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

Study overview and survey results of the 3rd EO survey with data status 31 October 2025

1 July 2026

Disclaimer

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- The study team has aggregated the data received from survey participants to prepare this presentation but cannot be held responsible for the quality and accuracy of the data.

Content

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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
AR	Authorised Representative(s)
CA(s)	Competent Authority / Competent Authorities
CE	Conformité Européenne
COCIR	The European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries
DBs	Distributor(s)
DG SANTE	Directorate-General for Health and Food Safety
EAAR	European Association of Authorised Representatives
EC	European Commission
EEN	European Enterprise Network
EMDN	European Medical Device Nomenclature
EO	Economic Operators
EU	European Union
EUDAMED	European Database on Medical Devices
EUROM VI	Association for Medical Technology within the European Federation of Precision Mechanical and Optical Industries
FWC	Framework contract
GÖG	Gesundheit Österreich GmbH / Austrian National Public Health Institute
HaDEA	European Health and Digital Executive Agency

List of abbreviations (2)

Abbreviation	Meaning
IMs	Importer(s)
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)
MDCG	Medical Device Coordination Group
MDs	Medical device(s)
MDD	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (Medical Device Regulation)
MFs	Manufacturer(s)
NBs	Notified body / bodies
OBL	Own brand labelling
OEM	Original equipment manufacturer
PPE	Personal Protective Equipment
PPT	MS Power Point
Q	Question
QMS	Quality Management System
SC	Special contract
SMCS	Single Market Compliance Space
SMEs	Small and medium-sized enterprise(s)
TF	Task Force

1. Introduction

1.1. About the study

- Study supporting the monitoring of availability of medical devices on the EU market
- Scope of the study
- Consultation activities
- Links to relevant documents in the context of this study

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 analysing 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

Scope of the study

- **Product scope:**
  - **Product types:** medical devices (MDs) and in vitro diagnostic medical devices (IVDs)
  - **Market status:** devices placed on the market (available under the new regulations) and those intended to be placed on the market in future (not yet available under the new regulations) and also taking into account legacy and new devices
  - **Risk classes:** devices belonging to all risk classes, but with a focus on devices requiring the involvement of notified bodies
  - **Focus** will be set on special product groups (e.g. orphan and/or niche devices) and those at risk of shortage.
- **Geographic scope:** 31 countries (27 EU Member States plus Iceland, Liechtenstein, Norway and Turkey)

Consultation activities

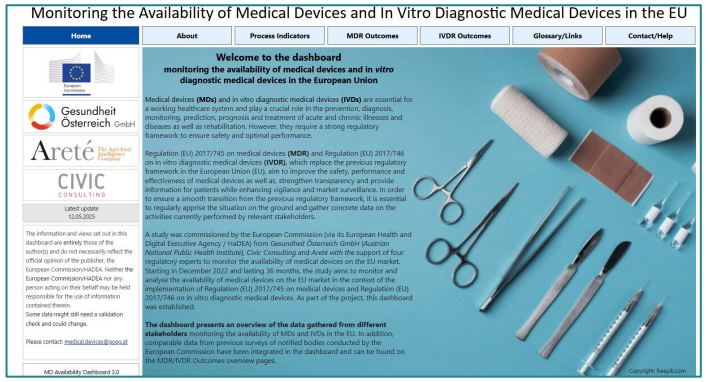
Surveys

Interviews

MDCG Taskforce Meetings

Results are presented in **aggregated form** in a **publicly available** and regularly updated dashboard

Published here: https://health.ec.europa.eu/study-supporting-monitoring-availability-medical-devices-eu-market_en.



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Links to relevant documents in the context of this study

- One-pager about the study
- Endorsement letter
- Study-related glossary
- Dashboard
- Instructions for use for the dashboard
- Privacy statement

1.2. About the 3rd EO survey with MF and AR

- Acknowledgements
- Survey development and management
- Survey timeline
- Survey structure and content
- Comparison of the surveys conducted with EO in the framework of the study

Acknowledgements

The study team would like to sincerely thank the following persons and institutions for their support in the 3rd EO survey:

- 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**;
- **Experts and representatives** of the following organisations for the review of a draft version of the survey and/or dissemination of the survey link: EUROM, European Federation of high-tech industries; European Association of Authorised Representatives (EAAR); European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries (COCIR); Enterprise Europe Network (EEN); MedTech Europe and all national associations, MedTech clusters;
- All **manufacturers and authorised representatives** of medical devices and in vitro diagnostic medical devices who took part in the survey or contributed to the pilot.

Survey development and management

- **Survey development:** The survey was developed by the study team in close consultation with DG SANTE/HaDEA and the MDCG TF on certification capacity monitoring. The draft survey was reviewed by industry representatives and piloted with different companies before the official launch.
- **Survey dissemination:** The survey link was shared via the European Commission, competent authorities for medical devices, national and European representative industry associations and clusters, direct contacts, and social media (LinkedIn, newsletter). Companies that participated to previous surveys were also invited.
- **Survey period:** The survey was launched on 15 January 2026 and closed on 19 March 2026.

Survey timeline for the 3rd EO survey
(data was requested until 31 October 2025)

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Survey structure and content

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

3rd survey for MD and IVD manufacturers and authorised representatives

HaDEA/2021/P3/03

Final version, 13 January 2026
Commissioned by the European Commission

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Gesundheit Österreich GmbH Areté CIVIC CONSULTING

1. Background and introduction

2. Questionnaire (Q1-Q59)

About 2.1. **ABOUT:** About you and your company (Q1-Q9)

MD 2.2. **MD:** Questionnaire on medical devices (Q10-Q30)

IVD 2.3. **IVD:** Questionnaire on in vitro diagnostic medical devices (Q31-Q54)

AR 2.4. **AR-MD/IVD:** Questionnaire for authorised representatives (Q55-Q57)

2.5. **Closing** (Q58-Q59)

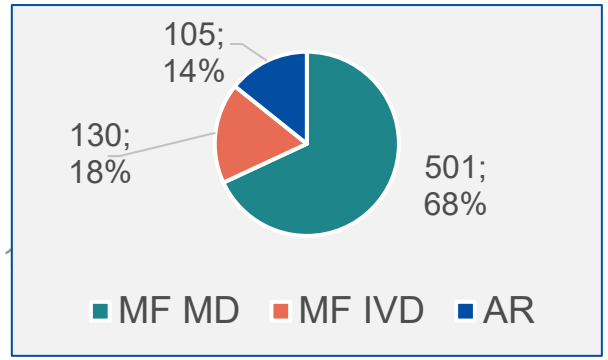
Link to the final survey (as PDF) including detailed questions

Abbreviations: AR = Authorised representative, IVD = in vitro diagnostic medical device, MD = medical device(s), Q = question

Comparison of the surveys conducted with EO in the framework of the study

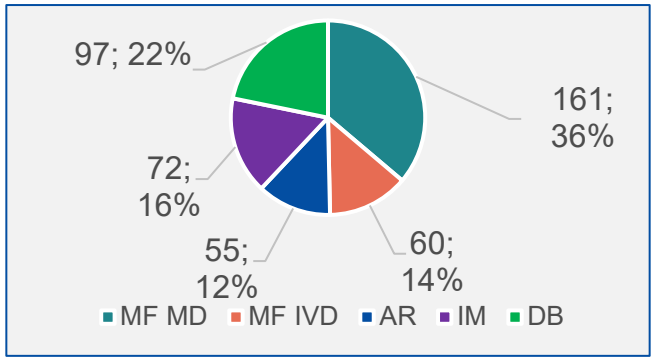
1st MF/AR survey

- Data period: 31/10/2023
- Targeting manufacturers (MF) and authorised representatives (AR)
- 658 responses considered for the data analysis (several roles possible)



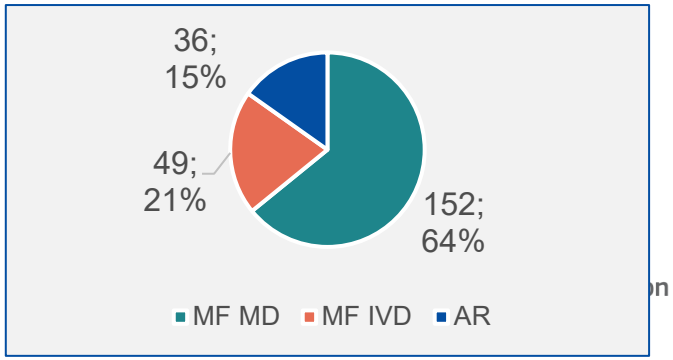
2nd EO survey

- Data period: 31/10/2024
- Targeting manufacturers (MF), authorised representatives (AR), importers (IM) and distributors (DB)
- 254 responses considered for the data analysis



3rd EO survey

- Data period: 31/10/2025
- Targeting manufacturers (MF) and authorised representatives (AR)
- 213 responses considered for the data analysis (several roles possible)



2. Results

Notes:

- The numbers of the questions corresponding to the **questionnaire** can be found at the **top left** of each slide (i.e., Q1 for question 1).

2.1. About the survey participants (responses)

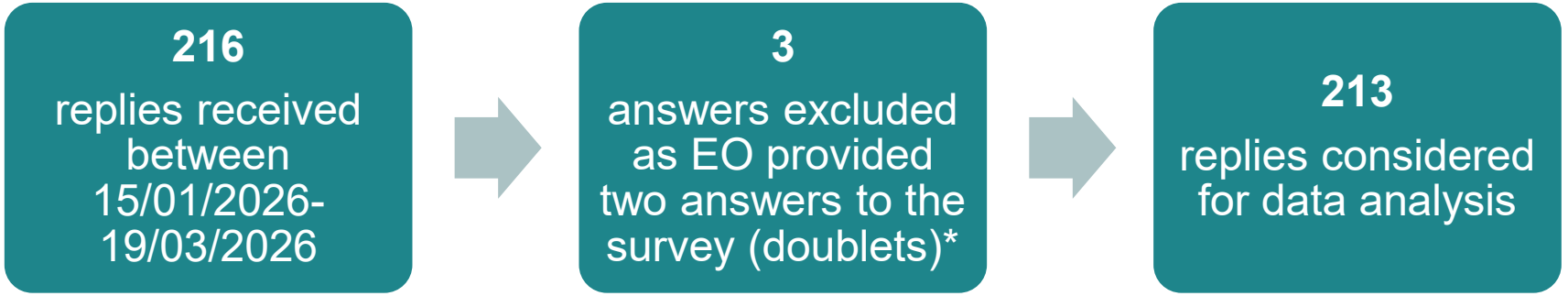
Questionnaire part 2.1. including questions 1 to 9

Note: Answers to question 1 (contact details) are not provided in this presentation.

Responses to 3rd EO survey received and to be considered for data analysis

About

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



* The newer answers were selected for data analysis.

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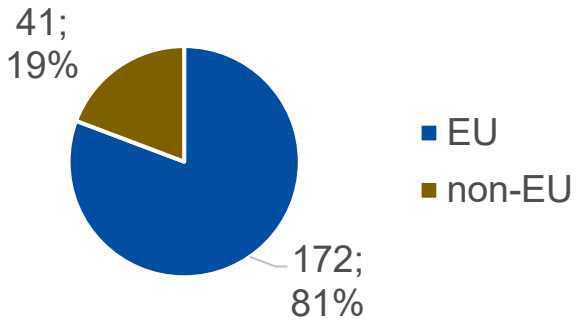
Country, where the company is based* (1)

About

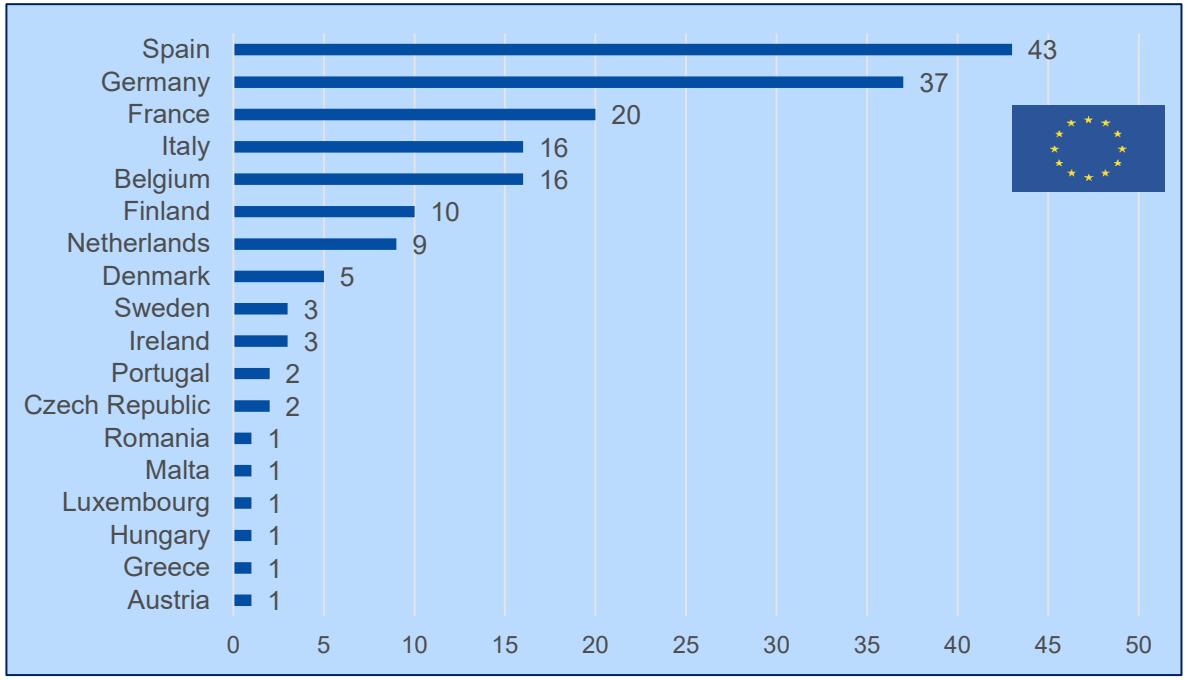
*In the case of a multinational company this is the country where the headquarters is located. In case of a reply by a subsidiary, the data provided only refers to the subsidiary.

Share of replies from EO from EU/non-EU countries

n = 213 MF/AR

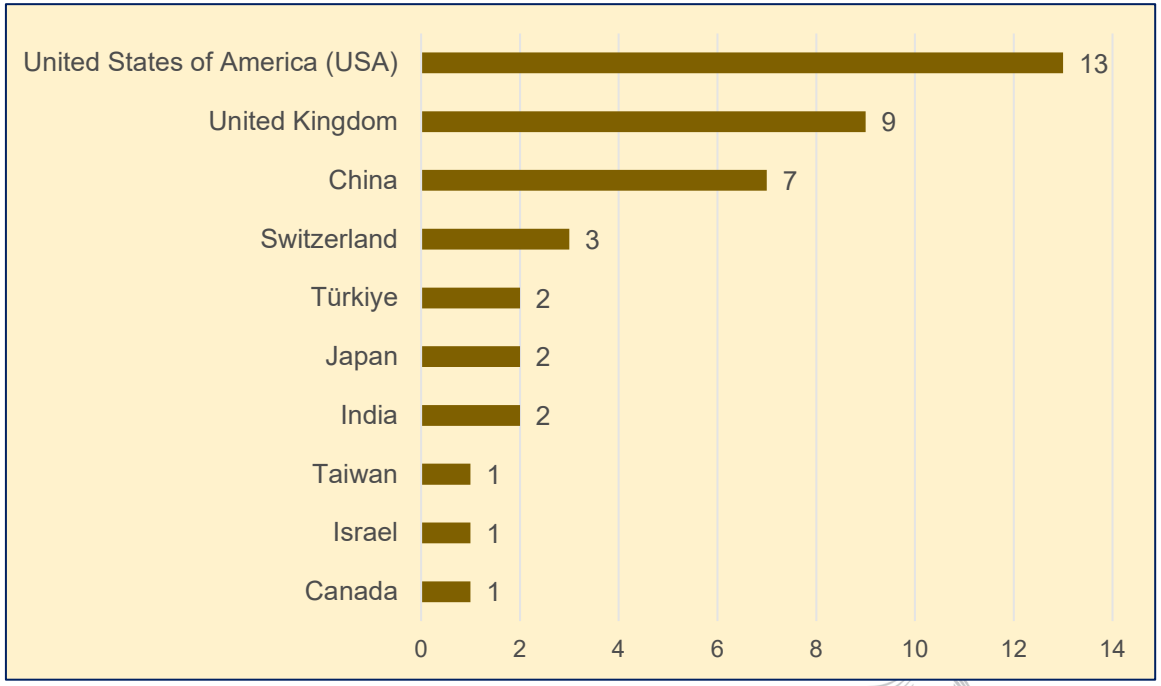


Number of replies per EU country



n = 172; photo credit: pixabay.com

Number of replies per non-EU country



n = 41

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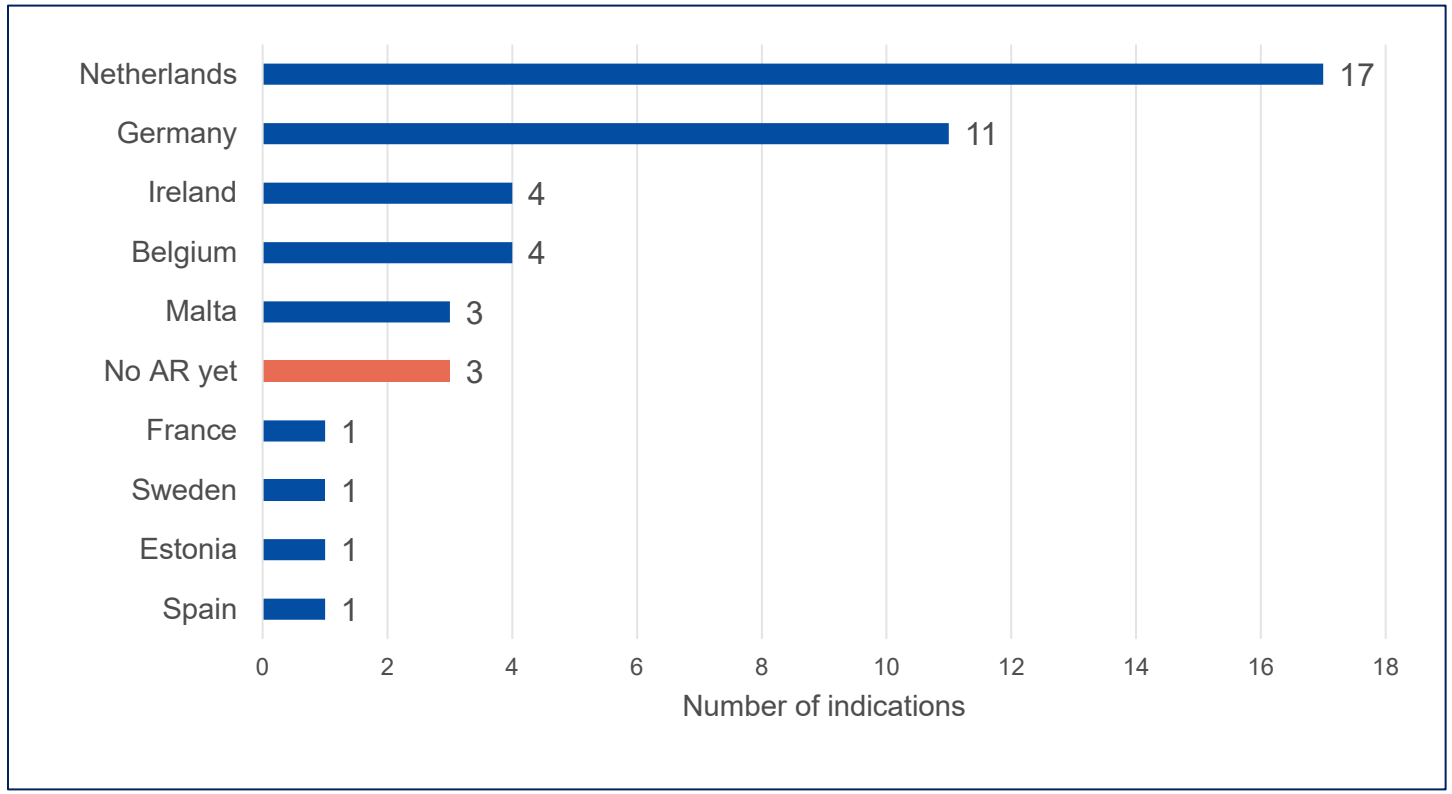
Country, where the company is based (2)

About

In case of ‘non-EU’ MF: country in which the AR(s) is/are resident

(multiple choice)



Most of the ARs of the non-EU MF that replied to the survey are located in:

1. The Netherlands
2. Germany
3. Ireland

Notes:

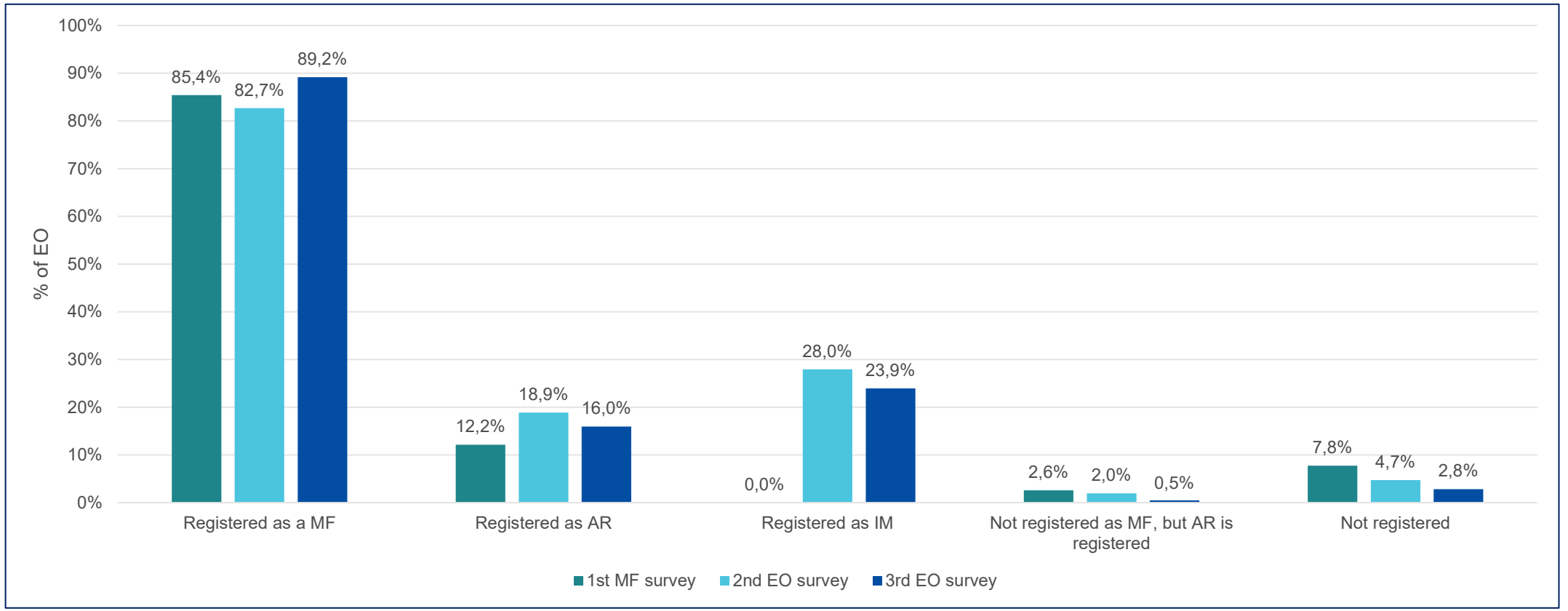
- Data of 41 non-EU MFs
- **Multiple choice:** 3 out of 41 non-EU MFs indicated more than one AR

European Commission

About

Registration in EUDAMED

Note: Some participants indicated several registrations (MF, AR, IM)



1st MF survey: n = 658 MF/ARs
2nd EO survey: n= 254 MF/ARs
3rd EO survey: n= 213 MF/ARs

European Commission

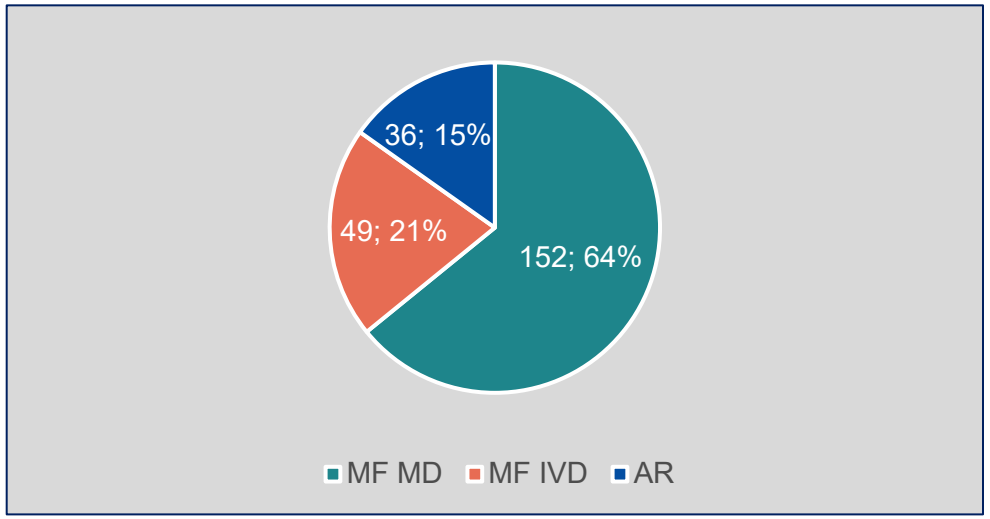
About

Company role

Of 213 replies received (several roles possible)

- **152** indicating acting as manufacturers (MFs) for MDs,
- **49** indicating acting as manufacturers (MFs) for IVDs,
- **36** indicating acting as authorised representatives (AR),

Note: This question led to the relevant survey(s) to be completed. Some companies indicated several roles.



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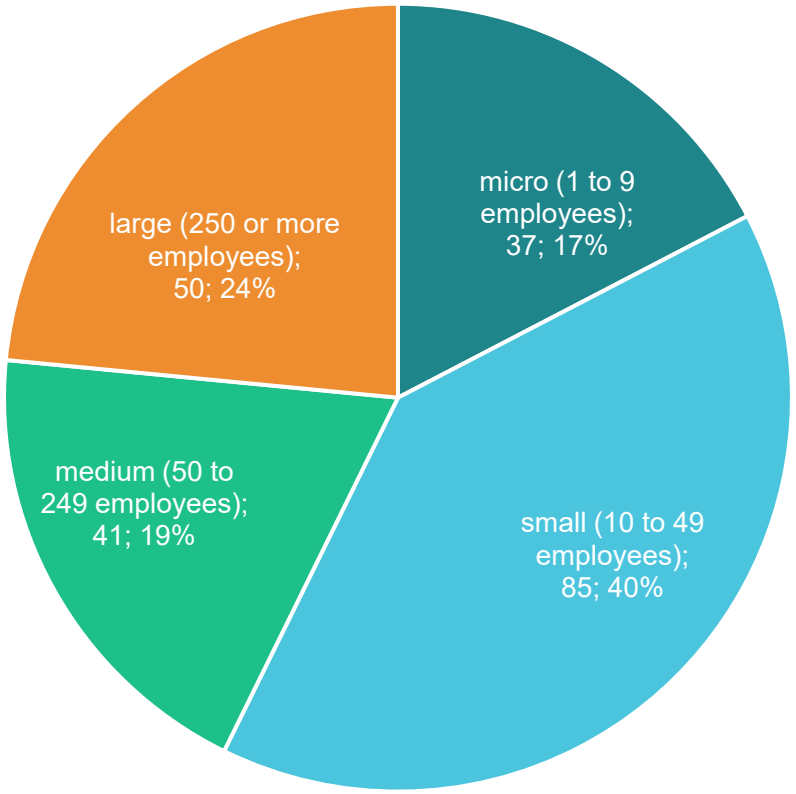
About

Size of organisation (globally) (1)

n = 213 companies participating in the survey



76 % of the responding companies have less than 250 employees.

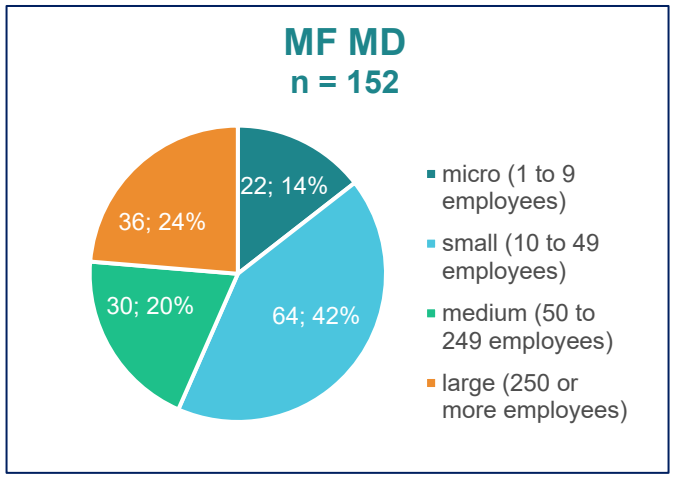
57 % represent small and micro companies.

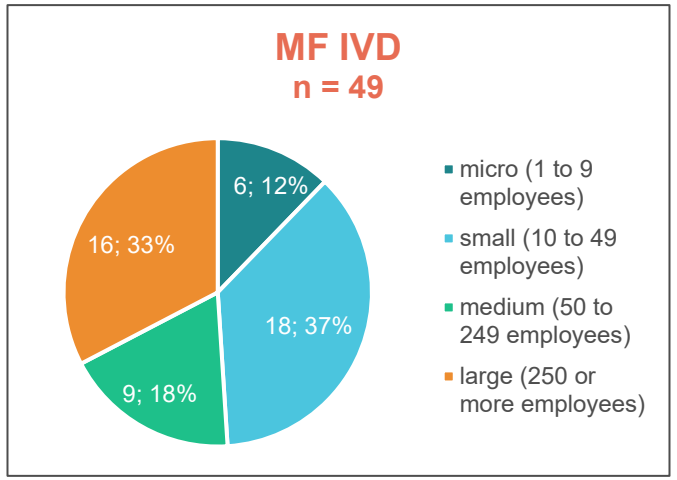
European Commission

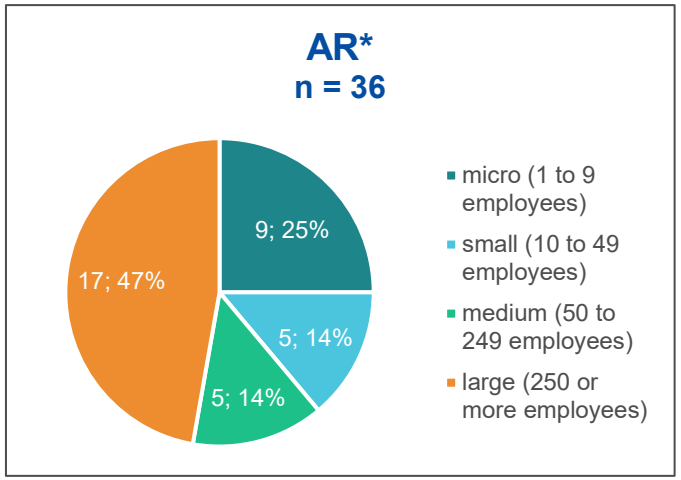
Size of organisation (globally) (2)

Company size by role (several roles possible)

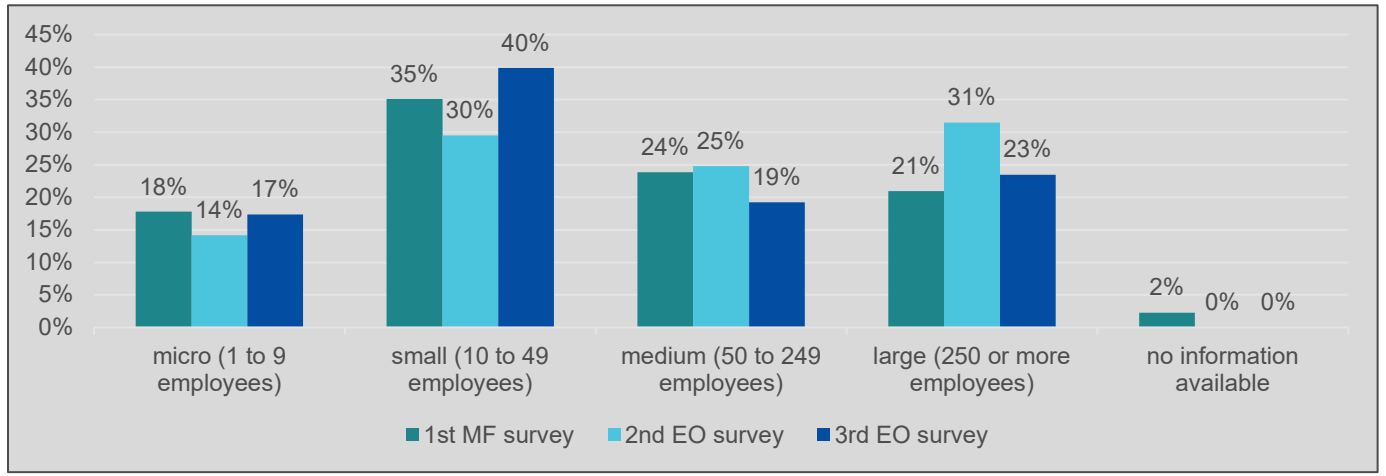
About

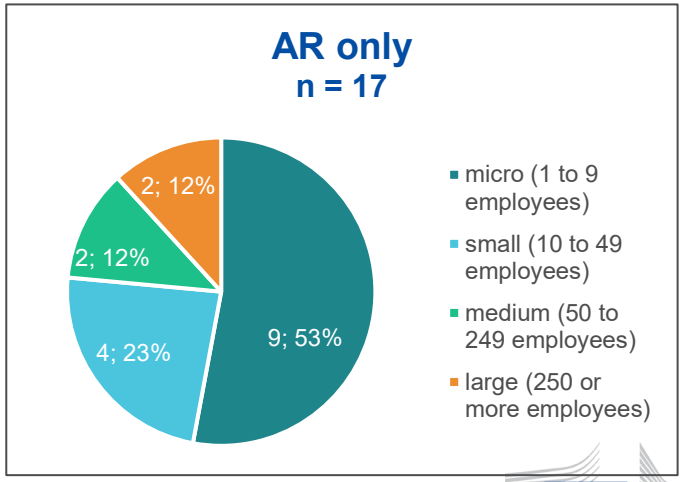






*n = 36 companies indicating to act as an authorised representative. Thereof 17 companies acted as AR only.





1st MF survey: n = 658 MF/ARs
2nd EO survey: n= 254 MF/ARs
3rd EO survey: n= 213 MF/ARs

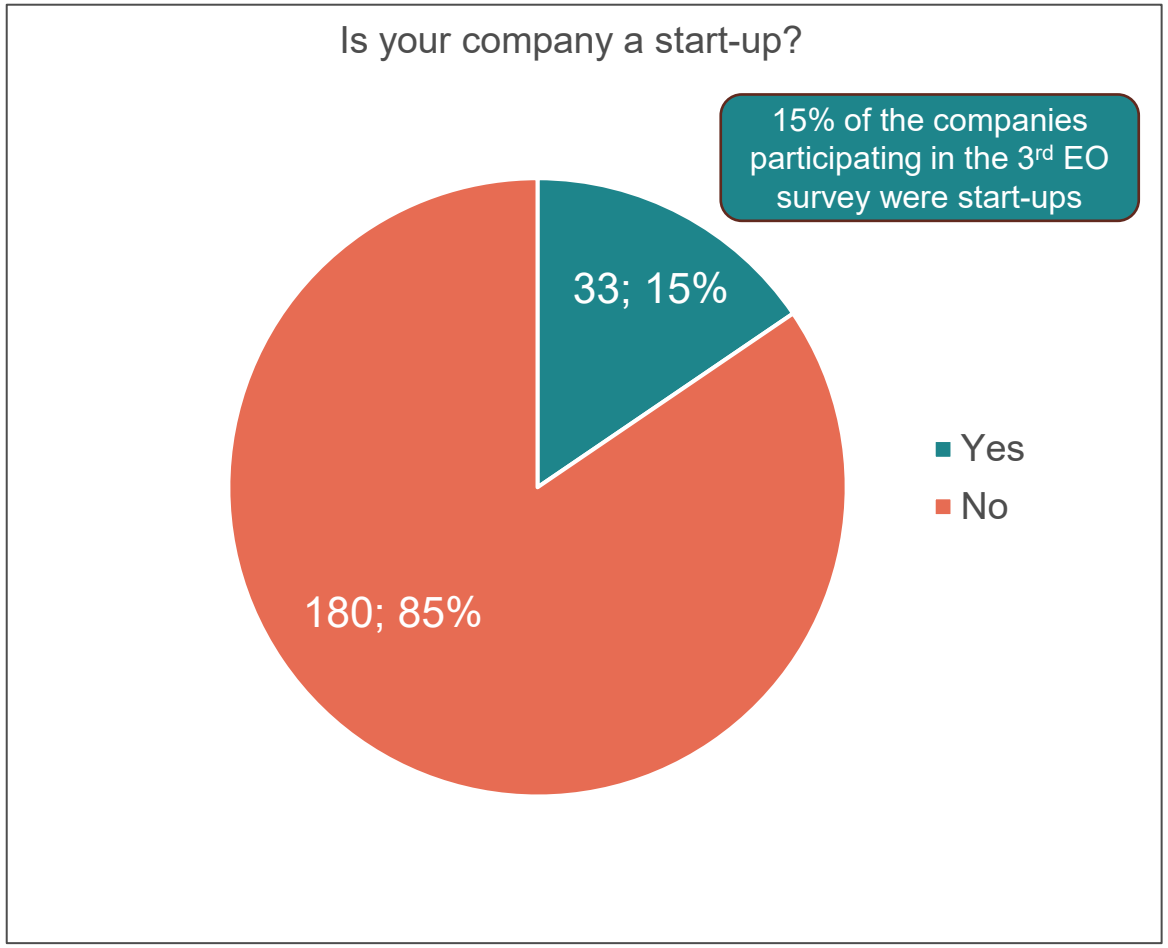
European Commission

Q5

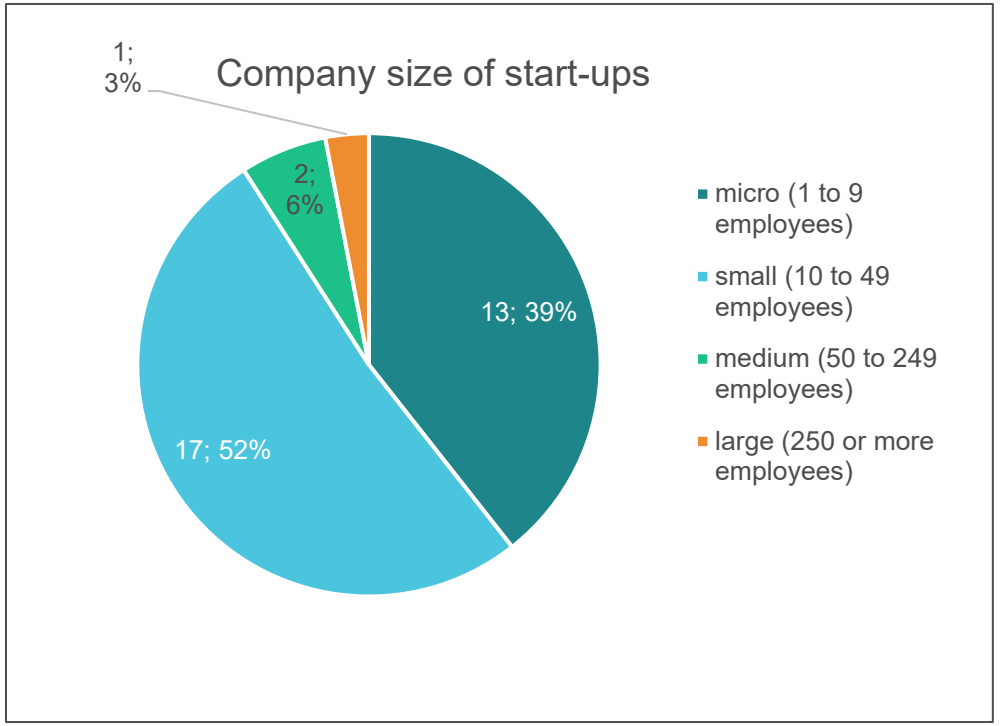
Start-ups*

About

* For the purpose of this study, start-ups are companies or ventures that are focused on new and innovative products or services that the founders want to bring to market



n = 213 companies participating in the survey



n = 33 start-ups participating in the survey

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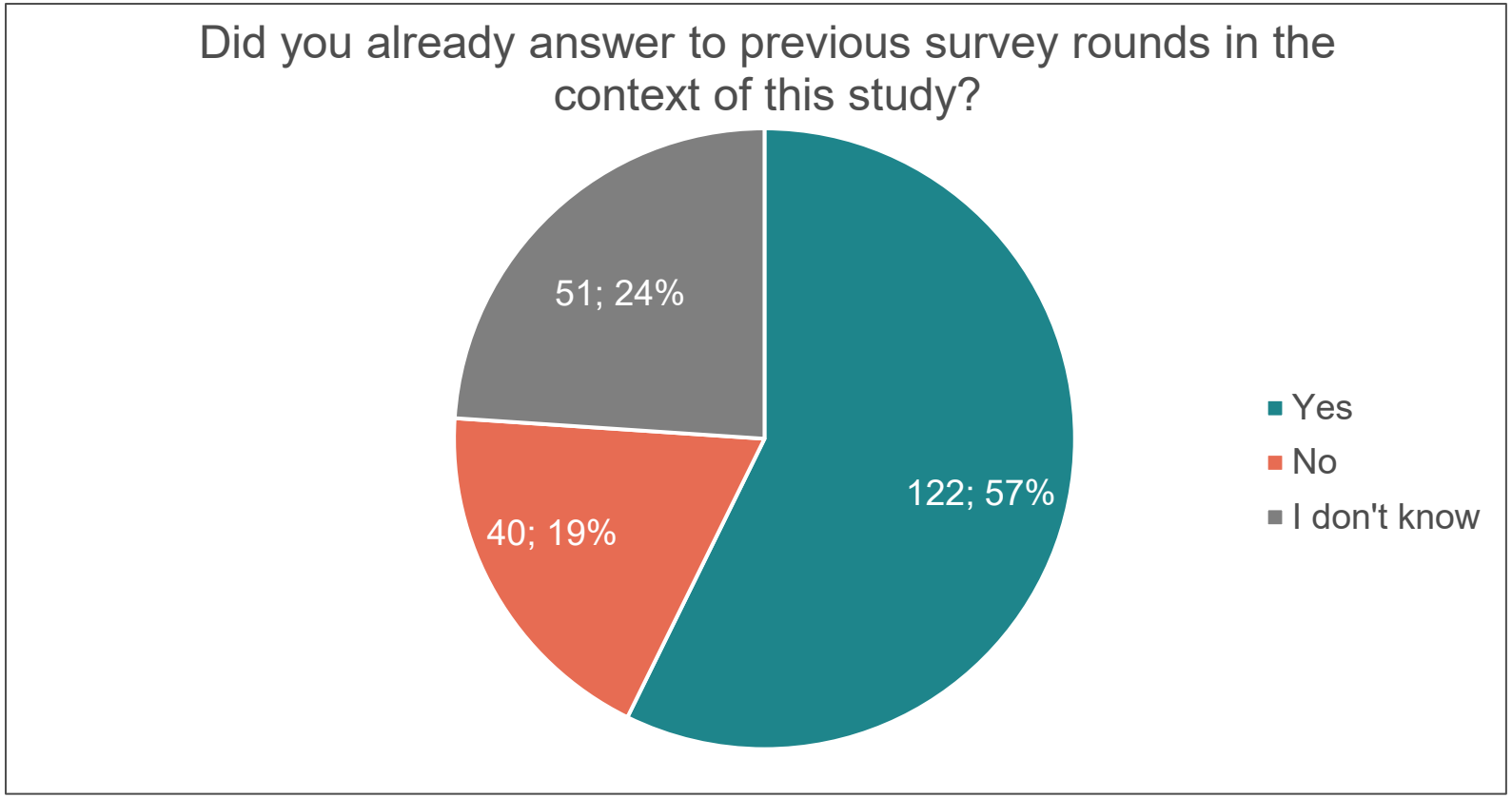
Q6

Participation in previous survey rounds



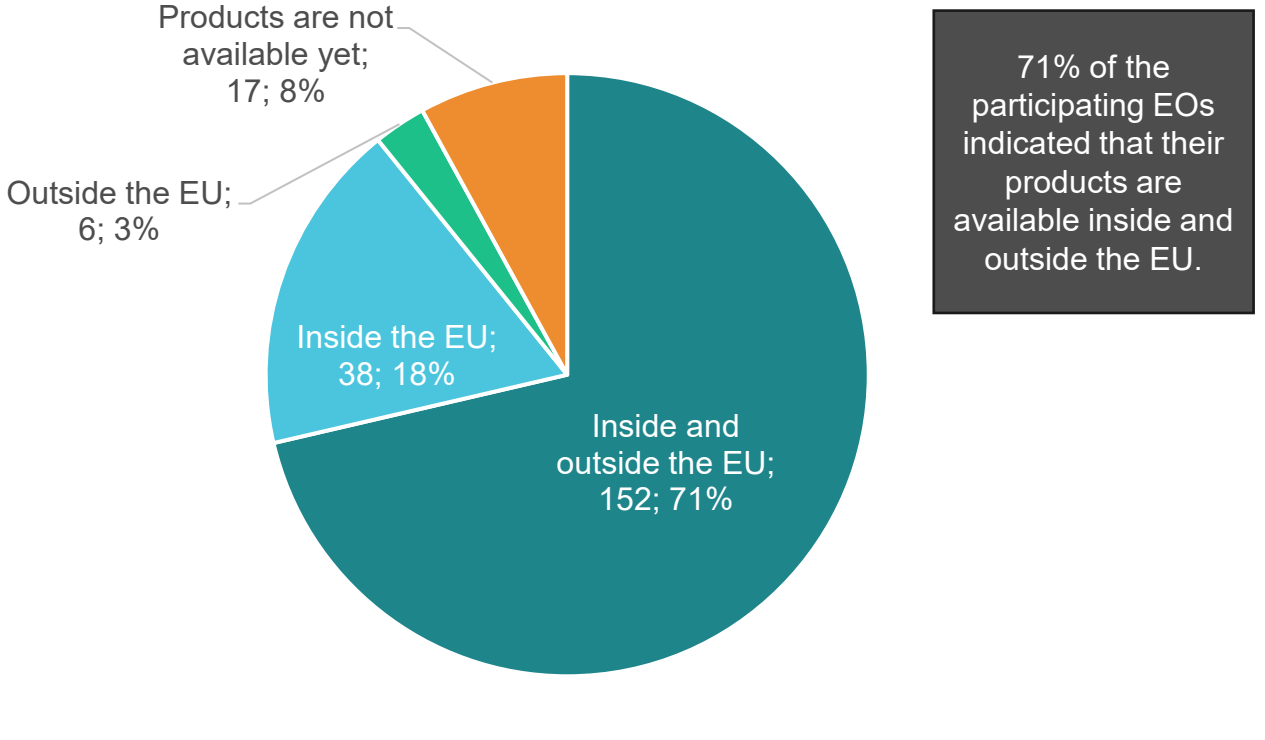
n = 213 companies participating in the survey

European Commission

Where are products available

About

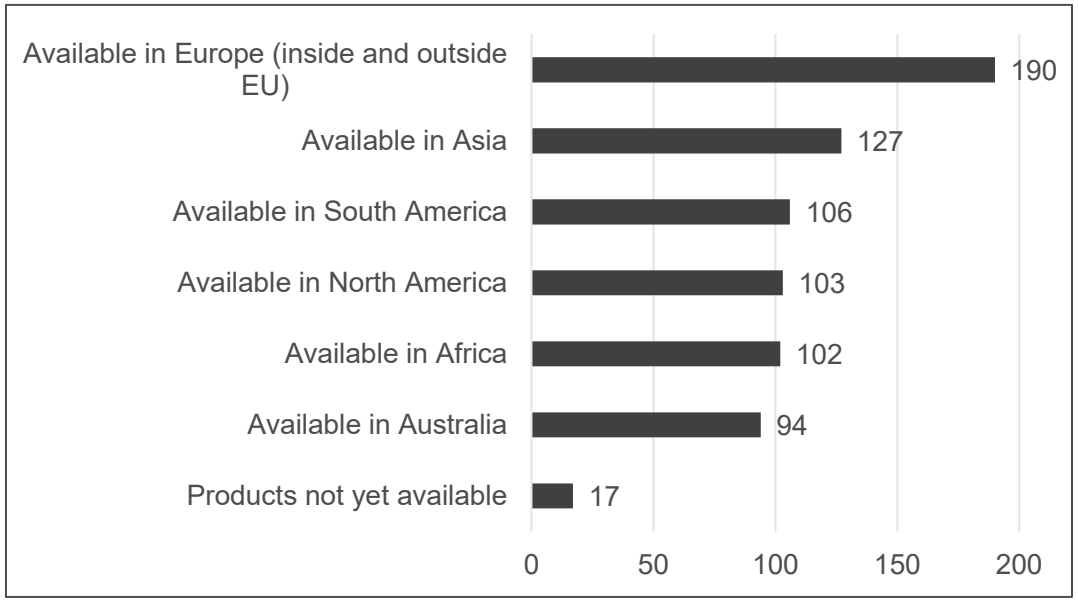
Availability of products by market



71% of the participating EOs indicated that their products are available inside and outside the EU.

n = 213 EOs participating in the survey

Availability of products by continent



Note: Respondents could give multiple answers.

n = 213 EOs participating in the survey, multiple responses possible

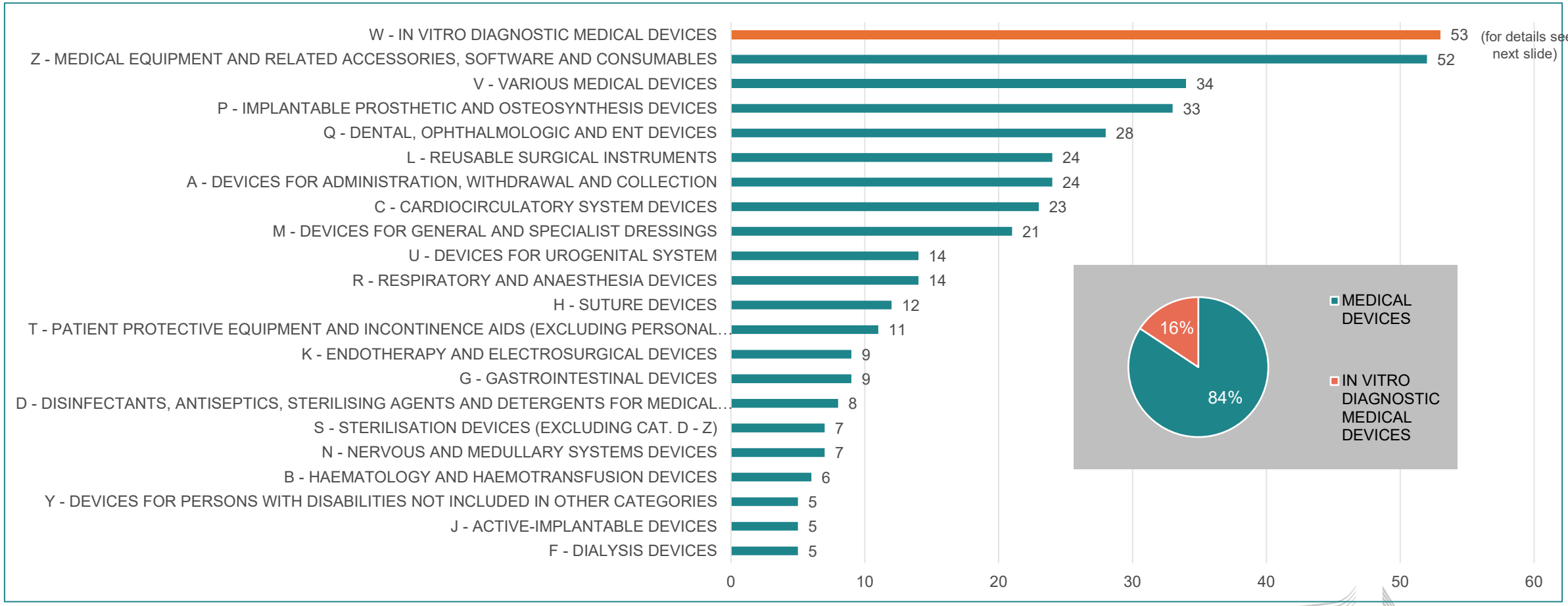
European Commission

Optional indication by companies: Device areas (EMDN categories) currently included in the product portfolio

About

(EMDN categories selected by EOs)

Total number of EMDN category indications: 347



205 out of 213 EOs answered this question (optional response was possible), resulting in 347 EMDN category indications
Category D: ... FOR MEDICAL DEVICES
Category T: … (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT PPE)

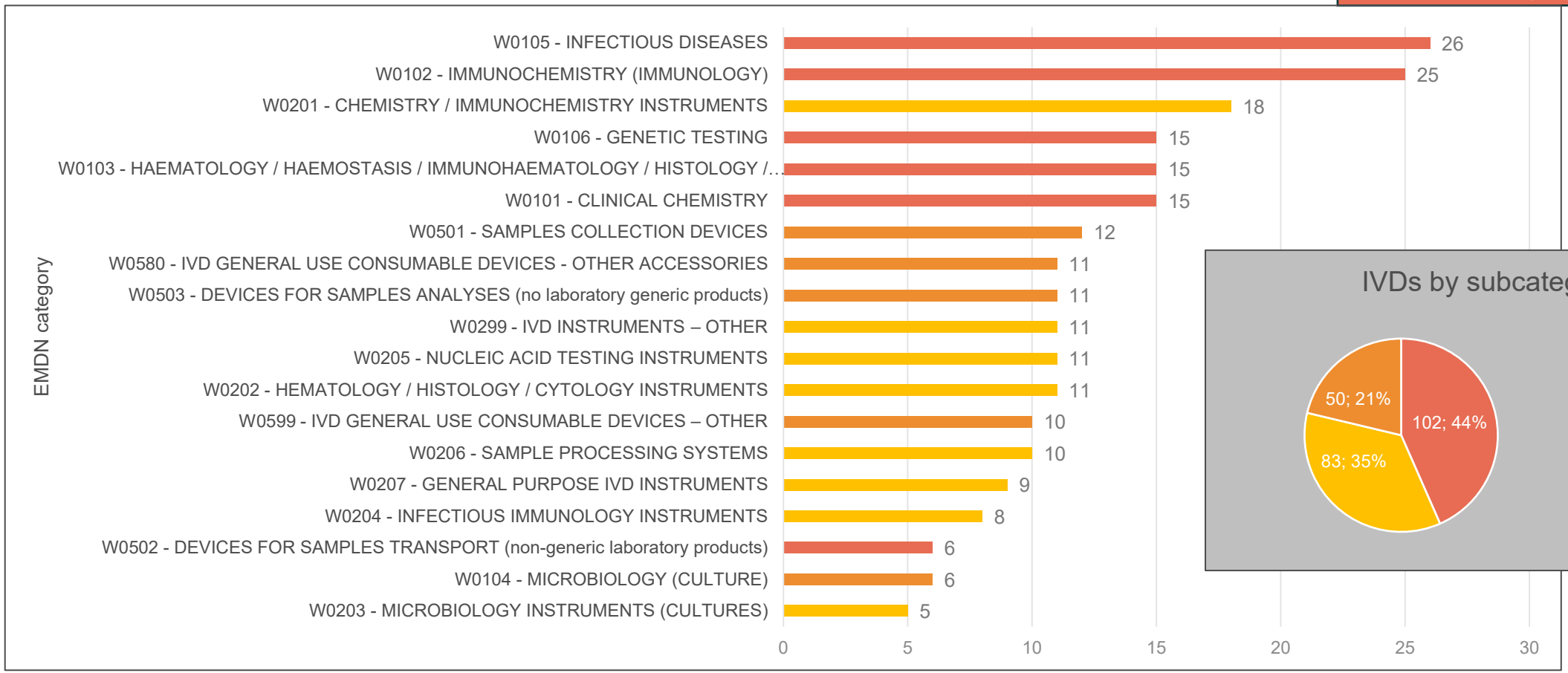
European Commission

Optional indication by companies: IVDs (EMDN categories) currently included in the product portfolio

(number of devices referring to catalogue numbers)

About

Total number of EMDN category indications: 235



37 out of 213 EOs answered this question (optional response was possible), resulting in 235 EMDN category indications for IVDs

European Commission

MD

2.2. Survey results for medical devices

Questionnaire part 2.2. including questions 10 to 30

Q14
Q17

Overview on applications and certificates by end of October 2025

MD

Number of applications lodged under MDR: **1319***

18th NB survey
(covering the same data period as the 3rd EO survey until 31/10/2025):

Ⓜ: 33107**
(MF sample: 4% were potentially covered in this survey)

Number of certificates issued for MDs under MDR: **772**

17.507
(MF sample: 4% were potentially covered in this survey)

Note: These figures relate to the 152 responses from the manufacturers of MDs as of the end of October 2025.
No. of applications: data of 152 MD MF
No. of certificates: data of 87 MD MF
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 and NBs, the MF might have a different interpretation of applications as NBs.
** The data shown comes from the medium data set Ⓜ – except for 3 NBs where the total number of applications filed was derived from the small data set Ⓢ since they could not provide the data per Annex.

European Commission

MD

AIMDD/MDD
legacy devices*

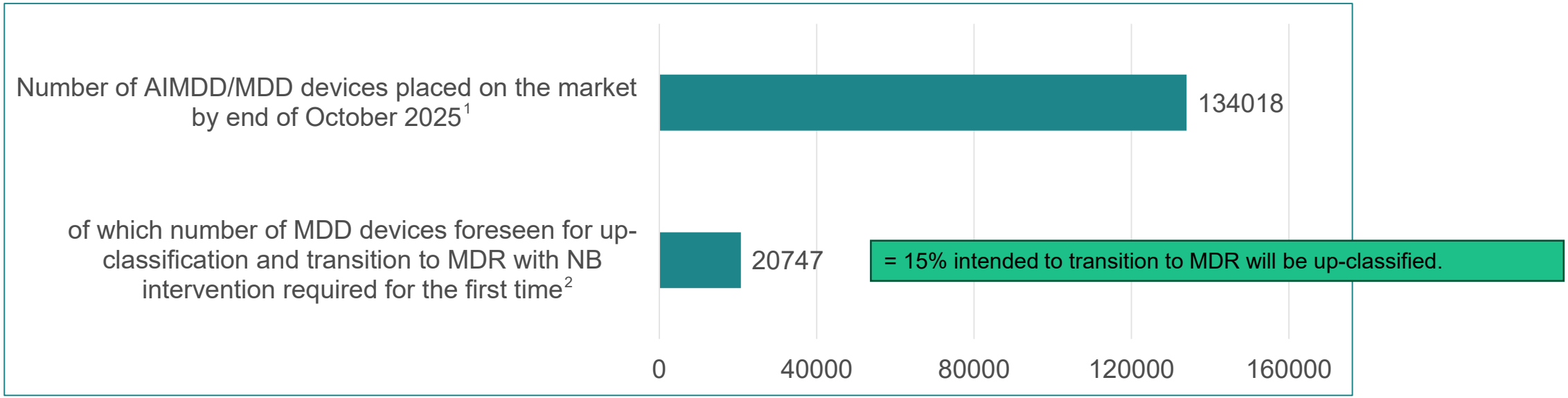
* In line with MDCG 2021-252 ‘legacy devices’ should be understood as devices, which, in accordance with the MDR’s transitional provisions, are placed on the market after the MDR’s date of application (i.e. 26 May 2021) if certain conditions are fulfilled.

AIMDD/MDD overview by the end of October 2025

(number of devices referring to catalogue numbers)

MD

Total responses from MFs for MDs: 152



Notes:
[1] Data of 152 MFs, including 43 MFs with the indication '0';
[2] Data of 152 MFs, including 96 MFs with the indication '0';

European Commission

MD

AIMDD/MDD overview by the end of October 2025

Total responses from MFs for MDs: 152
Total no of valid MDD/AIMDD certificates indicated by NBs (by end of April 2022): 25034

Total number of EC certificates issued in accordance with Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) prior to 26 May 2021 benefitting of the extended transitional period provided for in Article 120 MDR (QMS + product certificates): **2736**

(for comparison, value of the 2nd EO survey: 1168)

Notes:
3rd EO survey: Data of 152 MFs, including 49 MFs with the indication '0'
2nd EO survey: Data of 161 MFs, including 43 MFs with the indication '0'

MD

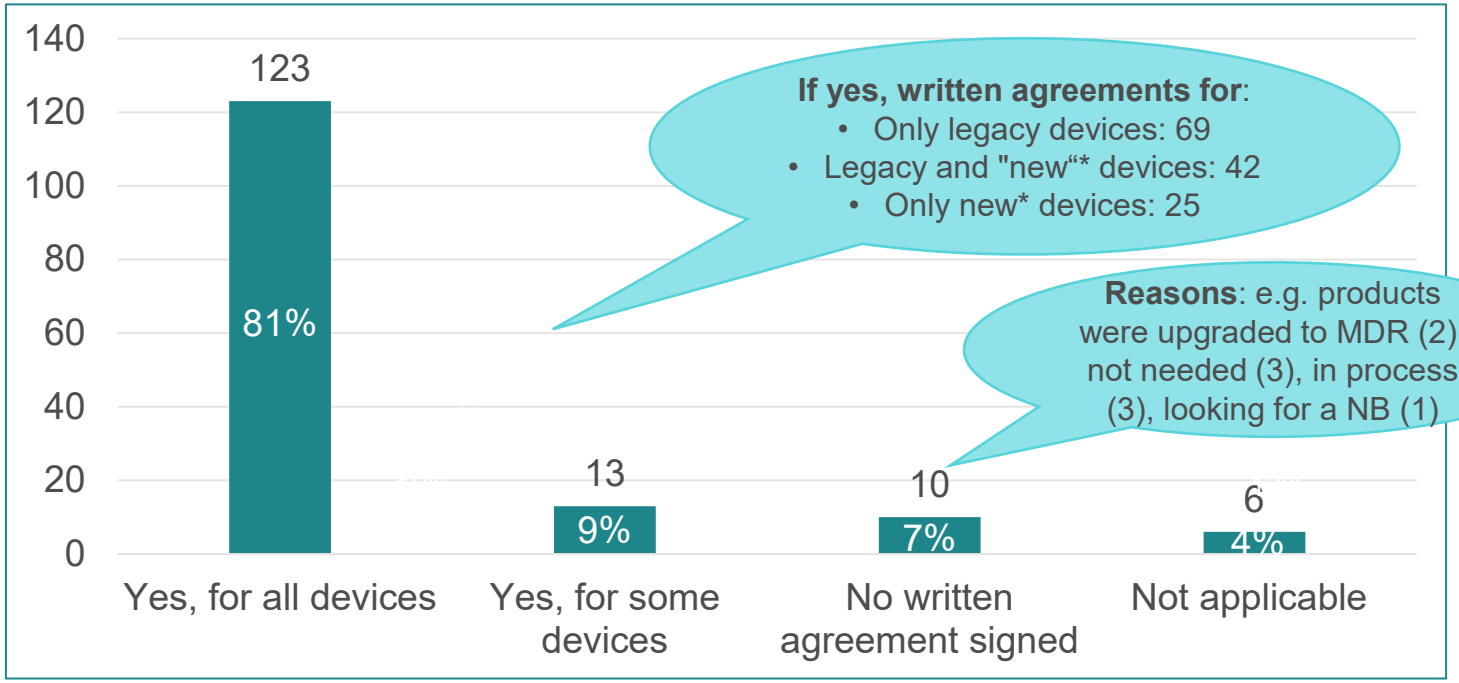
Notified bodies
written agreements, refused applications

Written agreements between MFs of MDs with Notified Bodies

MD

Total responses from 152 MFs for MDs

Number of companies with written agreements with a notified body/notified bodies designated under the MDR by the end of October 2025



Note: Replies of 152 MD MFs

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

- 90% of the MF have (a) written agreement(s) with NBs (2024: 90%, 2023: 67%)
- 7% of the MF that need a written agreement don't have one (2024: 4%, 2023: 20%)
  4% of the MF don't need a NB involvement (2024: 6%, 2023: 13%)

(In brackets the results of the 1st MF/AR survey (2023) and 2nd EO survey (2024) – replies of 501 and 161 MFs for MD respectively.)

*devices which have never been CE-marked but will need CE-marking under the MDR to access the EU market.

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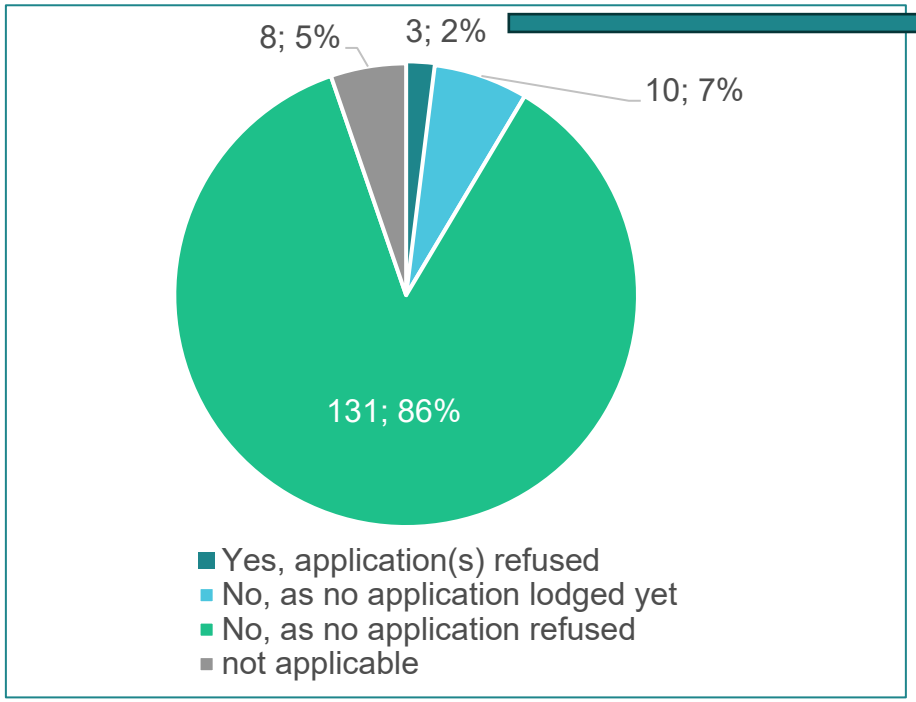
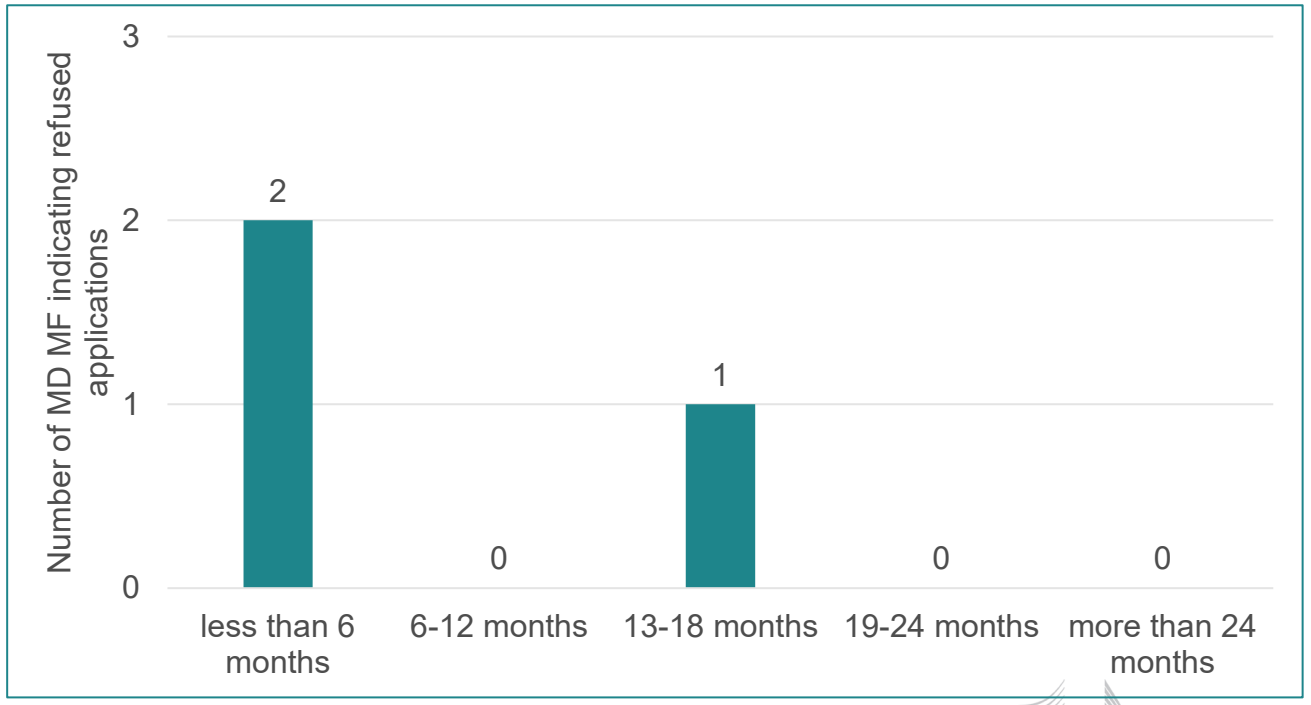
MD

Refusal of applications by Notified Bodies (1)

Did a notified body refuse an application under the MDR? (n=152)



Time from application to refusal (for MD MF indicating 'Yes, application(s) refused.') (n=3)



European Commission

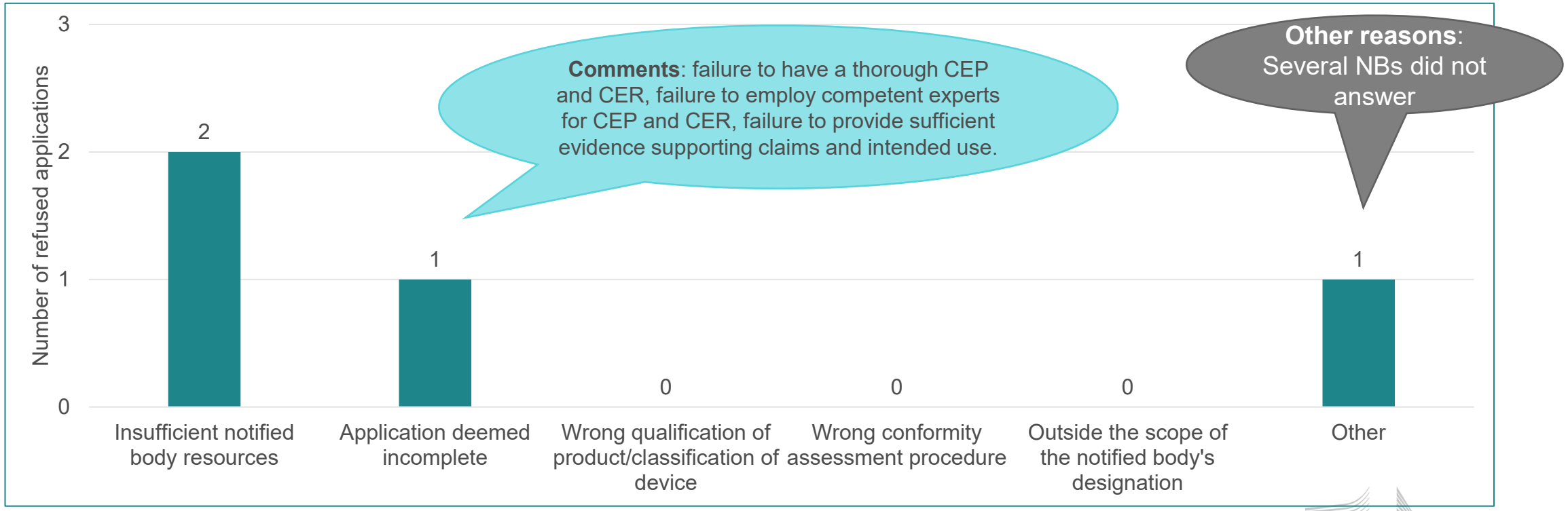
Refusal of applications by Notified Bodies (2)

MD

Number of refused applications by reason for refusal (n=3 companies reporting 4 refused applications)

Refusals for:
- Legacy devices: 1
- New* devices: 2

*devices which have never been CE-marked but will need CE-marking under the MDR to access the EU market.



European Commission

MD

MDR implementation
applications, certificates, re-certification, time periods

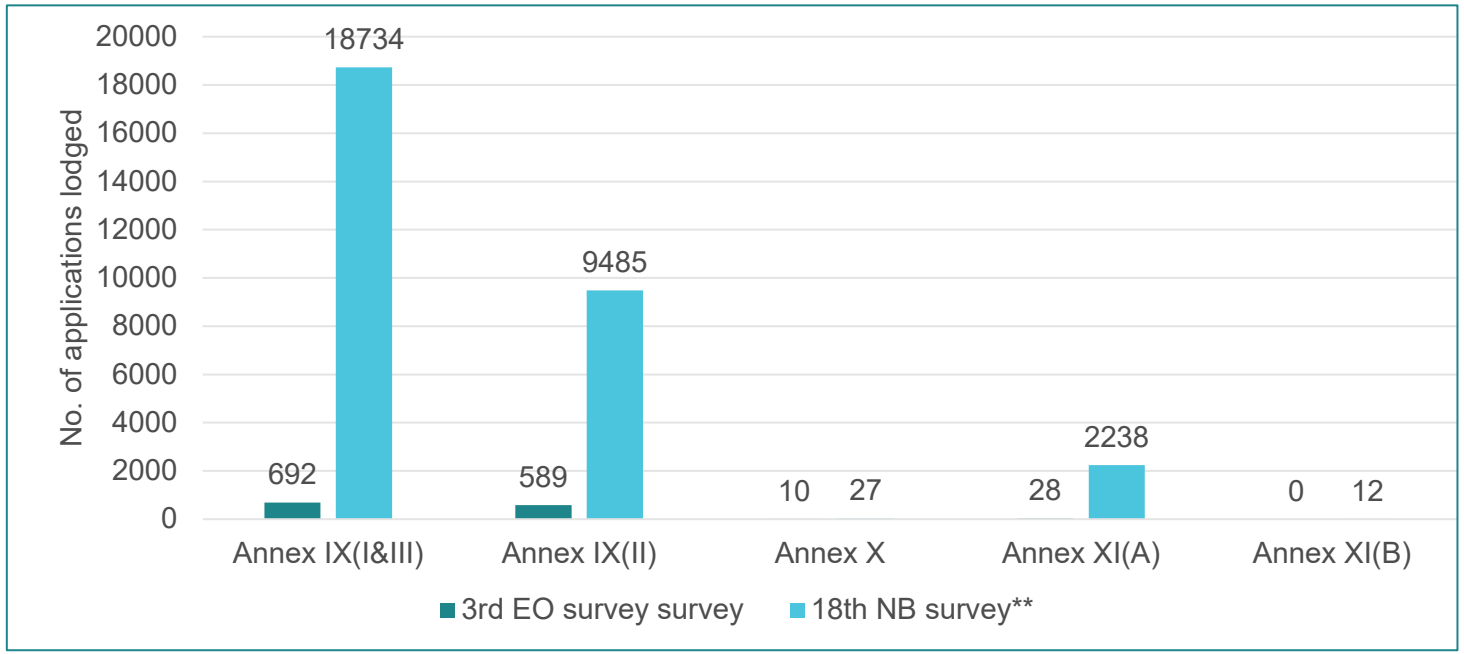
Applications lodged under MDR by end October 2025

MD

Total responses from 152 MFs for MDs

Number of applications lodged (total and for changes) under MDR to NBs by Annex*

Note: This number also includes applications with issued certificates, ongoing applications and applications that were ultimately refused. Please note that applications lodged for changes to existing MDR certificates are included as well and were asked to be indicated separately. Pre-application activities are not included. One application may cover several Annexes.



For comparison data of the 18th NB survey (covering the same data period until 31/10/2025):
Total number of applications filed by Annex Ⓜ: **33.107****
* Even though the questions were asked in the same way to MF/AR and NBs, data provided by MF seems not directly comparable with data provided by NB as they might interpret what an "application lodged" is in different ways.
** The data shown comes from the medium data set Ⓜ – 3 NBs could not provide the data per Annex.
18th NB survey: replies by 51 MDR designated NBs (=100% response rate)

Thereof no. of applications (all Annexes) covering new devices (devices which have never been CE-marked but will need CE-marking under the MDR to access the EU market – e.g. new devices, devices being up-classified, Annex XVI devices): 123 (9%)

Total number of applications: 1319
(thereof 779 (59%) applications for change)

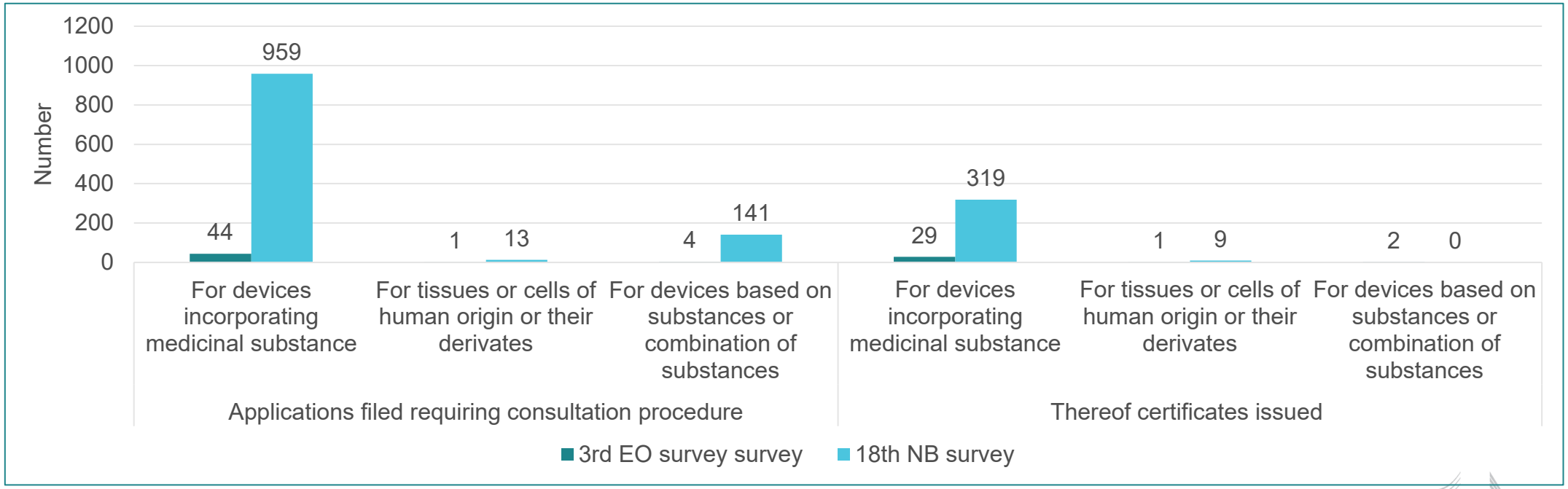
European Commission

MD

Applications lodged and certificates issued under MDR by end October 2025 for MD requiring consultation

Number of applications and certificates for Annex IX(II) products requiring consultation

Note: Responses from 152 MFs for MDs.



European Commission

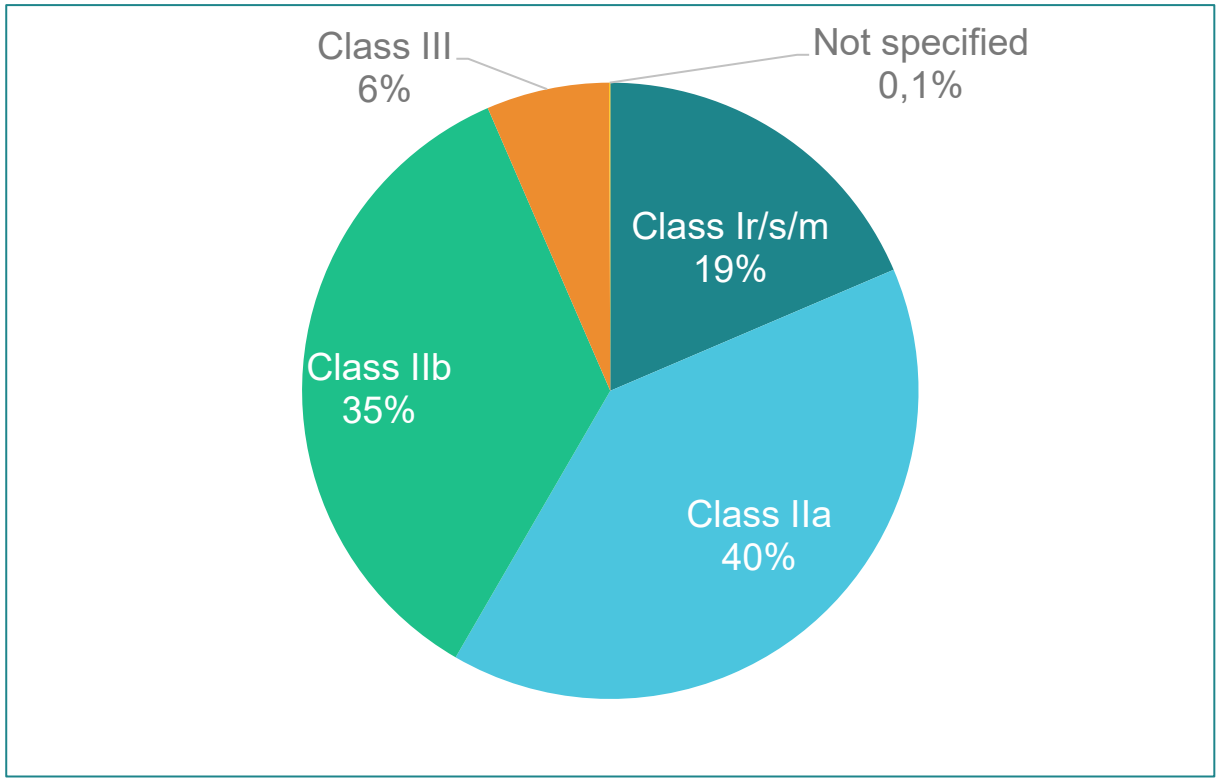
MD undergoing MDR conformity assessment by October 2025

MD

Total number of devices (by catalogue number) undergoing MDR conformity assessment (accepted MDR applications still under review by NB) by the end of October 2025: 78055

(Data of 152 MFs, including 46 MFs with the indication '0')

By risk class:



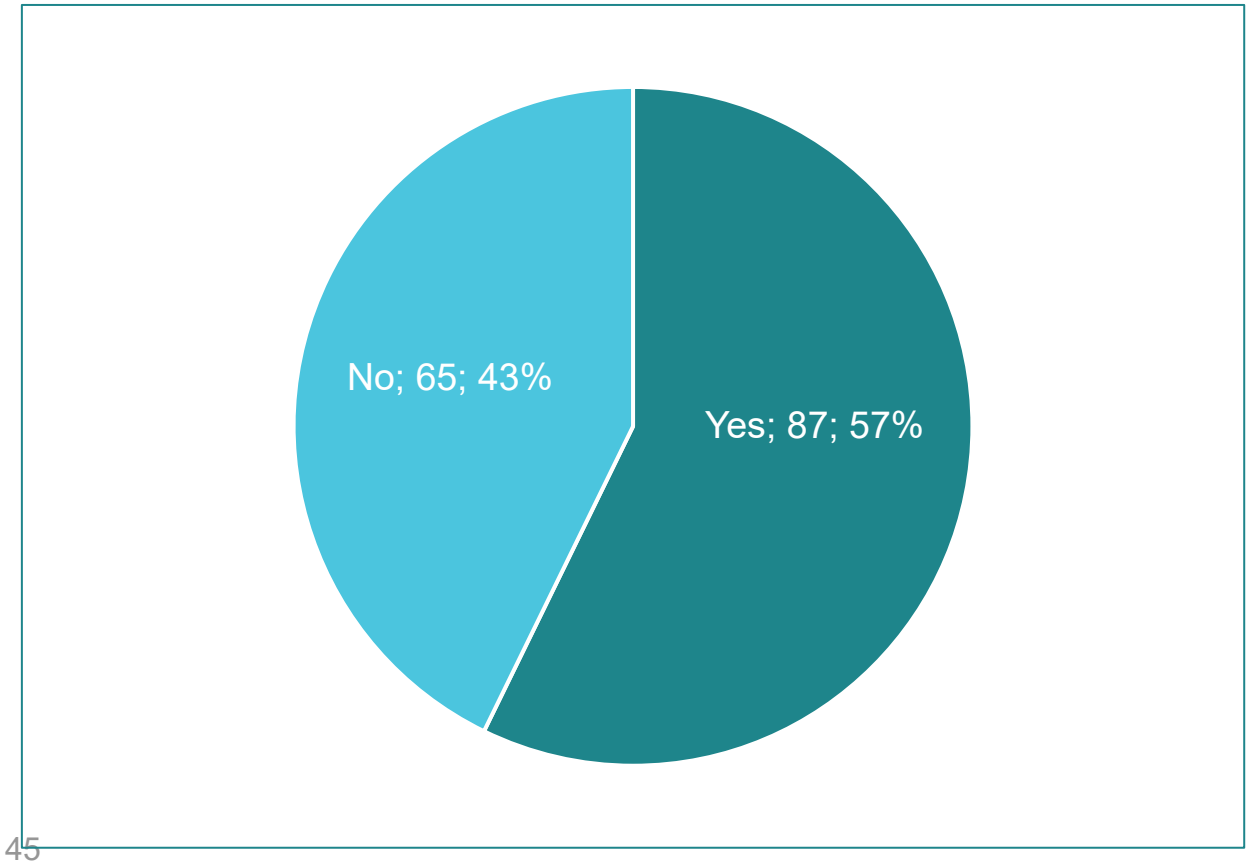
European Commission

MD

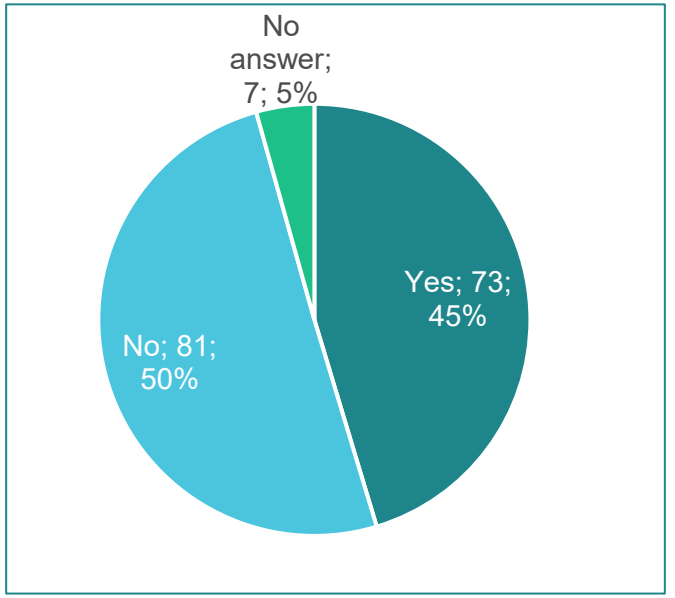
Certificates issued to MD MF under MDR

Total responses from 152 MFs for MDs

Have you already received certificates under the MDR to date up to 31/10/2025 (n=152)?



For comparison the results of the 2nd EO survey – replies of 161 MFs for MD, 31/10/2024



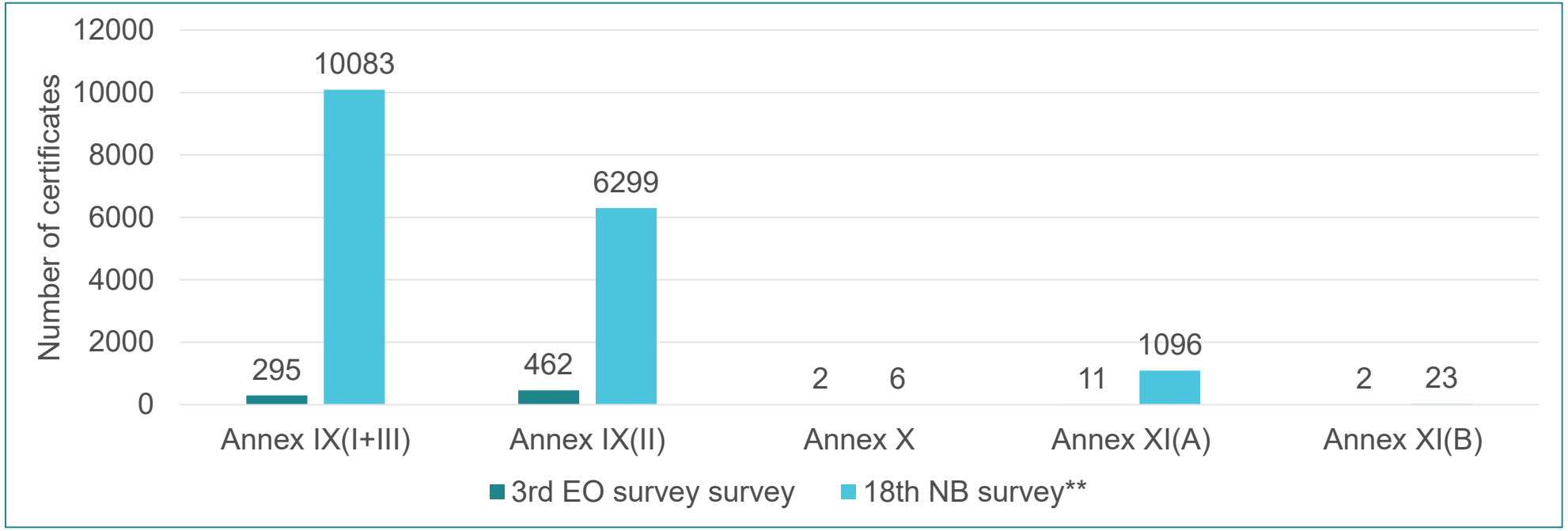
European Commission

MD

Certificates issued to MD MF under MDR

Number of certificates issued to MF for MDs under MDR by Annex by end October 2025

For comparison data of the 18th NB survey (covering the same data period until 31/10/2025): 17.507*
* The indicated no. of certificates by manufacturers is not directly comparable to the no. of certificates indicated by NBs since they might have a different understanding in counting (one certificate for each product group vs. one certificate for similar product groups).



No. of certificates: data of 87 MD MF

Total number of certificates: 772

European Commission

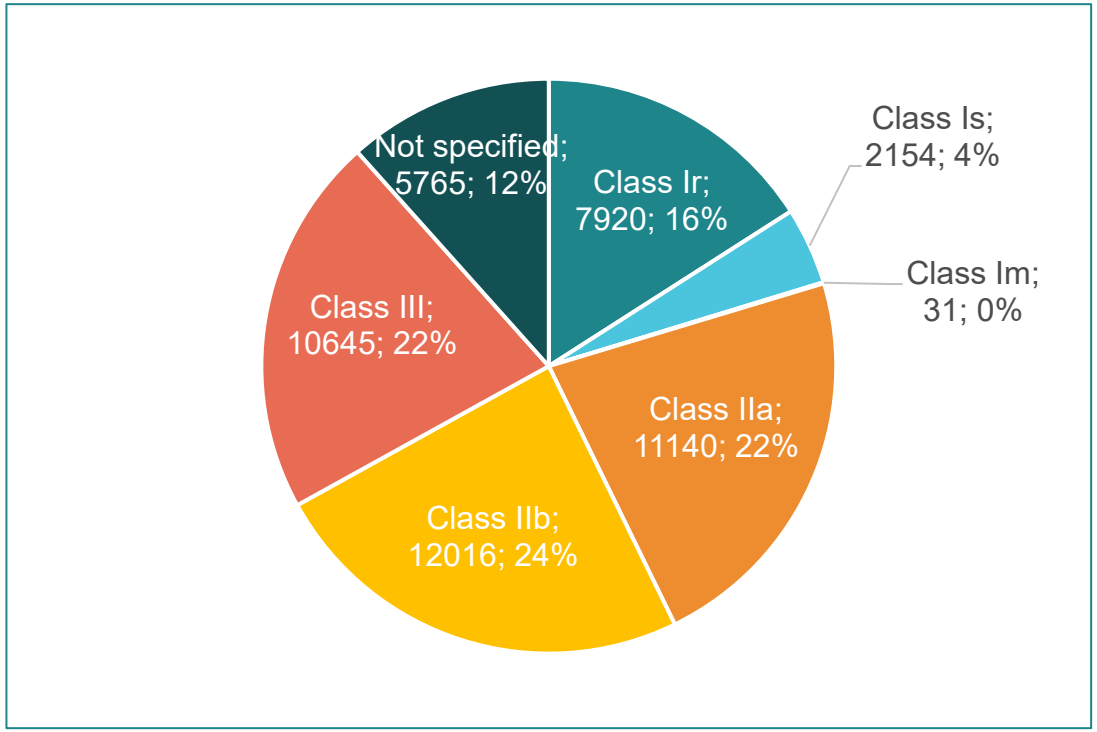
Device numbers (as per catalogue number) covered in MDR certificates

MD

Number of devices (catalogue numbers) covered in MDR certificates issued by end of October 2025: 49.671

of which new devices[1]: 3121 (6%)
- novel devices[2]: 16
- break-through devices[3]: 4

By risk class:



Note: n=86 MF

[1] Devices which have never been CE-marked before but will need CE-marking under the MDR to access the EU market
[2] When assessing novelty, relevant dimensions of a device in which novelty and innovation can be manifest may include, but are not limited to the ones listed: procedure-related items, device-related items. Novelty in this context typically means that there is a lack of experience in regard to the safety and performance of the device or specific features of the device or related clinical procedure, and there are no similar devices or insufficient experience with similar devices to enable straightforward appraisal of its future real-world safety and performance. For more information see definition in the Commission guidance in section 2.1: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC0807(01)&rid=5on see definition in the Commission guidance in section 2.1: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC0807(01)&rid=5
[3] Based on the MDCG 2025-9 Guidance on Breakthrough Devices (BtX) under Regulations 2017/745 & 2017/746, a MD or IVD will be considered a breakthrough device if it meets each of the following criteria:
1. Novelty: The device introduces a high degree of novelty with respect to the device technology, the related clinical procedure, and/or the application of the device in clinical practice,
AND
2. Positive clinical impact: The device is expected to provide a significant positive clinical impact on patients or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following:
  - o Offering a significant positive clinical impact on patients or public health compared to available alternatives and the state of the art, OR
  - o Fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.

For more information see MDCG 2025-9: https://health.ec.europa.eu/document/download/edca94c7-62ab-4dd5-8539-2b347bd14809_en?filename=mdcg_2025-9.pdf No dedicated breakthrough pathway available under MDR

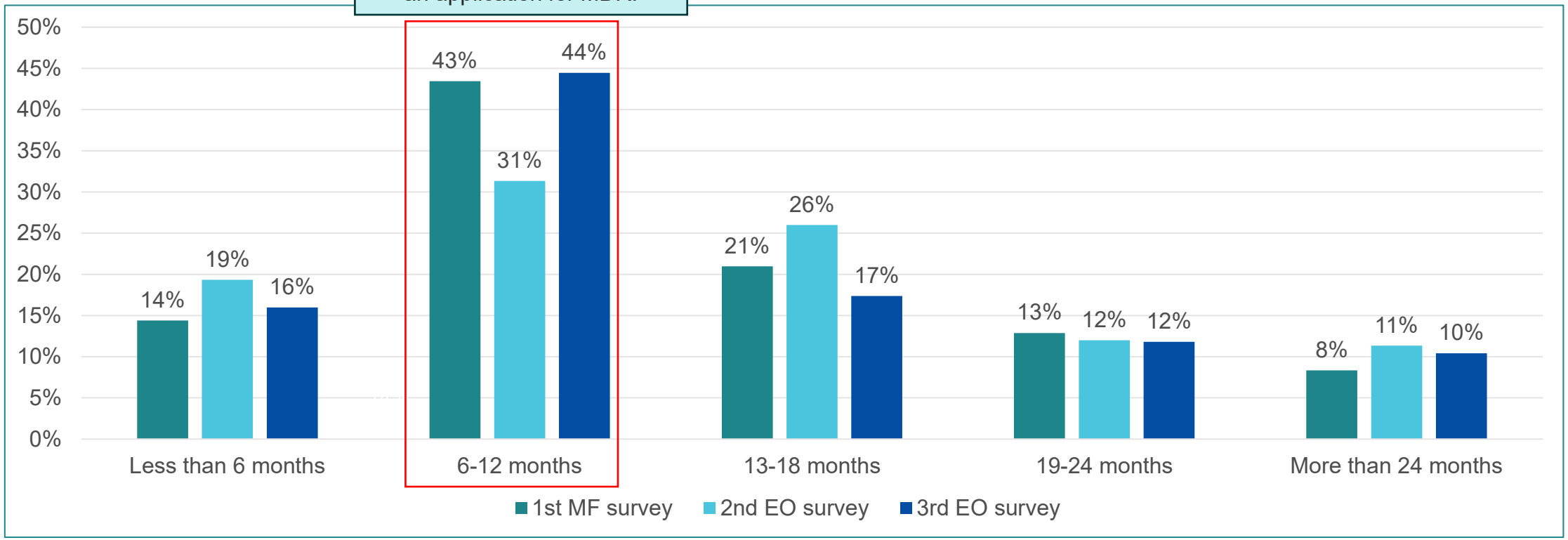
European Commission

MD

Time periods (1)

Average time to prepare an application for MDR (before submission to a NB) – *comparison of 3rd EO survey with previous surveys*

For 44% of the MD MFs it takes 6-12 months to prepare an application for MDR.



Note:

- **1st MF survey:** Replies of 396 MD MFs, 105 MFs indicated 'no information available'
- **2nd EO survey:** Replies of 150 MD MFs, 11 MFs indicated 'no information available'
- **3rd EO survey:** Replies of 144 MD MFs, 8 MFs indicated 'no information available'

European Commission

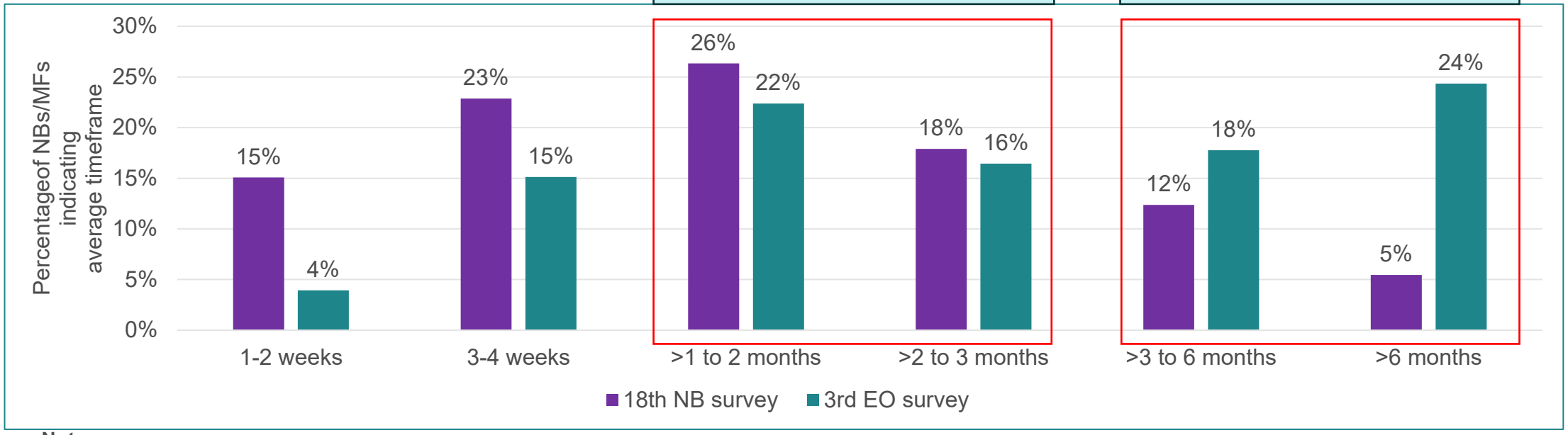
MD

Time periods (2)

Average timeframe between application lodged and written agreement signed – *comparison of 3rd EO survey with 18th NB survey*

For 38% of the companies, it takes **1 to 3 months** between application lodged and written agreement signed.

For 42 % of the companies, it takes **more than 3 months** between application lodged and written agreement signed.



Notes:

- **18th NB survey:** Replies of 51 NBs designated under MDR; data collection method: NBs indicated the number of files for each category which was converted into percent per category
- **3rd EO survey:** Replies of 152 MD MFs; data collection method: EOs selected one time period

European Commission

Time periods (3)

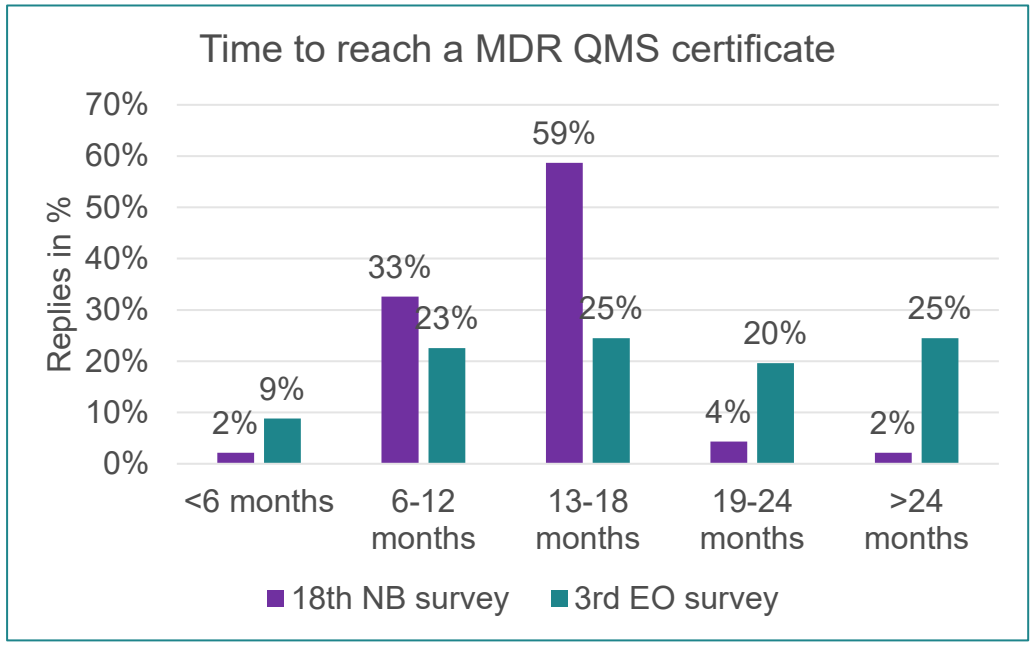
Total responses from 152 MFs for MDs

MD

Average time to reach/issue MDR certification for devices

(from written agreement signed to issuance) – *comparison of 3rd EO survey with 18th NB survey*

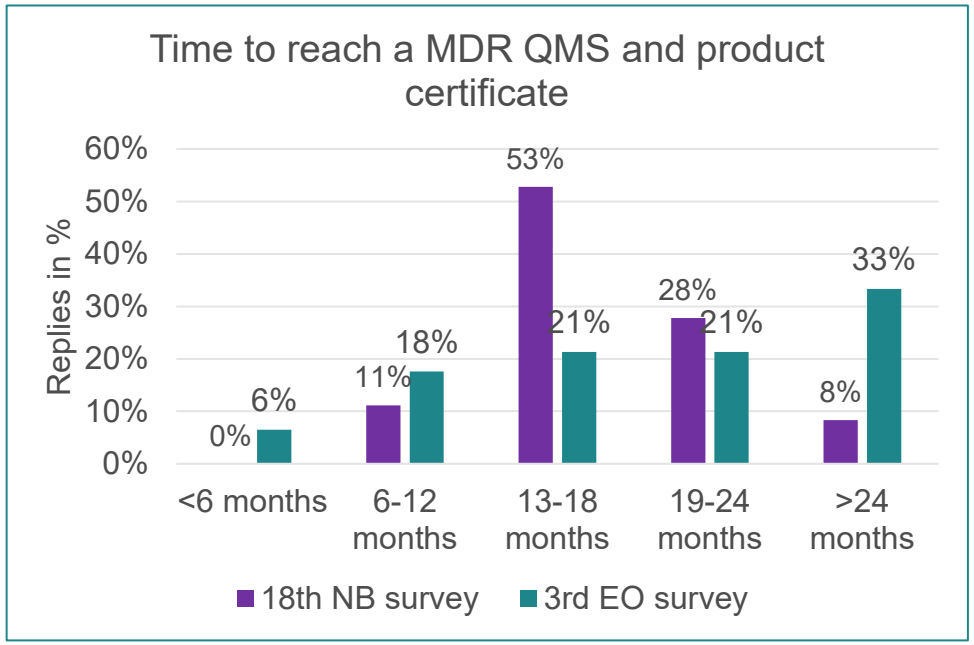
59% of the NBs indicated 13-18 months.
25% of the MD MFs indicated 13-18 months.



Notes QMS certificates:

- **18th NB survey:** QMS: Data of 46 NBs designated under MDR (covering the same data period until 31/10/2025)
- **3rd EO survey:** Data of 102 MD MFs; 50 MFs indicated 'no information available'

53% of the NBs indicated 13-18 months.
54% of the MD MFs indicated more than 19 months.



Notes QMS and product certificates:

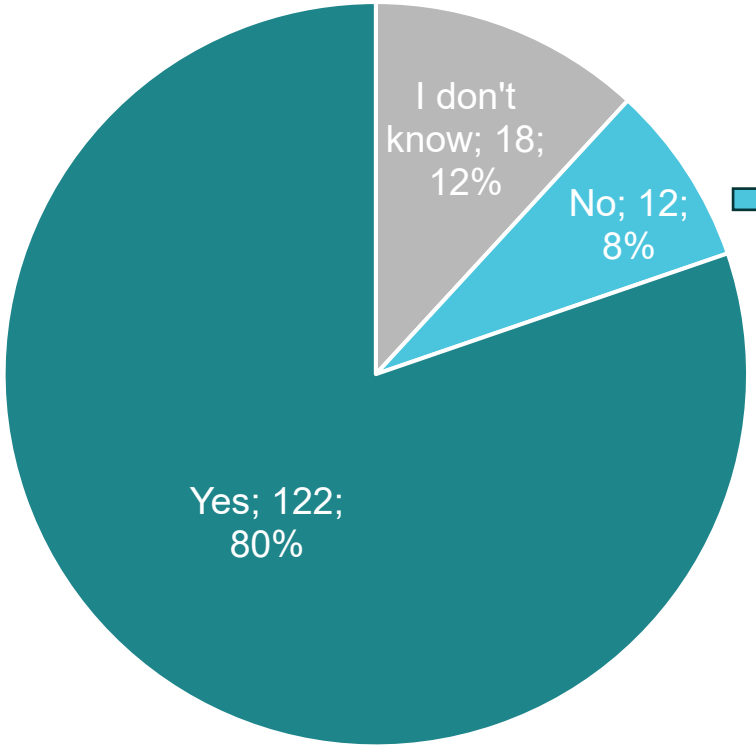
- **18th NB survey:** QMS+PRODUCT: Data of 36 NBs designated under MDR (covering the same data period until 31/10/2025)
- **3rd EO survey:** Data of 108 MD MFs; 44 MFs indicated 'no information available'

European Commission

MD

Compliance with deadlines

In general, do you comply with the deadlines agreed with your NB(s) for submitting data / information and subsequent further requests?



If not:

- Lack of ressources (3)
- More time needed (3)
- Timlines are challenging (1)
- Dozens of documentations have to be rewritten again and again, also during the application period (1)
- No timeline established (1)
- Timeline unclear (1)
- Legacy devices on the market for more than 30 years - difficult to find clinical assessments (1)
- Delay by NBs (1)

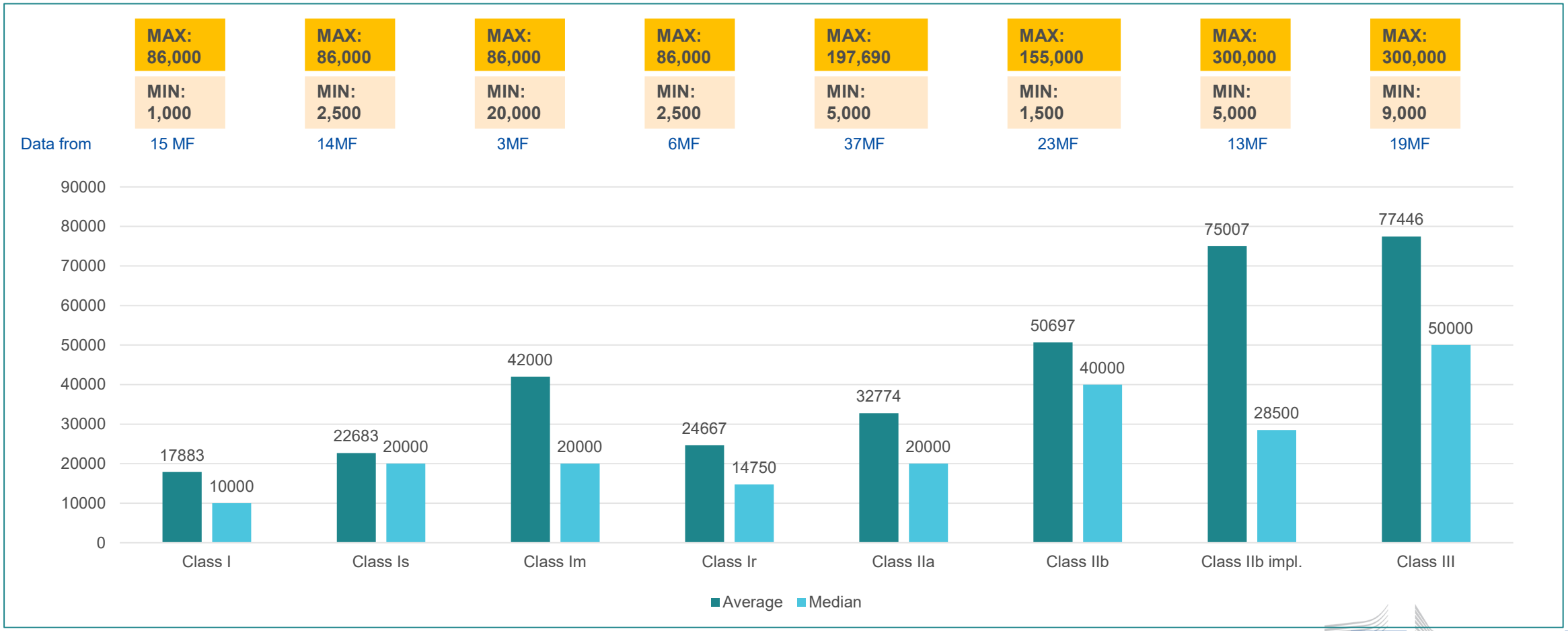
MD

Costs

MD

Costs for drawing up the clinical evaluation

Total cost in Euro of the last single device certified



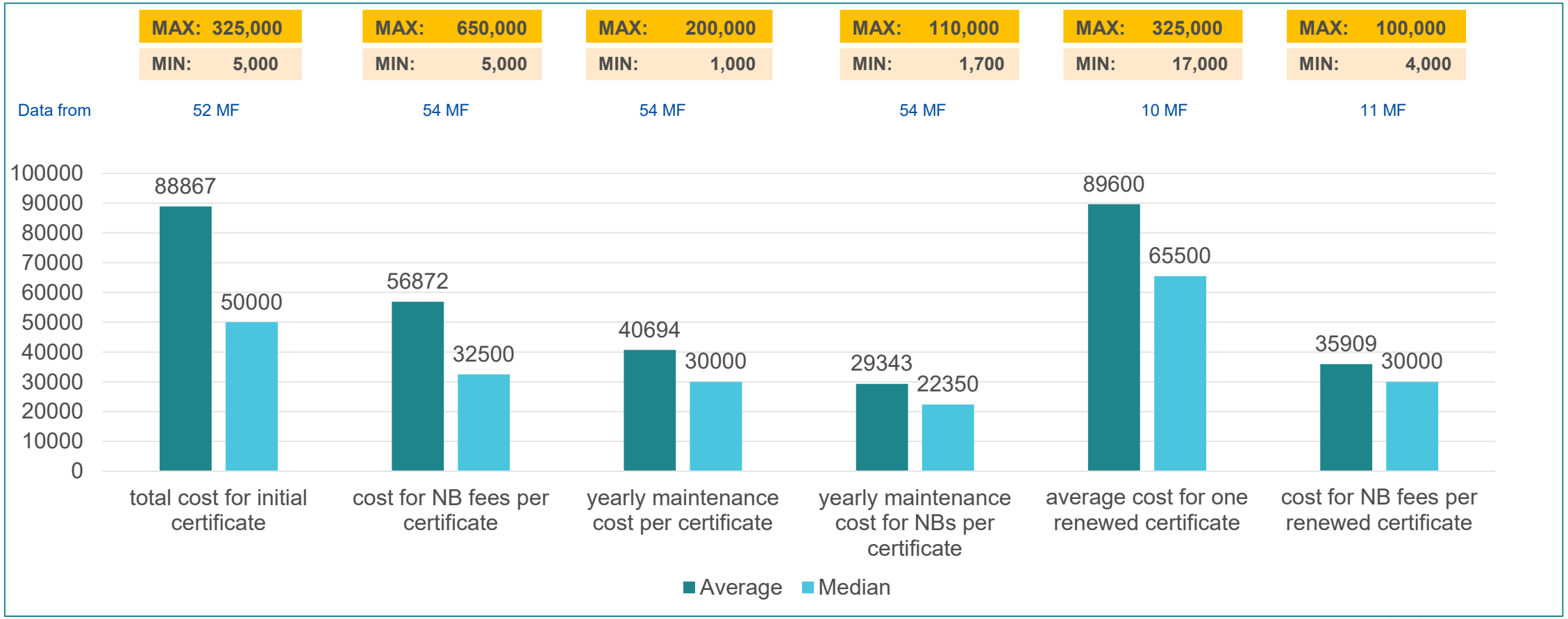
Notes: It is possible that MD MF have interpreted this question differently. Some MD MF provided ‚zero' as the questionnaire asked to do so, if no information is available. For this reason ‚zeros' are exluded (with the risk of overestimation). Outliers below 1000 Euros and above 1000000 were excluded.

European Commission

MD

Costs for MDR certification

Estimate direct average cost per already issued QMS certificate in Euro



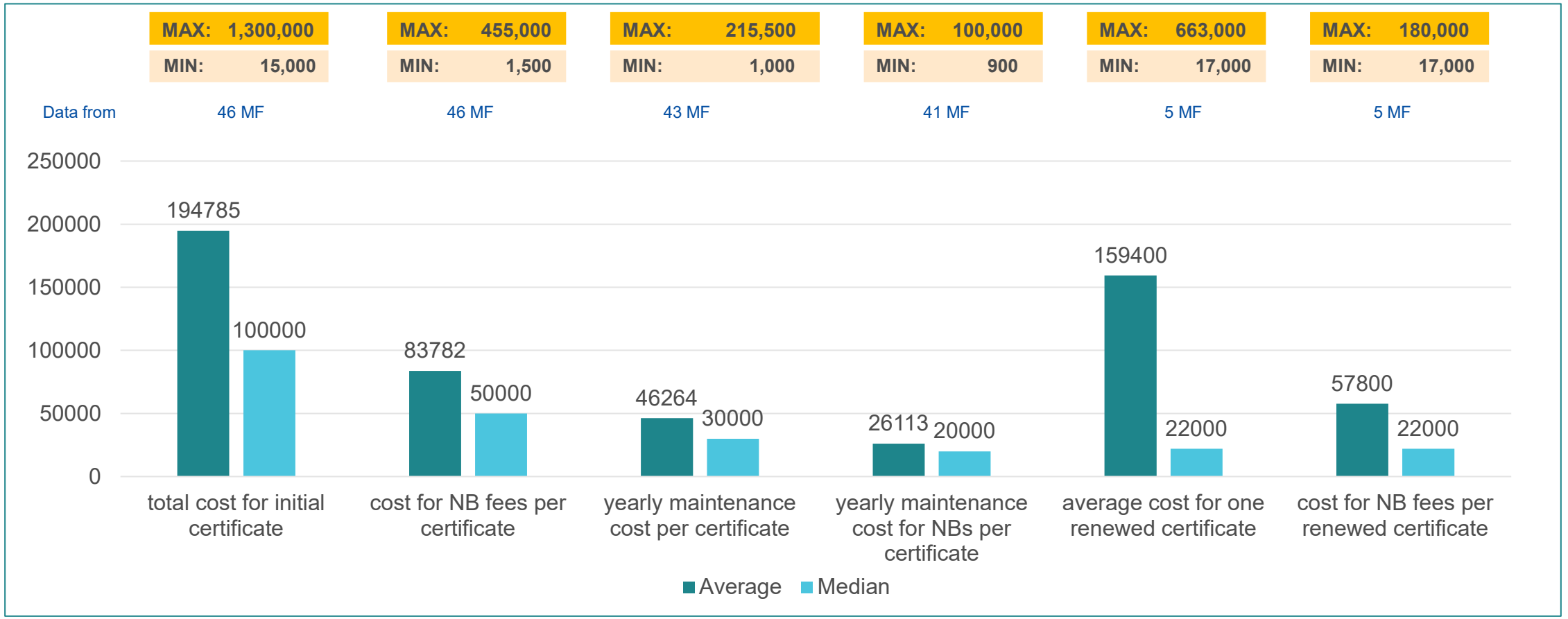
Notes: It is possible that MD MF have interpreted this question differently. Some MD MF provided ‚zero' as the questionnaire asked to do so, if no information is available. For this reason ‚zeros' are exluded (with the risk of overestimation). Outliers below 1000 Euros and above 1000000 were excluded.

European Commission

MD

Costs for MDR certification

Estimate direct average cost per already issued product certificate in Euro



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 exluded (with the risk of overestimation). Outliers below 900 Euros and above 10000000 were excluded.

European Commission

MD

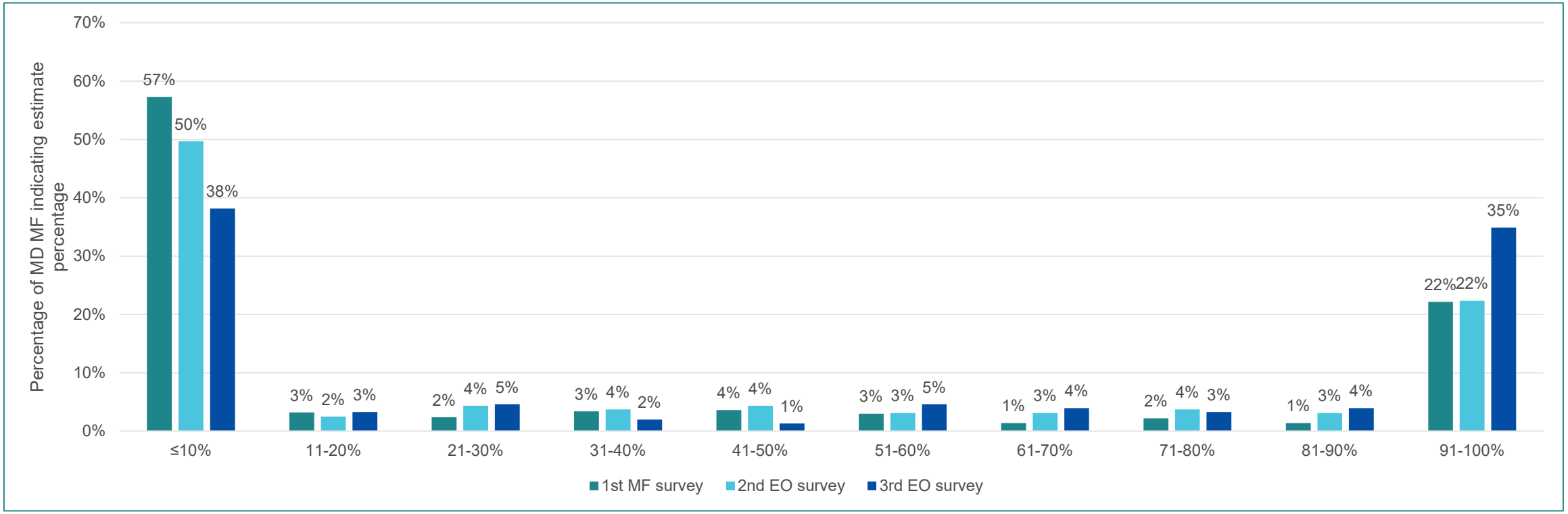
Estimates
Completed transition

MD

Completed transition

Total responses from 152 MFs for MDs

Estimate percentage of product portfolio foreseen for transition already having MDR certification (n=152)



European Commission

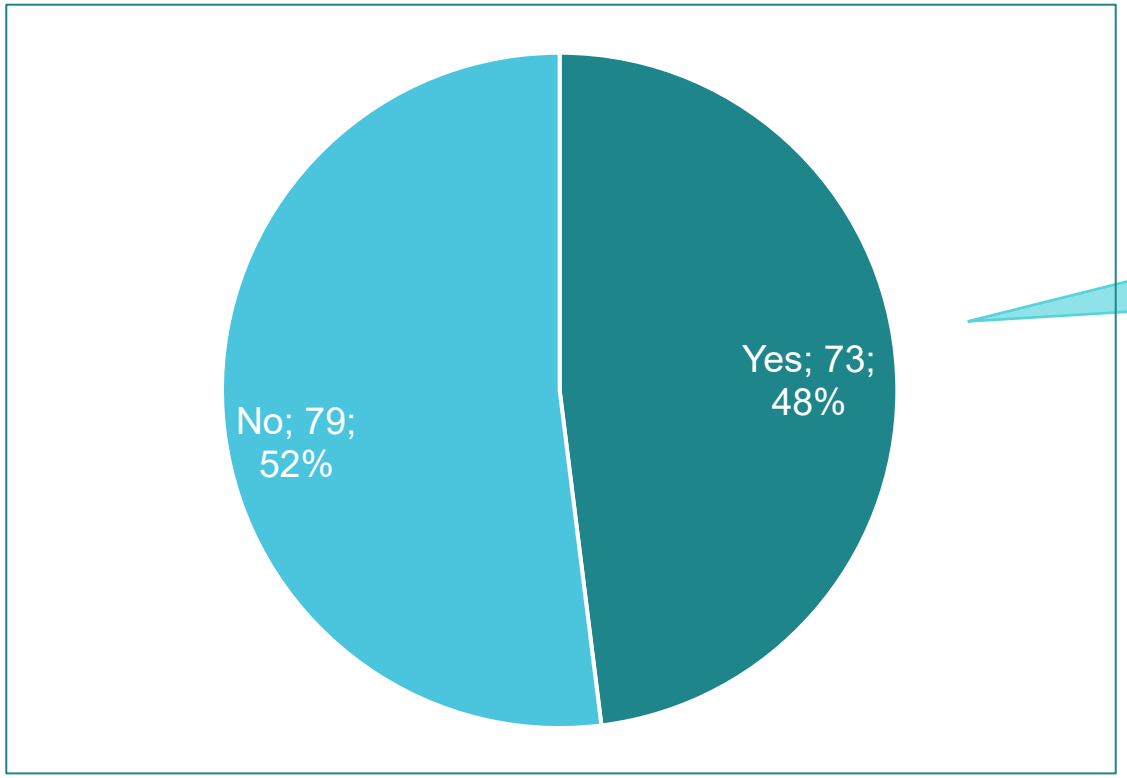
MD

Discontinuation of medical devices

MD

Discontinuation of medical devices (1)

Have you stopped the production/marketing/supply of some devices to the EU market since 2021? (n=152)



If yes, 7% of the MFs (5/73) indicated that orphan/niche devices* or orphan indications were affected.

*According to the MDCG 2024-10 document on clinical evaluation of orphan medical devices, a medical device or an accessory for a medical device should be regarded as 'orphan device', if it meets the following criteria: the device is specifically intended to benefit patients in the treatment, diagnosis, or prevention of a disease or condition that presents in not more than 12,000 individuals in the European Union per year; and at least one of the following criteria are met: there is insufficiency of available alternative options for the treatment, diagnosis, or prevention of this disease/condition, or the device will offer an option that will provide an expected clinical benefit compared to available alternatives or state of the art for the treatment, diagnosis, or prevention of this disease/condition, taking into account both device and patient population specific factors.

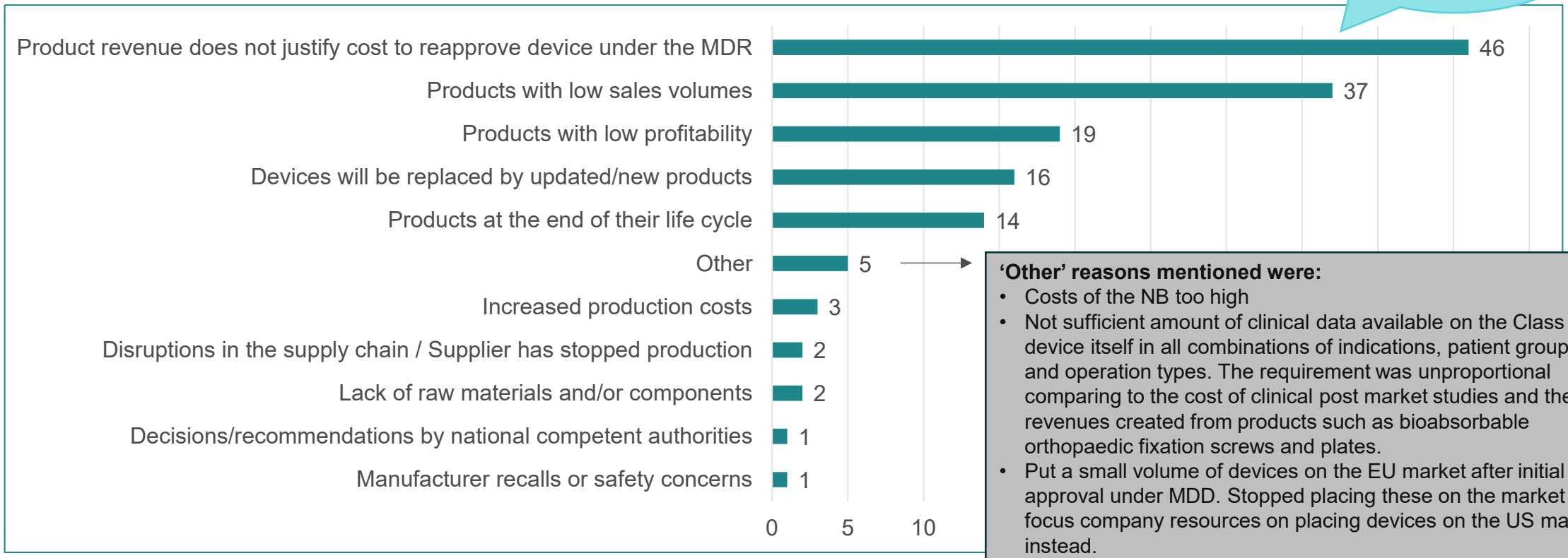
European Commission

MD

Discontinuation of medical devices (2)

63% of the MFs indicated this as one of the main reasons.

Main reasons for product discontinuation



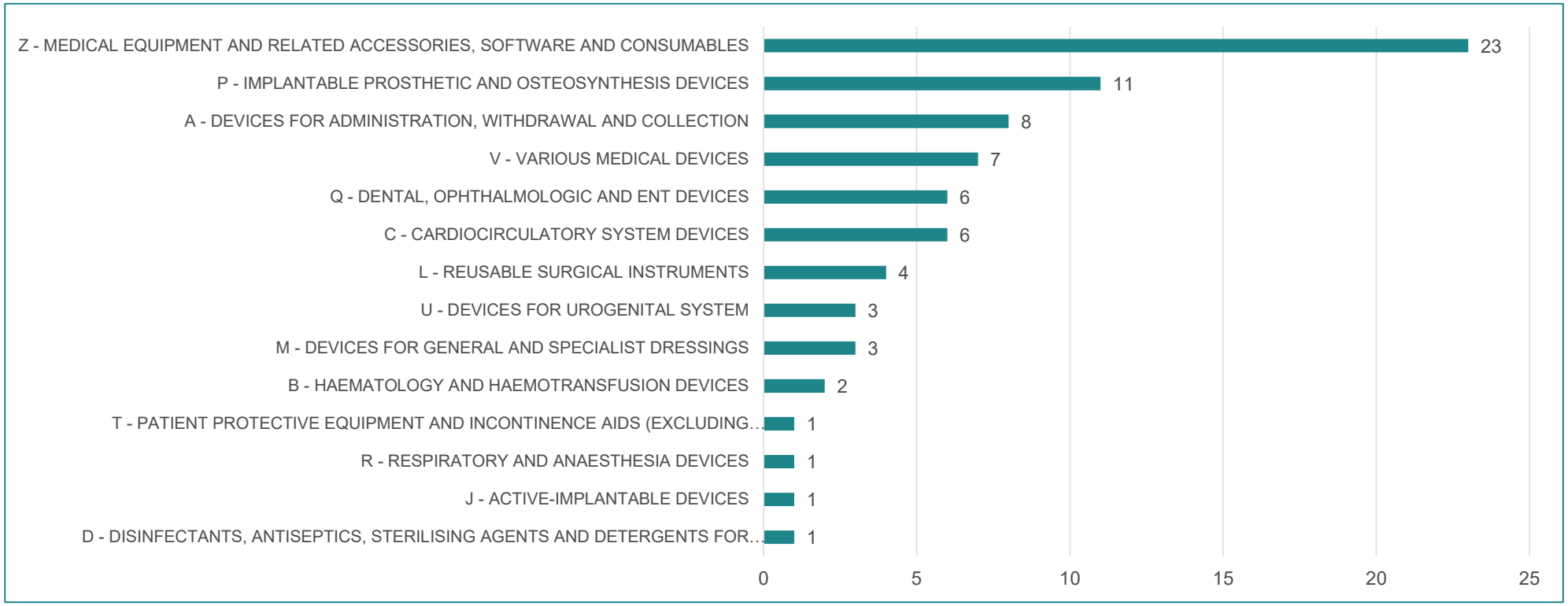
'Other' reasons mentioned were:

- Costs of the NB too high
- Not sufficient amount of clinical data available on the Class III device itself in all combinations of indications, patient groups and operation types. The requirement was unproportional comparing to the cost of clinical post market studies and the revenues created from products such as bioabsorbable orthopaedic fixation screws and plates.
- Put a small volume of devices on the EU market after initial approval under MDD. Stopped placing these on the market to focus company resources on placing devices on the US market instead.
- Up-classification to Class III because of new MDR classification rules

Notes: Number of mentions by 73 MFs having discontinued some products,
i.e. having answered question on previous slide with YES. Multiple answers per MF possible;

MD

Discontinuation of medical devices (3)



Types of MDs (by EDMN code) discontinued

Notes: Number of mentions by 73 MFs having discontinued some products, i.e. having answered question 30 with YES. Multiple answers per MF were possible.
Several answers had to be disregarded due to unclear EMDN code.
Category T: … (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT PPE)
Category D: …. FOR MEDICAL DEVICES

MD

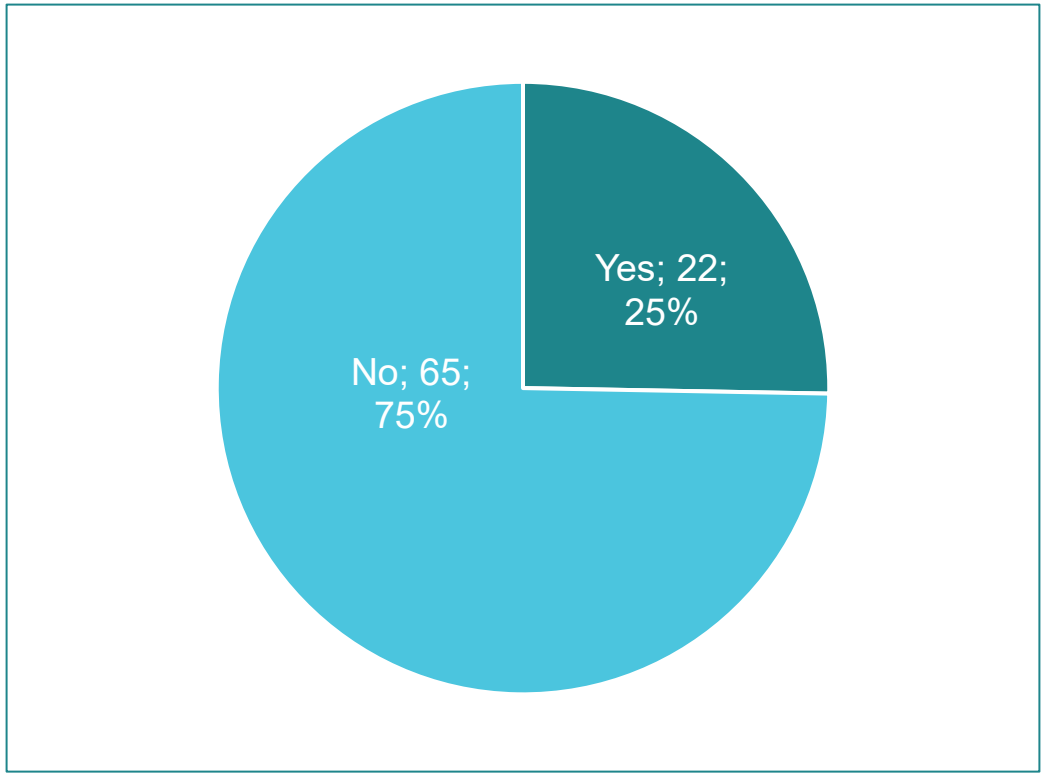
Re-certification

European Commission

MD

Re-certification (1)

Did you already have a certificate renewed under the MDR? (n=87) out of 152 companies that answered YES to Q16)

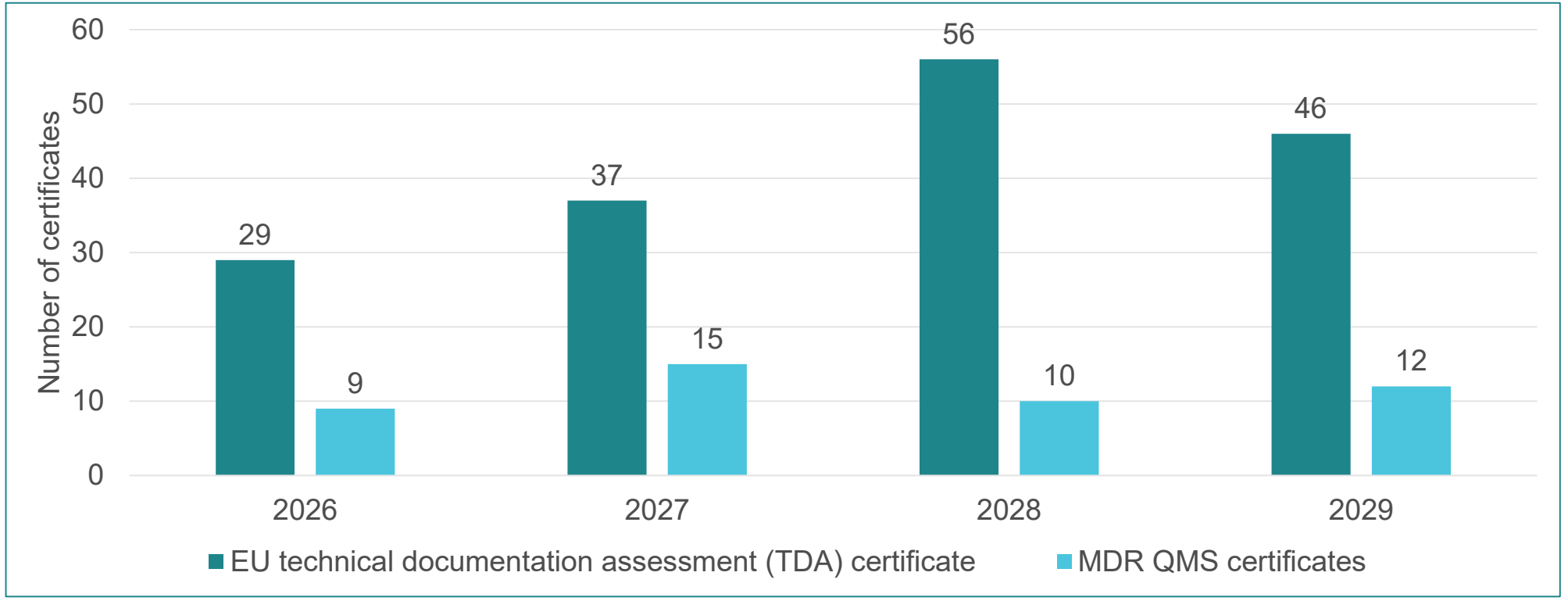


European Commission

MD

Re-certification (2)

Number of certificates expiring and due for re-certification in 2026-2029 (n=22 companies that answered YES to Q16.1)

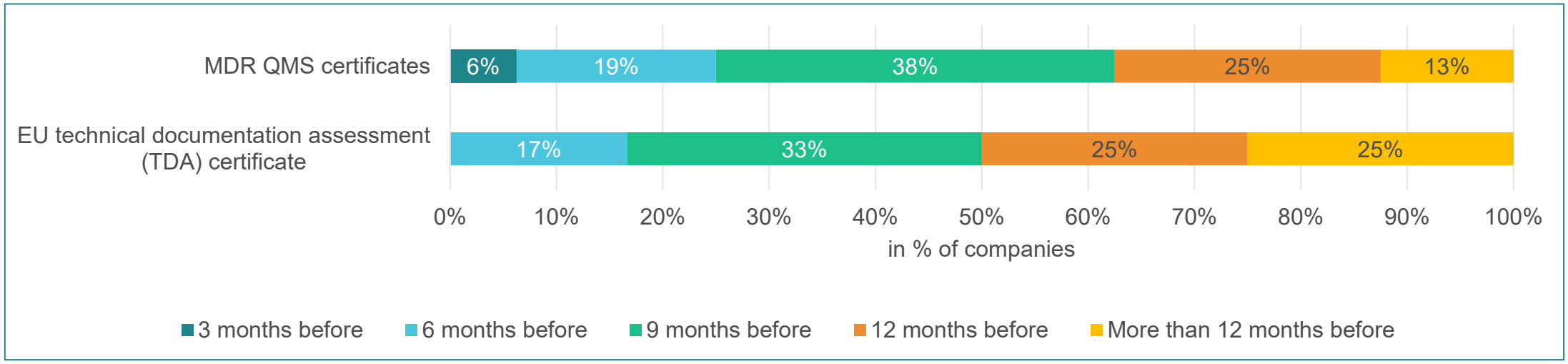


European Commission

MD

Re-certification (3)

On average, when do you need to submit the information for re-certification with the NB (before the certificate expires) to ensure you receive the renewal before expiration?

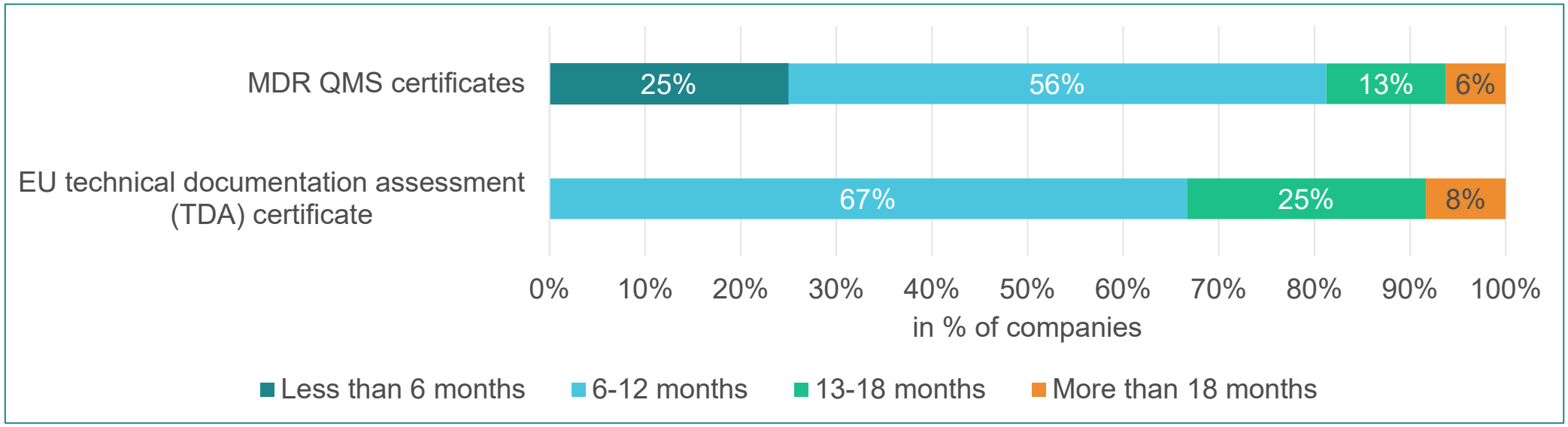


Note: Data of 22 MF

MD

Re-certification (4)

What is the average time taken to reach renewal of the certificate (from the submission to renewal)?



Note: Data of 22 MF ('no information available' was indicated by 10 MF for EU TDA certificates and by 6 for MDR QMS certificates)

IVD

2.3. Survey results for in vitro diagnostic medical devices

Questionnaire part 2.3. including questions 31 to 54

Q35
Q38

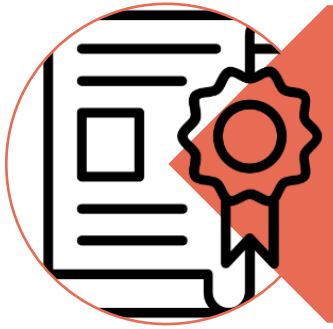
Overview on applications and certificates by end of October 2025

IVD

Number of applications lodged under IVDR: **1251***

18th NB survey
(covering the same data period as the 3rd EO survey until 31/10/2025):

3304
(MF sample: 38% were potentially covered in this survey)



Number of certificates issued for IVDs under IVDR: **357**

2192
(MF sample: 16% were potentially covered in this survey)

Note: These figures relate to the responses from 60 MFs of IVDs as of the end of October 2025.
No. of applications: Data of 31 IVD MF, 18 IVD MF with “0” applications.
No. of certificates: data of 24 IVD MF
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 might have a different interpretation as NBs.

European Commission

IVD

IVDD legacy devices*

* In line with MDCG 2022-8, ‘legacy devices’ should be understood as IVDs, which, in accordance with the IVDR’s transitional provisions, are placed on the market or put into service after the IVDR’s date of application (i.e. 26 May 2022) if certain conditions are fulfilled.

Q31
Q32

IVDD overview by the end of October 2025

IVD

Total responses from MFs for IVDs: 49

Total number of valid IVDD certificates by end of October 2025: **177**
(Data from 49 MFs, including 27 MFs with the indication '0')
(for comparison, value of the 2nd EO survey: 668 - Data from 60 MFs, including 23 MFs with the indication '0')

Notes:
* Data from 49 MFs, including 6 MFs with the indication '0';
** Data from 48 MFs, including 15 MFs with the indication '0';

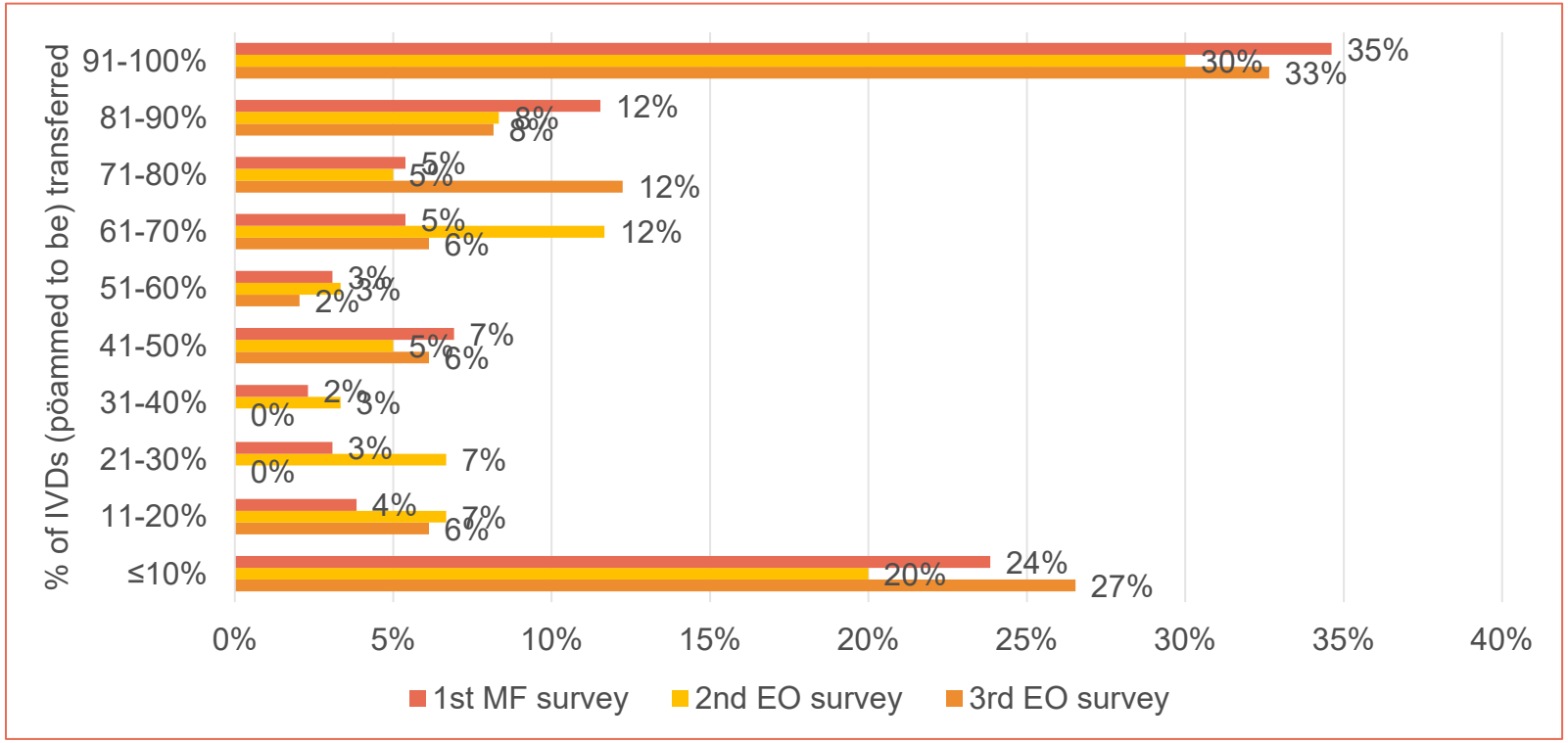
European Commission

Details on IVDD devices transition status to IVDR

IVD

Total responses from MFs for IVDs: 49

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



- 33% of the MFs of IVDs (16/49) indicated that 91-100% of IVDs have already been transferred to IVDR
- 30 MFs (61%) reported that more than 50% of their devices are already transferred or are planned to be transferred to IVDR
- 13 out of 49 MFs of IVDs (27%) indicated that ≤ 10% are already transferred to IVDR

Notes:
1st MF survey: Data from 130 MFs for IVDs
2nd EO survey: Data from 60 MFs for IVDs
3rd EO survey: Data from 49 MFs for IVDs

European Commission

IVD

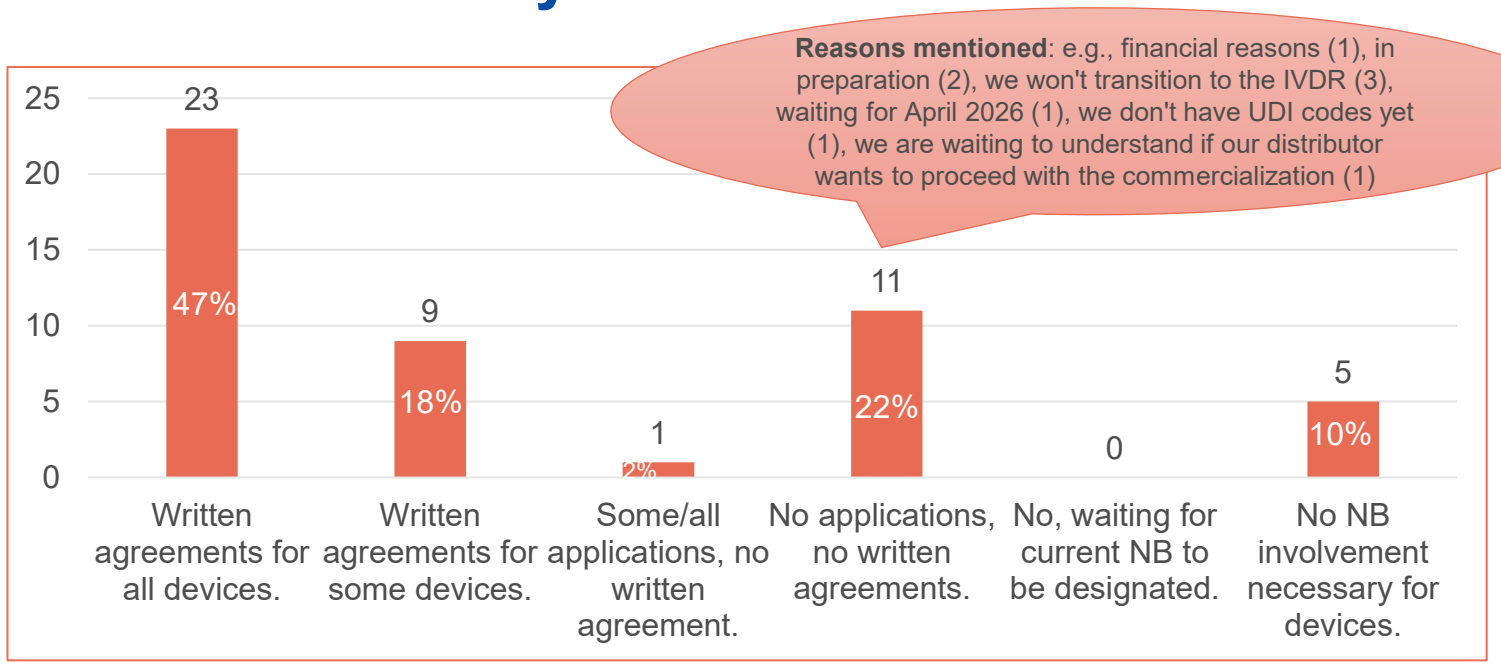
Notified bodies
written agreements, refused applications

Written agreements between MFs of IVDs with Notified Bodies

IVD

Total responses from MFs for IVDs: 49

Number of companies with written agreements with (a) NB(s) designated under the IVDR by the end of October 2025



Reasons mentioned: e.g., financial reasons (1), in preparation (2), we won't transition to the IVDR (3), waiting for April 2026 (1), we don't have UDI codes yet (1), we are waiting to understand if our distributor wants to proceed with the commercialization (1)

Data from 49 MFs

Only legacy devices: 15
Legacy and "new" devices: 15
Only new devices: 2

- **65% of the MF have (a) written agreement(s) with NBs** (2024: 62%, 2023: 48%)
- 22% of the MF that need a written agreement don't have one (2024: 37%, 2023: 42%)
- 10% of the MF don't need a NB involvement (2024: 2%, 2023: 10%)

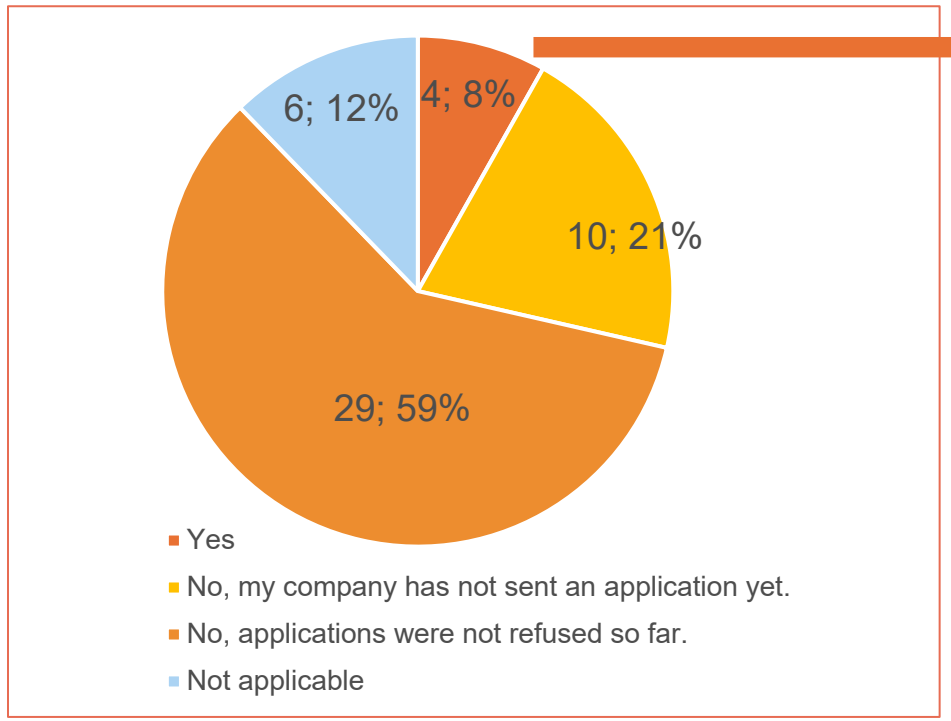
(in brackets the results of the 1st MF/AR survey and 2nd EO survey – replies of 130 and 60 MFs for IVDs respectively)

European Commission

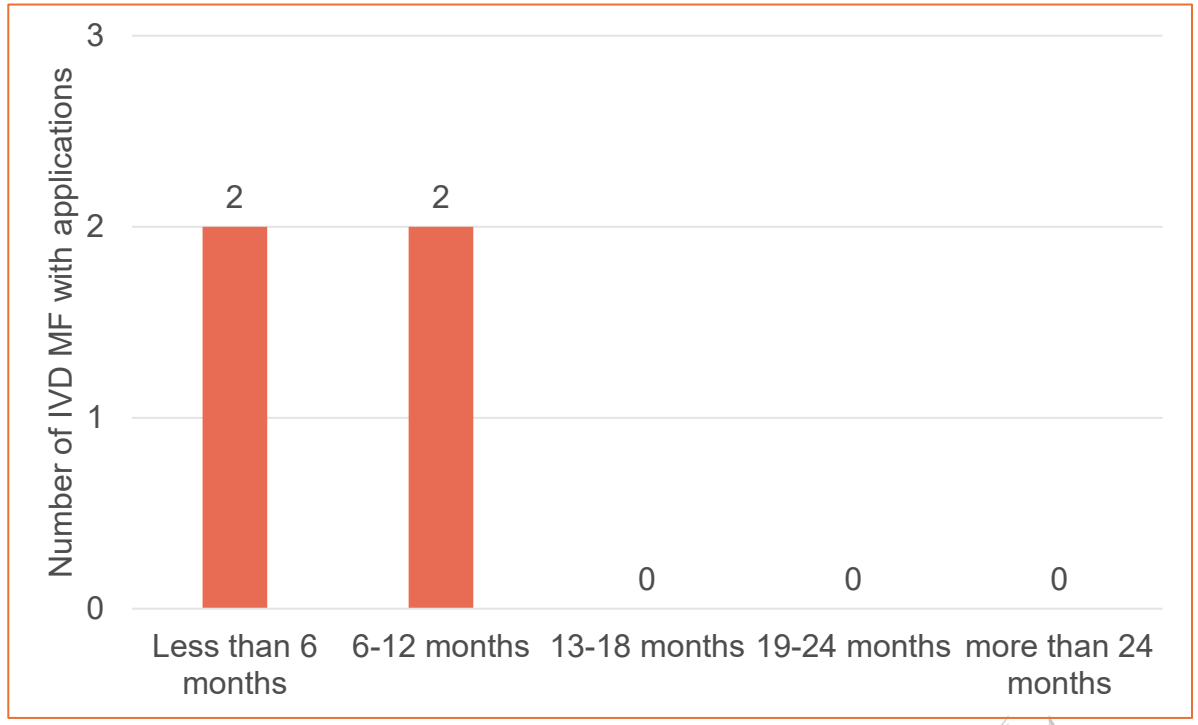
Refusal of applications by Notified Bodies (1)

IVD

Did a notified body refuse an application under the IVDR? (n=49)



Time from application to refusal (for IVD MF indicating 'Yes, application(s) refused.') (n=4)



European Commission

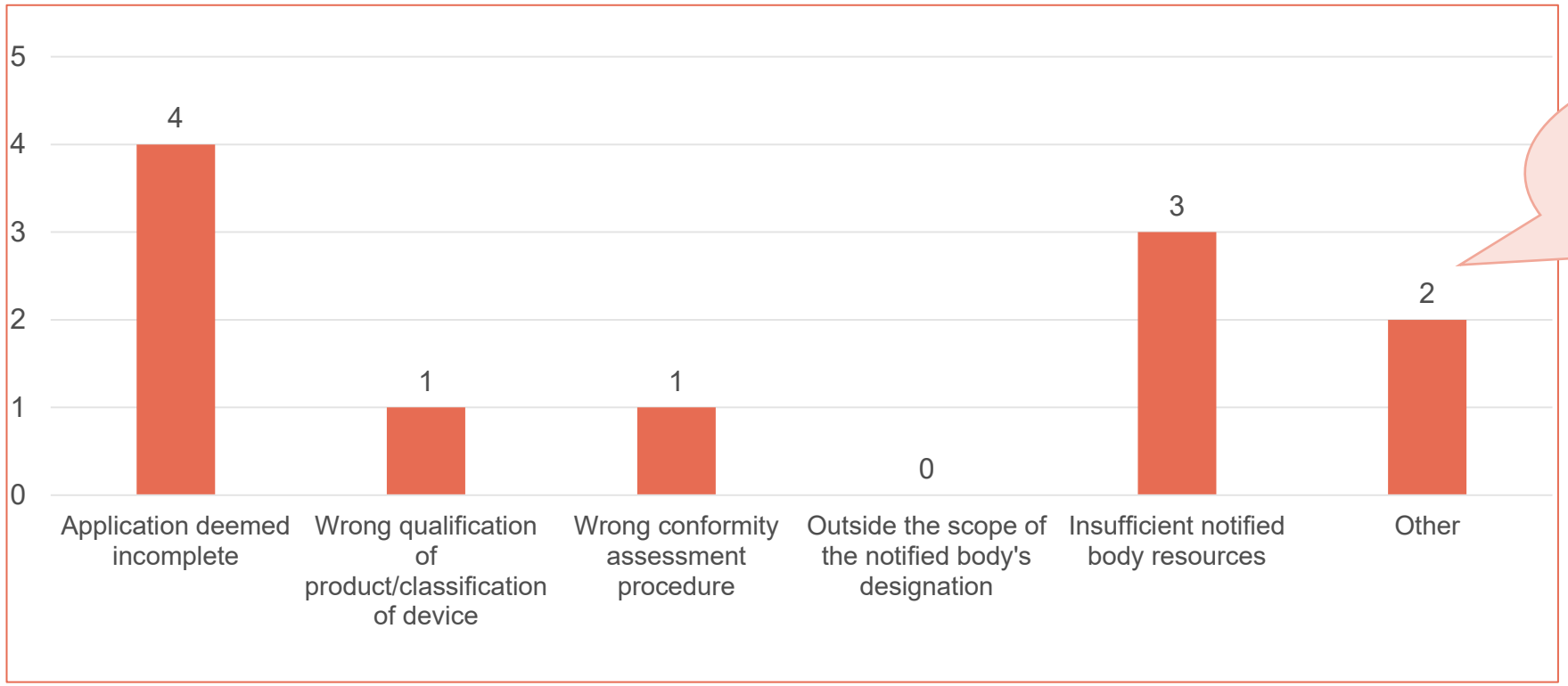
Refusal of applications by Notified Bodies (2)

IVD

Reasons for refusal (n=4 companies reporting 11 refused applications)

Refusals for:
- Legacy devices: 3
- New* devices: 2

*devices which have never been CE-marked but will need CE-marking under the MDR to access the EU market.



Other reason mentioned:
IFU not in accordance with NB's taste;
Not compliant with current state of the art per common specification

European Commission

IVD

IVDR implementation
applications, certificates, re-certification, time periods

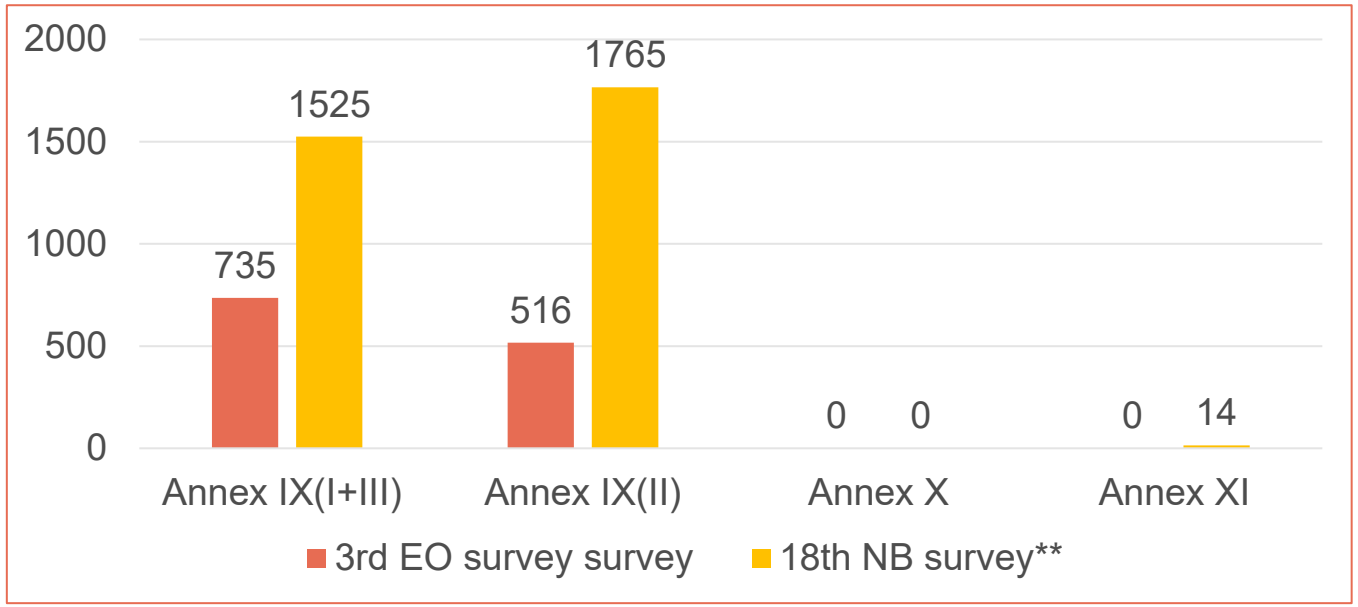
Applications lodged under IVDR by end October 2025

IVD

Total responses from MFs for IVDs: 49

Number of applications lodged (total and for changes) under IVDR to NBs by Annex

Note: This number also includes applications with issued certificates, ongoing applications and applications that were ultimately refused. Please note that applications lodged for changes to existing IVDR certificates are included as well and were asked to be indicated separately. Pre-application activities are not included. One application may cover several Annexes



- **Applications (all Annexes) for Class D devices:** 251
- **Applications (all Annexes) requiring consultation for companion diagnostics: 21**

** For comparison data of the 18th NB survey (covering the same data period until 31/10/2025): Total number of applications filed by Annex Ⅿ: 3.304

Total number of applications: 1251

(thereof 236 (19%) applications for change)

Notes: Data of 31 IVD MF, 18 IVD MF with "0" applications.

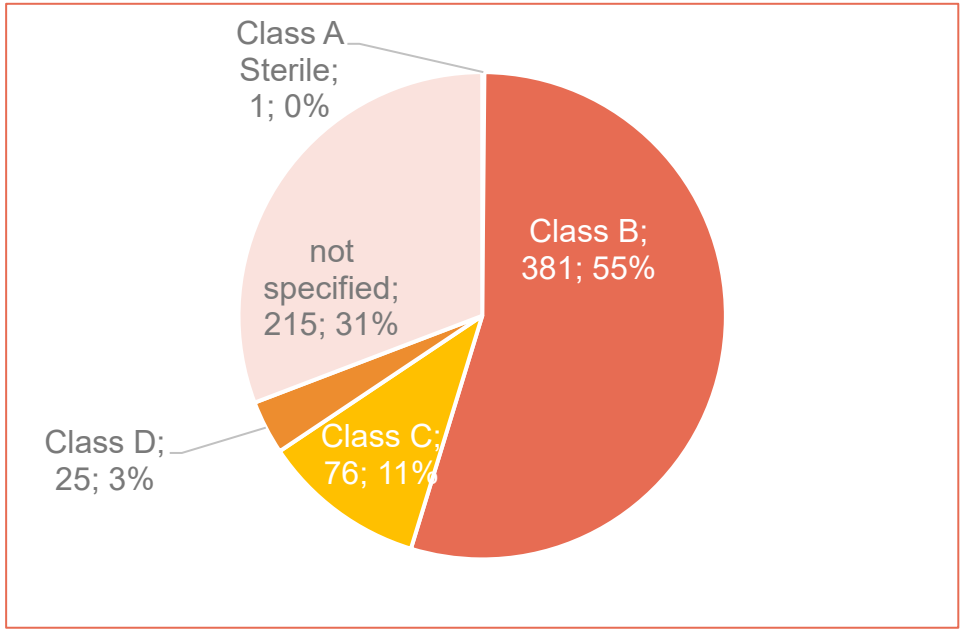
European Commission

IVDs undergoing IVDR conformity assessment by October 2025

IVD

Total number of devices (by catalogue number) undergoing IVDR conformity assessment (lodged IVDR applications still under review by NB) by end of October 2025: 689
(Data of 49 MFs, including 22 MFs with the indication ‘0’)

By risk class:



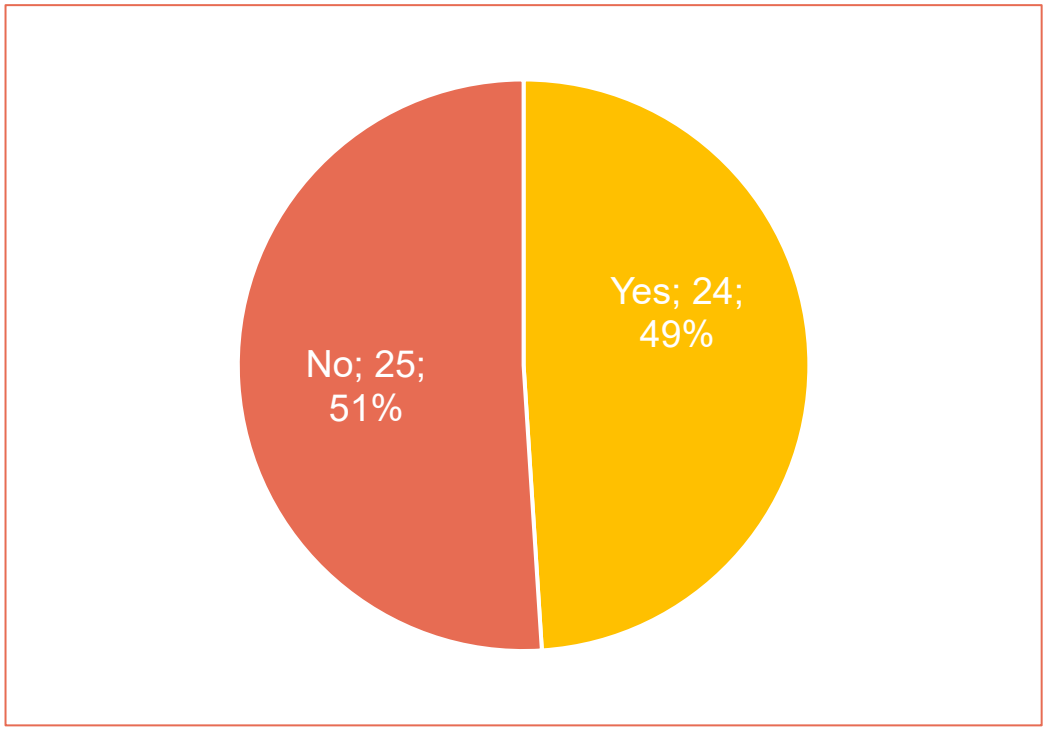
European Commission

IVD

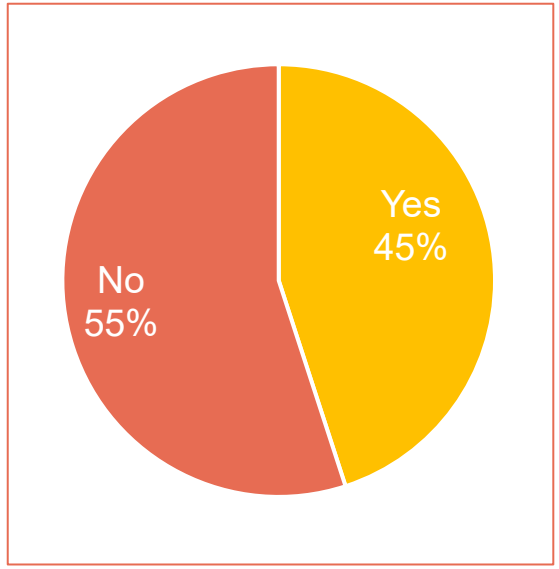
Certificates issued to IVD MF under IVDR

Total responses from 49 MFs for IVDs

Have you already received certificates under the IVDR to date up to 31/10/2025 (n=49)?



For comparison the results of the 2nd EO survey – replies of 60 MFs for IVD, 31/10/2024

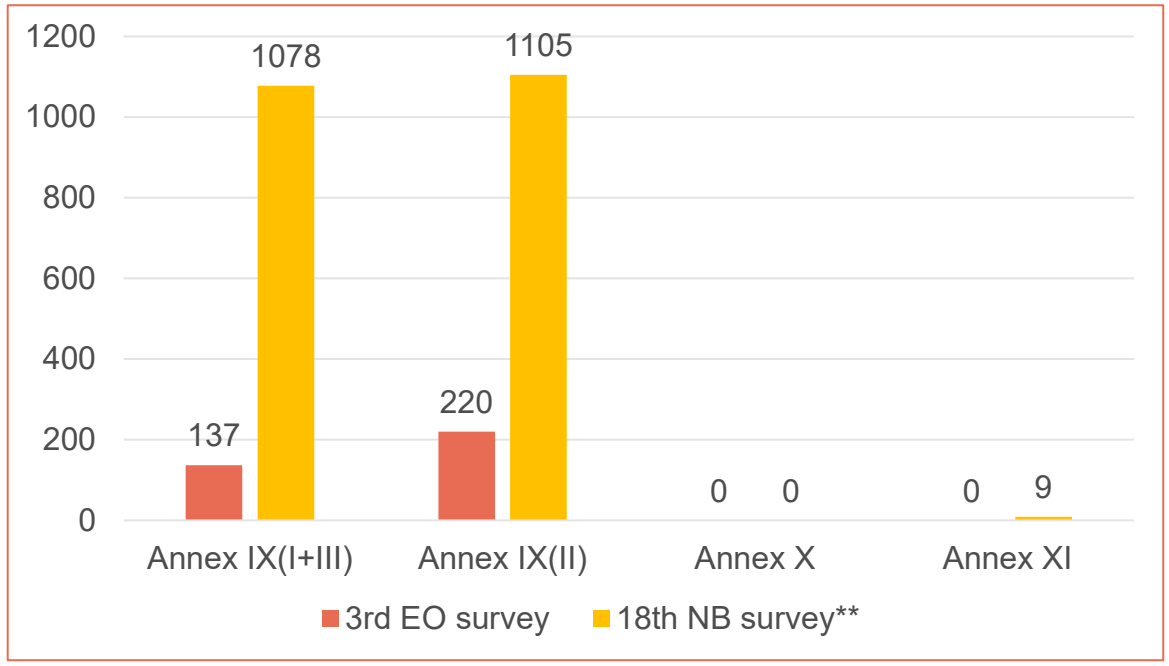


European Commission

IVD

Certificates issued to IVD MF under IVDR

Number of certificates issued to MF for IVDs under IVDR by Annex by end October 2025



Note: Replies from 24 IVD MFs

****For comparison data of the 18th NB survey (covering the same data period until 31/10/2025): 2192**

Disclaimer:
Please, note that the no. of certificates indicated by manufacturers is not directly comparable to the no. of certificates indicated by NBs since they might count differently. The study team has aggregated the data received from survey participants to prepare this presentation but cannot be held responsible for the quality and accuracy of the data.

Total number of certificates: 357

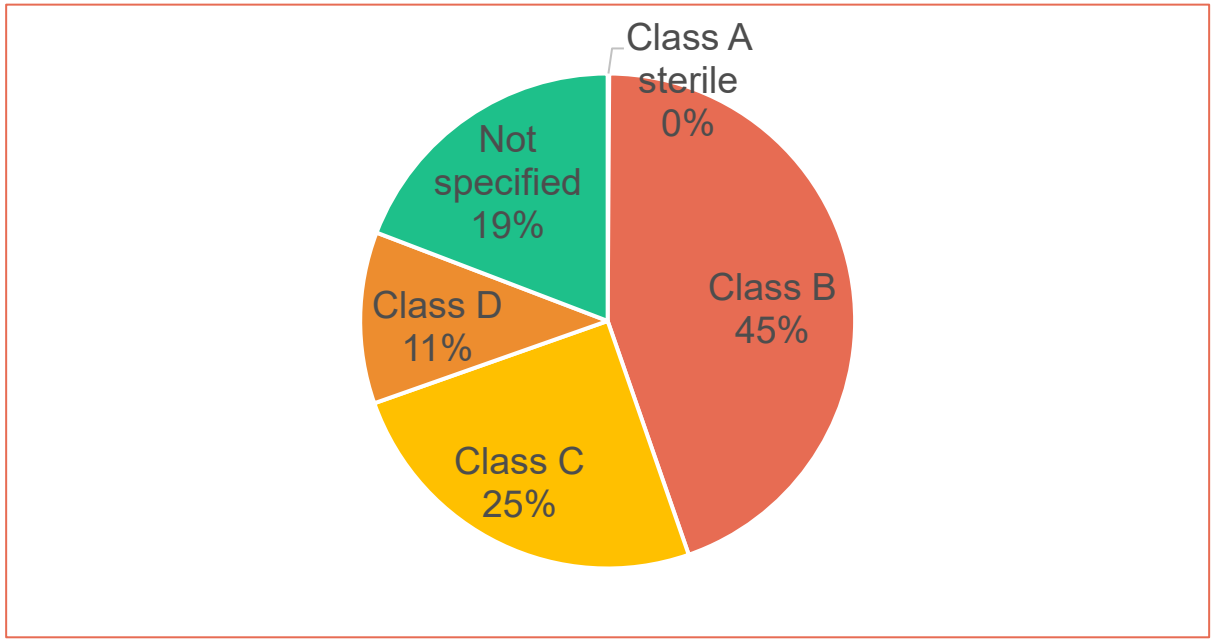
European Commission

Device numbers (as per catalogue number) covered in IVDR certificates

IVD

Number of devices (catalogue numbers) covered in IVDR certificates issued by end of October 2025:
3961

By risk class:



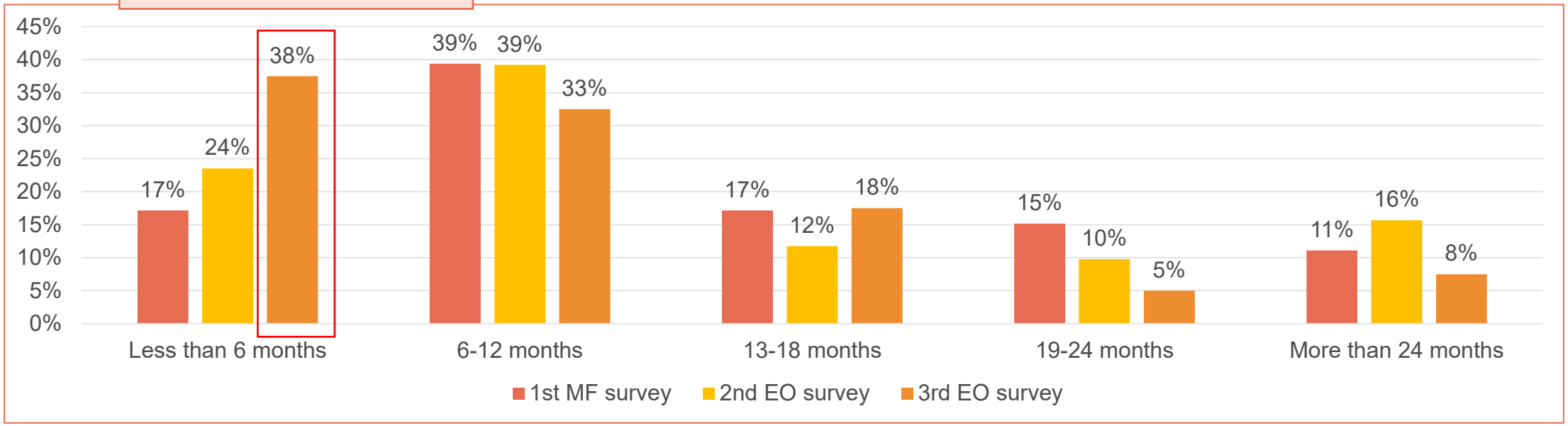
Note: Replies from 24 IVD MFs

IVD

Time periods (1)

Average time to prepare an application for IVDR (before submission to a NB) – *comparison of 3rd EO survey with previous surveys*

For 38% of the IVD MF it takes less than **6 months** to prepare an application for IVDR.



Notes:

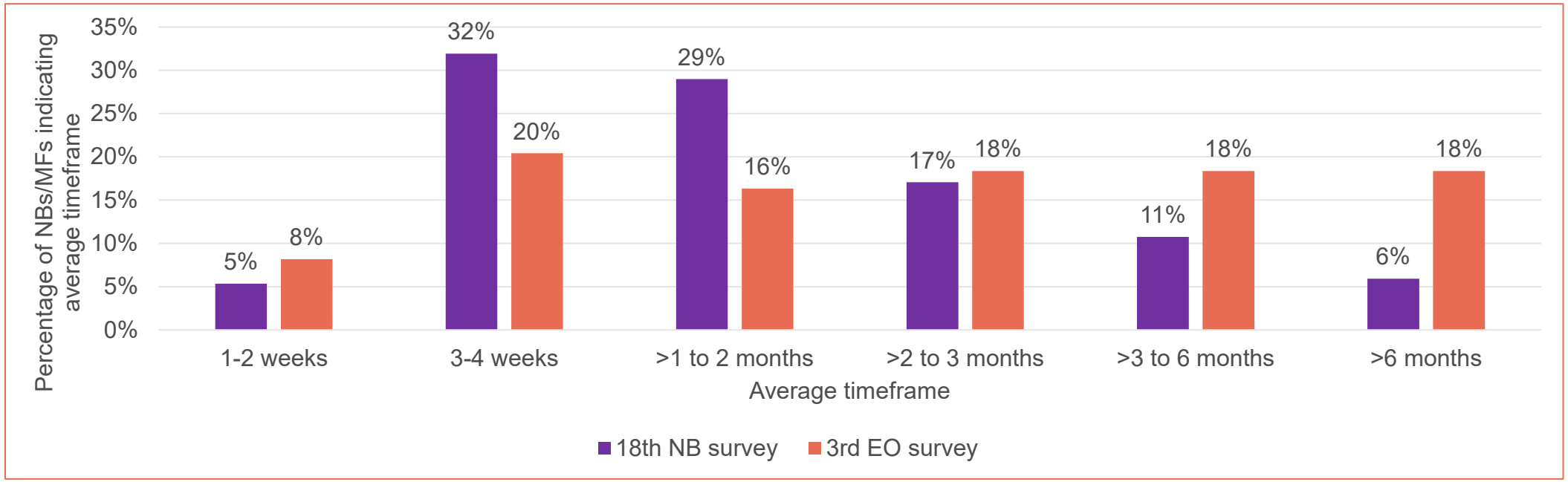
- **1st MF survey:** Replies of 99 IVD MFs, 31 MFs **indicated 'no information available'**
- **2nd EO survey:** Replies of 51 IVD MFs, 9 MFs indicated no information available'
- **3rd EO survey:** Replies of 49 IVD MFs, 9 MFs indicated no information available'

European Commission

IVD

Time periods (2)

Average timeframe between application lodged and written agreement signed – *comparison of 3rd EO survey with the 18th NB survey*



Notes:

- **18th NB survey:** Replies of 19 NBs designated under IVDR; data collection method: NBs indicated the number of files for each category which was converted into percent per category
- **3rd EO survey:** Replies of 49 IVD MFs; data collection method: EOs selected one time period

European Commission

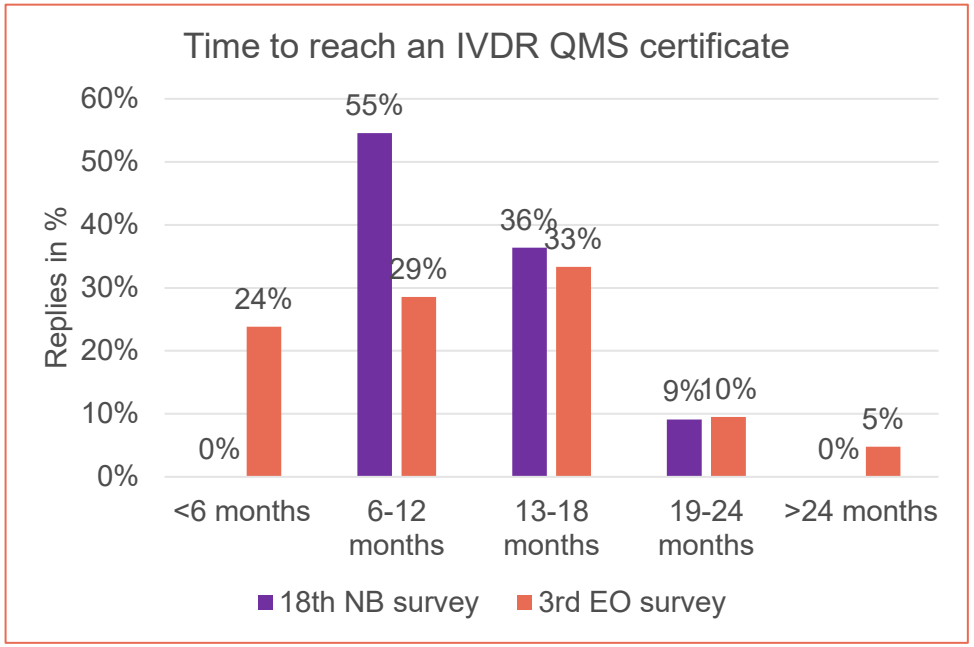
Time periods (3)

IVD

Average time to reach/issue IVDR certification for devices

(from written agreement signed to issuance) – *comparison of 3rd EO survey with the 18th NB survey*

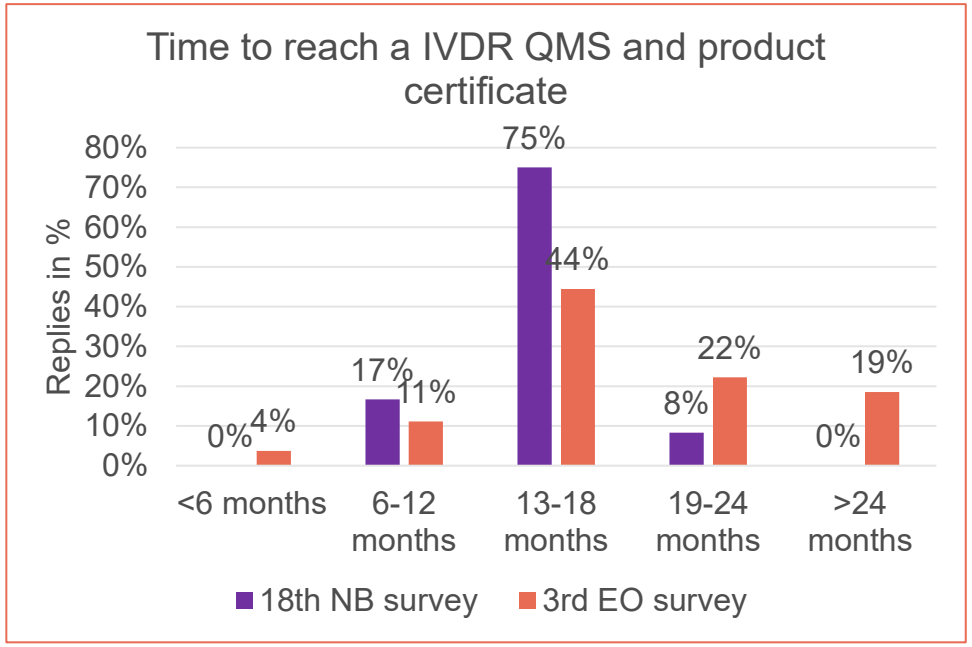
91% of the NBs indicated 6-18 months.
86% of the IVD MFs indicated less than 18 months.



Notes QMS certificates:

- **18th NB survey:** QMS: Data of 11 NBs designated under IVDR (covering the same data period until 31/10/2025)
- **3rd EO survey:** Data of 21 IVD MFs; 28 MFs indicated 'no information available'

92% of the NBs indicated 6-18 months.
59% of the IVD MFs indicated less than 18 months.



Notes QMS and product certificates:

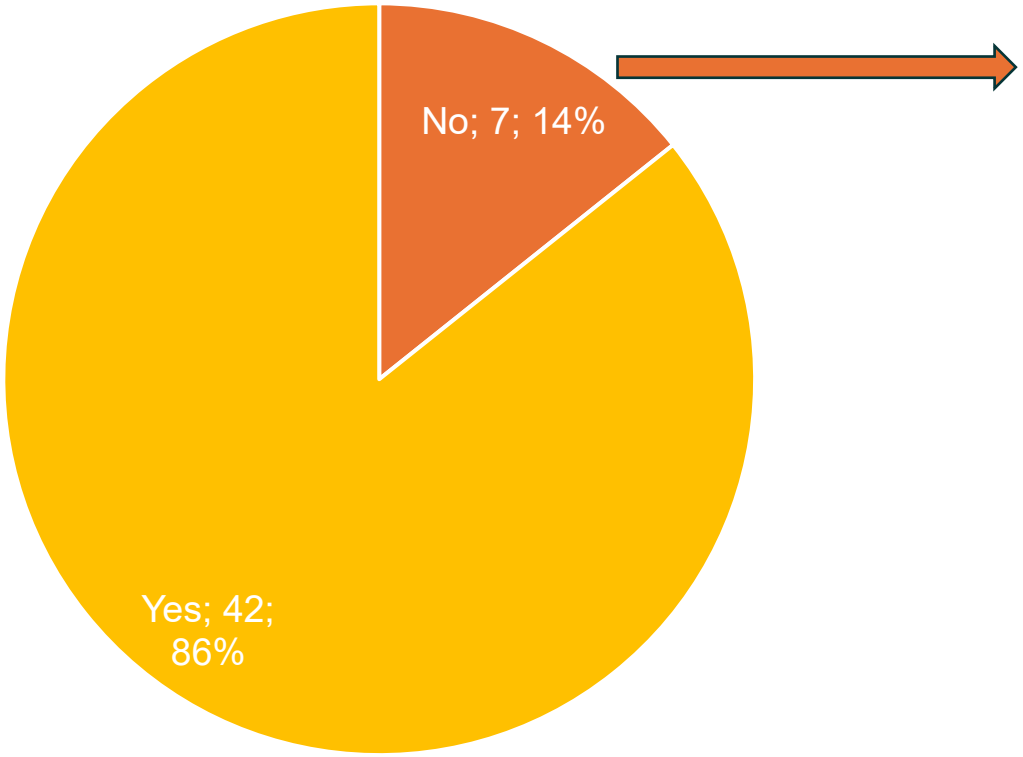
- **18th NB survey:** QMS: Data of 12 NBs designated under IVDR (covering the same data period until 31/10/2025)
- **3rd EO survey:** Data of 27 IVD MFs; 22 MFs indicated 'no information available'

European Commission

IVD

Compliance with deadlines

In general, do you comply with the deadlines agreed with your NB(s) for submitting data / information and subsequent further requests?



If not – e.g.:

- It takes too long even to confirm quickscan and then to apoint reviewer. (1)
- More time needed (1)
- Sometimes the number of inquires given in the first-round assessment was more than 50. It was impossible to reply and make adaptations in Technical Documentations for all the given inquires within 20 working days. (1)

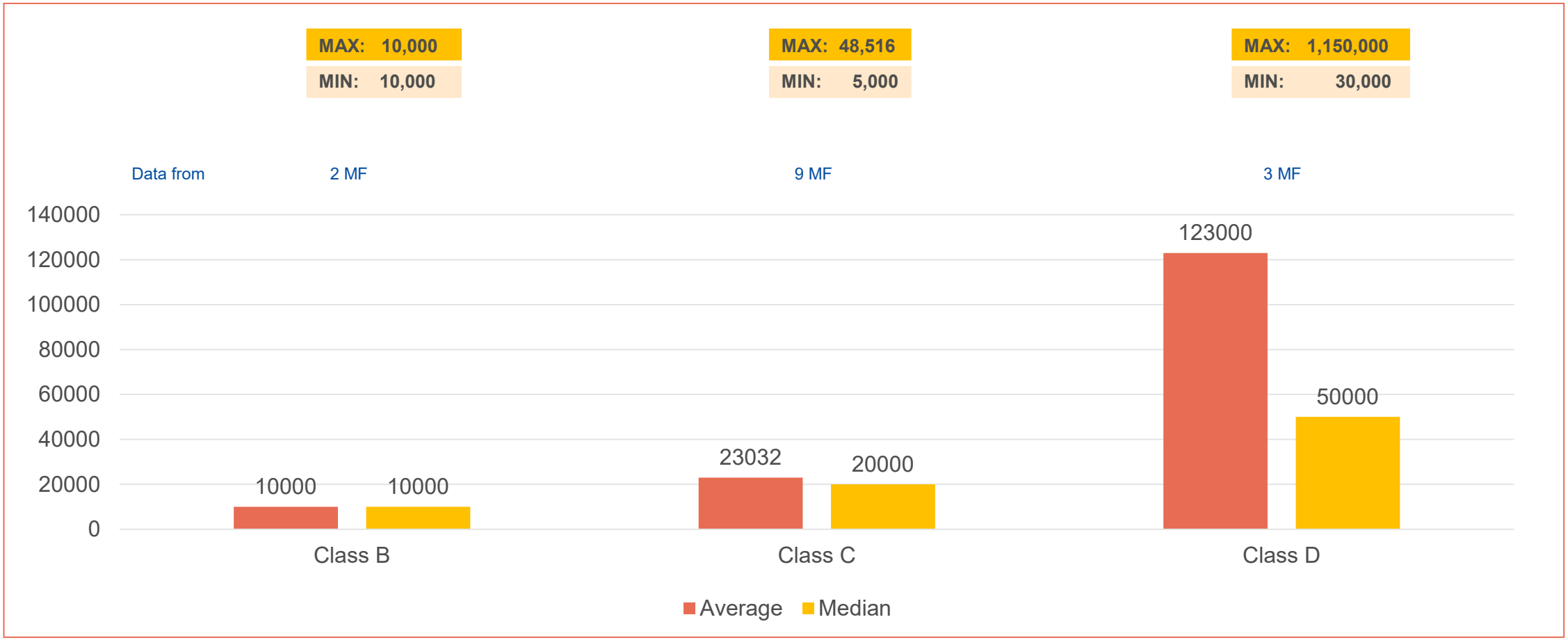
IVD

Costs

IVD

Costs for drawing up the clinical evaluation

Total cost in Euro of the last single device certified



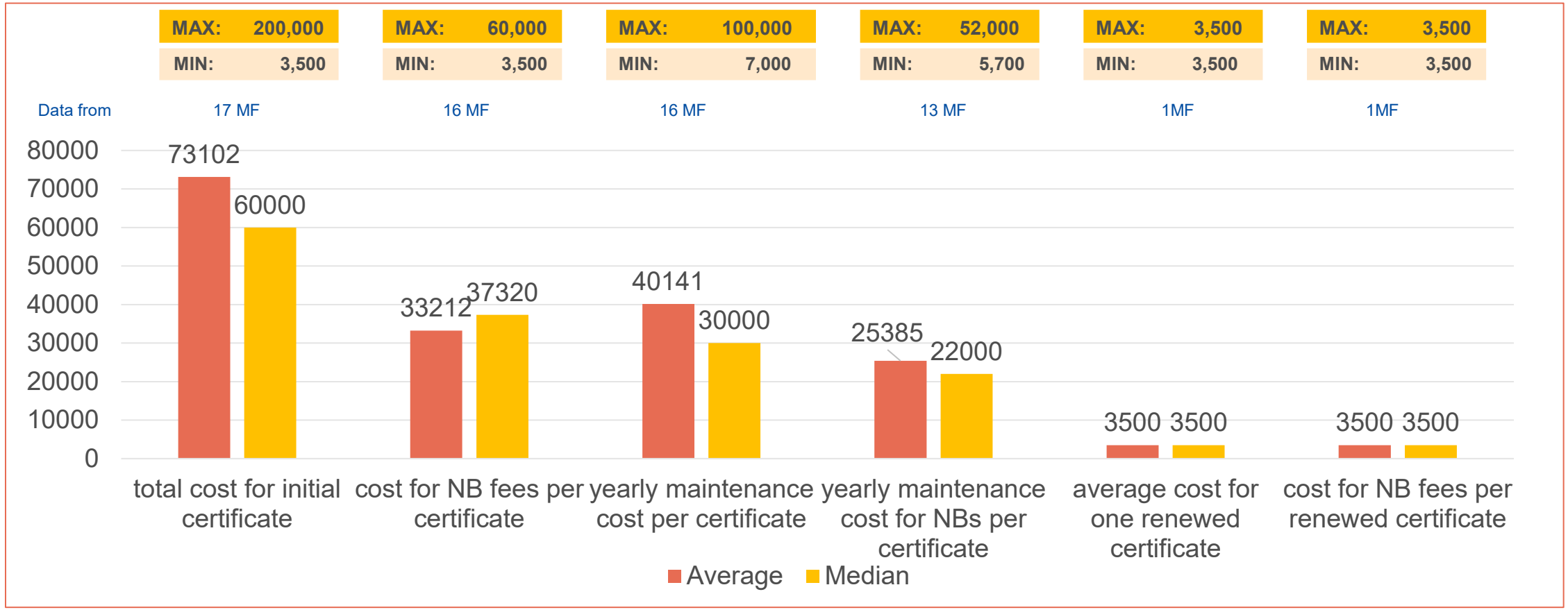
Notes: It is possible that IVD MF have interpreted this question differently. Some IVD MF provided ‚zero' as the questionnaire asked to do so, if no information is available. For this reason ‚zeros' are exluded (with the risk of overestimation). Outliers below 1000 Euros and above 1500000 were excluded.

European Commission

IVD

Costs for IVDR certification

Estimate direct average cost per already issued QMS certificate in Euro



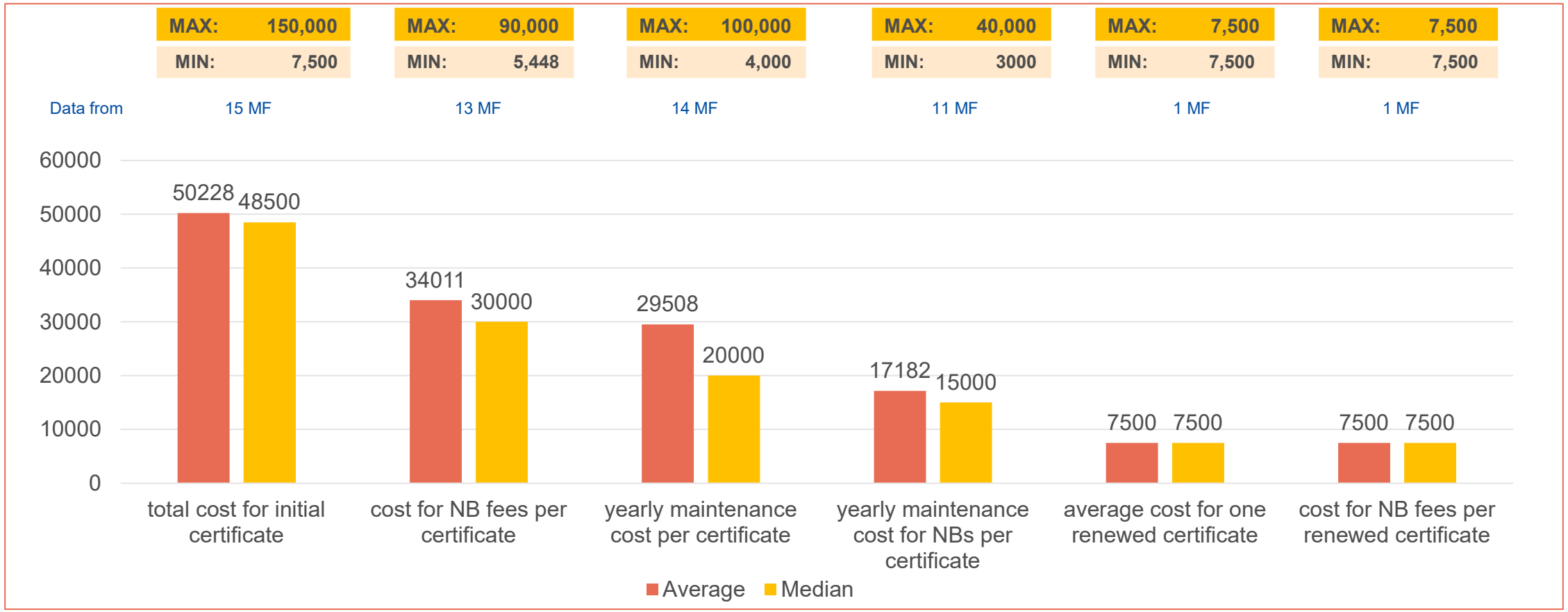
Notes: It is possible that MD MF have interpreted this question differently. Some MD MF provided ‚zero' as the questionnaire asked to do so, if no information is available. For this reason ‚zeros' are exluded (with the risk of overestimation). Outliers below 1000 Euros were excluded.

European Commission

IVD

Costs for IVDR certification

Estimate direct average cost per already issued product certificate in Euro



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 exluded (with the risk of overestimation). Outliers below 1000 Euros were excluded.

European Commission

IVD

Estimates

IVD

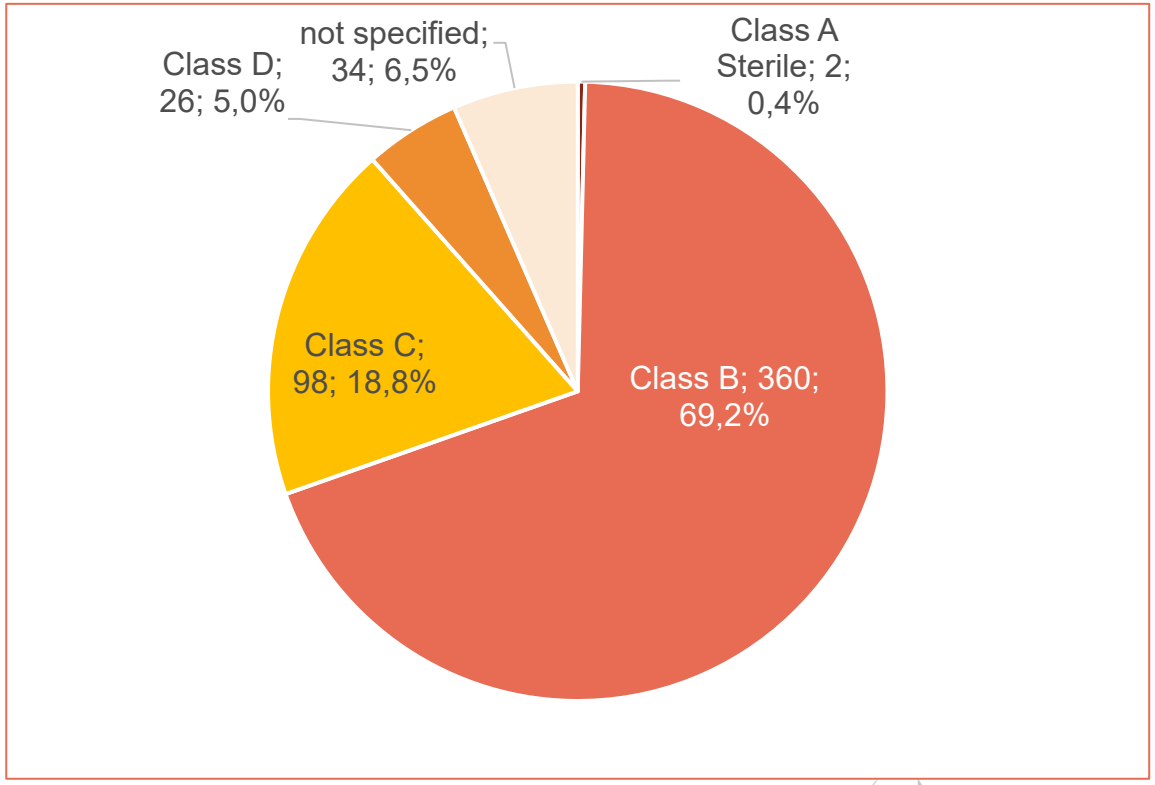
New devices

For how many new devices that were <u>not</u> in the IVDD portfolio do you plan to apply for a certificate under the IVDR?

520 new devices
(in total covering all risk classes)

Note: n=49 companies including 25 with the indication ‘0’

By risk class



European Commission

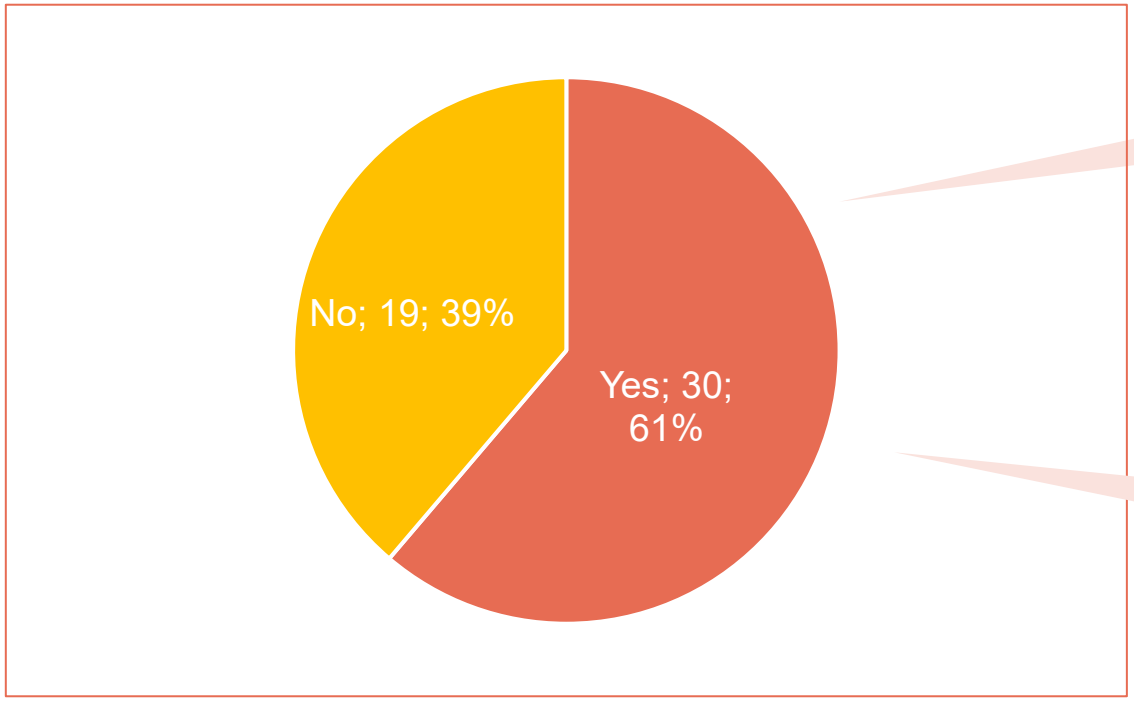
IVD

Discontinued in vitro diagnostic medical devices

IVD

Discontinuation of IVDs (1)

Have you stopped the production/marketing/supply of some IVDs to the EU market since 2022? (n=49)



If yes, were orphan/niche* devices affected?
0 MF said yes

*According to the MDCG 2024-10 document on clinical evaluation of orphan medical devices, a medical device or an accessory for a medical device should be regarded as 'orphan device', if it meets the following criteria: the device is specifically intended to benefit patients in the treatment, diagnosis, or prevention of a disease or condition that presents in not more than 12,000 individuals in the European Union per year; and at least one of the following criteria are met: there is insufficiency of available alternative options for the treatment, diagnosis, or prevention of this disease/condition, or the device will offer an option that will provide an expected clinical benefit compared to available alternatives or state of the art for the treatment, diagnosis, or prevention of this disease/condition, taking into account both device and patient population specific factors..

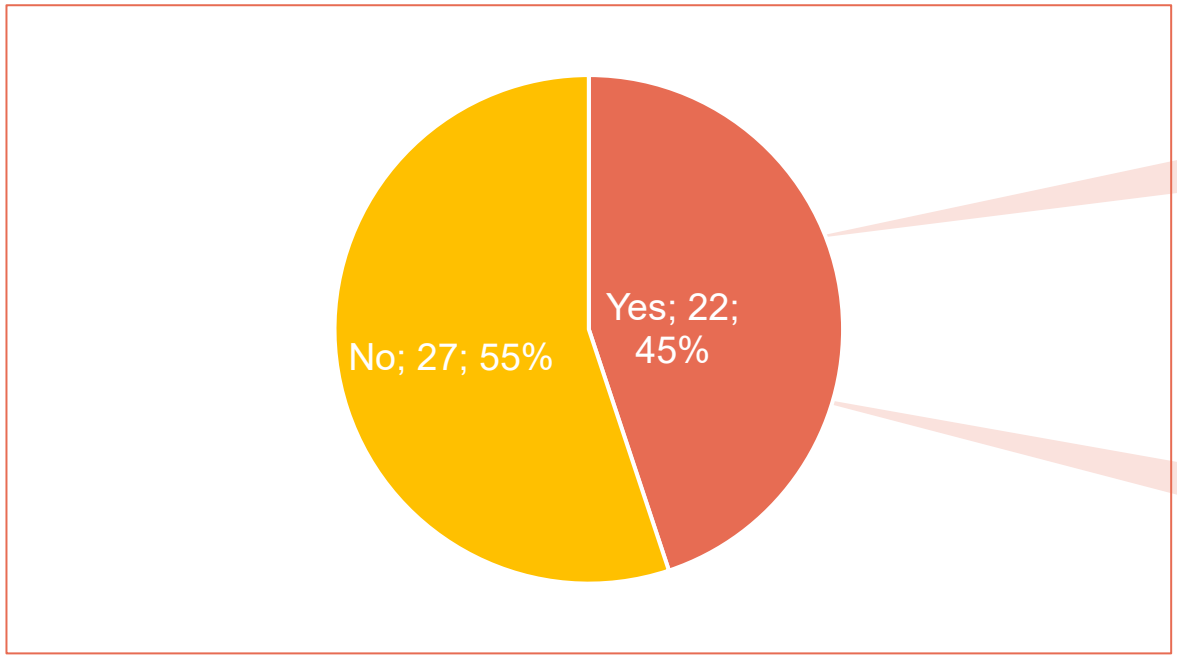
If yes, will Own Brand Labelled devices be affected?
9 MFs said yes
(= 30%; 9/30)

European Commission

IVD

Discontinuation of IVDs (2)

Do you plan to discontinue some IVDs on the EU market in the coming months? (n=49)



If yes, will orphan/niche devices be affected?
2 MFs said yes
(= 9%; 2/22)

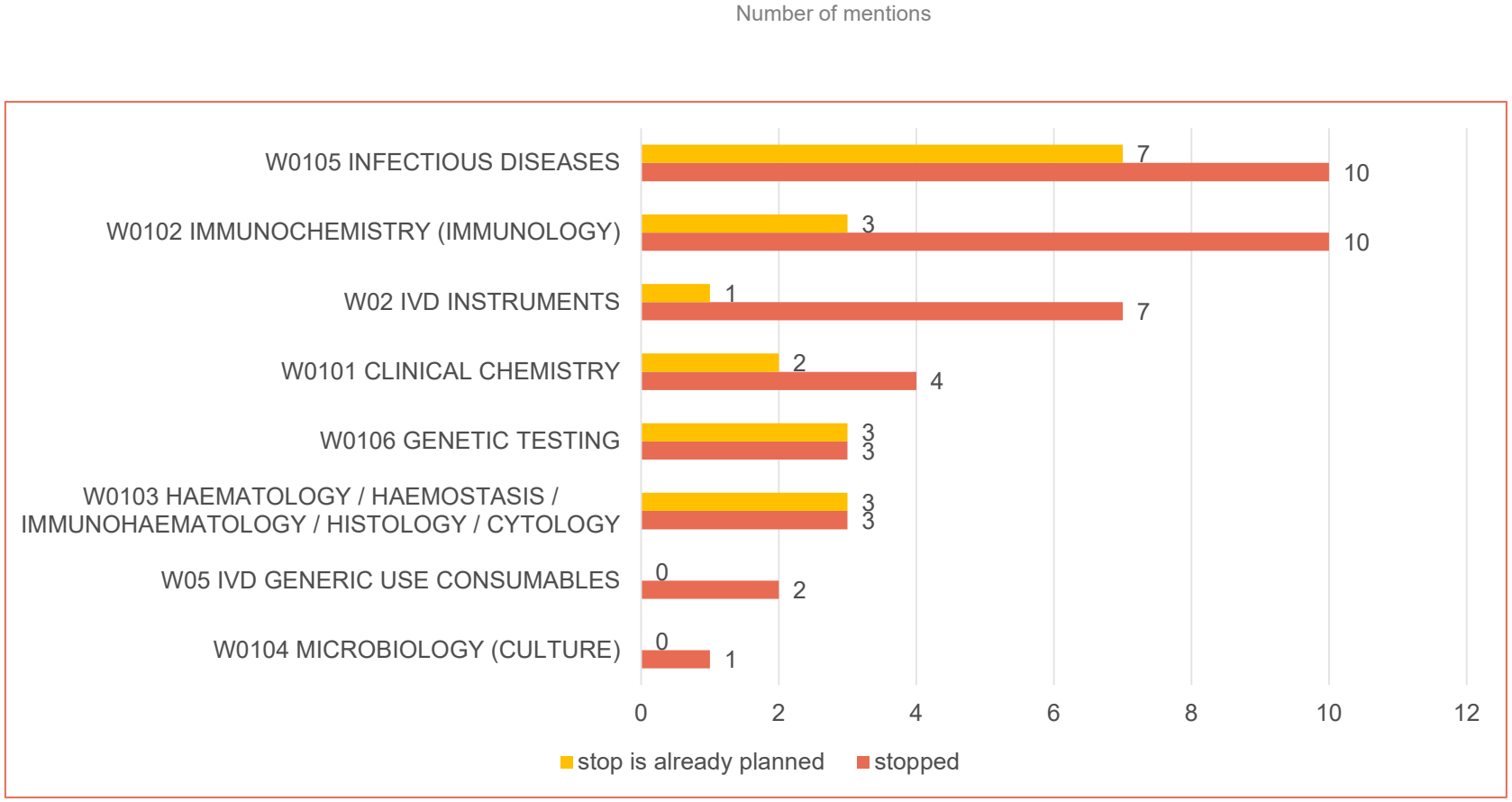
*According to the MDCG 2024-10 document on clinical evaluation of orphan medical devices, a medical device or an accessory for a medical device should be regarded as 'orphan device', if it meets the following criteria: the device is specifically intended to benefit patients in the treatment, diagnosis, or prevention of a disease or condition that presents in not more than 12,000 individuals in the European Union per year; and at least one of the following criteria are met: there is insufficiency of available alternative options for the treatment, diagnosis, or prevention of this disease/condition, or the device will offer an option that will provide an expected clinical benefit compared to available alternatives or state of the art for the treatment, diagnosis, or prevention of this disease/condition, taking into account both device and patient population specific factors.

If yes, will Own Brand Labelled devices be affected?
7 MFs said yes
(= 32%; 7/22)

Q51
Q52

IVD

Discontinuation of IVDs (3)



Types of IVDs (by EDMN code) stopped or for which "stop is already planned"

Notes: 30 MFs indicated the EMDN codes for the discontinued IVDs; 22 MF indicated the EMDN codes for the IVDs planned to be discontinued

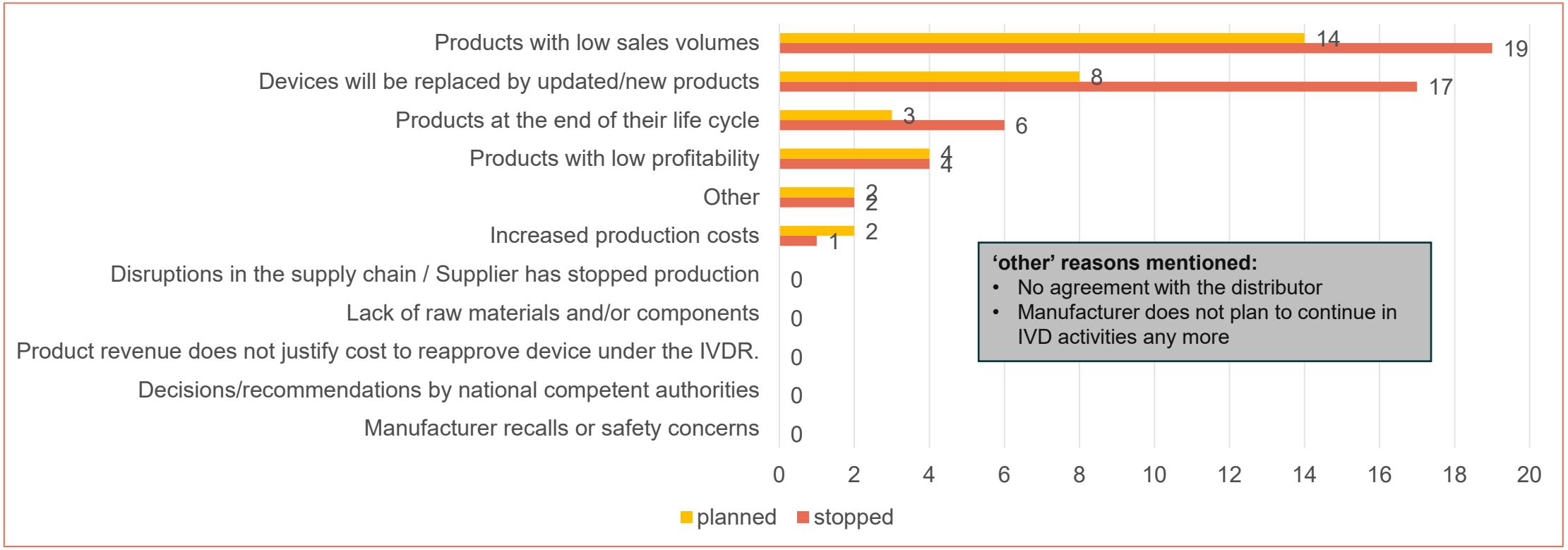
European Commission

Q64
Q63

IVD

Discontinuation of IVDs (4)

Reasons for MF having stopped or planning to stop production/marketing/supply of some IVDs to the EU market



Notes: Number of mentions; Multiple answers per MF possible; 30 MFs having stopped and 22 MF planning to stop participated in this survey question.

European Commission

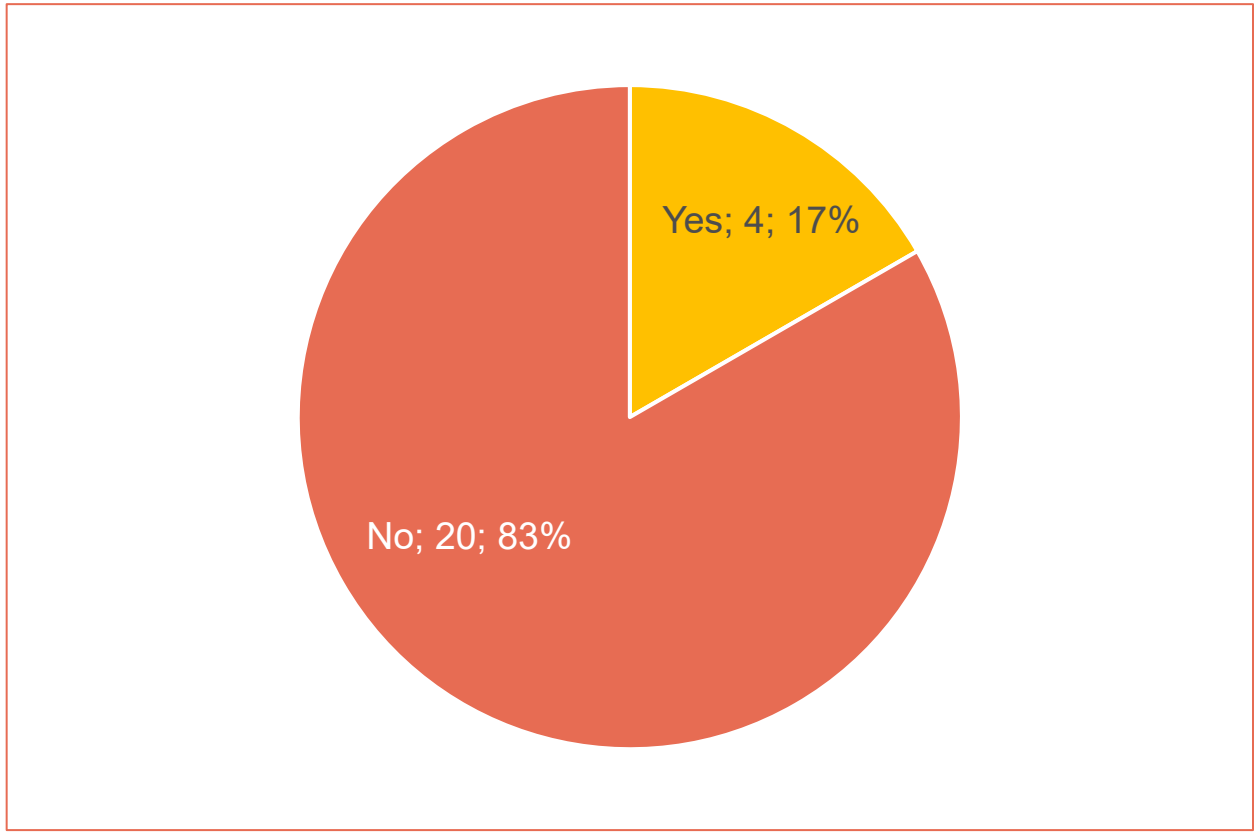
IVD

Re-certification

IVD

Re-certification (1)

Did you already have a certificate renewed under the IVDR? (n=24 out of 49 companies that answered YES to Q37)

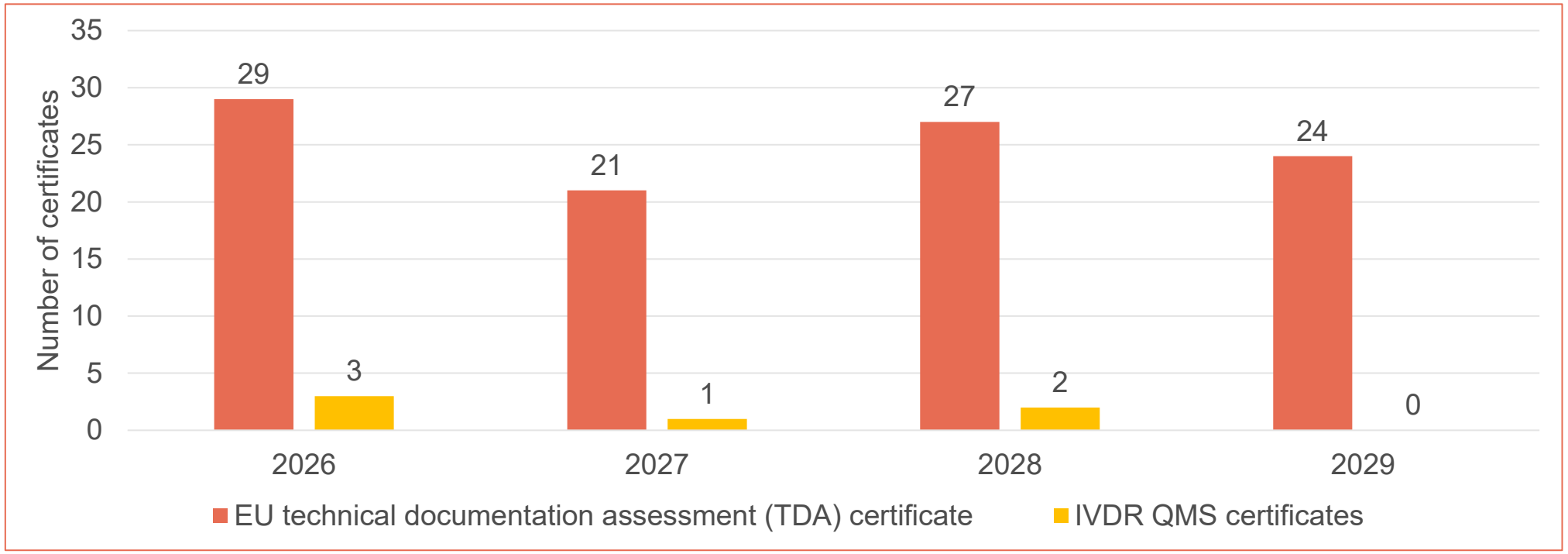


European Commission

IVD

Re-certification (2)

Number of certificates expiring and due for re-certification in 2026-2029 (n=24 out of 49 companies that answered YES to Q37)



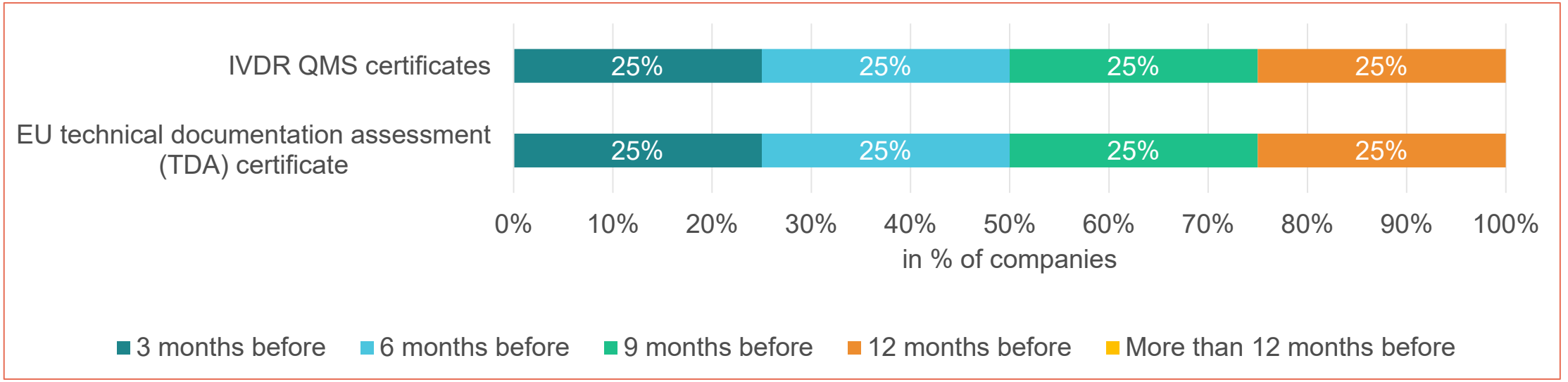
Note: Data of 4 MF

European Commission

IVD

Re-certification (3)

On average, when do you need to submit the information for re-certification to the NB (before the expiration of the certificate) to assure you receive the renewal before expiration?

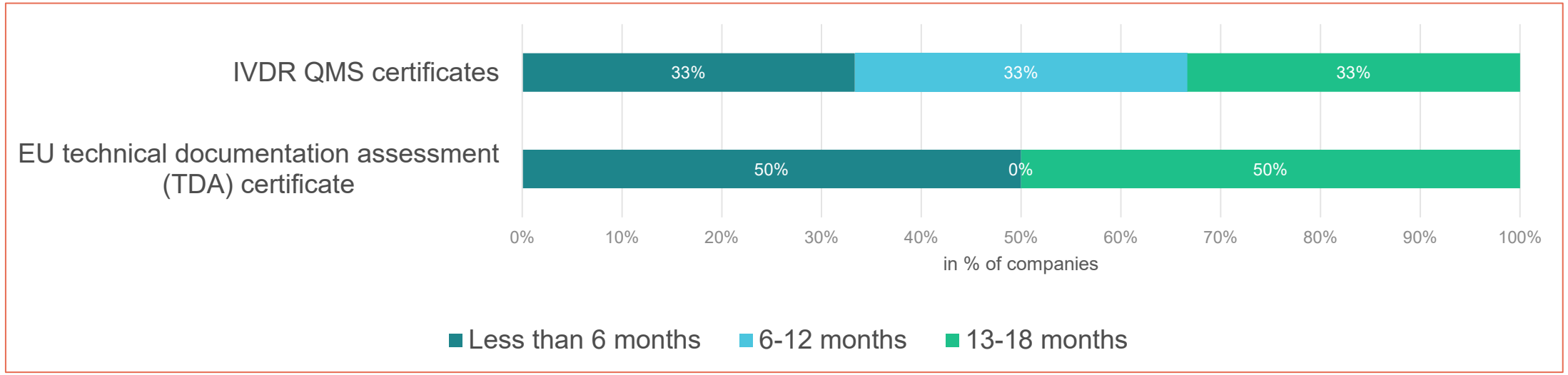


Note: Data of 4 MF

IVD

Re-certification (4)

What is the average time taken to reach renewal of the certificate (from the submission to renewal)?



Note: Data of 4 MF (no information available' was indicated by 2 MF for EU TDA certificates and by 1 for IVDR QMS certificates)

European Commission

IVD

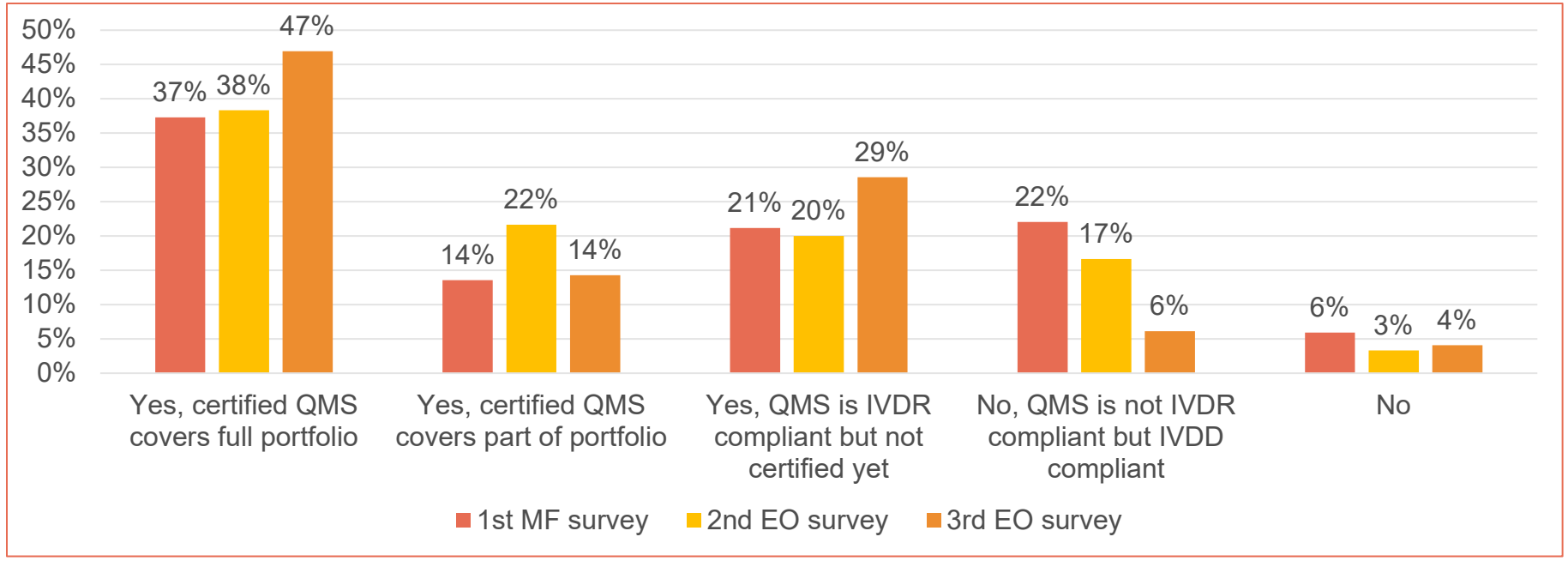
Preparedness of manufacturers

IVD

Preparedness of manufacturers (1)

Do you have an IVDR-compliant QMS?

This refers to EU QMS certification under the IVDR, not under ISO 13485 accreditation.



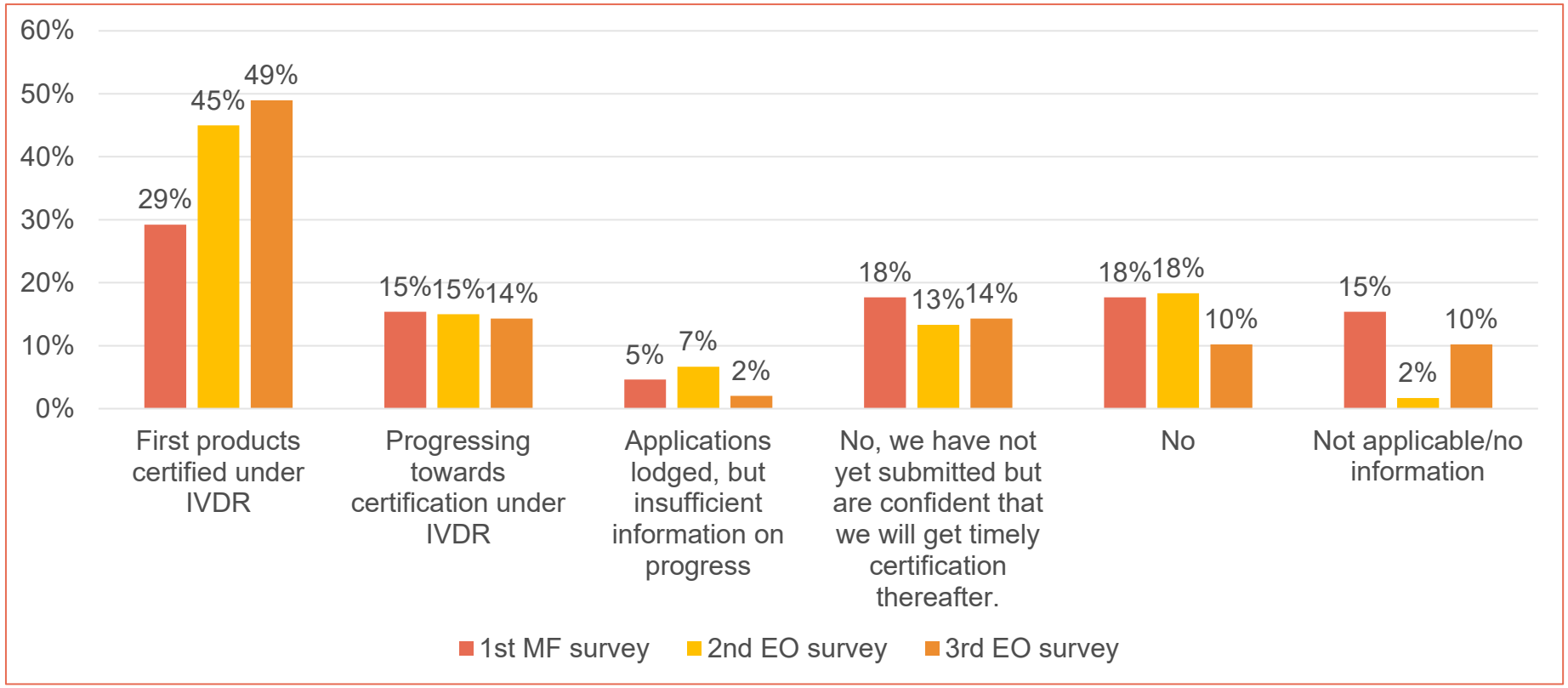
- **1st MF survey:** Data from 118 IVD MF
- **2nd EO survey:** Data from 60 IVD MF
- **3rd EO survey:** Data from 49 IVD MF

European Commission

IVD

Preparedness of manufacturers (2)

Have you already transferred your products/technical documentation to the IVDR?



- **1st MF survey:** Data from 130 IVD MF
- **2nd EO survey:** Data from 60 IVD MF
- **3rd EO survey:** Data from 49 IVD MF

European Commission

AR

2.4. Survey results for authorised representatives

Questionnaire part 2.4. including questions 55 to 57

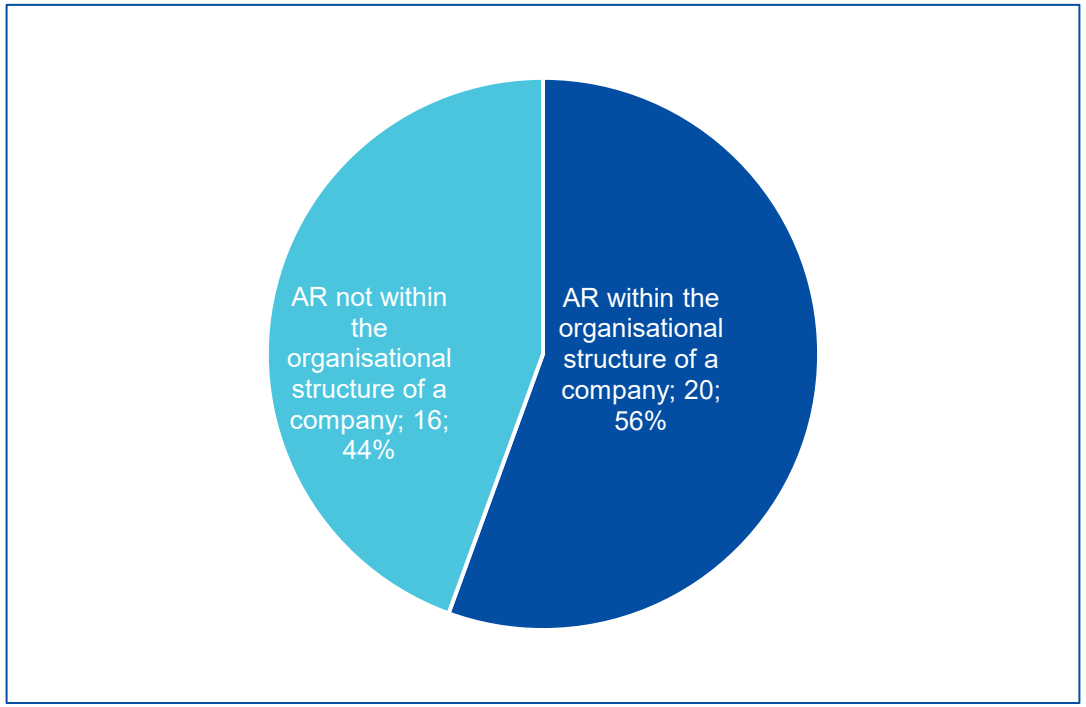
Q55
Q56

Authorised representatives (1)

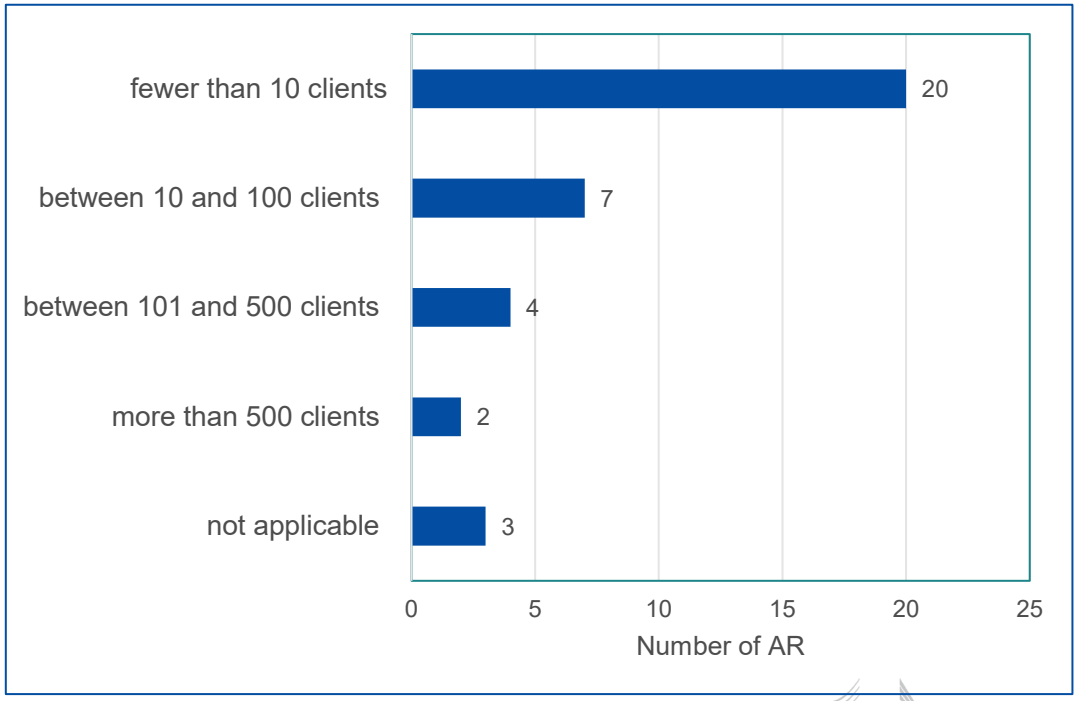
AR

Total responses from ARs: 36

Number of authorised representatives within the organisational structure of a legal manufacturer



Number of companies represented by authorised representatives



European Commission

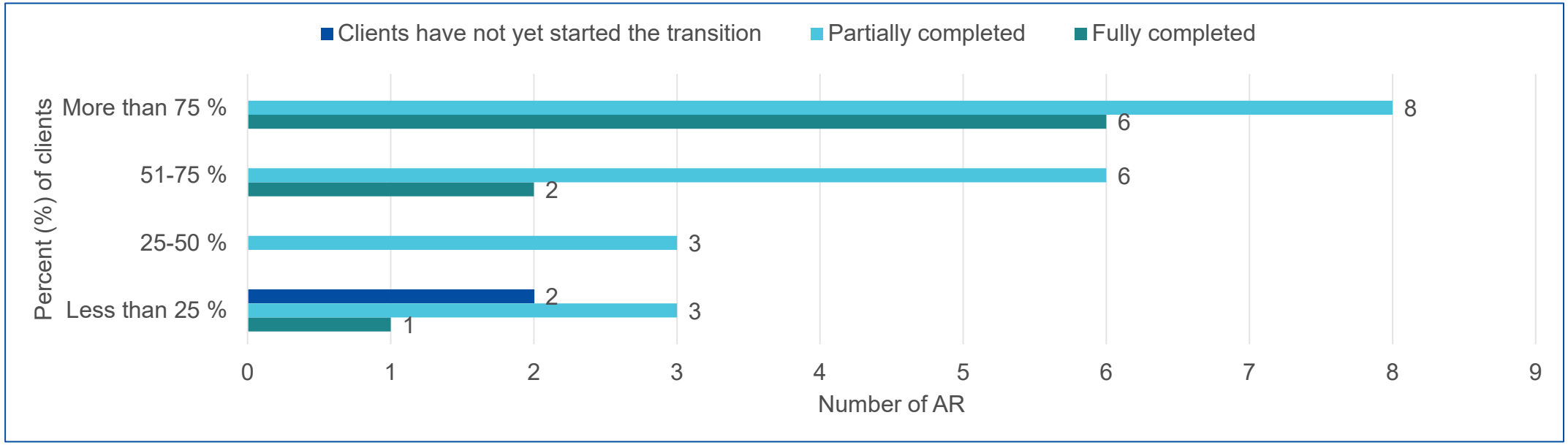
Q57

Authorised representatives Legacy devices transition

AR MD

Total responses from ARs: 36

Estimation for legacy devices (AIMDD/MDD): How many of your clients have completed the transition to the MDR (all devices are CE-marked)?



Note: 10 AR indicated 'I don't know / not applicable'.

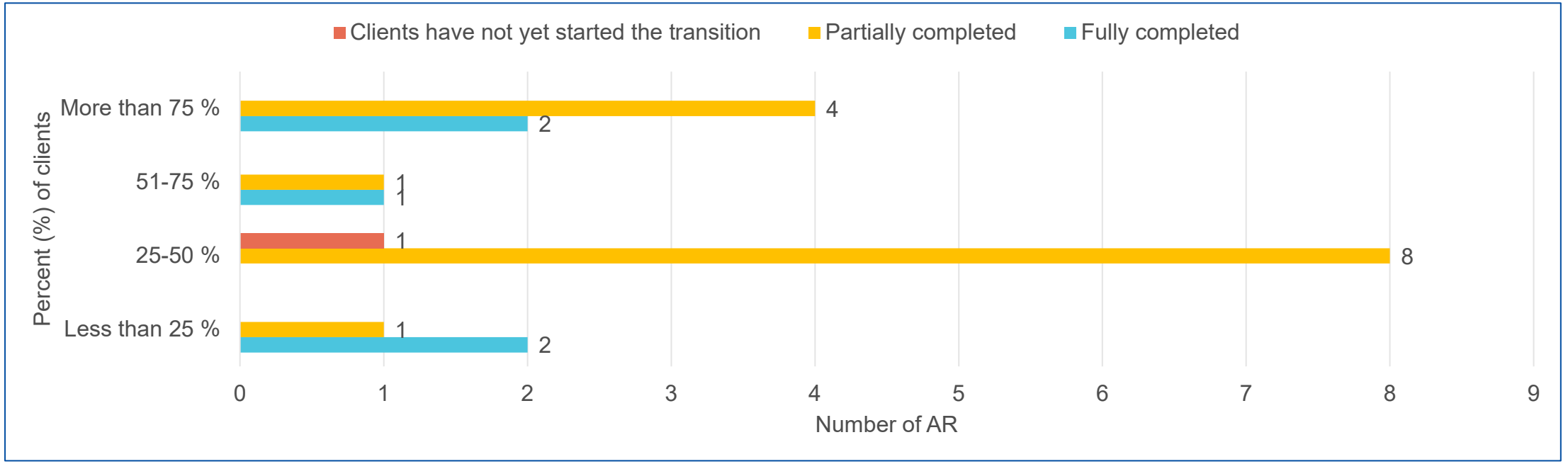
European Commission

Authorised representatives Legacy devices transition

AR IVD

Total responses from ARs: 36

Estimation for legacy devices (IVDD): How many of your clients have completed the transition to the IVDR (all devices are CE-marked)?



Note: 20 AR indicated 'I don't know / not applicable'.

European Commission

Thank you

Contact for questions: medical.devices@goeg.at

Austrian National Public Health Institute/ Gesundheit Österreich (GÖG)

European Commission