⓢ 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 **large dataset** contains additional data asked to notified bodies **once or twice a year**.

# NB survey overview

About

| NB survey | Survey period (survey launch – survey closure) | Requested 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%)** |
| 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%)** |
| 14th NB survey | 03/03/2025 – 08/04/2025 | SD14 + MD7 | from designation up to 28/02/2025 | 51 out of 51 NBs **(100%)** |
| 15th NB survey | 05/05/2025 – 23/05/2025 | SD15 | from designation up to 30/04/2025 | 51 out of 51 NBs **(100%)** |
| 16th NB survey | 01/07/2025 – 02/09/2025 | SD16 + MD8 + LD3 | from designation up to 30/06/2025 | 51 out of 51 NBs **(100%)** |
| 17th NB survey | 01/10/2025 – 04/11/2025 | SD17 | from designation up to 30/08/2025 | 51 out of 51 NBs **(100%)** |
| 18th NB survey | 14/11/2025 – 15/12/2025 | SD18 + MD9 | from designation up to 31/10/2025 | 52 out of 52 NBs **(100%)** |
| 19th NB survey | 12/01/2026 – 10/02/2026 | SD19 + LD4 | from designation up to 31/12/2025 | 53 out of 53 NBs **(100%)** |

19h NB survey results are presented in this PowerPoint presentation



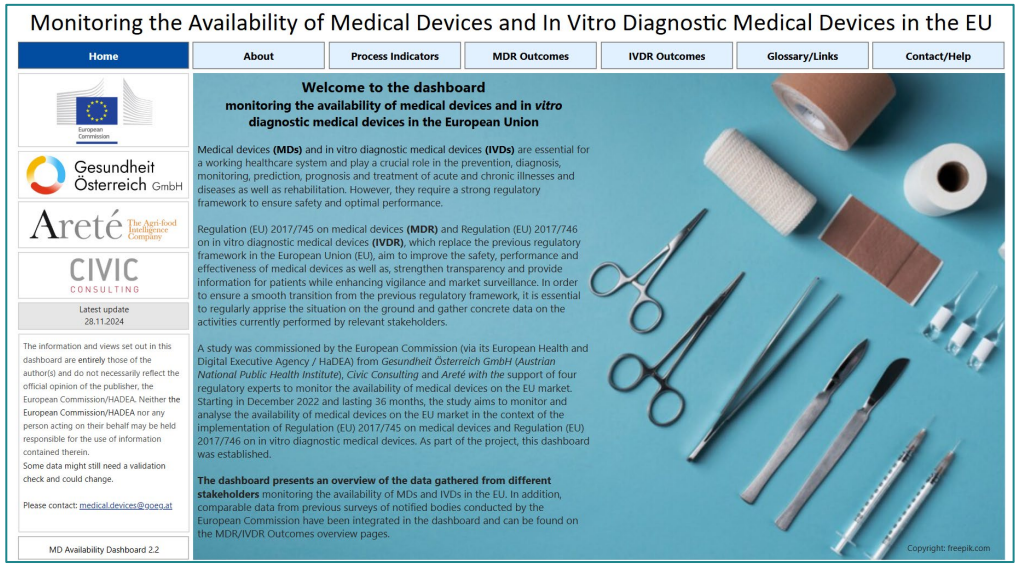
**Note:** SD = small dataset, MD = medium dataset, LD = large dataset

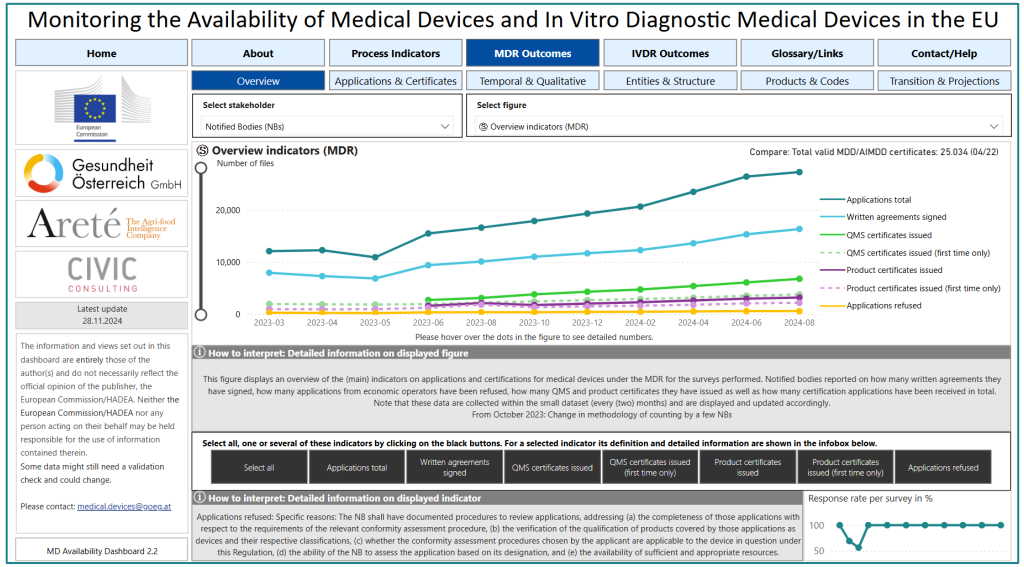
*** About the targeted evaluation:** Evaluations conducted by the European Commission assess how well a specific policy intervention has performed (or is performing) and whether it is still relevant and justified. Evaluations are a key component of the lifecycle of any policy intervention. For the MDR 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.

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)]
- [Instructions for use for the dashboard]





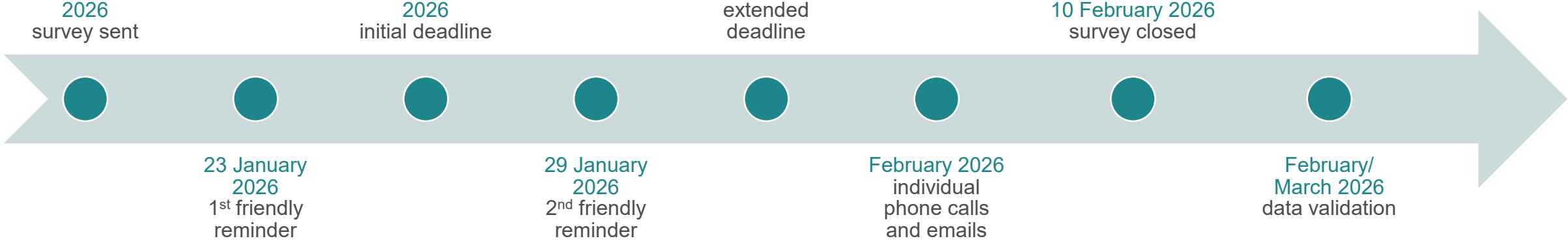

European Commission

# Timeline for the 19th NB survey

(conducted in January/February 2026 with requested data from designation up to 31/12/2025)

About

**53 notified bodies designated under MDR and/or IVDR**
(data status: 8 January 2026)




***Note:*** *Out of 53 notified bodies,* ***34 NBs*** *are designated under the* ***MDR*** *only,* ***18 NBs*** *are designated under* ***both the MDR and IVDR****, and* ***1 NB is*** *designated under the* ***IVDR only****.*

**Final result**
53 responses
(100% response rate)



European Commission

# Response rate for the 19th NB survey

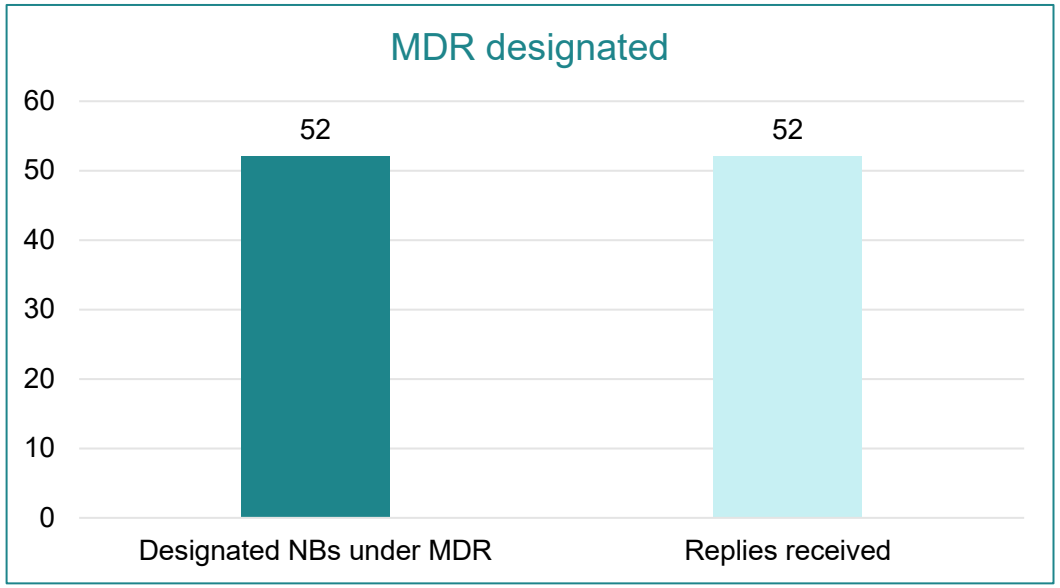
(conducted in January/February 2026 with requested data from designation up to 31/12/2025)

About

## 53 out of 53 notified bodies replies received (100% response rate)

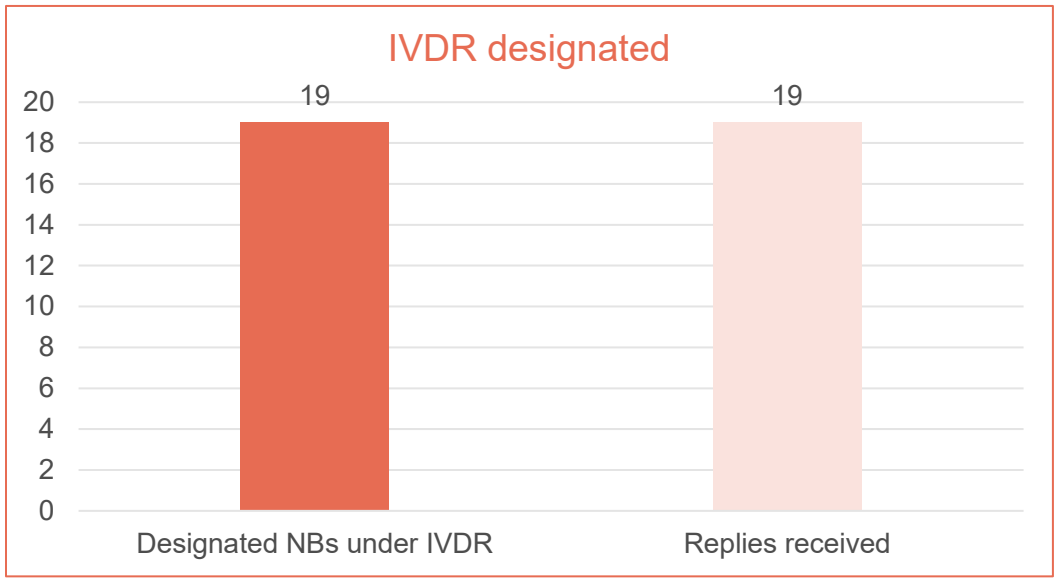
***Note:*** *Out of 53 notified bodies,* ***34 NBs*** *are designated under the* ***MDR*** *only,* ***18 NBs*** *are designated under* ***both the MDR and IVDR****, and* ***1 NB is designated under the IVDR only****.*

**MD**




100% response rate

**IVD**




100% response rate



European Commission

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** 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 or twice a year.**

MD

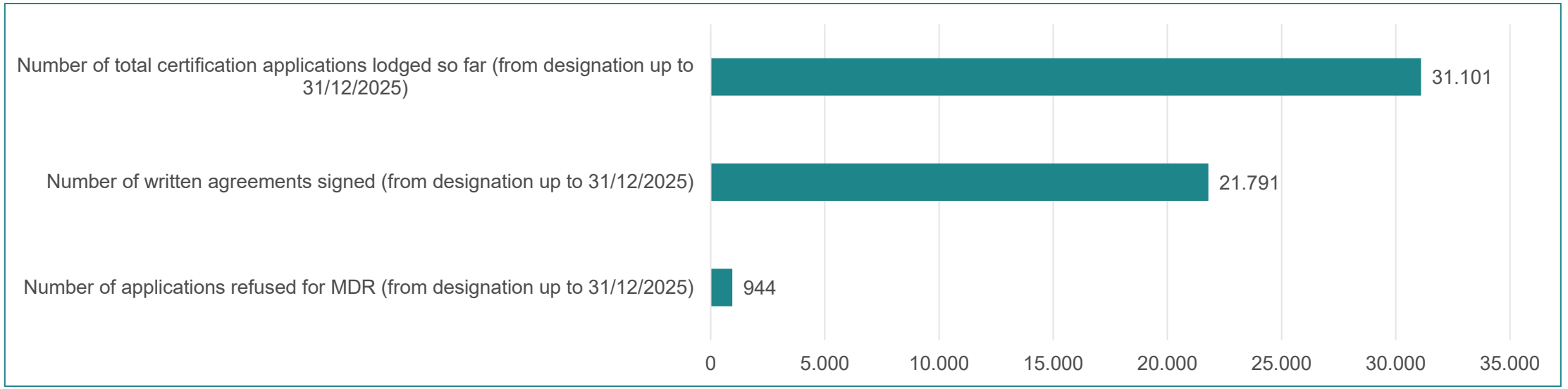
# Small dataset Ⓢ

The **small dataset** is a small set of questions asked to notified bodies **every two months.**

From April to July 2023, it was asked monthly.

# MDR applications filed and refused, written agreements signed

MD



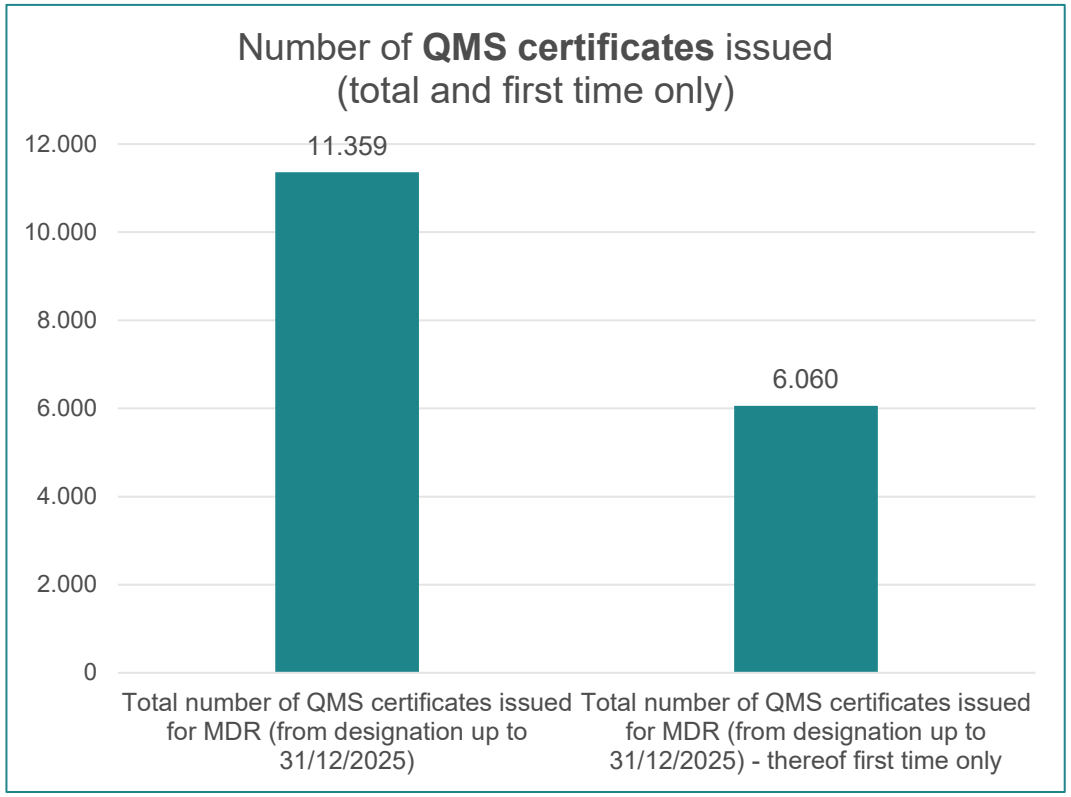

**Notes:**

- **Designated NBs for MD: 52**
- **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 31/12/2025), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included.
- **Written agreements signed:** This refers to the number of written agreements (contracts) between a NB and a manufacturer signed by both parties.

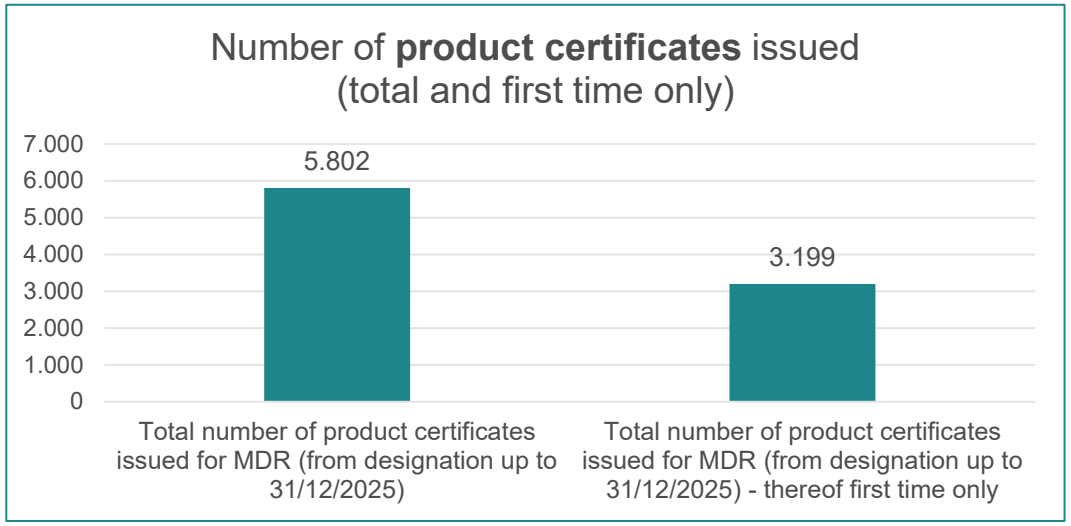


European Commission

# 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.



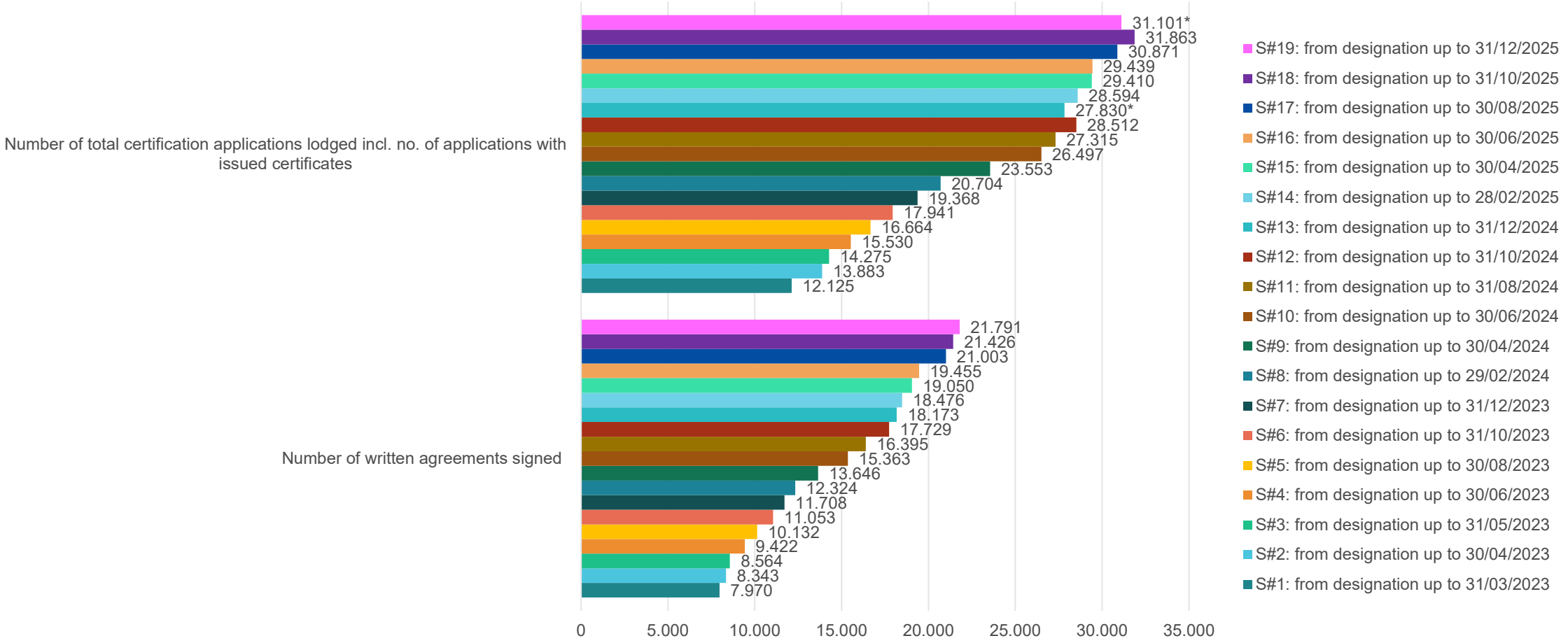

**Note PRODUCT Certificates:** This relates to Annex IX Chapter II, Annex X or Annex XI Part B according to MDR.



European Commission

MD

# Survey comparison – March 2023 to December 2025




**Notes:**

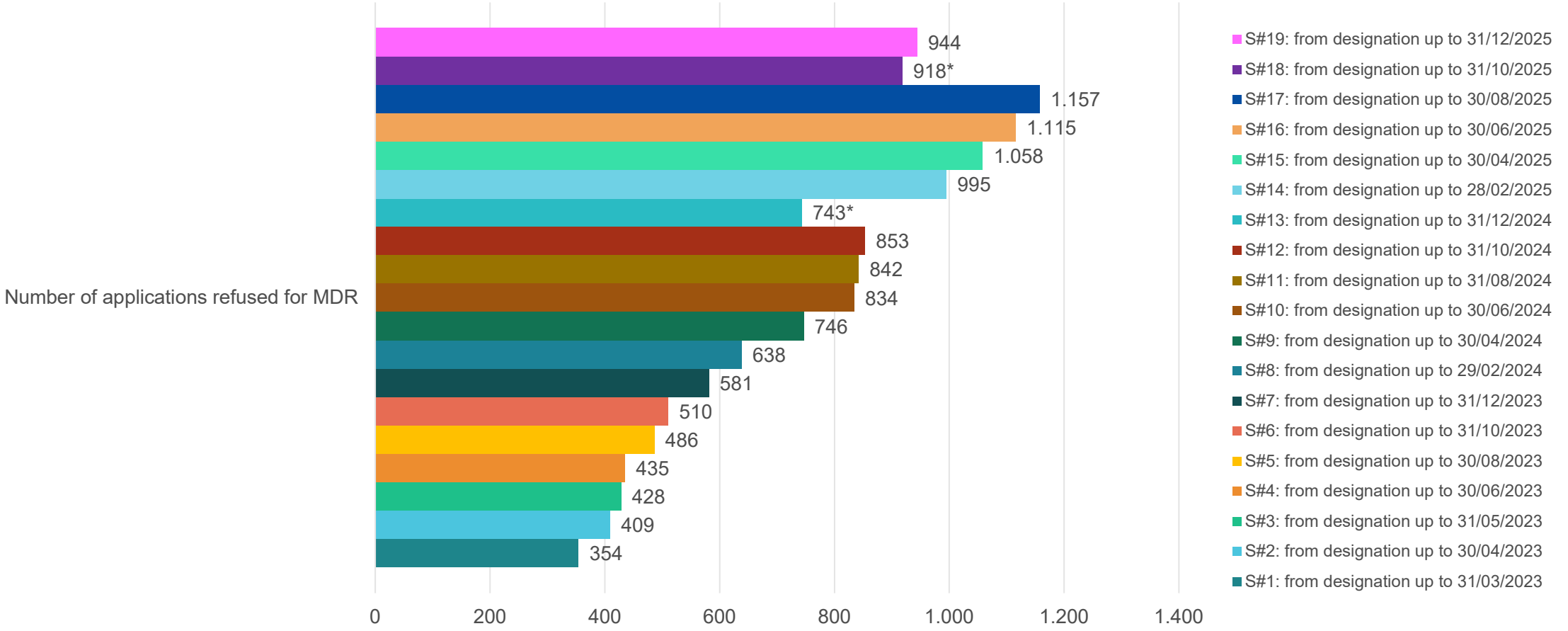
- S = Survey; # = number
- Survey **#19:** 52 designated NBs for MD
- Surveys **#2** and **#3** did not reach 100% response rate (#2: ~70%; #3: 56%). In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.
- * Change in methodology of counting applications by one NB in survey #13 and by one NB in survey #19, resulting in a decrease of total numbers.



European Commission

MD

# Survey comparison – March 2023 to December 2025




**Notes:**

- S = Survey; # = number
- Survey **#19:** 52 designated NBs for MD
- Surveys **#2** and **#3** did not reach 100% response rate (#2: ~70%; #3: 56%). In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.

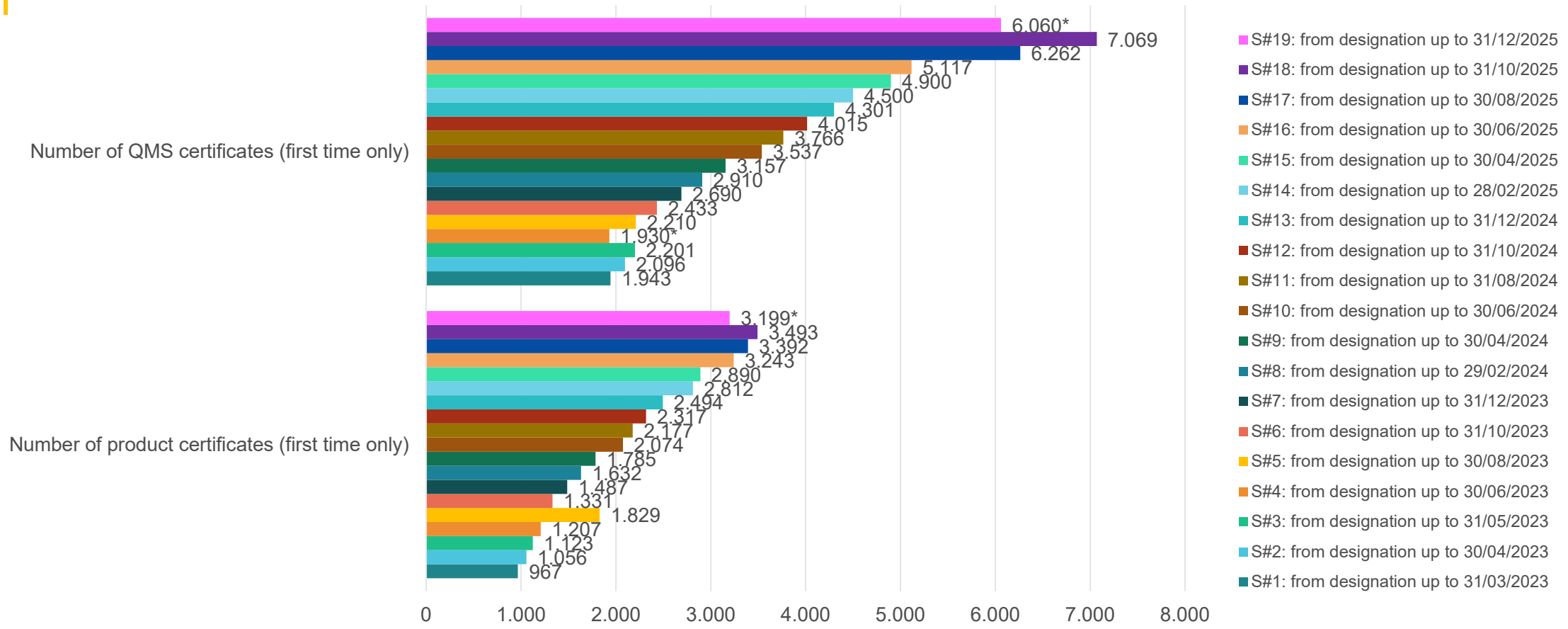
* Change in methodology of counting refused applications compared to previous surveys by NBs in surveys #13 and #18.



European Commission

# Survey comparison – March 2023 to December 2025

MD




S = Survey; # = number

**Notes:**

- Survey **#19:** 52 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 #19, resulting in a decrease of total numbers.



European Commission

MD

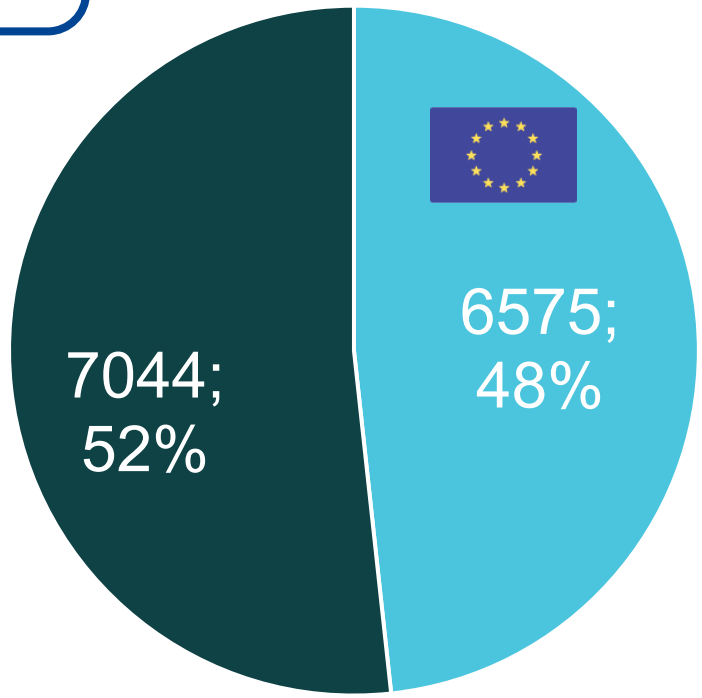
# Large dataset Ⓛ

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

# Number of clients for MDR

**December 2025**
**Total number of clients for MDR: 13.619***
**(June 2025: 14.003)**

Number of clients based **outside the EU**




Number of clients based **in the EU**

Data of 52 NBs designated under MDR
3 NBs: values of the 16th NB survey
* 1 NB changed methodology in counting clients
Photo credit EU flag: Flaticon.com

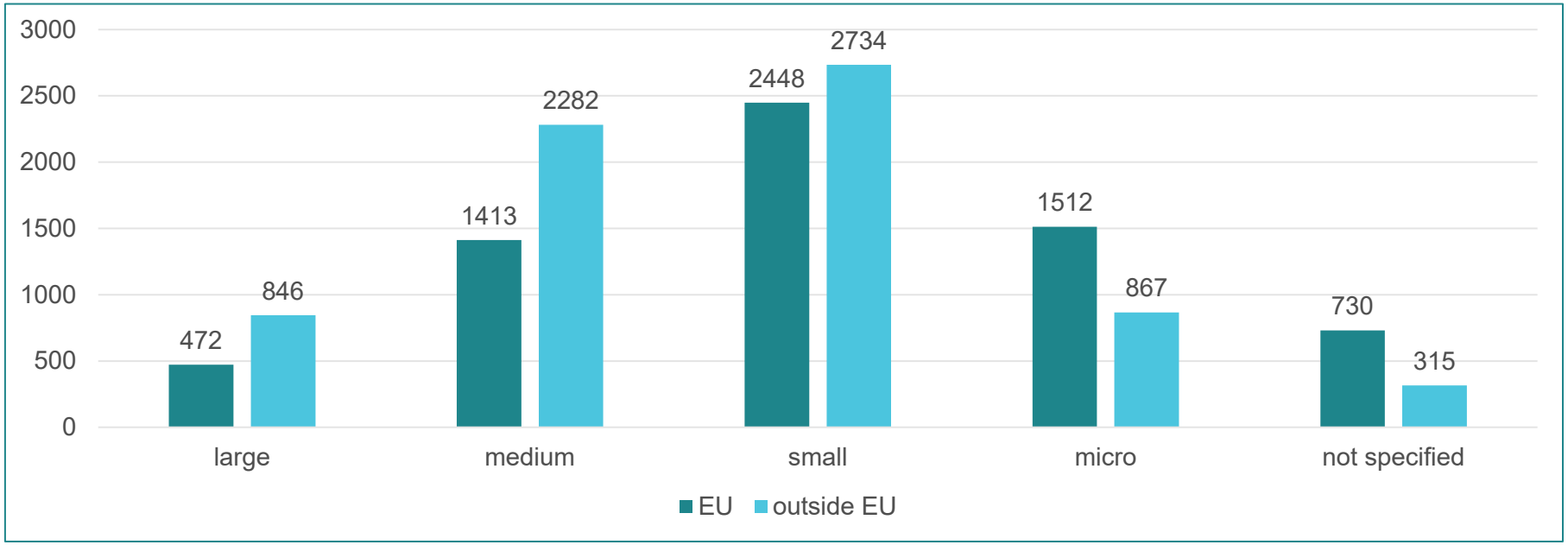


European Commission

MD

# Number of clients for MDR by size of enterprise

**December 2025**
**Total number of clients for MDR: 13.619**




**Clients (if specified):**

- **10% large companies** (EU: 8%, outside EU: 12%)
- **90% SMEs** (EU: 92%; outside EU: 88%)
- 36 NBs (73%) indicated that more than 90% of their clients are SMEs.

**Notes:**
Data of 52 NBs designated under MDR; 14 NBs indicated that the provided data is based on estimations (mainly FTE, as data on turnover is not available to them); 2 NBs indicated that the data does not contain all clients; 1 NB indicated that the no. is based on the accepted offers (not clients); 1 NB indicated that EU numbers include Turkey & Norway customers.

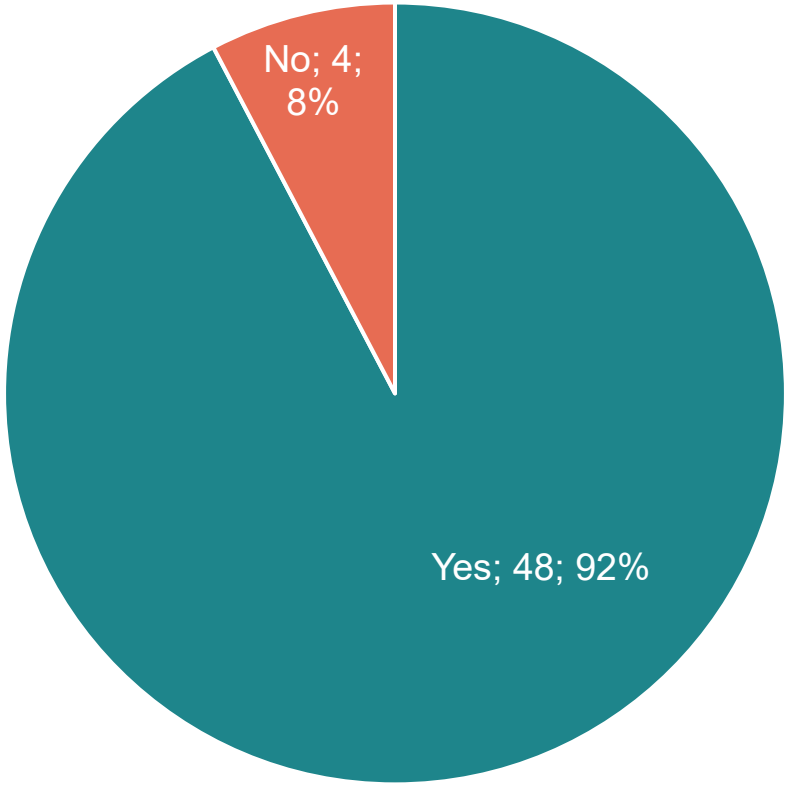
Definitions:
• Micro enterprise = an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not EUR 10 million
• Medium enterprise = an enterprise which employs between 51 and 250 persons, and which have an annual turnover not exceeding EUR 50exceed EUR 2 million
• Small enterprise = an enterprise which employs between 10 and 50 persons and whose annual turnover and/or annual balance sheet total does not exceed  million, and/or an annual balance sheet total not exceeding EUR 43 million.
• Large enterprise = an enterprise larger than a medium enterprise.
(Source: Extract of Article 2 of the annex to Recommendation 2003/361/EC)



European Commission

MD

# Does your NB take on new clients for MDR?




Data of 52 NBs designated under MDR

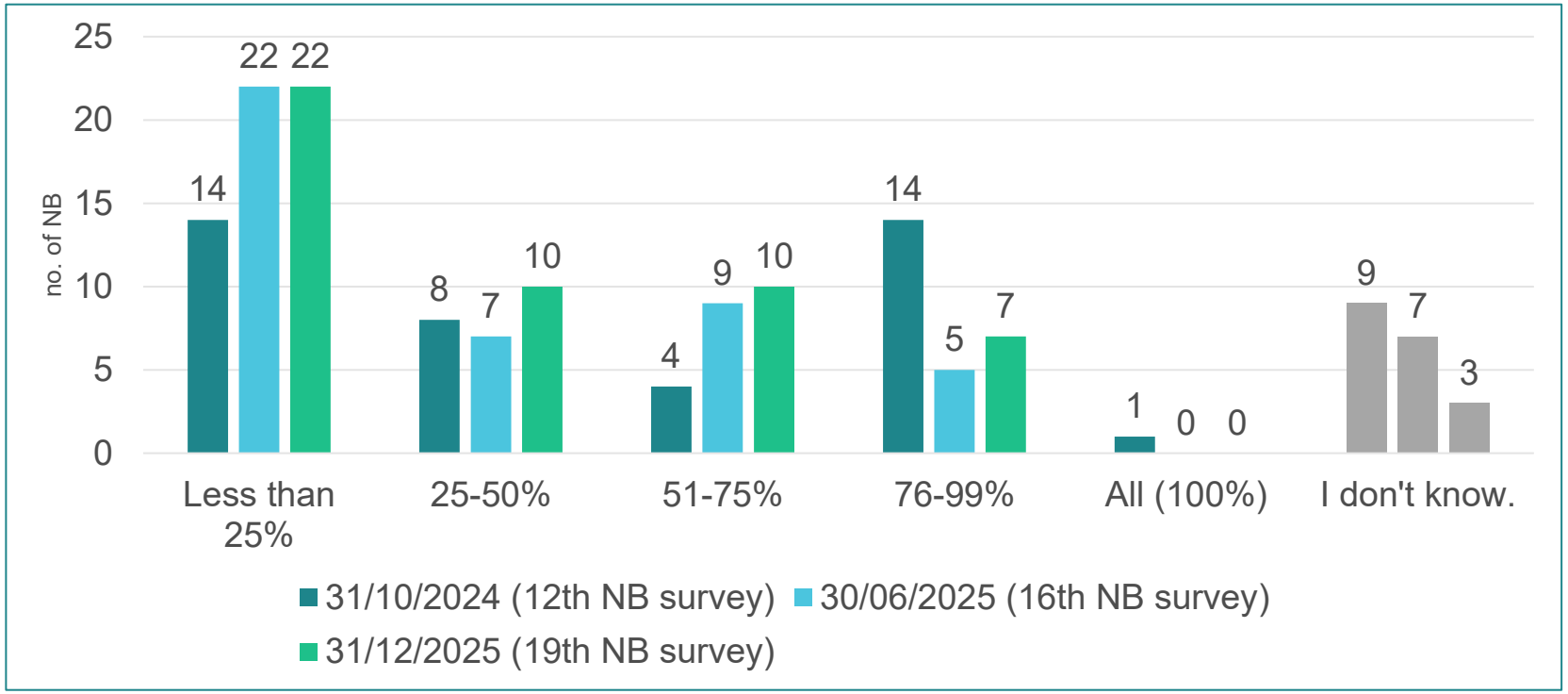


European Commission

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

MD

**December 2025**
**Total number of clients for MDR: 13.619**




- 22 NBs (42%) indicated that less than 25% of their clients with certificates under the Directives have completed the transfer to MDR of all devices intended to be certificated
- 7 NBs (14%) indicated that between 76 and 99% of their clients with certificates under the Directives have completed the transfer to MDR of all devices intended to be certificated
- No NB indicated that all clients have completed the transfer of all devices intended to be certificated.
- Slight improvement can be observed.

12th and 16th NB survey: Data of 50 NBs designated under MDR
19th NB survey: Data of 52 NBs designated under MDR

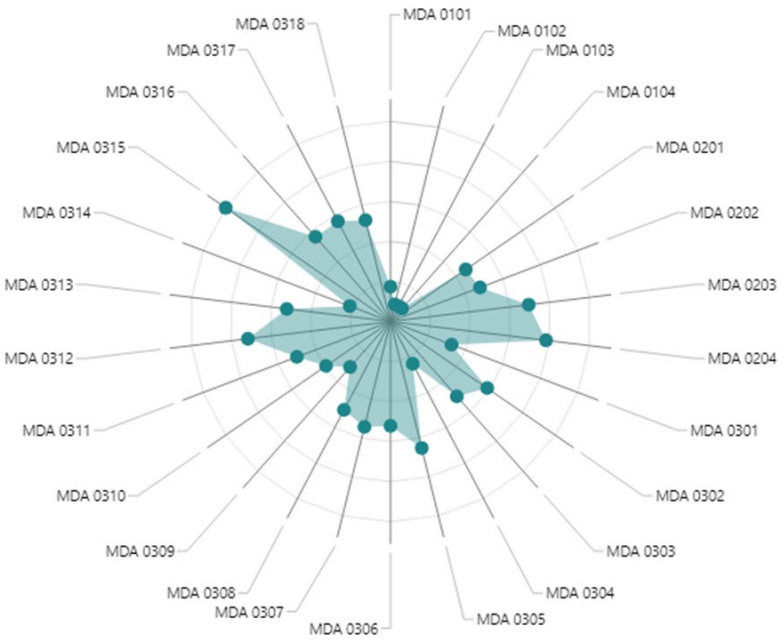


European Commission

# Which MDA codes are covered by MDR certificates?

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

**MDA = Active devices**




| | Number of NBs indicating devices/categories |
|---|---|
| MDA 0315 Software | 46 |
| MDA 0204 Other active non-implantable devices for monitoring and / or diagnosis | 36 |
| MDA 0312 Other active non-implantable surgical devices | 33 |
| MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters | 32 |
| MDA 0305 Active non-implantable devices for stimulation or inhibition | 30 |
| MDA 0302 Active non-implantable devices utilising non-ionizing radiation | 27 |
| MDA 0316 Medical gas supply systems and parts thereof | 26 |
| MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation | 26 |
| MDA 0307 Active non-implantable respiratory devices | 25 |
| MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis | 24 |
| MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport | 24 |
| MDA 0318 Other active non-implantable devices | 24 |
| MDA 0303 Active non-implantable devices utilising hyperthermia / hypothermia | 23 |
| MDA 0308 Active non-implantable devices for wound and skin care | 23 |
| MDA 0311 Active non-implantable dental devices | 23 |
| MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation | 22 |
| MDA 0201 Active non-implantable imaging devices utilising ionizing radiation | 21 |
| MDA 0310 Active non-implantable devices for ear, nose and throat | 18 |
| MDA 0301 Active non-implantable devices utilising ionizing radiation | 15 |
| MDA 0309 Active non-implantable ophthalmologic devices | 14 |
| MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy) | 11 |
| MDA 0314 Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART) | 10 |
| MDA 0101 Active implantable devices for stimulation / inhibition / monitoring | 8 |
| MDA 0102 Active implantable devices delivering drugs or other substances | 4 |
| MDA 0103 Active implantable devices supporting or replacing organ functions | 4 |
| MDA 0104 Active implantable devices utilising radiation and other active implantable devices | 4 |

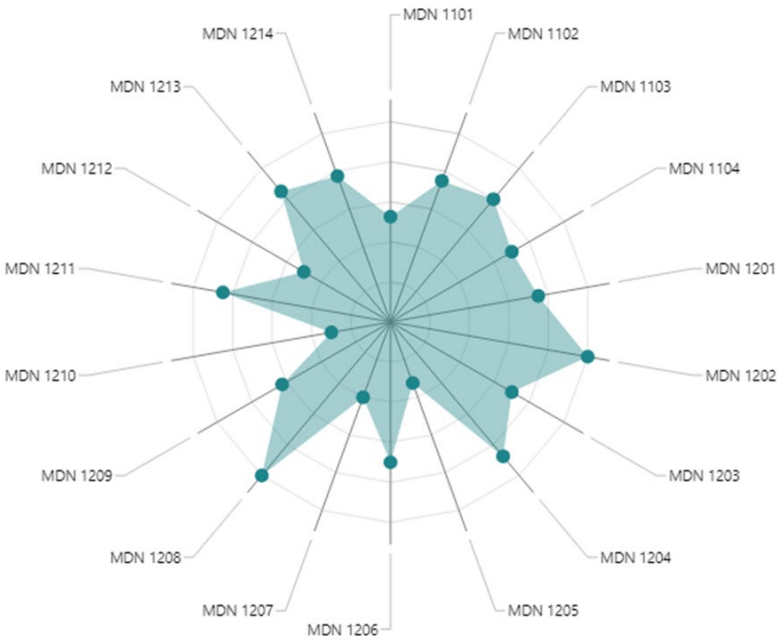


European Commission

# Which MDN codes are covered by MDR certificates?

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

**MDN = Non-active devices**

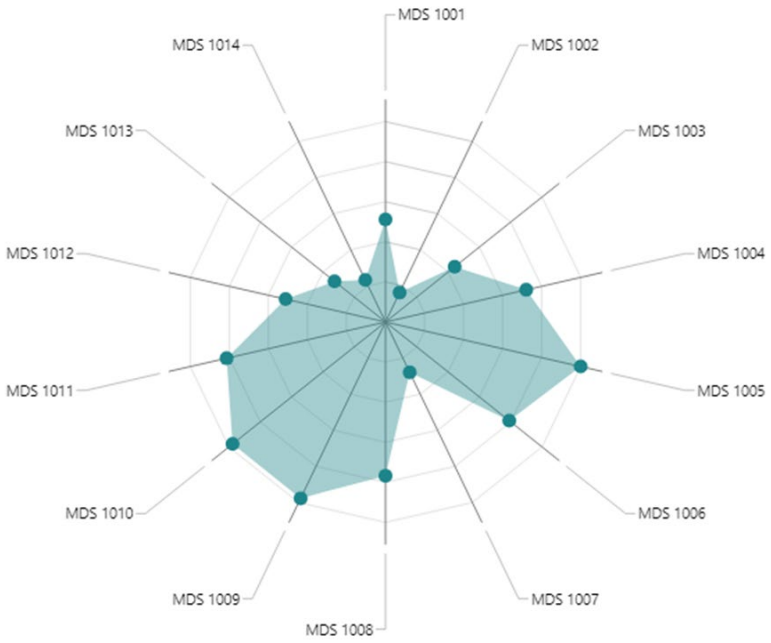



| | Number of NBs indicating devices/categories |
|---|---|
| MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis | 40 |
| MDN 1208 Non-active non-implantable instruments | 40 |
| MDN 1204 Non-active non-implantable devices for wound and skin care | 35 |
| MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing | 34 |
| 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 | 34 |
| MDN 1103 Non-active dental implants and dental materials | 32 |
| MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices | 31 |
| MDN 1102 Non-active osteo- and orthopaedic implants | 30 |
| MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care | 30 |
| MDN 1104 Non-active soft tissue and other implants | 28 |
| MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools | 28 |
| MDN 1206 Non-active non-implantable ophthalmologic devices | 28 |
| MDN 1209 Non-active non-implantable dental materials | 25 |
| MDN 1101 Non-active cardiovascular, vascular and neurovascular implants | 21 |
| MDN 1212 Non-active non-implantable devices for processing and pre-servation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART) | 20 |
| MDN 1207 Non-active non-implantable diagnostic devices | 16 |
| MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices | 13 |
| MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases | 12 |

# Which MDS codes are covered by MDR certificates?

## II Horizontal codes

**MDS = Devices with specific characteristics**




| | Number of NBs indicating devices/categories |
|---|---|
| MDS 1005 Devices in sterile condition | 43 |
| 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 | 42 |
| MDS 1010 Devices with a measuring function | 42 |
| MDS 1011 Devices in systems or procedure packs | 35 |
| MDS 1006 Reusable surgical instruments | 34 |
| MDS 1008 Devices utilising biologically active coatings and / or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body | 33 |
| MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council | 31 |
| MDS 1001 Devices incorporating medicinal substances | 22 |
| MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 | 22 |
| MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives | 19 |
| MDS 1013 Class III custom-made implantable devices | 14 |
| MDS 1007 Devices incorporating or consisting of nanomaterial | 12 |
| MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device | 10 |
| MDS 1002 Devices manufactured utilising tissues or cells of human origin, or their derivatives | 7 |

# Which MDT codes are covered by MDR certificates?

## II Horizontal codes

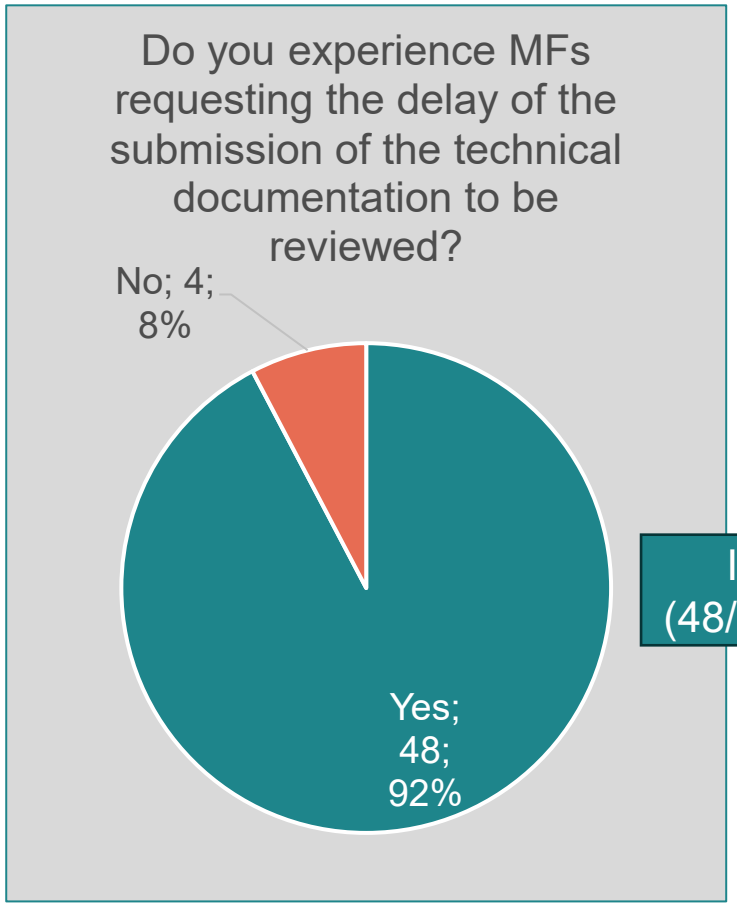
**MDT = Devices for which specific technologies or processes are used**


| | Number of NBs indicating devices/categories |
|---|---|
| MDT 2011 Devices which require packaging, including labelling | 46 |
| MDT 2001 Devices manufactured using metal processing | 44 |
| MDT 2002 Devices manufactured using plastic processing | 44 |
| MDT 2008 Devices manufactured in clean rooms and associated controlled environments | 43 |
| MDT 2010 Devices manufactured using electronic components including communication devices | 41 |
| MDT 2012 Devices which require installation, refurbishment | 41 |
| MDT 2006 Devices manufactured using chemical processing | 36 |
| MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper) | 34 |
| MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics) | 30 |
| MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals | 27 |
| MDT 2005 Devices manufactured using biotechnology | 21 |
| MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin | 21 |
| MDT 2013 Devices which have undergone reprocessing | 15 |

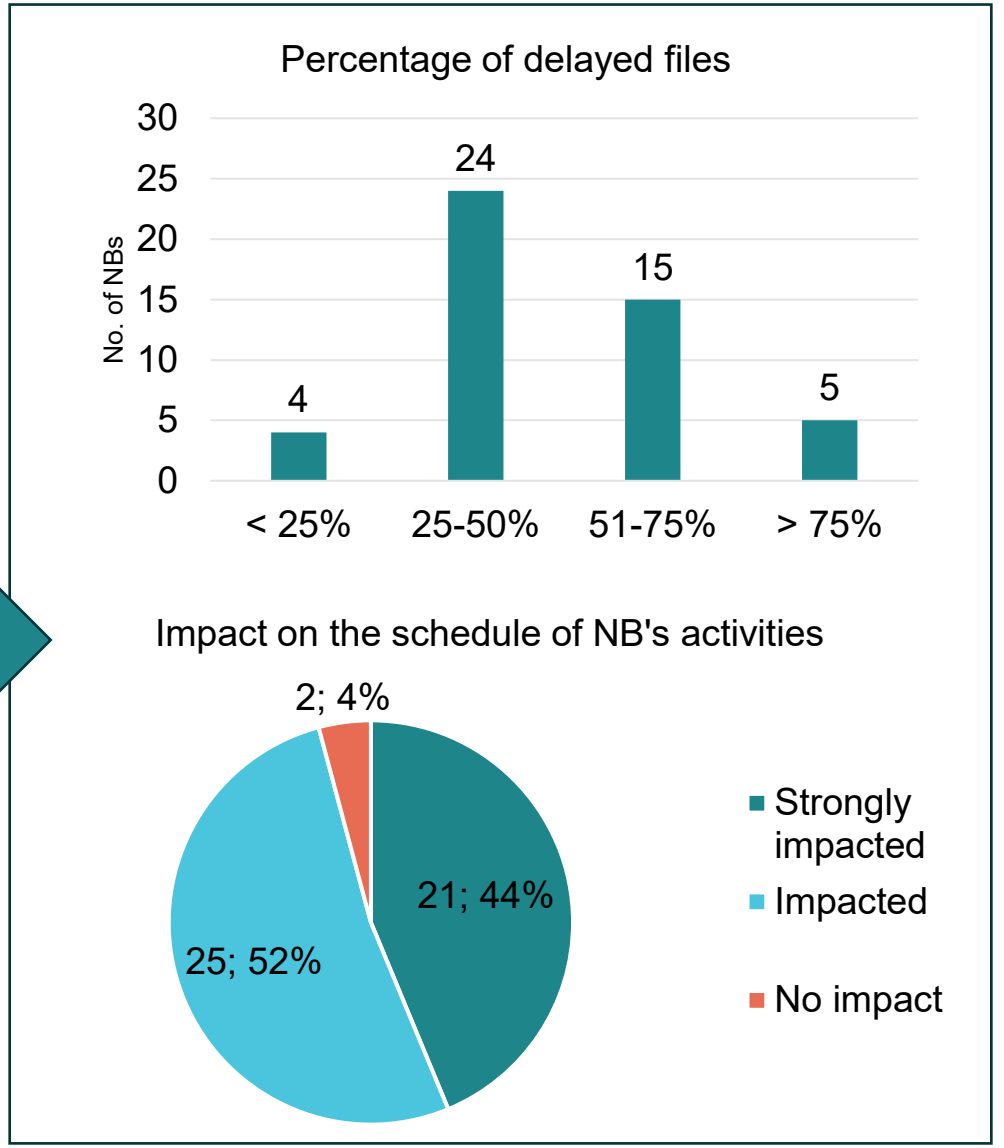


European Commission

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




If yes (48/52 NBs)

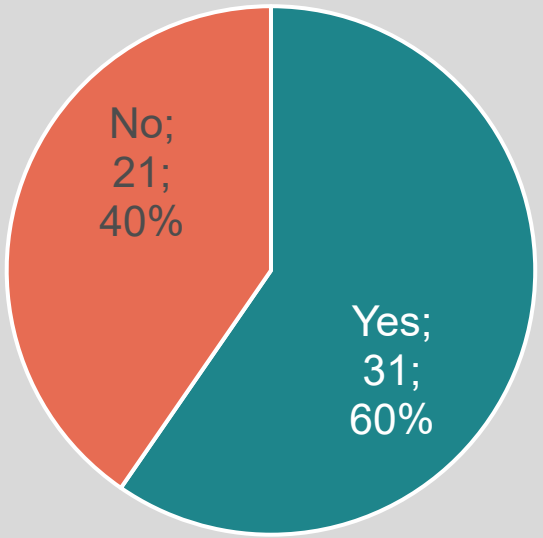



MDR designated NBs: 52

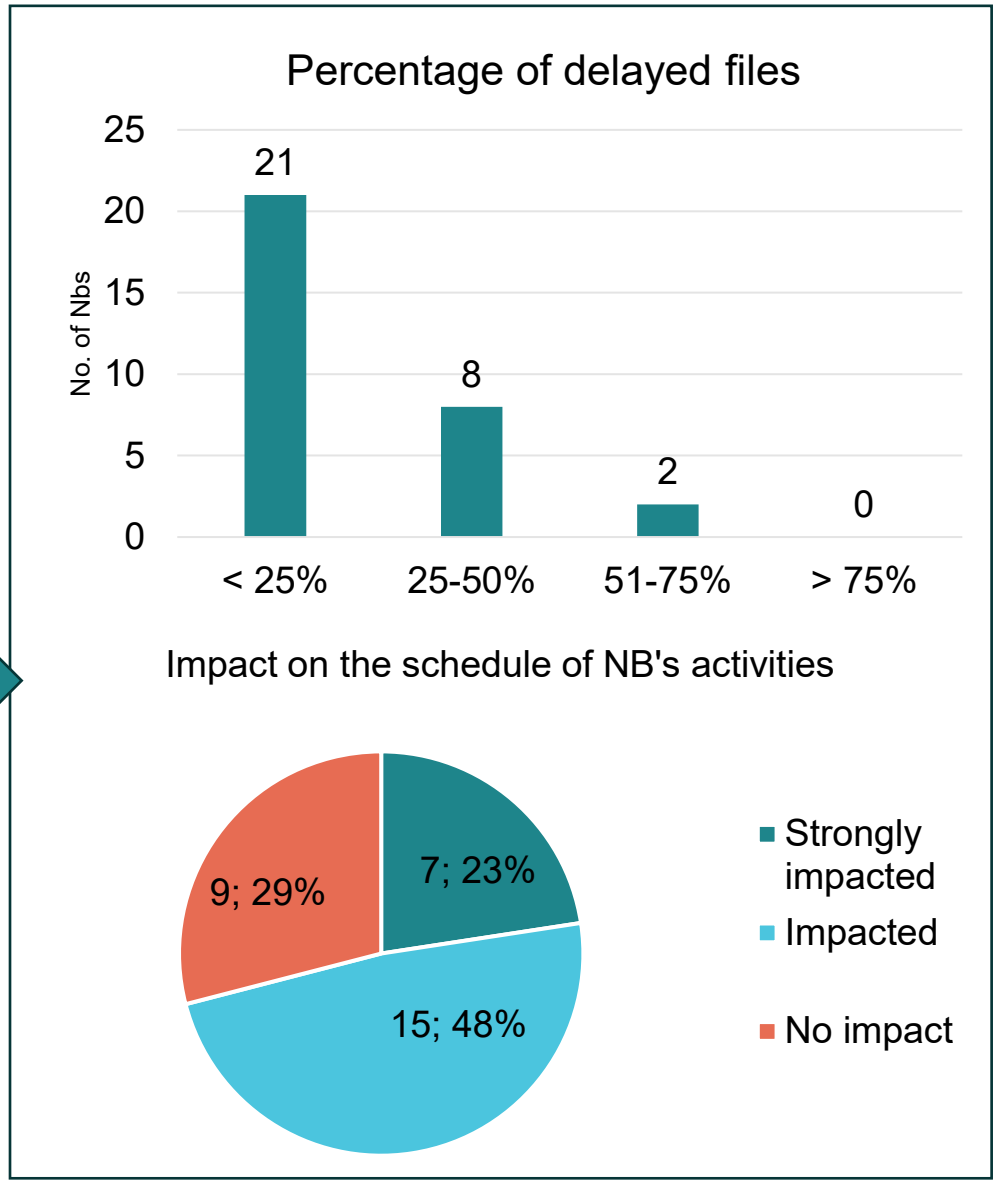
# Shifting of QMS audits from NBs‘ perspective

MD

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




If yes (31/52 NBs)




MDR designated NBs: 52



European Commission

IVD

# 3. Survey results for in vitro diagnostic medical devices

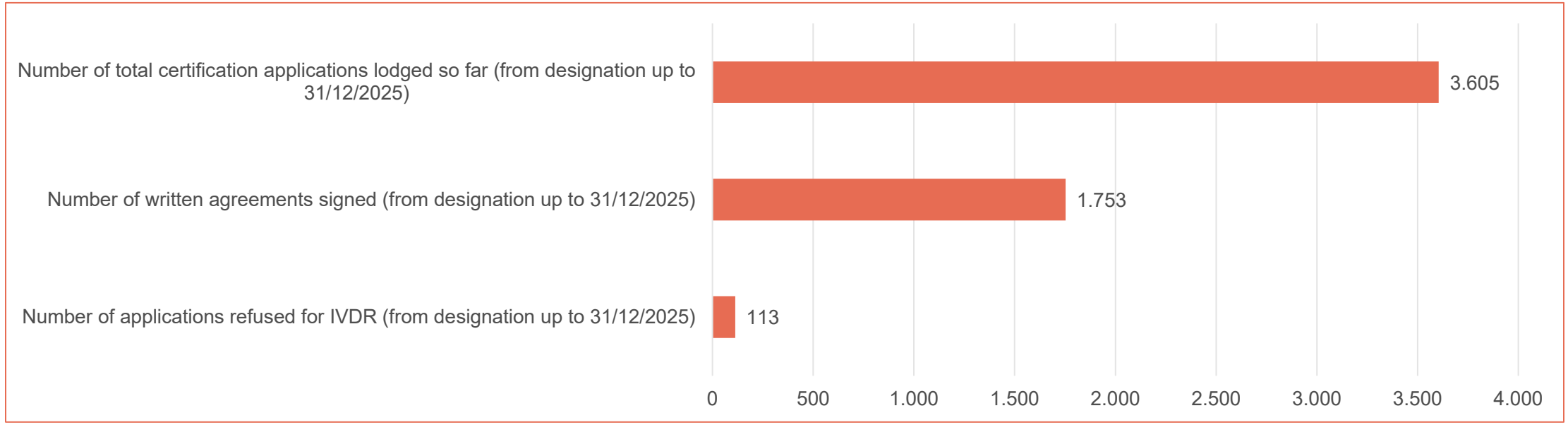
**Note:**

- 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** is a set of questions asked to notified bodies **every four months** concerning the activities they have been performing since their designation.
  Ⓛ The **large dataset** contains additional data asked to notified bodies **once a year**.

# IVDR applications filed and refused, written agreements signed

IVD




**Notes:**

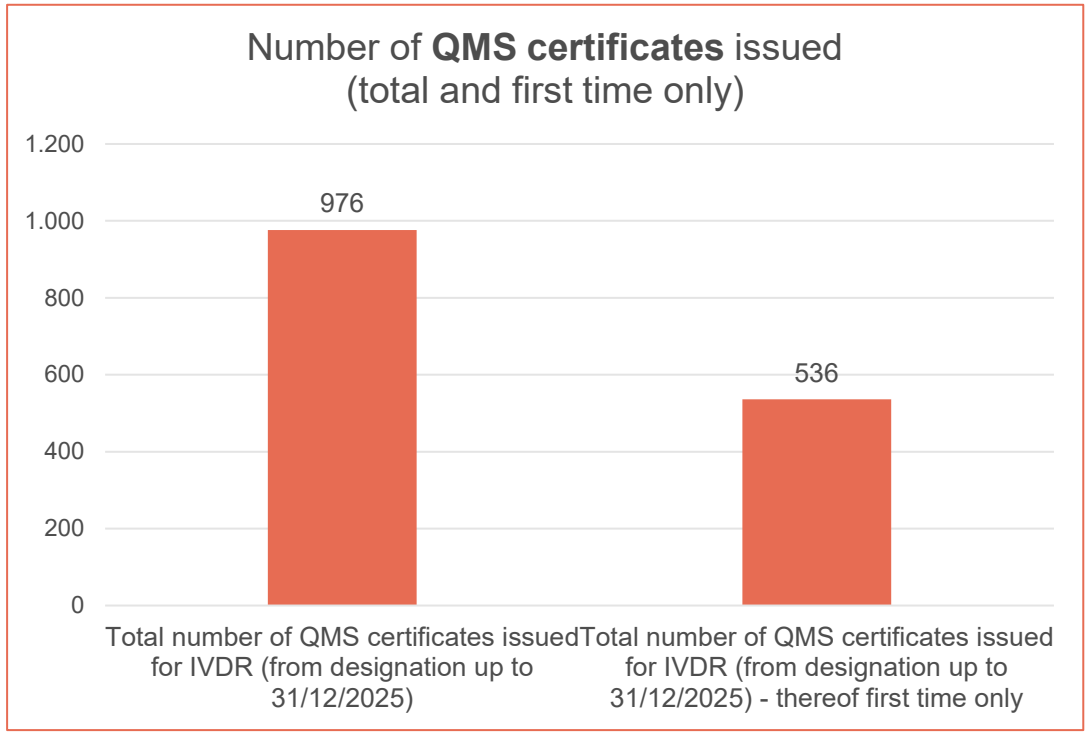
- **Designated NBs for IVD:** 19
- **Applications lodged**: This number includes **all applications lodged (syn. filed) so far** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 31/12/2025), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included.
- **Written agreements signed:** This refers to the number of written agreements (contracts) between a NB and a manufacturer signed by both parties.



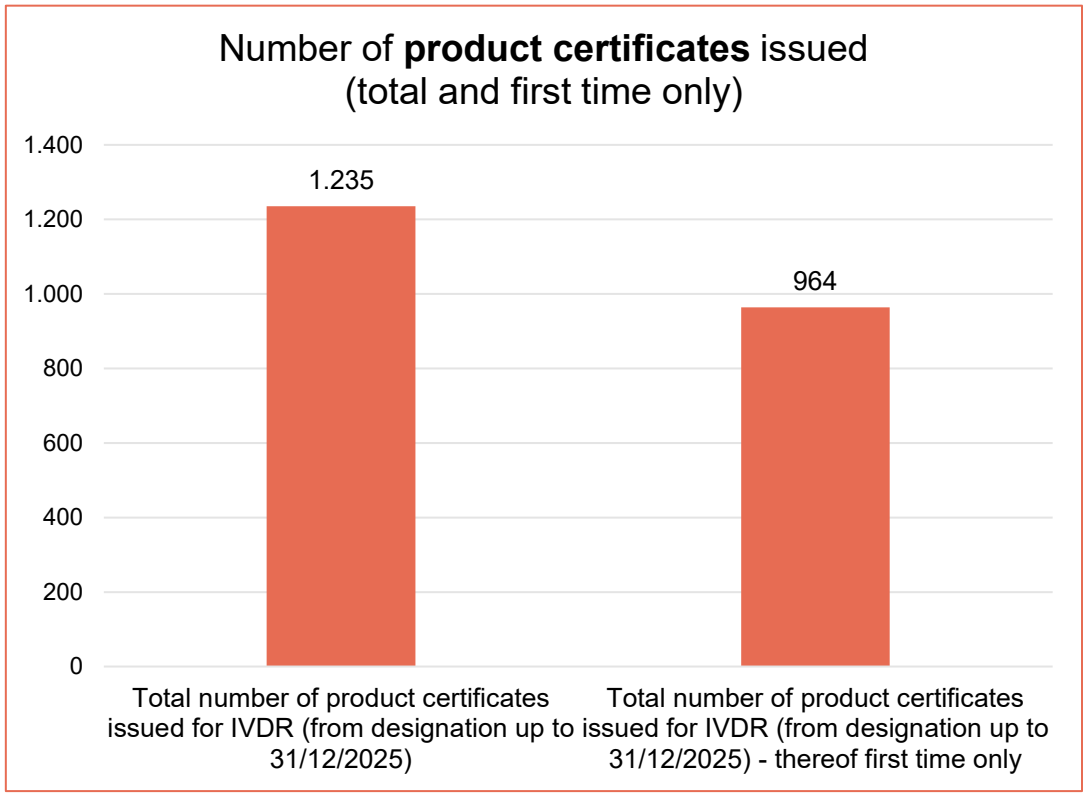
European Commission

# IVDR Number of QMS / product certificates issued

IVD




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



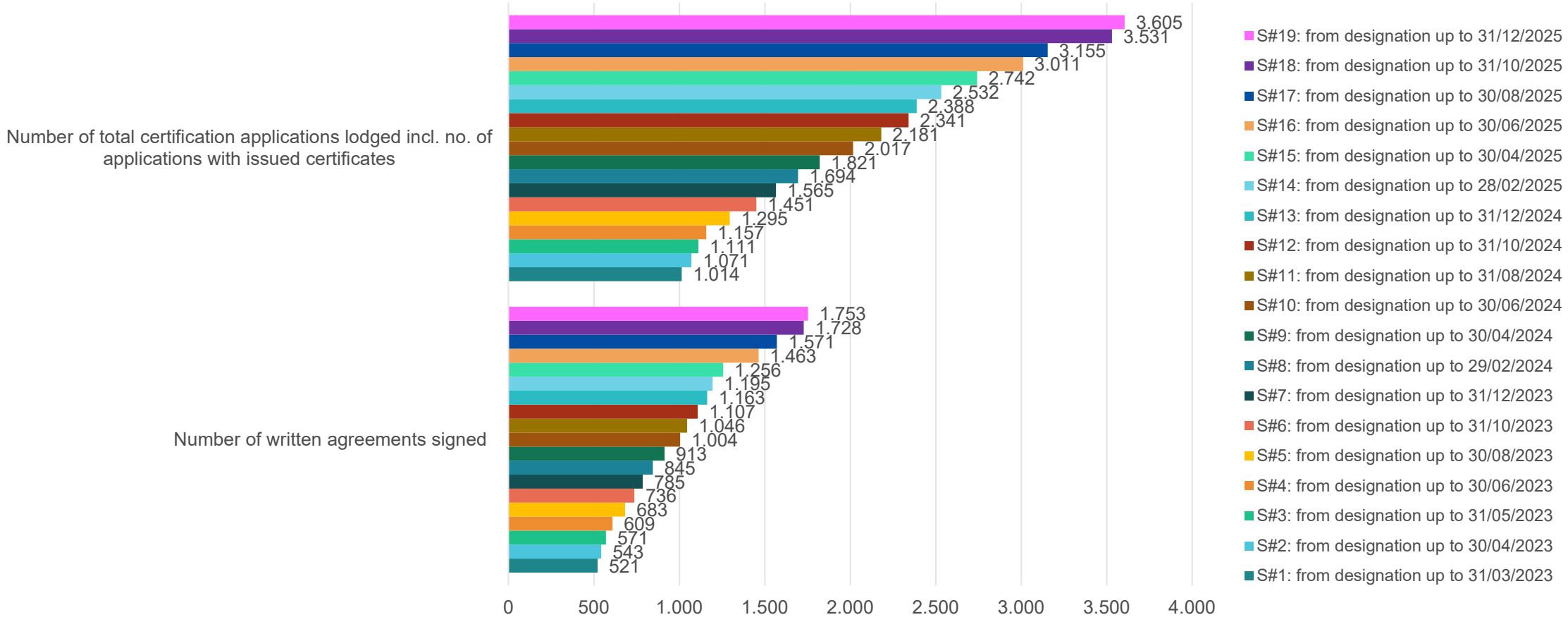

**Note PRODUCT Certificates:** This relates to Annex IX Chapter II or Annex X according to IVDR.



European Commission

IVD

# Survey comparison – March 2023 to December 2025




S = Survey; # = number

**Notes:**

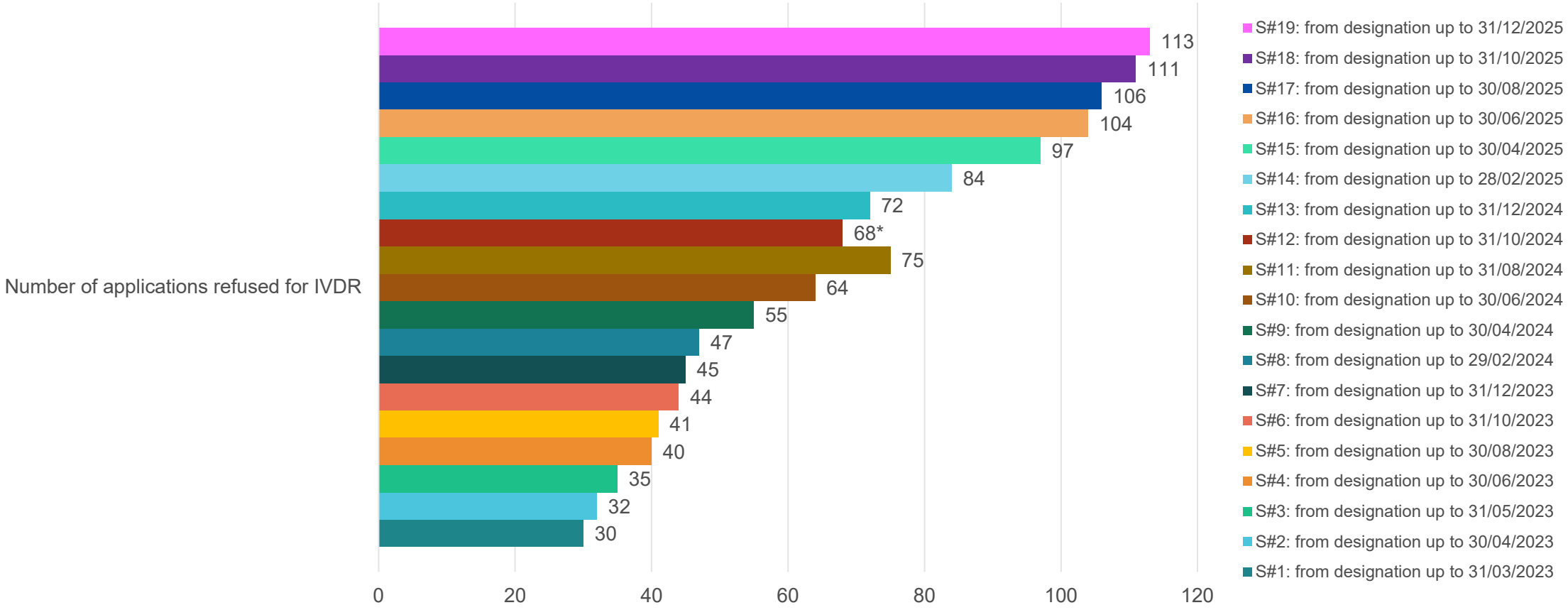
- Designated NBs for IVDs: S#1 to S#5: 10; S#6 to S#11: 12; S#12 to S#13: 13; S#14: 14; S#15: 16, S#16: 17, S#17: 18, S#18 & #19: 19
- Surveys **#2** and **#3** did not reach 100% response rate (S#2: ~70%; S#3: 56%). In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.



European Commission

IVD

# Survey comparison – March 2023 to December 2025




S = Survey; # = number

**Notes:**

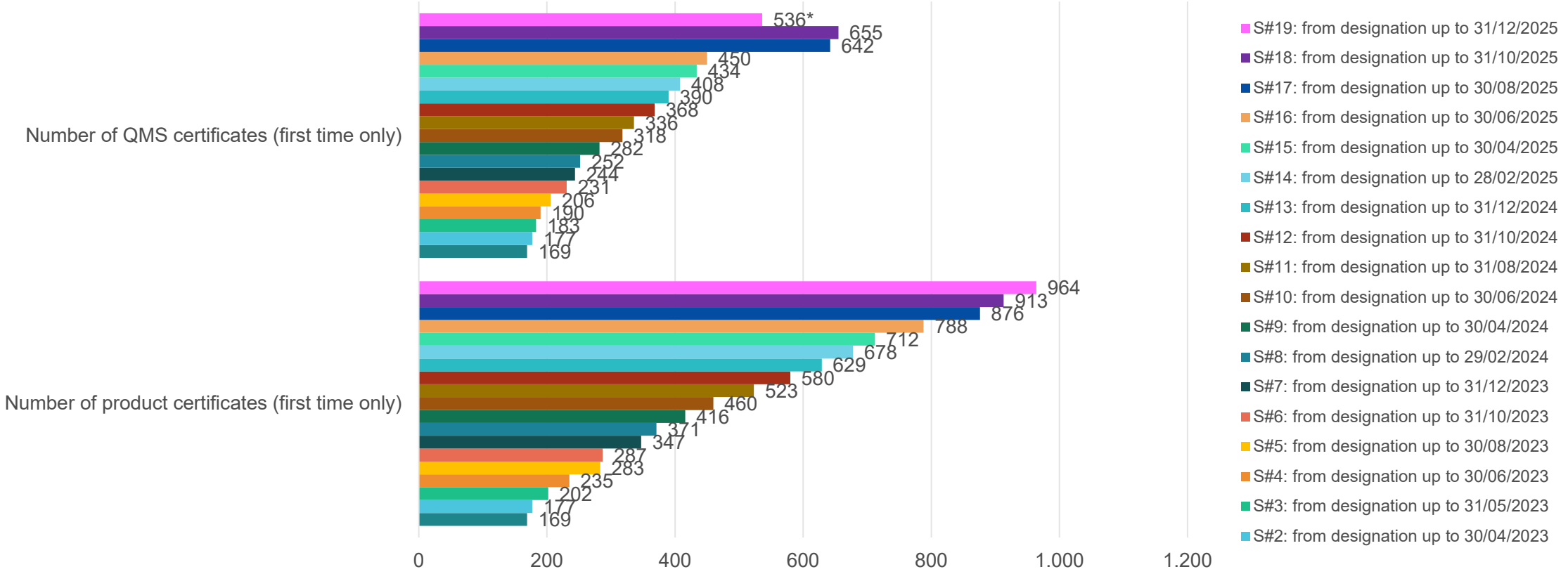
- Designated NBs for IVDs: S#1 to S#5: 10; S#6 to S#11: 12; S#12 to S#13: 13; S#14: 14; S#15: 16, S#16:16, S#17: 18, S#18 & #19: 19 (1 NB reporting 97 refused applications)
- Surveys **#2** and **#3** did not reach 100% response rate (S#2: ~70%; S#3: 56%). In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.
- * Change in methodology of counting refused applications compared to previous surveys by NBs in survey #12.



European Commission

IVD

# Survey comparison – March 2023 to December 2025




S = Survey; # = number

**Notes:**

- Designated NBs for IVDs: S#1 to S#5: 10; S#6 to S#11: 12; S#12 to S#13: 13; S#14: 14; S#15: 16, S#16: 17, S#17: 18, S#18 & #19: 19
- 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.
- * One NB revised its methodology for counting QMS certificates in survey #19, resulting in a decrease of total numbers.



European Commission

IVD

# Large dataset Ⓛ

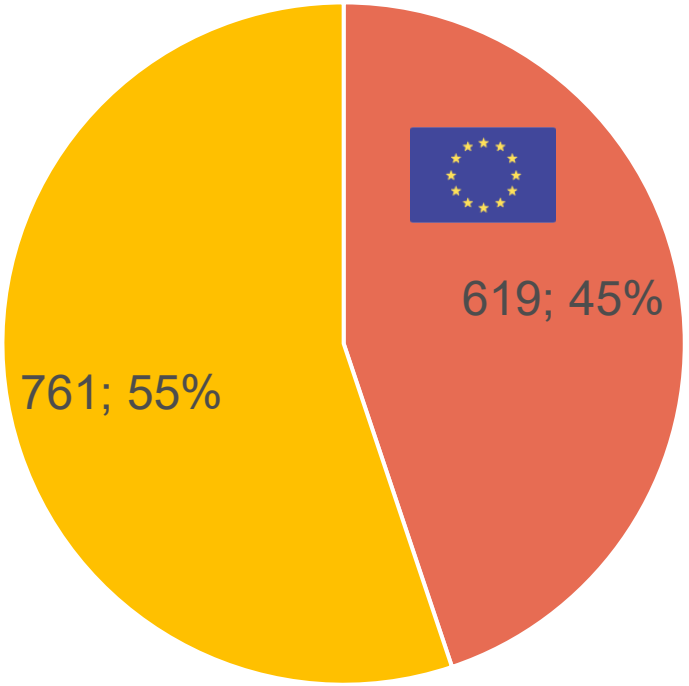
The **large dataset** contains additional data asked to notified bodies once or twice a year.

IVD

# Number of clients for IVDR

**December 2025**
**Total number of clients: 1.380**
**(June 2025: 1.073)**

Number of clients based **outside the EU**




Number of clients based **in the EU**

Notes: Data of 17 NBs (out of 19) designated under IVDR;
1 NB could not provide the data; 1 NB indicated that they do not have IVDR clients yet
Photo credit EU flag: Flaticon.com

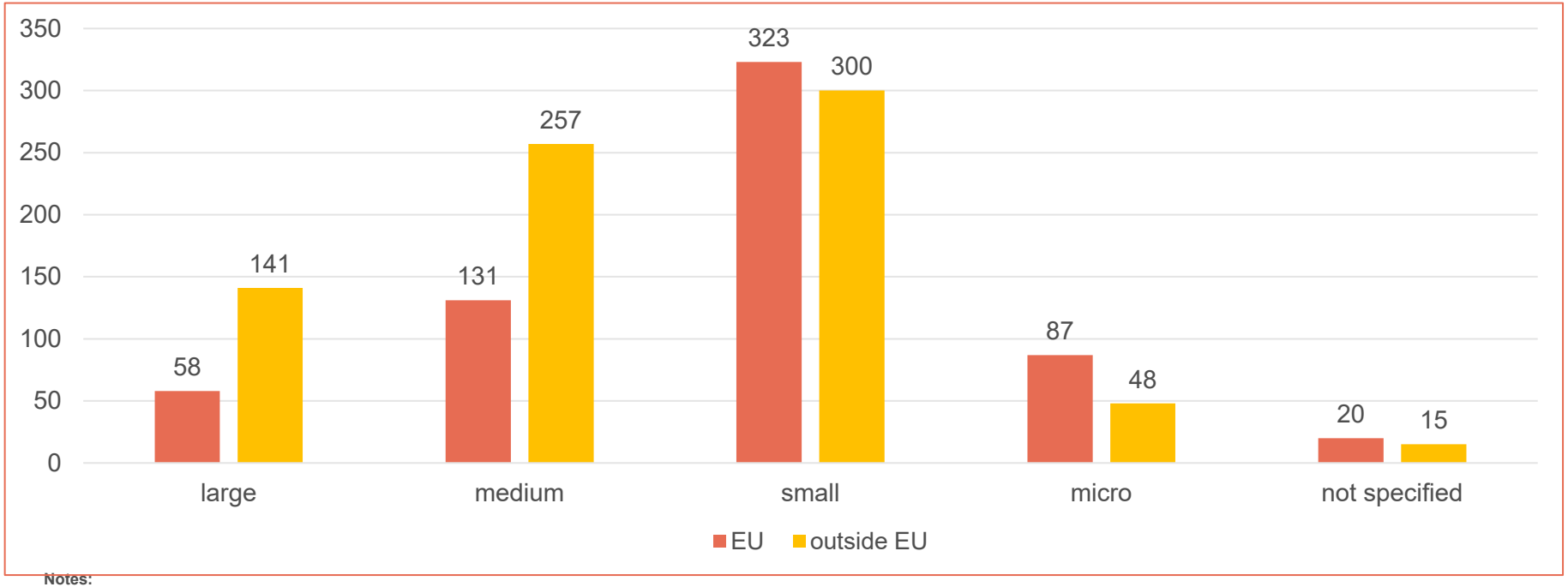


European Commission

IVD

# Number of clients for IVDR by size of enterprise

**December 2025**
**Total number of clients: 1.380**




**Clients:**

- **14% large companies** (EU: 9%, outside EU: 19%)
- **86% SMEs** (EU: 91%; outside EU: 81%)
- 9 NBs (53%) indicated that more than 90% of their clients are SMEs.

**Notes:**
Data of 17 NBs designated under IVDR; 7 NBs indicated that the provided data is based on estimations (mainly FTE, as data on turnover is not available to them); 1 NB indicated that EU numbers include Turkey & Norway customers;

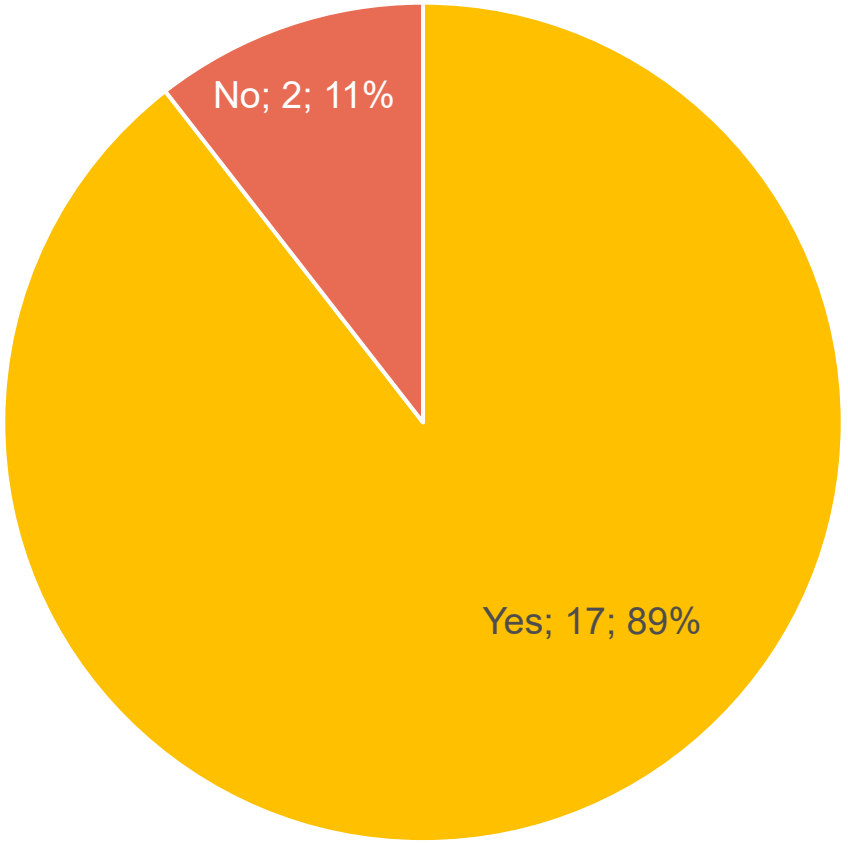
*Definitions:
• Micro enterprise = an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million
• Small enterprise = an enterprise which employs between 10 and 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million
• Medium enterprise = an enterprise which employs between 51 and 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.
• Large enterprise = an enterprise larger than a medium enterprise.
(Source: Extract of Article 2 of the annex to Recommendation 2003/361/EC)



European Commission

IVD

# Does your NB take on new clients for IVDR?




Data of 19 NBs designated under IVDR

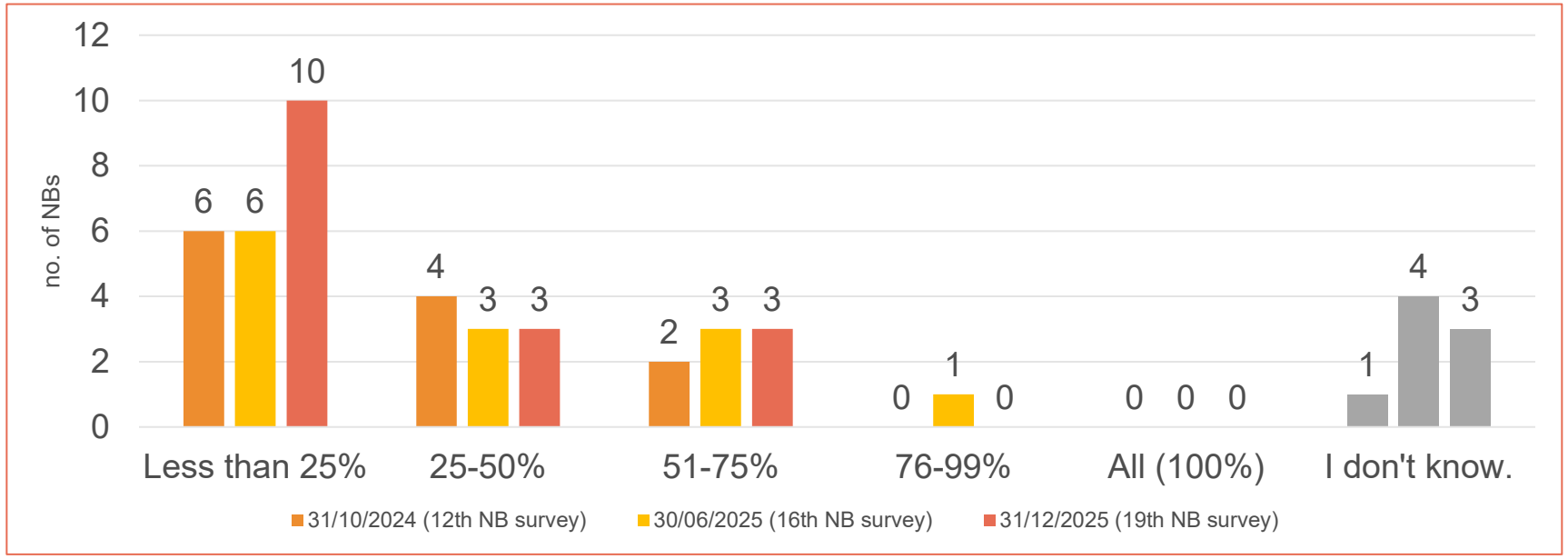


European Commission

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

IVD

**December 2025**
**Total number of clients: 1.380**




- 10 NBs (53%) indicated that less than 25 % of their clients with certificates under the Directive have completed the transfer to IVDR of all devices intended to be certificated
- 3 NBs (16%) indicated that > 50% of their clients have completed the transfer.
- No NB indicated that all clients have completed the transfer of all devices intended to be certificated.

12th NB survey: Data of 13 NBs designated under IVDR
16th NB survey: Data of 17 NBs designated under IVDR
19th NB survey: Data of 19 NBs designated under IVDR



European Commission

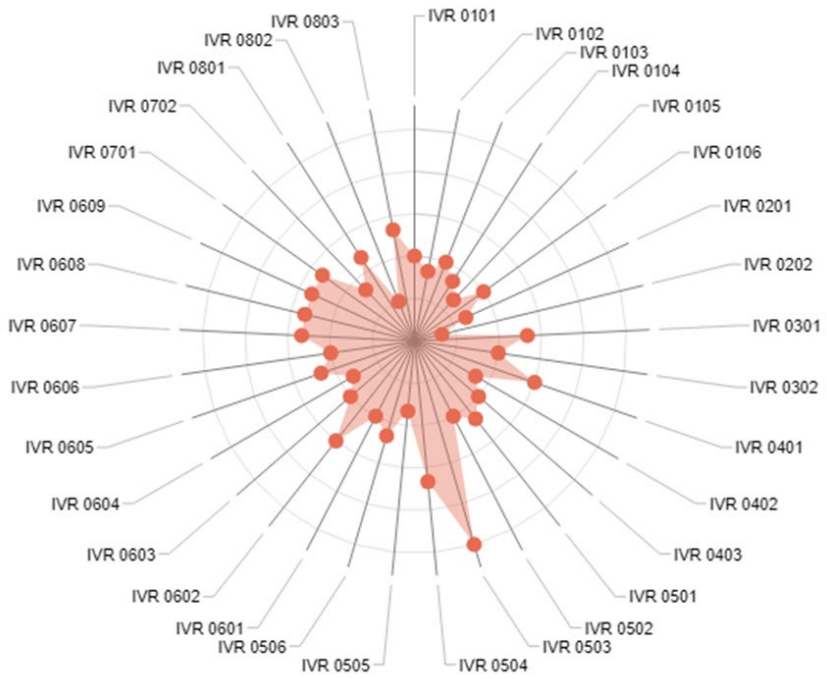
# Which IVR codes are covered by IVDR certificates?

IVD

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

### IVR

Devices for blood grouping, tissue typing, determination of markers of cancer and non-malignant tumours, human genetic testing, determination of markers of infection/immune status, non-infectious diseases, physiological markers, disorders/impairments (exept human genetic testing) and therapeutic measures, control materials without an assigned quantitative or qualitative value, class A devices in sterile condition




| | Number of NBs indicating devices/categories |
|---|---|
| IVR 0503 Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents | 15 |
| IVR 0504 Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging | 10 |
| IVR 0401 Devices intended to be used in screening/confirmation of congenital/inherited disorders | 9 |
| IVR 0602 Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease | 9 |
| IVR 0301 Devices intended to be used in screening, diagnosis, staging or monitoring of cancer | 8 |
| IVR 0607 Devices intended to be used for detection of pregnancy or fertility testing | 8 |
| IVR 0608 Devices intended to be used for screening, determination or monitoring of physiological markers | 8 |
| IVR 0609 Other devices intended to be used to define or monitor physiological status and therapeutic measures | 8 |
| IVR 0701 Devices which are controls without a quantitative assigned value | 8 |
| IVR 0803 Specimen receptacles referred to in point 2.5 (rule 5), under c), of Annex VIII to Regulation (EU) 2017/746 | 8 |
| IVR 0501 Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents | 7 |
| IVR 0506 Other devices intended to be used to determine markers of infections/immune status | 7 |
| IVR 0605 Devices intended to be used for monitoring of levels of medicinal products, substances or biological components | 7 |
| IVR 0801 Devices referred to in point 2.5 (rule 5), under a), of Annex VIII to Regulation (EU) 2017/746 | 7 |
| IVR 0101 Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)] | 6 |
| IVR 0103 Devices intended to determine markers of the Kell system [Kel1 (K)] | 6 |
| IVR 0106 Other devices intended to be used for blood grouping | 6 |

| | Number of NBs indicating devices/categories |
|---|---|
| IVR 0302 Other devices intended to be used for markers of cancer and non-malignant tumours | 6 |
| IVR 0403 Other devices intended to be used for human genetic testing | 6 |
| IVR 0502 Devices intended to be used to detect the presence of, or exposure to transmissible agents in blood, blood components, cells, tissues or organs, or in any of their derivatives, to assess their suitability for transfusion, transplantation or cell administration | 6 |
| IVR 0601 Devices intended to be used for screening/confirmation of specific disorders/impairment | 6 |
| IVR 0603 Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances | 6 |
| IVR 0606 Devices intended to be used for non-infectious disease staging | 6 |
| IVR 0102 Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)] | 5 |
| IVR 0104 Devices intended to determine markers of the Kidd system [JK1 (Jka), JK2 (Jkb)] | 5 |
| IVR 0402 Devices intended to be used to predict genetic disease/disorder risk and prognosis | 5 |
| IVR 0505 Devices intended to be used to grow/isolate/identify and handle infectious agents | 5 |
| IVR 0604 Other devices intended to be used for a specific disease | 5 |
| IVR 0702 Devices which are controls without a qualitative assigned value | 5 |
| IVR 0105 Devices intended to determine markers of the Duffy system [FY1 (Fya), FY2 (Fyb)] | 4 |
| IVR 0201 Devices intended to be used for tissue typing (HLA A, B, DR) to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration | 4 |
| IVR 0802 Instruments intended specifically to be used for in vitro diagnostic procedures referred to in point 2.5 (rule 5), under b), of Annex VIII to Regulation (EU) 2017/746 | 3 |
| IVR 0202 Other devices intended to be used for tissue typing | 2 |

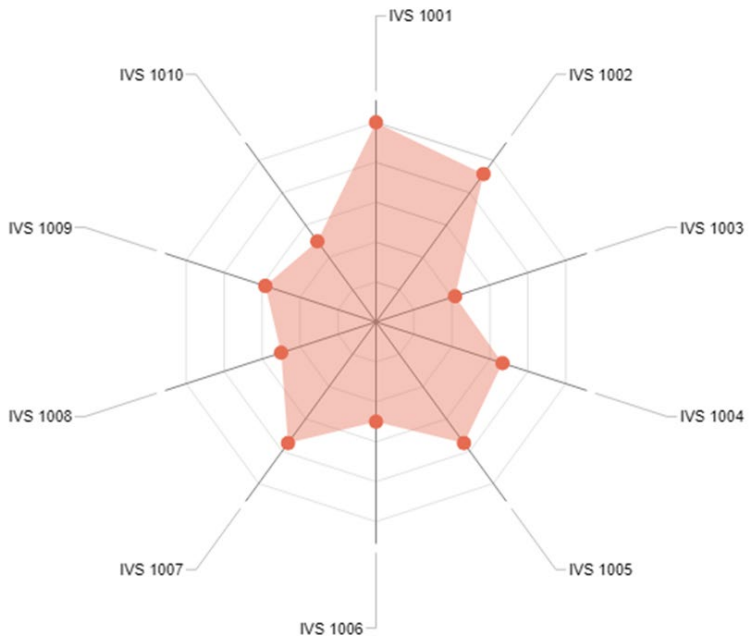
# Which IVS codes are covered by IVDR certificates?

IVD

## II: Horizontal codes

### IVS

In vitro diagnostic devices with specific characteristics




| | Number of NBs indicating devices/categories |
|---|---|
| IVS 1001 Devices intended to be used for near-patient testing | 12 |
| IVS 1002 Devices intended to be used for self-testing | 11 |
| IVS 1005 Devices in sterile condition | 9 |
| IVS 1007 Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes (point 1.6 of Annex VIII to Regulation (EU) 2017/746) | 9 |
| IVS 1004 Devices manufactured utilising tissues or cells of human origin, or their derivatives | 8 |
| IVS 1009 Software that are devices in themselves including software apps, software for data analysis, and for defining or monitoring therapeutic measures | 7 |
| IVS 1006 Calibrators (point 1.5 of Annex VIII to Regulation (EU) 2017/746) | 6 |
| IVS 1008 Instruments, equipment, systems or apparatus | 6 |
| IVS 1010 Devices incorporating software/utilising software/controlled by software | 6 |
| IVS 1003 Devices intended to be used as companion diagnostics | 5 |



European Commission

# Which IVT codes are covered by IVDR certificates?

IVD

## II: Horizontal codes

### IVT

In vitro diagnostic devices
for which specific technologies are used


| | Number of NBs indicating devices/categories |
|---|---|
| IVT 2005 In vitro diagnostic devices manufactured using biotechnology | 13 |
| IVT 2011 In vitro diagnostic devices which require packaging, including labelling | 13 |
| IVT 2006 In vitro diagnostic devices manufactured using chemical processing | 12 |
| IVT 2009 In vitro diagnostic devices manufactured using processing of materials of human, animal or microbial origin | 12 |
| IVT 2008 In vitro diagnostic devices manufactured in clean rooms and associated controlled environments | 11 |
| IVT 2002 In vitro diagnostic devices manufactured using plastic processing | 8 |
| IVT 2010 In vitro diagnostic devices manufactured using electronic components including communication devices | 7 |
| IVT 2003 In vitro diagnostic devices manufactured using non-metal mineral processing (e.g. glass, ceramics) | 4 |
| IVT 2001 In vitro diagnostic devices manufactured using metal processing | 3 |
| IVT 2004 In vitro diagnostic devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper) | 1 |
| IVT 2007 In vitro diagnostic devices which require knowledge regarding the production of pharmaceuticals | 1 |

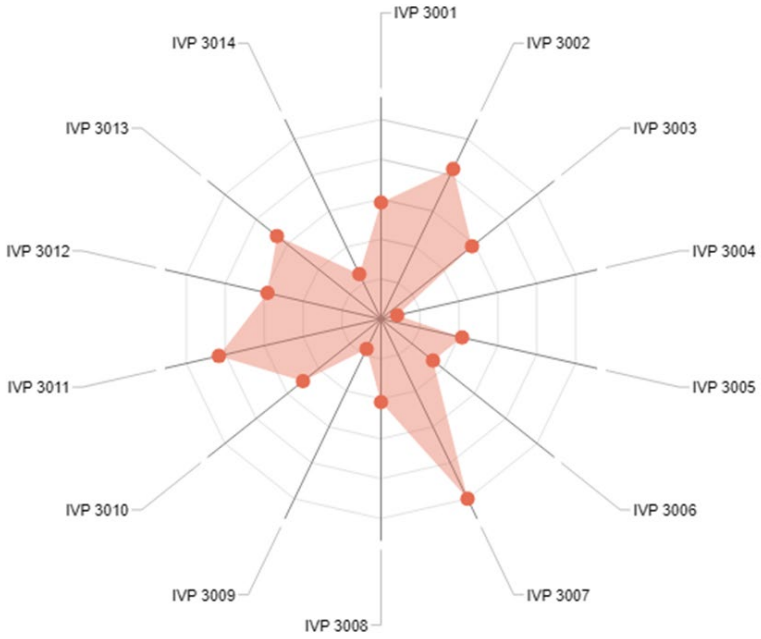
# Which IVP codes are covered by IVDR certificates?

IVD

## II: Horizontal codes

### IVP

In vitro diagnostic devices
which require specific knowledge in examination
procedures for the purpose of product verification




| | Number of NBs indicating devices/categories |
|---|---|
| IVP 3007 In vitro diagnostic devices which require knowledge regarding immunoassays | 12 |
| IVP 3002 In vitro diagnostic devices which require knowledge regarding biochemistry | 10 |
| IVP 3011 In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS) | 10 |
| IVP 3013 In vitro diagnostic devices which require knowledge regarding spectroscopy | 8 |
| IVP 3001 In vitro diagnostic devices which require knowledge regarding agglutination tests | 7 |
| IVP 3003 In vitro diagnostic devices which require knowledge regarding chromatography | 7 |
| IVP 3012 In vitro diagnostic devices which require knowledge regarding physical chemistry including electrochemistry | 7 |
| IVP 3010 In vitro diagnostic devices which require knowledge regarding microscopy | 6 |
| IVP 3005 In vitro diagnostic devices which require knowledge regarding coagulometry | 5 |
| IVP 3008 In vitro diagnostic devices which require knowledge regarding lysis based testing | 5 |
| IVP 3006 In vitro diagnostic devices which require knowledge regarding flow cytometry | 4 |
| IVP 3014 In vitro diagnostic devices which require knowledge regarding tests of cell function | 3 |
| IVP 3009 In vitro diagnostic devices which require knowledge regarding measurement of radioactivity | 2 |
| IVP 3004 In vitro diagnostic devices which require knowledge regarding chromosomal analysis | 1 |



European Commission

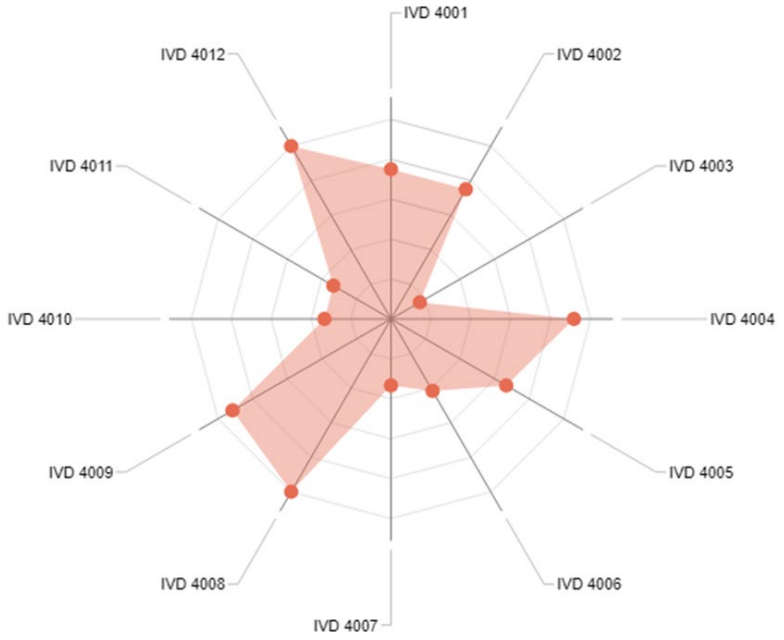
# Which IVD codes are covered by IVDR certificates?

IVD

## II: Horizontal codes

### IVD

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

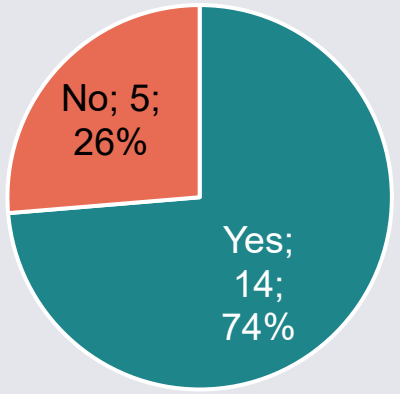



| | Number of NBs indicating devices/categories |
|---|---|
| IVD 4008 In vitro diagnostic devices which require knowledge regarding immunology | 12 |
| IVD 4012 In vitro diagnostic devices which require knowledge regarding virology | 12 |
| IVD 4004 In vitro diagnostic devices which require knowledge regarding genetics | 11 |
| IVD 4009 In vitro diagnostic devices which require knowledge regarding molecular biology/diagnostics | 11 |
| IVD 4001 In vitro diagnostic devices which require knowledge regarding bacteriology | 9 |
| IVD 4002 In vitro diagnostic devices which require knowledge regarding clinical chemistry/biochemistry | 9 |
| IVD 4005 In vitro diagnostic devices which require knowledge regarding haematology/haemostasis, including coagulation disorders | 8 |
| IVD 4006 In vitro diagnostic devices which require knowledge regarding histocompatibility and immunogenetics | 5 |
| IVD 4007 In vitro diagnostic devices which require knowledge regarding immunohistochemistry/histology | 4 |
| IVD 4010 In vitro diagnostic devices which require knowledge regarding mycology | 4 |
| IVD 4011 In vitro diagnostic devices which require knowledge regarding parasitology | 4 |
| IVD 4003 In vitro diagnostic devices which require knowledge regarding detection of transmissible agents (without organisms or viruses) | 2 |

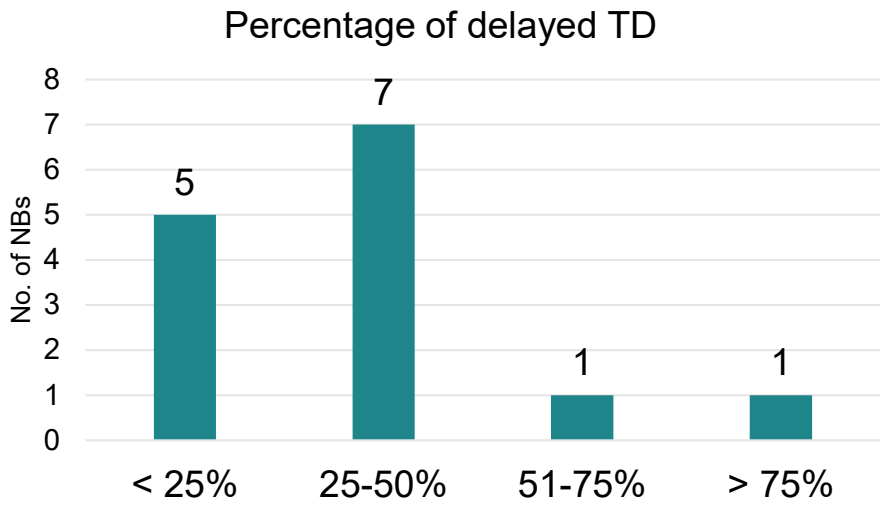
# Technical documentation (TD) – shifting of submission from NBs‘ perspective

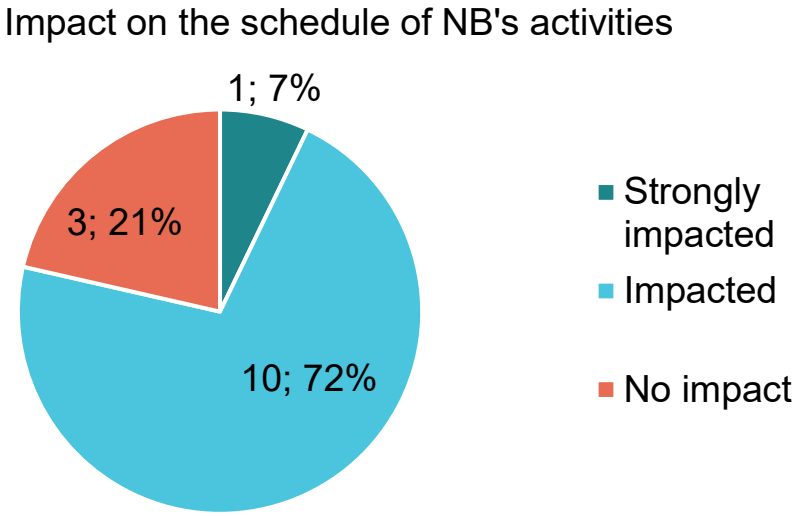
IVD

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




If yes (14/19 NBs)




IVDR designated NBs: 19

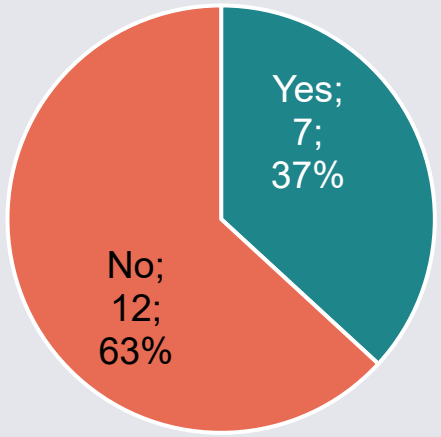


European Commission

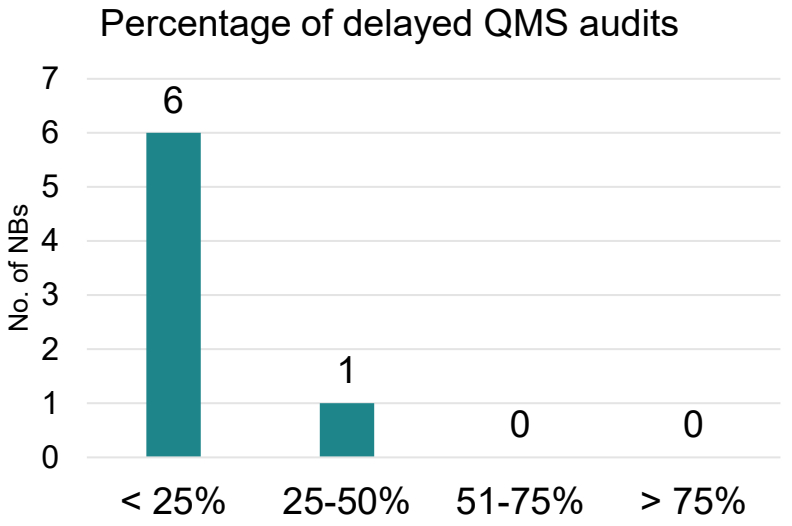
IVD

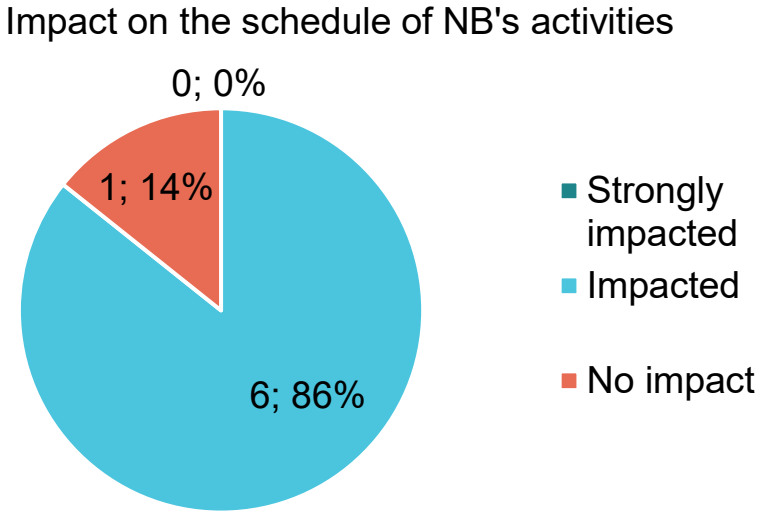
# Shifting of QMS audits from NBs‘ perspective

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




If yes (7/19 NBs)




IVDR designated NBs: 19



European Commission

IVD

MD

# 4. Survey results regarding NB staff

**Note:**

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

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

# Staff: Number of people employed by NBs in the field of medical devices (MDR & IVDR)

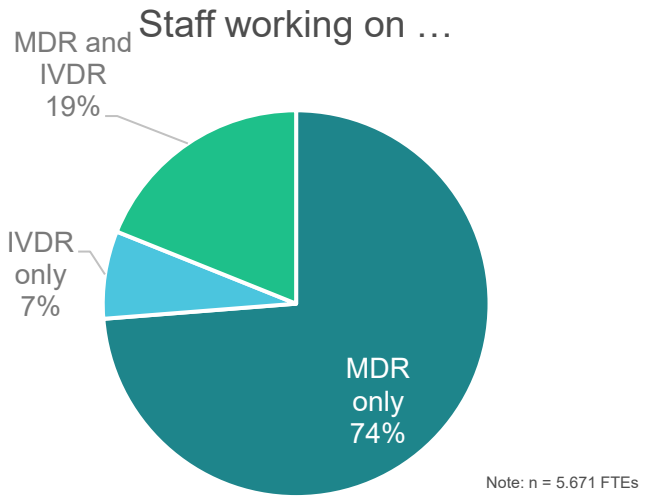
MD

IVD

**Note:** Out of 53 notified bodies, 34 NBs are designated under the MDR only, 18 NBs are designated under both the MDR and IVDR, and 1 NB is designated under the IVDR only.

**December 2025**
Total number of FTEs with conformity assessment activities and within administrative and supporting activities: **6.198**
(internal staff and external contractors;
- 1% compared to 30/06/25)

- Thereof number of personnel with relevant clinical expertise: 854 FTEs




Note: n = 5.671 FTEs

**Notes:**
- Data status: 31/12/2025
- By employee type
- Counted in Full Time Equivalents (FTE)*

**Employees within conformity assessment activities: 4.897 FTE** (+0,2% compared to 30/06/25)
- Internal: 3.765 FTEs (+4%)
- External contractors: 1.132 FTEs (-11%)

**Employees within administrative and supporting activities (in relation to Regulations): 1.301 (FTE; -7% compared to 30/06/2025)**
- Internal: 1.274 FTEs (-3%)
- External contractors: 27 FTEs (-67%)

Employees within the conformity assessment activities is the personnel referred to in Sections from 3.2.3 to 3.2.7 of Annex VII MDR/IVDR in addition to the personnel referred to in Section 4.4, second paragraph, of Annex VII MDR/IVDR ([…individual responsible for ensuring that the assessment of that application is conducted in accordance with the relevant procedures and for ensuring that the appropriate resources including personnel are utilised for each of the tasks of the assessment…].
Other roles would fit under employees within "administrative and supporting activities", including e.g. commercial operations team, marketing team, sales team, training team etc.
Data of 53 NBs;
*Approximation of FTEs as some experts work part-time



European Commission

# 5. Medical device single audit program (MDSAP) and monitoring conformity assessment activities

MD

IVD

L

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

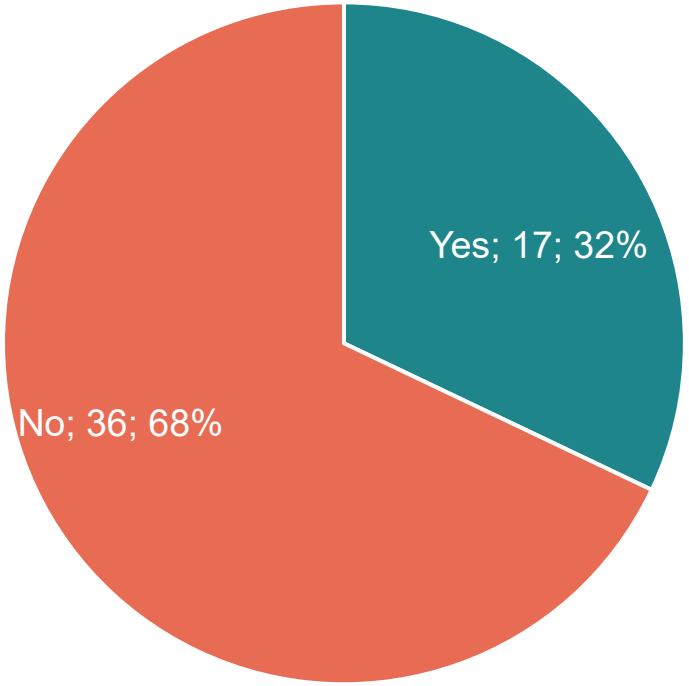
Q17

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

MD

IVD

MDSAP auditing organisation




If yes:

**1620 MDR certificates** and
**226 IVDR certificates**
have already been issued on the basis of the MDSAP/MDR-IVDR combined audit

**Notes:**

- MDR: Data from 17 NBs (thereof 4 NBs indicated „0“)
- IVDR: Data from 10 NBs (thereof 5 NBs indicated „0“)

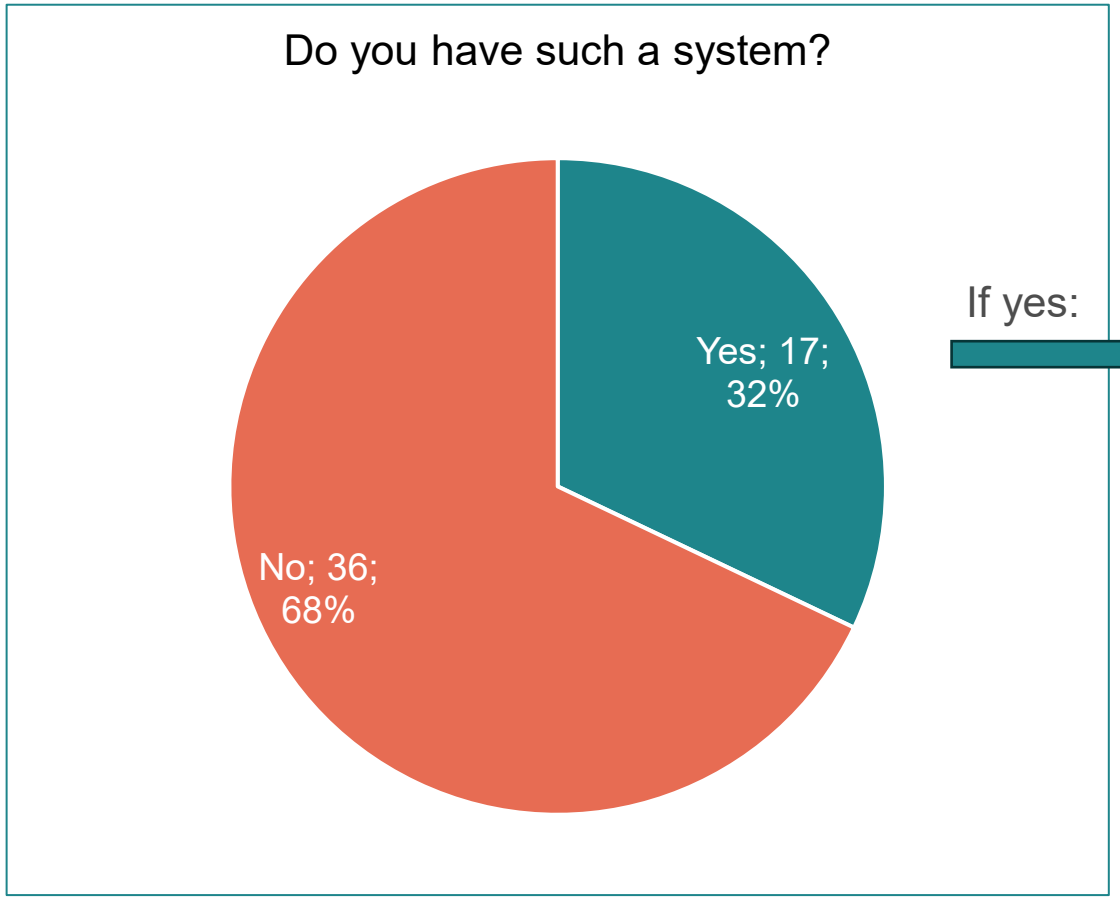
Data of 53 NBs designated under MDR and/or IVDR



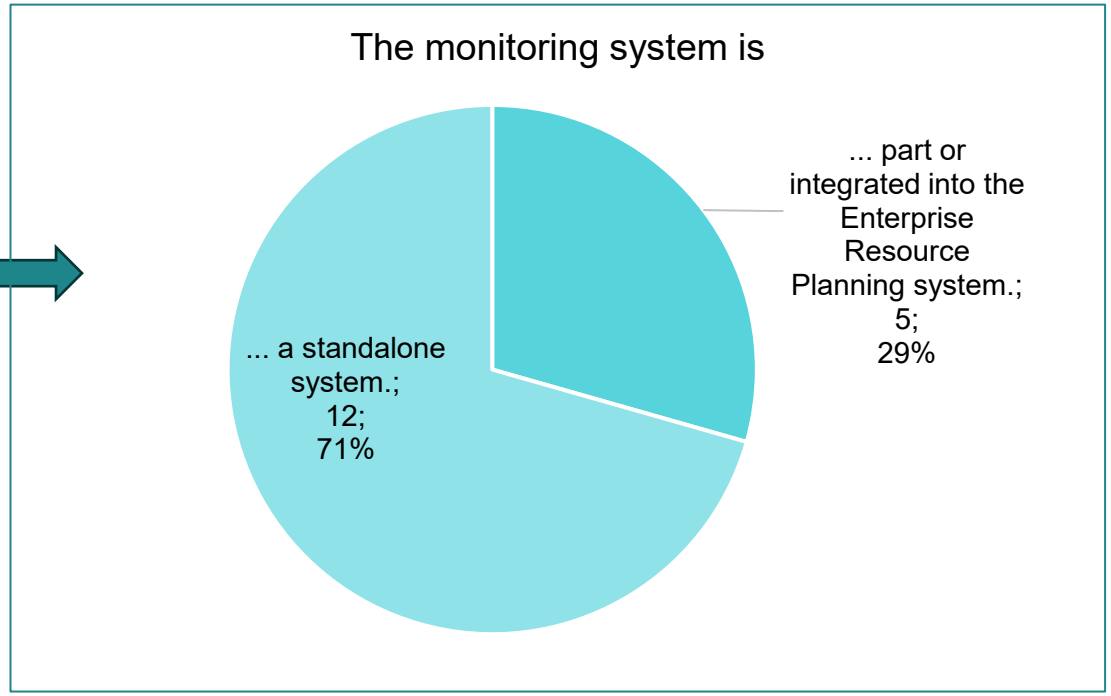
European Commission

# System for monitoring the conformity assessment activities that can provide data on certification **timelines**

MD
IVD



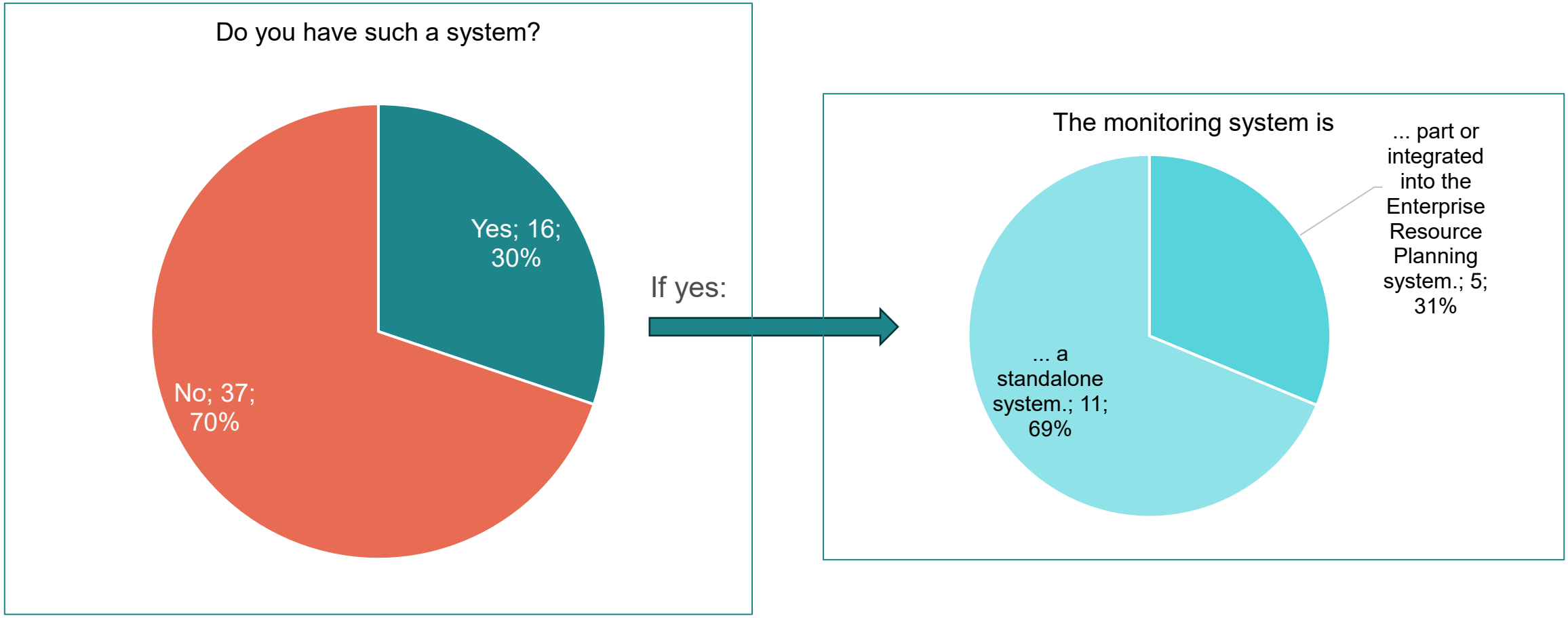

If yes:




Data of 53 NBs designated under MDR and/or IVDR

# System for monitoring the conformity assessment activities that can provide data on certification **costs**

MD
IVD




Data of 53 NBs designated under MDR and/or IVDR

# Thank you

## Contact for questions: medical.devices@goeg.at

Austrian National Public Health Institute/ Gesundheit Österreich (GÖG)





European Commission