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

Study overview and survey results of the 2nd EO survey with data status 31 October 2024

28 November 2025

Disclaimer

- This document was produced in the frame of the SC 2021 P3 03 under the DG SANTE Framework contract (FWC SANTE/2021/OP/0002) for evaluation, impact assessment, monitoring and other related services in relation to health and food policies.
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- 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

Please note that as part of this survey we also collected data for the **'Targeted Evaluation'** carried out by the European Commission (EC). These results are **not included** in this PowerPoint presentation and will be published by the EC separately.

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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	Authorized 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
FTE	Full Time Equivalent
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

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

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

Areté The Agri-food Intelligence Company — Areté

CIVIC CONSULTING — Civic Consulting

Supported by experts from the medical devices sector

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

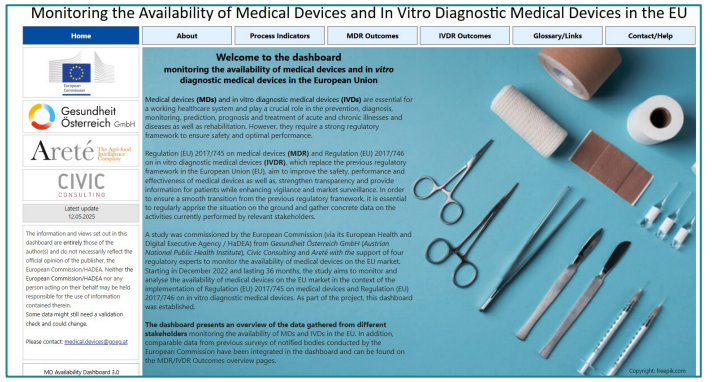
Surveys

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 2nd EO survey with MF, AR, IM, DB

- Acknowledgements
- Survey development and management
- Survey timeline
- Survey structure and content
- 1st MF/AR survey vs. 2nd EO survey

Acknowledgements

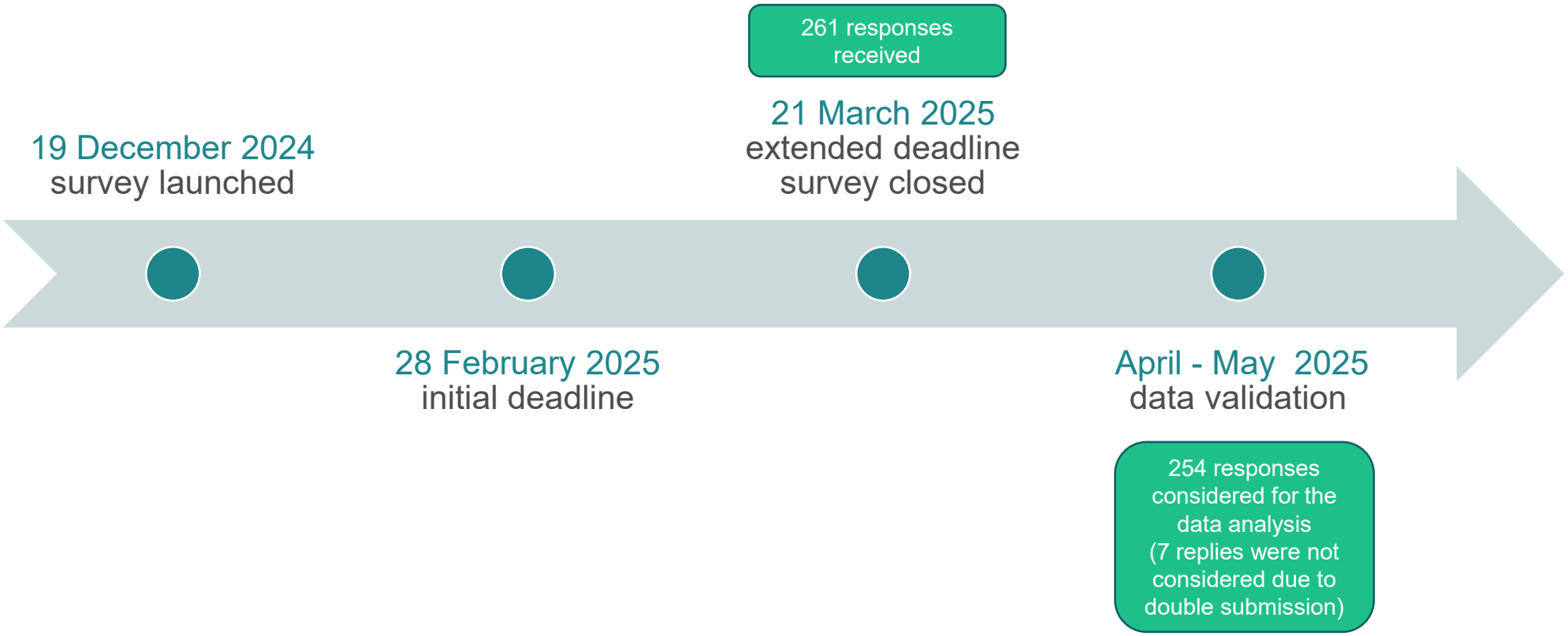
The study team would like to sincerely thank the following persons and institutions for the support in the 2nd EO survey:

- 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; MedTech Europe; European Association of Authorized Representatives (EAAR)
- All **manufacturers, authorized representatives, importers and distributors** 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 the 1st MF/AR survey were also invited.
- **Survey period:** The survey was launched on 19 December 2024 on the EUSurvey platform and closed on 21 March 2025.

Survey timeline for the 2nd EO survey conducted in December 2024
(data was requested until 31 October 2024)



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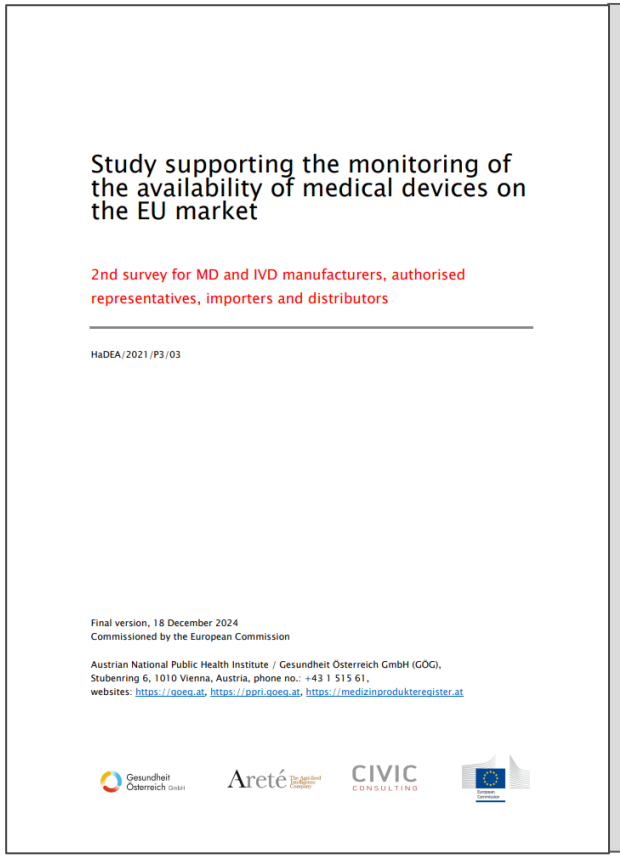
Survey structure and content



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

2nd survey for MD and IVD manufacturers, authorised representatives, importers and distributors

HaDEA/2021/P3/03

Final version, 18 December 2024
Commissioned by the European Commission

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Gesundheit Österreich GmbH Areté CIVIC CONSULTING

1. Background and introduction

2. Questionnaire (Q1-Q81)*

- About — 2.1. **ABOUT:** About you and your company (Q1-Q9)
- MD — 2.2. **MD:** Questionnaire on medical devices (Q10-Q39)
- IVD — 2.3. **IVD:** Questionnaire on in vitro diagnostic medical devices (Q40-Q72)
- AR — 2.4. **AR-MD/IVD:** Questionnaire for authorised representatives (Q73-Q75)
- IM — 2.5. **IM-MD/IVD:** Questionnaire for importers (Q76-Q77)
- DB — 2.6. **DB-MD/IVD:** Questionnaire for distributors (Q78-Q79)
- 2.7. **Closing** (Q80-Q81)

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

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

* Please note that as part of this survey we also collected data for the 'Targeted Evaluation' carried out by the European Commission (EC). These results are not included in this PowerPoint presentation and will be published by the EC.

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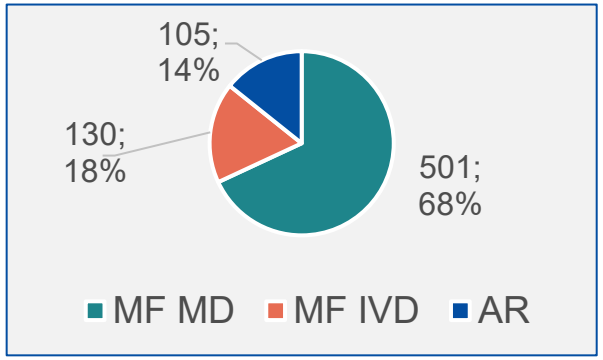
1st MF/AR survey vs. 2nd EO survey

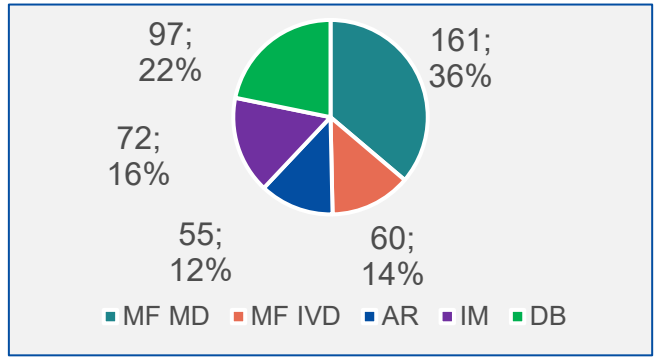
1st MF/AR survey

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



2nd EO survey

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



2. Results

Notes:

- As part of this survey, we also collected data for the **'Targeted Evaluation'** carried out by the European Commission (EC). These results are not included in this PowerPoint presentation and will be published by the EC separately.
- 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).

About

2.1. About the survey participants (responses)

Questionnaire part 2.1. including questions 1 to 9

Note: Answers to question 1 (contact details) and question 5 (staff; part of the targeted evaluation) are not provided in this presentation.

Responses to 2nd 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).

261
replies received between 19/12/2024-21/03/2025

7
answers excluded as EO provided two answers to the survey (doublets)*

254
replies considered for data analysis

* The newer answers were selected for data analysis.

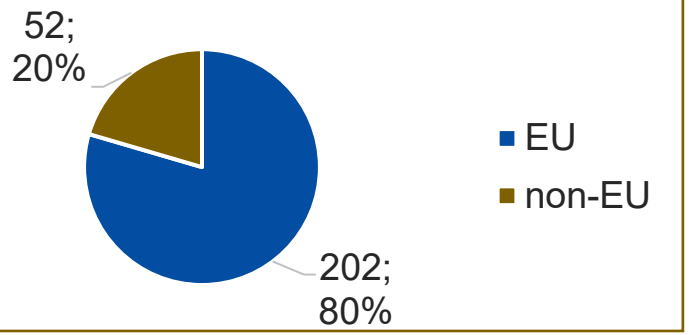
Country, where the company is based* (1)

About

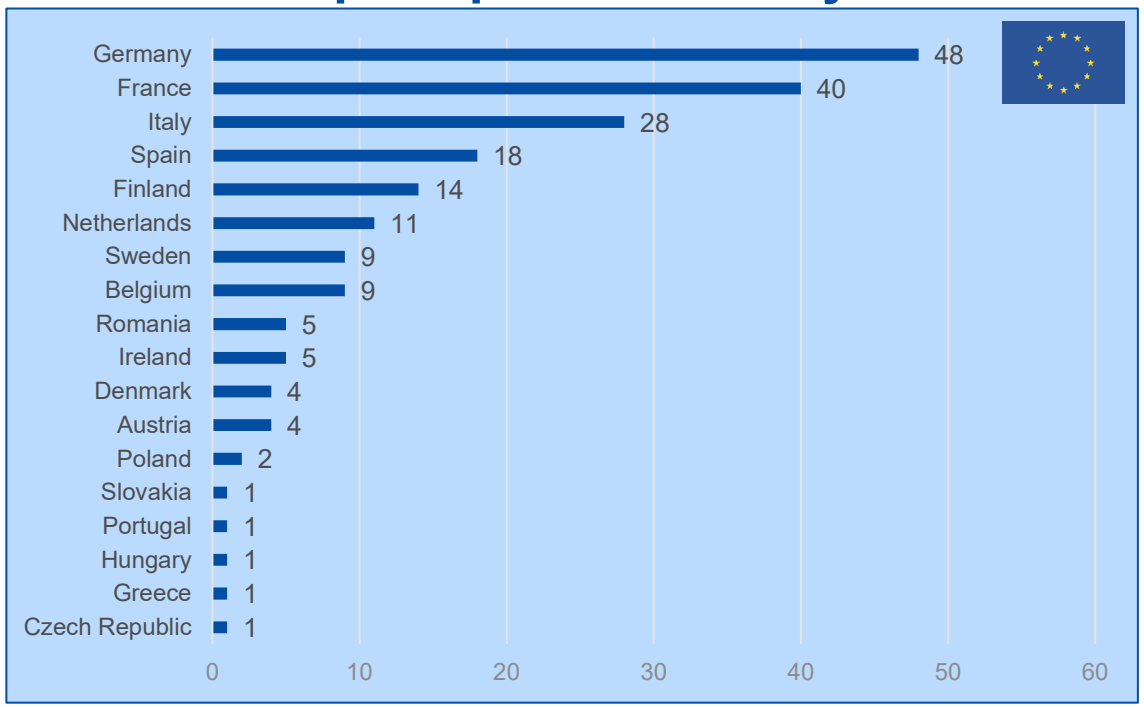
*In the case of a multinational company this is the country where the headquarters is located. In case of a reply by a subsidiary, the data provided only refers to the subsidiary.

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

n = 254 MF/AR/IM/DB

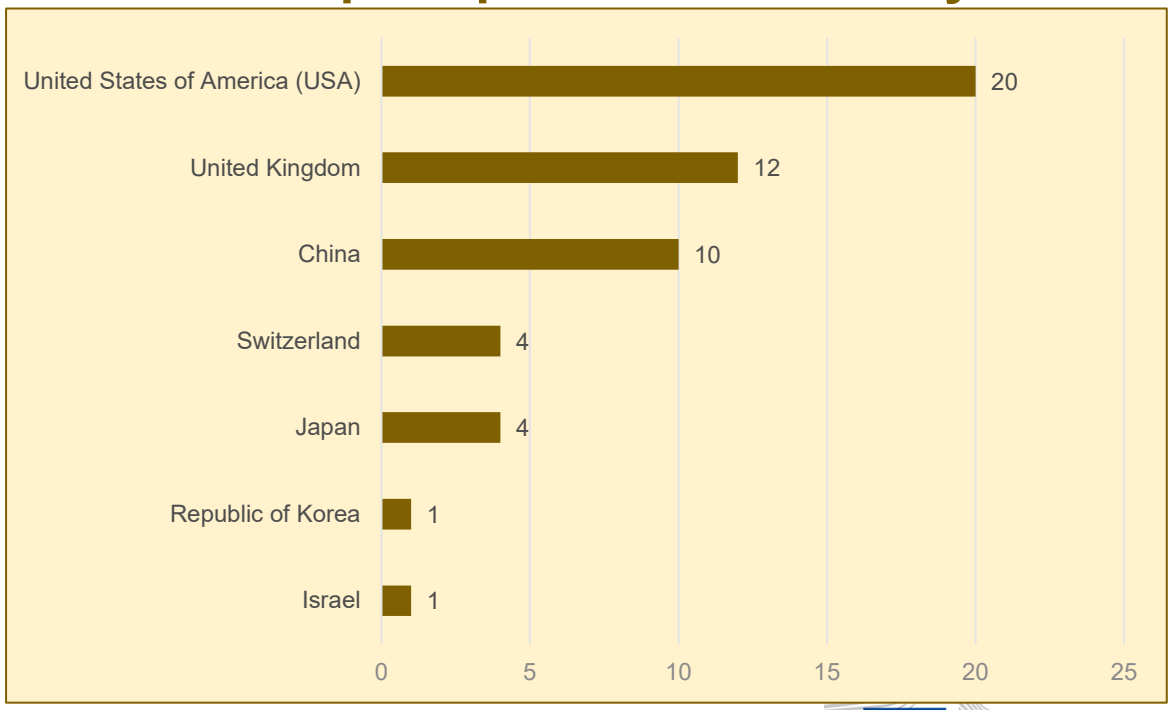


Number of replies per EU country



n = 202; photo credit: pixabay.com

Number of replies per non-EU country



n = 52

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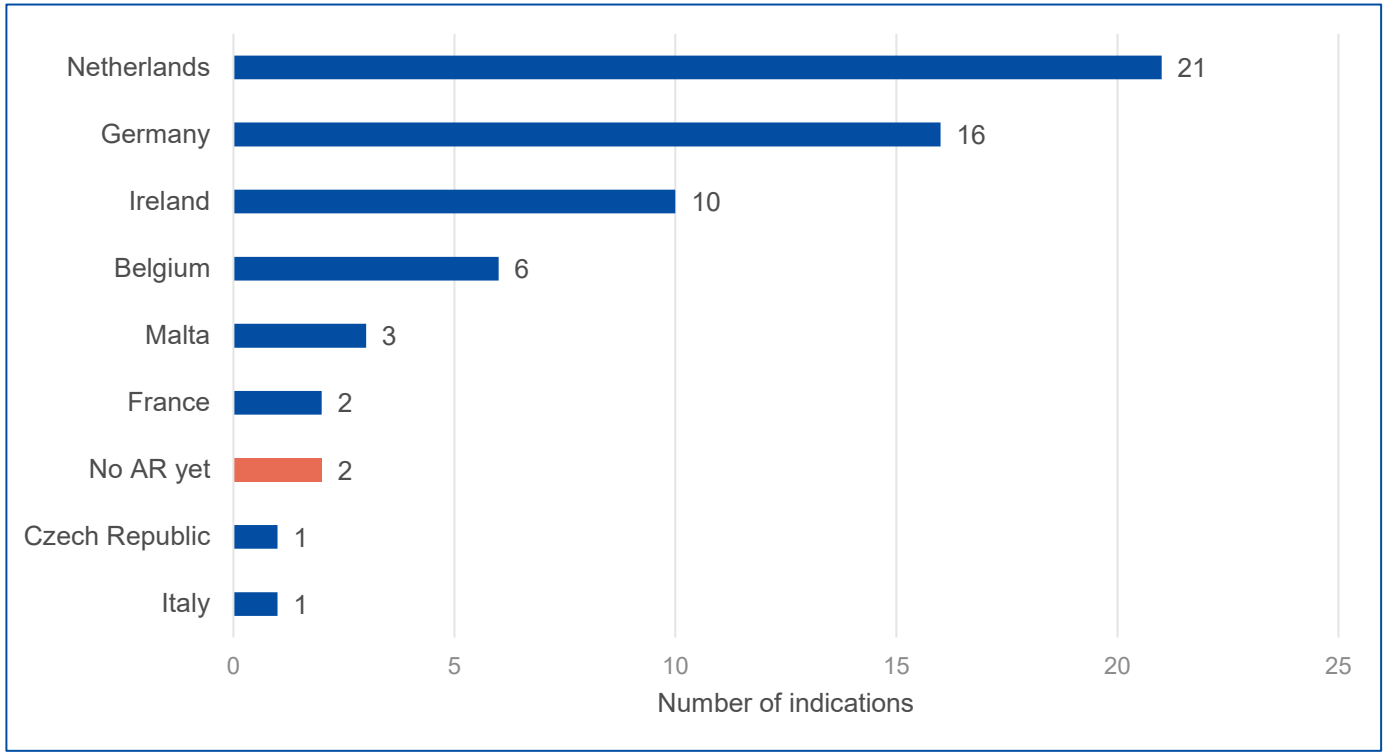
Country, where the company is based (2)

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 52 non-EU MFs
- **Multiple choice:** 4 out of 52 non-EU MFs indicated more than one AR; in total 62 AR locations were mentioned.

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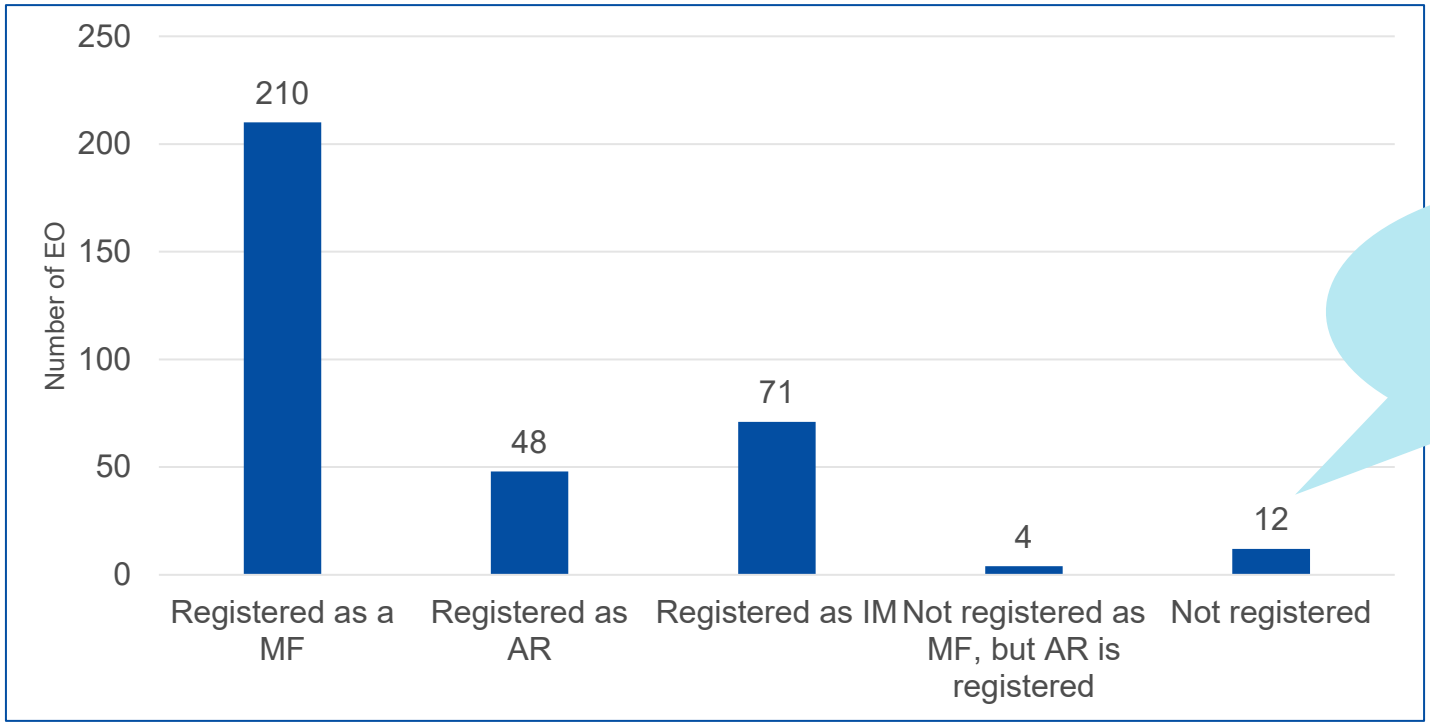
Registration in EUDAMED

About



Only 5% of the participating MF/ARs are not registered in EUDAMED (yet).

n = 254 MF/ARs participating in the survey
Note: Some participants indicated several registrations (MF, AR, IM)

European Commission

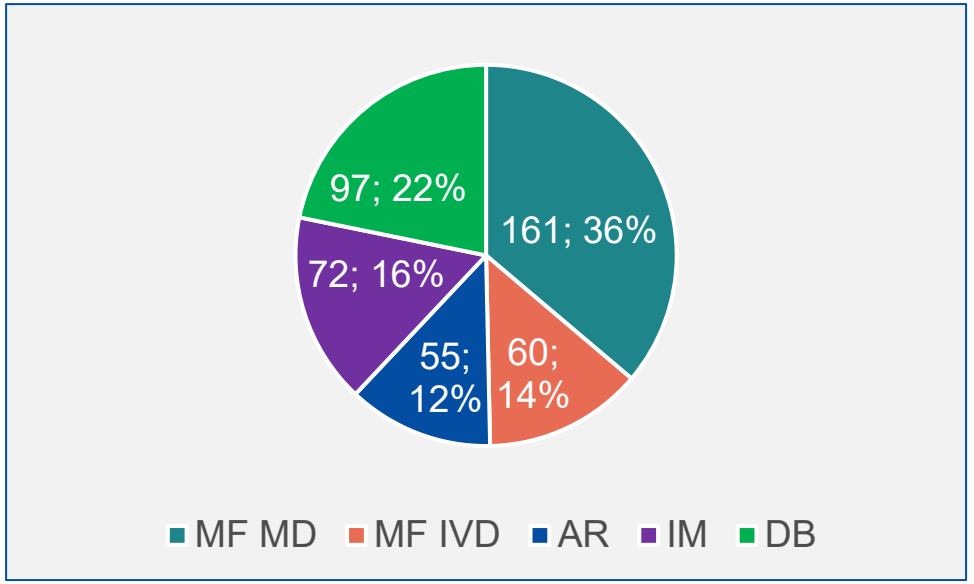
About

Company role

Of 254 replies received (several roles possible)

- **161** indicating acting as manufacturers (MFs) for MDs,
- **60** indicating acting as manufacturers (MFs) for IVDs,
- **55** indicating acting as authorised representatives (AR),
- **72** indicating acting as importer (IM),
- **97** indicating acting as distributor (DB).

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



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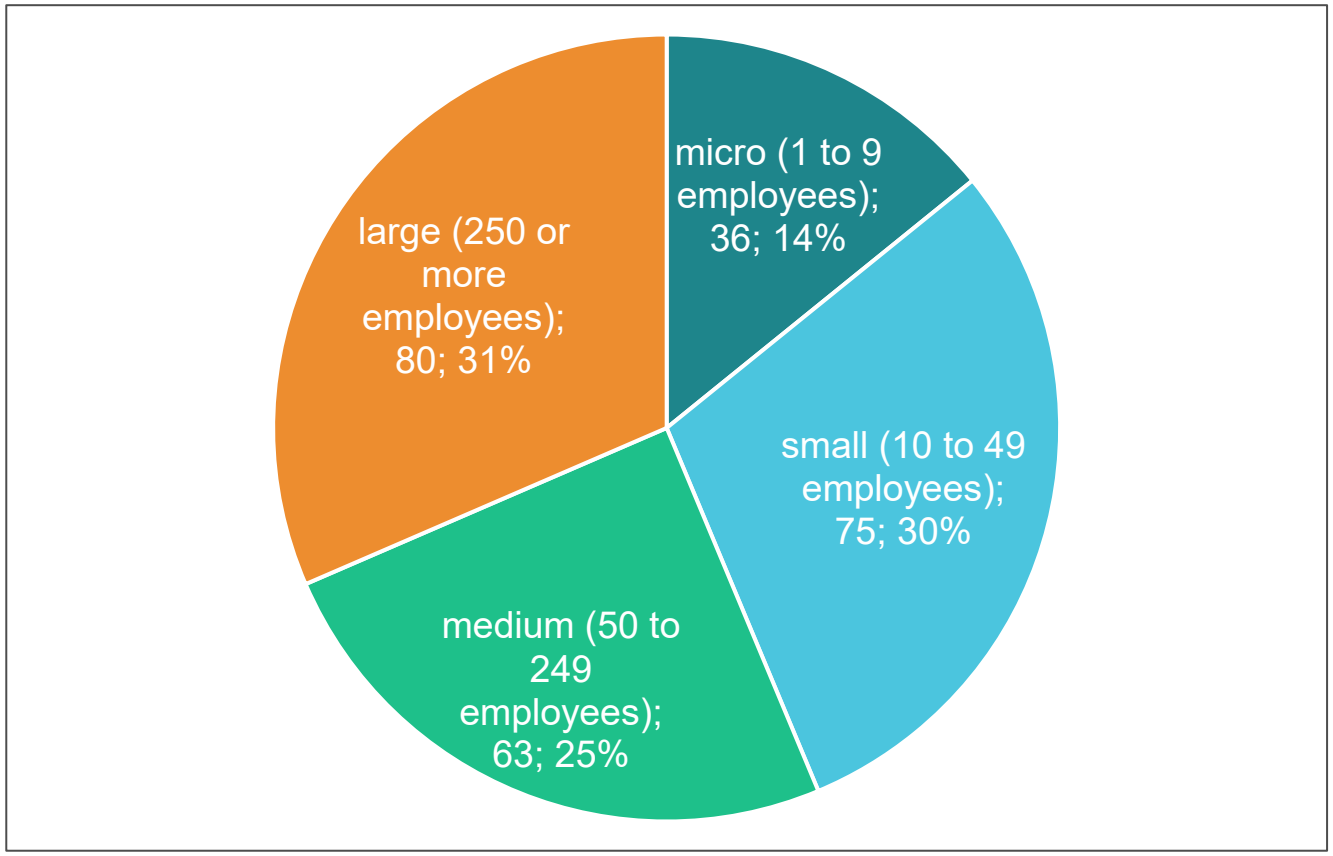
About

Size of organisation (globally) (1)

n = 254 companies participating in the survey

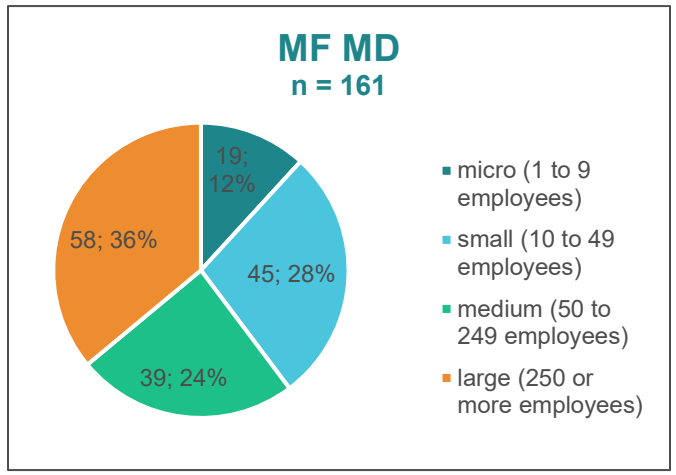


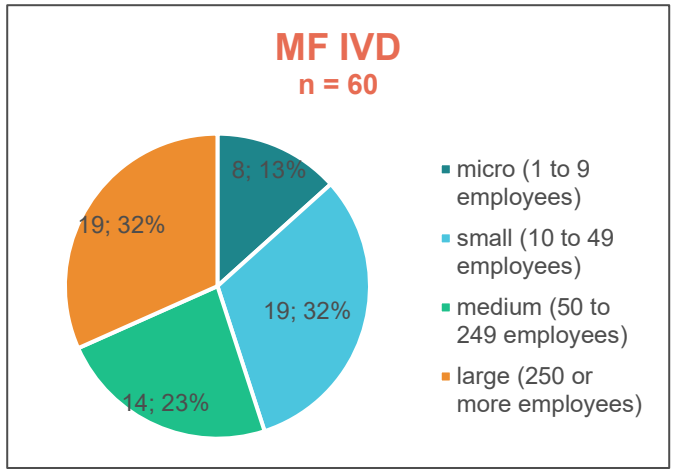
69% of the responding companies have less than 250 employees.

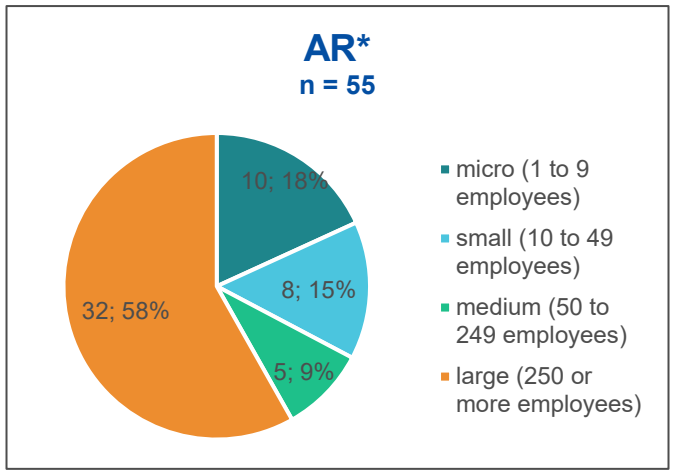
Size of organisation (globally) (2)

About

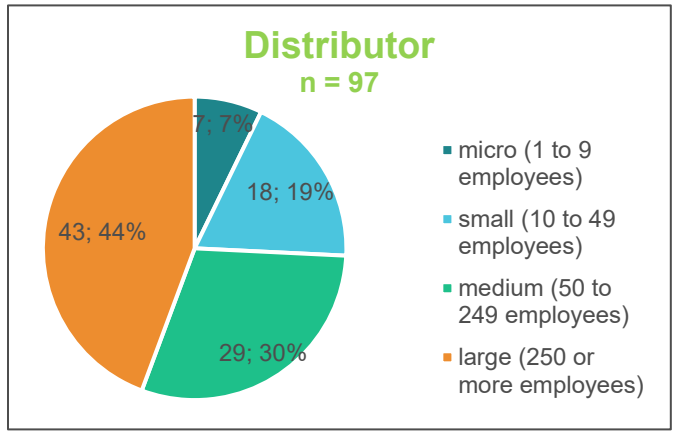
Company size by role (multiple choice)

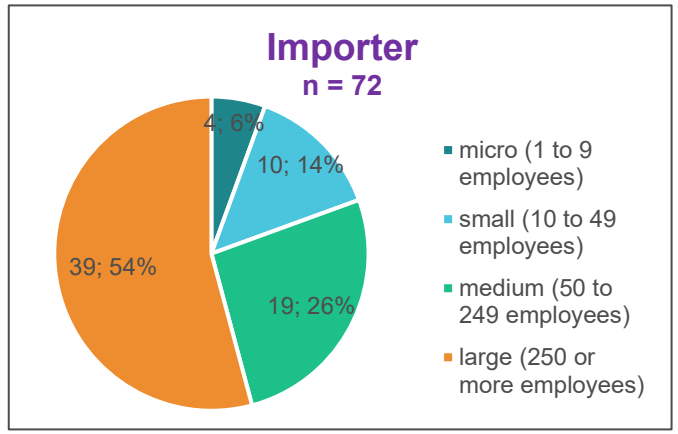


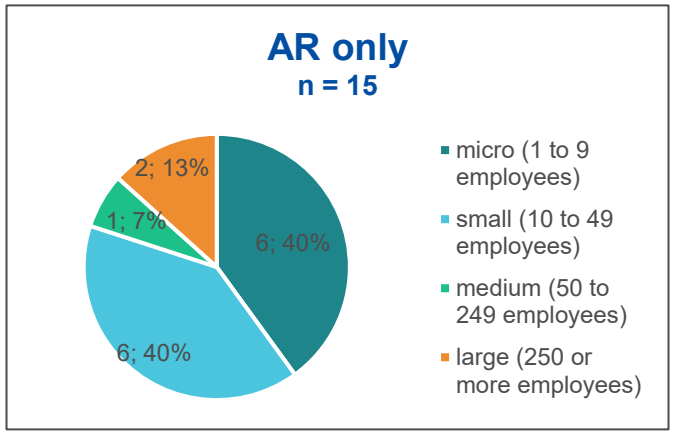




*n = 55 companies indicating to act as an authorised representative. Thereof 15 companies acted as AR only.







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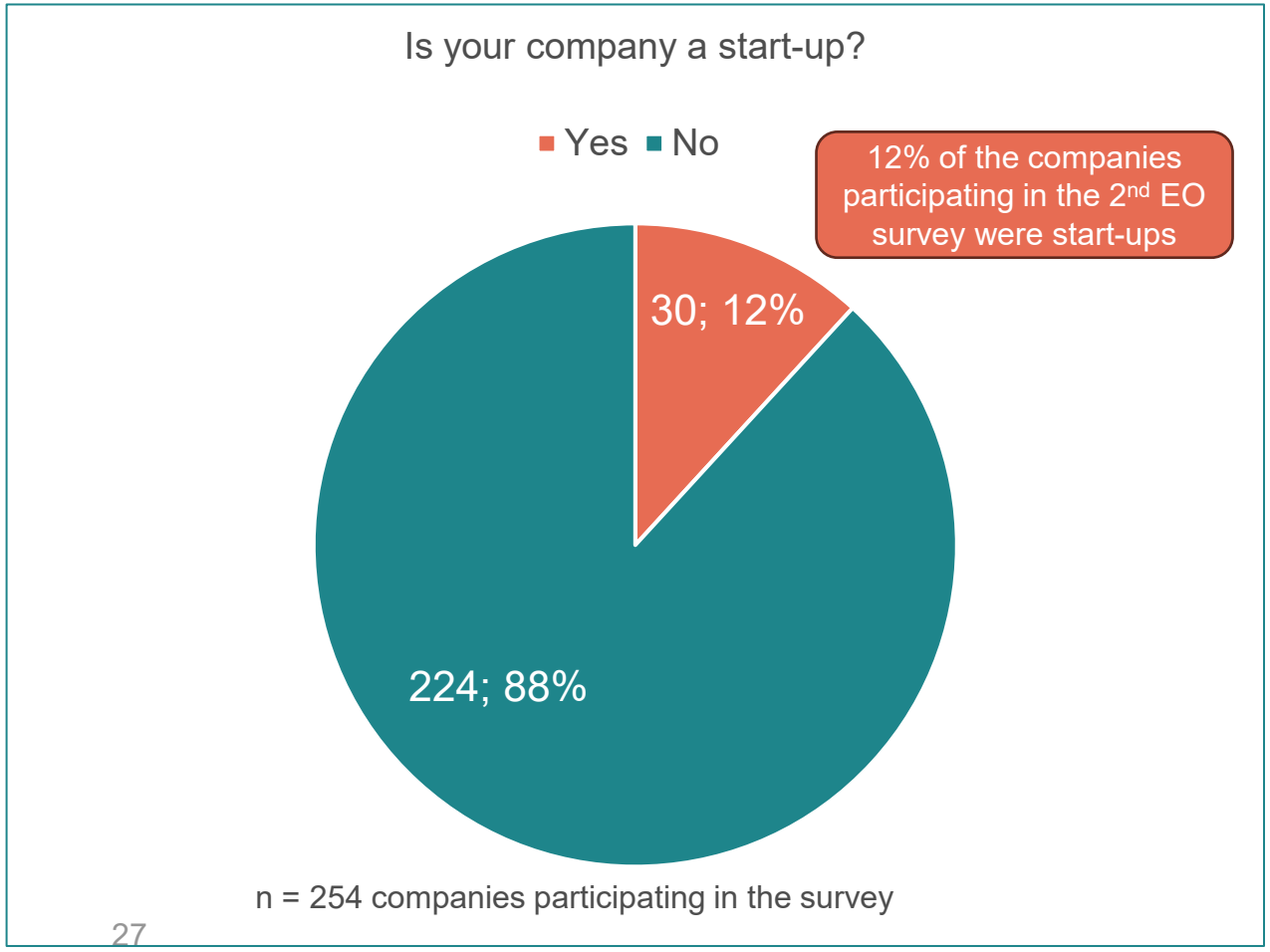
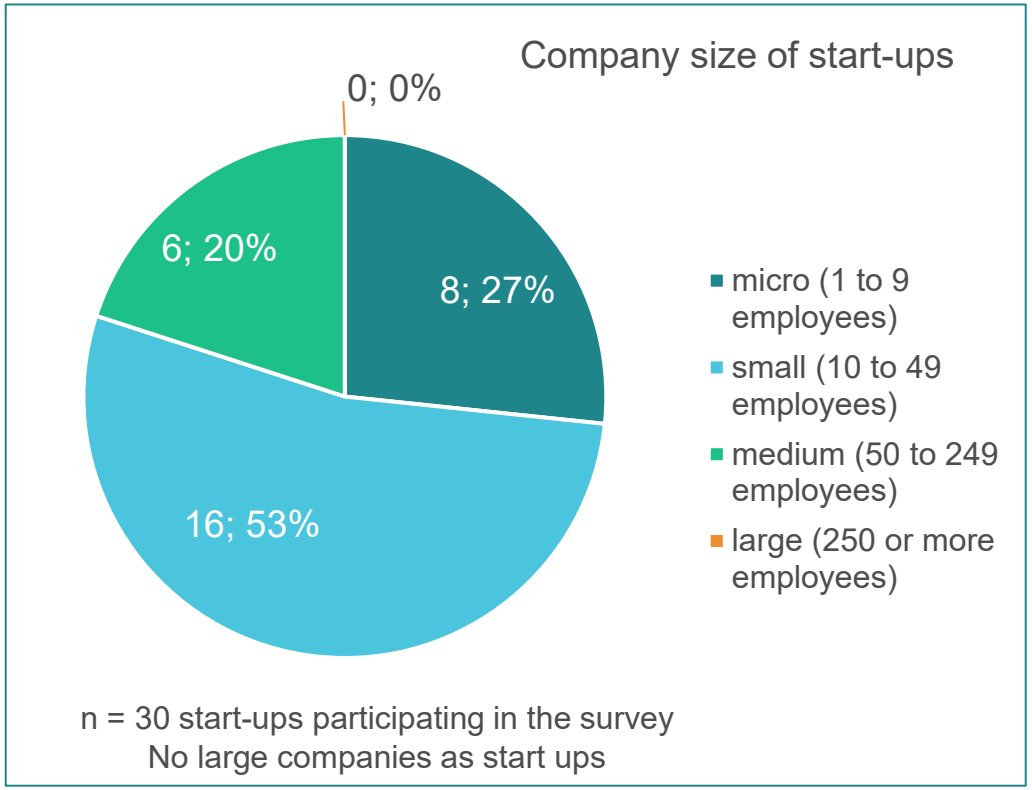
Start-ups*

About

* 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 = 254 companies participating in the survey



n = 30 start-ups participating in the survey
No large companies as start ups

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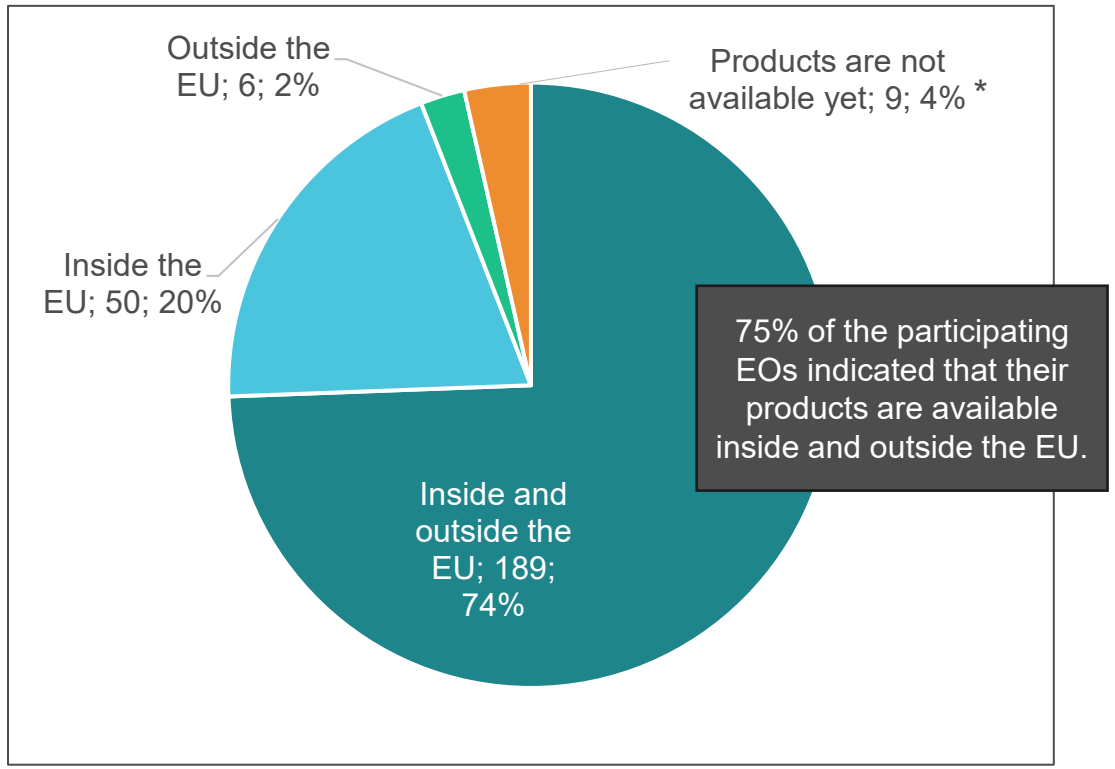
Where are products available

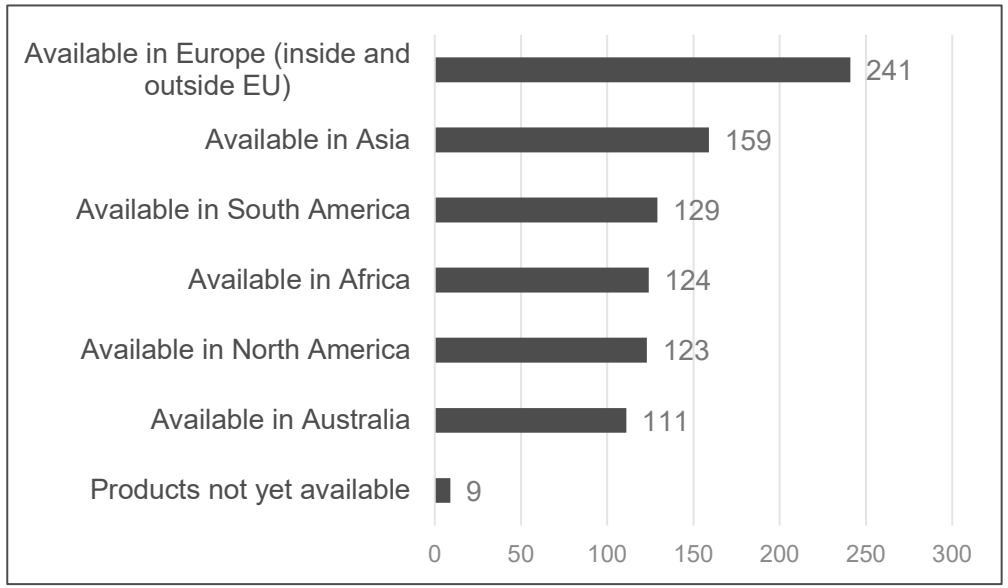
About

Availability of products by market



n = 254 EOs participating in the survey
* incl. one AR who indicated “inside and outside the EU” and “products are not available yet” for different clients

Availability of products by continent



Note: Respondents could give multiple answers.

n = 254 EOs participating in the survey, multiple responses possible

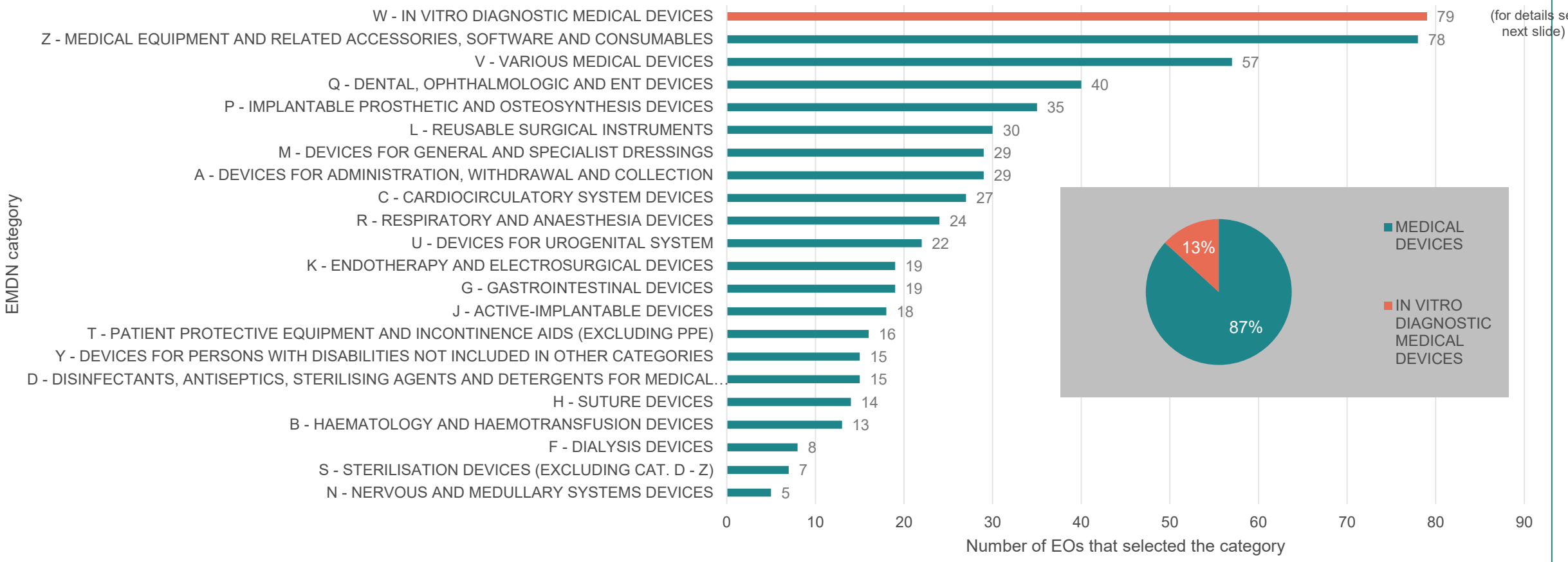
European Commission

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

(EMDN categories selected by EOs)

About

Total number of EMDN category indications: 599



239 out of 254 EOs answered this question (optional response was possible), resulting in 599 EMDN category indications
Categorie T: EXCLUDING PPE = PERSONAL PROTECTIVE EQUIPMENT;

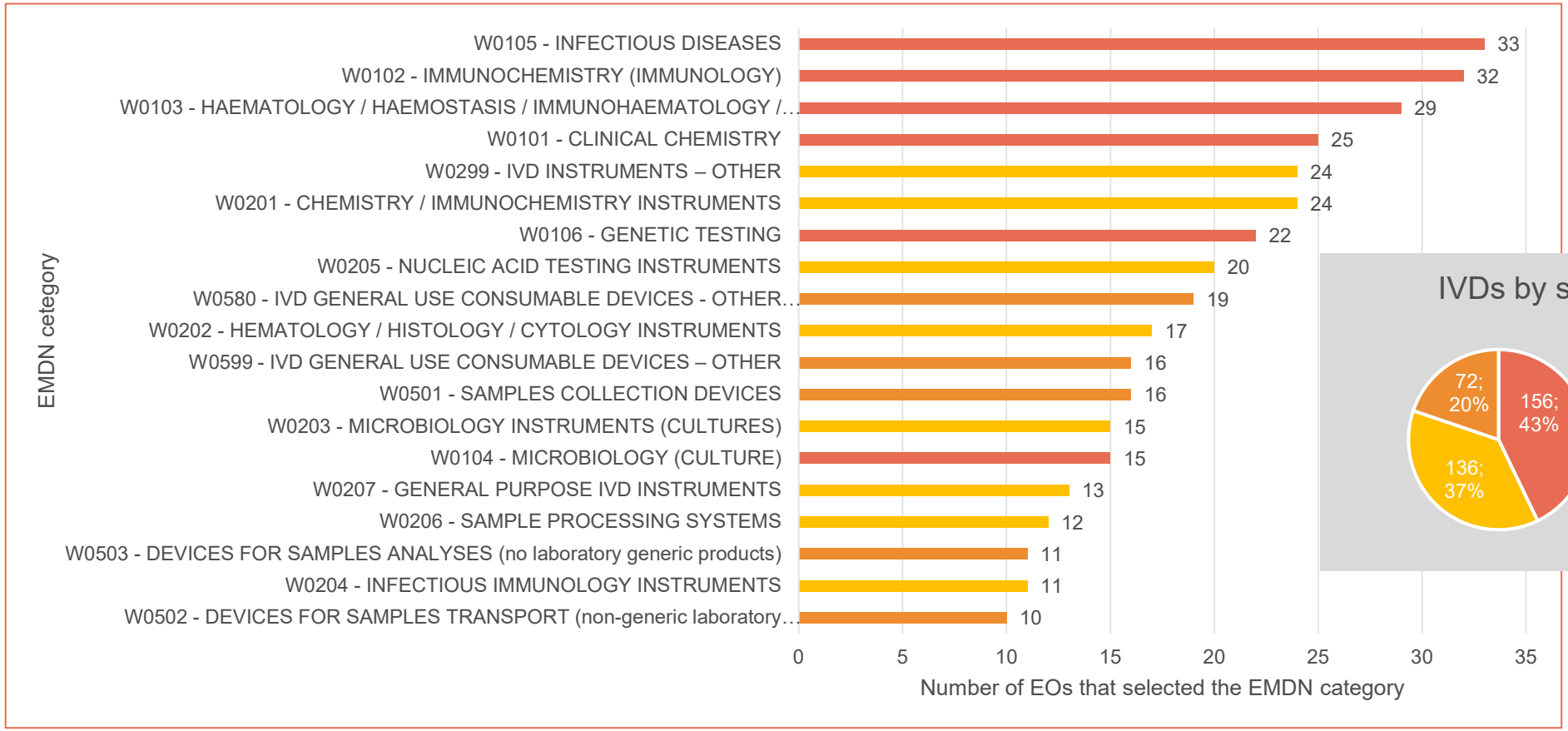
European Commission

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: 364



58 out of 254 EOs answered this question (optional response was possible), resulting in 364 EMDN category indications for IVDs

European Commission

MD

2.2. Survey results for medical devices

Questionnaire part 2.2. including questions 10 to 38

Note: Answers to the following questions are not provided in this presentation as they are part of the targeted evaluation: 29, 35 to 39

Q14
Q17

Overview on applications and certificates by end of October 2024

MD

Number of applications lodged under MDR: **2137***

12th NB survey
(covering the same data period until 31/10/2024):

Ⓜ: 28069**
(MF sample: 7,6% were potentially covered in this survey)

Number of certificates issued for MDs under MDR: **1117**

10554
(MF sample: 11% were potentially covered in this survey)

Note: These figures relate to the 161 responses from the manufacturers of MDs as of the end of October 2024.
No. of applications: data of 143 MD MF, 18 MD MF with "0" applications.
No. of certificates: data of 72 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.

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MD

AIMDD/MDD
legacy devices*

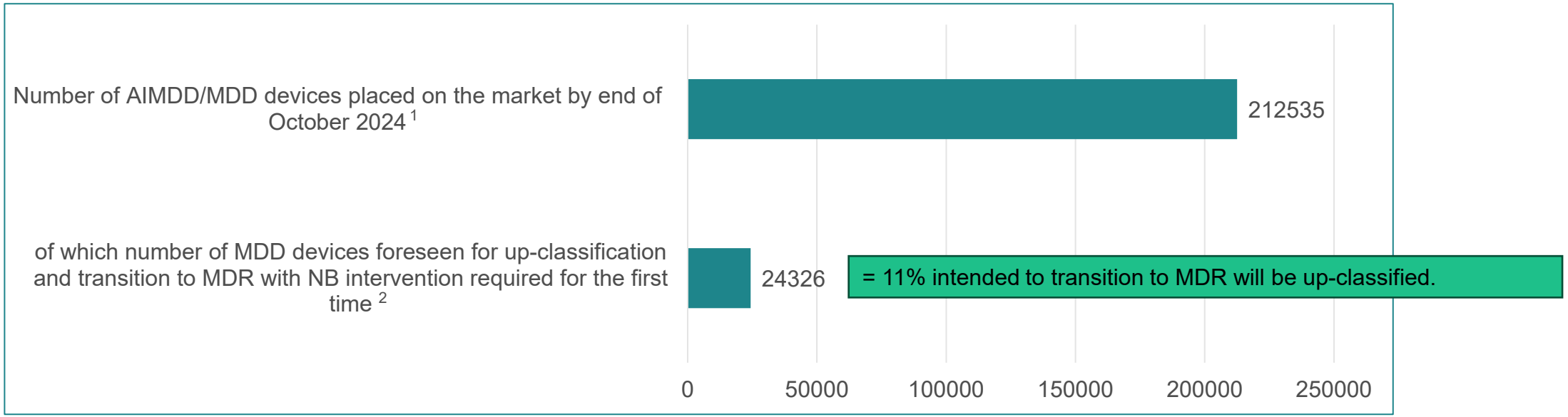
* In line with MDCG 2021-252 ‘legacy devices’ should be understood as devices, which, in accordance with the MDR’s transitional provisions, are placed on the market after the MDR’s date of application (i.e. 26 May 2021) if certain conditions are fulfilled.

AIMDD/MDD overview by the end of October 2024

(number of devices referring to catalogue numbers)

MD

Total responses from MFs for MDs: 161



Notes:
[1] Data of 161 MFs, including 33 MFs with the indication '0';
[2] Data of 161 MFs, including 103 MFs with the indication '0';

European Commission

MD

AIMDD/MDD overview by the end of October 2024

Total responses from MFs for MDs: 161
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): **1168**

Notes:
[1] Data of 161 MFs, including 43 MFs with the indication '0';

MD

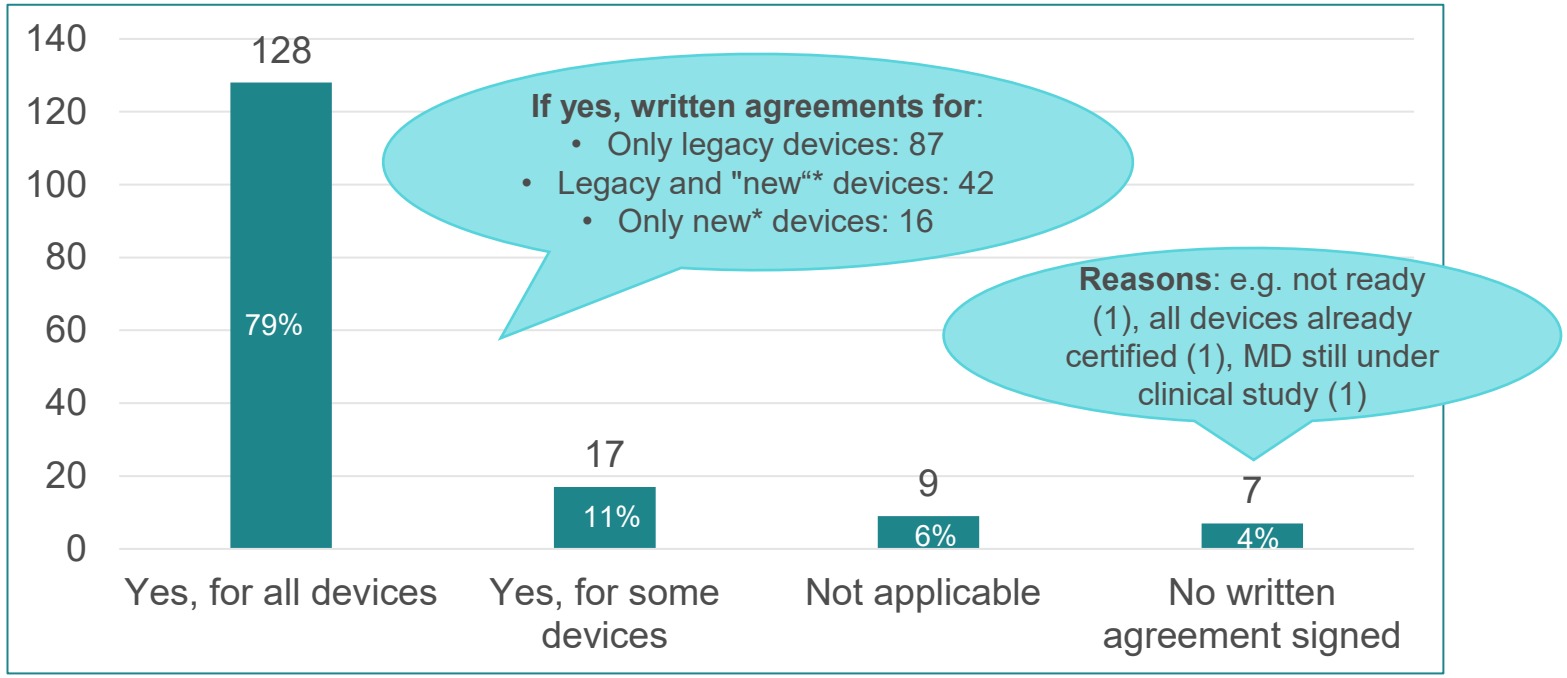
Notified bodies
written agreements, refused applications

Written agreements between MFs of MDs with Notified Bodies

MD

Total responses from 161 MFs for MDs

Number of companies with written agreements with a notified body/notified bodies designated under the MDR by the end of October 2024



Note: Replies of 161 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 (2023: 67%)
- 4% of the MF that need a written agreement don't have one (2023: 20%)
- 6% of the MF don't need a NB involvement (2023: 13%)

(in brackets the results of the 1st MF/AR survey – situation up to 31/10/2023; replies of 501 MFs for MDs)

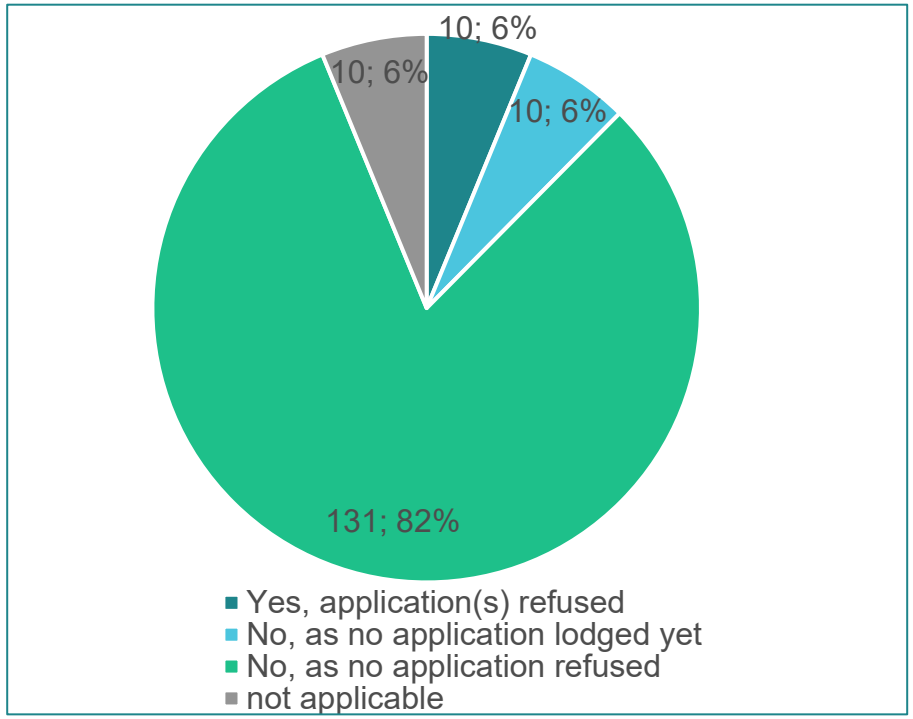
*devices which have never been CE-marked but will need CE-marking under the MDR to access the EU market.

Q13

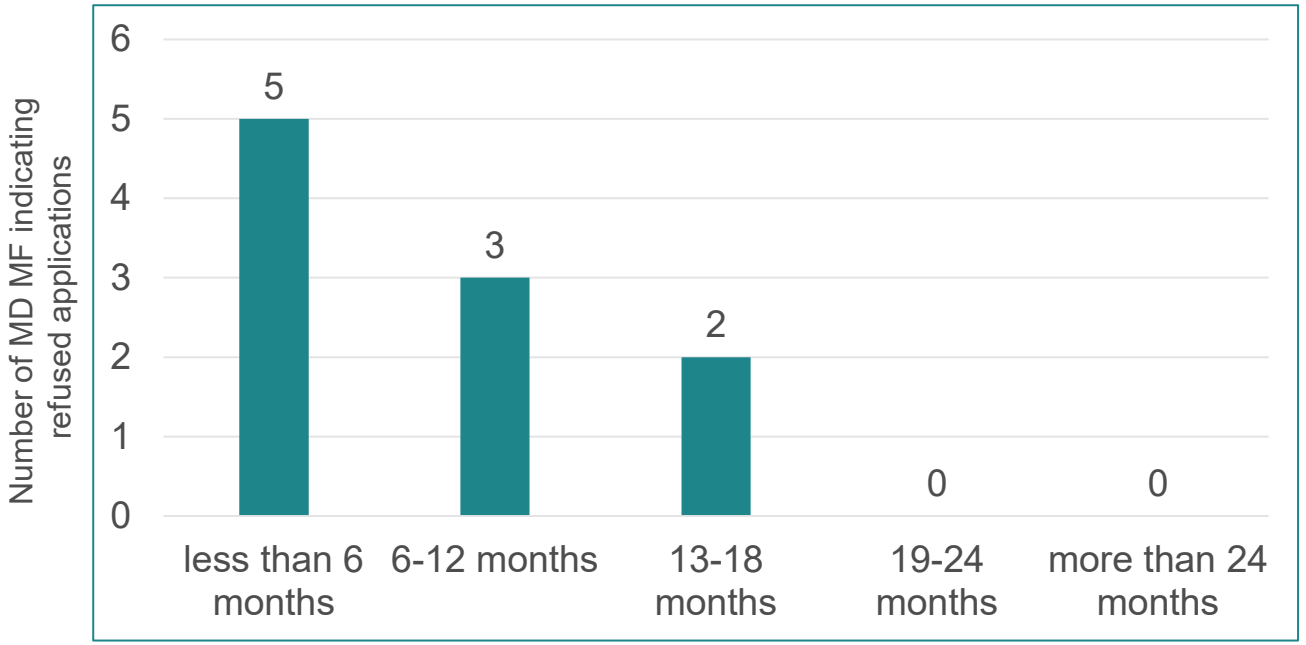
Refusal of applications by Notified Bodies (1)

MD

Did a notified body refuse an application under the MDR? (n=161)



Time from application to refusal (for MD MF indicating 'Yes, application(s) refused.') (n=10)



European Commission

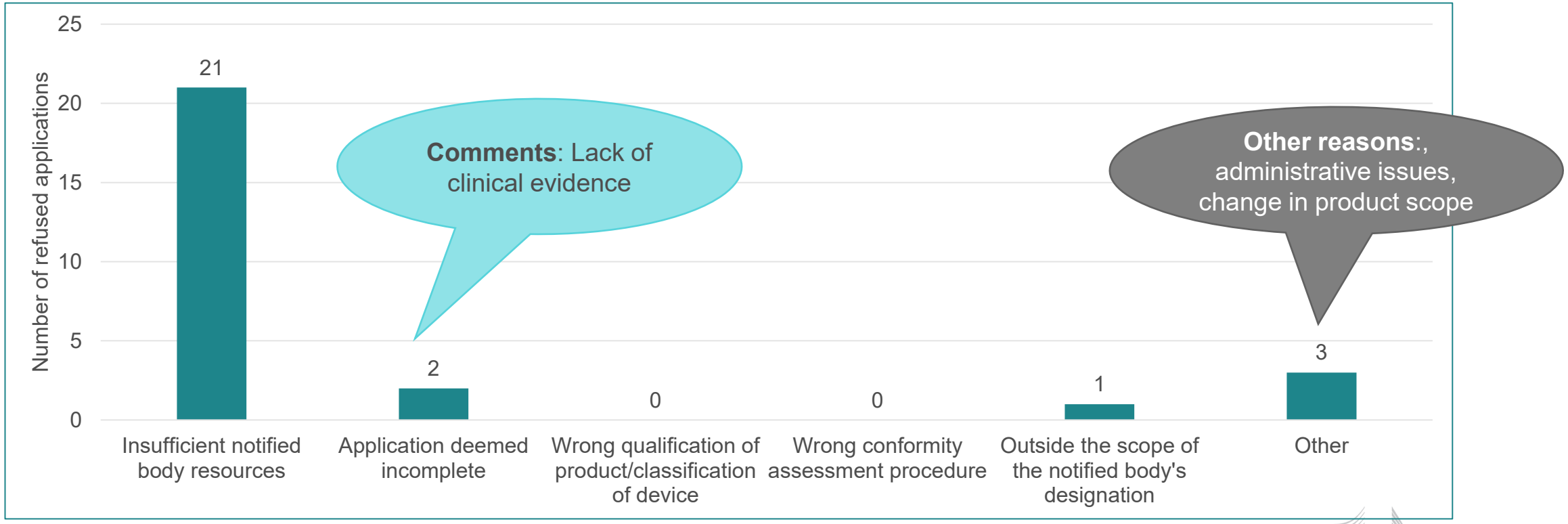
Refusal of applications by Notified Bodies (2)

MD

Refusals for:
- Legacy devices: 7
- New* devices: 3

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

Number of refused applications by reason for refusal (n=10 companies reporting 27 refused applications)



European Commission

MD

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

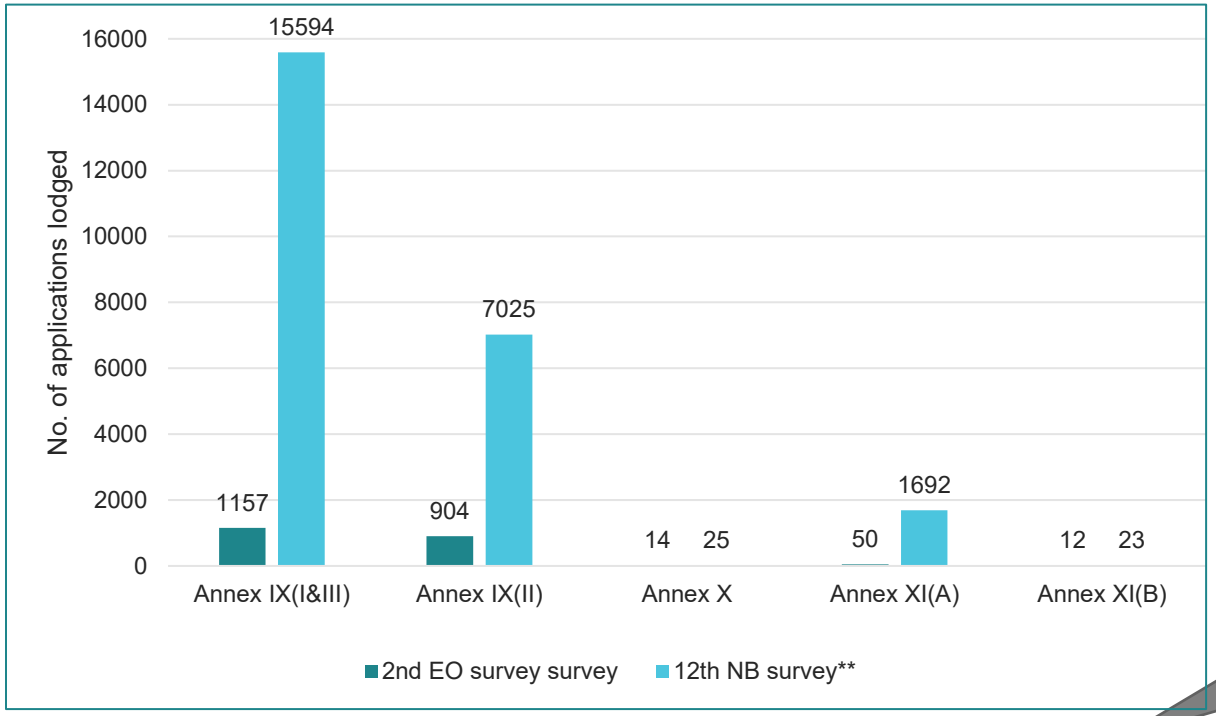
Applications lodged under MDR by end October 2024

MD

Total responses from 161 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 12th NB survey (covering the same data period until 31/10/2024):
Total number of applications filed by Annex Ⓜ: **28.069****
* 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.
12th NB survey: replies by 50 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): 155 (7%)

Total number of applications: 2137
(thereof 788 (37%) applications for change)

European Commission

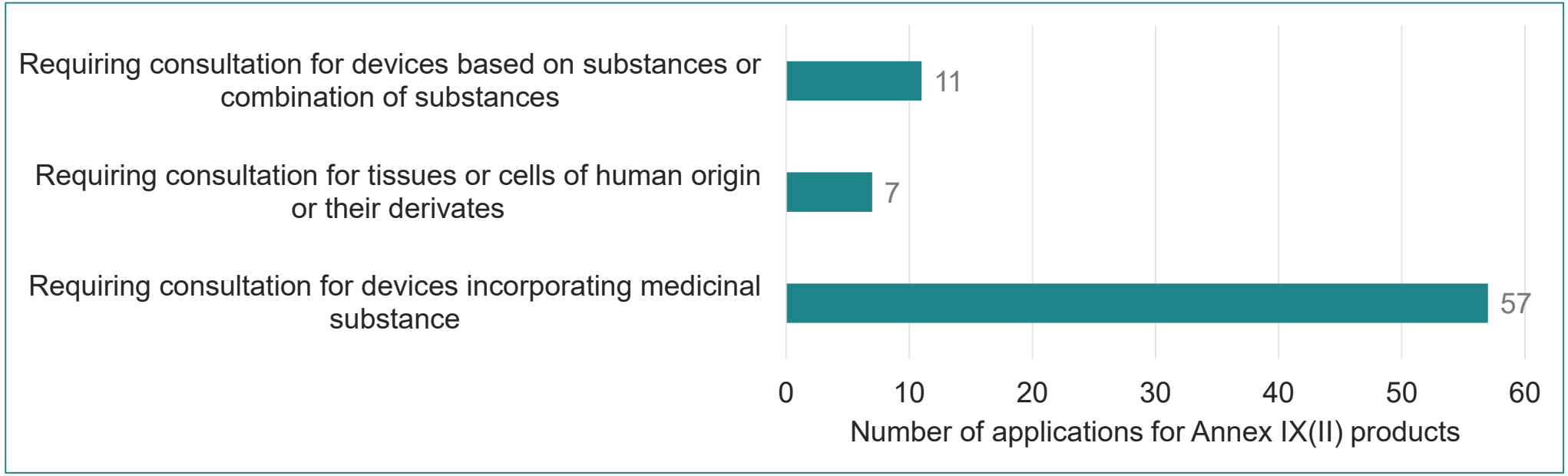
Applications lodged under MDR by end October 2024 for MD requiring consultation

MD

Total responses from 161 MFs for MDs

Application for product certificates requiring consultations

Note: Responses from 161 MFs for MDs.



European Commission

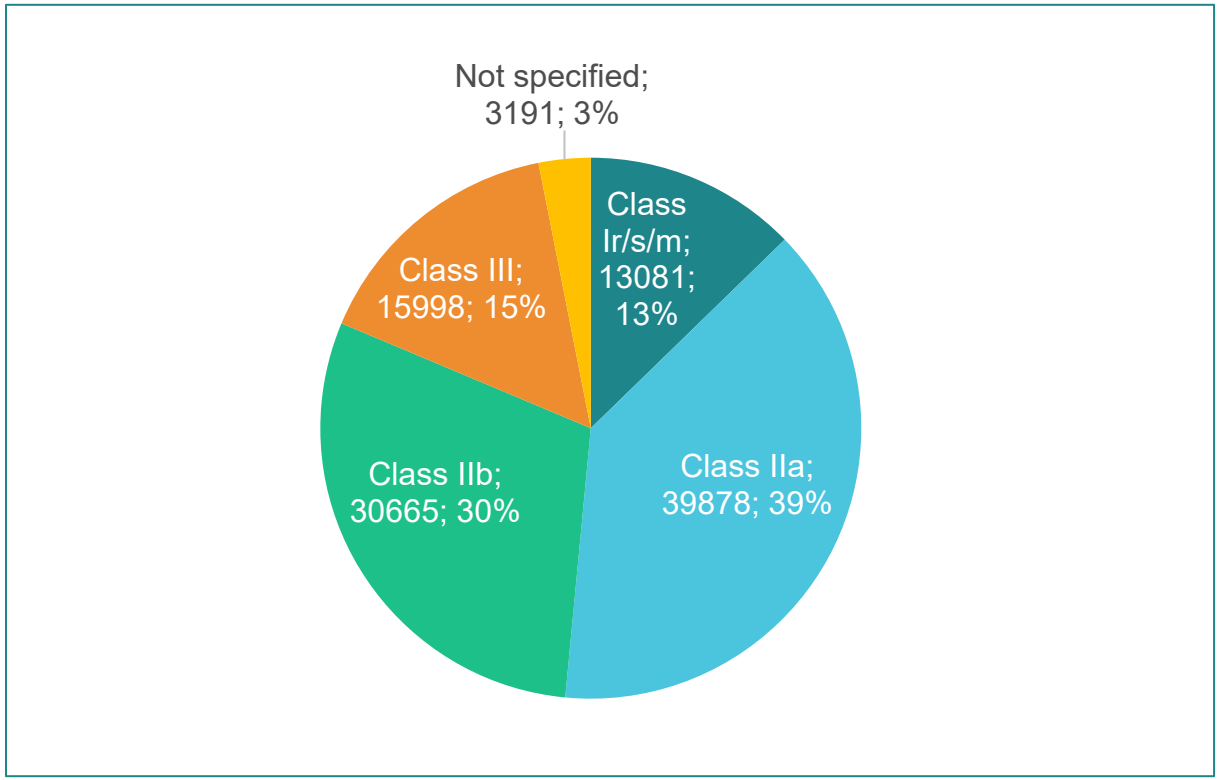
MD undergoing MDR conformity assessment by October 2024

MD

Total number of devices (by catalogue number) undergoing MDR conformity assessment (accepted MDR applications still under review by NB) by end of October 2024: 102813

(Data of 161 MFs, including 37 MFs with the indication '0')

By risk class:



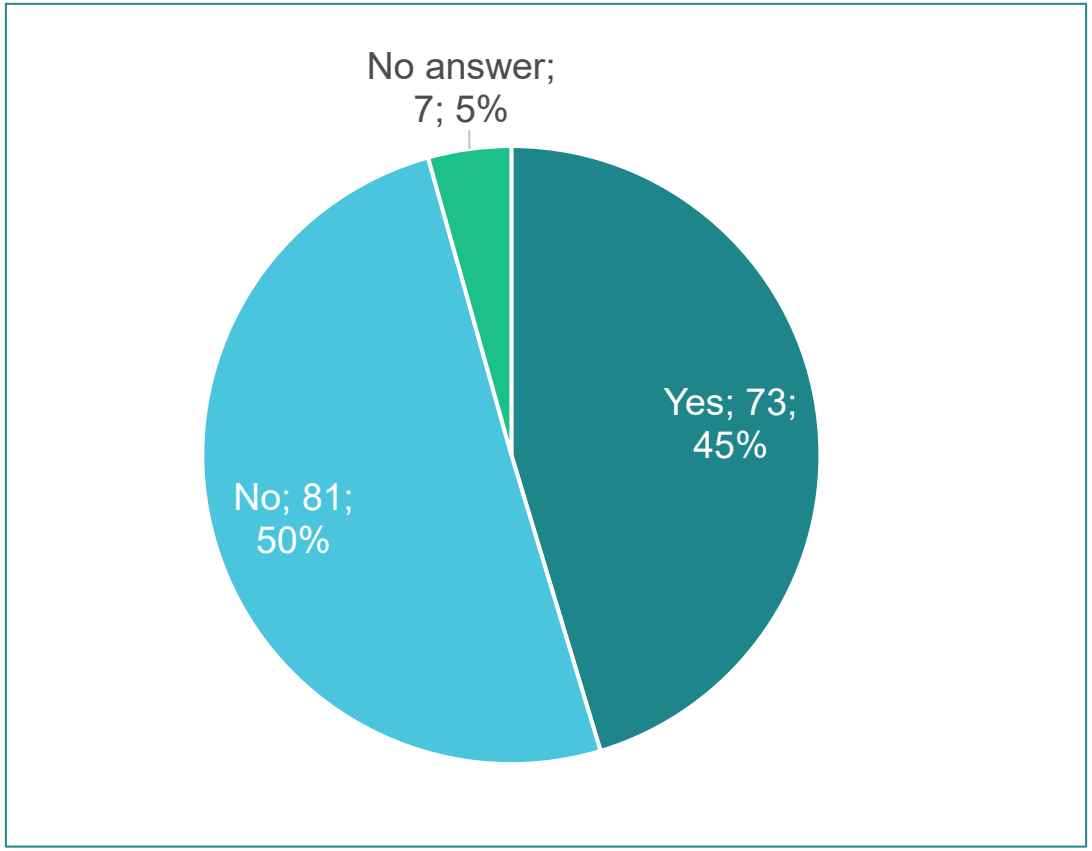
European Commission

MD

Certificates issued to MD MF under MDR

Total responses from 161 MFs for MDs

Have you already received certificates under the MDR to date up to 31/10/2024 (n=161)?



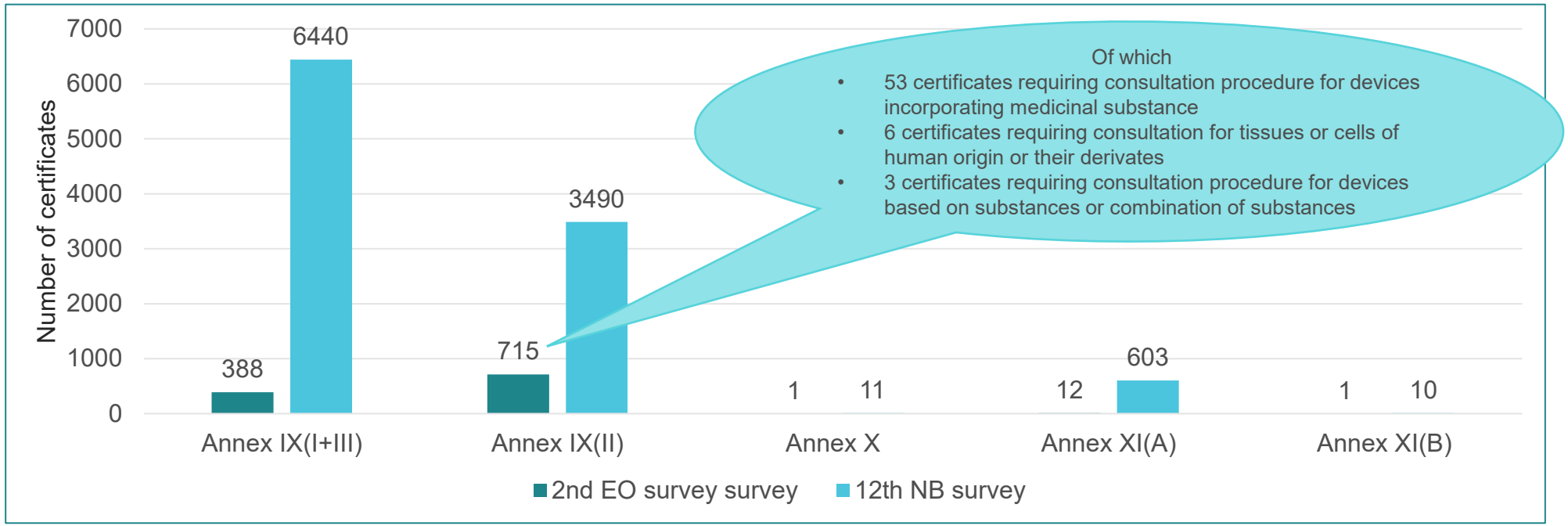
European Commission

MD

Certificates issued to MD MF under MDR

Number of certificates issued to MF for MDs under MDR by Annex by end October 2024

For comparison data of the 12th NB survey (covering the same data period until 31/10/2024): 10.554*
* 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 72 MD MF; 1 MF did not specify the Annex

Total number of certificates: 1.117

European Commission

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

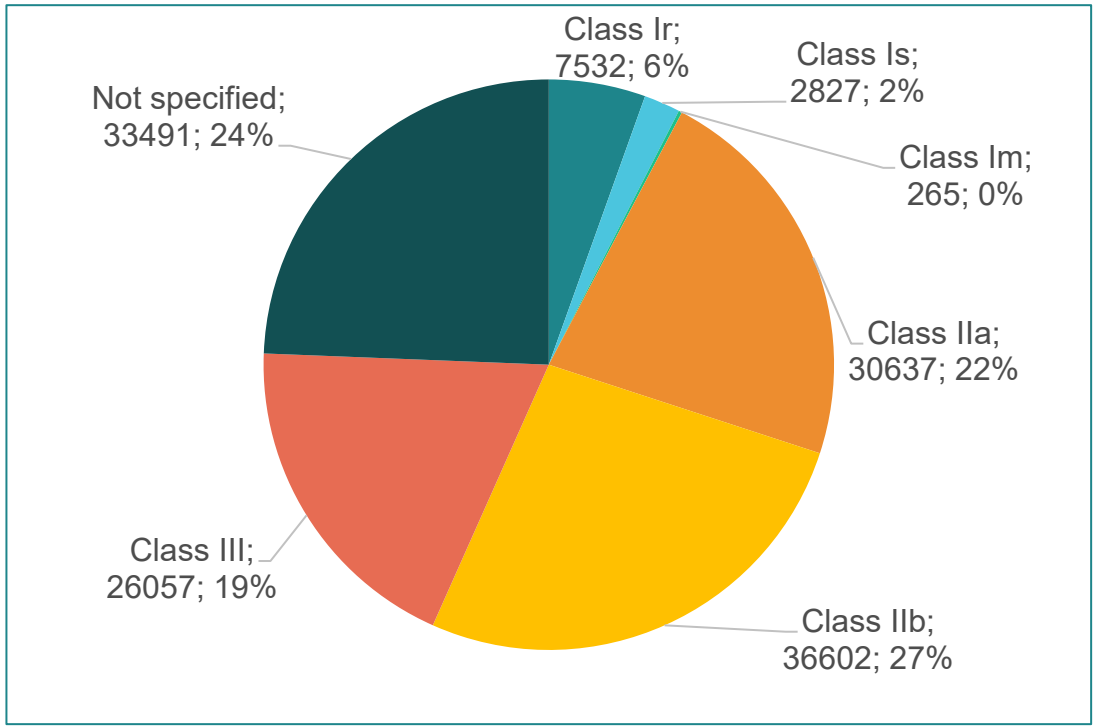
MD

Number of devices (catalogue numbers) covered in MDR certificates issued by end of October 2024: 137.411

of which new devices[1]: 5007 (3,6%)
- novel devices[2]: 4
- break-through devices[3]: 0

[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=5
[3] For the purpose of this survey, a medical device or IVD will be considered a breakthrough medical device or IVD (BTxMD or BTxIVD) if it meets the following criteria:
• Unmet Need: The device is intended for use in the treatment, diagnosis, or prevention of life-threatening or irreversibly debilitating conditions, and there are no alternative therapies or current options are significantly inferior. The device demonstrates potential to address a critical public health need, reduce morbidity, or drastically improve clinical outcomes for patients.
• Clinical Benefit: The device offers substantial improvements in patient outcomes compared to existing solutions, in terms of clinical effectiveness, safety, or quality of life.
• Innovative Design or Technology: The device incorporates a novel technology, such as AI, robotics, or next-generation diagnostics, that is not yet widely available on the market.
No dedicated breakthrough pathway available under MDR

By risk class:



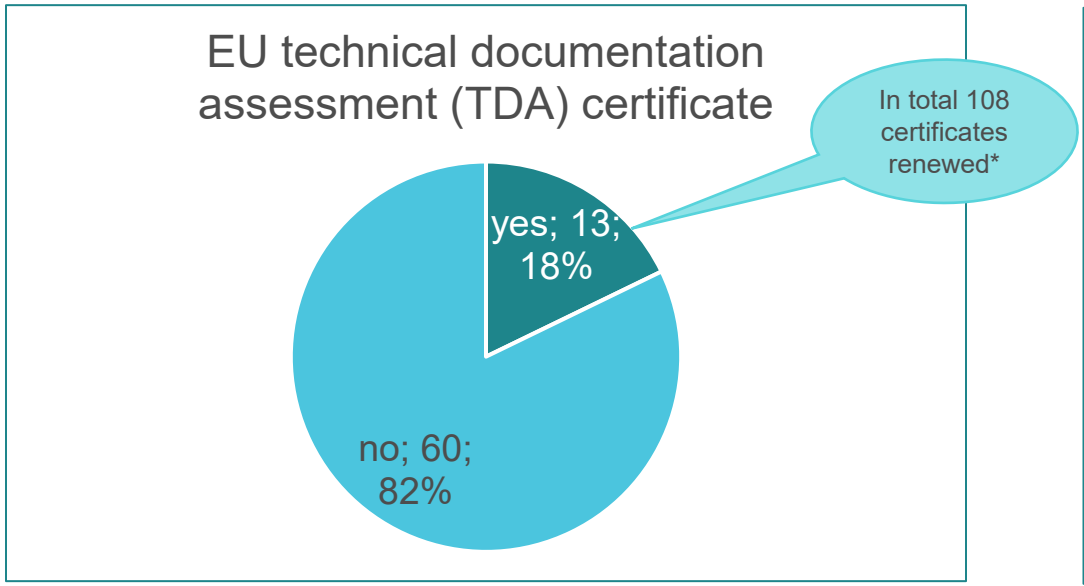
Note: n=73 MF

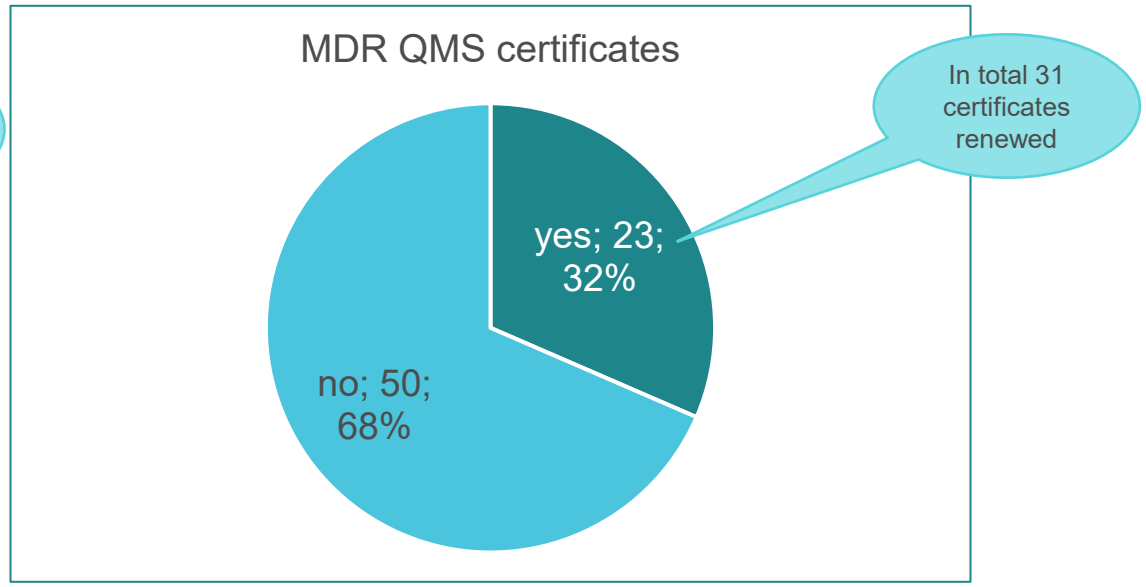
European Commission

MD

Re-certification (1)

Did you already have a certificate renewed under the MDR? (n=73 out of 161 companies that answered YES to Q16)





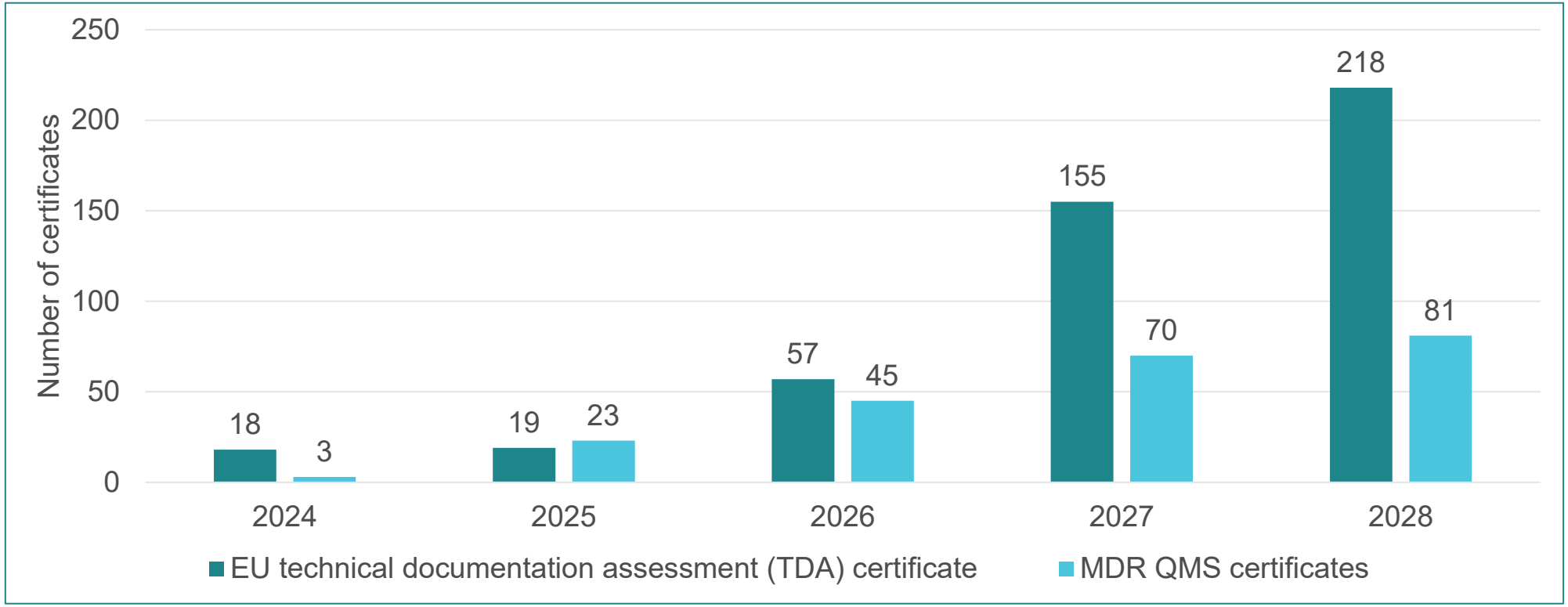
Note: * 1 company reported 96 renewed certificates.

European Commission

MD

Re-certification (2)

Number of certificates expiring and due for re-certification in 2024-2028 (n=73 companies that answered YES to Q16)



For comparison data of the 12th NB survey: total number of MDR certificates by 31/10/2024: 10.554

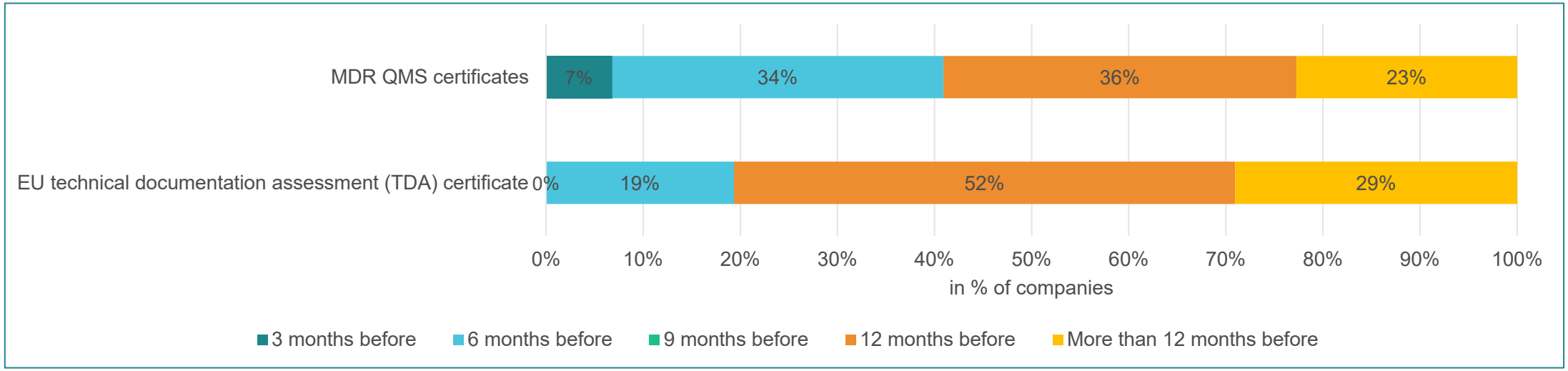
Note: Data of 73 MF including 9 with the indication '0' in all 5 years

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?



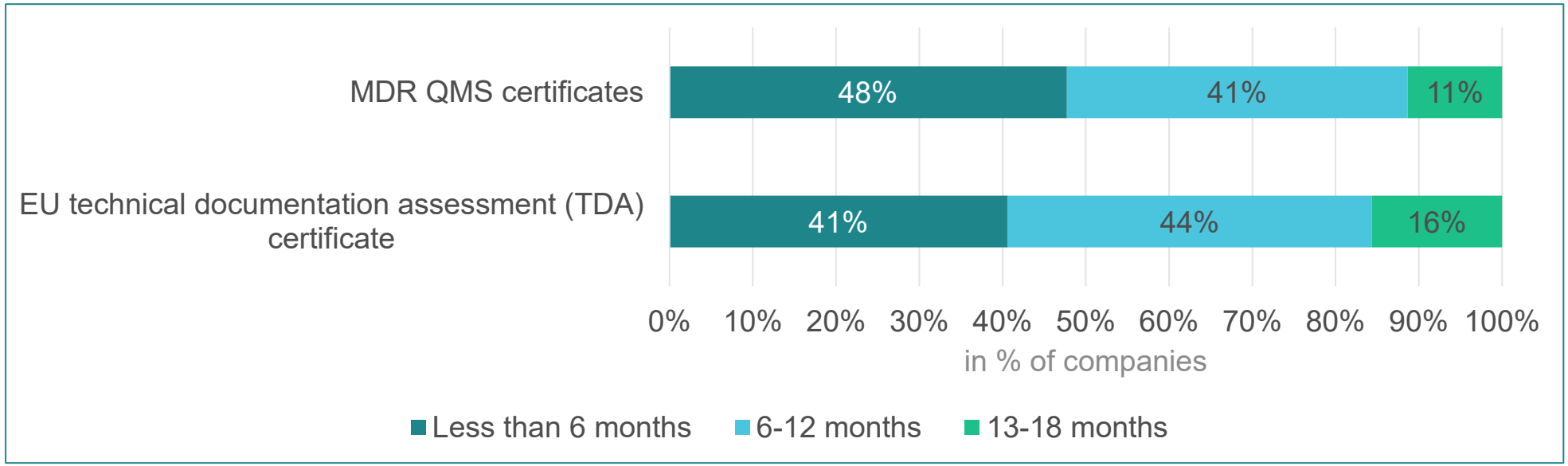
Note: Data of 73 MF
For MDR QMS certificates 29 companies indicated 'no information available'
For EU TDA certificates 42 companies 'no information available'

European Commission

MD

Re-certification (4)

What is the average time taken to prepare a re-certification dossier (before submission)?



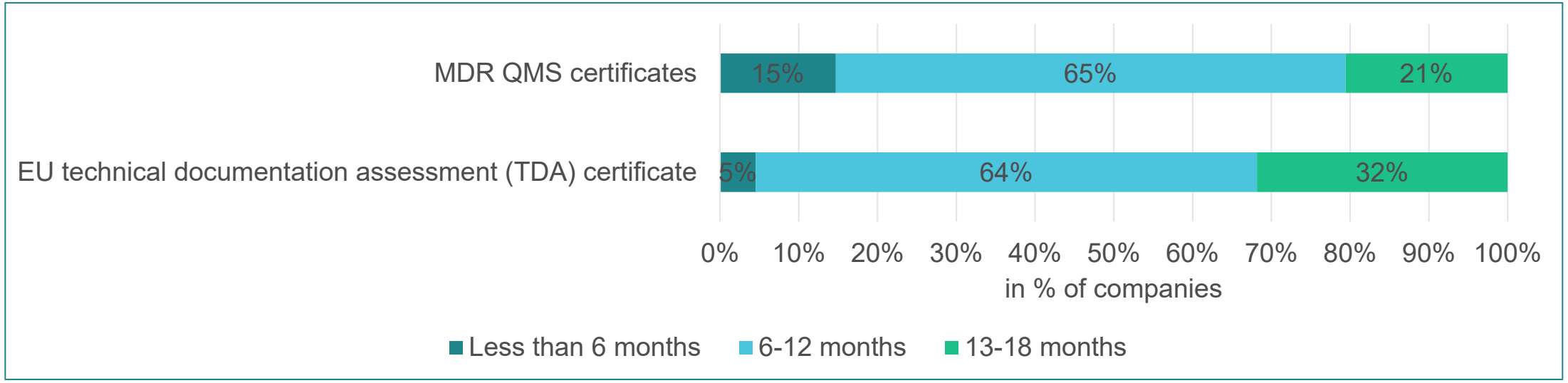
Note: Data of 73 MF
For MDR QMS certificates 29 companies indicated 'no information available'
For EU TDA certificates 41 companies 'no information available'

European Commission

MD

Re-certification (5)

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



Note: Data of 73 MF
For MDR QMS certificates 39 companies indicated 'no information available'
For EU TDA certificates 51 companies 'no information available'

European Commission

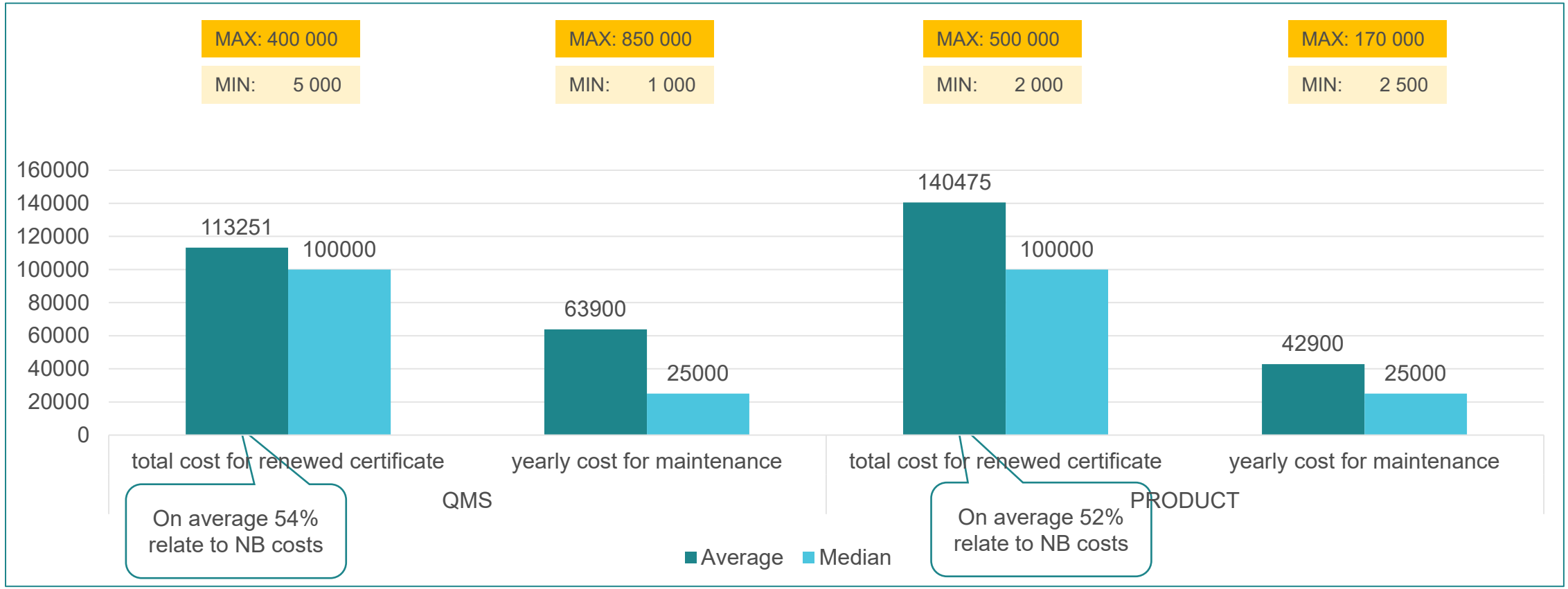
Costs of the last renewed certificate issued (between 01/01/2022-31/10/2024) in EURO

MD

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).
For MDR QMS certificates (Annex IX(I+III), Annex XI Part A) data of 7 companies; 4 companies indicated that all costs relate to NB costs, three companies indicated that on average 60% relate to NB costs and 40% to internal costs. For maintenance: 5 MFs taken into account with responses >0.
For MDR product certificates (Annex IX(II), Annex X, Annex XI Part B) data of 5 companies; 4 companies indicated that all costs relate to NB costs, one company indicated 40% of the cost relate to NB and 60% to internal costs. For maintenance: 5 MFs taken into account with responses >0

MD

Estimations of costs of re-certification

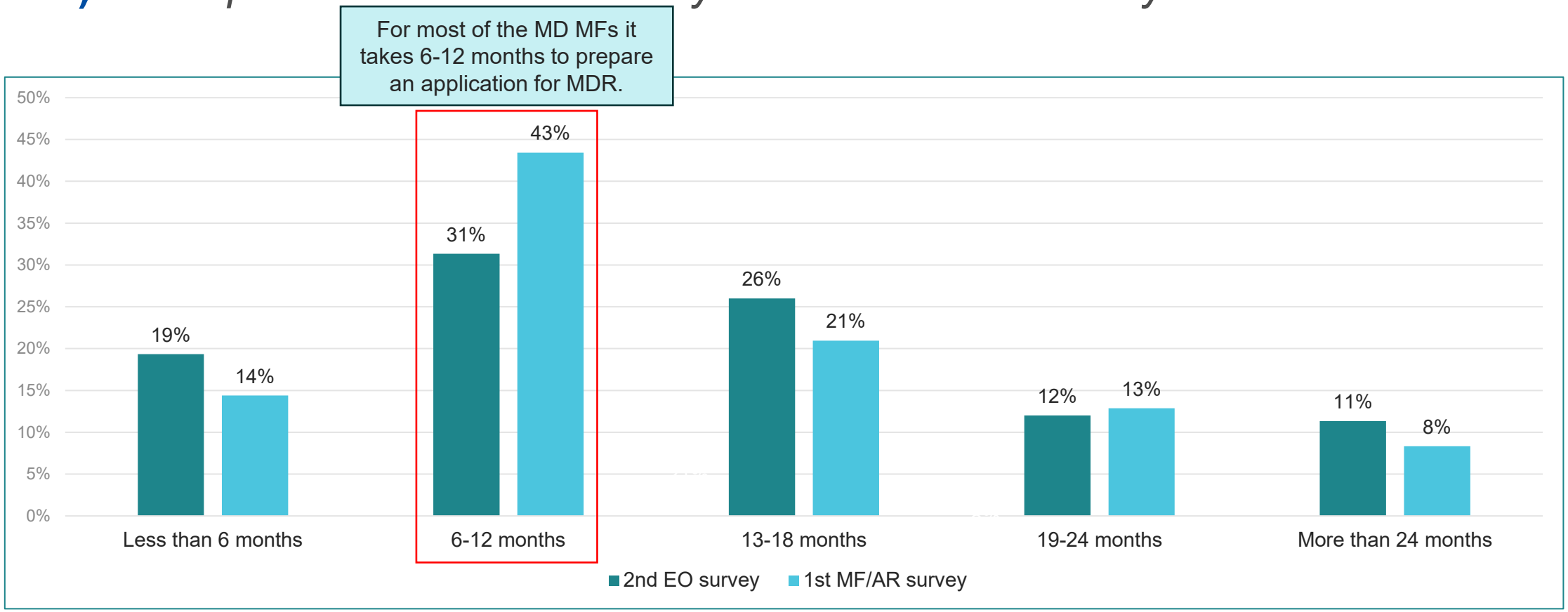


Notes: In case companies have not received a renewed certificate, they could indicate an estimation.
iIt is possible that MD MF have interpreted this question differently. Some MD MF provided ‚zero' as the questionnaire asked to do so, if no information is available. For this reason ‚zeros' are exluded (with the risk of overestimation).
For MDR QMS certificates (Annex IX(I+III), Annex XI Part A) data of 37 companies; 7 companies indicated that all costs relate to NB costs, 30 companies indicated that on average 54% relate to NB costs and 46% to internal costs. For maintenance: 33 MFs taken into account with responses >0.
For MDR product certificates (Annex IX(II), Annex X, Annex XI Part B) data of 20 companies; 5 companies indicated that all costs relate to NB costs, 15 companies indicated on average 52% of the cost relate to NB and 48% to internal costs. For maintenance: 15 MFs taken into account with responses >0

MD

Time periods (1)

Average time to prepare an application for MDR (before submission to a NB) – *comparison of 2nd EO survey with 1st MF/AR survey*



Note:

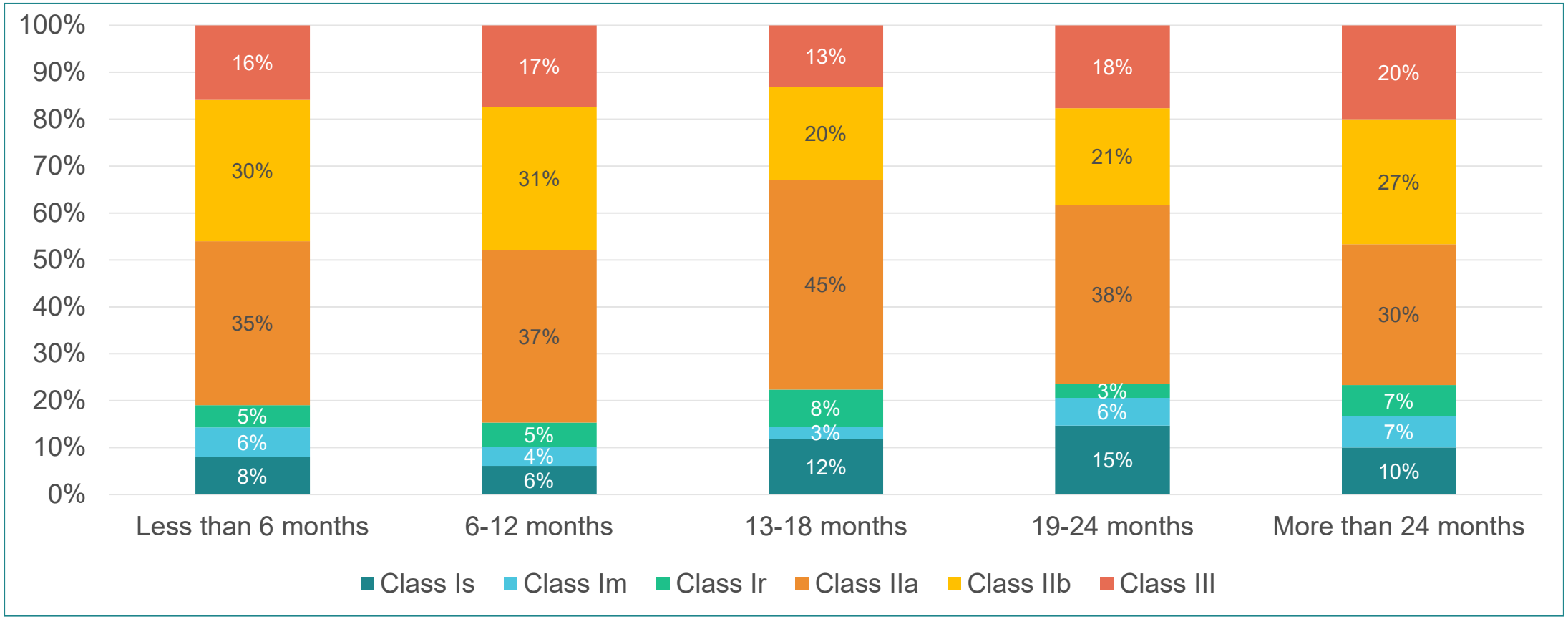
- **2nd EO survey:** Replies of 150 MD MFs, 11 MFs indicated 'no information available'
- **1st MF survey:** Replies of 396 MD MFs, 105 MFs indicated 'no information available'

European Commission

Time periods (2)

MD

Which device risk classes are included in this average time calculation ?



Note:

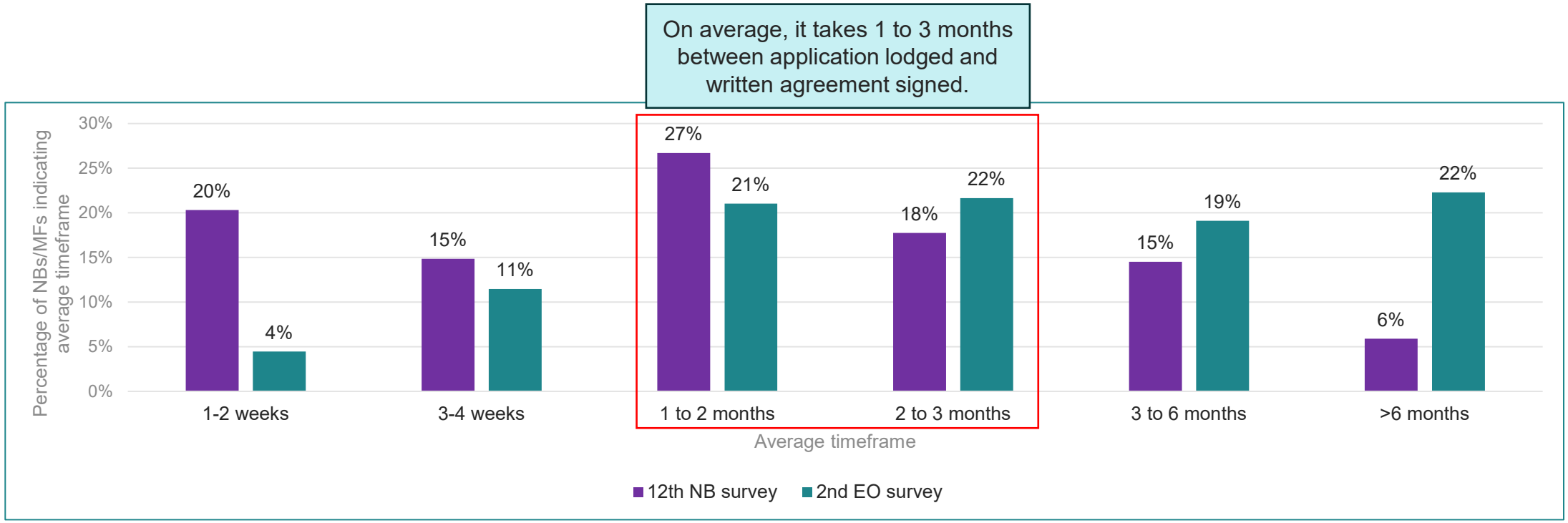
- **2nd EO survey:** Replies of 150 MD MFs, 11 MFs indicated 'no information available'

European Commission

MD

Time periods (3)

Average timeframe between application lodged and written agreement signed – *comparison of 2nd EO survey with 12th NB survey*



Notes:

- **12th NB survey:** Replies of 50 NBs designated under MDR; data collection method: NBs indicated the number of files for each category which was converted into percent per category
- **2nd EO survey:** Replies of 157 MD MFs; data collection method: EOs selected one time period

European Commission

Time periods (4)

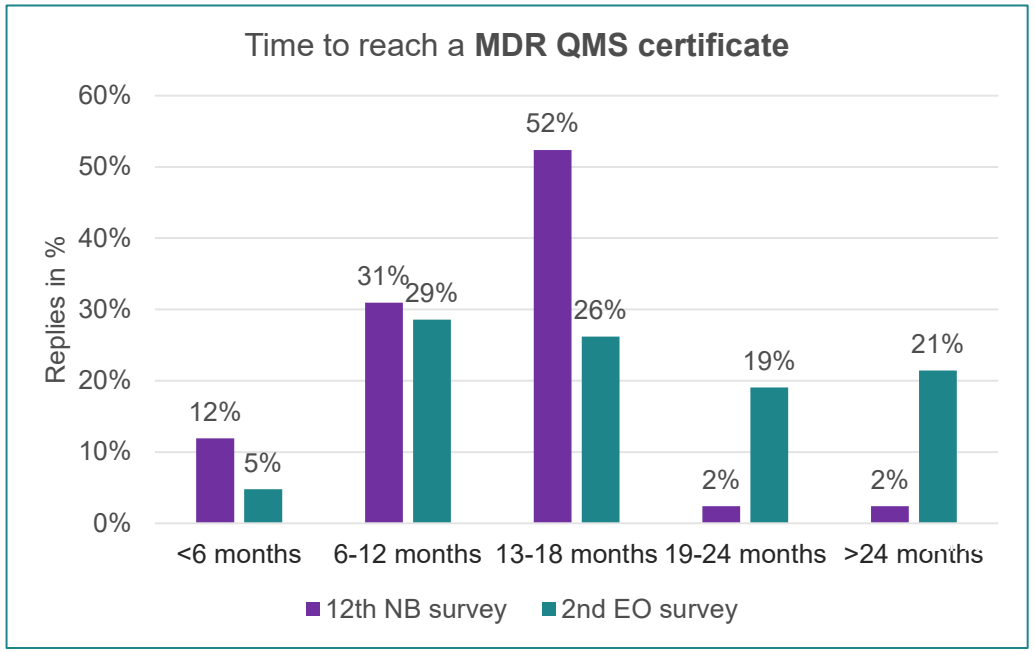
Total responses from 161 MFs for MDs

MD

Average time to reach/issue MDR certification for devices

(from written agreement signed to issuance) – *comparison of 2nd EO survey with 12th NB survey*

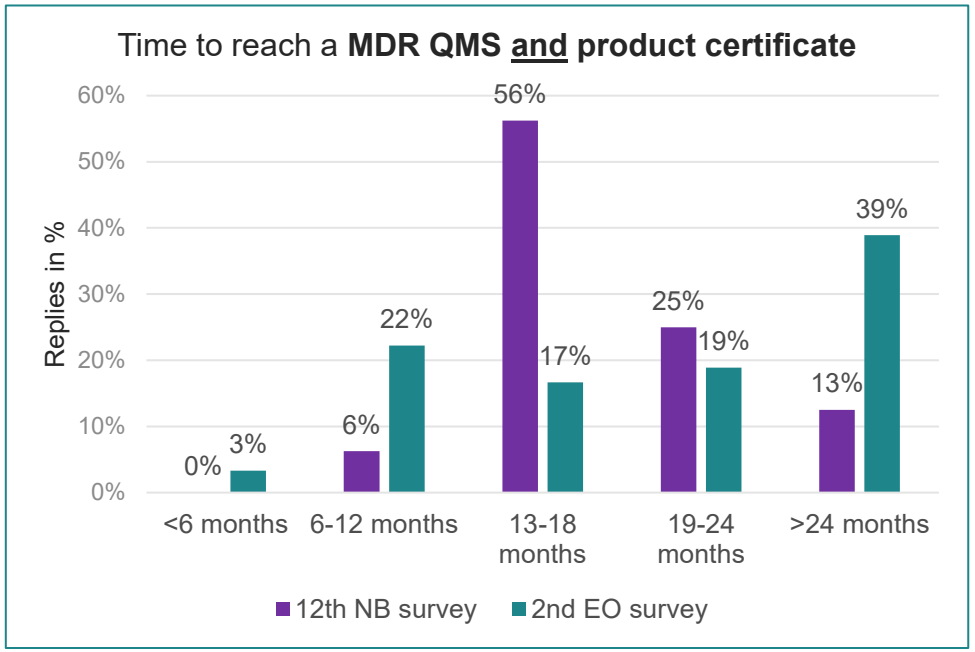
52% of the NBs indicated 13-18 months.
55% of the MD MFs indicated 6-18 months.



Notes QMS certificates:

- **12th NB survey:** QMS: Data of 42 NBs designated under MDR (covering the same data period until 31/10/2024)
- **2nd EO survey:** Data of 84 MD MFs; 76 MFs indicated 'no information available'

56% of the NBs indicated 13-18 months.
58% of the MD MFs indicated more than 19 months.



Notes QMS and product certificates:

- **12th NB survey:** QMS+PRODUCT: Data of 32 NBs designated under MDR (covering the same data period until 31/10/2024)
- **2nd EO survey:** Data of 90 MD MFs; 70 MFs indicated 'no information available'

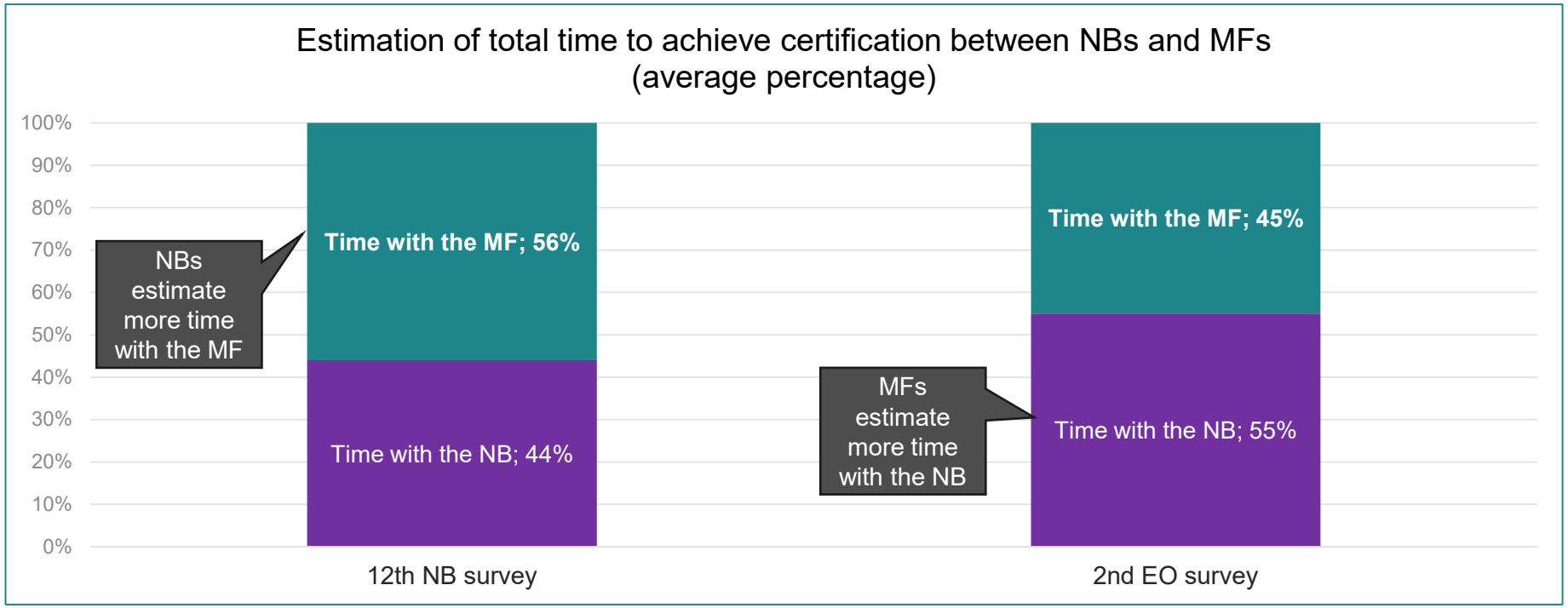
European Commission

Estimation of the total time* to achieve certification between NB and MF

– *comparison of 2nd EO survey with 12th NB survey*

MD

* from written agreement signed to issuance of a new certificate



Notes:

- Data of 32 NBs designated under MDR; data of 145 MD MFs (the other 16 MD MF indicated that they don't know it)
- This indicator shows an estimate of the allocation of the total time to certification (from signing the written agreement to issuance) between the notified body and the manufacturer.
- Time with the NB means time for checking the documents including application and technical documentation.
- Time with the MF means time for revising the documents including application and technical documentation.

MD

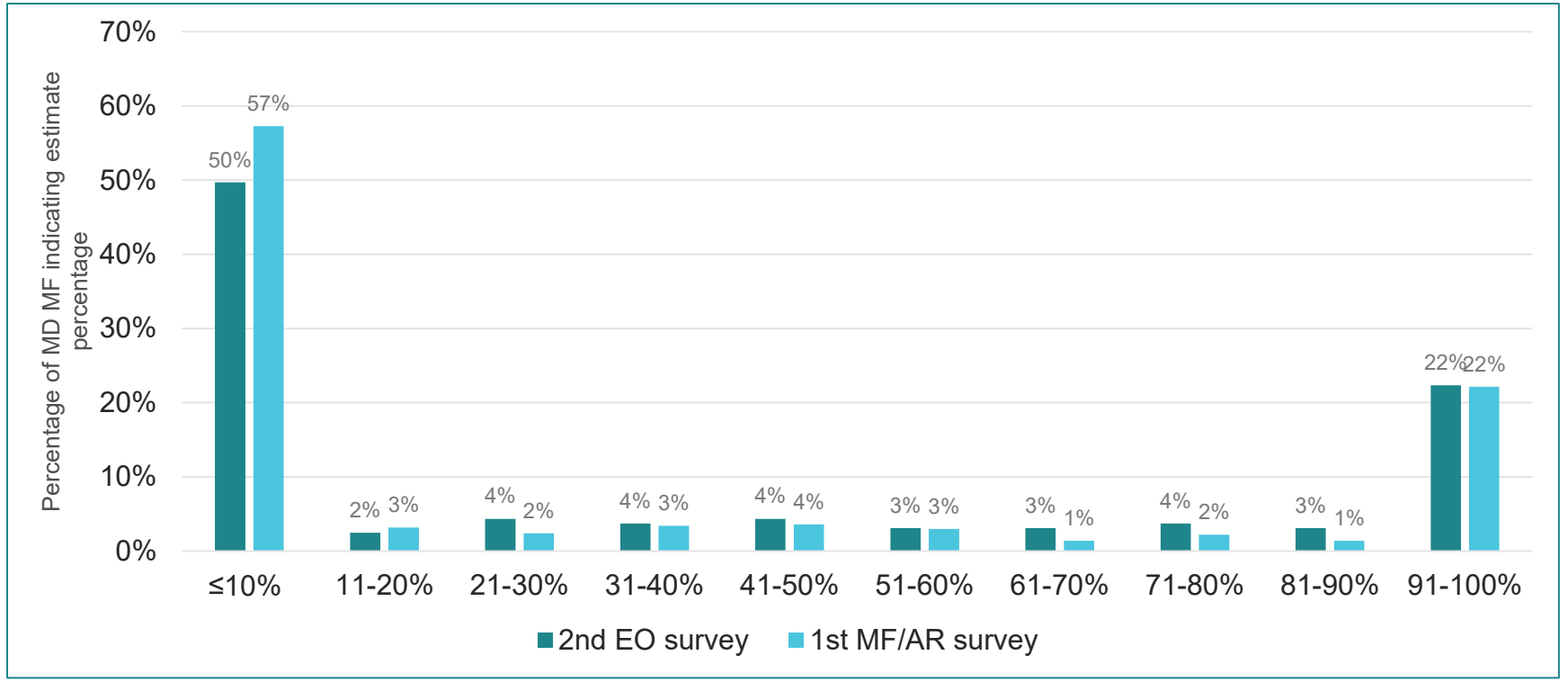
Estimates
Completed transition

MD

Completed transition

Estimate percentage of product portfolio foreseen for transition already having MDR certification (n=161)

Total responses from 161 MFs for MDs



- **22%** of the MF indicated that more than **90 % of their portfolio** that requires an MDR certificate, is already MDR certified (2023: 22%)
- **50% of the MF indicated that less than 10% of their product portfolio requiring MDR certification has transitioned (2023: 57%)**

(in brackets the results of the 1st MF/AR survey – situation up to 31/10/2023; replies of 501 MFs for MDs)

European Commission

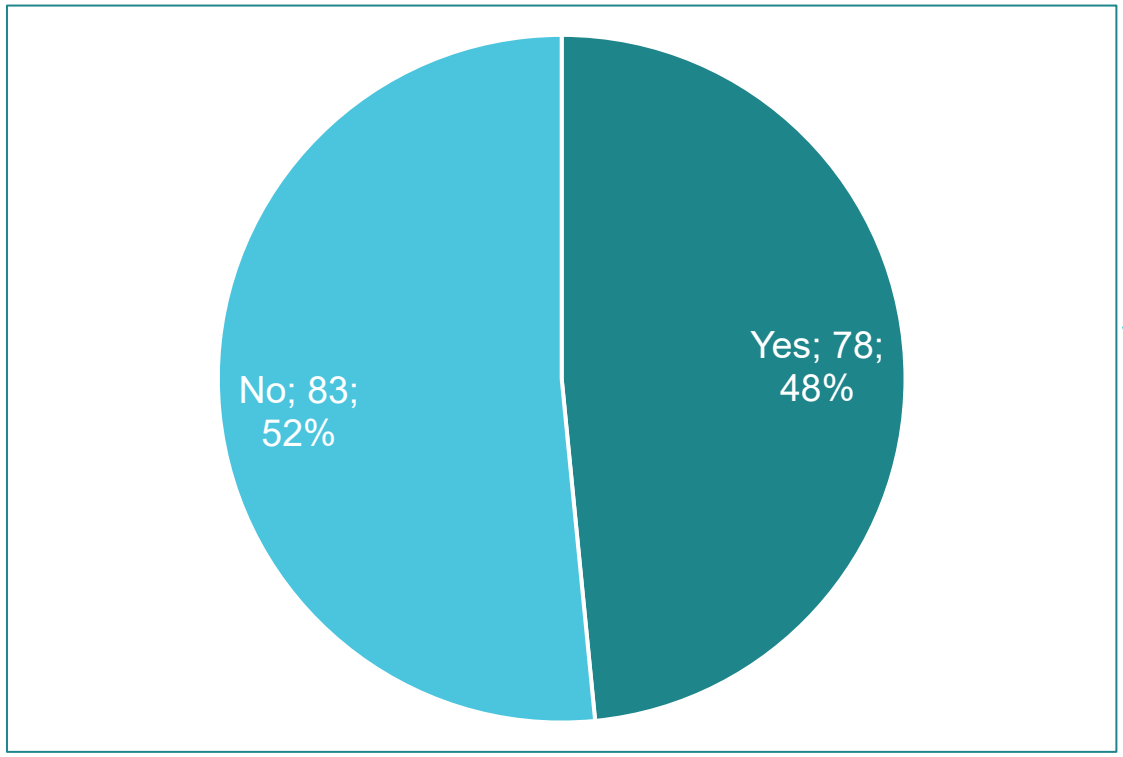
MD

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=161)



If yes, 12% of the MFs (9/78) 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.

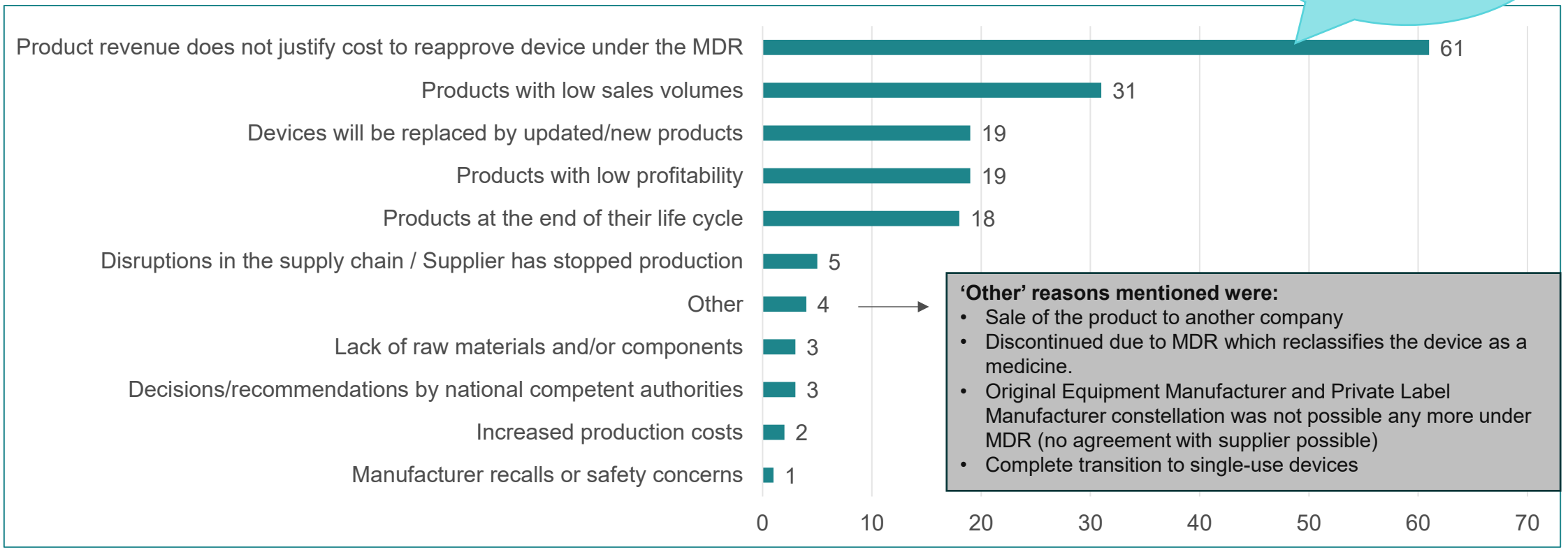
European Commission

MD

Discontinuation of medical devices (2)

Main reasons for product discontinuation

78% of the MFs indicated this as one of the main reasons.



'Other' reasons mentioned were:

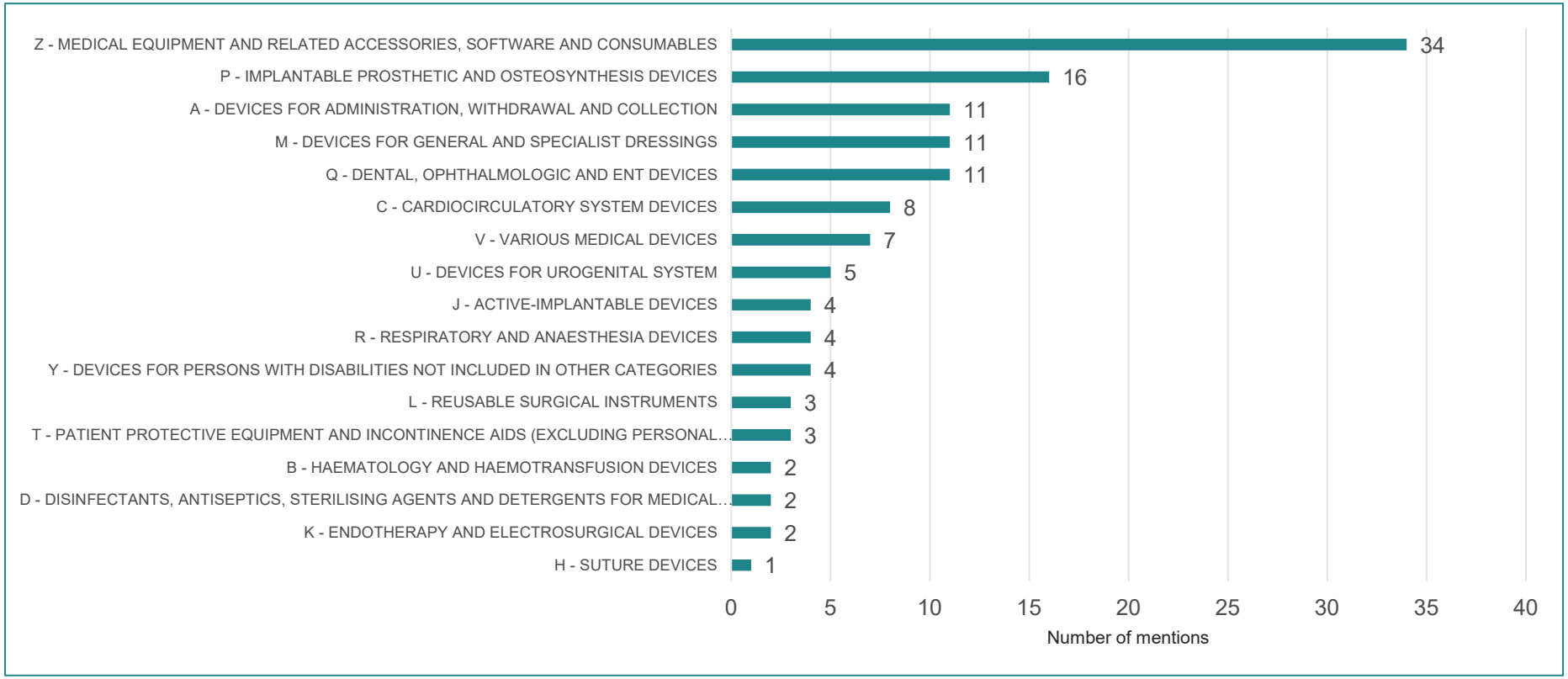
- Sale of the product to another company
- Discontinued due to MDR which reclassifies the device as a medicine.
- Original Equipment Manufacturer and Private Label Manufacturer constellation was not possible any more under MDR (no agreement with supplier possible)
- Complete transition to single-use devices

Notes: Number of mentions by 78 MFs having discontinued some products, i.e. having answered question on previous slide with YES. Multiple answers per MF possible;

European Commission

MD

Discontinuation of medical devices (2)



Types of MDs (by EDMN code) discontinued

Notes: Number of mentions by 78 MFs having discontinued some products, i.e. having answered question 33 with YES. Multiple answers per MF were possible.
Several answers had to be disregarded due to unclear EMDN code.

European Commission

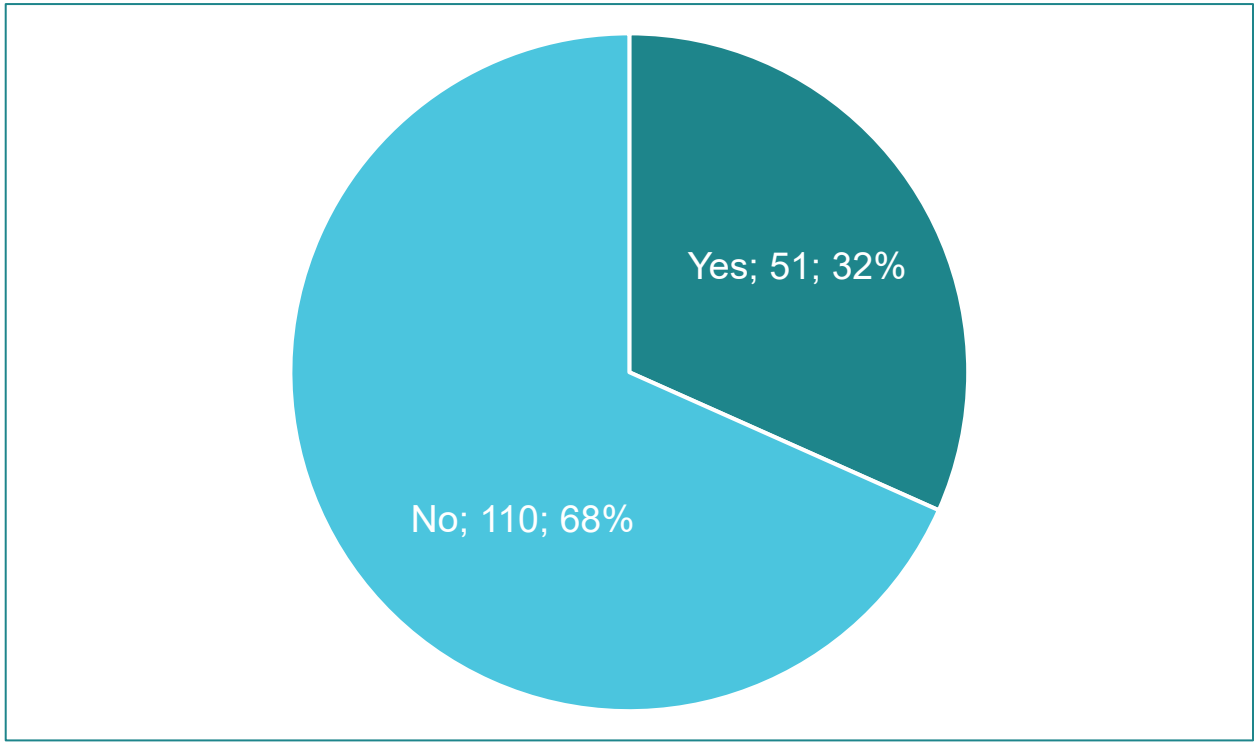
MD

Preparedness of manufacturers

MD

Preparedness of manufacturers

Did the revised transitional periods for MDR (Regulation (EU) 2023/607) have an impact on your company's decisions to transfer your product portfolio to MDR? (i.e. in general allowing more products to be transitioned) (n=161)



European Commission

IVD

2.3. Survey results for in vitro diagnostic medical devices

Questionnaire part 2.3. including questions 40 to 72

Note: Answers to the following questions are not provided in this presentation as they are part of the targeted evaluation: 59, 68 to 72

Q44
Q47

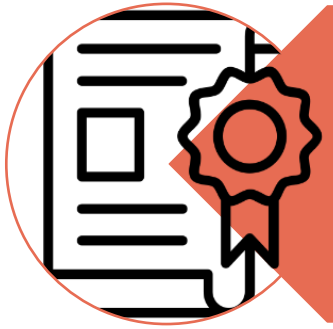
Overview on applications and certificates by end of October 2024

IVD

Number of applications lodged under IVDR: **1246***

12th NB survey
(covering the same data period until 31/10/2024):

2201
(MF sample: 57% were potentially covered in this survey)



Number of certificates issued for IVDs under IVDR: **423**

1273
(MF sample: 33% were potentially covered in this survey)

Note: These figures relate to the responses from 60 manufacturers of IVDs as of the end of October 2024.
No. of applications: data of 41 IVD MF, 19 IVD MF with “0” applications.
No. of certificates: data of 27 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.

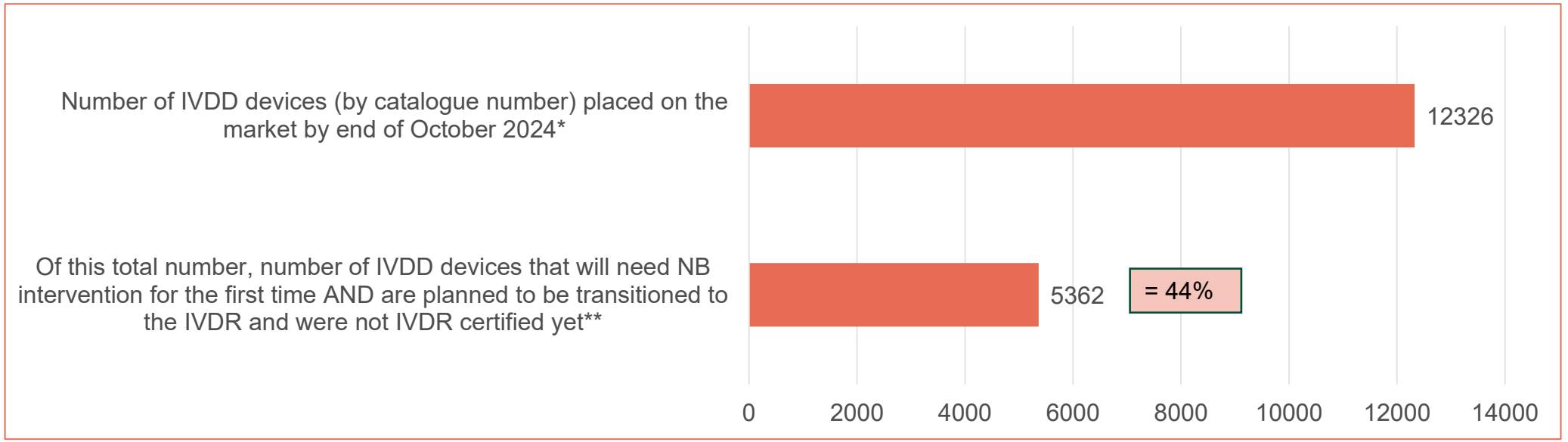
Q40
Q40.2
Q41

IVDD overview by the end of October 2024

IVD

Total responses from MFs for IVDs: 60

Total number of valid IVDD certificates by end of October 2024: **668**
(Data from 60 MFs, including 23 MFs with the indication '0')



Notes:
* Data from 60 MFs, including 4 MFs with the indication '0';
** Data from 60 MFs, including 10 MFs with the indication '0';

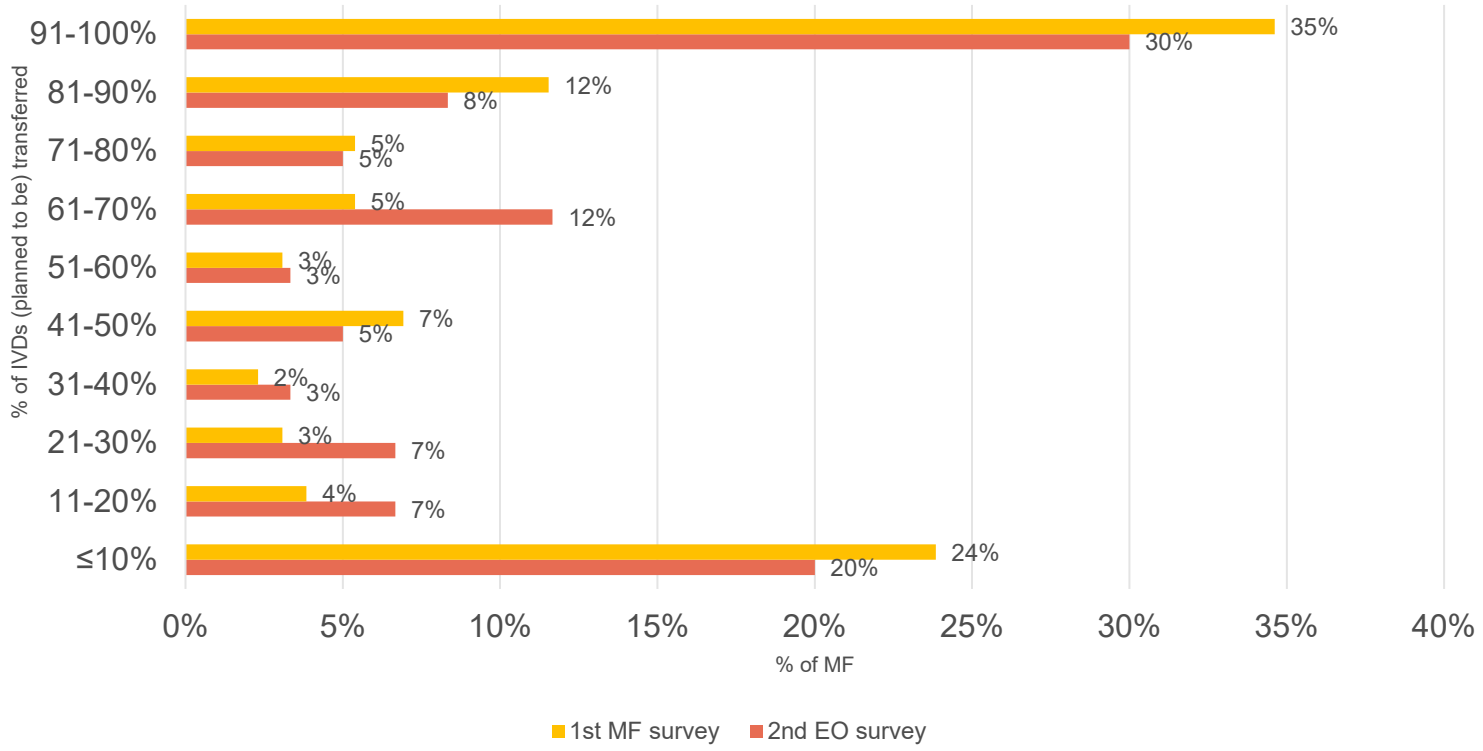
European Commission

Details on IVDD devices transition status to IVDR

IVD

Total responses from MFs for IVDs: 60

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



- 30% of the MFs of IVDs (18/60) indicated that 91-100% of IVDs have already been transferred to IVDR
- 35 MFs (58%) reported that more than 50% of their devices are already transferred or are planned to be transferred to IVDR
- 12 out of 60 MFs of IVDs (20%) 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

European Commission

IVD

Notified bodies
written agreements, refused applications

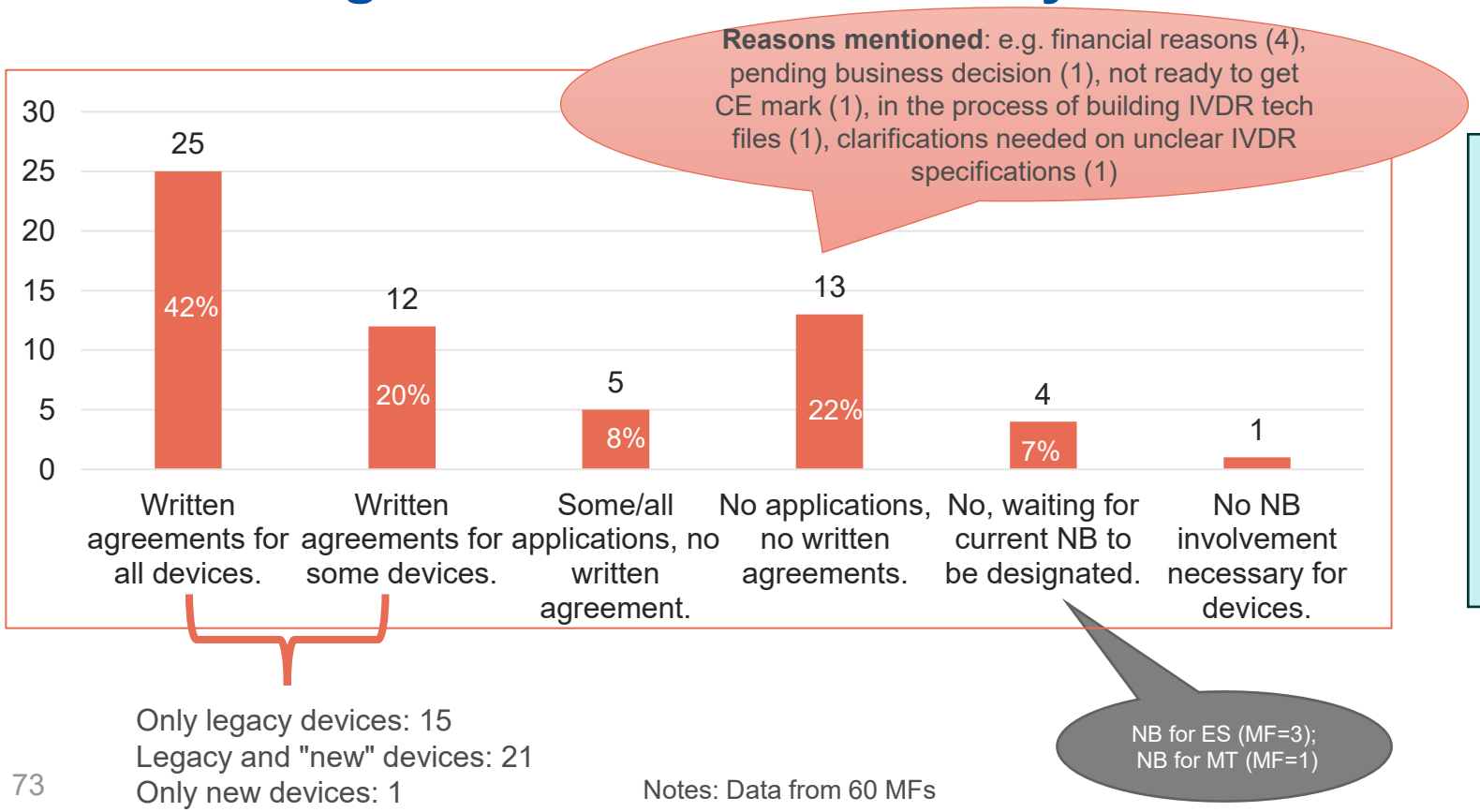
Q42

Written agreements between MFs of IVDs with Notified Bodies

IVD

Total responses from MFs for IVDs: 60

Number of companies with written agreements with a notified body/notified bodies designated under the IVDR by the end of October 2024



More than 60% of the companies have one or more **written agreements with one or several NBs:**

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

(in brackets the results of the 1st MF/AR survey – situation up to 31/10/2023; replies of 130 MFs for IVDs)

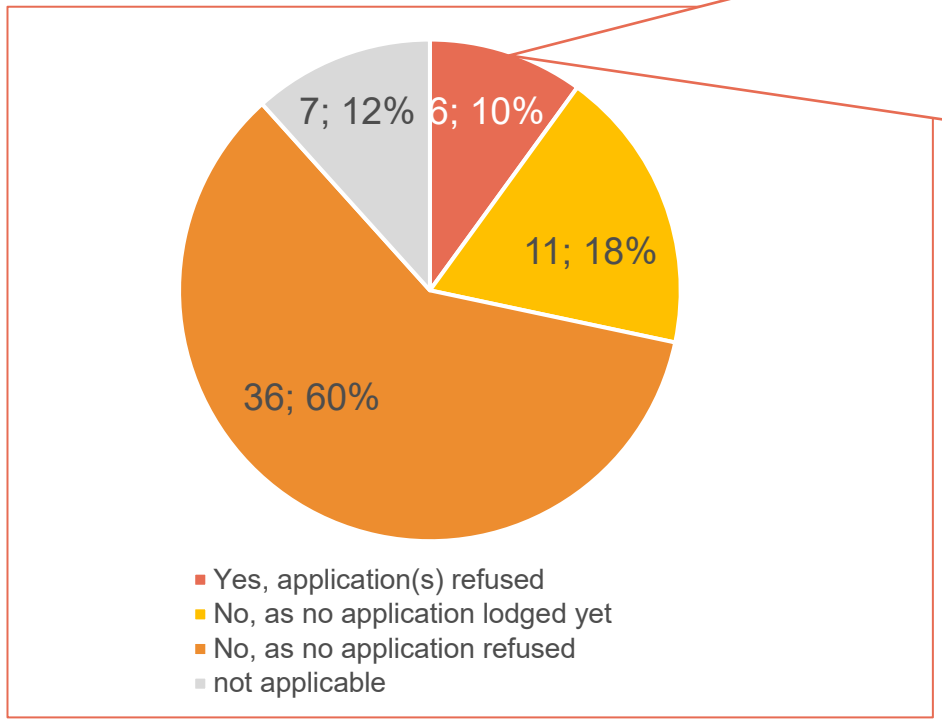
Notes: Data from 60 MFs

European Commission

Refusal of applications by Notified Bodies (1)

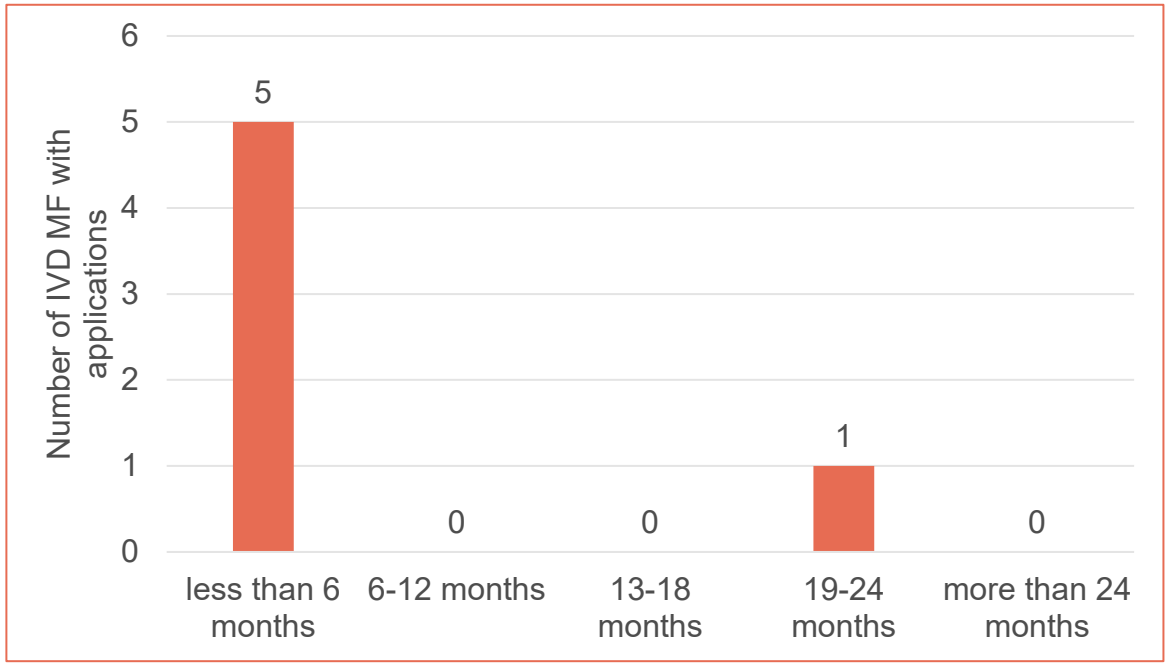
IVD

Did a notified body refuse an application under the IVDR? (n=60)



If yes

Average time passed since application was sent until refusal



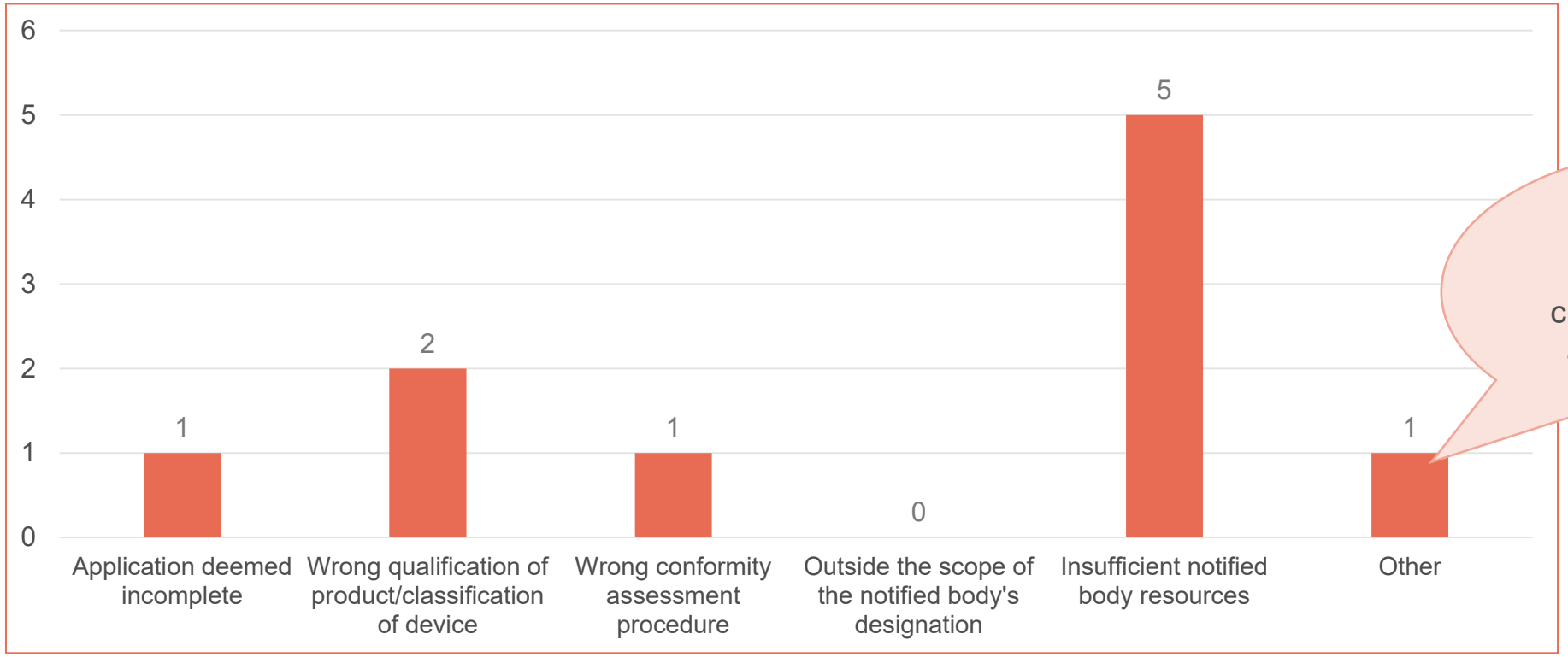
European Commission

Refusal of applications by Notified Bodies (2)

IVD

Reasons for refusal (n=6 companies reporting 10 refused applications)

Refusals were reported only for legacy devices



Other reason mentioned: Not compliant with the current state of the art acc. to the common specification

European Commission

IVD

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

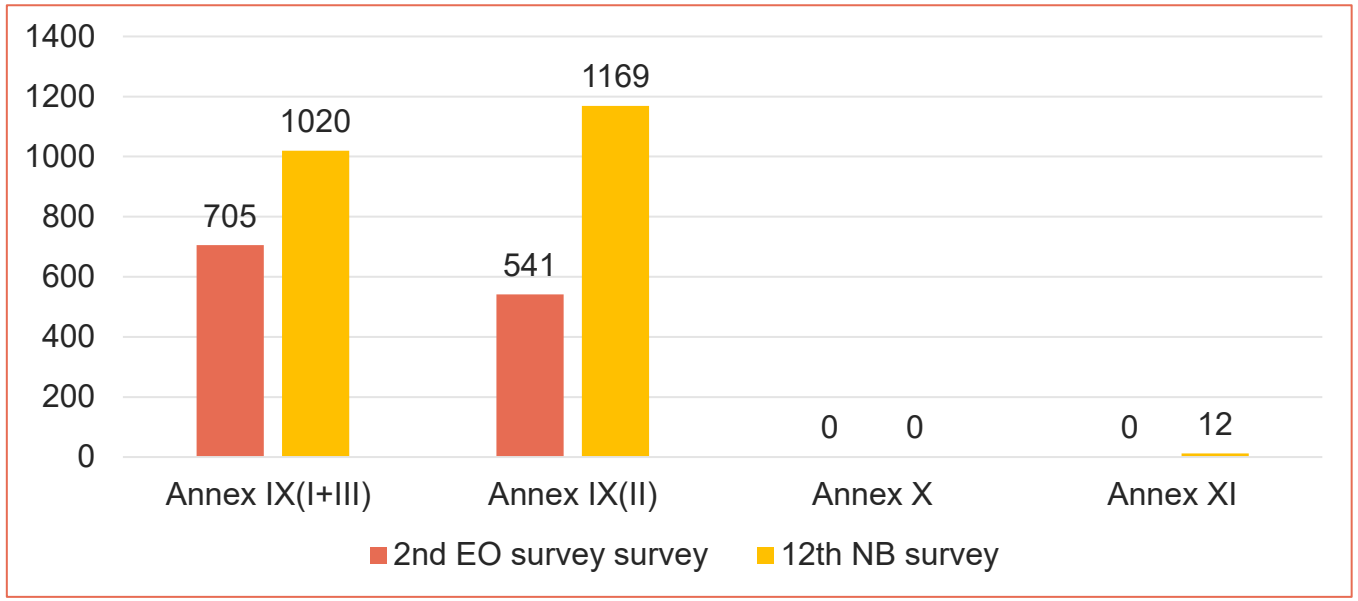
Applications lodged under IVDR by end October 2024

IVD

Total responses from MFs for IVDs: 60

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:** 295
- **Applications (all Annexes) requiring consultation for companion diagnostics:** 32

For comparison data of the 12th NB survey (covering the same data period until 31/10/2024): Total number of applications filed by Annex Ⓜ: **2.201**

Total number of applications: 1246

(thereof 314 (25%) applications for change)

Notes: Data of 41 IVD MF, 19 IVD MF with "0" applications.

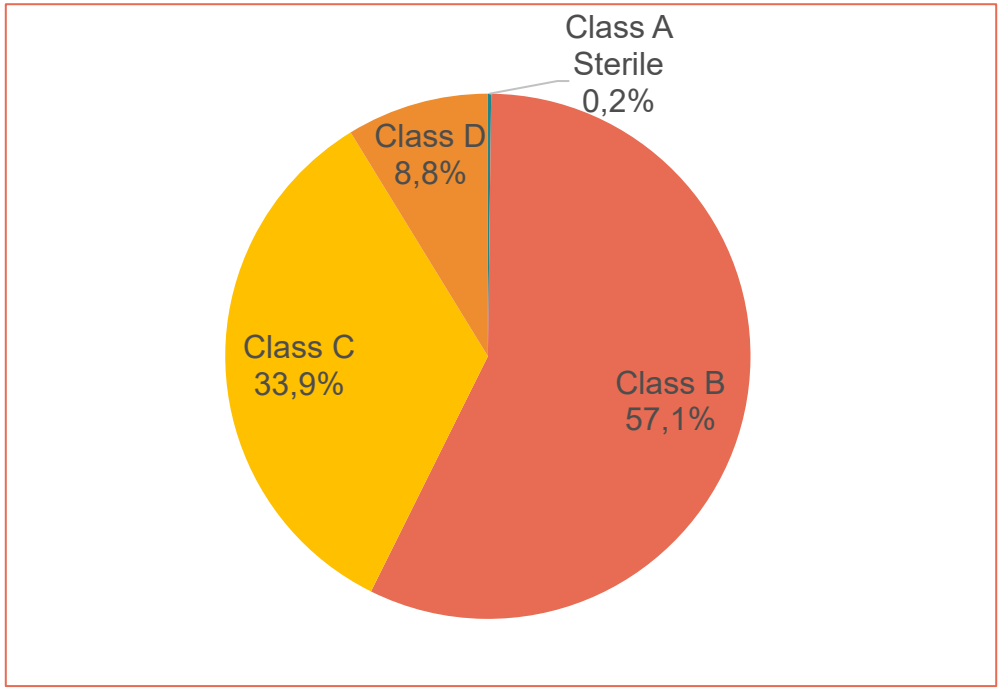
European Commission

IVDs undergoing IVDR conformity assessment by October 2024

IVD

Total number of devices (by catalogue number) undergoing IVDR conformity assessment (lodged IVDR applications still under review by NB) by end of October 2024: 1646
(Data of 60 MFs, including 27 MFs with the indication ‘0’)

By risk class:



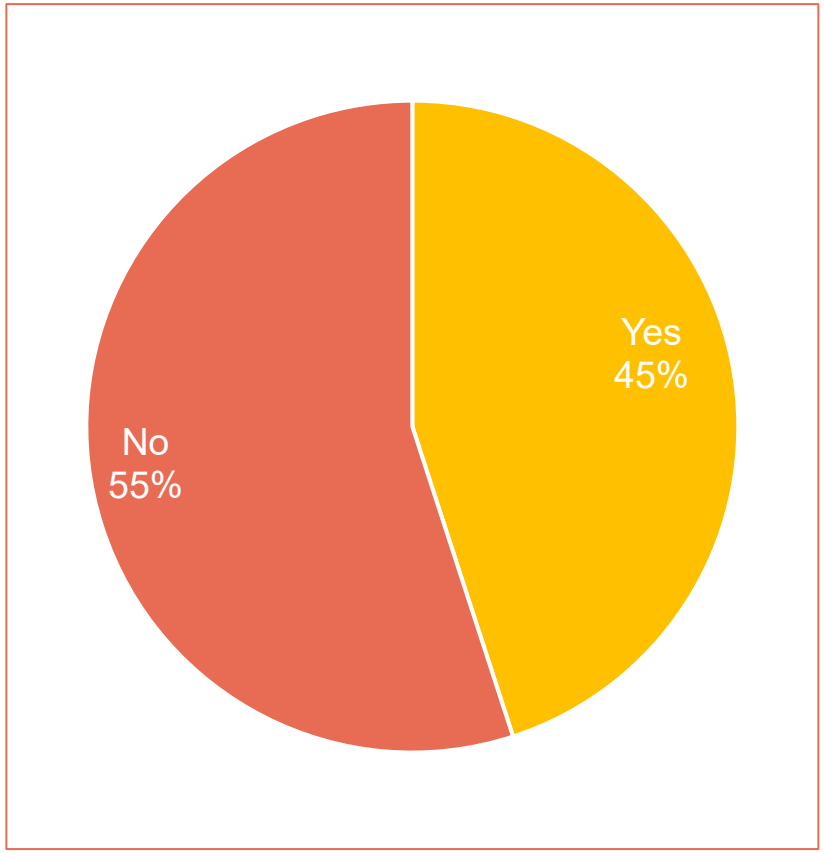
European Commission

IVD

Certificates issued to IVD MF under IVDR

Total responses from 60 MFs for IVDs

Have you already received certificates under the IVDR to date up to 31/10/2024 (n=60)?

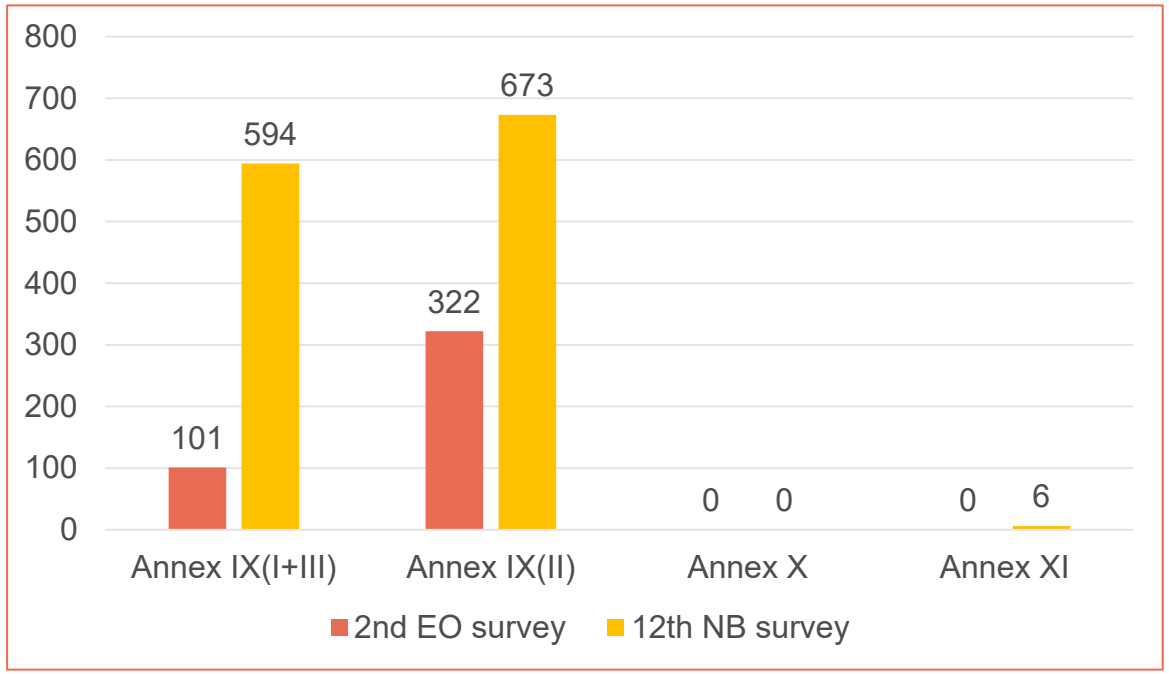


European Commission

IVD

Certificates issued to IVD MF under IVDR

Number of certificates issued to MF for IVDs under IVDR by Annex by end October 2024



Note: Replies from 27 IVD MFs

Total number of certificates: 423

Number of devices (catalogue numbers) covered in IVDR certificates issued by end of October 2024: 5419

For comparison data of the 12th NB survey (covering the same data period until 31/10/2024): 1273

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.

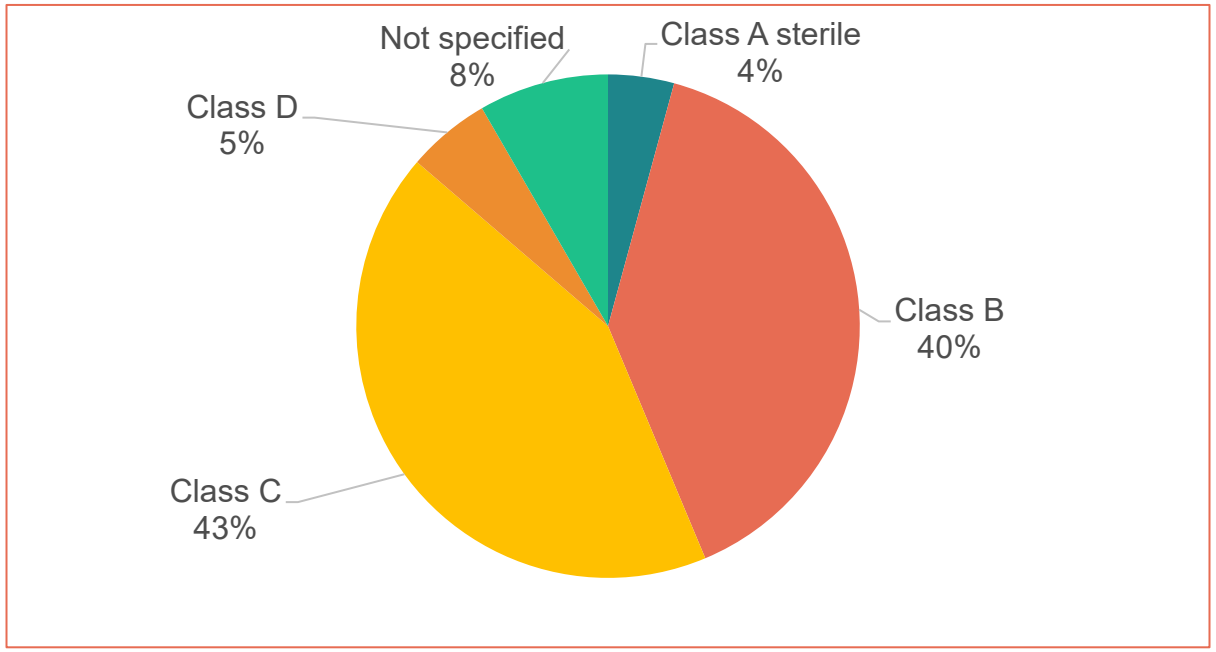
European Commission

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 2024:
5419

By risk class:

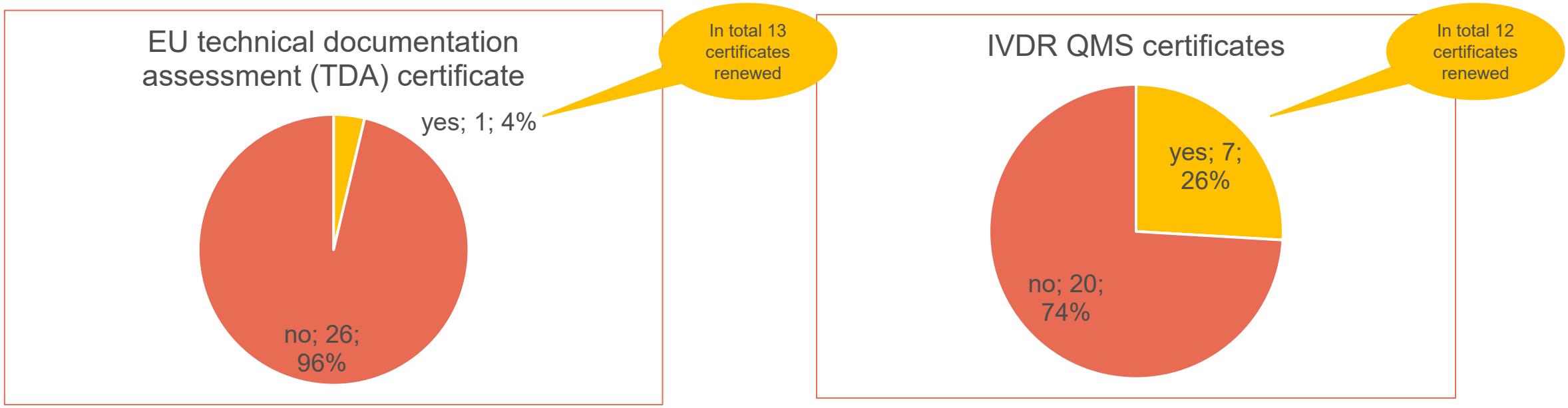


Note: Replies from 27 IVD MFs

IVD

Re-certification (1)

Did you already have a certificate renewed under the IVDR? (n=27 out of 60 companies that answered YES to Q46)

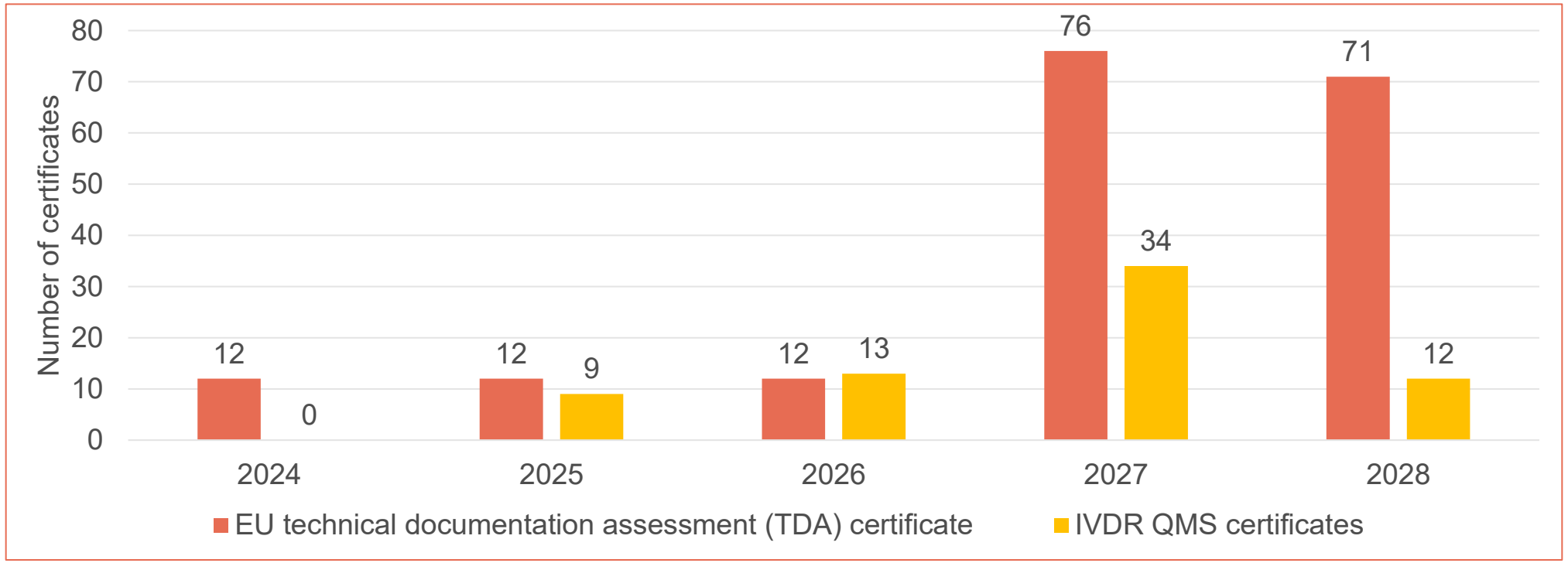


European Commission

IVD

Re-certification (2)

Number of certificates expiring and due for re-certification in 2024-2028 (n=27 companies that answered YES to Q46)



For comparison data of the 12th NB survey: total number of IVDR certificates by 31/10/2024: 1.273

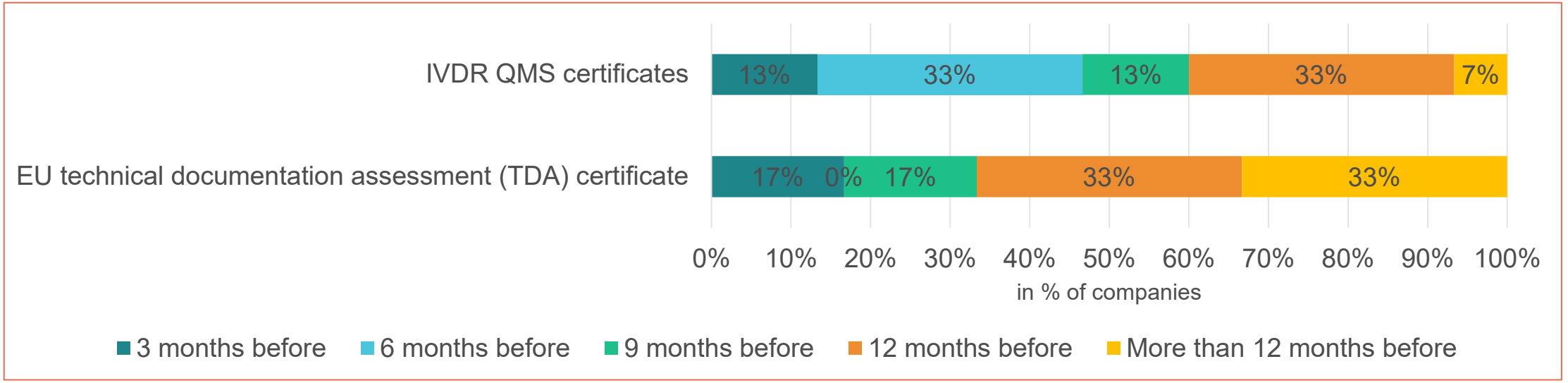
Note: Data of 27 MF including 4 with the indication '0' in all 5 years

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?



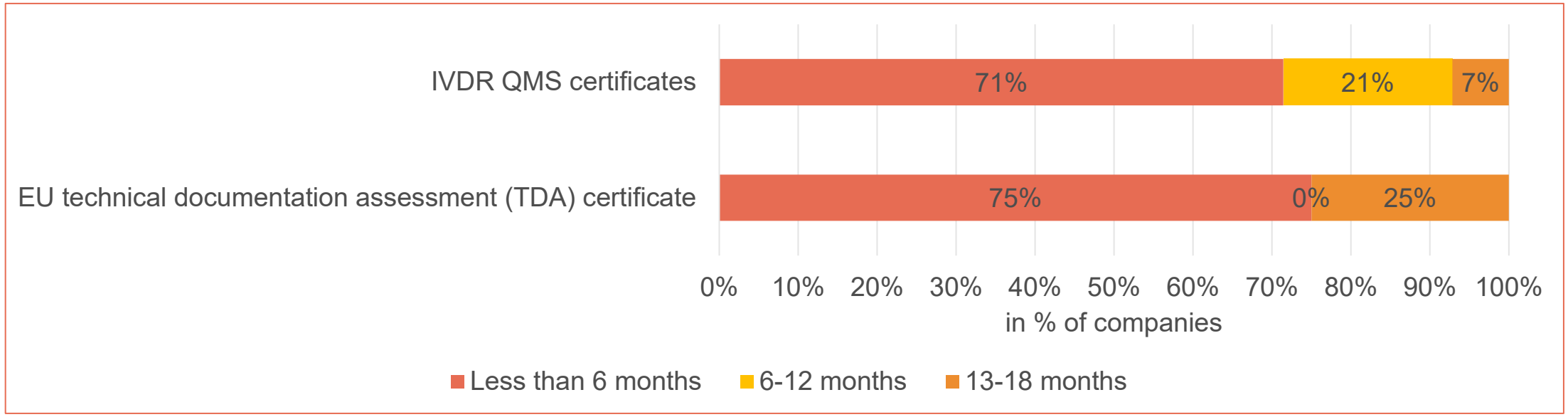
Note: Data of 27 MF
For IVDR QMS certificates 12 companies indicated ‘no information available’
For EU TDA certificates 21 companies ‘no information available’

European Commission

IVD

Re-certification (4)

What is the average time taken to prepare a re-certification dossier (before submission)?



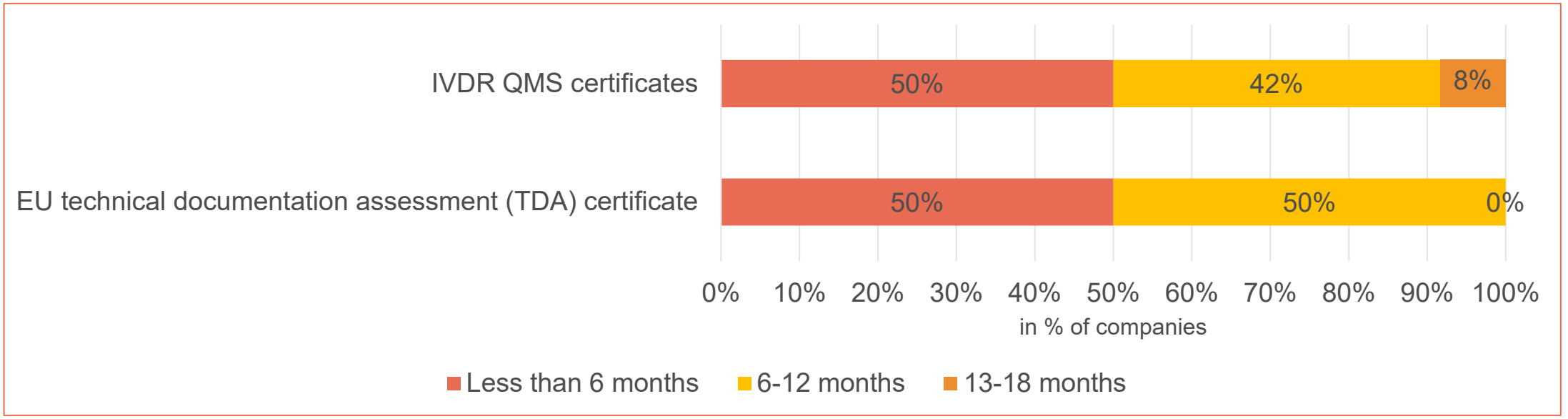
Note: Data of 27 MF
For IVDR QMS certificates 13 companies indicated 'no information available'
For EU TDA certificates 19 companies 'no information available'

European Commission

IVD

Re-certification (5)

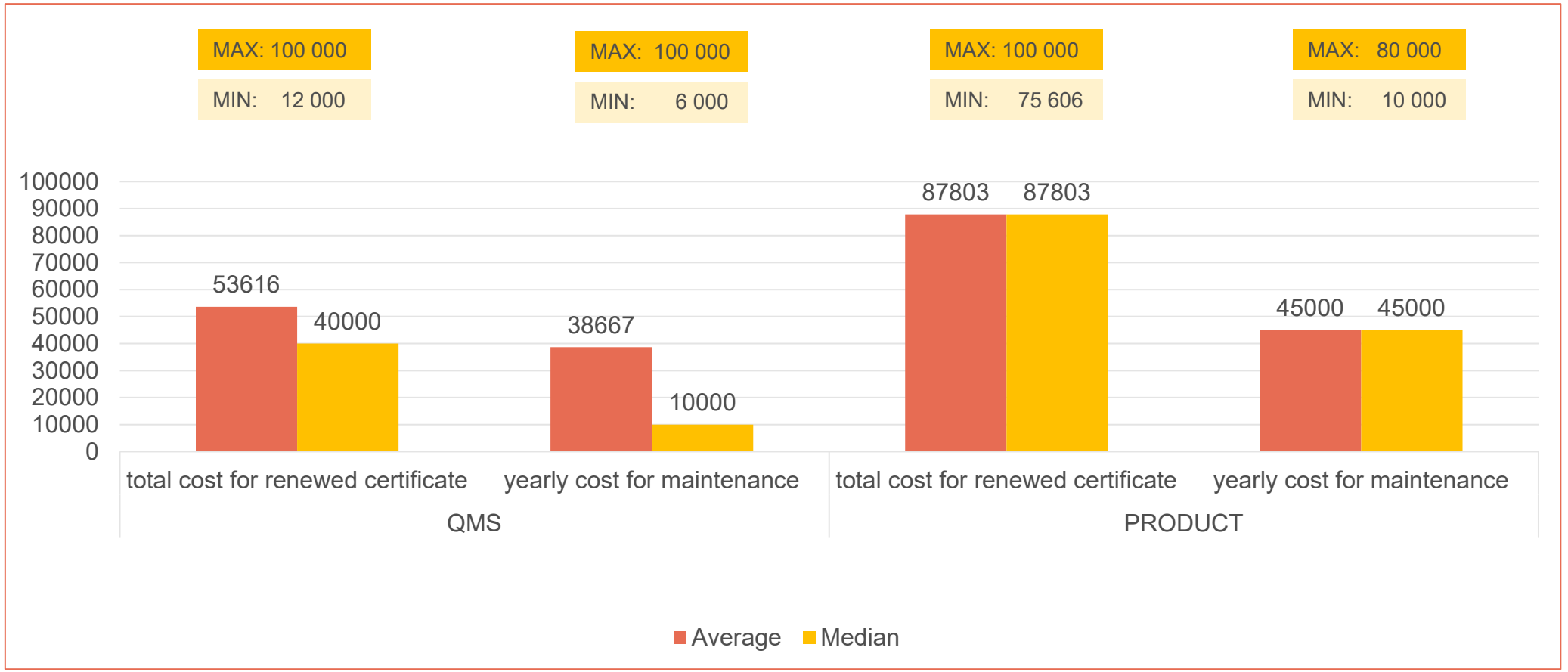
What is the average time taken to reach renewal of the certificate (from the submission to renewal)?



Note: Data of 27 MF
For IVDR QMS certificates 15 companies indicated 'no information available'
For EU TDA certificates 21 companies 'no information available'

Costs of the last renewed certificate issued (between 01/01/2022-31/10/2024) in EURO

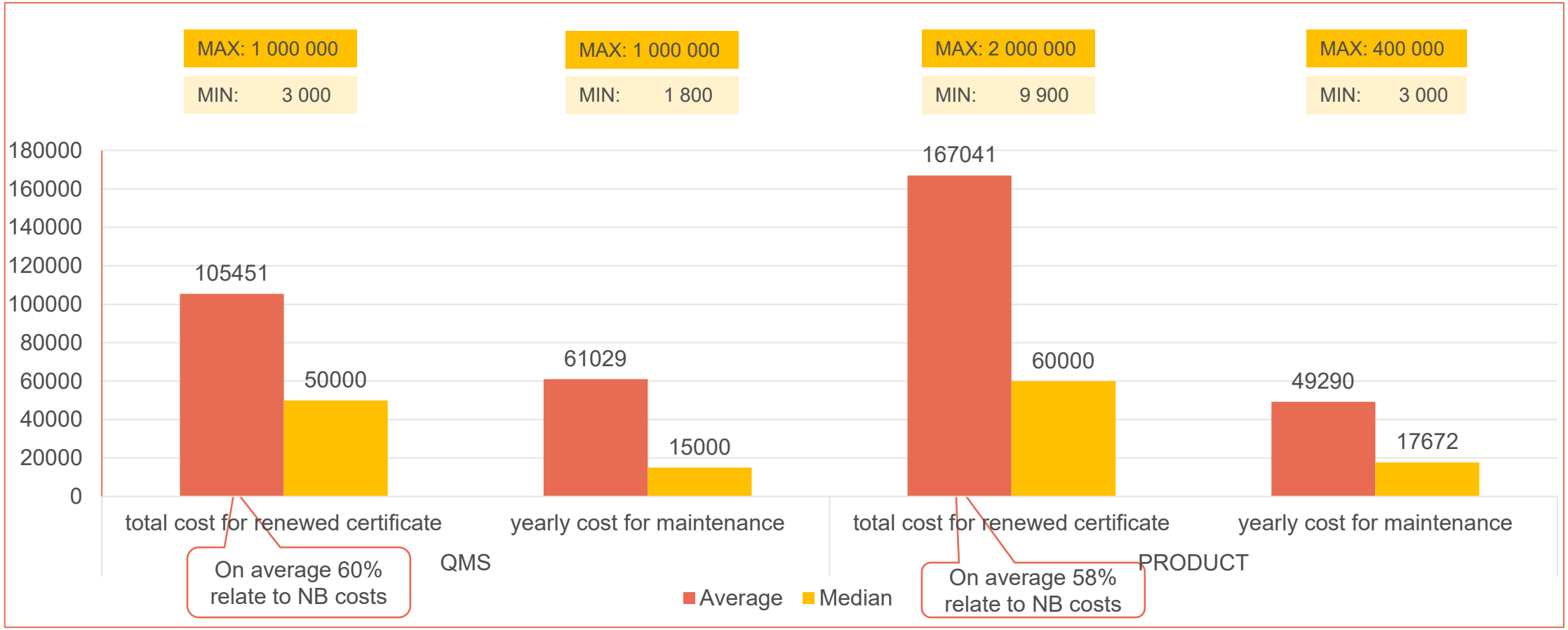
IVD



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).
For IVDR QMS certificates (Annex IX(I+III),Annex XI) data of 5 companies; 1 company indicated that all costs relate to NB costs, four companies indicated that on average 52% relate to NB costs and 48% to internal costs. For maintenance: 3 MFs taken into account with responses >0.
For IVDR product certificates (Annex IX(II), Annex X) data of 2 companies; 1 company indicated that all costs relate to NB costs, one company indicated 70% of the cost relate to NB and 30% to internal costs. For maintenance: 2 MFs taken into account with responses >0

IVD

Estimations of costs of re-certification



Notes: In case companies have not received a renewed certificate, they could indicate an estimation.
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).
For IVDR QMS certificates (Annex IX(I+III),Annex XI) data of 31 companies; 3 companies indicated that all costs relate to NB costs, 28 companies indicated that on average 60% relate to NB costs and 40% to internal costs. For maintenance: 28 MFs taken into account with responses >0.
For IVDR product certificates (Annex IX(II), Annex X) data of 25 companies; 2 companies indicated that all costs relate to NB costs, 23 companies indicated on average 58% of the cost relate to NB and 42% to internal costs. For maintenance: 23 MFs taken into account with responses >0

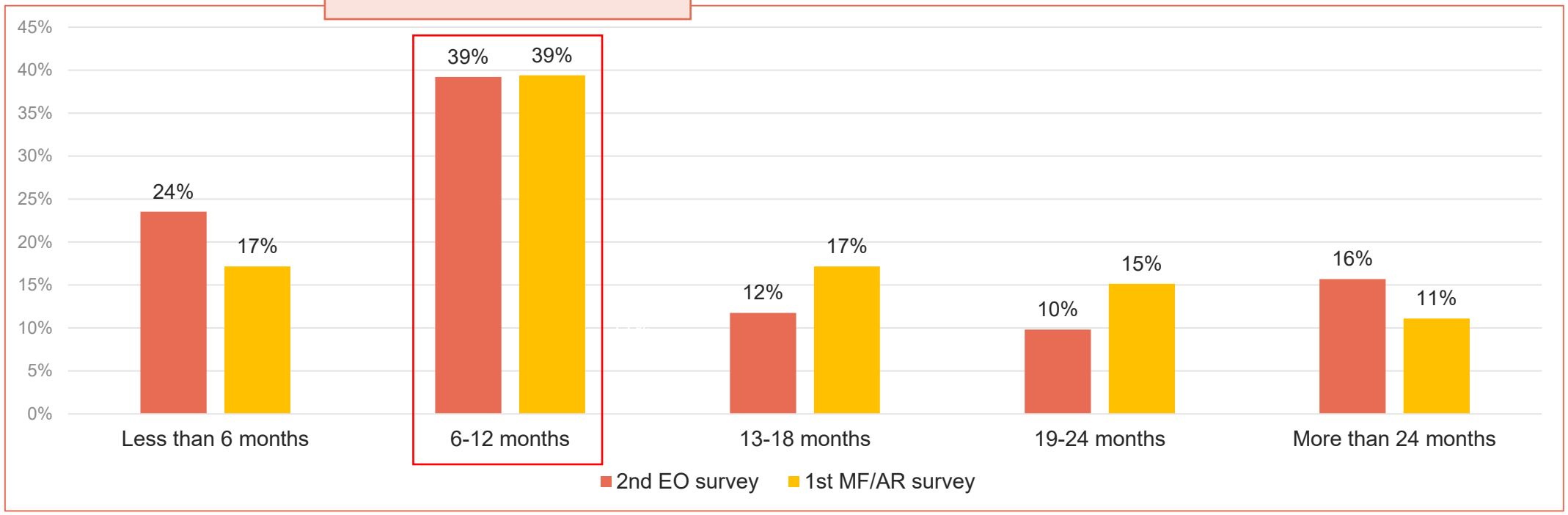
European Commission

IVD

Time periods (1)

Average time to prepare an application for IVDR (before submission to a NB) – *comparison of 2nd EO survey with 1st MF/AR survey*

For most of the MD MFs it takes **6-12 months** to prepare an application for IVDR.



Notes:

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

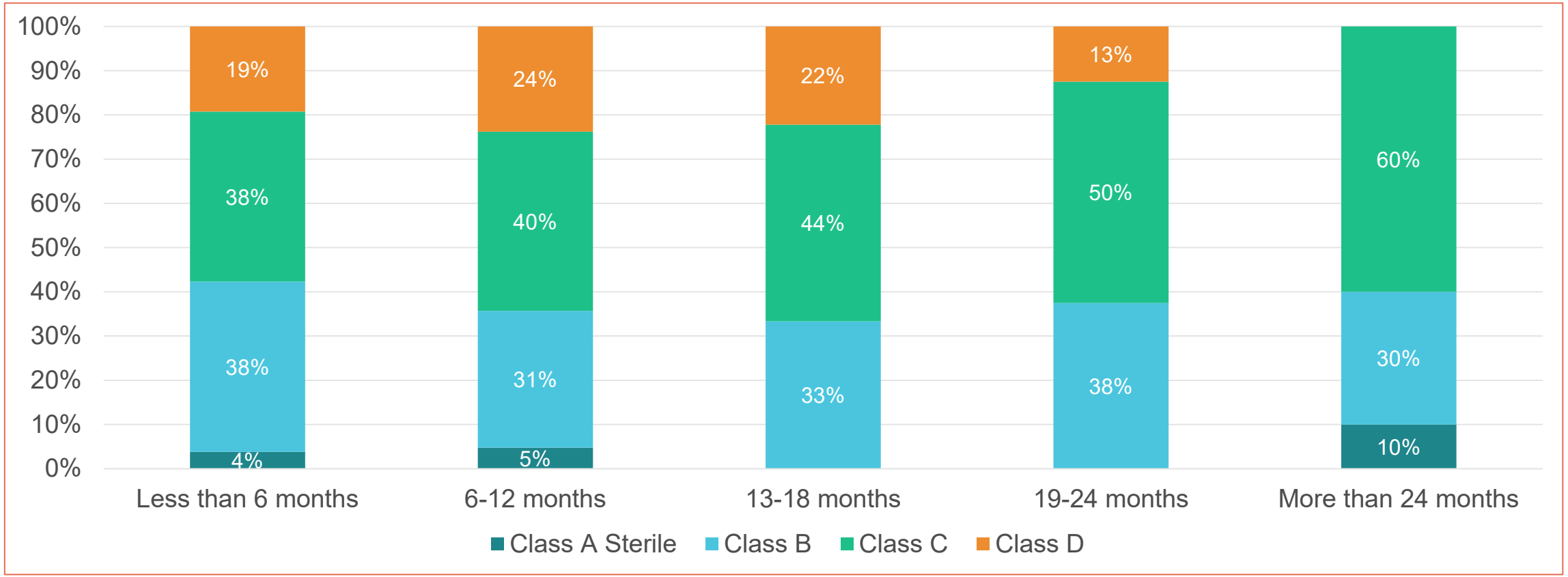
European Commission

Q54.1

Time periods (2)

IVD

Which device risk classes are included in this average time calculation?



Note:

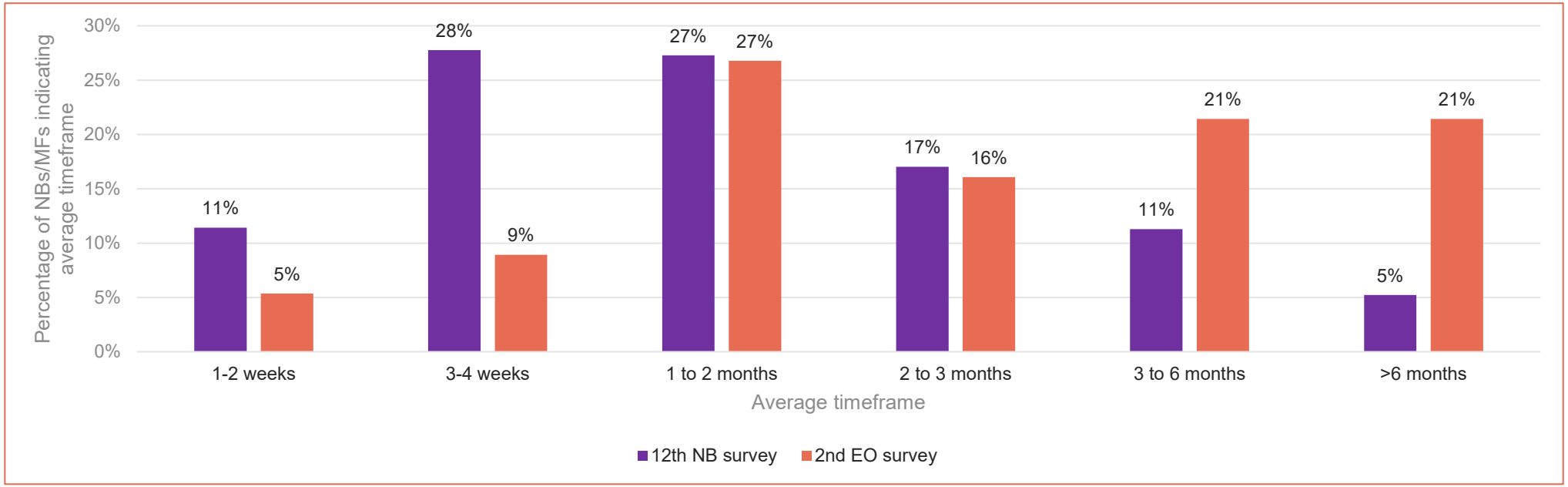
- **2nd EO survey:** Replies of 51 IVD MFs, 9 MFs indicated no information available'

European Commission

IVD

Time periods (3)

Average timeframe between application lodged and written agreement signed – *comparison of 2nd EO survey with 12th NB survey*



Notes:

- **12th NB survey:** Replies of 13 NBs designated under IVDR; data collection method: NBs indicated the number of files for each category which was converted into percent per category
- **2nd EO survey:** Replies of 56 IVD MFs; data collection method: EOs selected one time period

European Commission

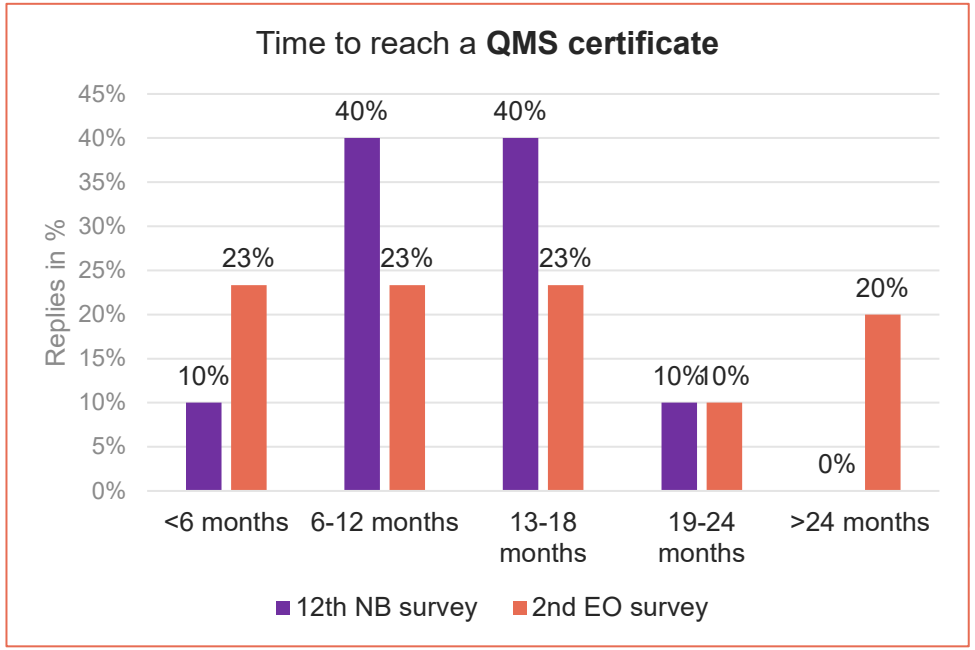
Time periods (4)

IVD

Average time to reach/issue IVDR certification for devices

(from written agreement signed to issuance) – *comparison of 2nd EO survey with 12th NB survey*

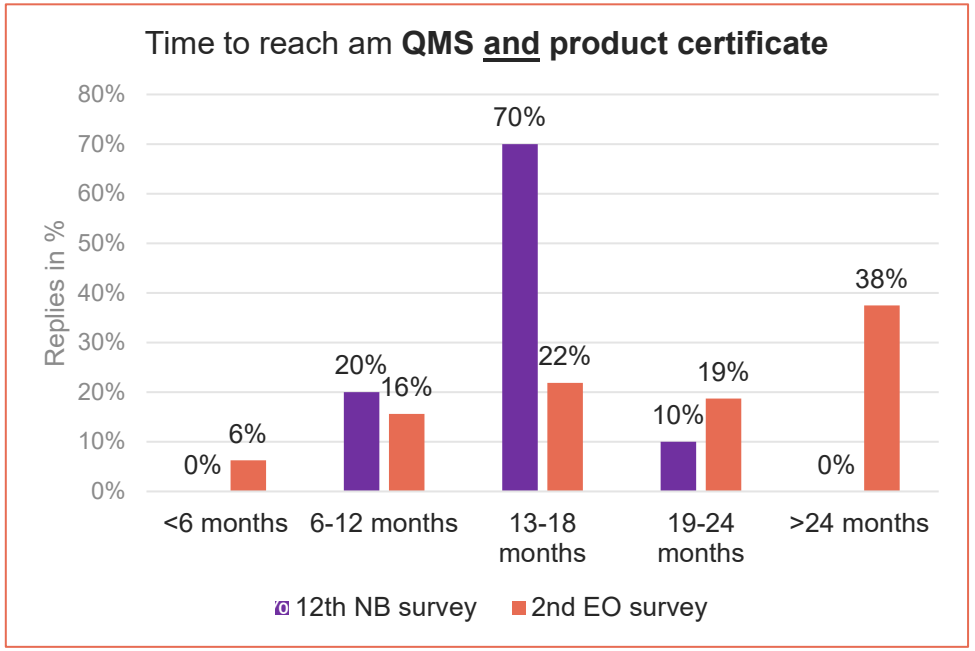
80% of the NBs indicated 6-18 months.
69% of the IVD MFs indicated less than 18 months.



Notes QMS certificates:

- **12th NB survey:** QMS: Data of 10 NBs designated under IVDR (covering the same data period until 31/10/2024)
- **2nd EO survey:** Data of 30 IVD MFs; 28 MFs indicated 'no information available'

70% of the NBs indicated 13-18 months.
38% of the IVD MFs indicated more than 24 months.



Notes QMS and product certificates:

- **12th NB survey:** QMS: Data of 10 NBs designated under IVDR (covering the same data period until 31/10/2024)
- **2nd EO survey:** Data of 32 IVD MFs; 26 MFs indicated 'no information available'

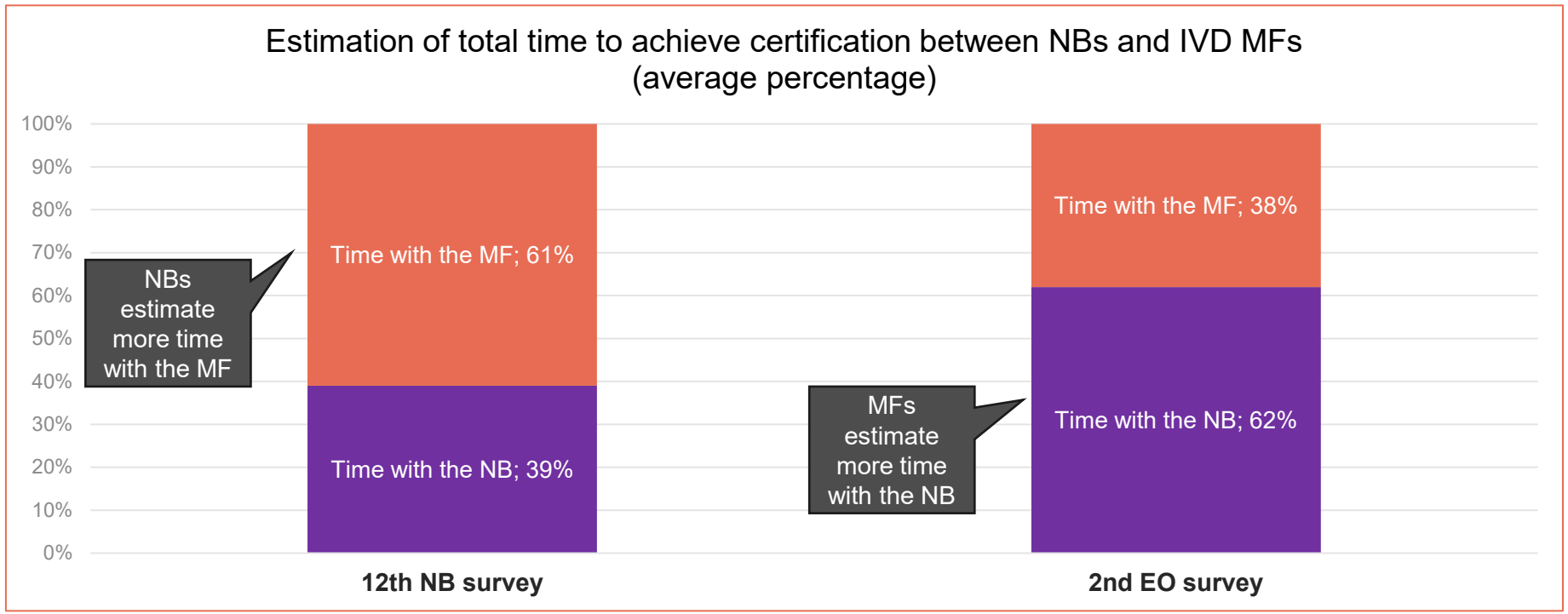
European Commission

Estimation of the total time* to achieve certification between NB and MF

– *comparison of 2nd EO survey with 12th NB survey*

IVD

* from written agreement signed to issuance of a new certificate



Notes:

- Data of 10 NBs designated under IVDR; data of 49 IVD MFs (the other 11 IVD MF indicated that they don't know it)
- This indicator shows an estimate of the allocation of the total time to certification (from signing the written agreement to issuance) between the notified body and the manufacturer.
- Time with the NB means time for checking the documents including application and technical documentation.
- Time with the MF means time for revising the documents including application and technical documentation.

IVD

Estimates

IVD

Estimates

Total responses from MFs for IVDs: 60

	Total number of IVDs (referring to catalogue numbers)
Total no. of devices included in the product portfolio by 31/10/2024	**11562**
a) Thereof no. of devices requiring IVDR certification by NBs (Class As, B, C, D) – in % of total	9662 (= 83,6% of total)
b) Thereof no. of devices planned to be transitioned	7265 (= 62,8 % of total)
c) Thereof no. of devices included in already lodged applications	3452 (= 47,5% of all devices planned to be transitioned (c/b*100))
d) Thereof no. of devices included in already issued certificates	5419 (= 56,1% of all devices requiring IVDR certification by NBs (d/a*100))

Notes:
Total: Data of 60 IVD MFs including 5 with the indication '0'
a) Data of 60 IVD MFs including 6 with the indication '0'
b) Data of 60 IVD MFs including 13 with the indication '0'
c) Data of 60 IVD MFs including 29 with the indication '0'; Difference to Q45 is that in Q62 it was asked if dev. are included in already lodged applications (but unclear of review by NB has started)
d) Q48: Data of 60 IVD MFs including 33 with the indication '0'

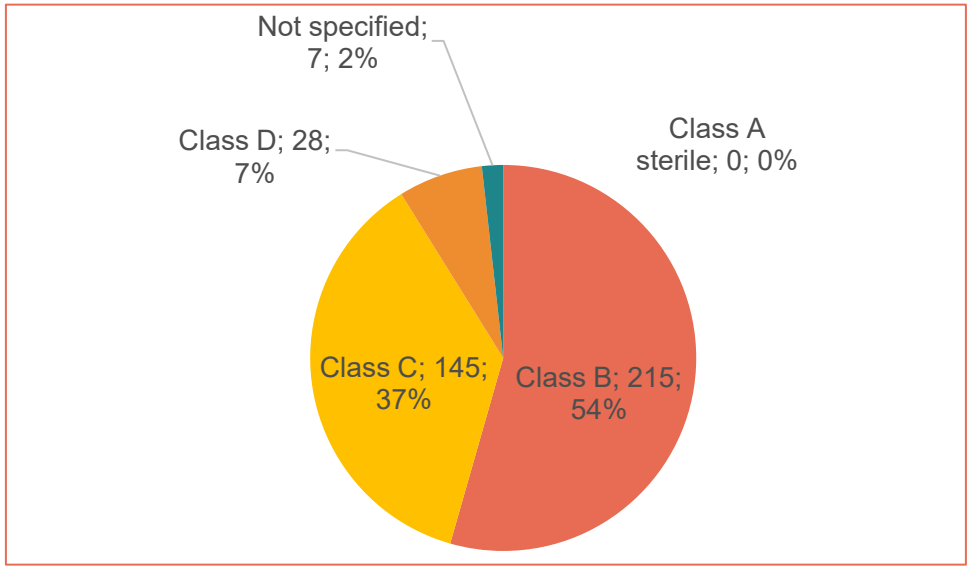
IVD

New devices

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

395 new devices (in total covering all risk classes)
(Note: n=60 companies including 31 with the indication '0')

By risk class



European Commission

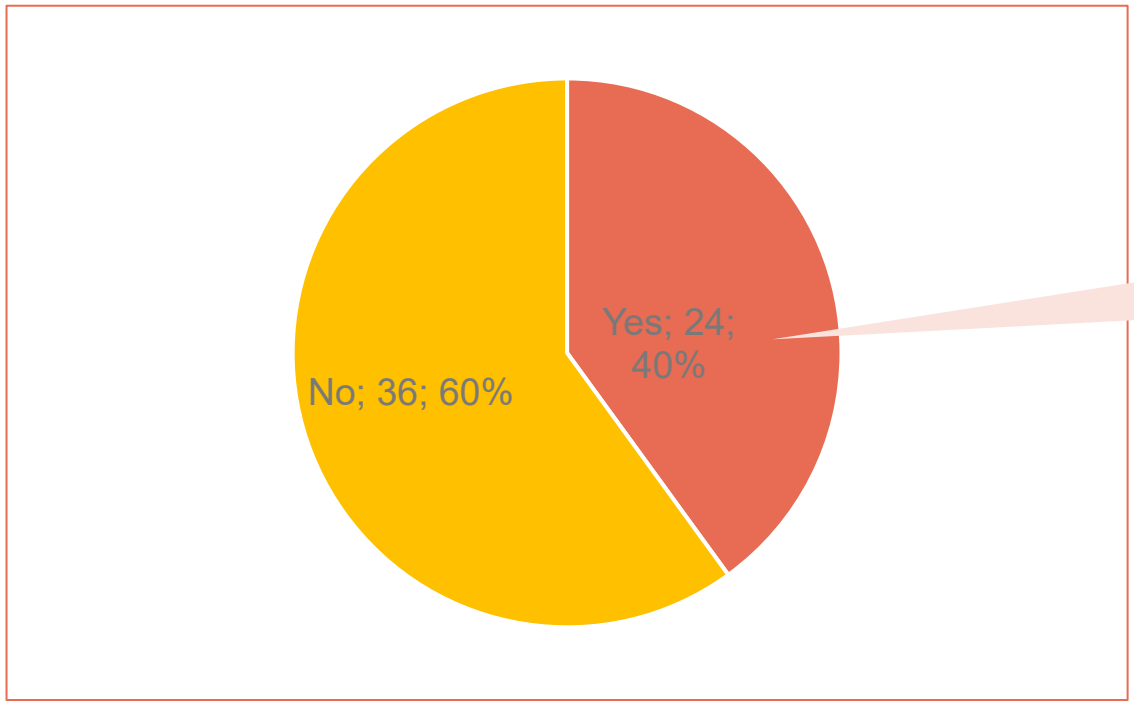
IVD

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=60)



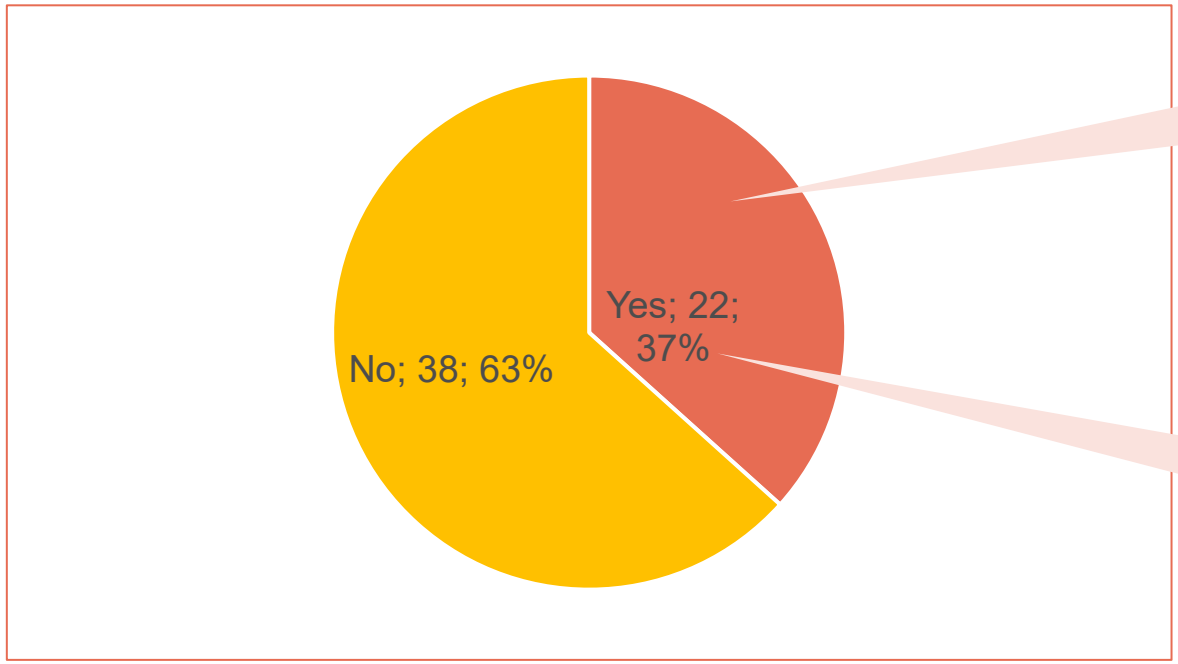
If yes, were orphan/niche* devices affected?
1 MF said yes
(= 4%; 1/24)

*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.

IVD

Discontinuation of IVDs (2)

Do you plan to discontinue some IVDs on the EU market in the coming months? (n=60)



If yes, will orphan/niche devices be affected?
3 MFs said yes
(= 14%; 3/22)

*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.

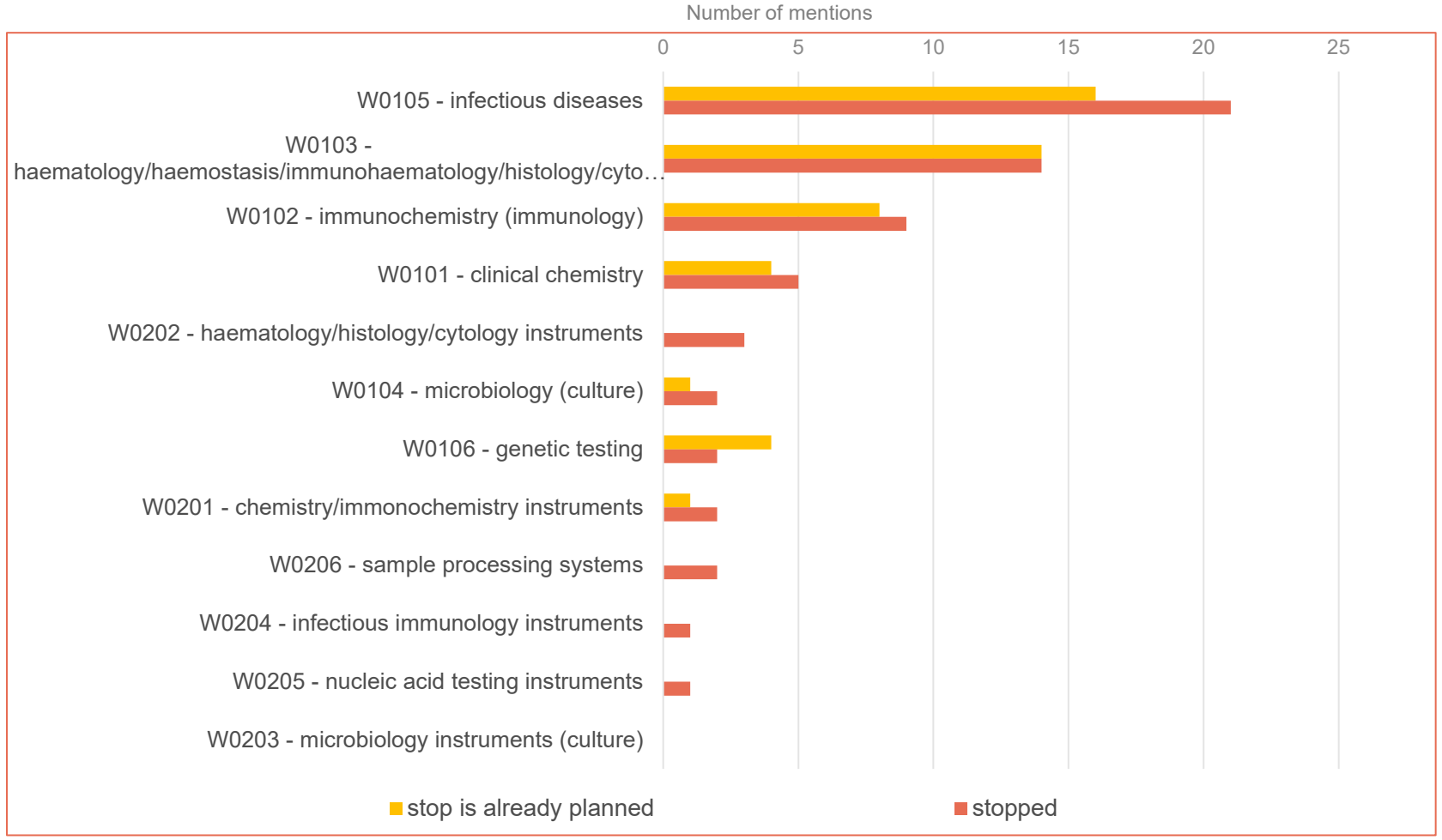
If yes, will Own Brand Labelled devices be affected?
8 MFs said yes
(= 36%; 8/22)

European Commission

Q64
Q63

IVD

Discontinuation of IVDs (3)



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

Notes: 17 MFs indicated the EMDN codes for the discontinued IVDs; 15 MF indicated the EMDN codes for the IVDs planned to be discontinued

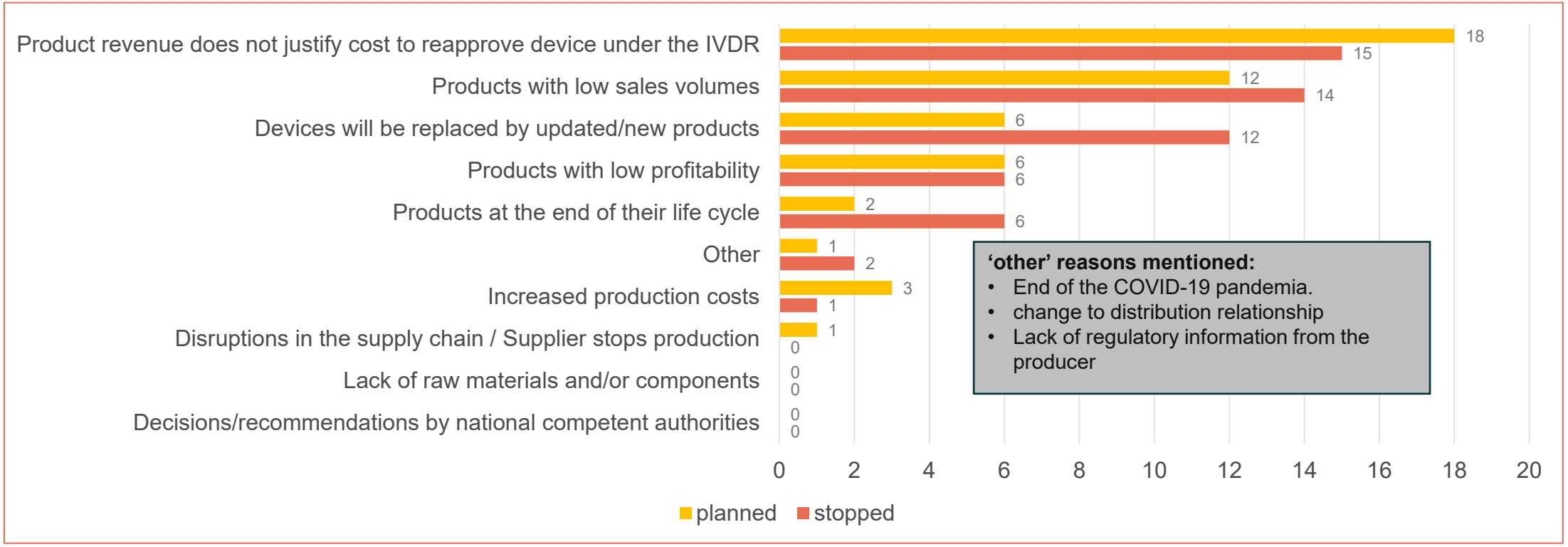
European Commission

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; 24 MFs having stopped and 22 MF planning to stop participated in this survey question.

European Commission

IVD

Preparedness of manufacturers

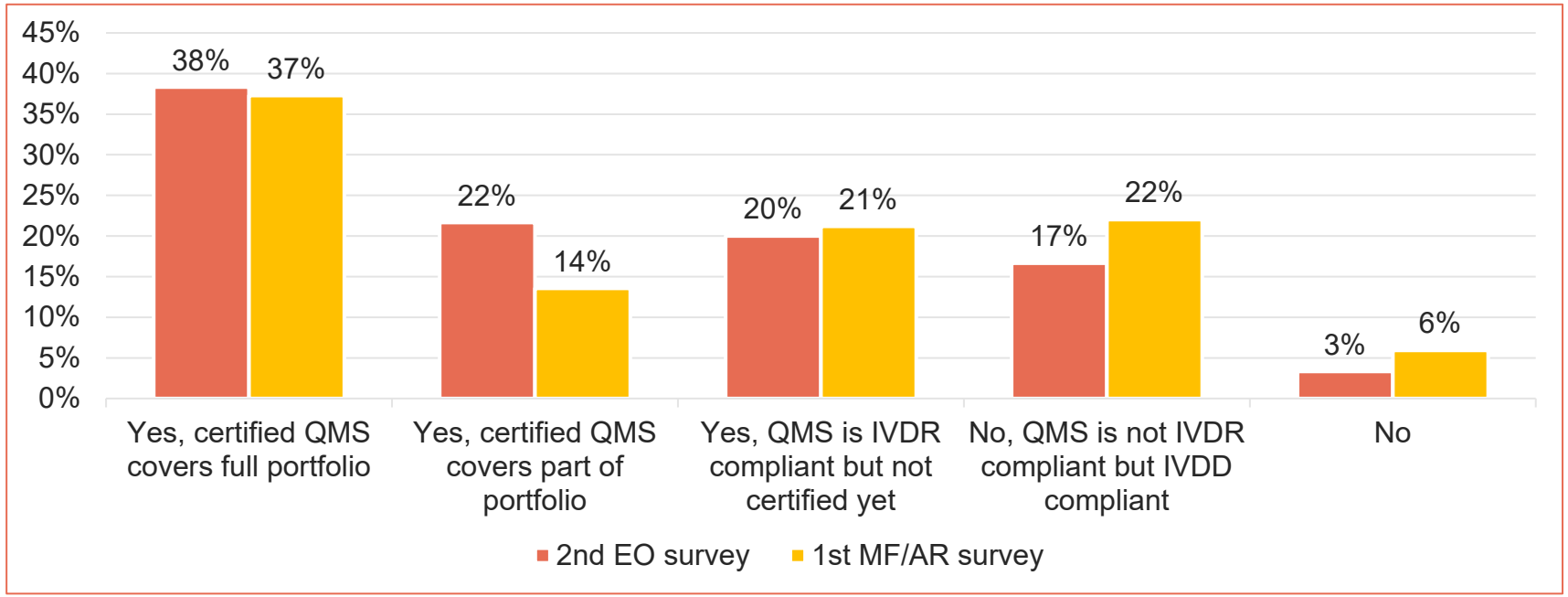
IVD

Preparedness of manufacturers (1)

Total responses from MFs for IVDs: 60

Do you have an IVDR-compliant QMS?

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



For comparison, data of the 1st MF/AR survey (covering the data period until 31/10/2023) was added. Data of 130 IVD MF (Category 'not applicable' selected by 12 companies is not included in this graph (e.g. their products had not been available yet.)

2nd EO survey: Data from 60 IVD MF

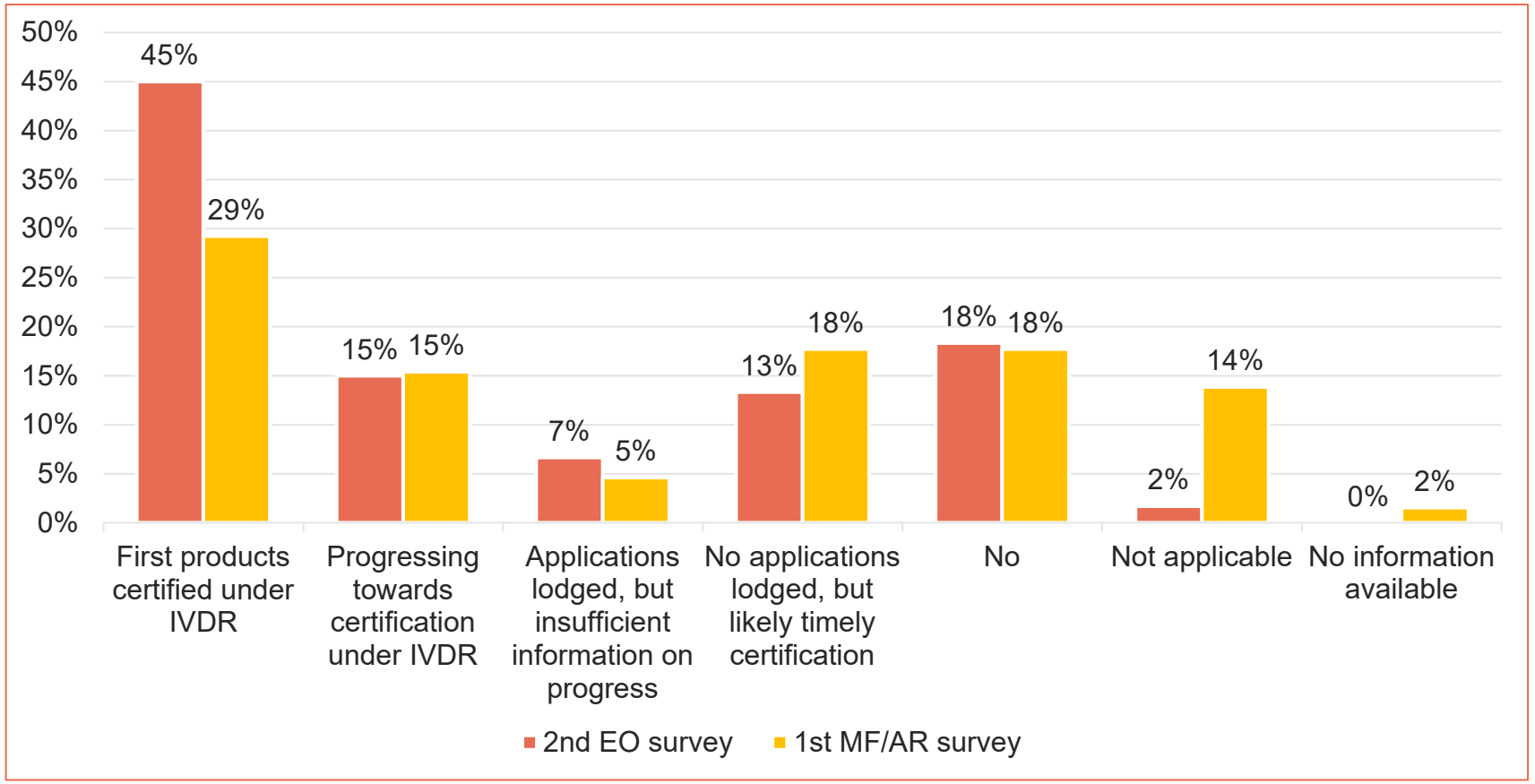
European Commission

IVD

Preparedness of manufacturers (2)

Total responses from MFs for IVDs: 60

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



For comparison data of the 1st MF/AR survey (covering the data period until 31/10/2023) was added:
Data of 130 IVD MF

2nd EO survey: Data from 60 IVD MF

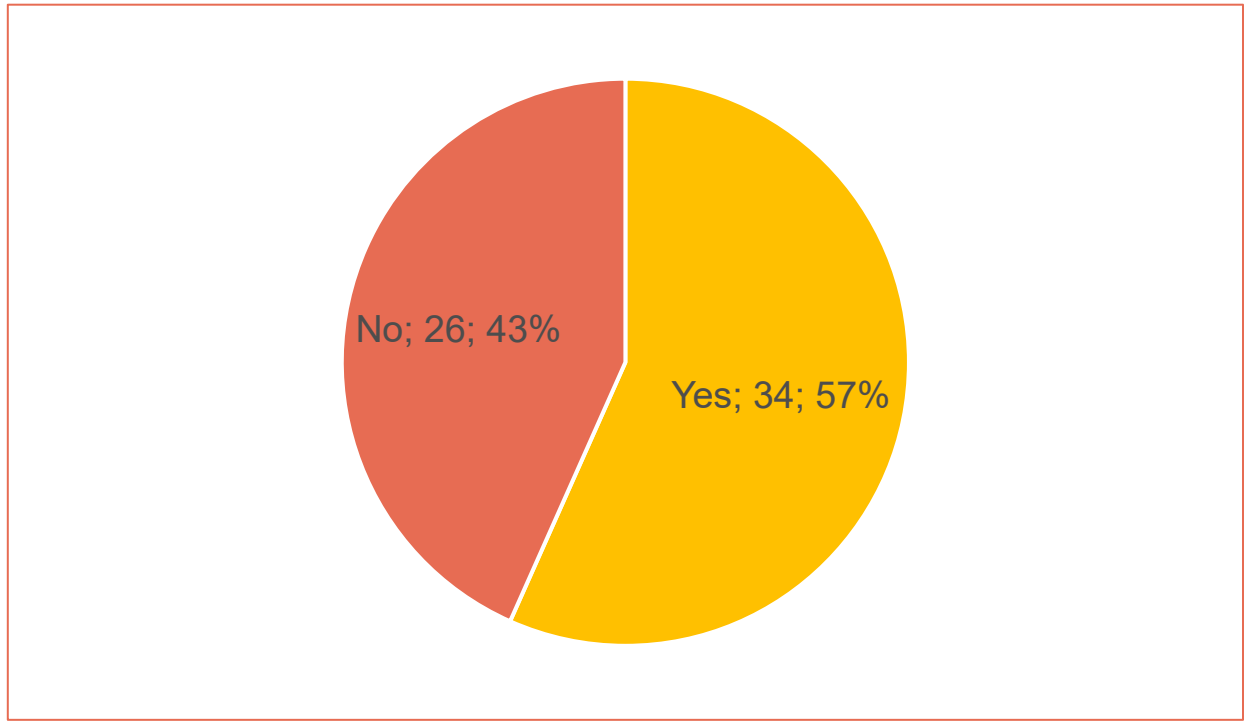
European Commission

IVD

Preparedness of manufacturers (3)

Total responses from MFs for IVDs: 60

Did the revised transitional periods for IVDR (Regulation (EU) 2024/1860) have an impact on your company's decisions to transfer your product portfolio to IVDR? (i.e. in general allowing more products to be transitioned)



European Commission

AR

2.4. Survey results for authorised representatives

Questionnaire part 2.4. including questions 73 to 75

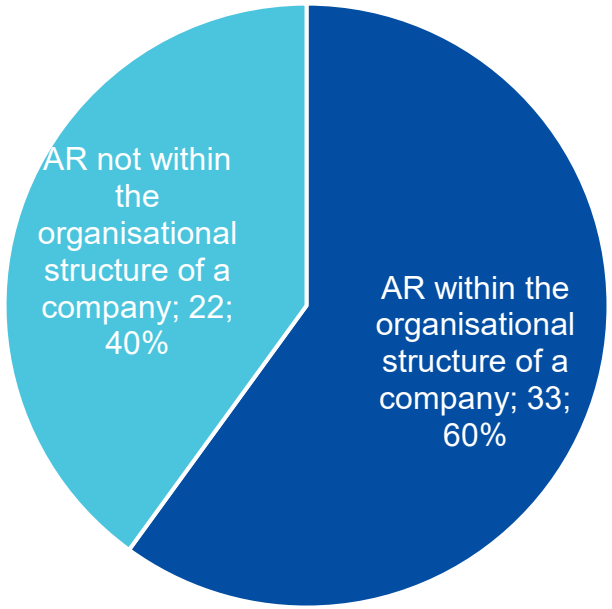
Q73
Q74

Authorised representatives (1)

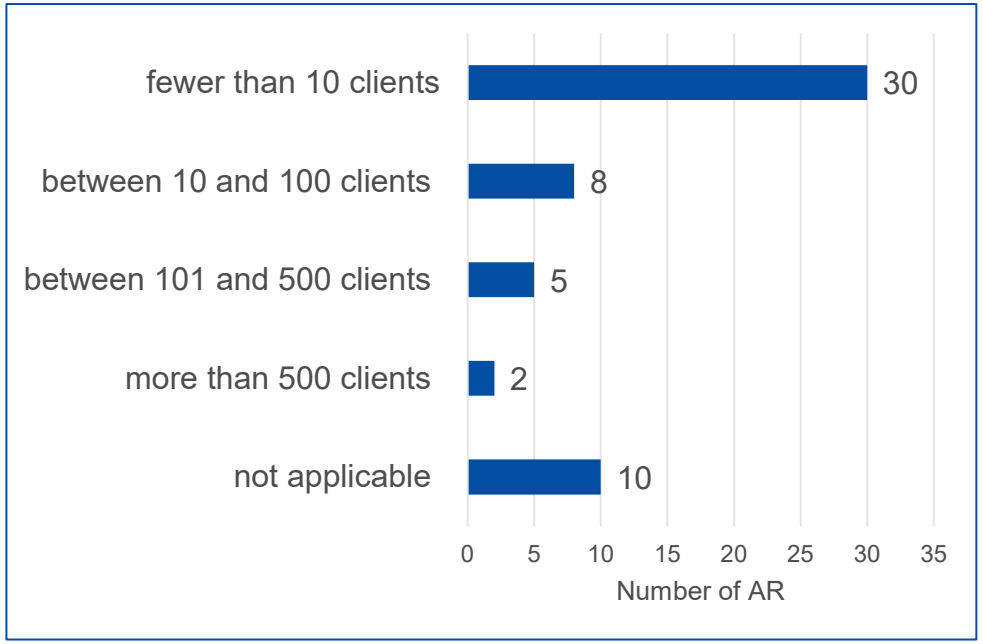
AR

Total responses from ARs: 55

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



Number of companies represented by authorised representatives



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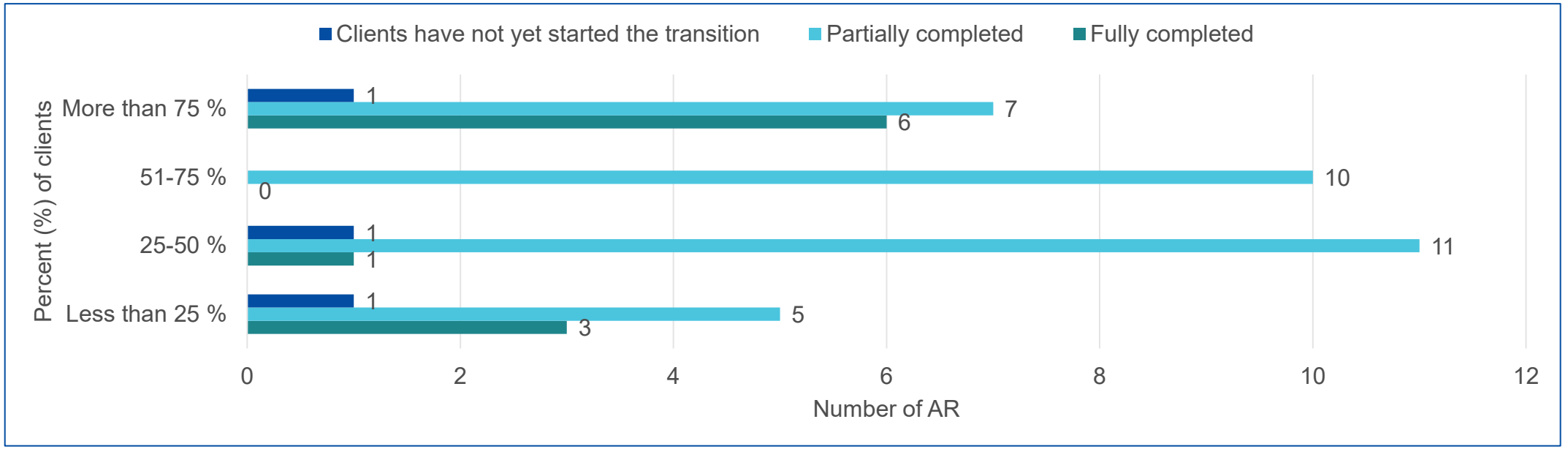
Authorised representatives Legacy devices transition

AR MD

Total responses from ARs: 55

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



Note: 15 AR indicated 'I don't know / not applicable'.

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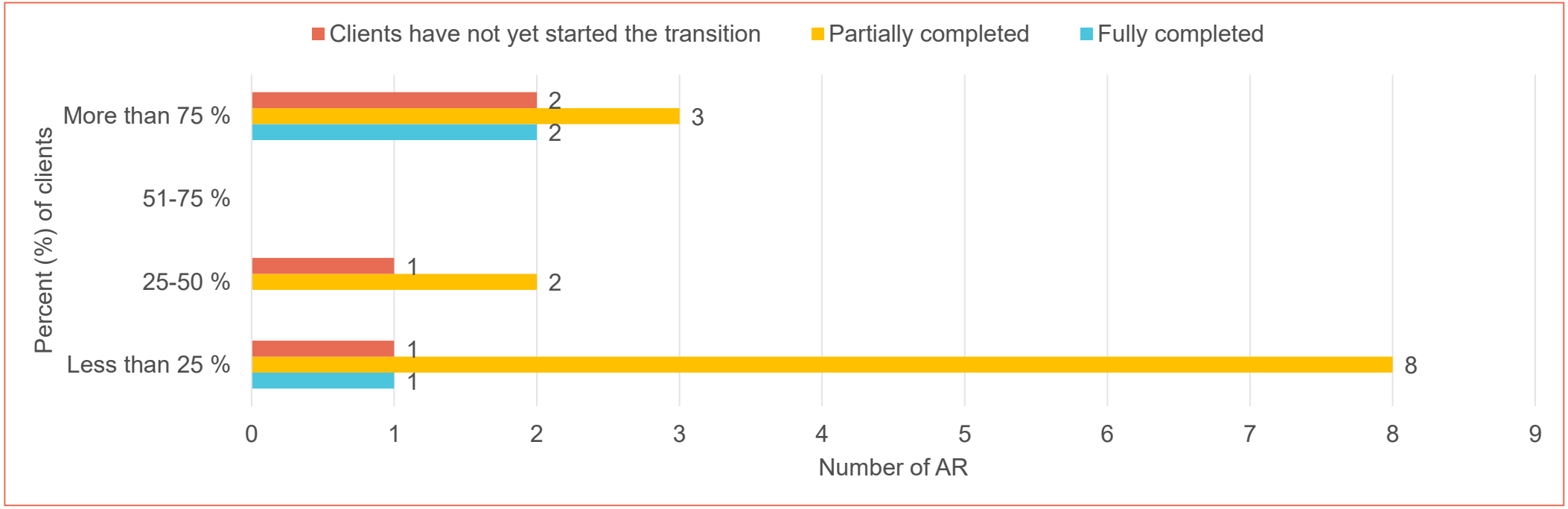
Q75

Authorised representatives Legacy devices transition

AR IVD

Total responses from ARs: 55

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



Note: 37 AR indicated 'I don't know / not applicable'.

European Commission

IM

2.5. Survey results for importers

Questionnaire part 2.5. including questions 76 and 77

Note: Both questions were asked for the **Targeted Evaluation** carried out by the European Commission (EC). These results are **not included** in this PowerPoint presentation and will be published by the EC separately.

DB

2.6. Survey results for distributors

Questionnaire part 2.6. including questions 78 and 79

Note: Both questions were asked for the **Targeted Evaluation** carried out by the European Commission (EC). These results are **not included** in this PowerPoint presentation and will be published by the EC separately.

Thank you

Contact for questions: medical.devices@goeg.at

Austrian National Public Health Institute/ Gesundheit Österreich (GÖG)

European Commission