

# MDCG meeting

Study supporting the monitoring of availability of  
medical devices on the EU market  
(HaDEA/2021/P3/03)

24 April 2024



Videoconference

**Areté** The Agri-food  
Intelligence  
Company

**CIVIC**  
CONSULTING

**Gesundheit Österreich**  
GmbH 



# Content

1. About the study
2. Ongoing and planned survey activities
  - a. Survey with notified bodies
  - b. Survey with manufacturers and authorised representatives
  - c. Survey with health service providers
3. Dashboard





# 1. About the study

# 1. About the “Study supporting the monitoring of availability of medical devices on the EU market”

## Commissioned by:

The European Commission’s Directorate-General for Health and Food Safety (DG SANTE) via the European Health and Digital Executive Agency (HaDEA) - HADEA/2021/P3/03

**Aim:** To support monitoring and analyzing the availability of medical devices and in vitro diagnostic 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**

**Geographic scope:** 30 countries (27 EU Member States plus Iceland, Liechtenstein and Norway)

## Duration:

2 December 2022 – 1 December 2025 (36 months)

## Study team:

- **Project lead:** Gesundheit Österreich GmbH (GÖG) / Austrian National Public Health Institute → project lead
- **Project partners:** Areté, Civic Consulting
- **Supported by an Expert Advisory Group:** Four MD experts providing methodological and thematic support

## Contact:



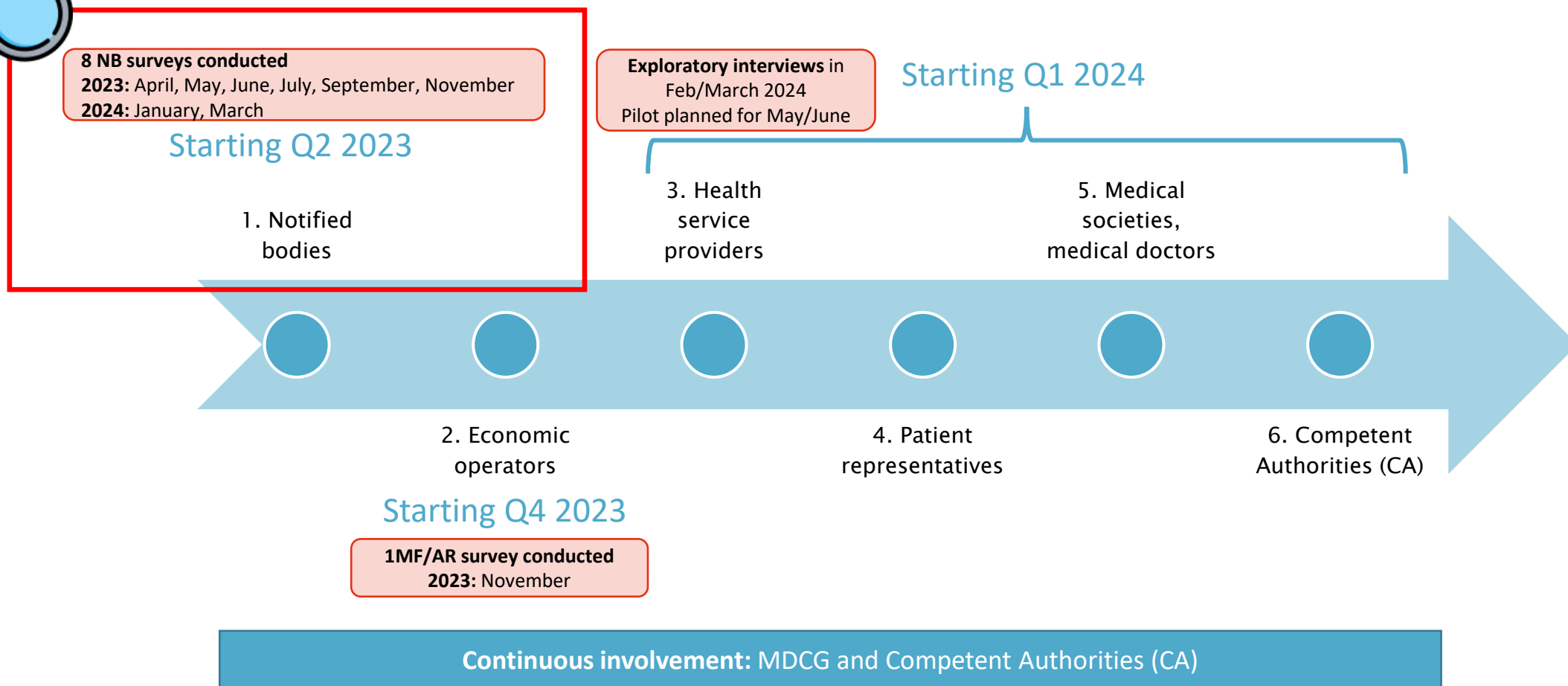
→ [medical.devices@goeg.at](mailto:medical.devices@goeg.at)



## 2. Ongoing and planned survey activities

- a. Survey with notified bodies
- b. Survey with manufacturers and authorised representatives
- c. Survey with health service providers

## 2a. Survey with notified bodies



Source: GÖG

# NB survey overview

NB surveys already conducted by the study team

NB Survey	Survey period (survey launch – survey closure)	Requested dataset* SD = small dataset MD = medium dataset LD = large dataset	Requested data	Response rate
1 <sup>st</sup> NB survey	03/04/2023 - 05/05/2023	SD1 + MD1	from designation up to 31/03/2023	39 out of 39 NBs** <b>100%</b>
2 <sup>nd</sup> NB survey	12/05/2023 - 05/06/2023	SD2	from designation up to 30/04/2023	27 out of 39 NBs** <b>~70%</b>
3 <sup>rd</sup> NB survey	05/06/2023 - 19/06/2023	SD3	from designation up to 31/05/2023	22 out of 39 NBs** <b>~56%</b>
4 <sup>th</sup> NB survey	03/07/2023 - 28/07/2023	SD4 + MD2	from designation up to 30/06/2023	39 out of 39 NBs** <b>100%</b>
5 <sup>th</sup> NB survey	01/09/2023 - 06/10/2023	SD5	from designation up to 31/08/2023	40 out of 40 NBs** <b>100%</b>
6 <sup>th</sup> NB survey	03/11/2023 - 22/12/2023	SD6 + MD3 + LD1	from designation up to 31/10/2023	41 out of 41 NBs** <b>100%</b>
7 <sup>th</sup> NB survey	08/01/2024 - 05/02/2024	SD7	from designation up to 31/12/2023	45 out of 45 NBs** <b>100%</b>
8 <sup>th</sup> NB survey	04/03/2024 - 20/03/2024	SD8 + MD4	from designation up to 29/02/2024	45 out of 45 NBs** <b>100%</b>

Survey results included in the published dashboard version 1.0

Survey results will be published this week in dashboard version 1.1

Selected preliminary results of the 8<sup>th</sup> NB survey are shown on the following slides

\* Datasets:

7

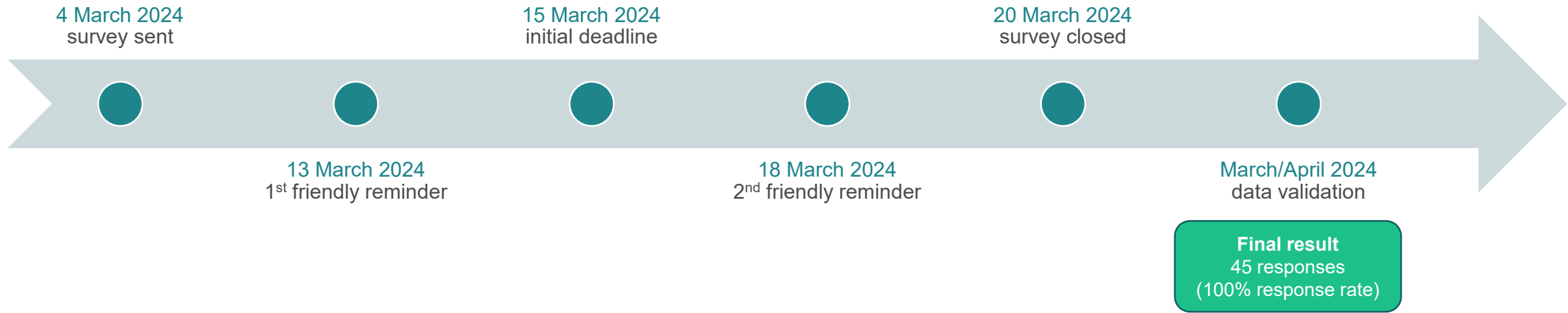
- The **small dataset** is a small set of questions (6 indicators) asked to notified bodies **every two months**. Note: From April to July 2023, it was asked monthly.
- The **medium dataset** is a set of questions asked to notified bodies **every four months** concerning the activities they have been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

\*\* designated under MDR and/or IVDR

# Timeline for the 8<sup>th</sup> NB survey

(conducted in March 2024 with requested data from designation up to 29/02/2024)

45 notified bodies  
designated under MDR  
and/or IVDR  
(Data status: 1 March 2024)



**Note:** Out of 45 notified bodies, 33 NBs are designated under the **MDR only**, 10 NBs are designated under the **MDR and IVDR**, 2 NBs are designated under the **IVDR only**.

# MDR applications filed and certificates issued (sum of Annexes)

**! preliminary results**

**MD**



February 2024

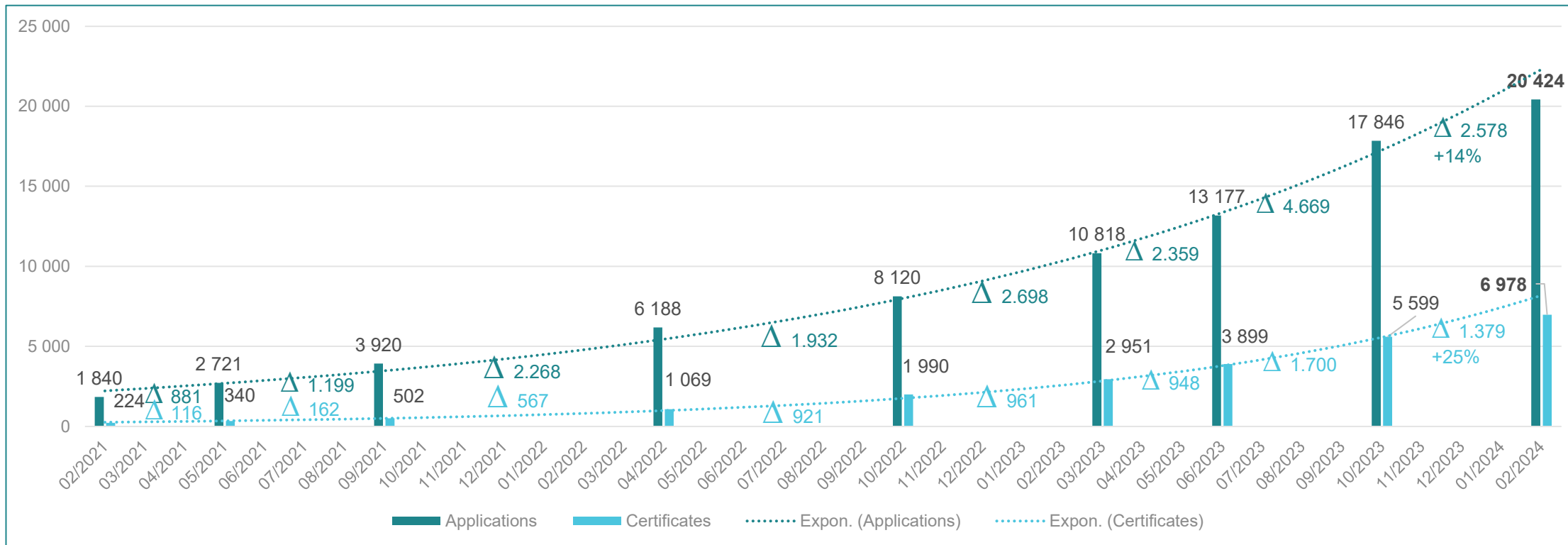
**MDR Applications:**

Total number of applications filed by Annex **M**: 20.424\*

**MDR Certificates:**

Total number of certificates by Annex **M**: 6.978

Total valid MDD/AIMDD certificates by Annex (data status: April 2022): **25.034**



**Notes: February 2024:** Designated NBs for MD: 43; NBs that included Annex XVI products in the numbers provided: 20

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

• Δ (Delta) = Difference in MDR Applications / MDR Certificates from one survey to the next one


• **Applications filed:** This number includes **all applications filed (syn. lodged) so far** according to MDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the [Single Market Compliance Space](#) to the date of the survey up to 29/02/2024), 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. One application can correspond to more than one certificate.

• **Certificates issued:** This number includes **certificates issued so far** (from designation up to 29/02/2024) under the MDR.

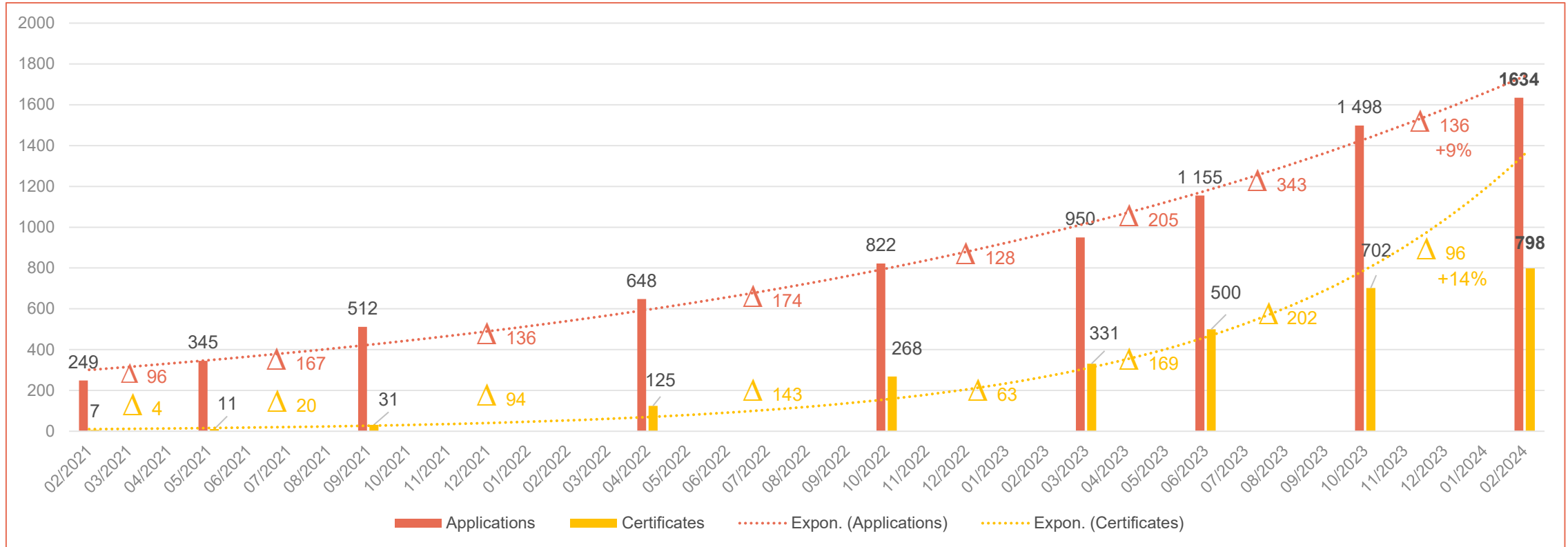
# IVDR applications lodged and certificates issued

**preliminary results**

**February 2024**  
**IVDR Applications: 1.634**  
**IVDR Certificates: 798**

IVD 

Total valid IVDD certificates by Annex (data status: October 2022): **1.551**



**Notes:** Designated NBs for IVDR: 12

- Δ (Delta) = Difference in IVDR Applications / IVDR Certificates from one survey to the next one
- **Applications lodged:** This number includes **all applications lodged (syn. filed) so far** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the [Single Market Compliance Space](#) to the date of the survey up to 29/02/2024), 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 IVDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
- **Certificates issued:** This number includes **certificates issued so far** (from designation up to 29/02/2024) under the IVDR.

# 2b. Survey with manufacturers and authorised representatives

**8 NB surveys conducted**  
2023: April, May, June, July, September, November  
2024: January, March

Starting Q2 2023

1. Notified bodies

**Exploratory interviews in**  
Feb/March 2024  
Pilot planned for May/June

Starting Q1 2024

3. Health service providers

5. Medical societies, medical doctors



2. Economic operators

Starting Q4 2023

**1MF/AR survey conducted**  
2023: November

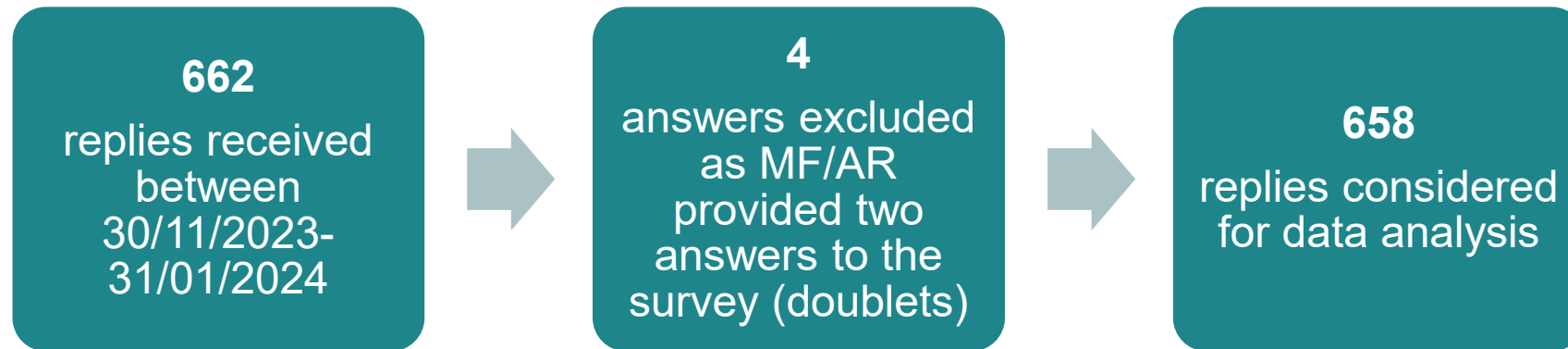
4. Patient representatives

6. Competent Authorities (CA)

Continuous involvement: MDCG and Competent Authorities (CA)

Source: GÖG

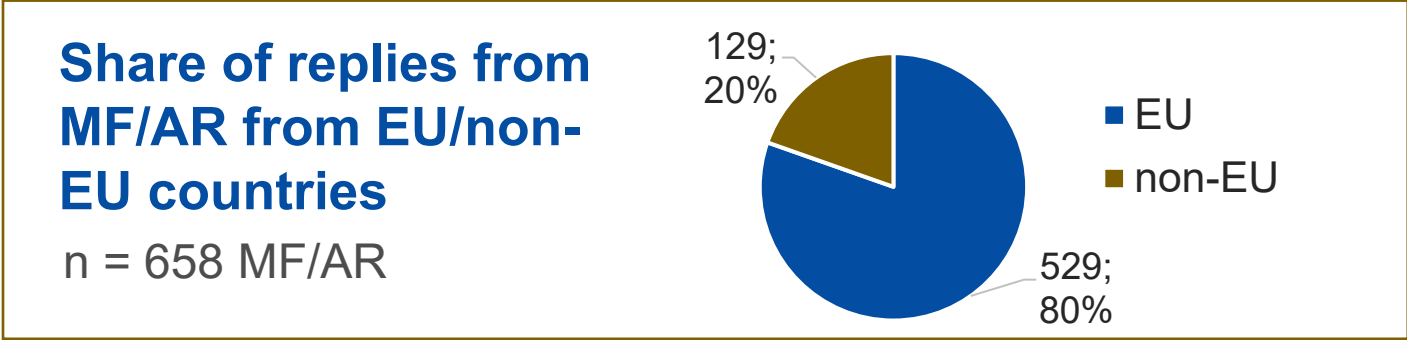
# Survey responses to 1<sup>st</sup> MF/AR survey received and considered for data analysis



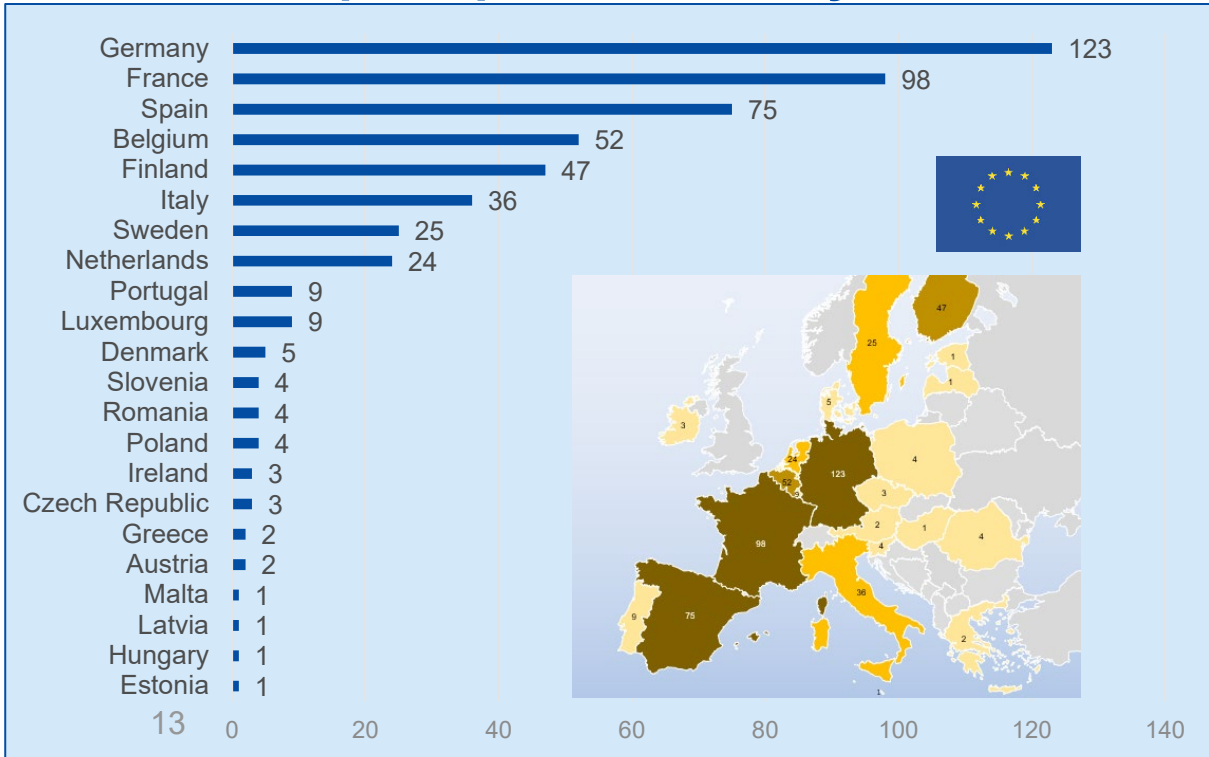
**No response rate available** as no information on number of MF/AR reached in total (wide distribution of survey via various channels).

# Responses to 1<sup>st</sup> MF/AR survey by country\*

\* Country where the company is based. In the case of a multinational company this is the country where the headquarters is located. In case of a reply by a subsidiary, the data provided only refers to the subsidiary.

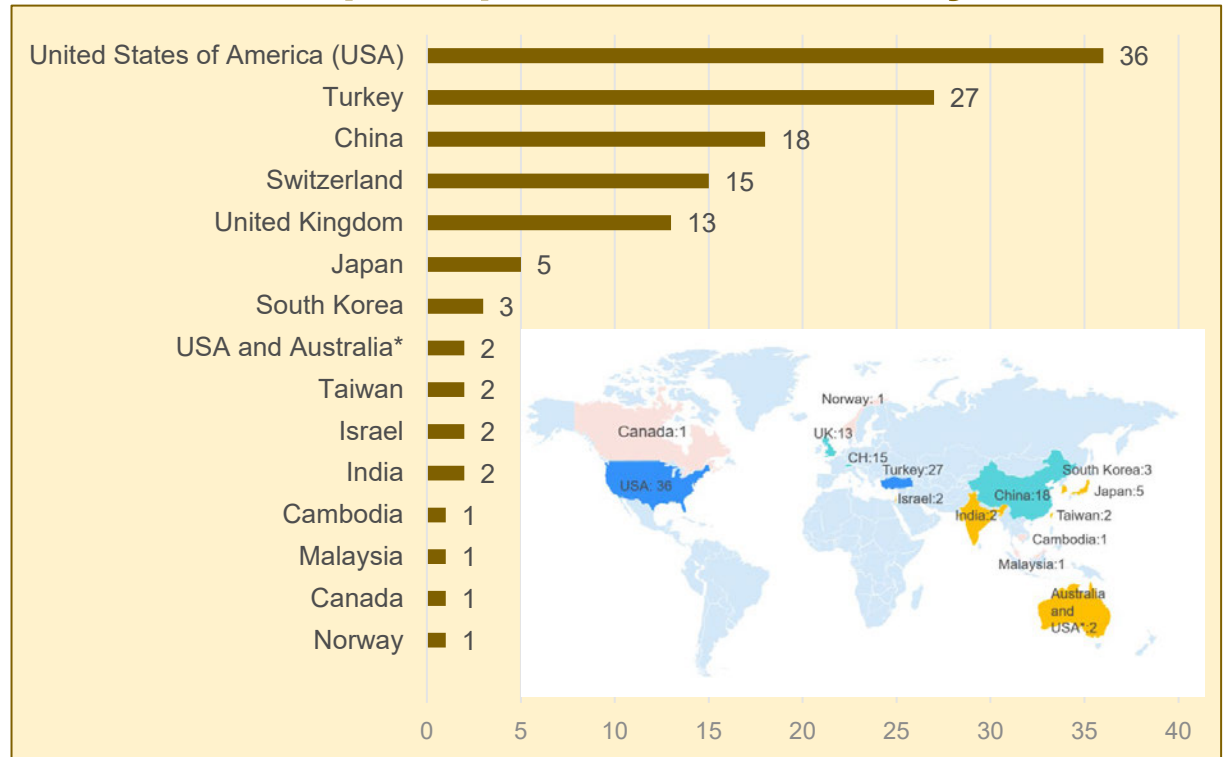


## Number of replies per EU country



n = 529; photo credit: [pixabay.com](https://www.pixabay.com)

## Number of replies per non-EU country



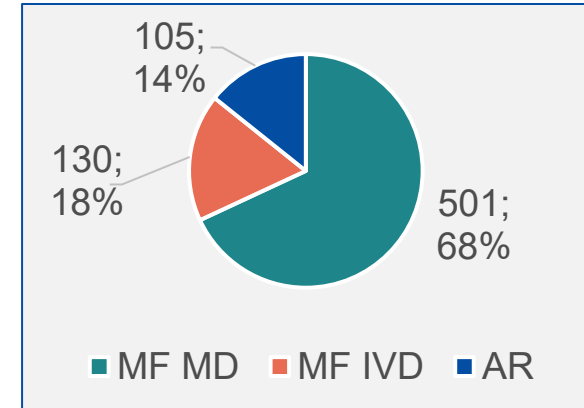
n = 129; \* 2 respondents indicated USA and Australia

# Responses to 1<sup>st</sup> MF/AR survey by company role

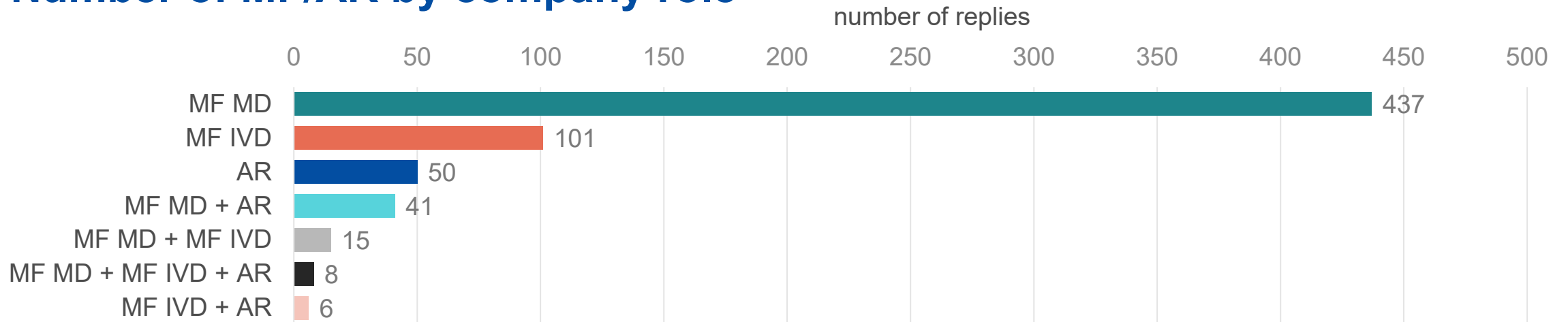
## Of 658 replies received (several roles possible)

- 501 indicating acting as manufacturers (MFs) for MDs,
- 130 indicating acting as manufacturers (MFs) for IVDs,
- 105 indicating acting as authorised representatives (AR).

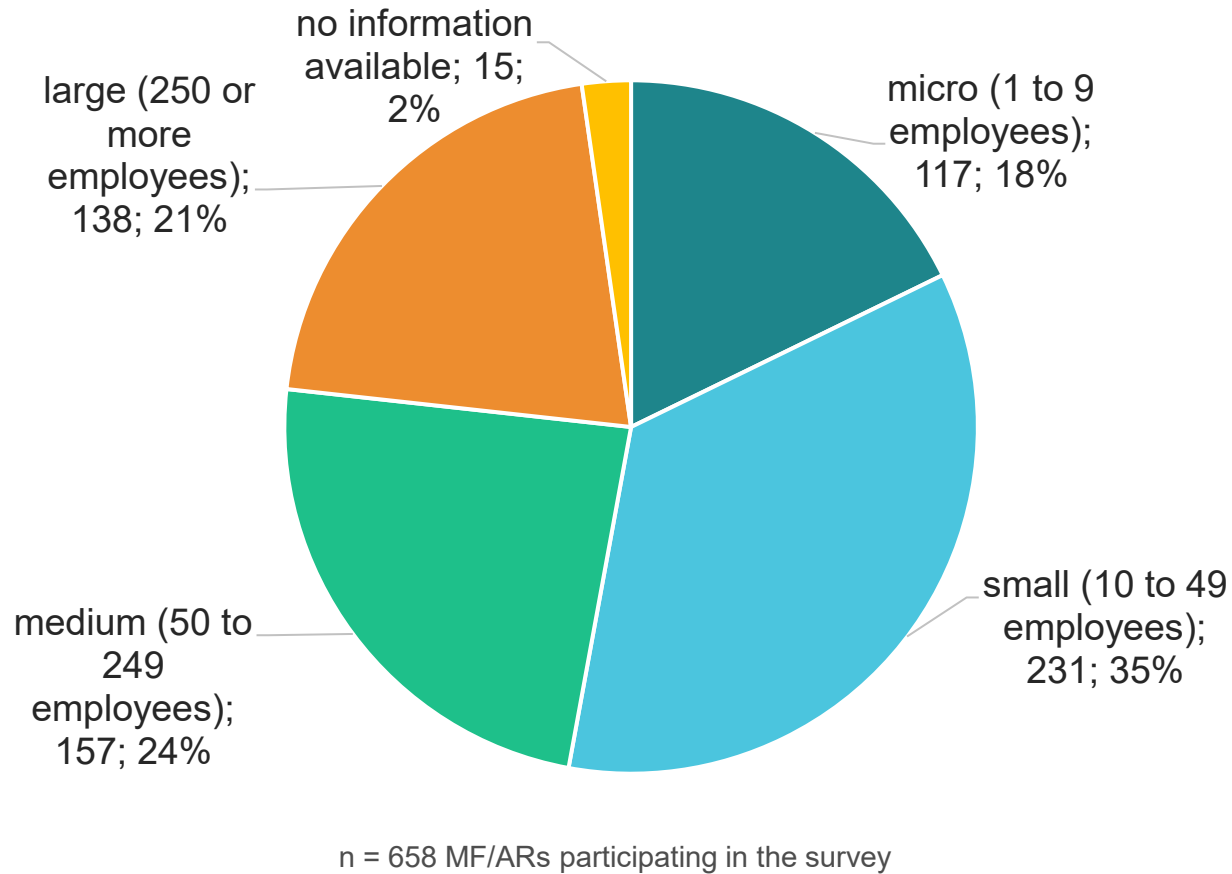
Note: This question led to the relevant survey(s) to be completed.



## Number of MF/AR by company role



# Responses to 1<sup>st</sup> MF/AR survey by size of legal entity of organisation (globally)



77% of the responding MFs/ARs are **SMEs**  
(micro, small and medium organisations;  
1 to 249 employees)

# Overview on applications, written agreements and certificates by end of October 2023

MD



Number of applications lodged under MDR: **7636\***

6<sup>th</sup> NB survey  
(covering the same data period until 31/10/2023):

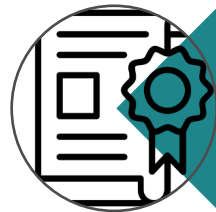
Ⓜ: 17.846\*\*  
(43%)

MF  
sample!



Number of written agreements under MDR with NBs: **1645**

11503  
(14%)



Number of certificates issued for MDs under MDR: **1212**

5599  
(22%)

Note: These figures relate to the 501 responses from the manufacturers of MDs as of the end of October 2023.

**Written agreements** can be framework agreements with NBs (covering several applications) or contracts for each application (signed by the NB and manufacturer)

The **total number of applications** lodged also includes applications with issued certificates, ongoing applications and applications that were eventually refused.

Please, note that applications lodged for changes of existing MDR certificates are included as well.

\* Even though the questions were asked in the same way to MF/AR and NBs, the MF seem to have a different interpretation of applications as NBs.

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

According to the 6<sup>th</sup> NB survey, NBs have 13.398 clients for MDR/MDD/AIMDD.

# Overview on applications, written agreements and certificates by end of October 2023

IVD

6<sup>th</sup> NB survey  
(covering the same data  
period until 31/10/2023):



Number of applications lodged  
under IVDR: **1532\***

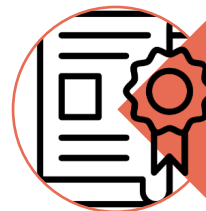
1498  
(MF: 102%)

MF  
sample!



Number of written agreements  
with NBs under IVDR: **175**

736  
(MF: 23%)



Number of certificates issued for  
IVDs under IVDR: **298**

702  
(MF: 42%)

Note: These figures relate to the responses from 130 manufacturers of IVDs as of the end of October 2023.

**Written agreements** can be framework agreements with NBs (covering several applications) or contracts for each application (signed by the NB and manufacturer)

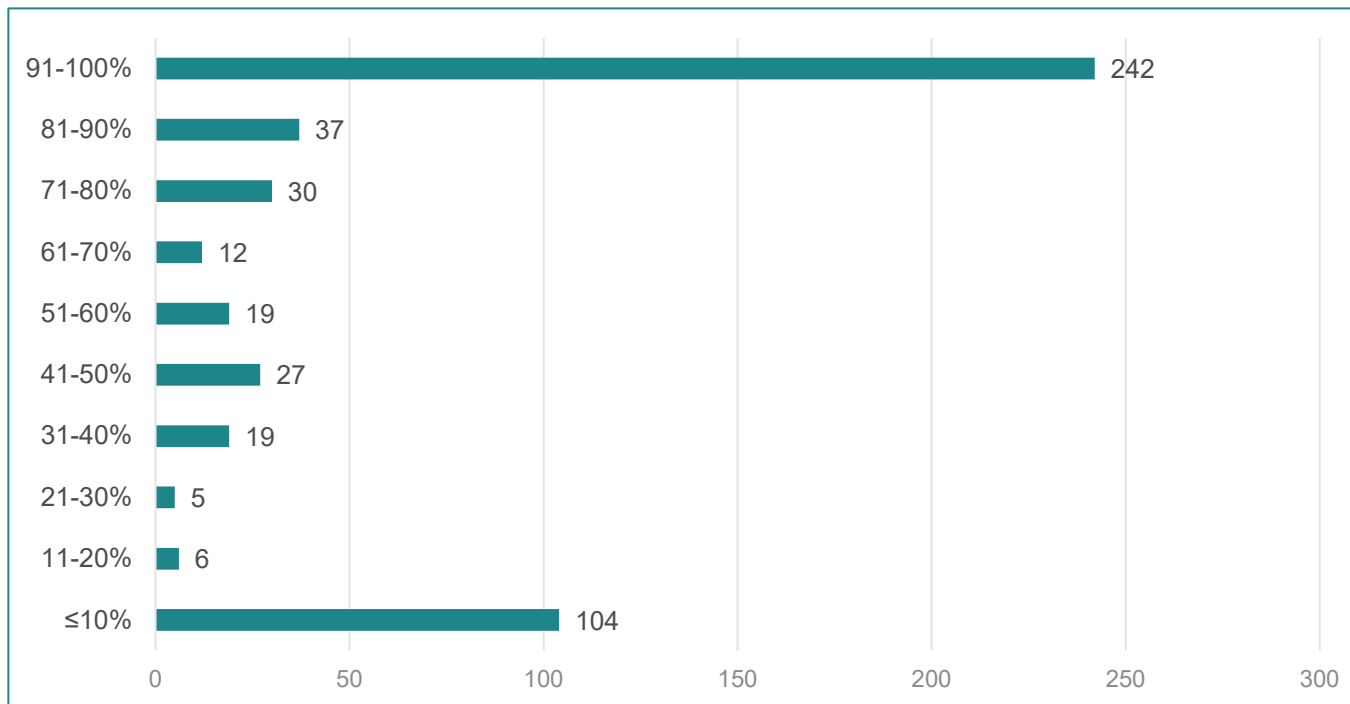
The **total number of applications** lodged also includes applications with issued certificates, ongoing applications and applications that were eventually refused. Please, note that applications lodged for changes of existing IVDR certificates are included as well.

\* Even though the questions were asked in the same way to MF/AR and NBs, the MF seem to have a different interpretation as NBs. According to the 6<sup>th</sup> NB survey, NBs have 720 clients for IVDR/IVDD.

# Details on AIMDD/MDD devices transition status to MDR

Total responses from 501 MFs for MDs

## Percentage of MDs already transferred or planned to be transferred by number of MFs

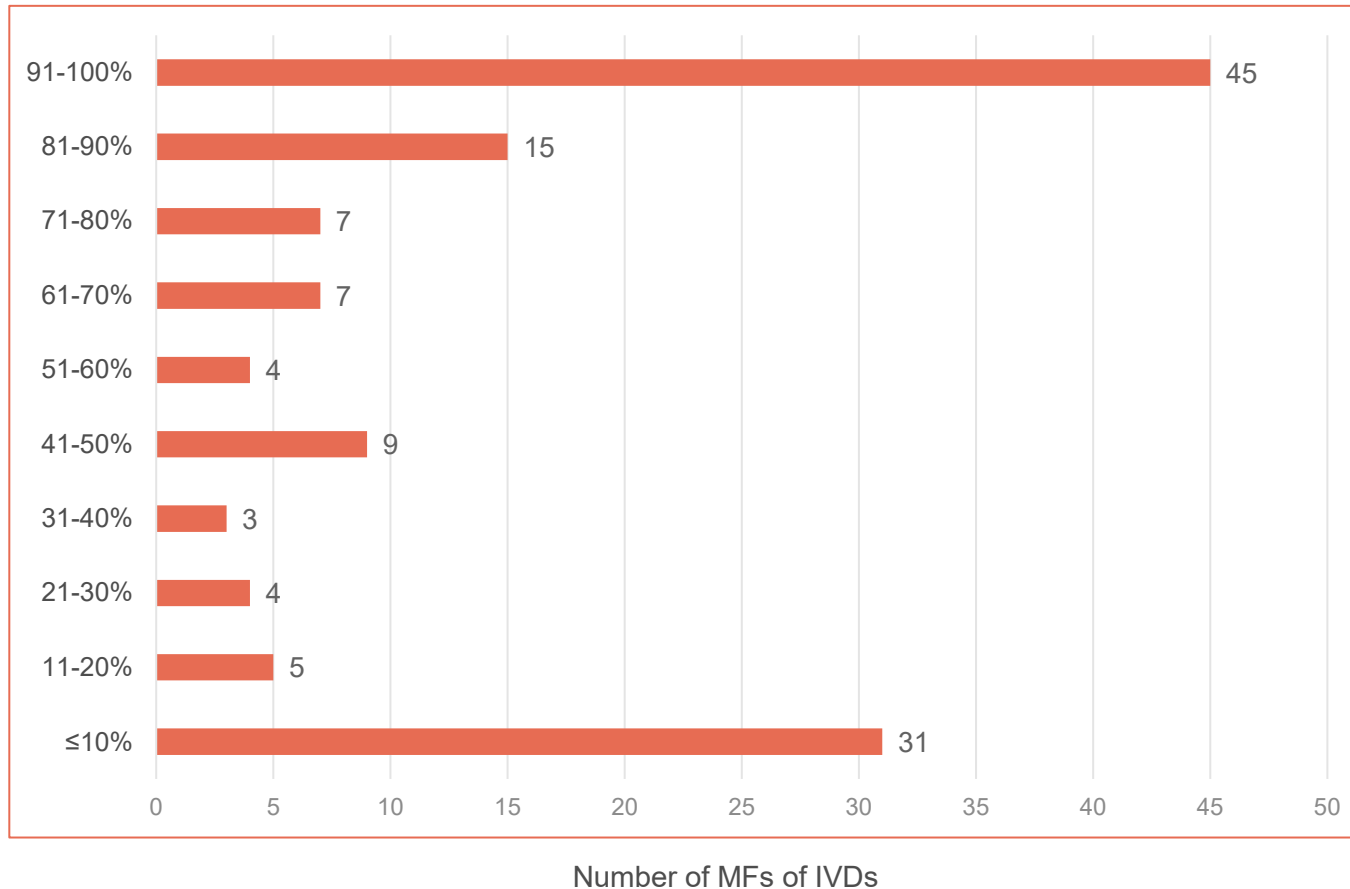


- Around half of the MFs of MDs (242 out of 501; 48%) indicated that 91-100% of MDs have already been transferred to MDR or are planned to be transferred
- 340 MFs (68%) reported that more than 50% of their devices are already transferred or are planned to be transferred to MDR
- 104 out of 501 MFs of MDs (21%) indicated that  $\leq 10\%$  of MDs are transferred or planned to be transferred to MDR

# Details on IVDD devices transition status to IVDR

Total responses from MFs for IVDs: 130

## Percentage of IVDs already transferred or planned to be transferred to IVDR



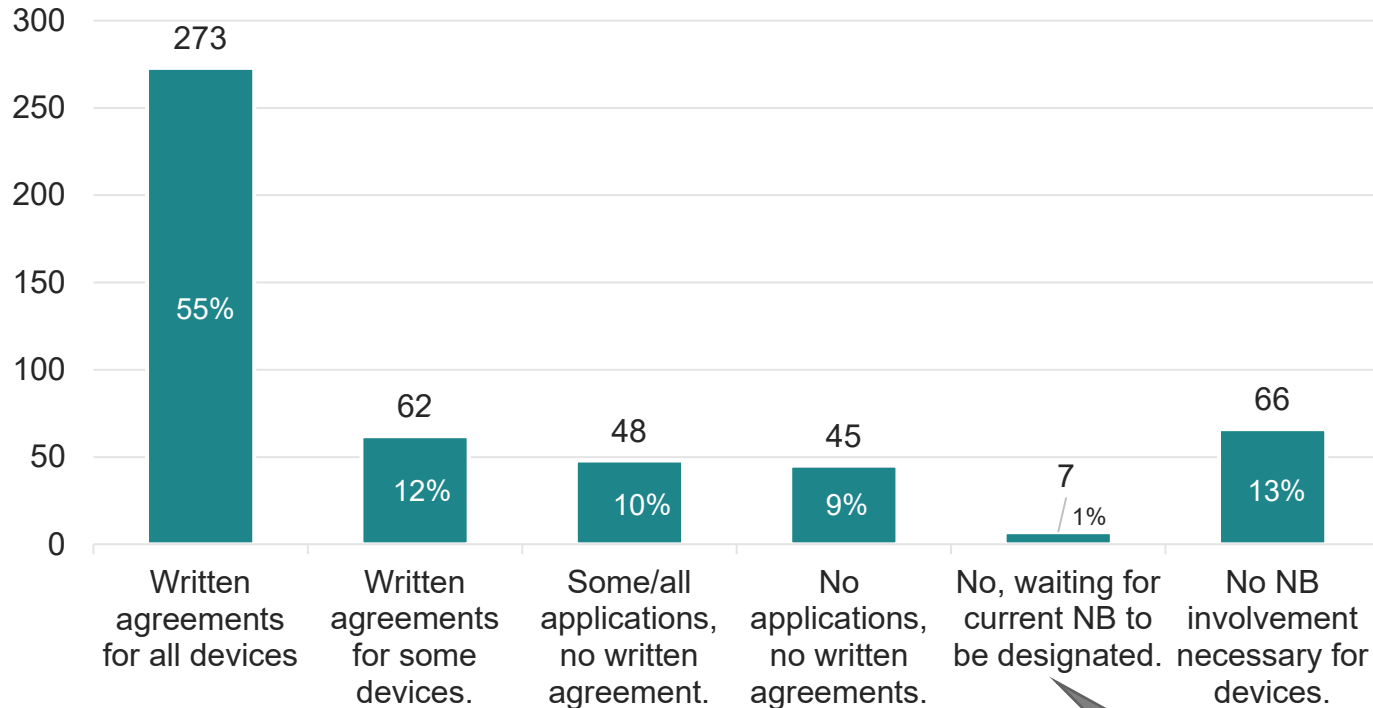
- About one third of the MFs of IVDs (45 out of 130; 34%) indicated that 91-100% of IVDs have already been transferred to IVDR
- 78 MFs (60%) reported that more than 50% of their devices are already transferred or are planned to be transferred to IVDR
- 31 out of 130 MFs of IVDs (24%) indicated that ≤10% are already transferred to IVDR

# Written agreements between MFs of MDs with Notified Bodies

MD

Total responses from 501 MFs for MDs

## Number of companies with written agreements with (a) notified body(ies) designated under the MDR



Note: Replies of 501 MD MFs

FI (MF=2); BE & DE (MF=1); non-EU (MF=4)

## Total number of written agreements under MDR with NBs: 1645\*

\*Replies from 496 MFs (thereof 163 MFs indicated „0“) with data status up to 31/10/2023

6<sup>th</sup> NB survey (covering the same data period until 31/10/2023): 11.503

The **majority of the companies** has one or more **written agreements with one or several NBs**:

- 67% of the MF have (a) written agreement(s) with NBs
- 20% of the MF that need a written agreement don't have it yet
- 13% of the MF don't need a NB involvement

Reasons still to be analysed

# Written agreements between MFs of IVDs with Notified Bodies

IVD

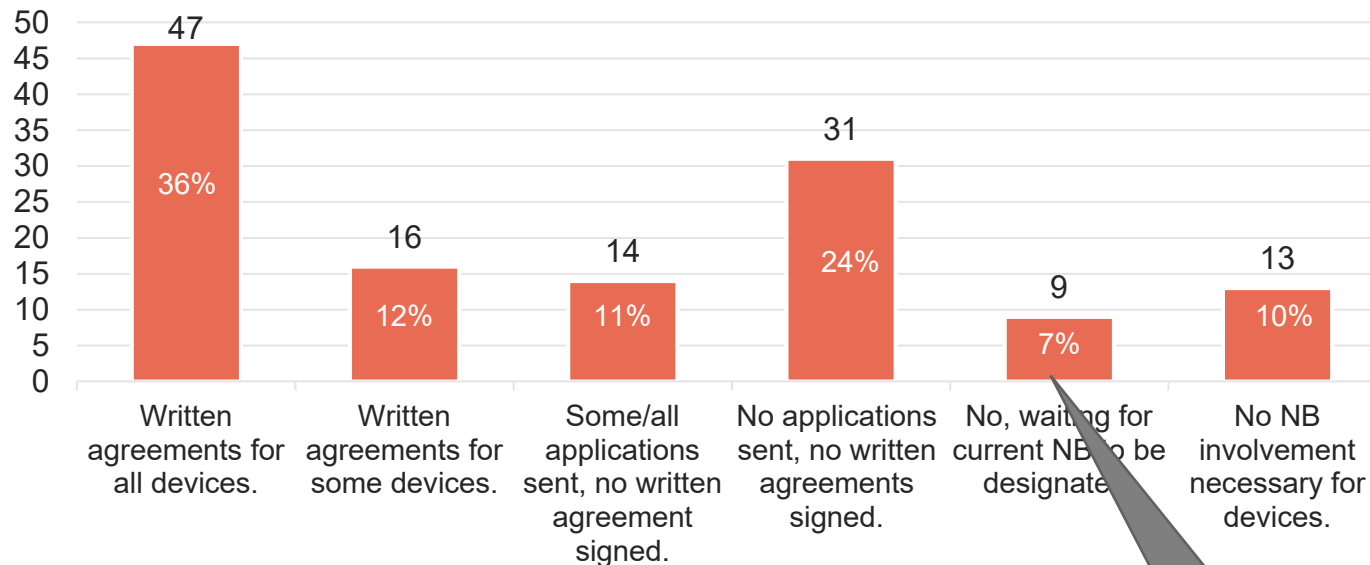
Total responses from MFs for IVDs: 130

## Number of companies with written agreements with (a) notified body(ies) designated under the IVDR

### Total number of written agreements signed under the IVDR with NBs: 175\*

\*Replies from 128 MFs (thereof 69 MFs indicated „0“) with data status up to 31/10/2023

(6<sup>th</sup> NB survey covering the same data period until 31/10/2023: 736)



Note: Replies from 130 IVD MFs

ES (MF=5); DE (MF=1); non-EU (MF=3)

Almost half of the companies have one or more **written agreements with one or several NBs:**

- 48% of the MF have (a) written agreement(s) with NBs
- 42% of the MF that need a written agreement don't have it yet
- 10% of the MF don't need a NB involvement

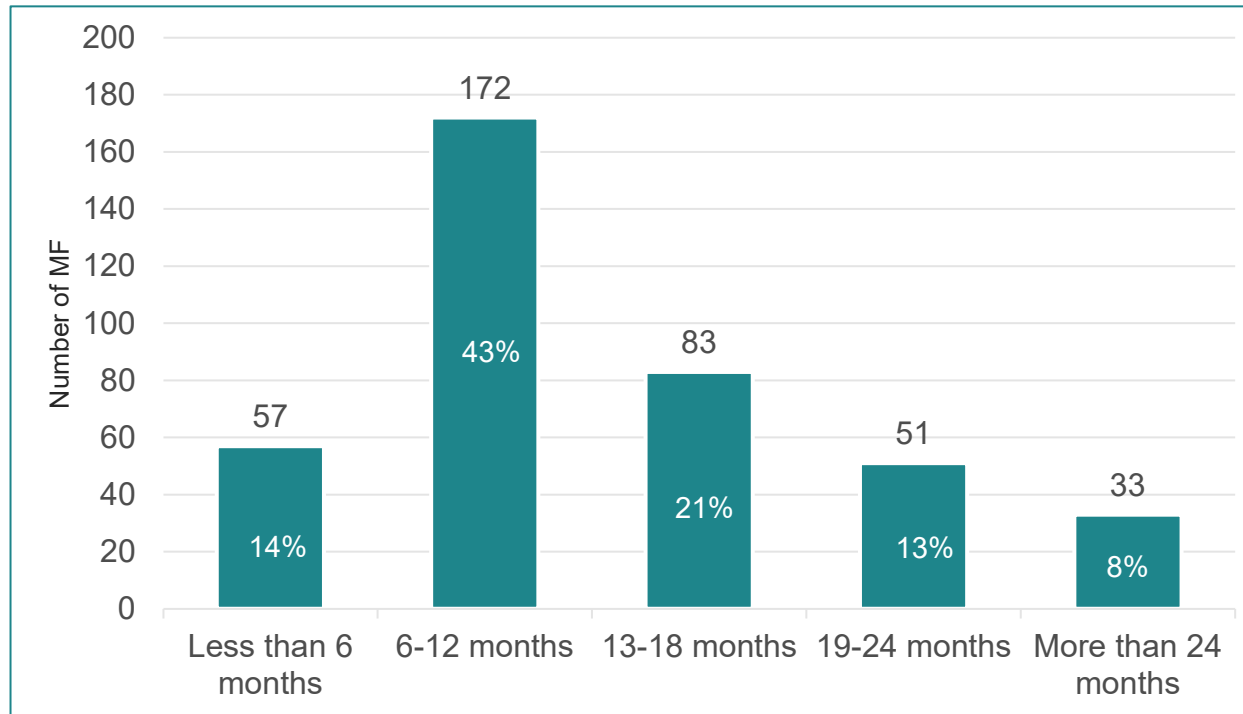
Reasons still to be analysed

# Timelines

## Time to prepare an application for MDR (before submission to NB)\*

\*This does not necessarily cover full documentation needed to reach MDR certification

Total responses from  
501 MFs for MDs

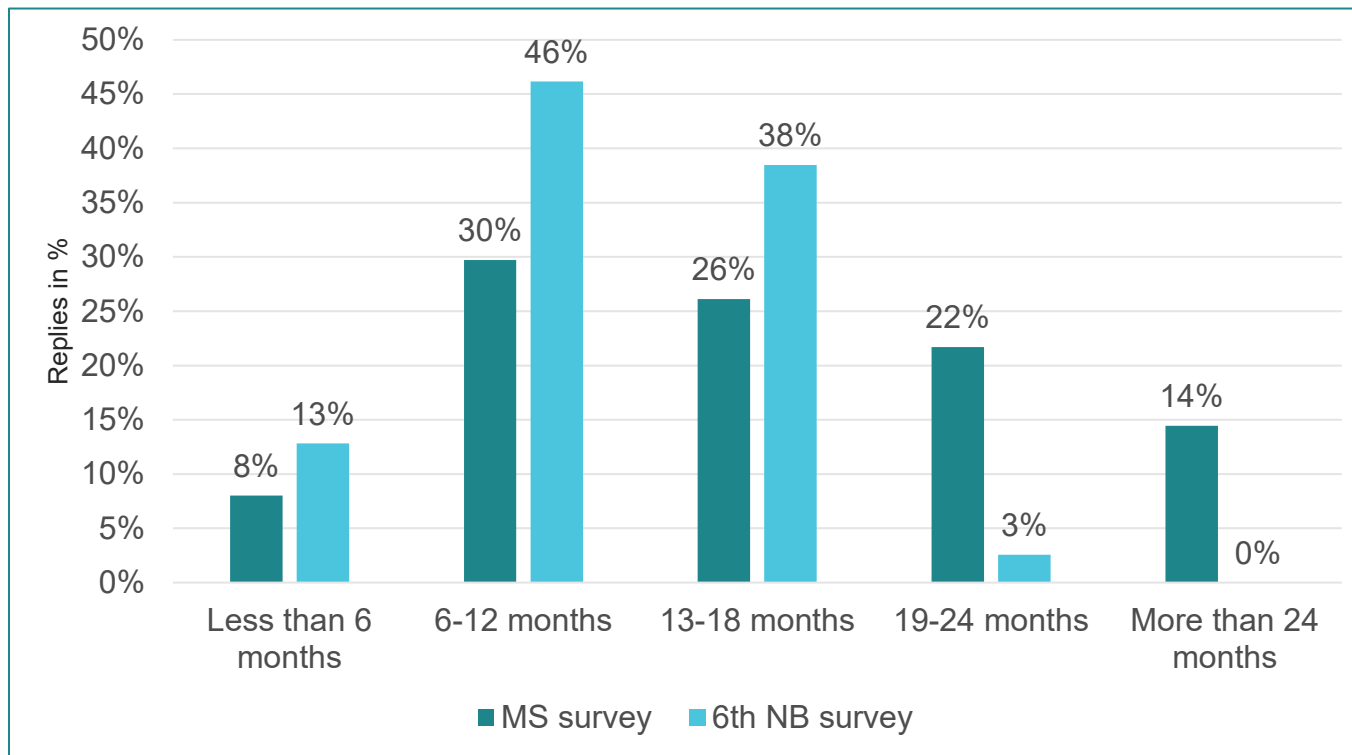


- **57%** of the MFs that provided information on this question indicated that it **takes less than a year** to prepare an application for MDR; for **almost 80%** less than 18 months.

**Note:** Replies of 396 MD MFs  
105 MFs indicated „no information available“

# Timelines

**Time to reach/issue MDR certification for devices that only need QMS certificates (from written agreement signed to issuance)**



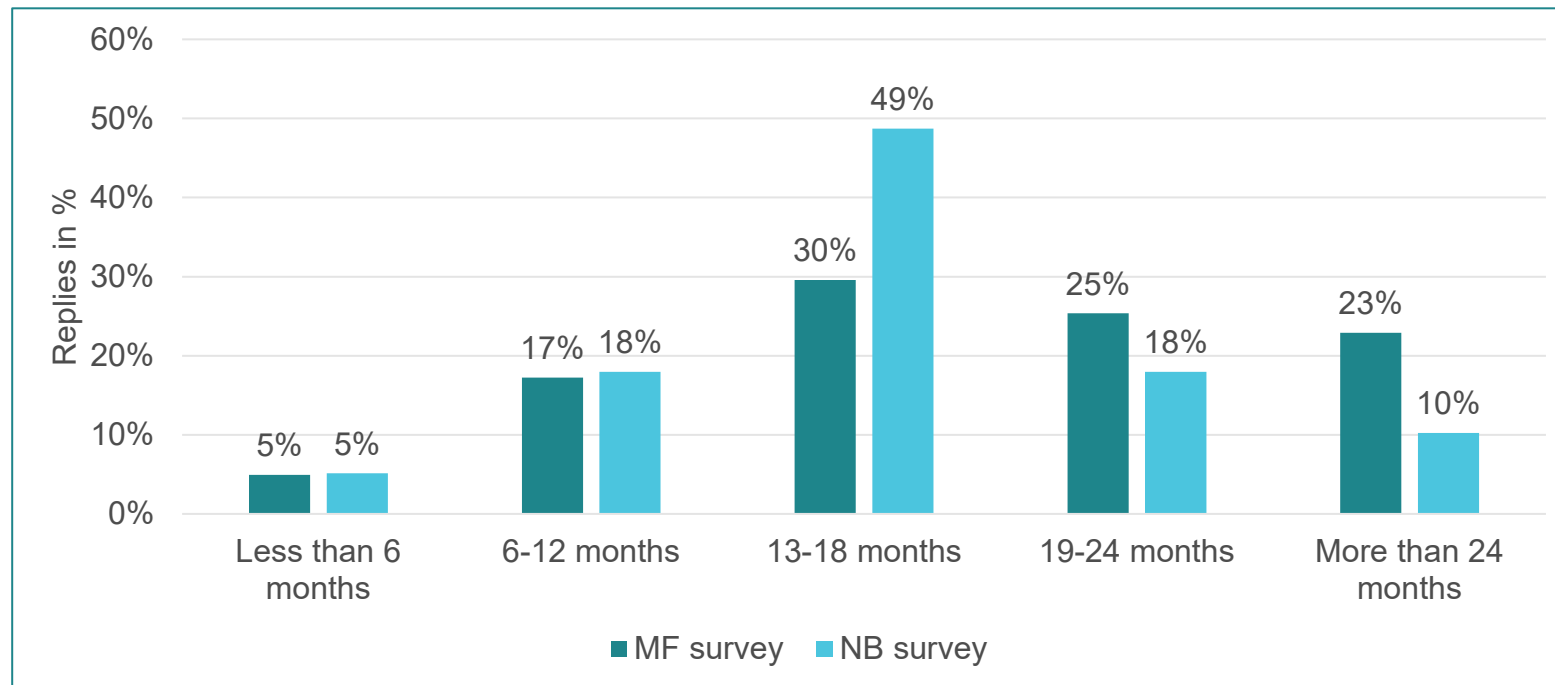
Total responses from  
501 MFs for MDs

**Note:** Replies of 249 MD MFs; 252 MFs indicated „no information available“  
For comparison data of the 6th NB survey (covering the same data period until 31/10/2023):  
Data of 39 notified bodies

# Timelines

**Time to reach/issue MDR certification for devices that need QMS and product certificates**  
(from written agreement signed to issuance)

Total responses from  
501 MFs for MDs

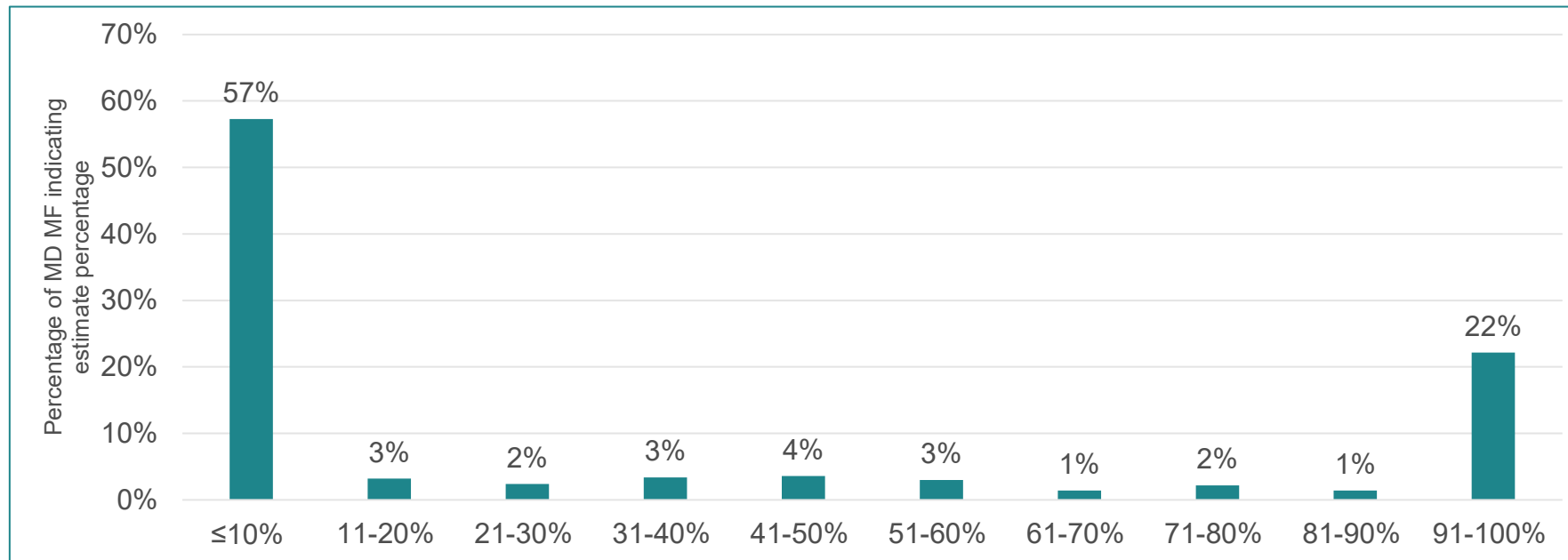


**Note:** Replies of 284 MD MFs; 217 MFs indicated „no information available“  
For comparison data of the 6th NB survey (covering the same data period until 31/10/2023):  
Data of 39 notified bodies

# Transition completion status

Estimate percentage of product portfolio foreseen for transition already having MDR certification (n=501)

Total responses from  
501 MFs for MDs

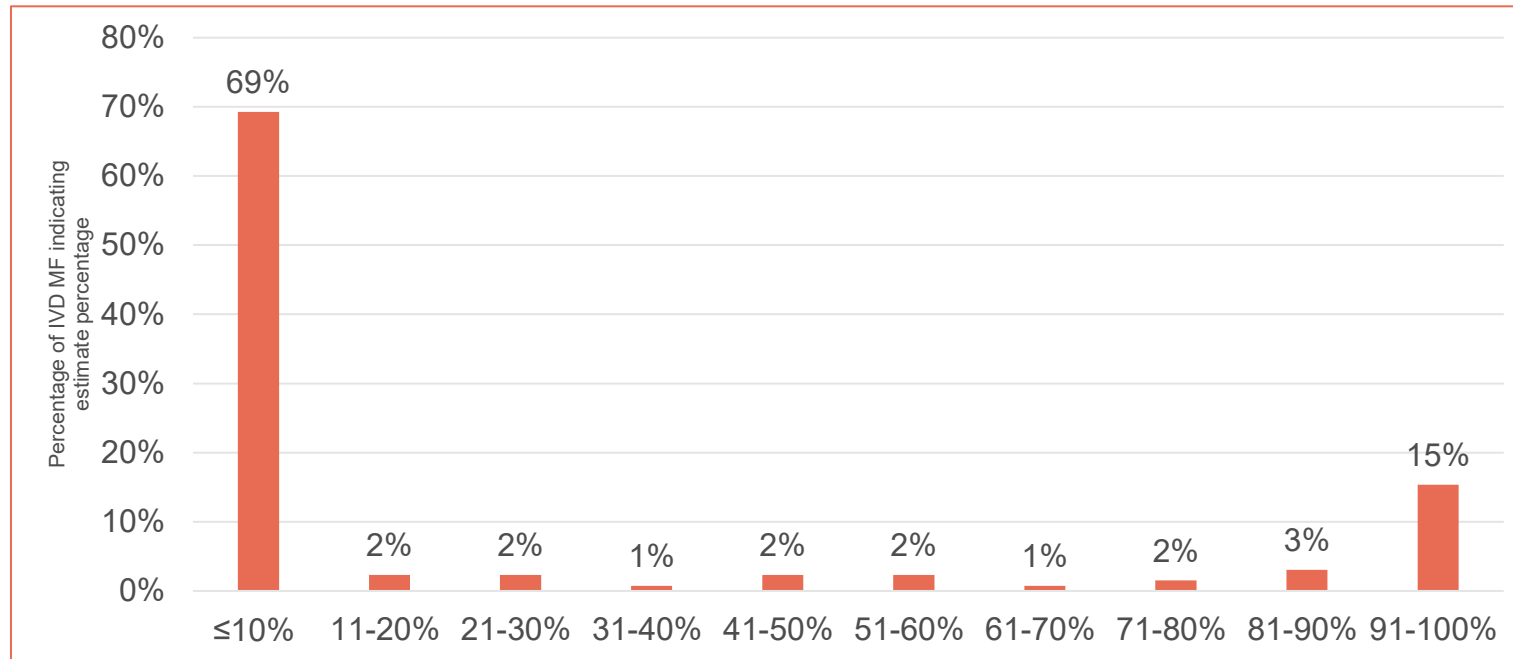


- **22%** of the MF indicated that more than **90 % of their portfolio** that requires an MDR certificate, is already MDR certified
- **57%** of the MF indicated that **less than 10%** of their product portfolio requiring MDR certification has reached it

# Transition completion status

Estimate percentage of product portfolio foreseen for transition already having IVDR certification (n=130)

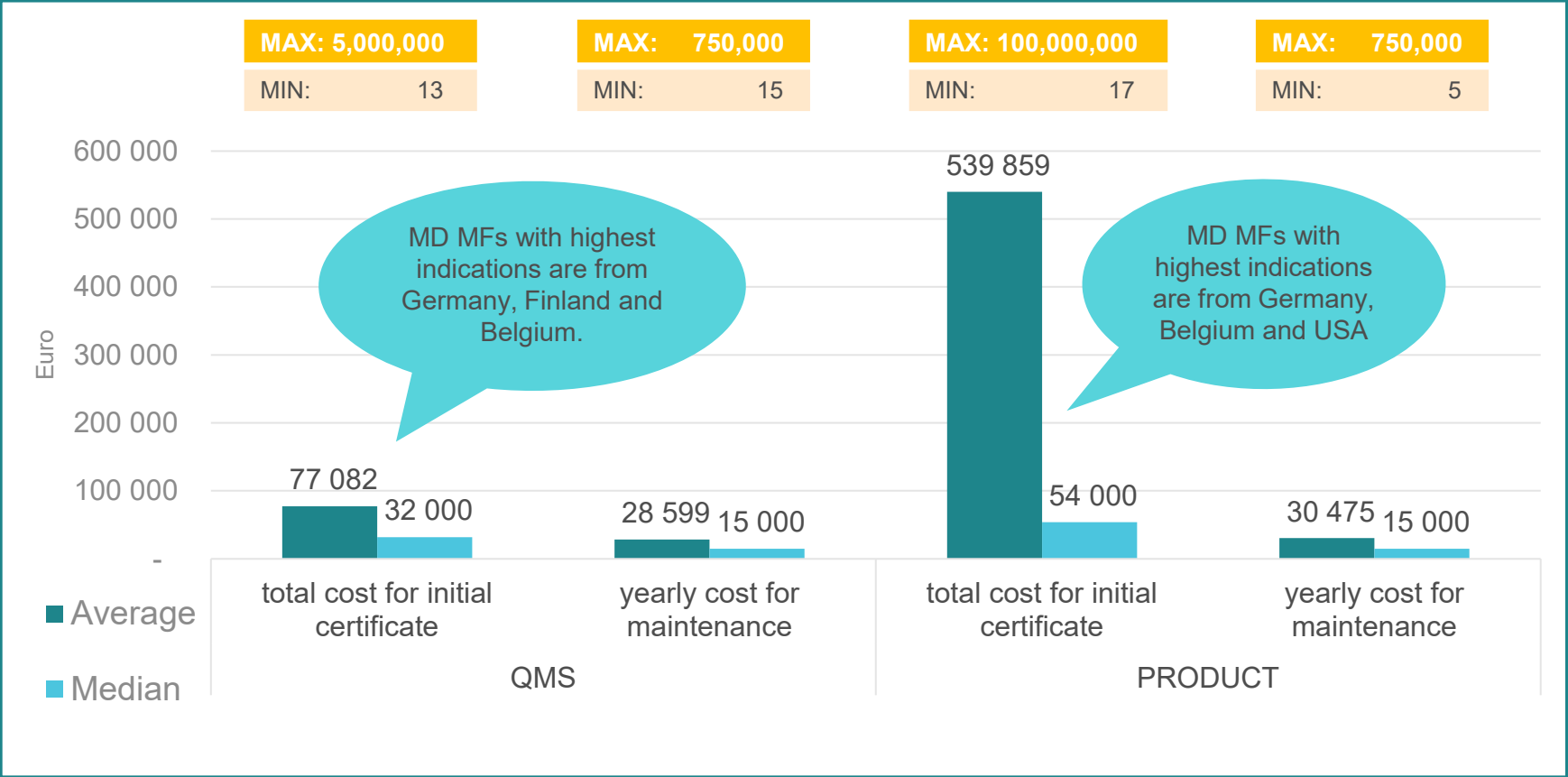
Total responses from MFs for IVDs: 130



- **15%** of the MF indicated that more than **90 % of their portfolio** that requires an IVDR certificate, is already IVDR certified
- **69% of the MF indicated that less than 10% of their product portfolio requiring IVDR certification has reached it**

# Costs for MDR certification

Estimate direct average cost\* per already issued certificate by 10/2023 in Euro



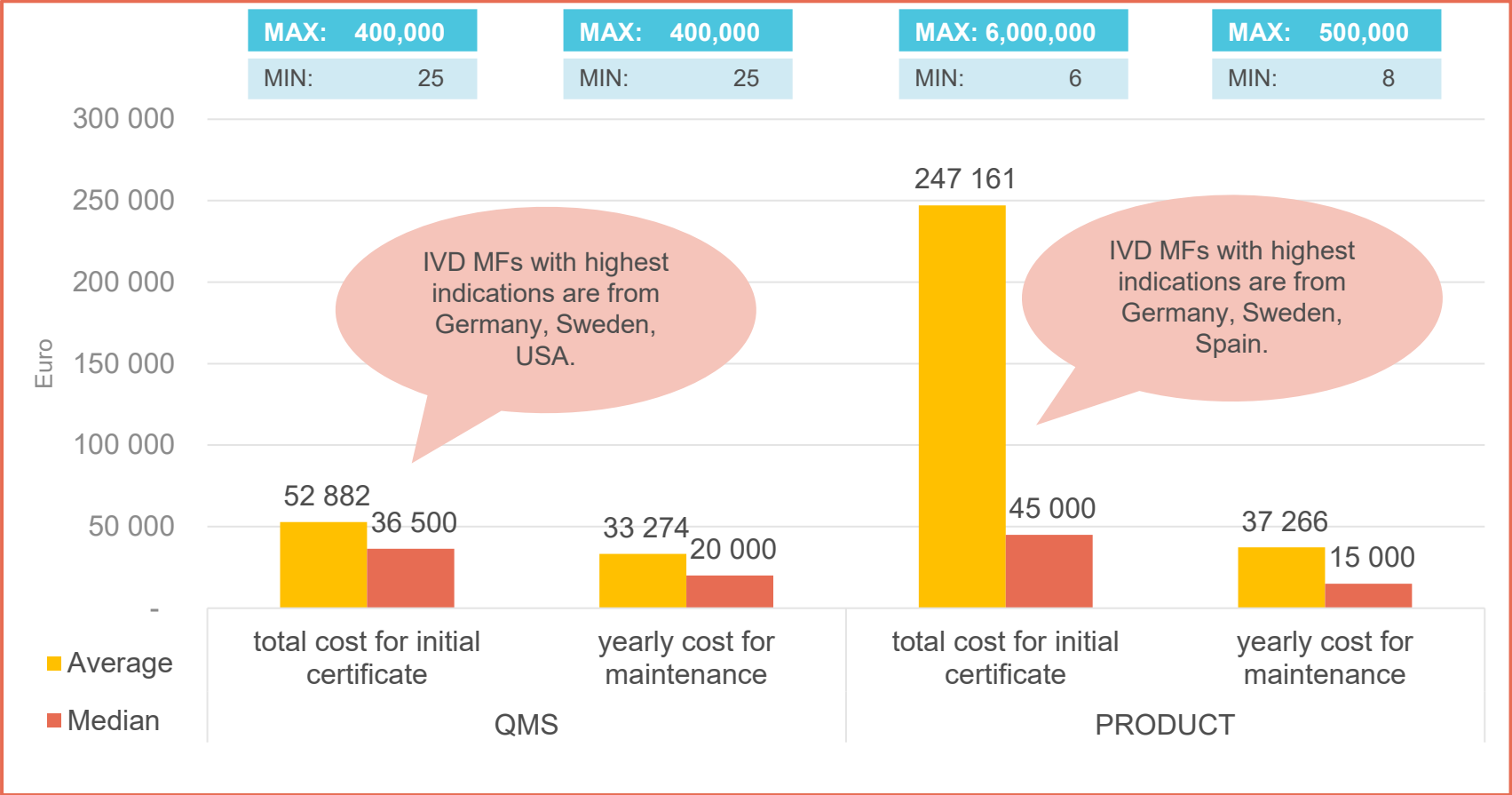
\*Only costs to be paid to notified bodies for audits and assessments leading to the initial certification [first line asked for] as well as follow-up costs for the notified body activities required by the Regulations to maintain the validity of certificates per year [second line asked for, i.e. fees for surveillance activities like annual audits, unannounced audits, evaluation of periodic safety update reports (PSUR), evaluation of summary of safety and clinical performance (SSCP)] should be provided. Internal cost as well as other external costs (e.g. costs of clinical investigations, consultant costs for helping with upgrading the QMS system and existing technical documentation to become MDR compliant or to prepare applications) should not be included. It is clear that these costs only show part of the picture and are not representative for the overall costs for MDR/IVDR certification.

**Notes:** It is possible that MD MF have interpreted this question differently. Some MD MF provided ,zero' as the questionnaire asked to do so, if no information is available. For this reason ,zeros' are excluded (with the risk of overestimation).

- QMS: estimations of costs for initial certificate by 266 MFs; for maintenance: 251 MFs taken into account with responses >0.
- Product: estimations of costs for initial certificate by 235 MFs; for maintenance: 195 MFs taken into account with responses >0.

# Costs for IVDR certification

Estimate direct average cost\* per already issued certificate by 10/2023 in Euro



\*Only costs to be paid to notified bodies for audits and assessments leading to the initial certification [first line asked for] as well as follow-up costs for the notified body activities required by the Regulations to maintain the validity of certificates per year [second line asked for, i.e. fees for surveillance activities like annual audits, unannounced audits, evaluation of periodic safety update reports (PSUR), evaluation of summary of safety and clinical performance (SSCP)] should be provided. Internal cost as well as other external costs (e.g. costs of clinical investigations, consultant costs for helping with upgrading the QMS system and existing technical documentation to become IVDR compliant or to prepare applications) should not be included. It is clear that these costs only show part of the picture and are not representative for the overall costs for MDR/IVDR certification.

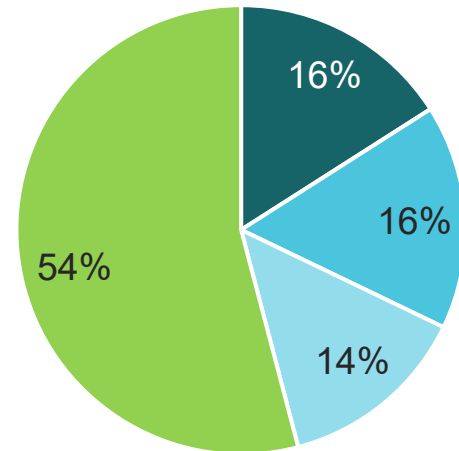
**Notes:** It is possible that IVD MF have interpreted this question differently. Some IVD MF provided ,zero' as the questionnaire asked to do so, if no information is available. For this reason ,zeros' are excluded (with the risk of overestimation).

- QMS: estimations of costs for initial certificate by 56 MFs; for maintenance: 53 MFs taken into account with responses >0.
- Product: estimations of costs for initial certificate by 36 MFs; for maintenance: 30 MFs taken into account with responses >0.

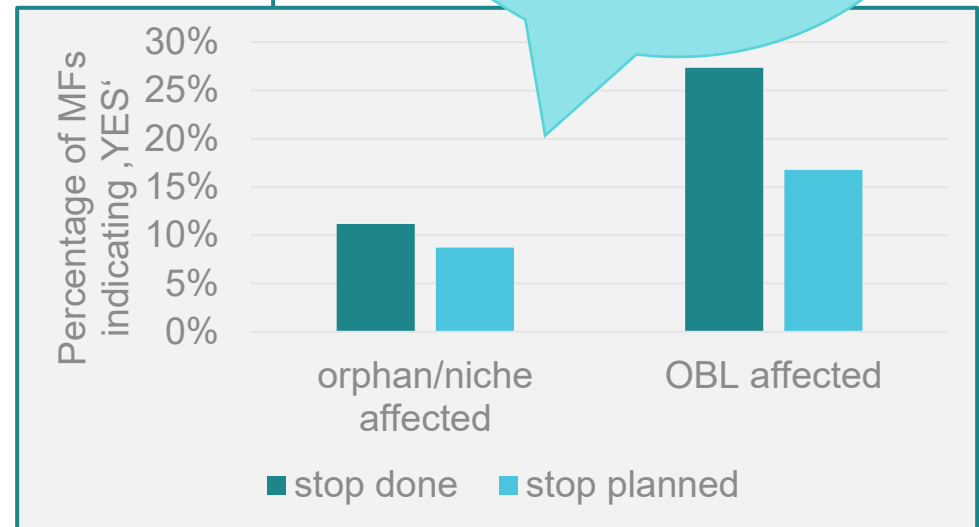
# Discontinuation of medical devices

Number and percentage of MFs having stopped or planning to stop production/marketing/supply of some devices to the EU market since 2021 (n=501)

MFs having stopped (n=161) or are planning to stop (n=149) could indicate whether orphan/nice devices or OBL are affected from the discontinuation.



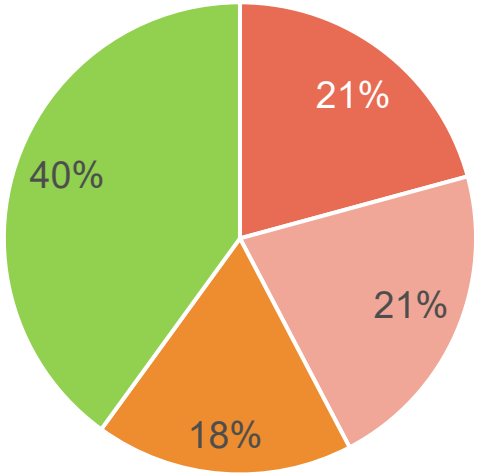
- Production/marketing/supply stop already done and planned
- Production/marketing/supply stop already done but not planned
- Production/marketing/supply stop not yet done but planned
- Production/marketing/supply stop neither done nor planned



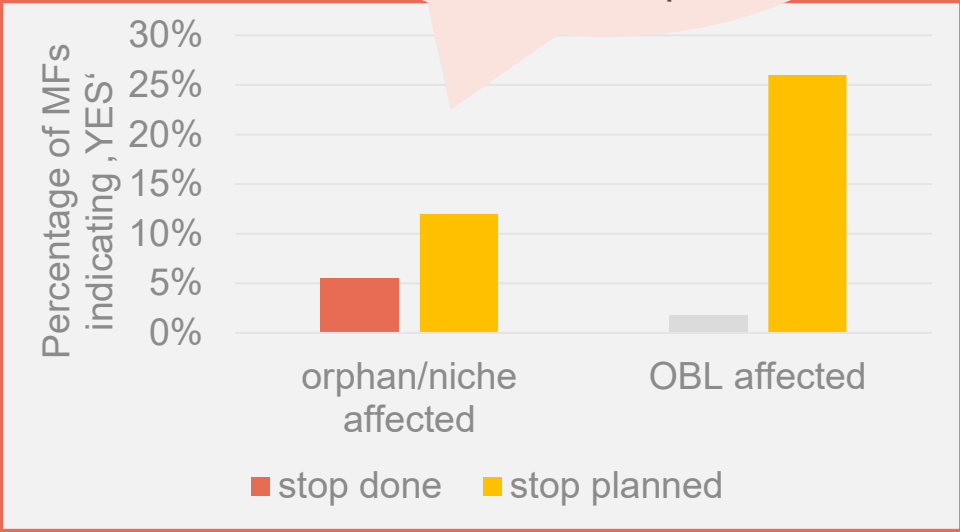
# Discontinuation of IVDs

## Number and percentage of MFs having stopped or planning to stop production/marketing/supply of some IVDs to the EU market since 2021 (n=130)

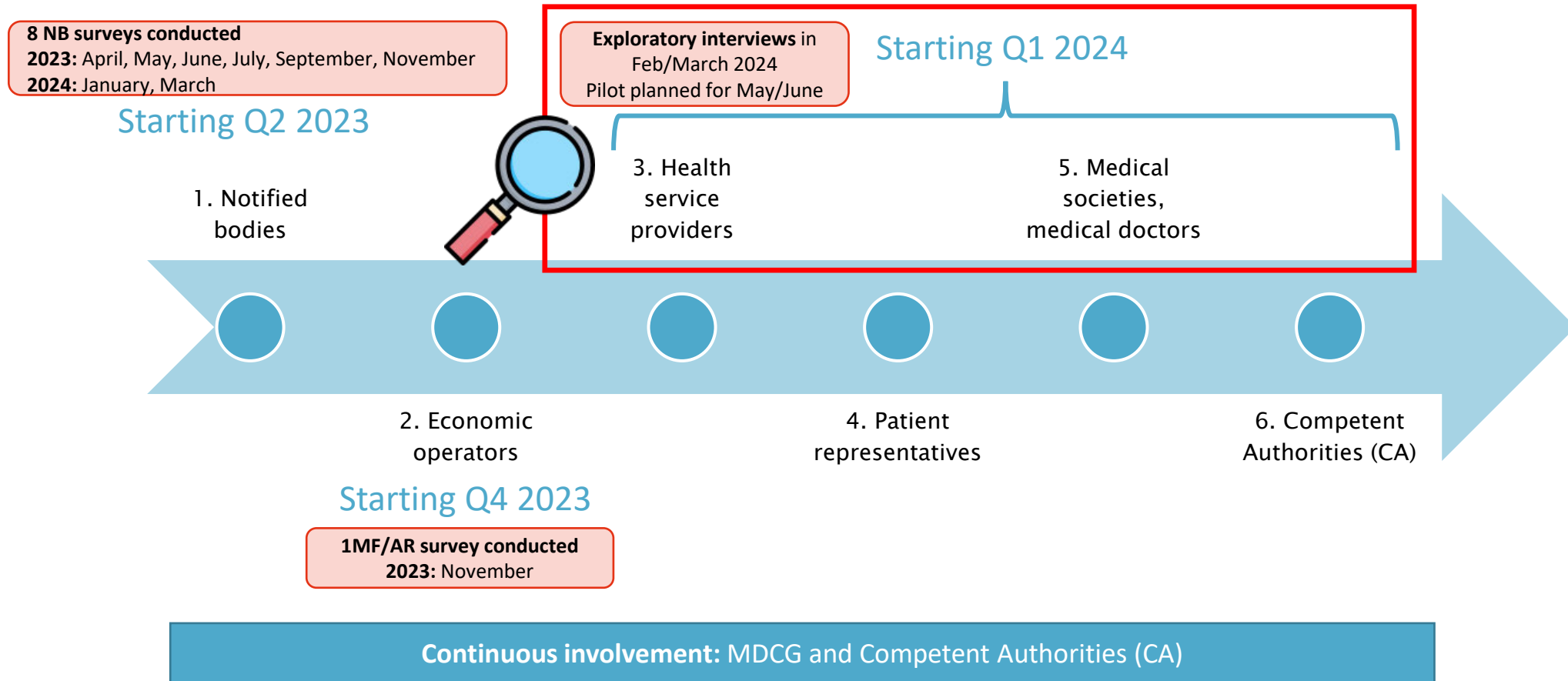
MFs having stopped (n=55) or are planning to stop (n=50) could indicate whether orphan/niche devices or OBL are affected from the discontinuation. Information for OBL stop done incomplete.



- Production/marketing/supply stop already done and planned
- Production/marketing/supply stop already done but not planned
- Production/marketing/supply stop not yet done but planned
- Production/marketing/supply stop neither done nor planned



# 2c. Surveys with health service providers & medical societies, medical doctors



Source: GÖG

# Survey with health service providers & medical societies, medical doctors

What do we want to know from these target groups?

**Aim:** to gather data from health service providers about unavailability of devices in the context of the implementation of MDR and IVDR

Identify areas of MDs/IVDs where unavailability occurs

**Health service providers** in the context of the study:

“individual health professional” or a “health institution” licensed to provide health care diagnosis and treatment services or the promotion of (public) health.

Medical doctors

Other health professionals

Hospitals, procurement bodies etc.

# Survey with health service providers & medical societies, medical doctors

How do we collect the data/information from these target groups?

- **Methodology:**
  - Online survey
  - Pilot test with several health service providers
  - Full survey with all health service providers, medical societies and medical doctors and **full coverage of these target groups is not expected**
  - Open survey (anyone can reply)
  - Distribution via national competent authorities, representative organisations, professional associations etc.
  - Pilot / Roll-out planned in May/June 2024

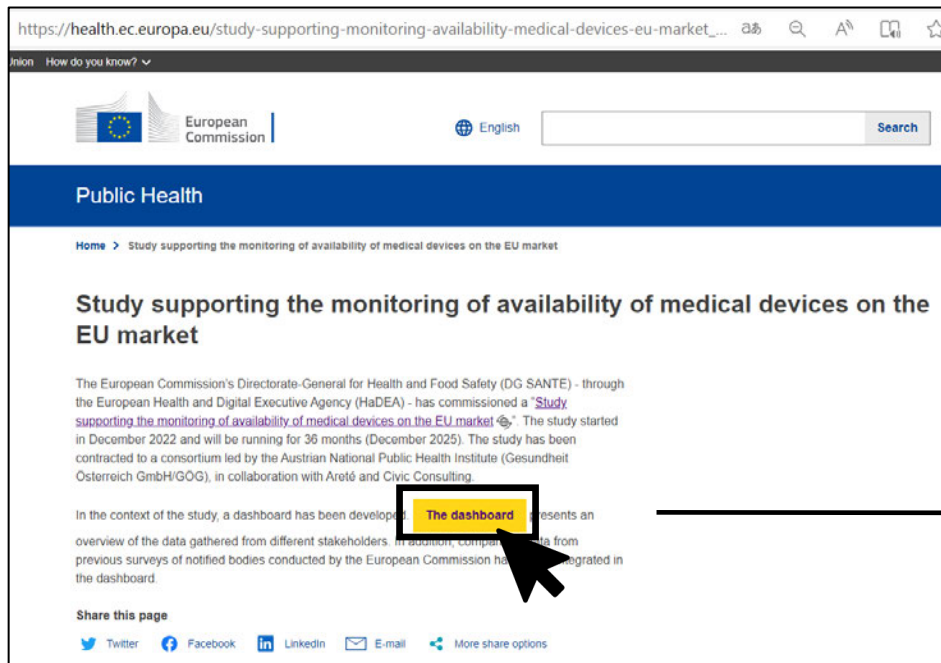


## 3. Dashboard

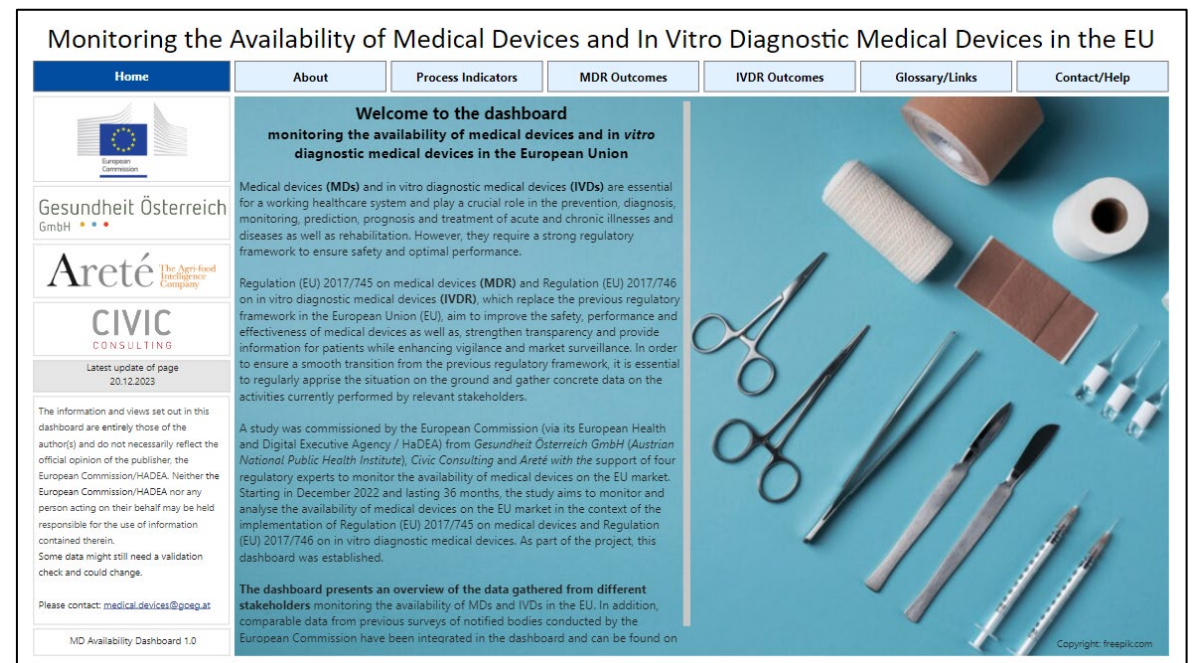
# Dashboard published on 9 January 2024

- Study results are presented in aggregated form in a publicly available and regularly updated dashboard
- Content (data status 24/04/2024):
  - Results of five notified body surveys: *March 2023, April 2023, May 2023, June 2023, August 2023*
  - Data available from previous surveys starting in 2021
- Next steps:
  - Publication of dashboard version 1.1 this week: *including results of 6<sup>th</sup> NB survey (October 2023) and 7<sup>th</sup> NB survey (December 2023)*
  - Publication of dashboard version 2.0: *including results of the 1<sup>st</sup> MF/AR survey (November 2023)*

## [LINK](#) to the study



## [DIRECT LINK](#) to the published dashboard





# Thank you for your attention!

Please contact the study team in case of questions, suggestions or comments!

[medical.devices@goeg.at](mailto:medical.devices@goeg.at)

