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

Study overview and survey results of the 1st MF/AR survey with data status 31 October 2023

25 September 2024

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

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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
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
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
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
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
- Overview on ongoing and planned survey activities with the key stakeholders
- 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

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

Consultation activities

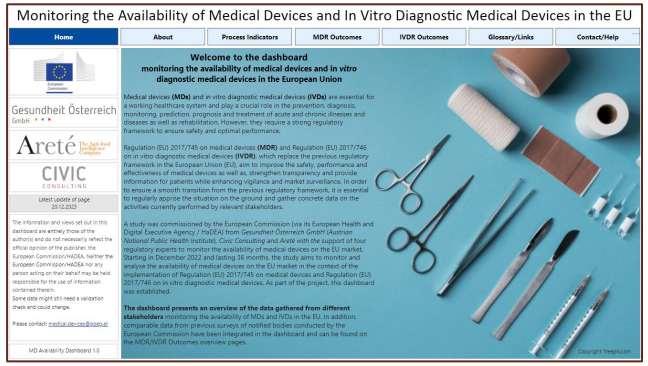
Surveys

Interviews

MDCG Taskforce Meetings

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

Published on **9 January 2024** and available at: https://health.ec.europa.eu/study-supporting-monitoring-availability-medical-devices-eu-market_en.



Source icons:
https://www.flaticon.com/de/kostenlose-icons/fragebogen
https://www.flaticon.com/de/kostenlose-icons/interview
https://www.flaticon.com/de/kostenlose-icons/diskussion

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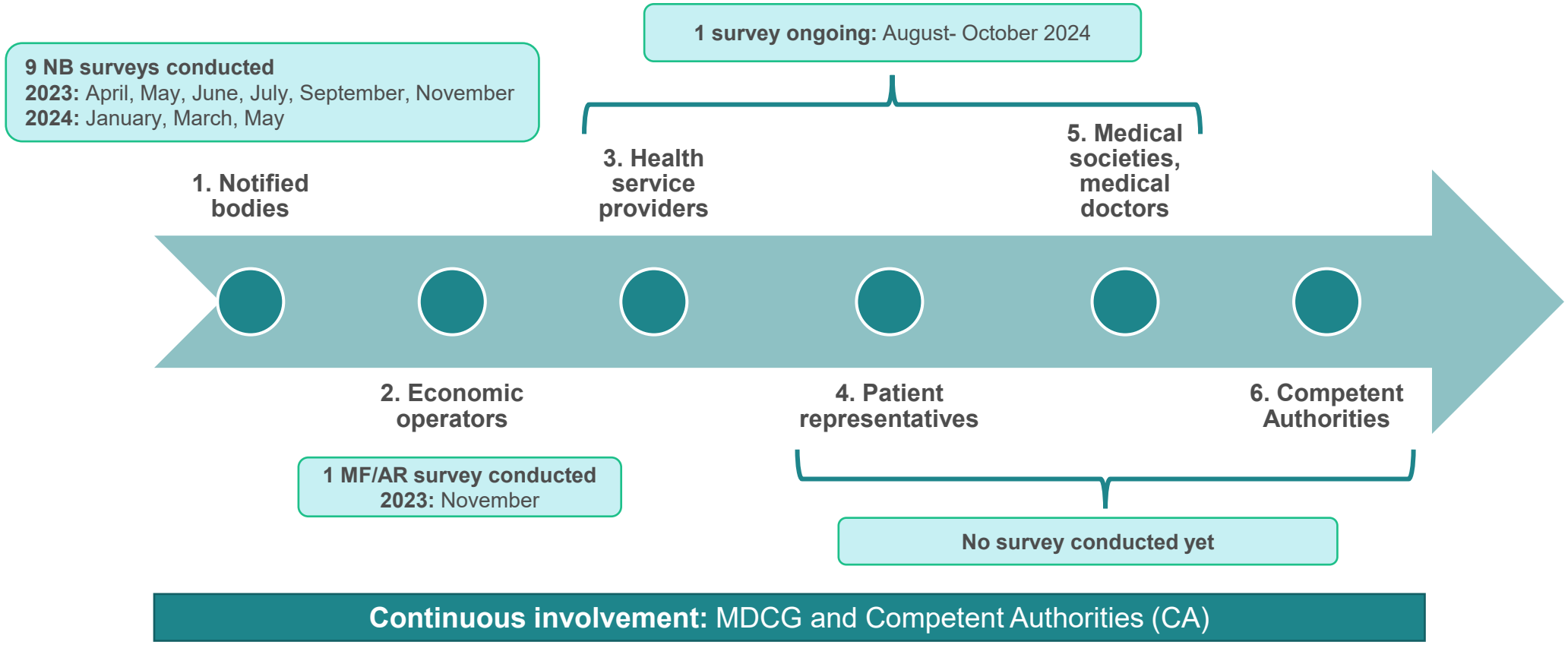
Overview of ongoing and planned survey activities with the key stakeholders



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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

1.2. About the 1st survey with MF and AR

- Acknowledgements
- Survey development and management
- Survey timeline
- Survey structure and content

Acknowledgements

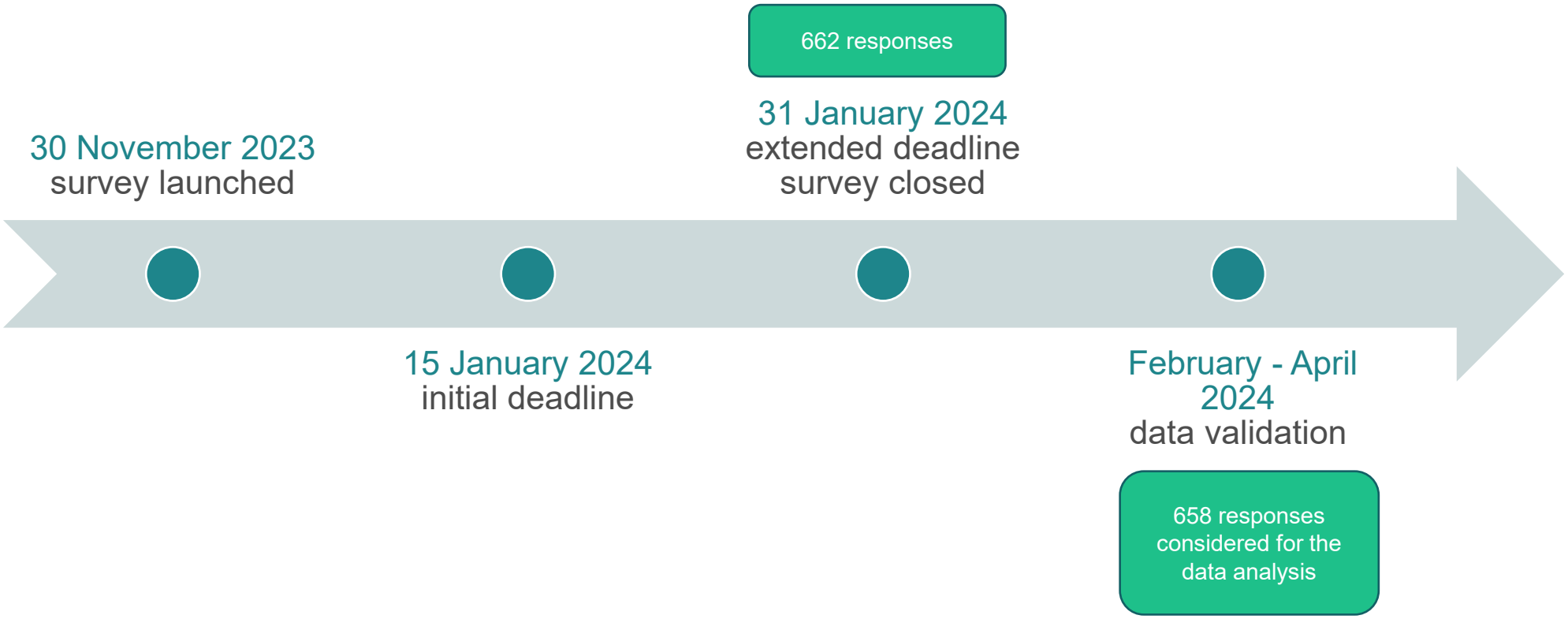
The study team would like to sincerely thank the following persons and institutions for the support in the 1st MF/AR survey:

- 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** who were available for exploratory interviews;
- **Experts and representatives** of the following organizations (in alphabetical order) for the review of a draft version of the survey and/or dissemination of the survey link: EUROM VI The Medical Technology Committee; European Association of Authorized Representatives (EAAR); European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries (COCIR); Enterprise Europe Network (EEN); Industrie und Handelskammer zu Lübeck; MedTech Europe and all national associations, MedTech clusters;
- All **manufacturers** and **authorized representatives** of medical devices and in vitro diagnostic medical devices who took part in the survey.

Survey development and management

- **Survey development:** The survey for manufacturers and authorized representatives 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 associations and clusters, direct contacts (email, telephone), personal contacts (conferences, trainings, etc.) and social media (LinkedIn, newsletter).
- **Survey period:** The survey was launched on 30 November 2023 on the EUSurvey platform and closed on 31 January 2024.

Survey timeline for the 1st MF/AR survey conducted in November 2023
(data was requested until 31 October 2023)



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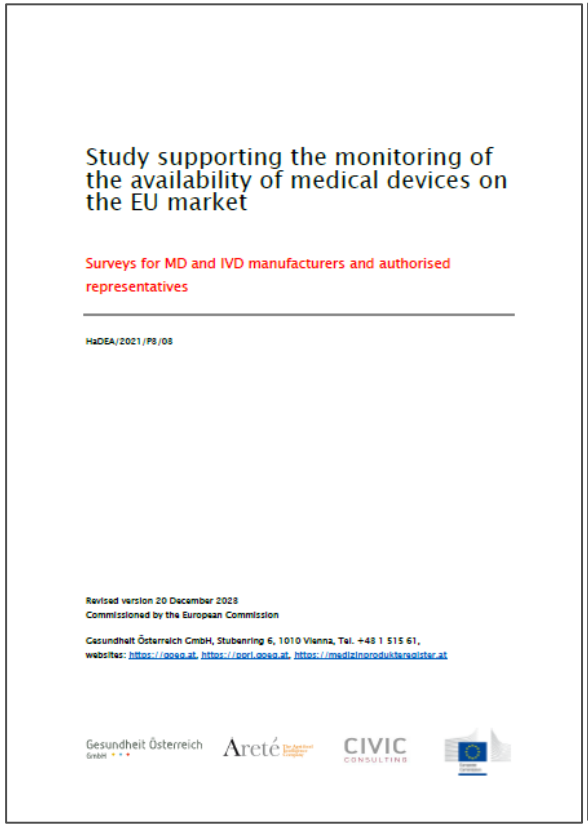
Survey structure and content


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

Surveys for MD and IVD manufacturers and authorised representatives

HaDEA/2021/PS/08

Revised version 20 December 2023
Commissioned by the European Commission

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Gesundheit Österreich Areté CIVIC CONSULTING

1. **Background and introduction**
2. **Questionnaire** (Q1-Q53)

About 2.1. **ABOUT:** About you and your company (Q1-Q7)
MD 2.2. **MD:** Questionnaire on medical devices (Q8-Q29)
IVD 2.3. **IVD:** Questionnaire on in vitro diagnostic medical devices (Q30-Q49)
AR 2.4. **AR-MD/IVD:** Questionnaire for authorised representatives (Q50-Q53)

3. **Closing** (Q54-Q55)

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

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2. Results

2.1. About the survey participants (responses)

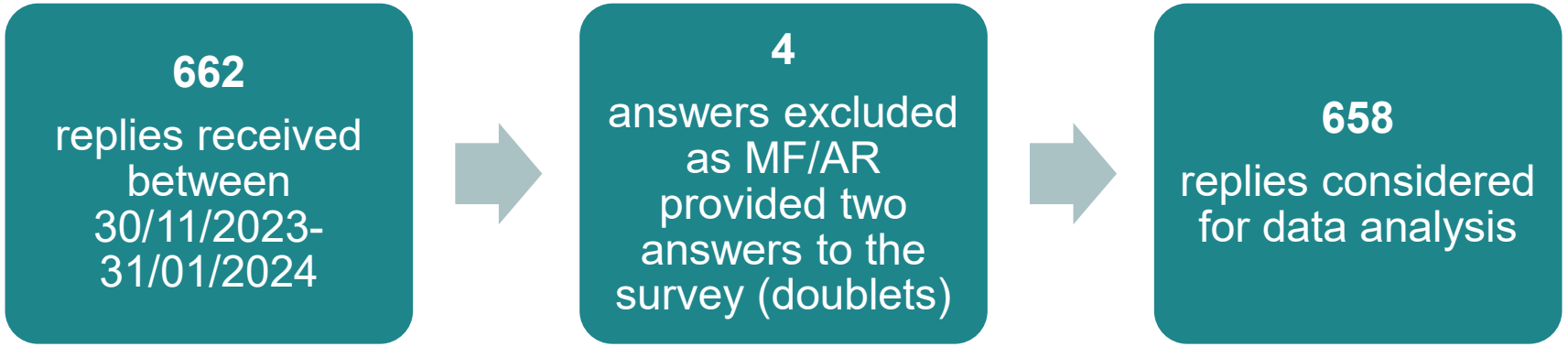
Questionnaire part 2.1. including questions 1 to 7

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

Survey responses to 1st MF/AR survey received and considered for data analysis

About

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



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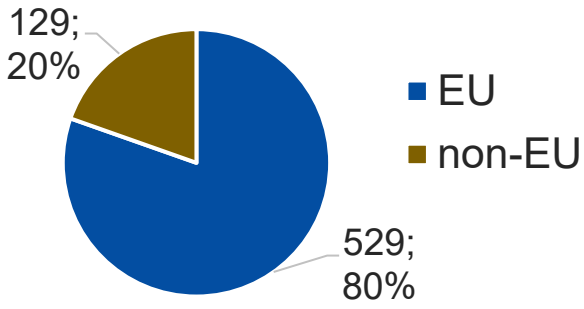
Responses to 1st MF/AR survey by country*

About

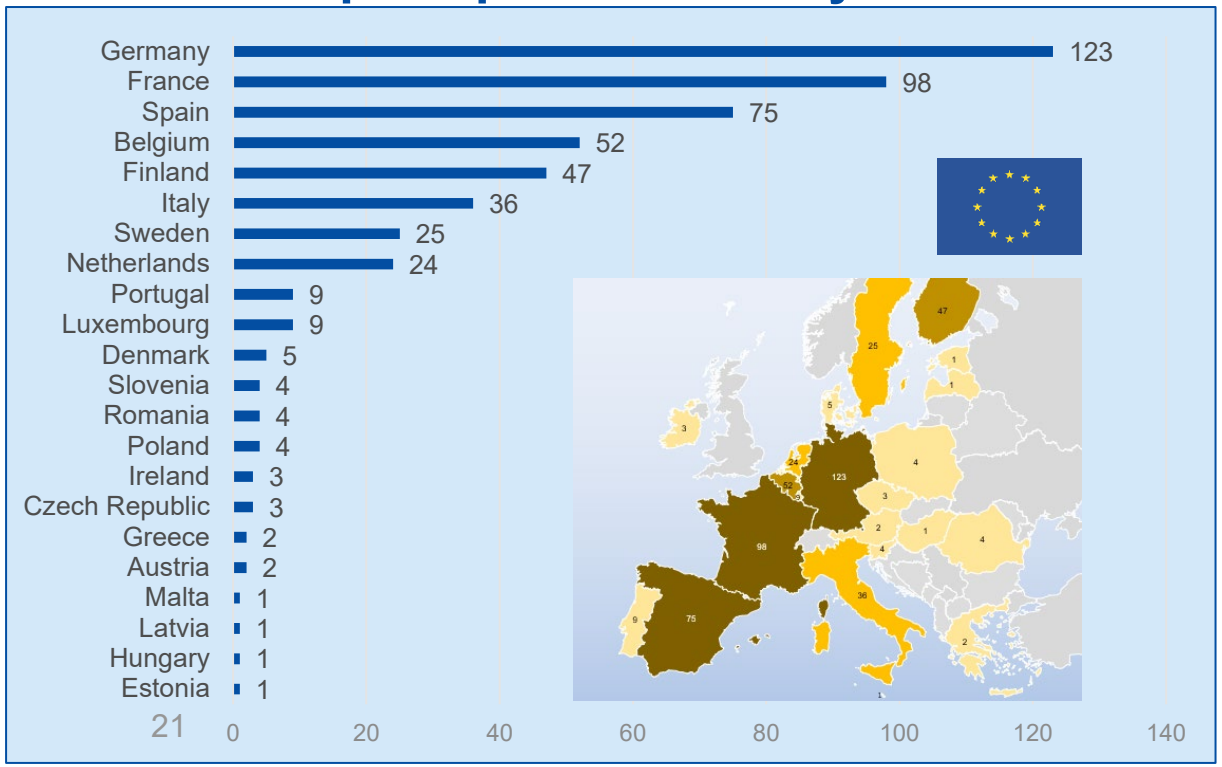
* Country where the company is based. In the case of a multinational company this is the country where the headquarters is located. In case of a reply by a subsidiary, the data provided only refers to the subsidiary.

Share of replies from MF/AR from EU/non-EU countries

n = 658 MF/AR

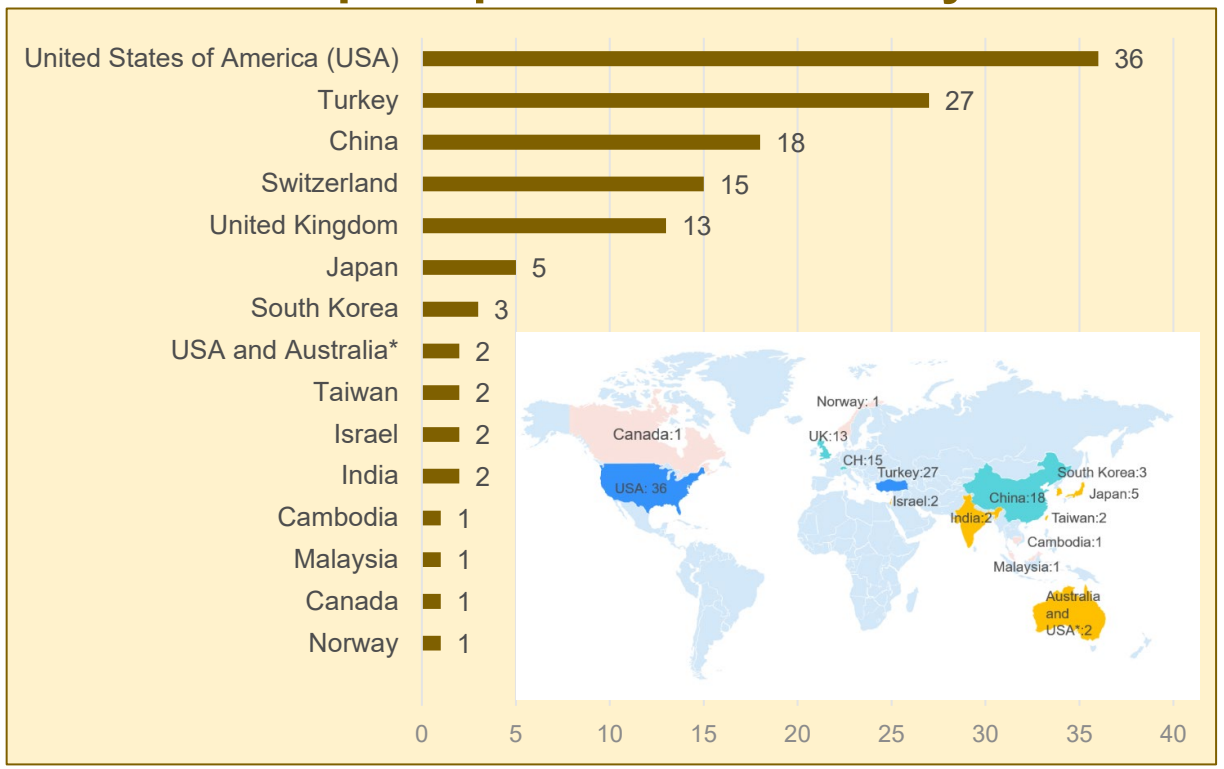


Number of replies per EU country



n = 529; photo credit: pixabay.com

Number of replies per non-EU country



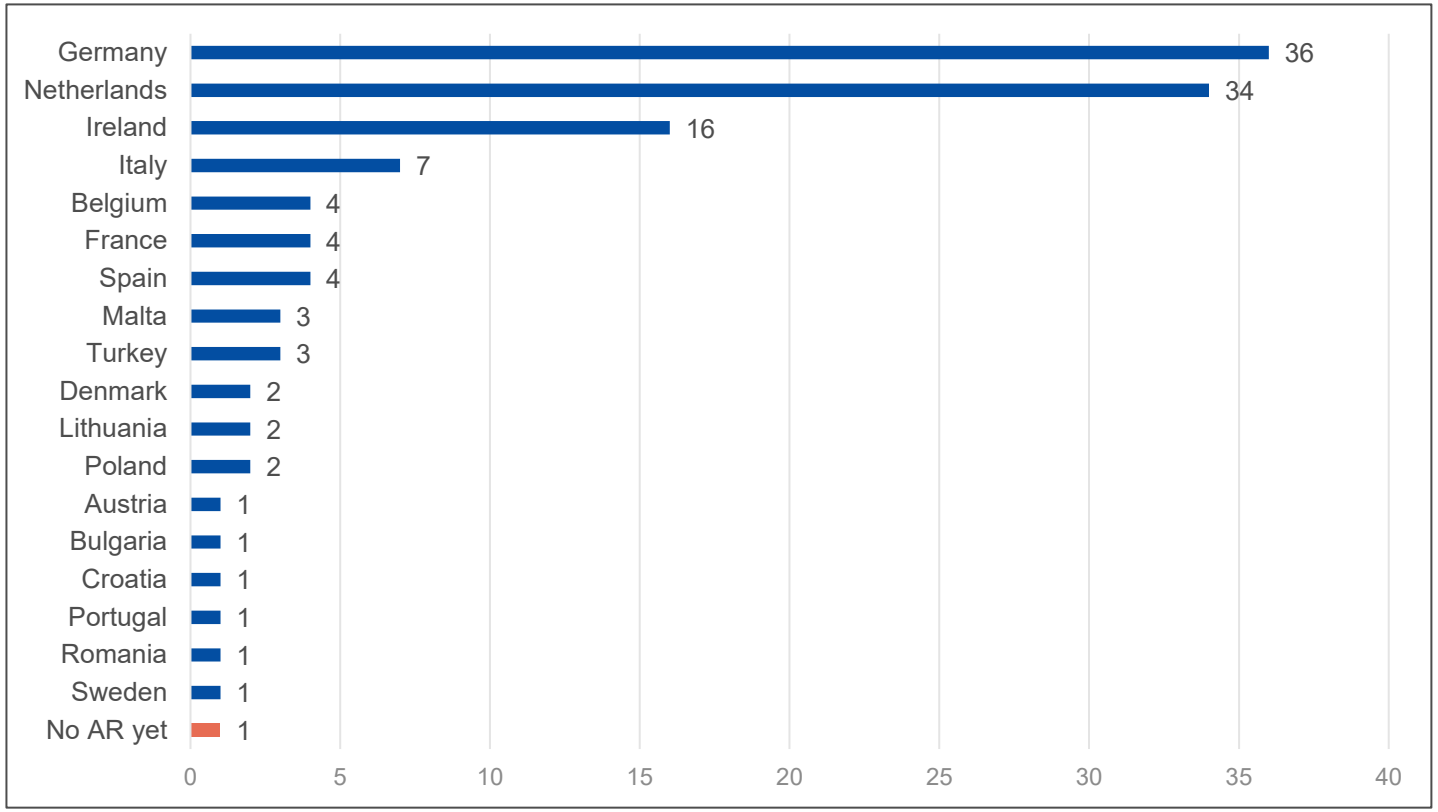
n = 129; * 2 respondents indicated USA and Australia

About

Responses to 1st MF/AR survey by country

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

(multiple choice)



Most of the ARs are located in:

1. Germany
2. Netherlands
3. Ireland

Notes:

- Data of 129 non-EU MFs
- **Multiple choice:** 7 out of 129 non-EU MFs indicated more than one AR; in total 149 ARs were mentioned.
- 26 out of 129 non-EU MFs indicated an AR based in Switzerland (*Note: Swiss ARs are not shown in the bar chart)*

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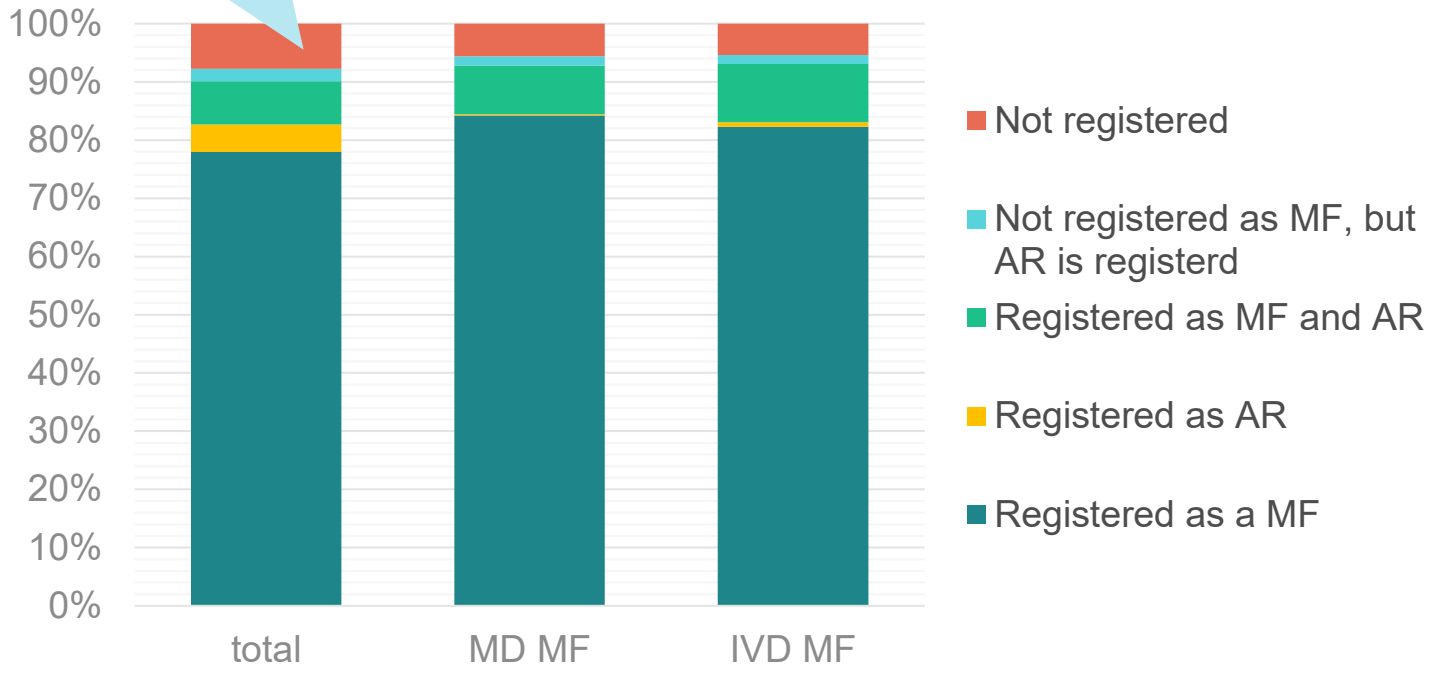
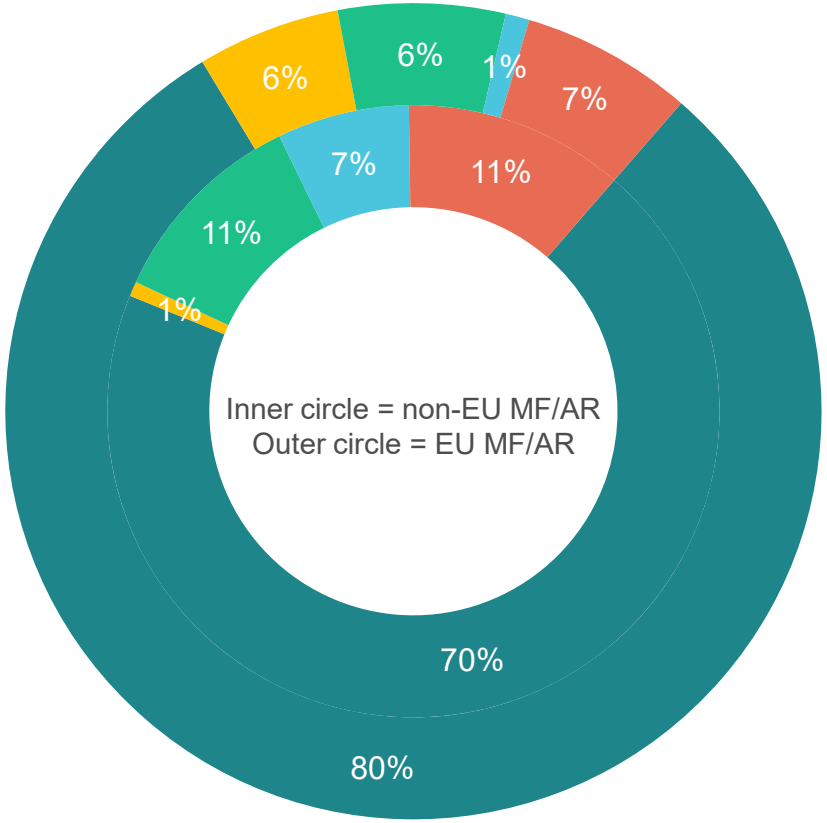
Responses to 1st MF/AR survey by registration in EUDAMED

About

Only 8% of the participating MF/ARs are not registered in EUDAMED (yet).

Registration status of respondents in EUDAMED





n = 658 MF/ARs participating in the survey
Note: Some participants may be in several categories (MD MF, IVD MF, AR)

European Commission

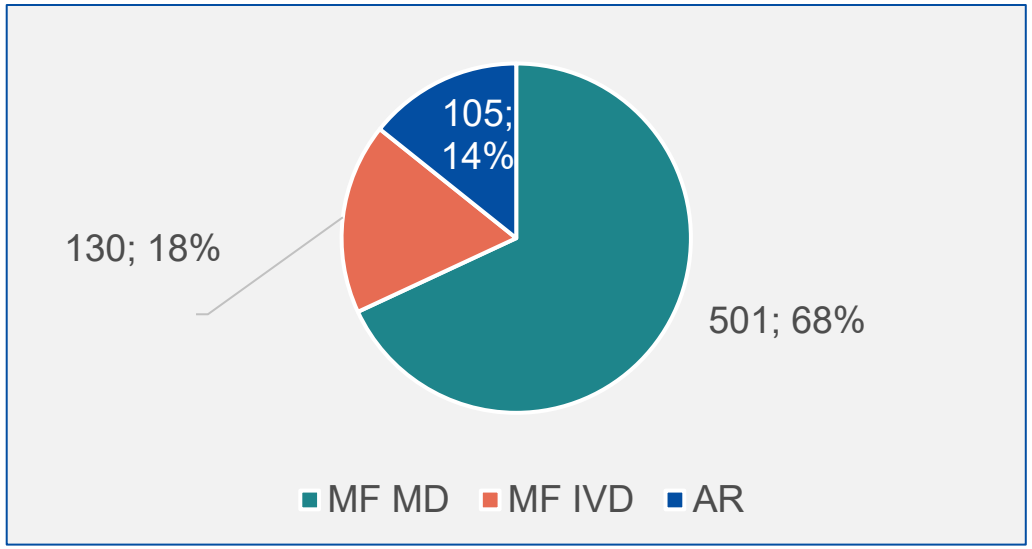
Responses to 1st MF/AR survey by company role

About

Of 658 replies received (several roles possible)

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

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



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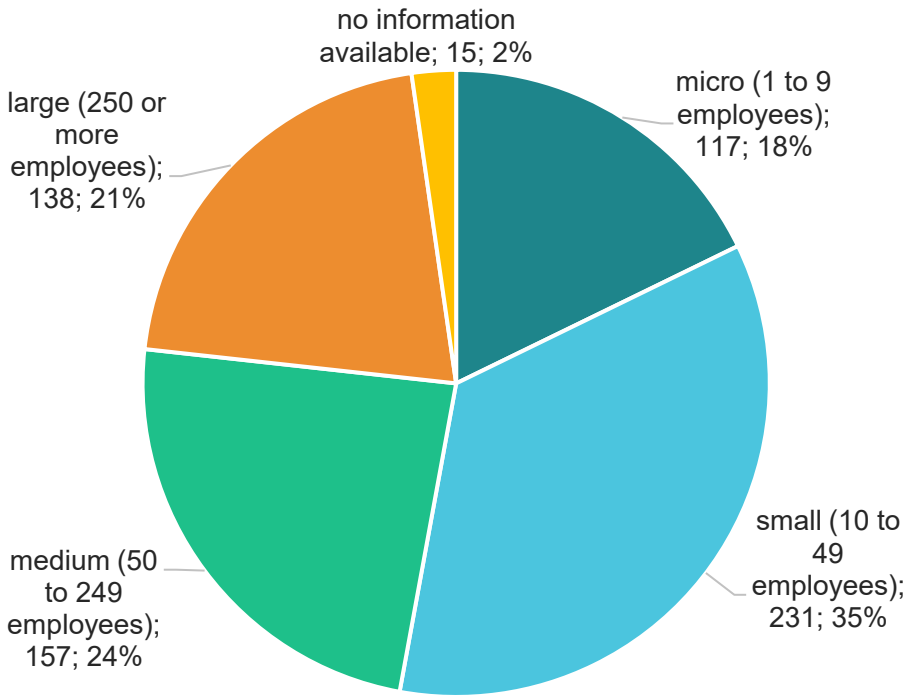
Responses to 1st MF/AR survey
by size of legal entity of organisation (globally)

About

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

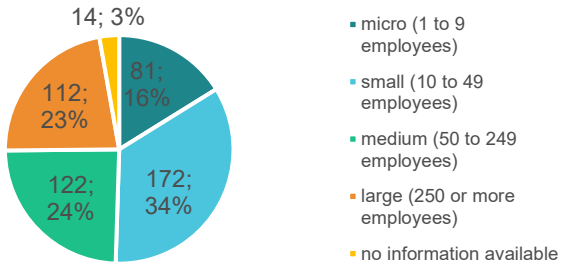
n = 658 companies participating in the survey



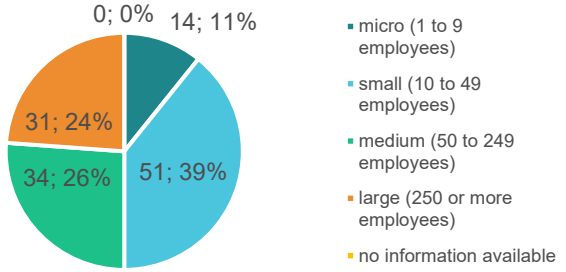
The MFs are mainly SMEs.

Company size by role (multiple choice)

MF MD

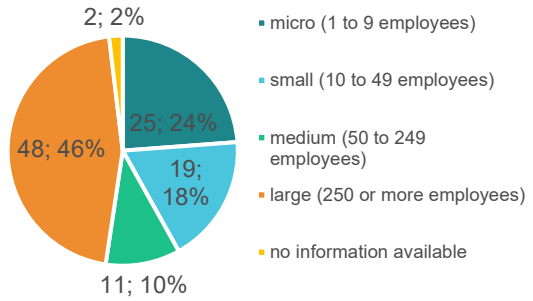


MF IVD

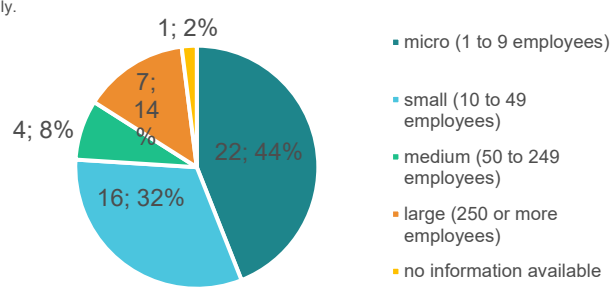


AR*

*n = 105 companies indicating to act as an authorised representative. Thereof 50 companies acted as AR only.



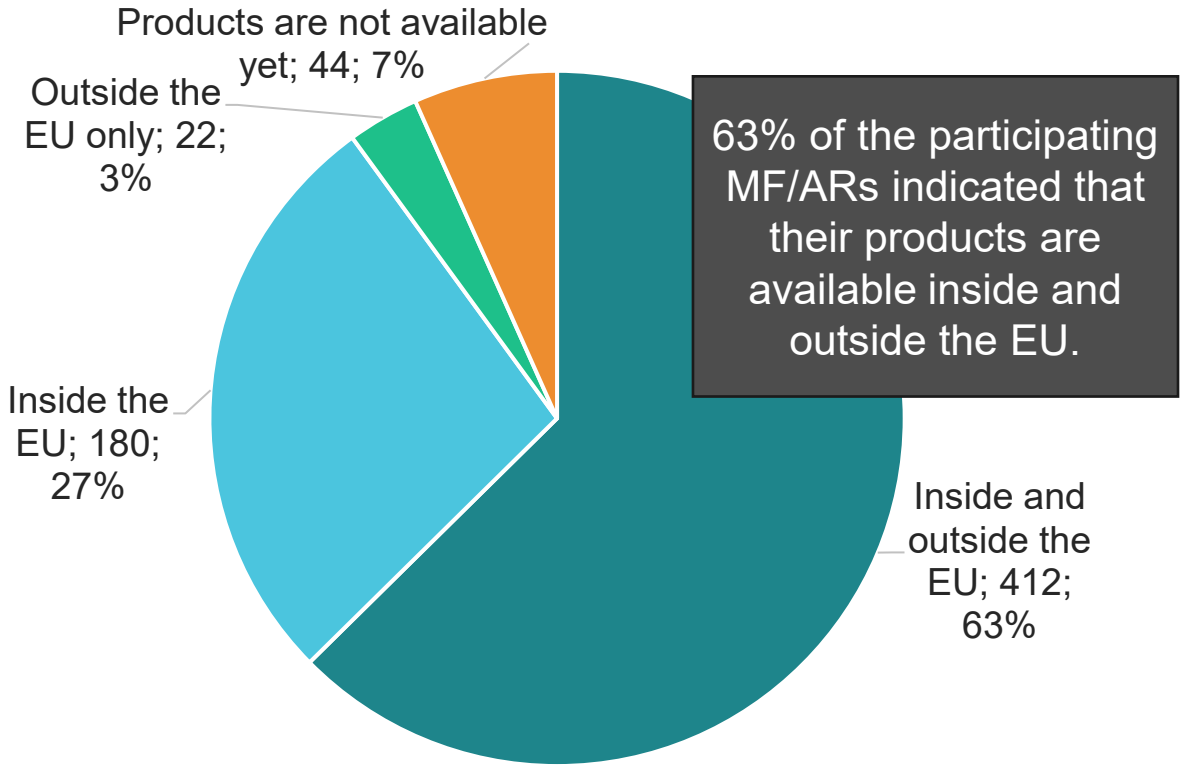
AR only



Responses to 1st MF/AR survey by location of product availability

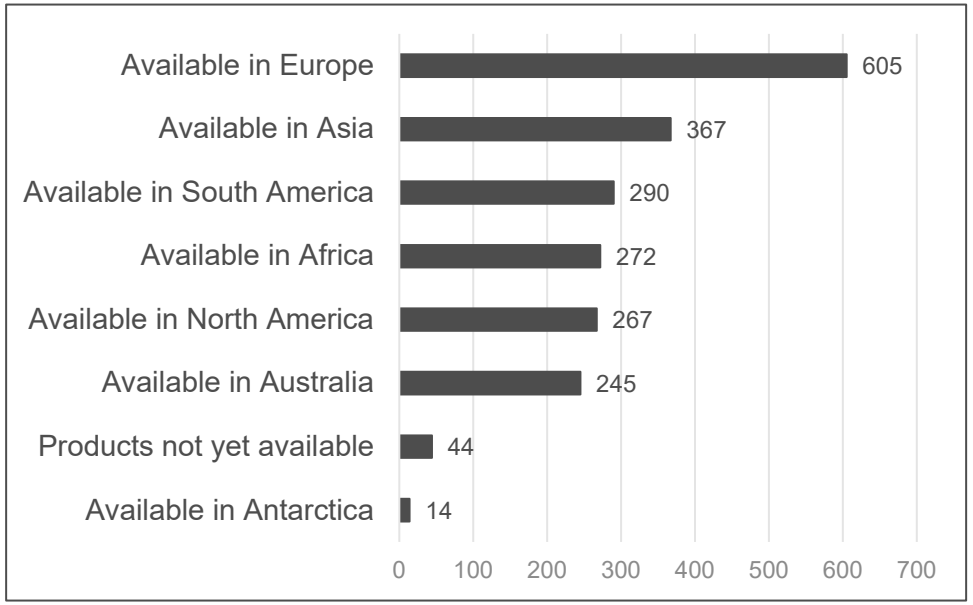
About

Availability of products by market



n = 658 MF/ARs participating in the survey

Availability of products by continent



Note: Respondents could give multiple answers. Some respondents did not connect the answers for questions 'by market' and 'by continent', which may lead to some discrepancies.

n = 658 MF/ARs participating in the survey, multiple responses possible

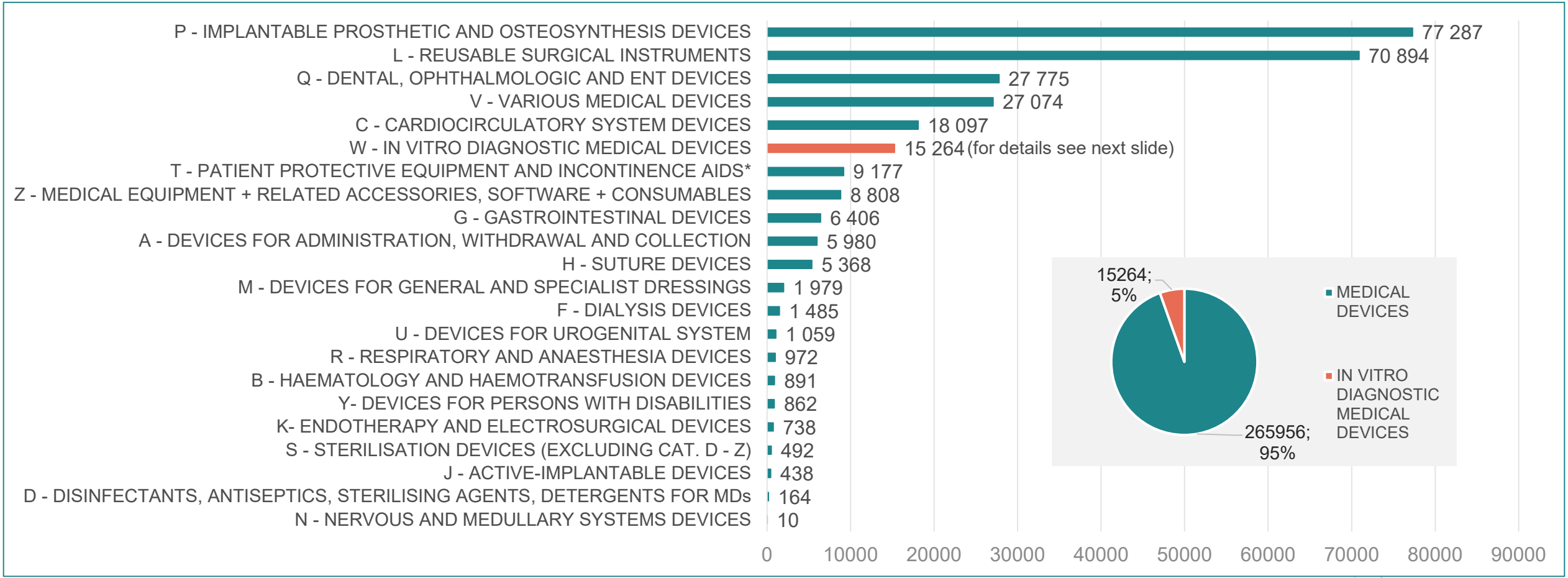
European Commission

Device areas (EMDN categories) currently included in the product portfolio

(number of devices referring to catalogue numbers)

About

Total number of devices referring to catalogue numbers: 281 220



* EXCLUDING PERSONAL PROTECTIVE EQUIPMENT – PPE; 507 out of 658 MF/AR answered this question (optional response was possible)

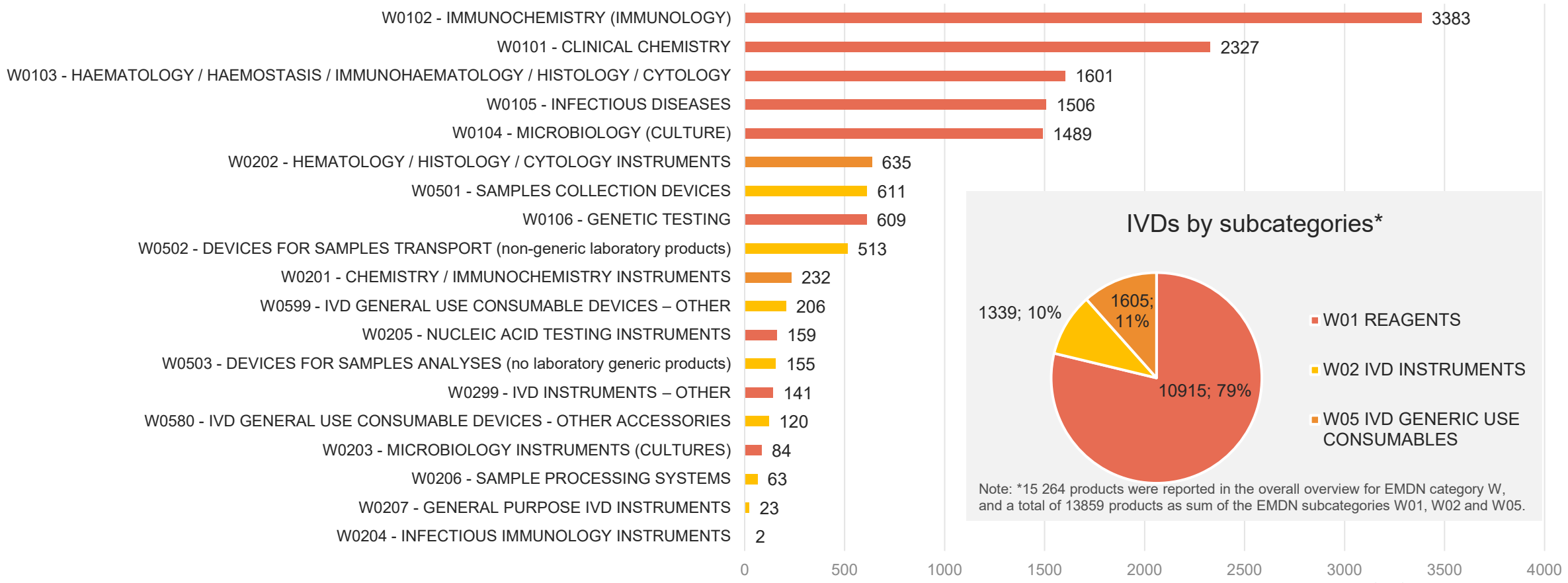
European Commission

IVDs (EMDN categories) currently included in the product portfolio

(number of devices referring to catalogue numbers)

About

Total number of IVDs referring to catalogue numbers (sum of subcategories): 15 264*



Data of 102 IVD MFs/AR

European Commission

MD

2.2. Survey results for medical devices

Questionnaire part 2.2. including questions 8 to 29

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

MD

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

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

Ⓜ: 17.846
(43%)

MF sample!

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

11503
(14%)

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

5599
(22%)

Note: These figures relate to the 501 responses from the manufacturers of MDs as of the end of October 2023.
Written agreements can be framework agreements with NBs (covering several applications) or contracts for each application (signed by the NB and manufacturer)
The **total number of applications** lodged also includes applications with issued certificates, ongoing applications and applications that were eventually refused.
Please, note that applications lodged for changes of existing MDR certificates are included as well.
* Even though the questions were asked in the same way to MF/AR and NBs, the MF seem to have a different interpretation of applications as NBs.
** The data shown comes from the medium data set Ⓜ – except for 2 NBs where the total number of applications filed was derived from the small data set Ⓢ since they could not provide the data per Annex.
According to the 6th NB survey, NBs have 13.398 clients for MDR/MDD/AIMDD.

MD

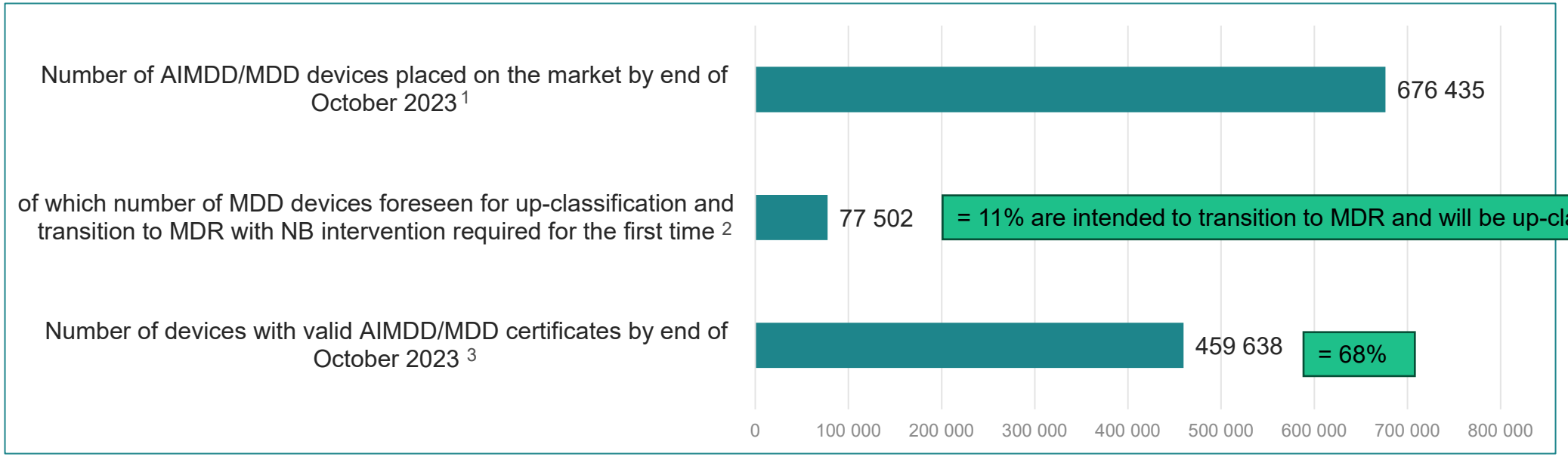
AIMDD/MDD
devices and certificates

AIMDD/MDD overview by the end of October 2023

(number of devices referring to catalogue numbers)

MD

Total responses from MFs for MDs: 501



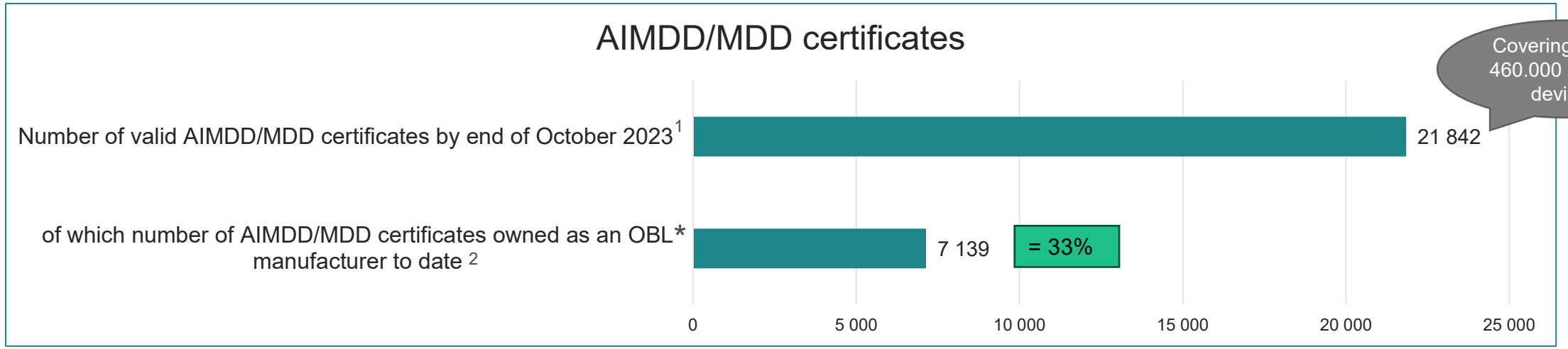
Notes:
[1] Data of 495 MFs, including 73 MFs with the indication '0';
[2] Data of 494 MFs, including 246 MFs with the indication '0';
[3] Data of 489 MFs, including 118 MFs with the indication '0'

European Commission

MD

AIMDD/MDD overview by the end of October 2023

Total responses from MFs for MDs: 501
Total no of valid MDD/AIMDD certificates indicated by NBs (by end of April 2022): 25.034



* Own Brand Labelling (OBL) means that a manufacturer of medical devices markets a CE marked device by an Original Equipment Manufacturer (OEM) under its own name. This practice is also known as a private label manufacturer or virtual manufacturer.

Notes:
[1] Data of 495 MFs, including 121 MFs with the indication '0';
[2] Data of 487 MFs, including 377 MFs with the indication '0';

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

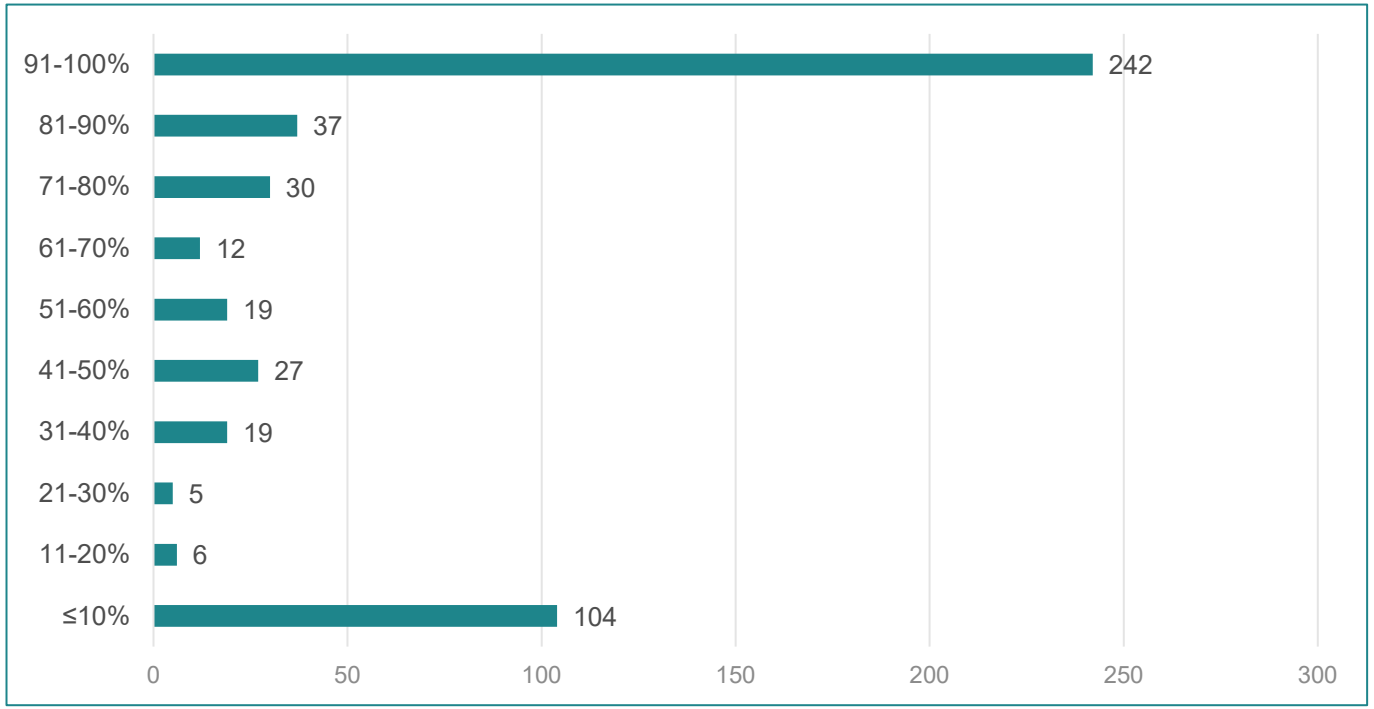
Details on AIMDD/MDD devices transition status to MDR (1)

MD

Total responses from 501 MFs for MDs

Some companies do not aim achieving 100% - see reasons why on the next slide

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



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

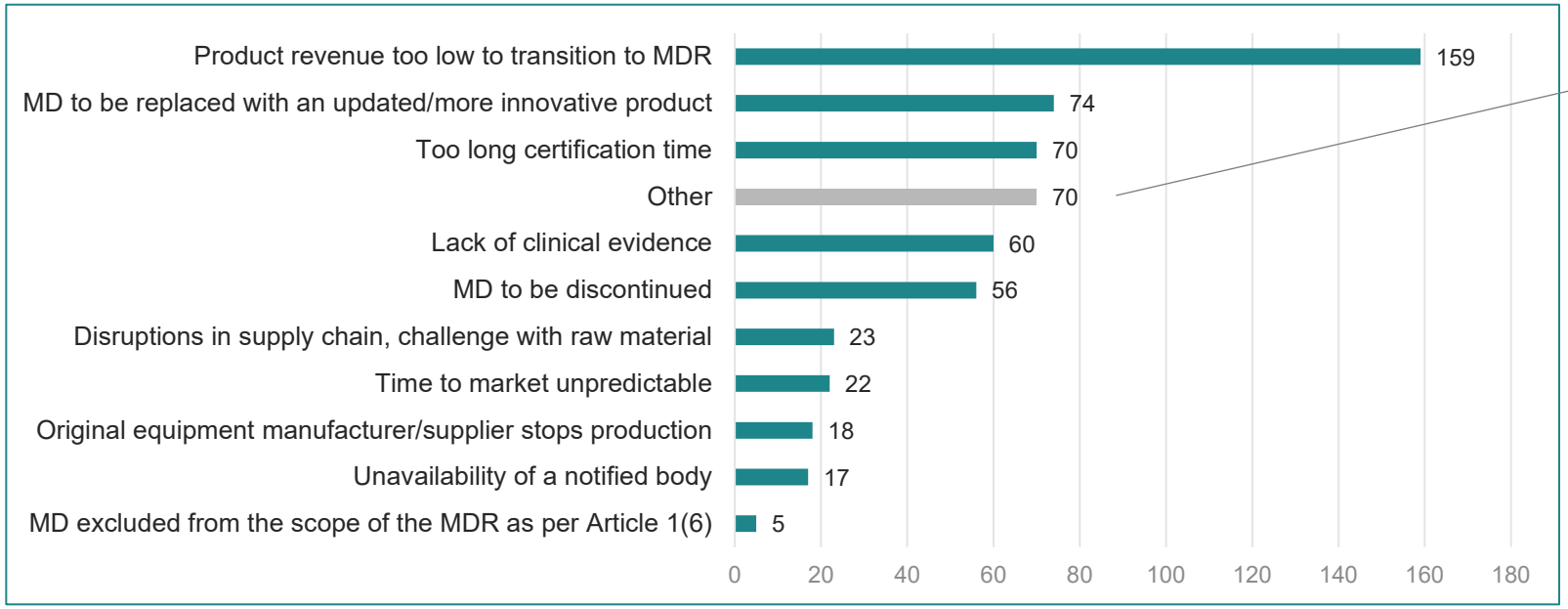
European Commission

Details on AIMDD/MDD devices transition status to MDR (2)

MD

Total responses from 501 MFs for MDs

If not all (100%) of the products have been transitioned or are planned to be transitioned to the MDR, what are the main reasons?



Some indicated 'other' reasons:

- business and top management decision;
- strategic rationalization/simplification of the product portfolio;
- some products are not yet ready for MDR certification;
- lack of time and resources;
- too many product groups with comprehensive technical documentation, therefore step-by-step implementation;
- some devices were disqualified as medical devices per MDCG 2019-11.

Notes: Number of mentions; Multiple answers per MF possible;
202 MFs (40%) indicated that this question is not applicable because 100% of products were already transferred

European Commission

MD

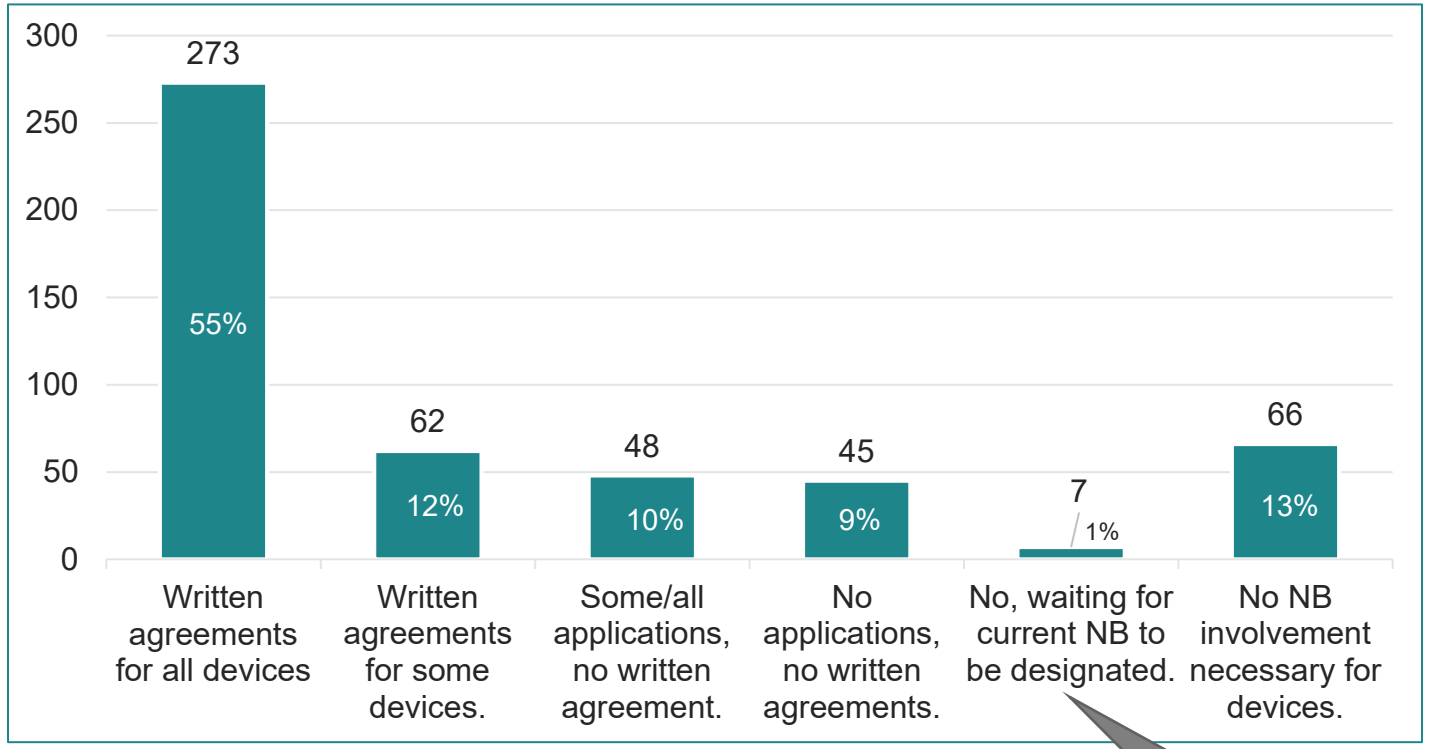
Notified bodies
written agreements, refused applications

Written agreements between MFs of MDs with Notified Bodies

MD

Total responses from 501 MFs for MDs

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



Note: Replies of 501 MD MFs

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

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

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

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

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

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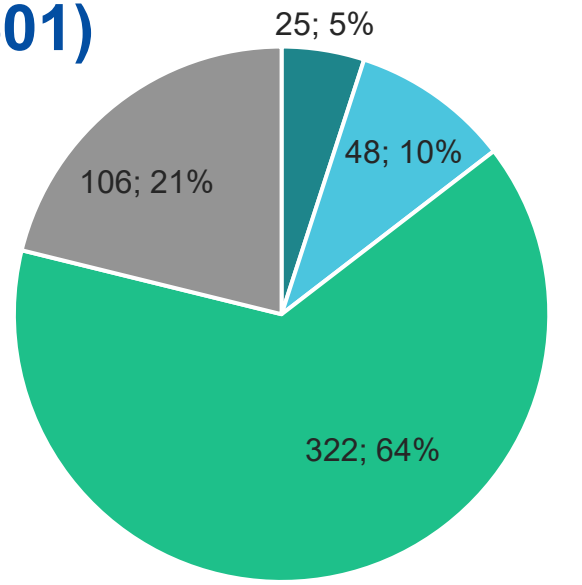
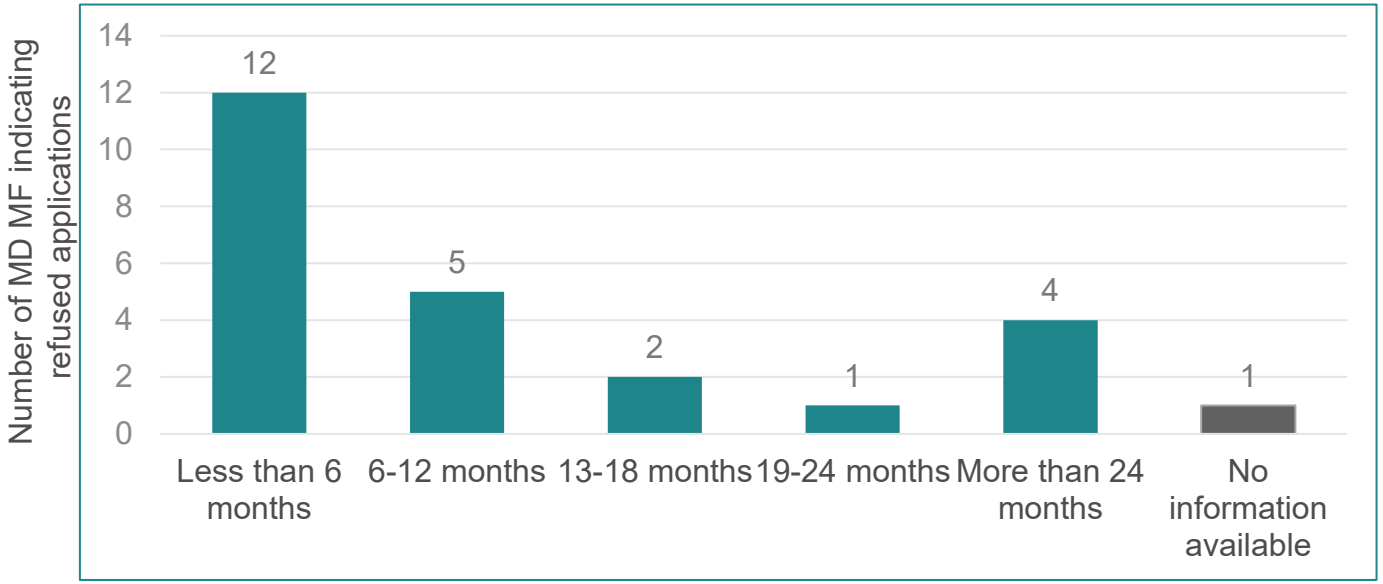
Refusal of applications from MD MF by Notified Bodies (1)

MD

Number of MD MF having been refused applications (n=501)



Time from application to refusal (for MD MF indicating 'Yes, application(s) refused.') (n=25)

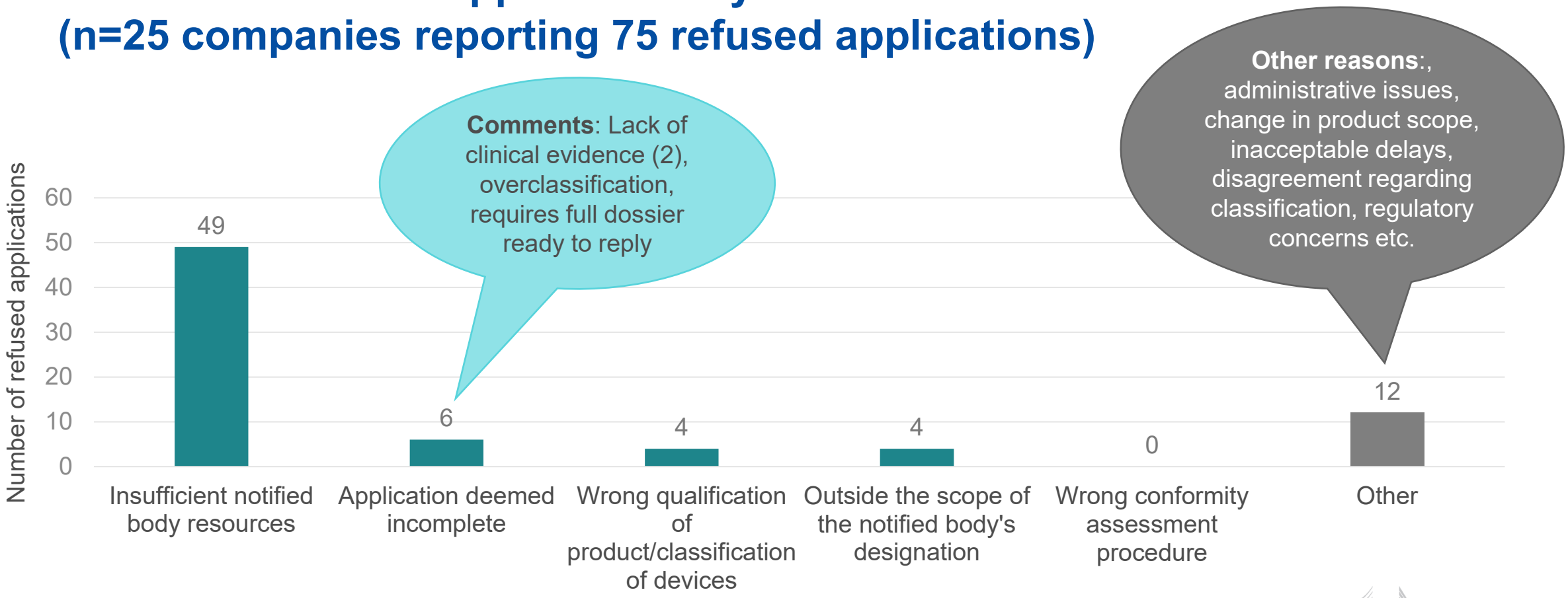


European Commission

Refusal of applications from MD MF by Notified Bodies (2)

MD

Number of refused applications by reason for refusal (n=25 companies reporting 75 refused applications)



European Commission

MD

MDR implementation
applications, certificates, timelines

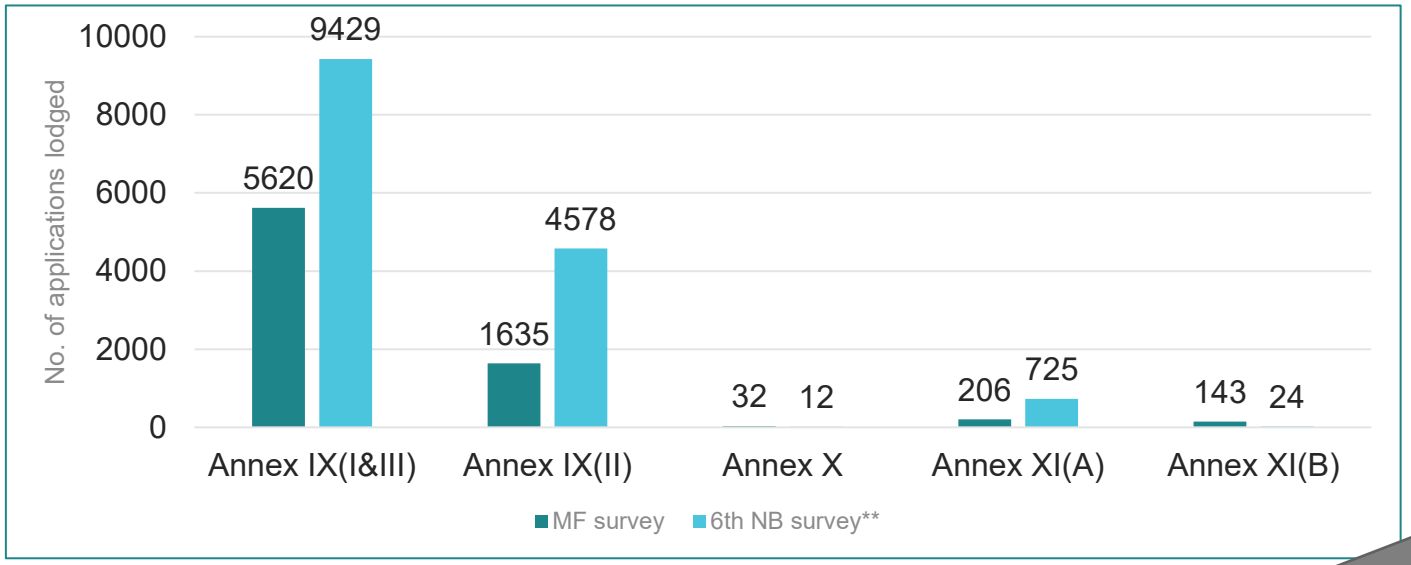
European Commission

Applications lodged under MDR by end October 2023

MD

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 6th NB survey (covering the same data period until 31/10/2023):
Total number of applications filed by Annex Ⓜ: **14.768****
* 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 Ⓜ – 2 NBs could not provide the data per Annex.

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): 440 (6%)

Total number of applications: 7636
(thereof 1163 (15%) applications for change)

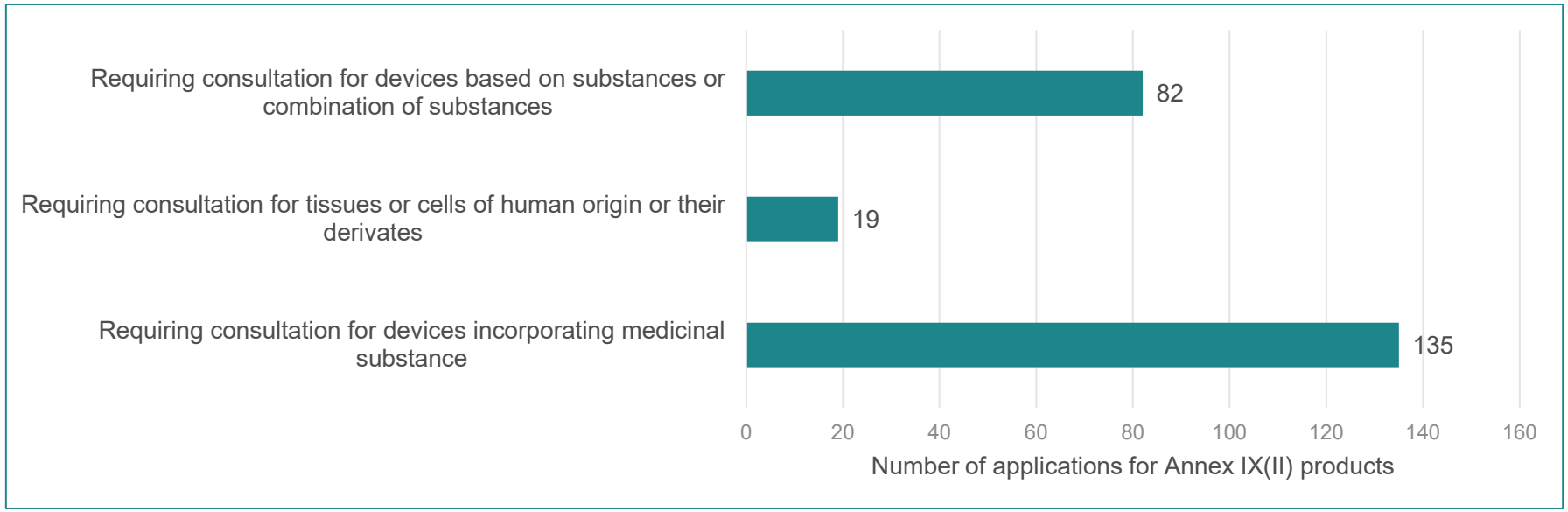
European Commission

Applications lodged under MDR for MD requiring consultation by end October 2023

MD

Applications for Annex IX(II) products requiring consultation

Note: Responses from 501 MFs for MDs.



European Commission

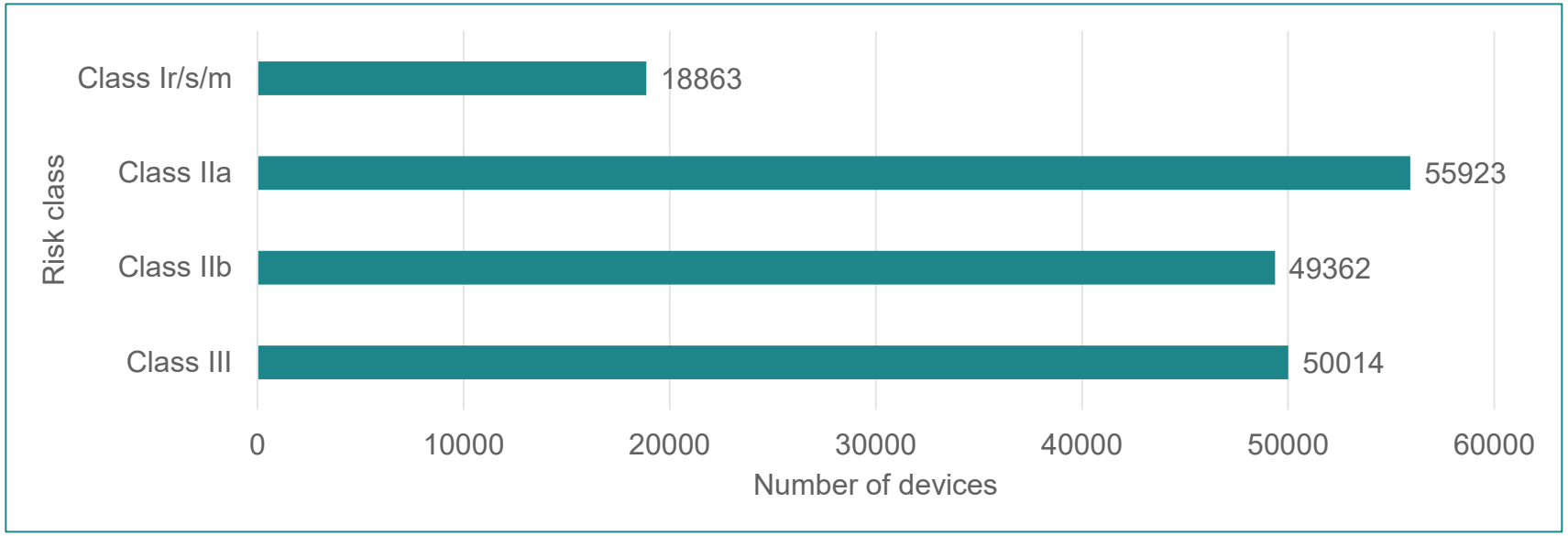
MD undergoing MDR conformity assessment by October 2023

MD

Total number of MDs referring to catalogue numbers reported in this survey: 265.956

Total number of devices (by catalogue number) undergoing MDR conformity assessment by end of October 2023: 175.853 (= 66% of reported MDs)

By risk class:



Note: A total of 174162 devices were indicated by risk classes.

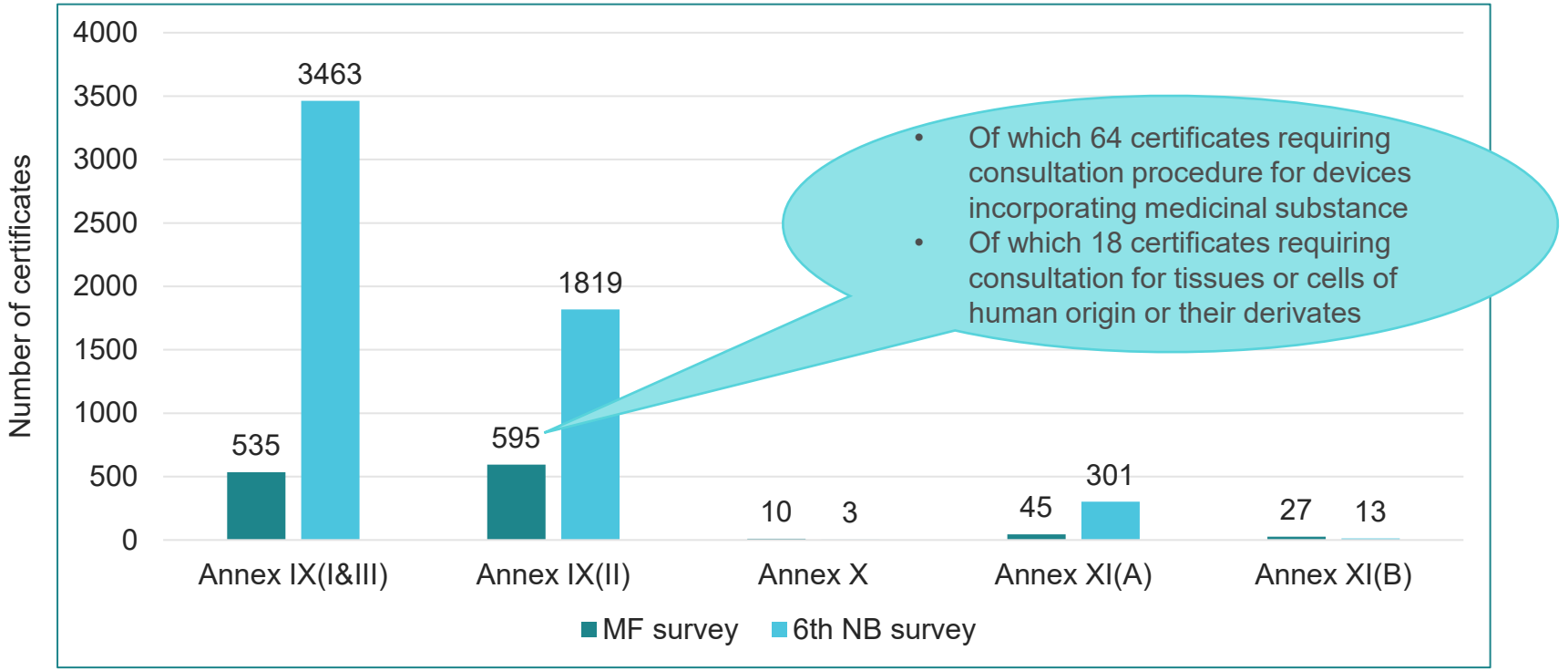
European Commission

MD

Certificates issued to MD MF under MDR

Number of certificates issued to MF for MDs under MDR by Annex by end October 2023

For comparison data of the 6th NB survey (covering the same data period until 31/10/2023):
For comparison data of the 6th NB survey (covering the same data period until 31/10/2023): 5599*
* 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.



Number of devices (catalogue numbers) covered in MDR certificates issued by end of October 2023: 187152

Thereof **new** devices (devices which have never been CE-marked before but need CE-marking under the MDR to access the EU market): 1206

Total number of certificates: 1212

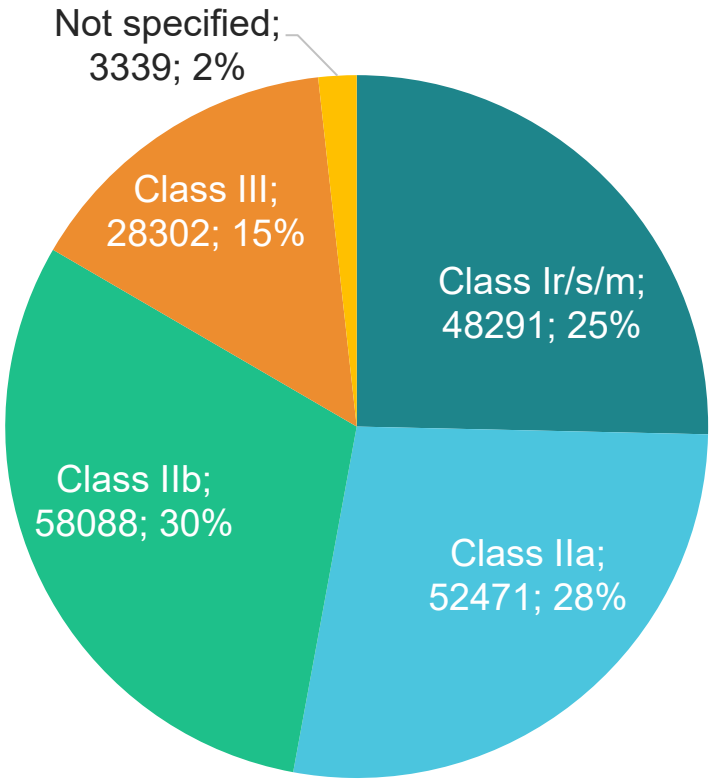
European Commission

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 2023:
190491

of which new devices*:
1206; 0,6%



Note: n=196 MF; 305 MF indicated '0'

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

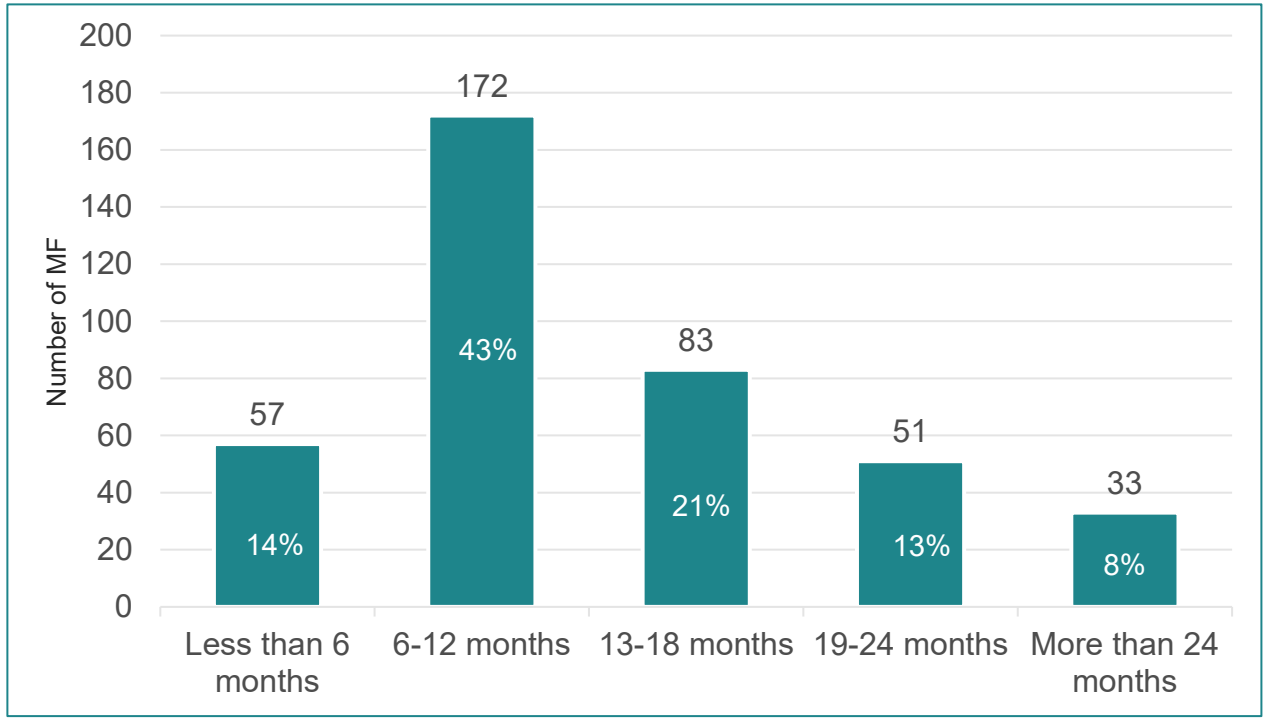
European Commission

MD

Timelines

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

Total responses from 501 MFs for MDs



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

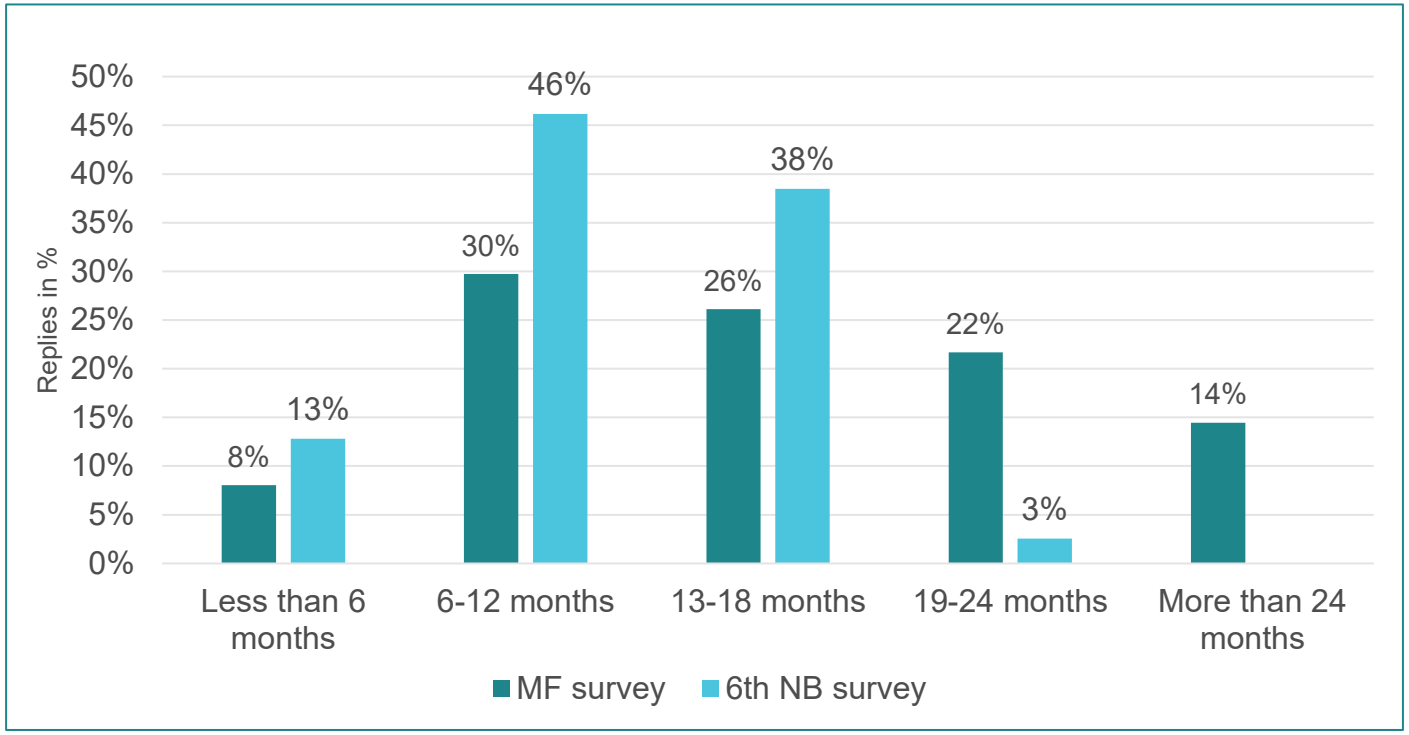
Note: Replies of 396 MD MFs
105 MFs indicated 'no information available'

European Commission

MD

Timelines

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



Total responses from 501 MFs for MDs

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

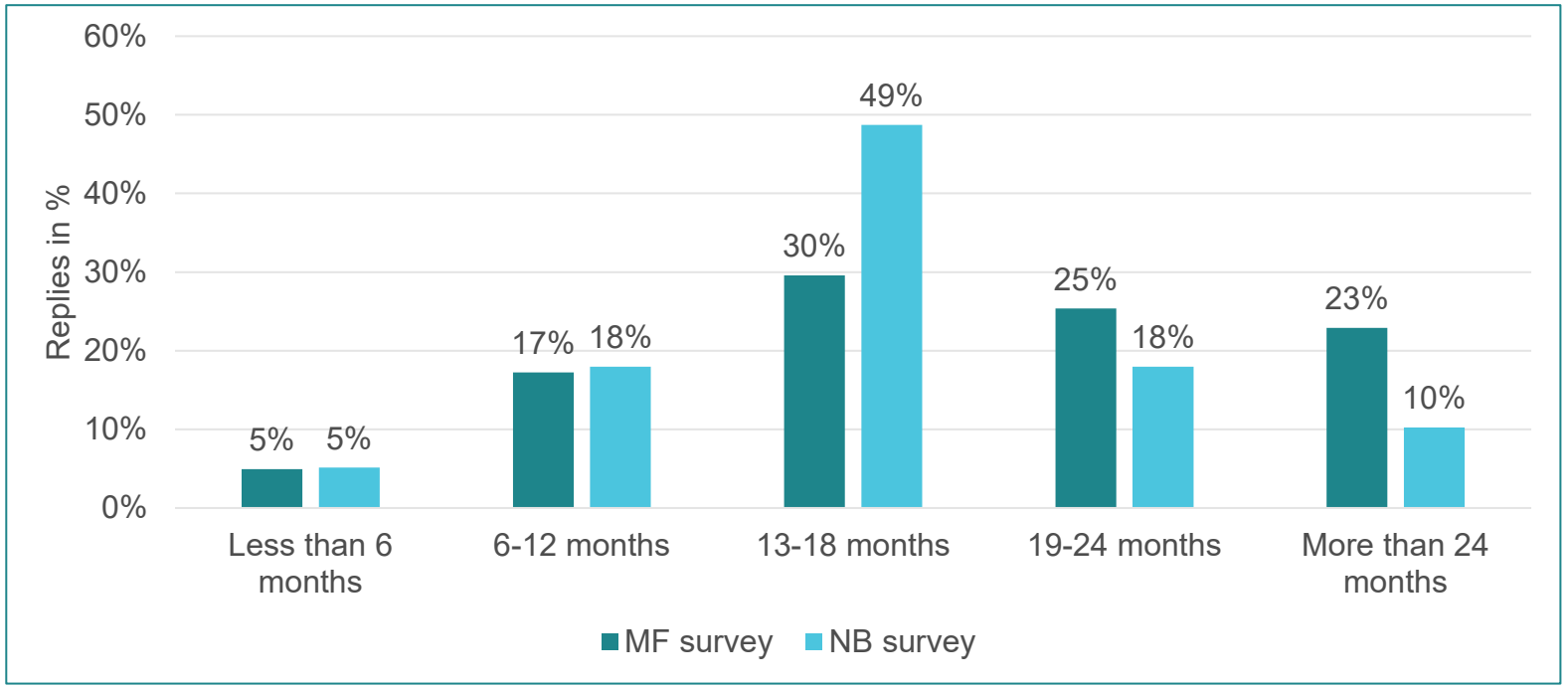
European Commission

MD

Timelines

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

Total responses from 501 MFs for MDs



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

European Commission

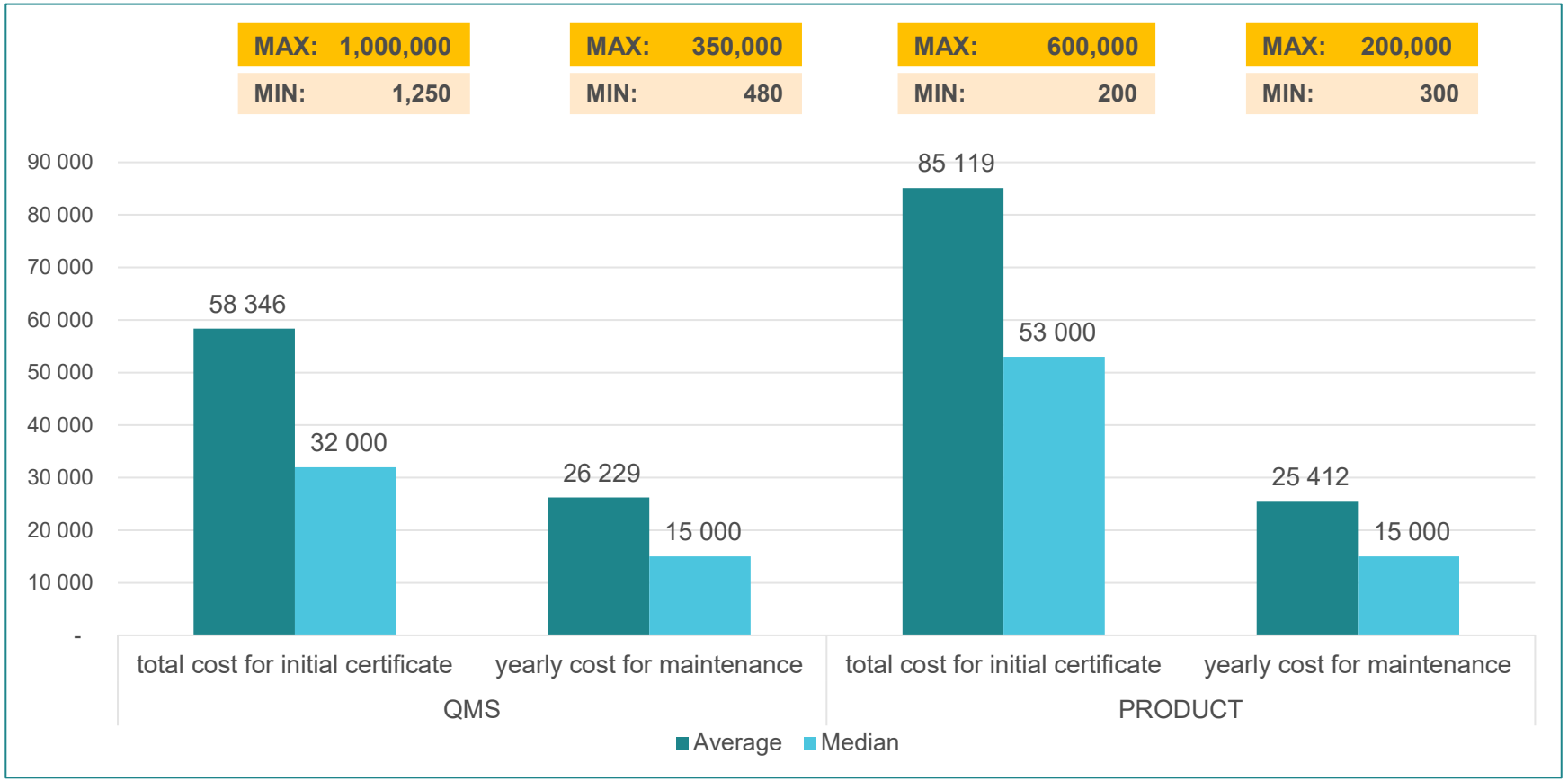
MD

Estimates

MD

Costs for MDR certification

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



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

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

- QMS: estimations of costs for initial certificate by 262 MFs; for maintenance: 247 MFs taken into account with responses >0.
- Product: estimations of costs for initial certificate by 233 MFs; for maintenance: 193 MFs taken into account with responses>0.

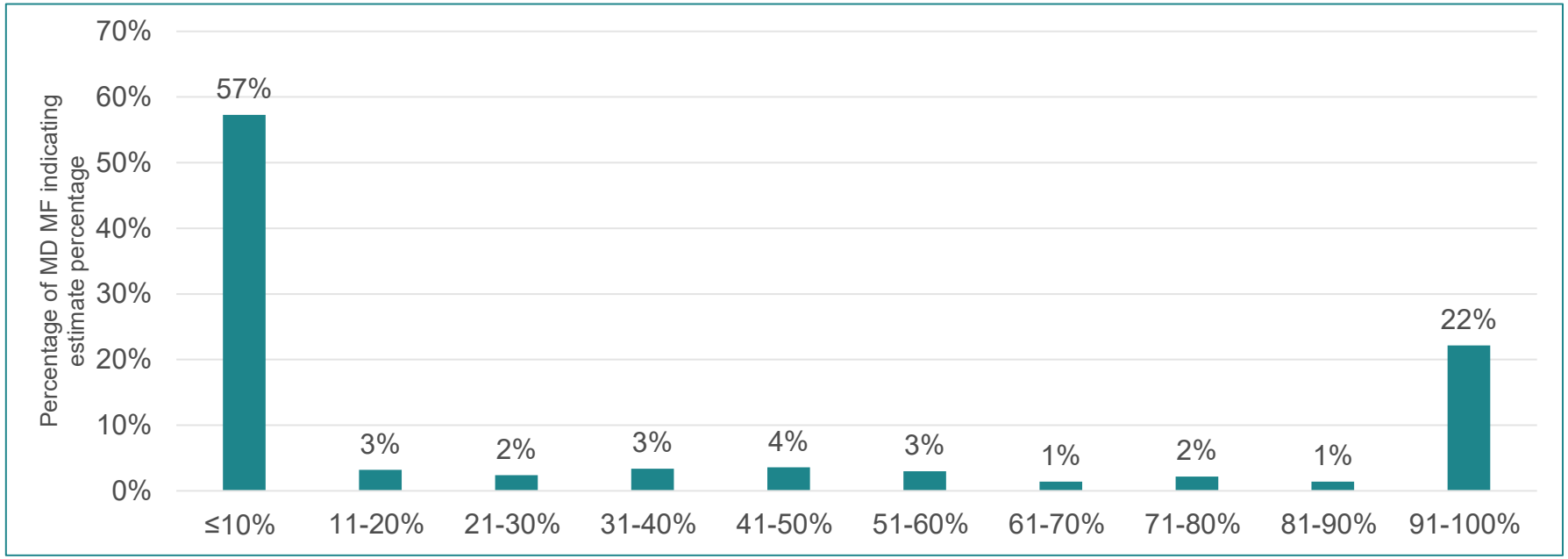
European Commission

MD

Transition completion status

Total responses from 501 MFs for MDs

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



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

European Commission

MD

New devices

Estimate number of new devices (which have never been certified before) for which applications will be submitted to a NB in the next 12-18 months:

21,823 new devices (sum)

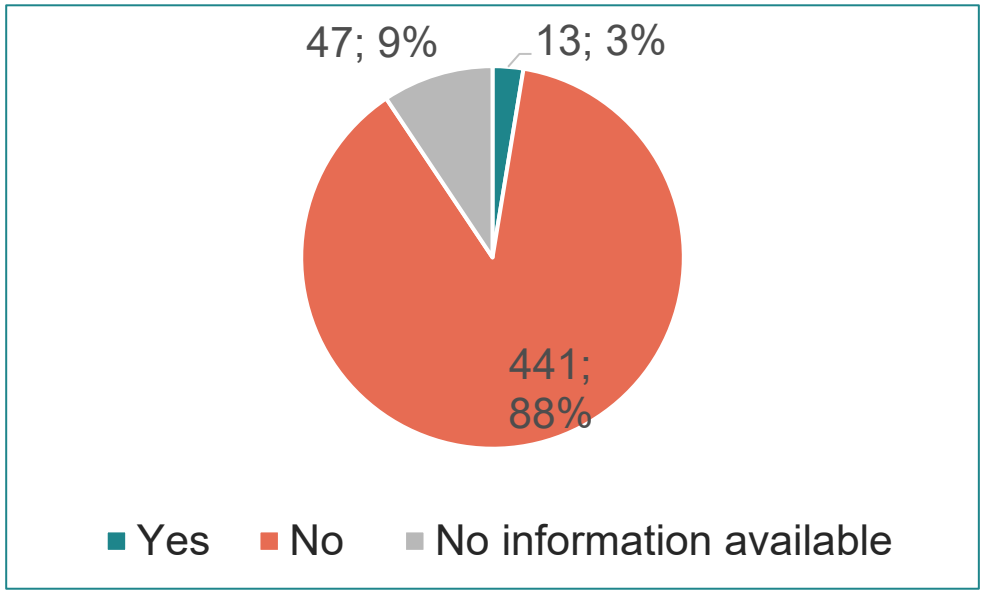
(Note: n=181 companies)

MD

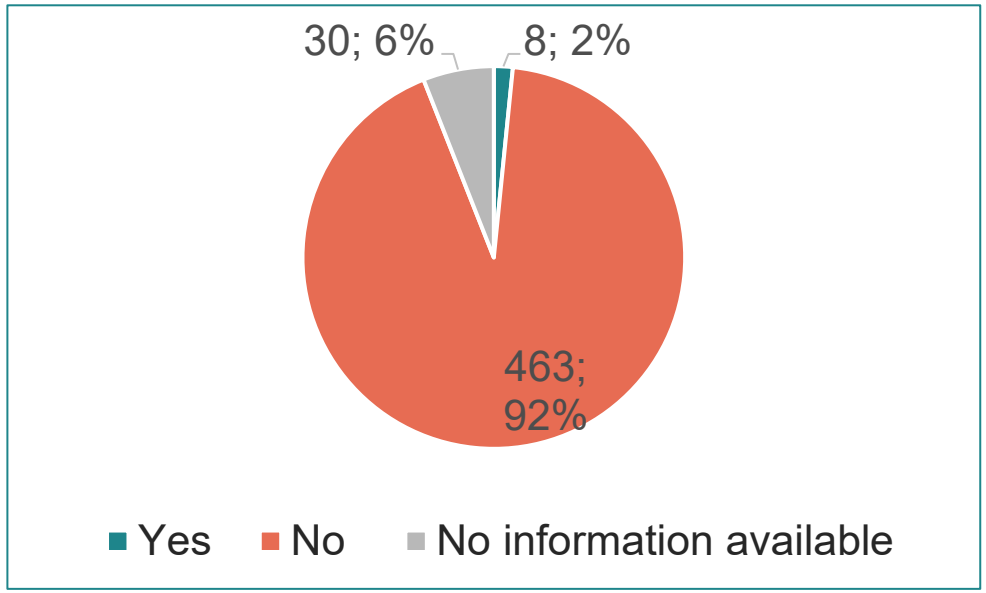
Plans to transition specific products

Plans to transition products without intended medical purpose* listed in Annex XVI to the MDR (n=501)

Note: Products without an intended medical purpose that are listed in Annex XVI to the MDR are covered by that Regulation from 22 June 2023, which is the date of application of Annex XVI common specifications set out in Commission Implementing Regulation (EU) 2022/2346.



Plans to transition products with dual purpose (medical and non-medical intended purpose) to the MDR (n=501)

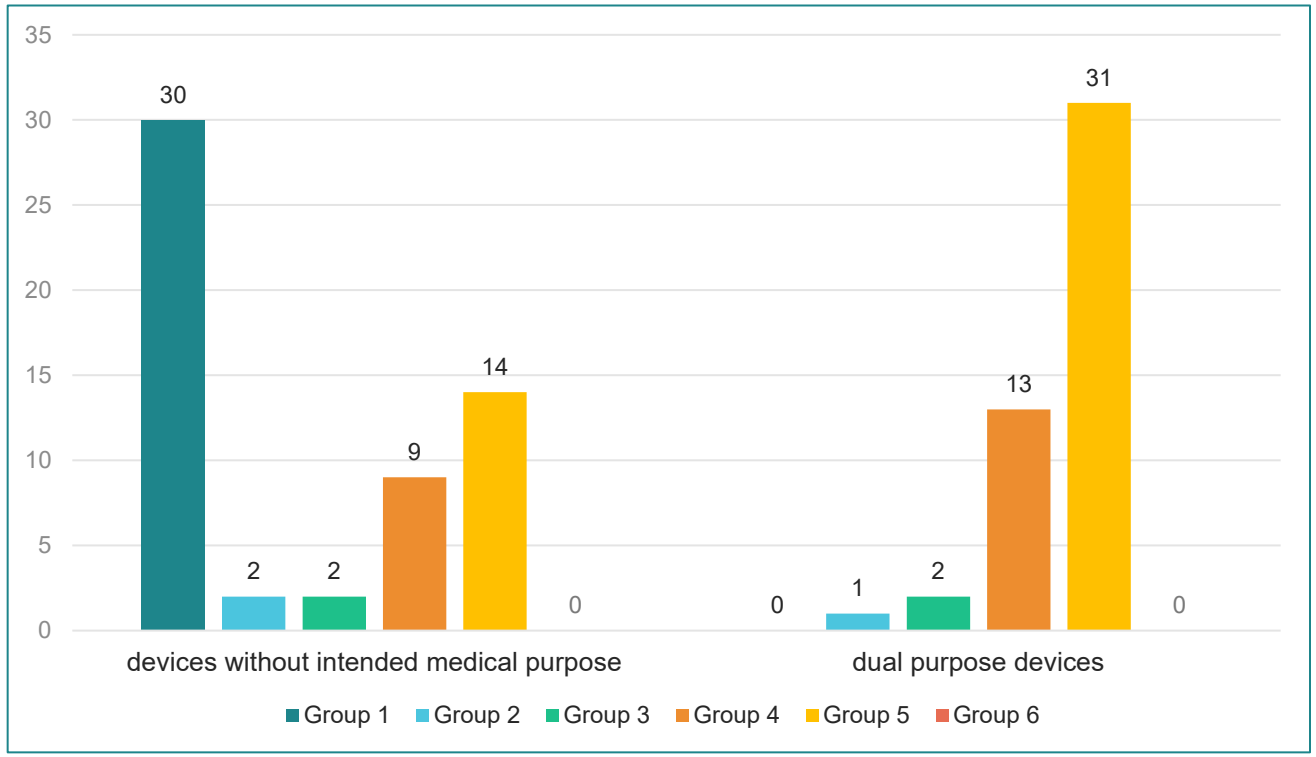


European Commission

MD

Plans to transition specific products

Number of types of products without an intended medical purpose listed in Annex XVI and dual purpose devices planned to transition to the MDR per group (if yes in previous slide, n<501)



LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE REFERRED TO IN ARTICLE 1(2) MDR

1. Contact lenses or other items intended to be introduced into or onto the eye.
2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
3. Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.
4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
5. High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.
6. Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

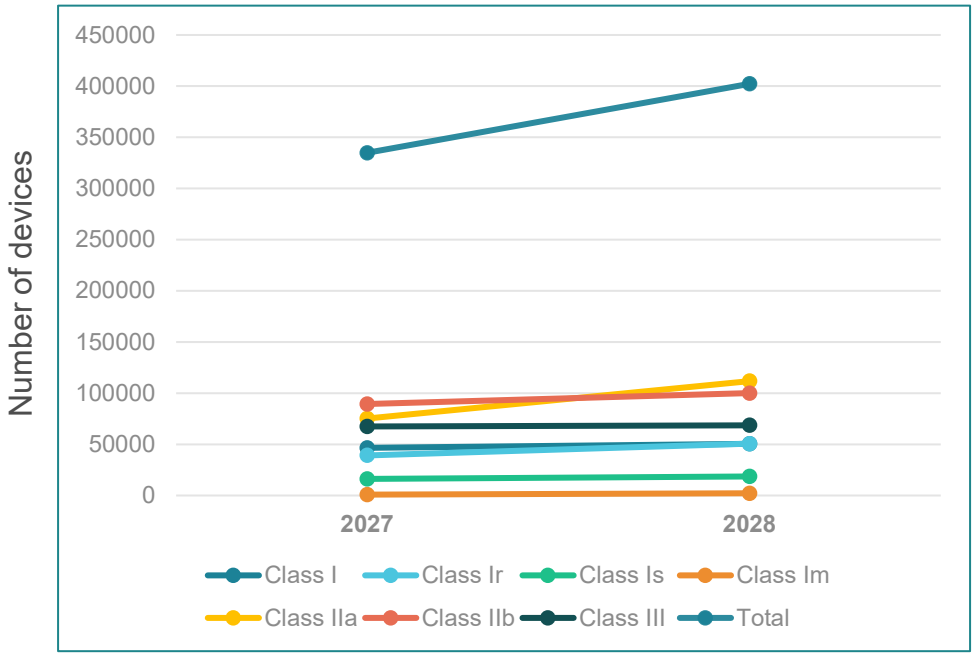
Note: **Products without an intended medical purpose** that are listed in Annex XVI to the MDR are covered by that Regulation from 22 June 2023, which is the date of application of Annex XVI common specifications set out in Commission Implementing Regulation (EU) 2022/2346.

European Commission

MD

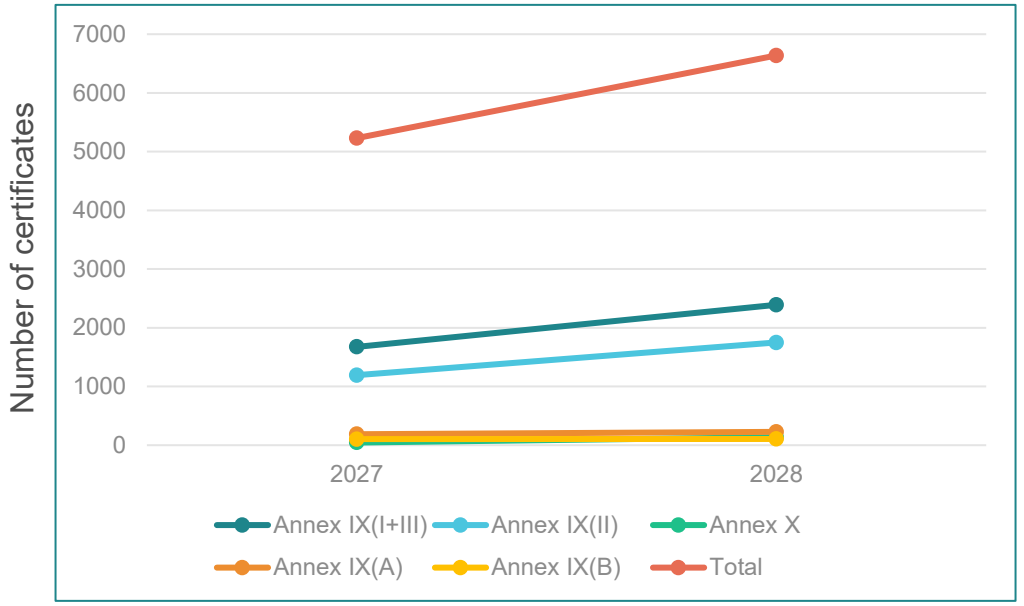
Future projections

Estimate number of MDR devices per class placed on the market at the end of the transitional period (2027 or 2028) (n=501)



Notes:
- Selected data for some MD MF not available.
- Many actors have entered the same data for 2027 and 2028. For actors that entered data for the year 2027 and "0" for 2028, the same data as for 2027 was taken for 2028.

Estimate number of MDR certificates per annex by the end of the applicable transitional period (2027 or 2028) (n=501)



Notes:
- No data available for two MD MFs.
- Many actors have entered the same data for 2027 and 2028. For actors that entered data for the year 2027 and "0" for 2028, the same data as for 2027 was taken for 2028.

European Commission

MD

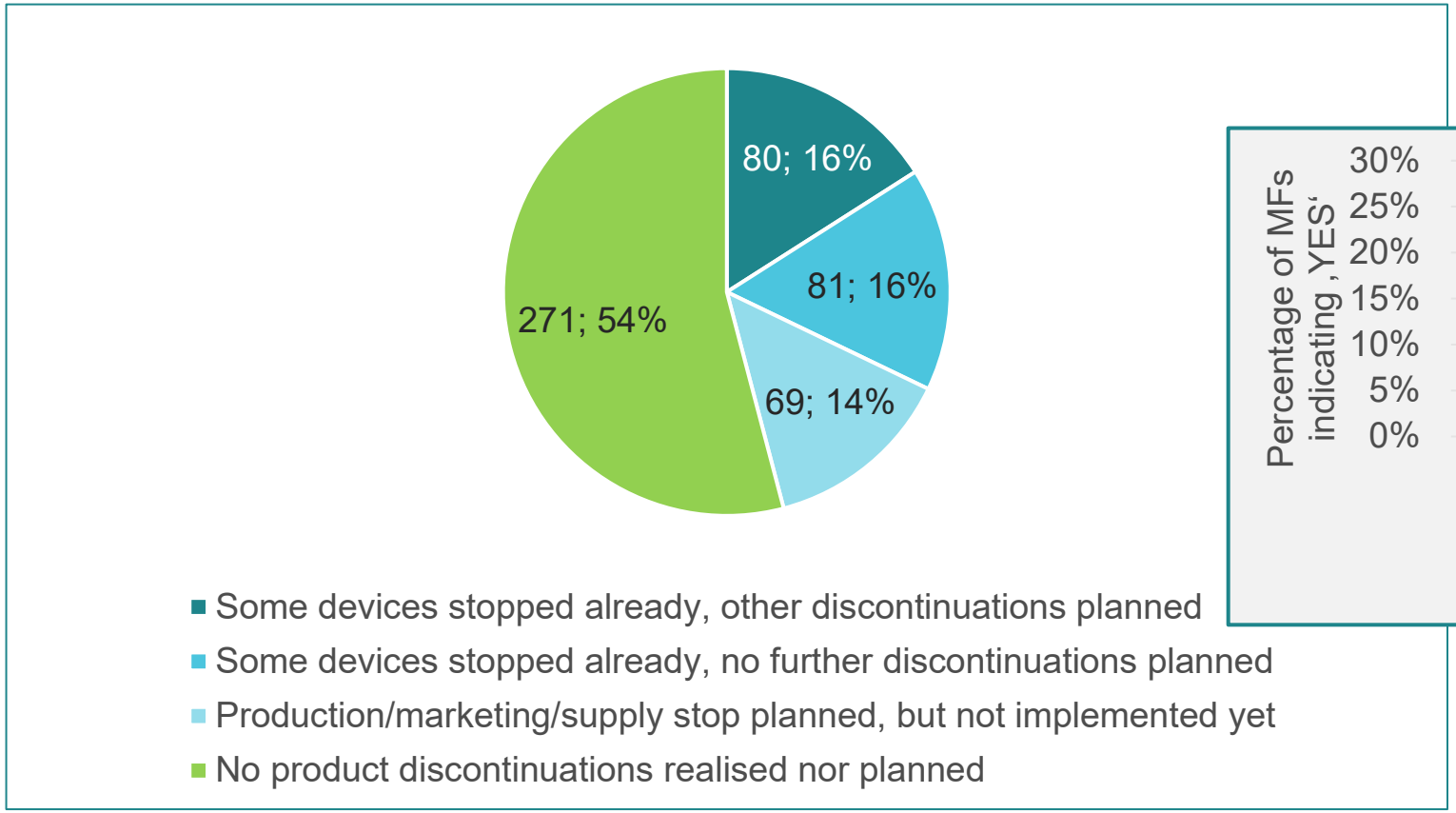
Discontinuation medical devices

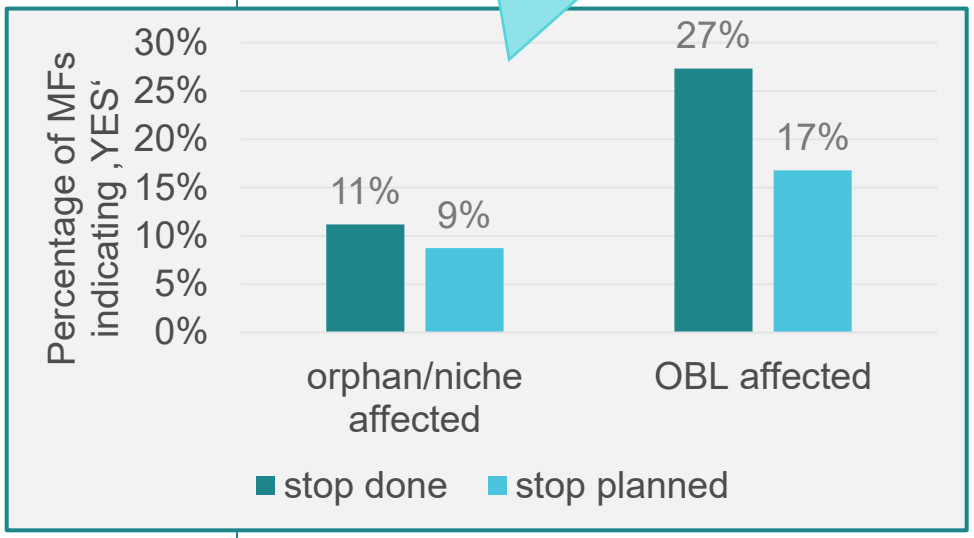
Discontinuation of medical devices (1)

MD

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

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

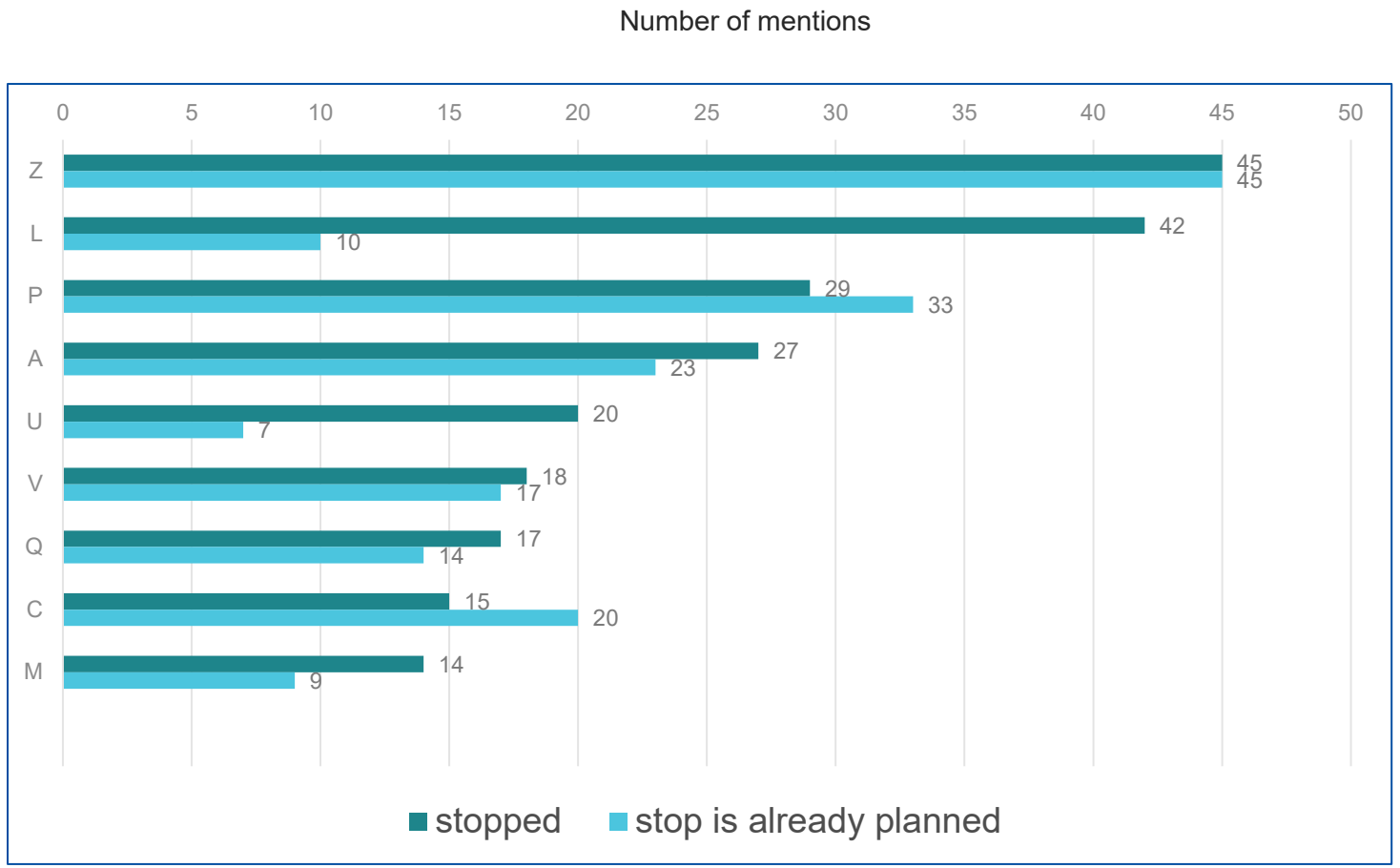




European Commission

MD

Discontinuation of medical devices (2)



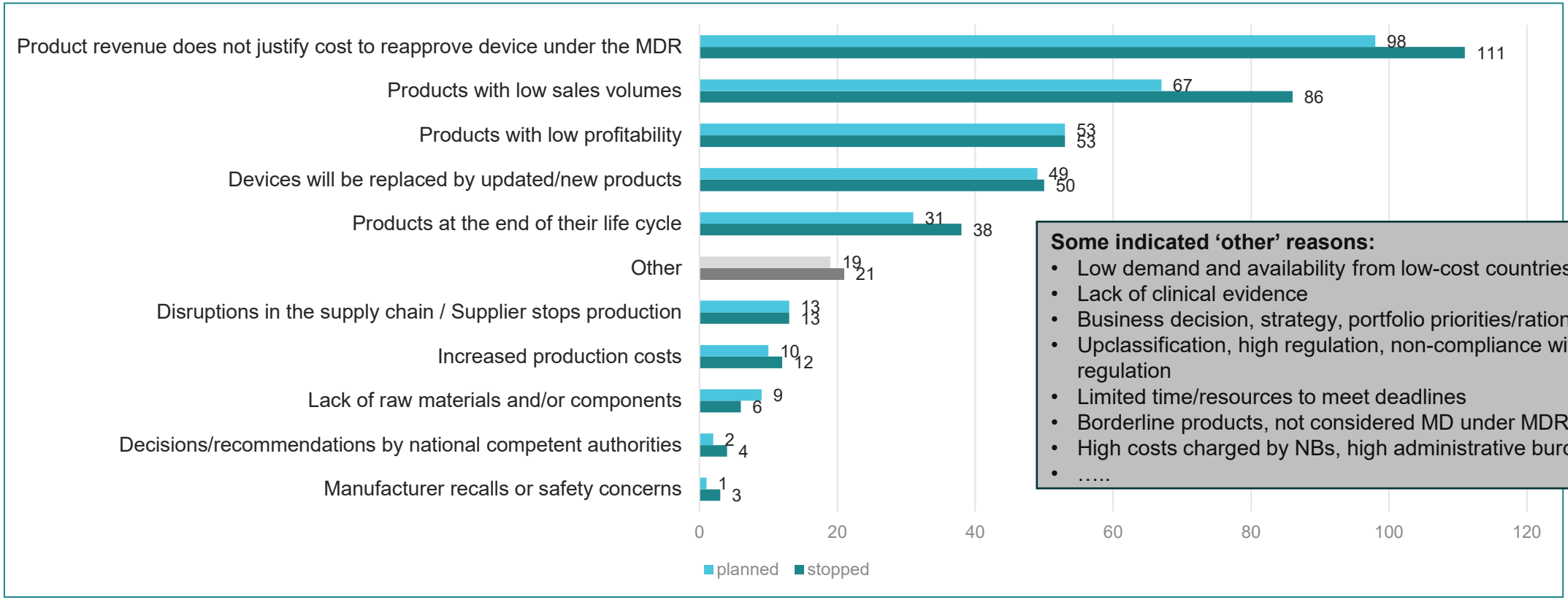
Types of MDs (by EDMN code) stopped or where "stop is already planned" (top mentions in comment section)

European Commission

MD

Discontinuation of medical devices (3)

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



Some indicated 'other' reasons:

- Low demand and availability from low-cost countries
- Lack of clinical evidence
- Business decision, strategy, portfolio priorities/rationalisation
- Upclassification, high regulation, non-compliance with regulation
- Limited time/resources to meet deadlines
- Borderline products, not considered MD under MDR
- High costs charged by NBs, high administrative burden
- …..

Notes: Number of mentions; Multiple answers per MF possible; 161 MFs having stopped and 149 MF planning to stop participated in this survey question.

European Commission

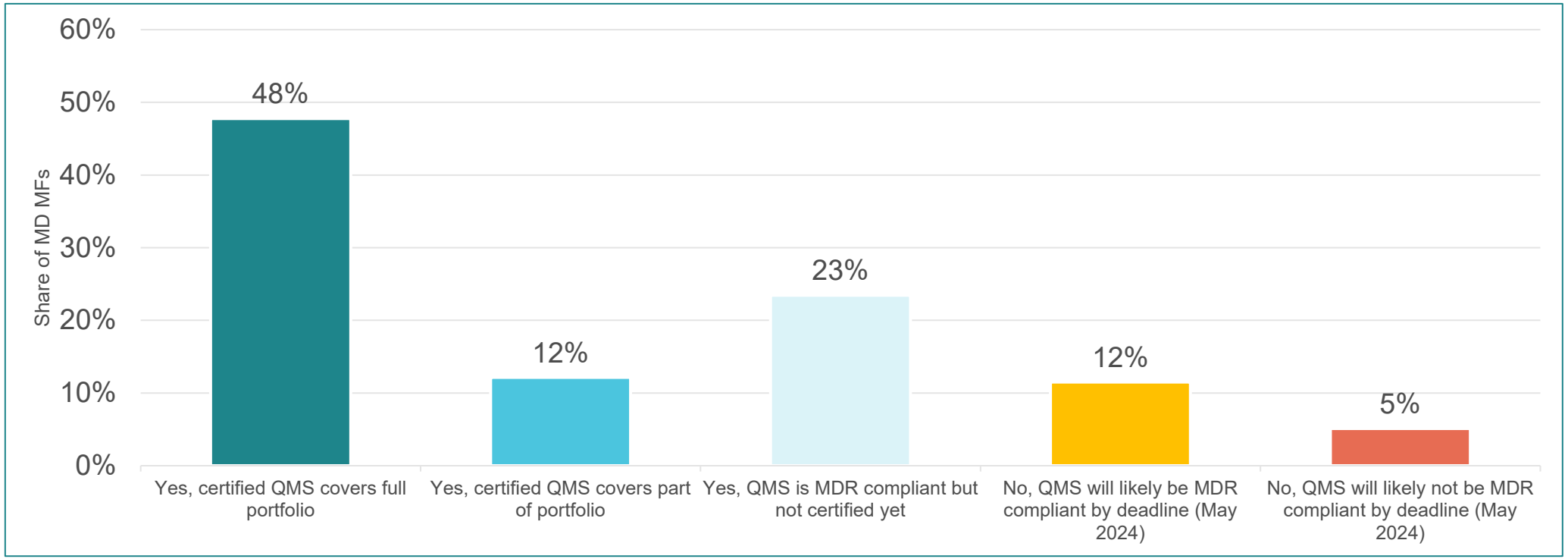
MD

Preparedness of manufacturers

MD

Preparedness of manufacturers (1)

Share of MD MF with MDR compliant QMS (n=469)



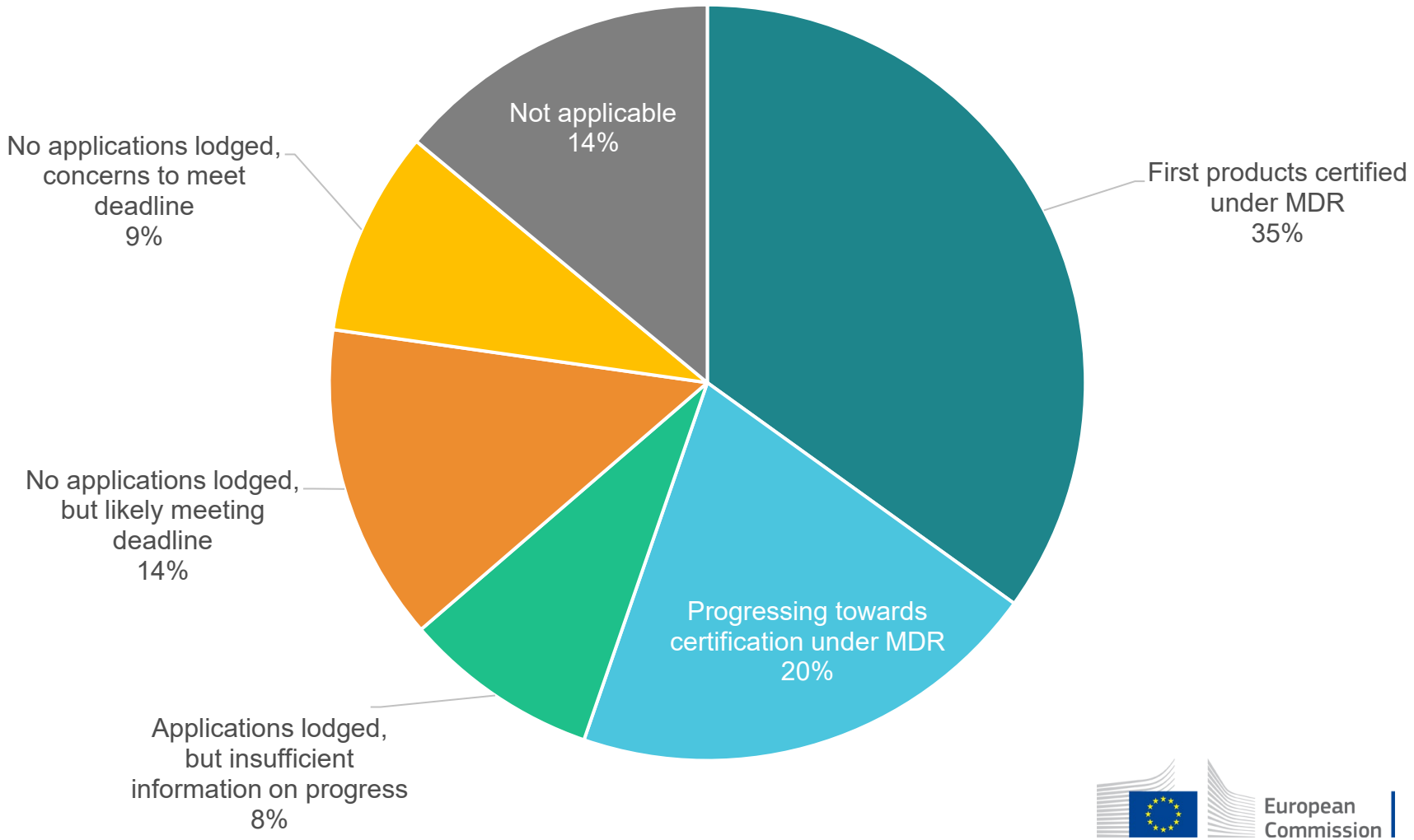
Note: Category 'not applicable' selected by 32 companies is not included in this graph (e.g. their products are not available yet)

European Commission

MD

Preparedness of manufacturers (2)

Share of MD MF having transferred products/ technical documentation to the MDR (n=501)



European Commission

IVD

2.3. Survey results for in vitro diagnostic medical devices

Questionnaire part 2.3. including questions 30 to 49

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

IVD

MF sample!

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

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

1498
(MF: 102%)

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

736
(MF: 23%)

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

702
(MF: 42%)

Note: These figures relate to the responses from 130 manufacturers of IVDs as of the end of October 2023.
Written agreements can be framework agreements with NBs (covering several applications) or contracts for each application (signed by the NB and manufacturer)
The **total number of applications** lodged also includes applications with issued certificates, ongoing applications and applications that were eventually refused. Please, note that applications lodged for changes of existing IVDR certificates are included as well.
* Even though the questions were asked in the same way to MF/AR and NBs, the MF seem to have a different interpretation as NBs. According to the 6th NB survey, NBs have 720 clients for IVDR/IVDD.

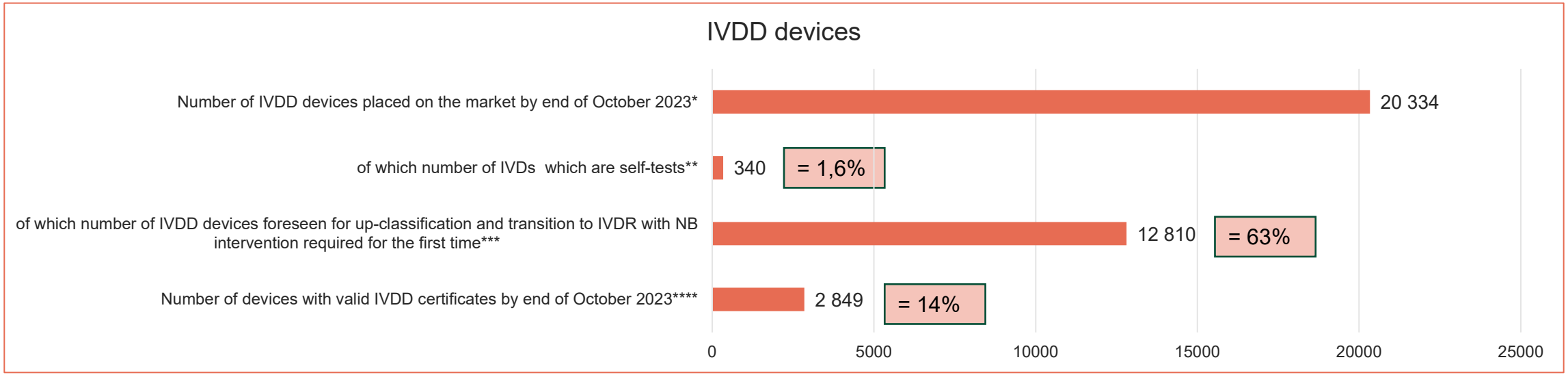
IVD

IVDD devices and certificates

IVDD overview by the end of October 2023

IVD

Total responses from MFs for IVDs: 130



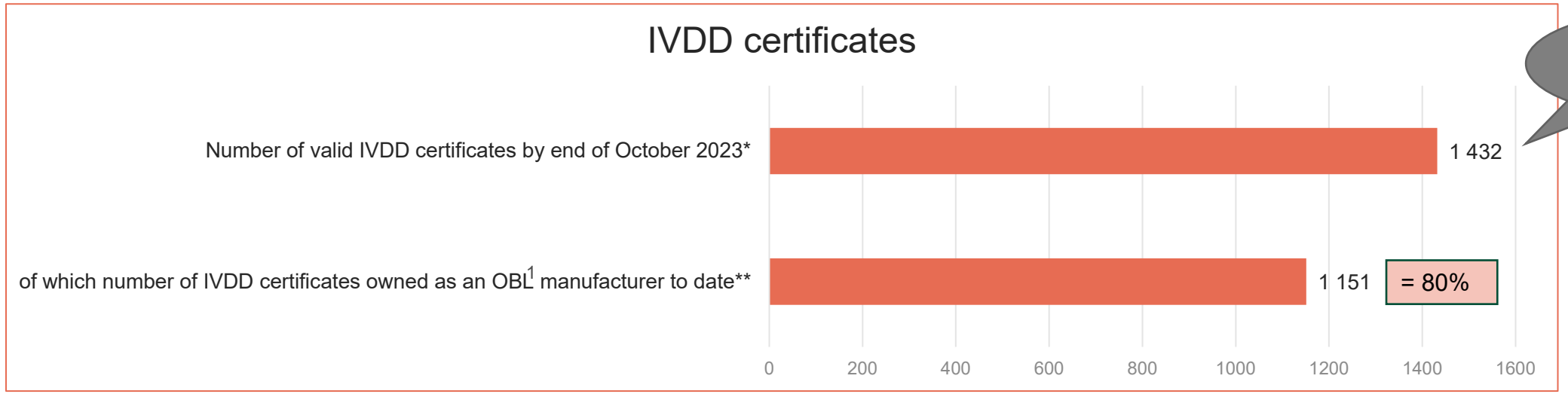
Notes:
* Data from 128 MFs, including 12 MFs with the indication '0';
** Data from 128 MFs, including 114 MFs with the indication '0';
*** Data from 122 MFs, including 31 MFs with the indication '0'
**** Data from 125 MFs, including 65 with the indication '0'
According to the 6th NB survey, NBs have 720 clients for IVDR/IVDD.

European Commission

IVD

IVDD overview by the end of October 2023

Total responses from MFs for IVDs: 130
Tot. valid IVDD certificates indicated by NBs (by end of October 2022): 1.551



[1] Own Brand Labelling (OBL) means that a manufacturer of medical devices markets a CE marked device by an Original Equipment Manufacturer (OEM) under its own name. This practice is also known as a private label manufacturer or virtual manufacturer.

Notes:
* Data from 125 MFs, including 64 MFs with the indication '0';
** Data from 124 MFs, including 98 MFs with the indication '0';

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.

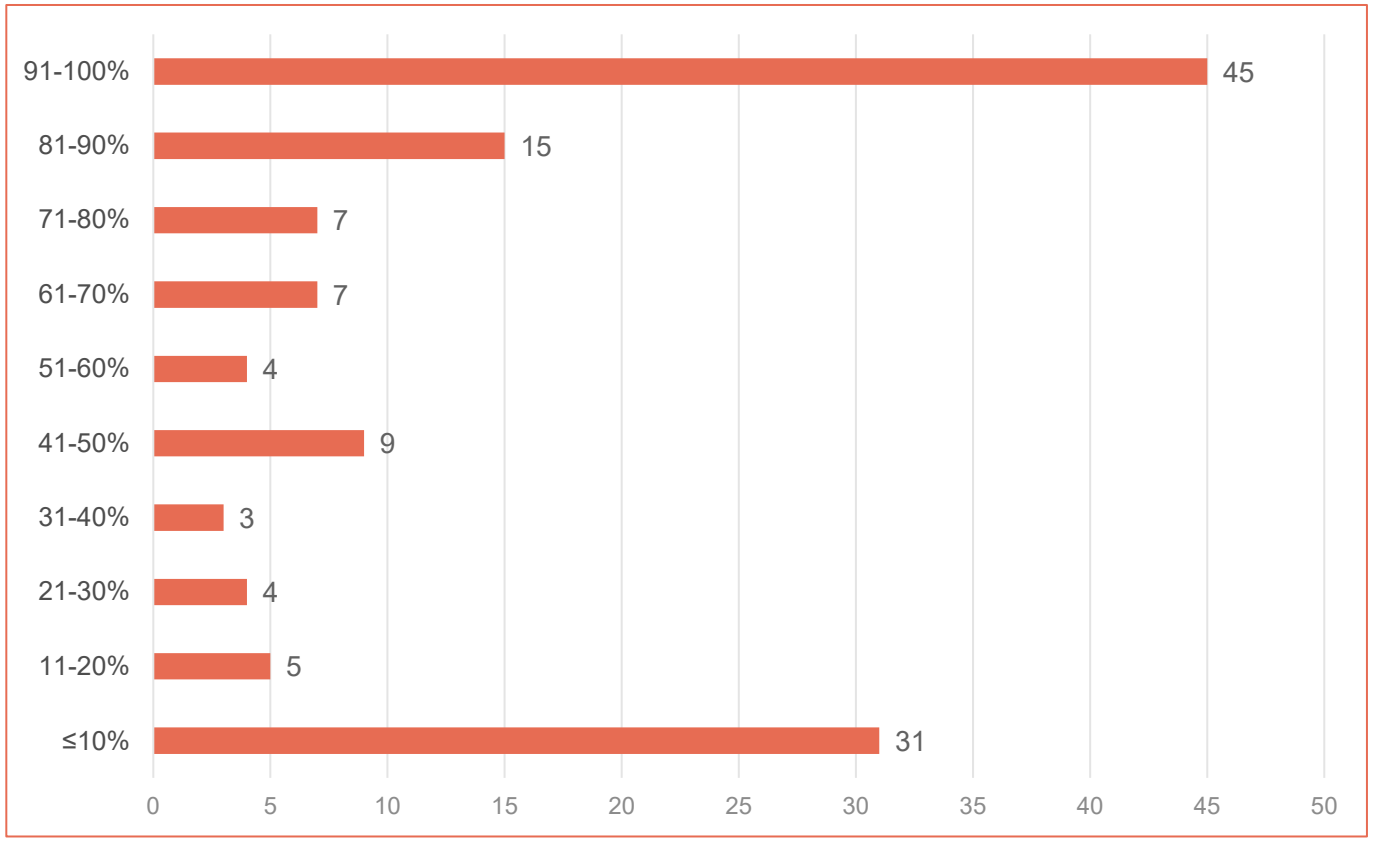
European Commission

Details on IVDD devices transition status to IVDR (1)

IVD

Total responses from MFs for IVDs: 130

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



Some companies do not aim achieving 100% - see reasons why on the next slide

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

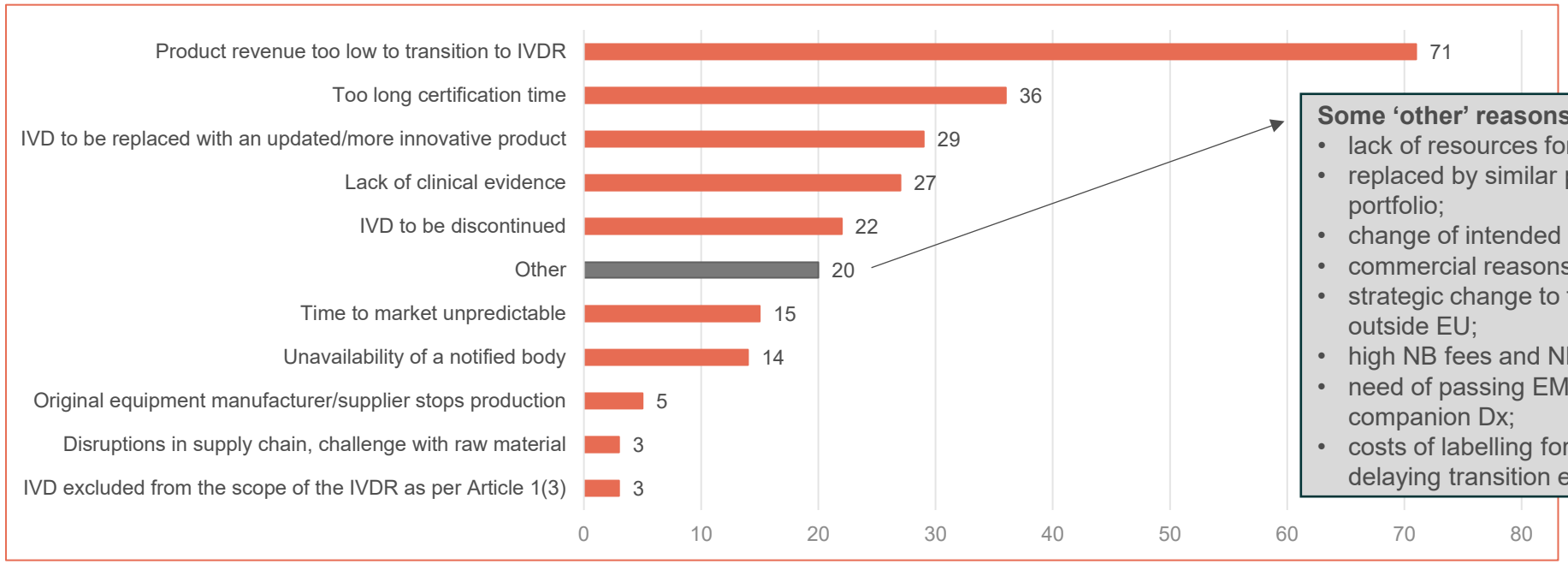
European Commission

Details on IVDD devices transition status to IVDR (2)

IVD

Total responses from MFs for IVDs: 130

If not all (100%) of the products have been transitioned or are planned to be transitioned to IVDR, what are the main reasons?



Some 'other' reasons:

- lack of resources for transition;
- replaced by similar product within company portfolio;
- change of intended purpose;
- commercial reasons;
- strategic change to focus on markets outside EU;
- high NB fees and NB costs;
- need of passing EMA process for companion Dx;
- costs of labelling for class D devices are delaying transition etc.

Notes: Number of mentions; Multiple answers per MF possible
26 MFs (20%) indicated that this question is not applicable because 100% of products were already transferred.

European Commission

IVD

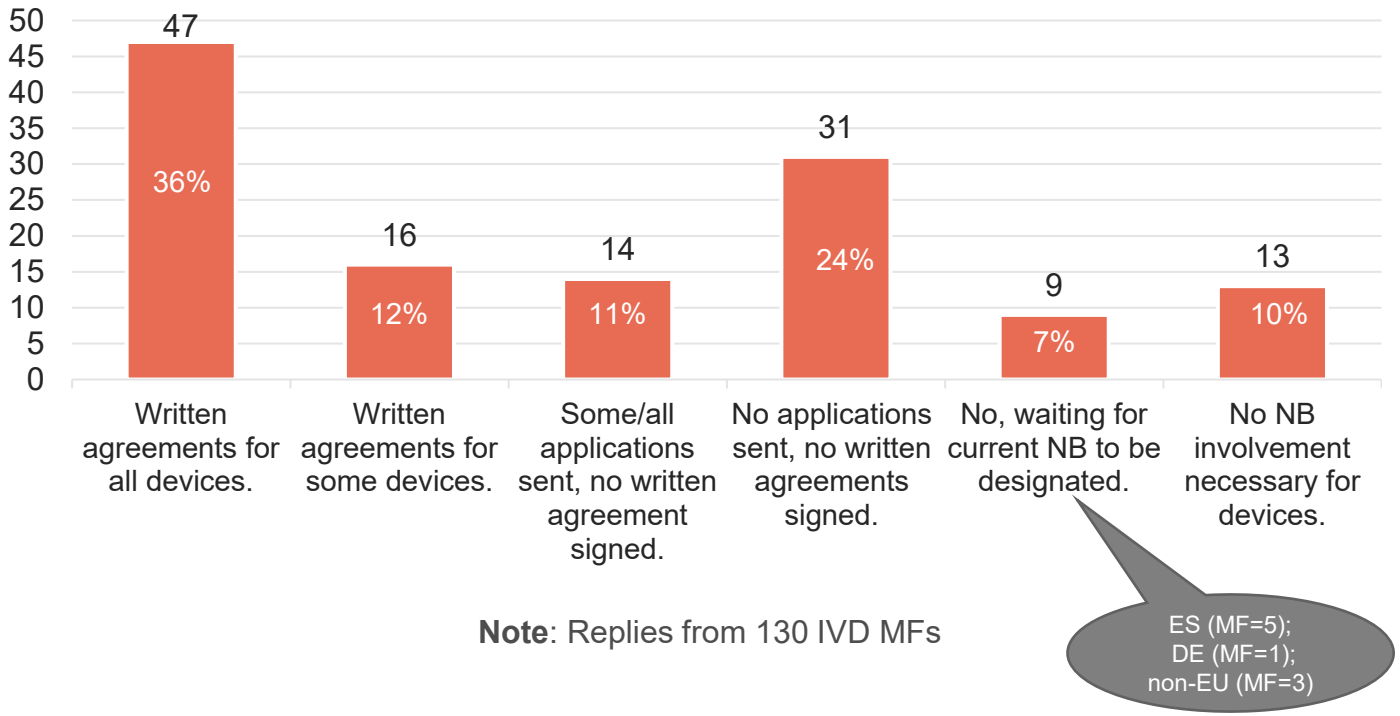
Notified bodies
written agreements, refused applications

Written agreements between MFs of IVDs with Notified Bodies

IVD

Total responses from MFs for IVDs: 130

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



Note: Replies from 130 IVD MFs

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

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

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

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

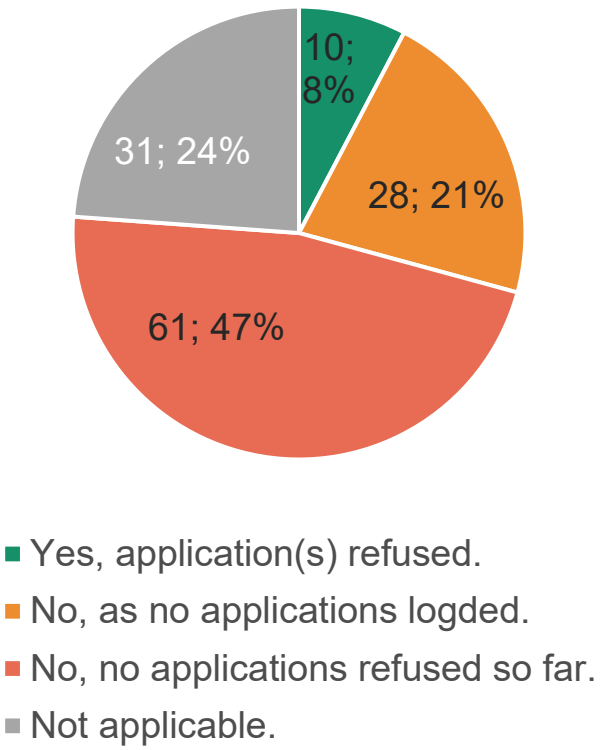
- 48% of the MF have (a) written agreement(s) with NBs
- 42% of the MF that need a written agreement don't have it yet
- 10% of the MF don't need a NB involvement

European Commission

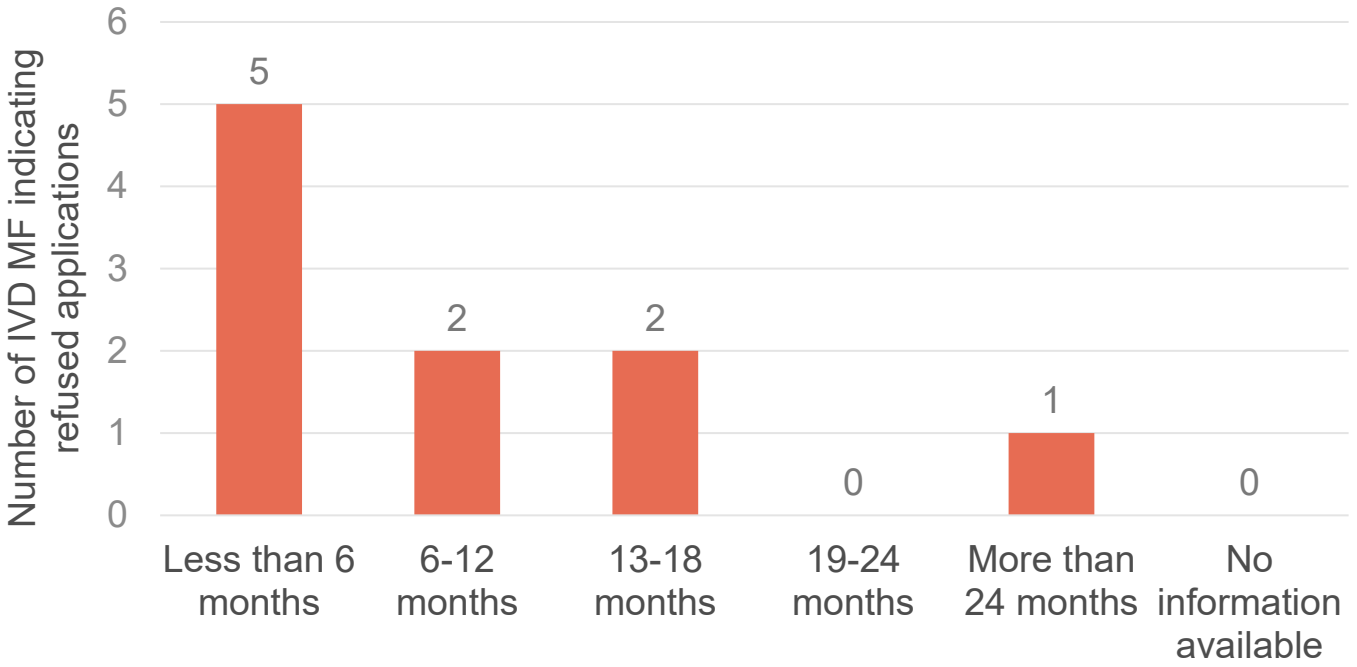
Refusal of applications from IVD MF by Notified Bodies (1)

IVD

Number of IVD MF having been refused applications (n=130)



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

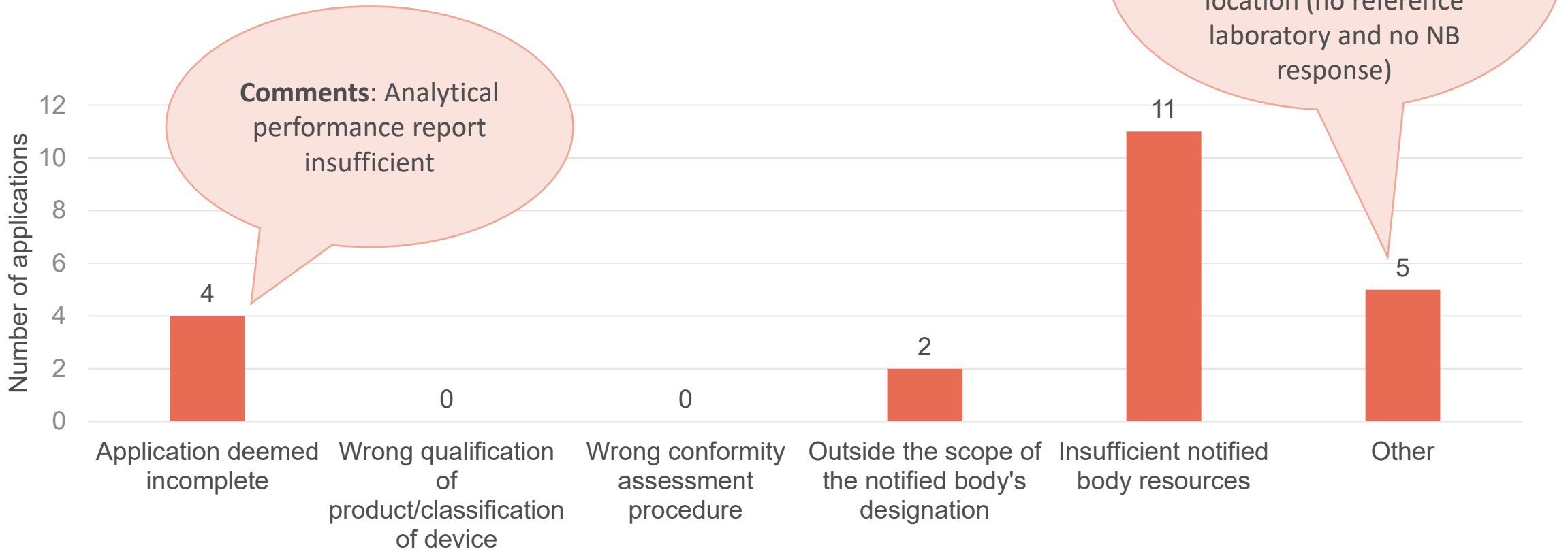


European Commission

IVD

Refusal of applications from IVD MF by Notified Bodies (2)

Number of refused applications by reason for refusal (n=10 companies reporting 20 refused applications)



European Commission

IVD

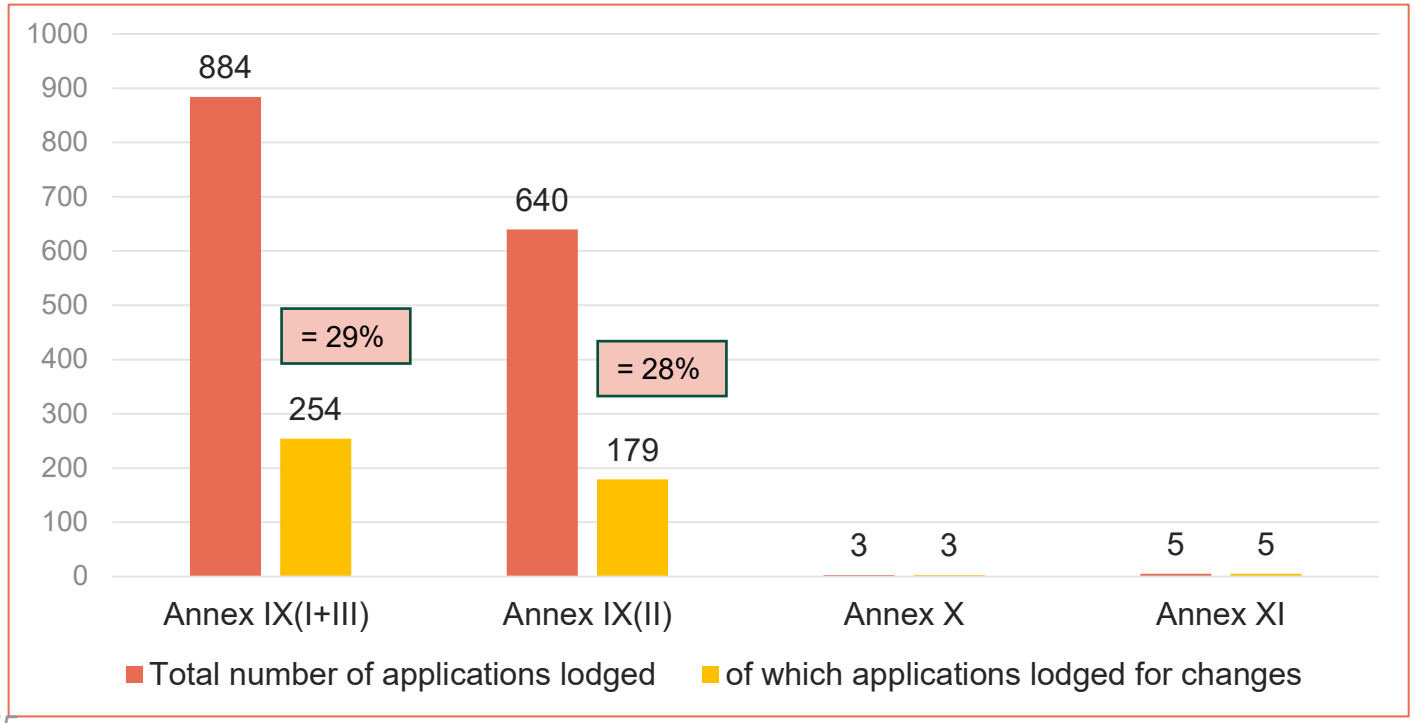
IVDR implementation
applications, written agreements, certificates, timelines

Applications lodged under IVDR by end October 2023

IVD

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:** 252
- **Applications (all Annexes) requiring consultation for companion diagnostics:** 17

Total number of applications: 1532 (6th NB survey: 1.498)

European Commission

IVDs undergoing IVDR conformity assessment by October 2023

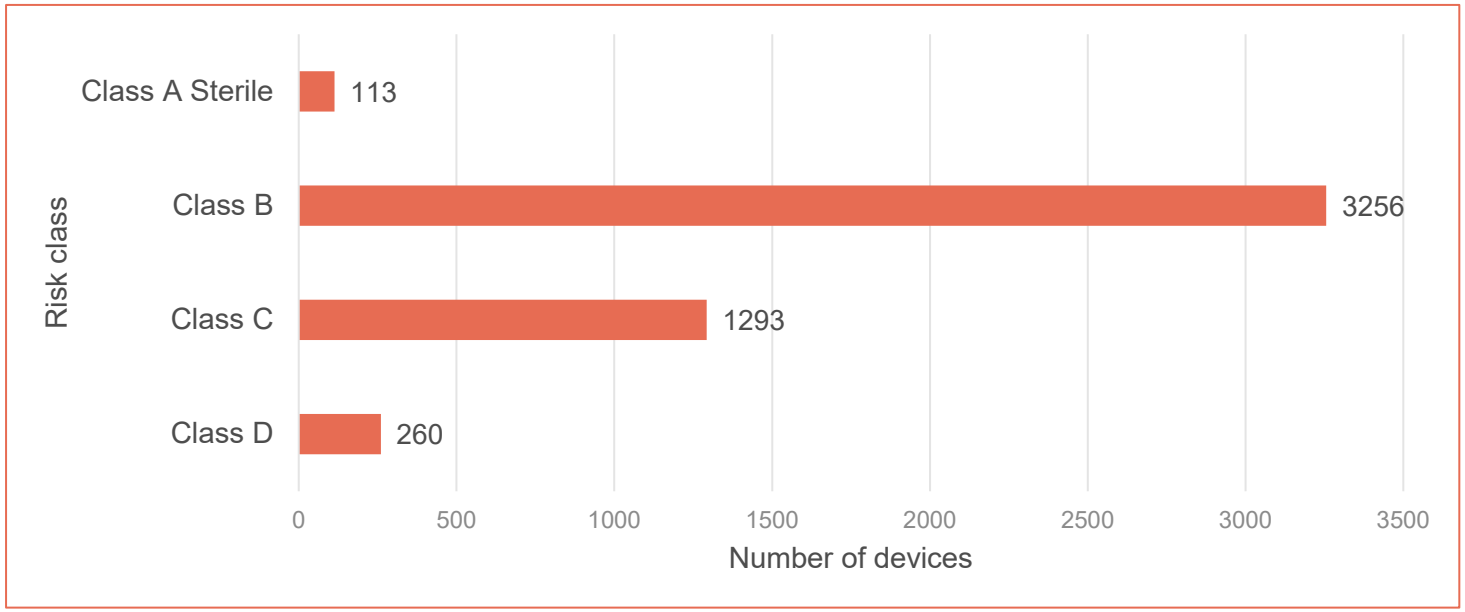
IVD

Total number of IVDs referring to catalogue numbers (sum of subcategories) in this survey: 15 264*

Note: *15 264 products were reported in the overall overview for EMDN category W, and a total of 13859 products as sum of the EMDN subcategories W01, W02 and W05.

Total number of devices (by catalogue number) undergoing IVDR conformity assessment by end of October 2023: 5429 (= 36% of reported IVDs)

By risk class:



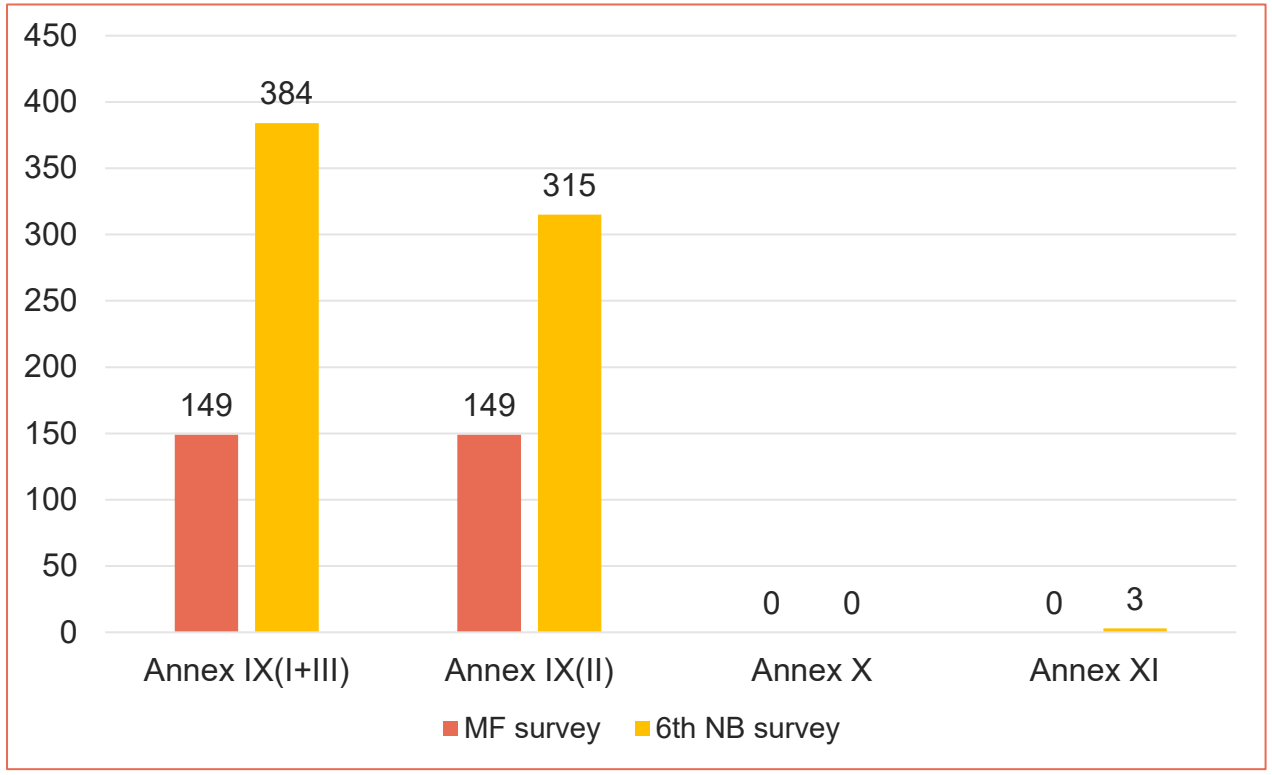
Note: A total of 4922 devices were indicated by risk classes.

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 2023



Note: Replies from 34 IVD MFs

Total number of certificates: 298

Number of devices (catalogue numbers) covered in IVDR certificates issued by end of October 2023: 4539

For comparison data of the 6th NB survey (covering the same data period until 31/10/2023): 702

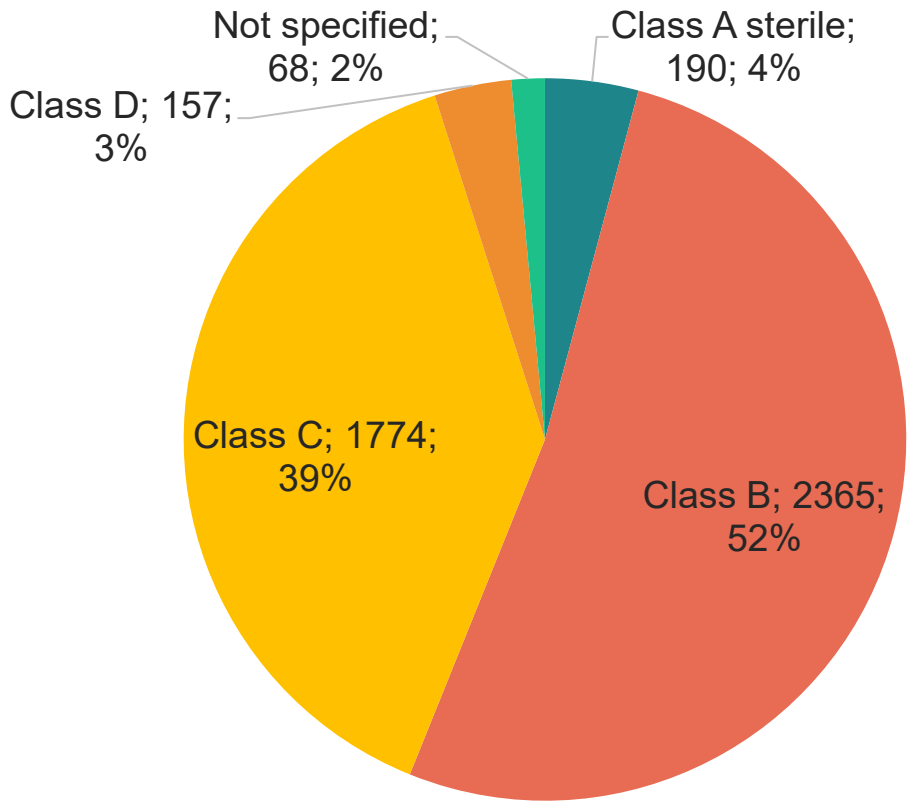
Disclaimer:
Please, note that the no. of certificates indicated by manufacturers is not directly comparable to the no. of certificates indicated by NBs since they might count differently. The study team has aggregated the data received from survey participants to prepare this presentation but cannot 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 2023:
4.554



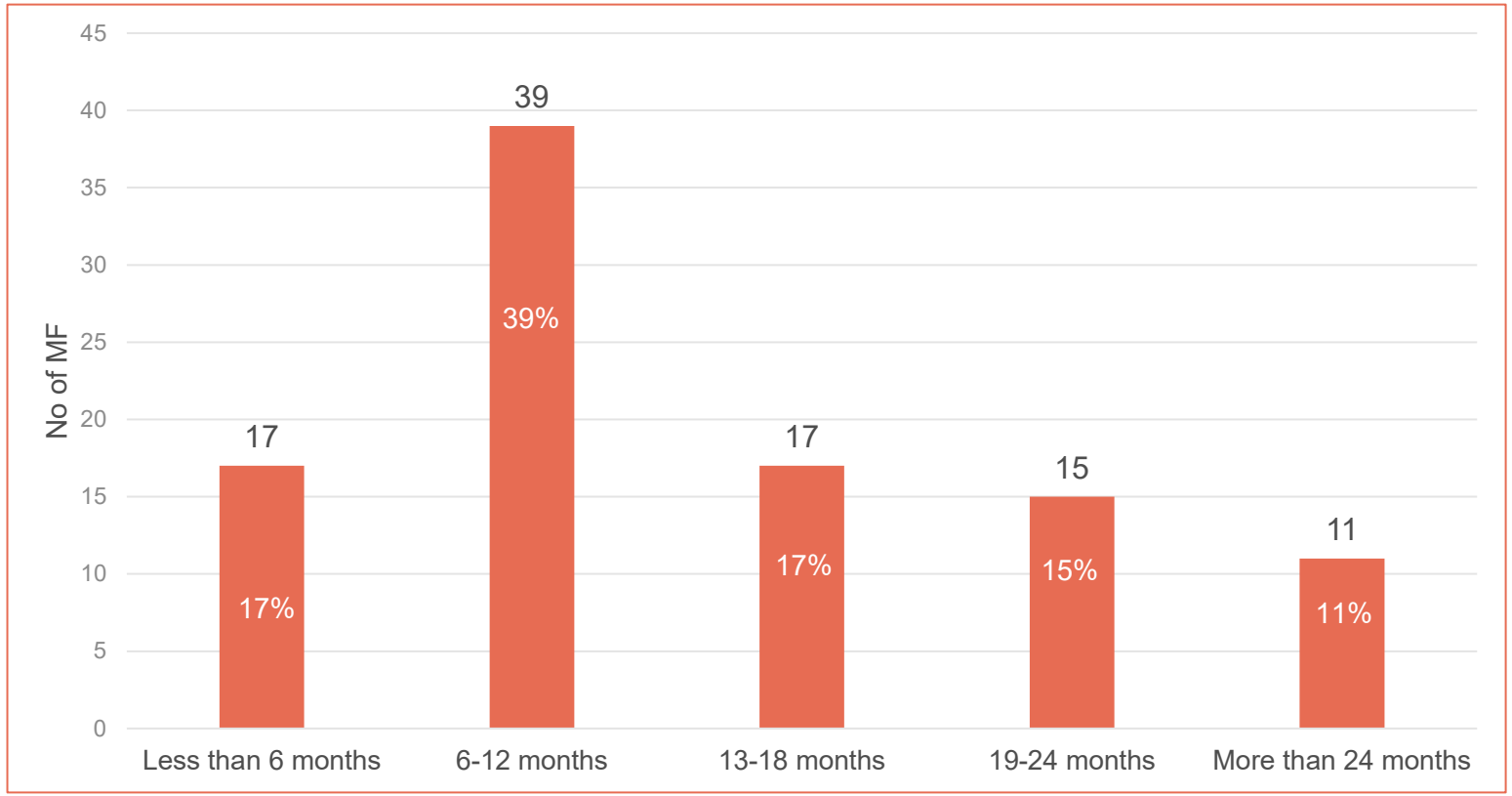
Note: n=38 MF; 92 MF indicated '0'

European Commission

IVD

Timelines

Time to prepare an application for IVDR (before submission to NB)*



Total responses from MFs for IVDs: 130

- **56%** of the MFs that provided information on this question indicated that it **takes less than a year** to prepare an application for IVDR; f**or 73% less than 18 months.**

Notes:
- Replies of 99 IVD MFs
- 31 MFs indicated 'no information available'

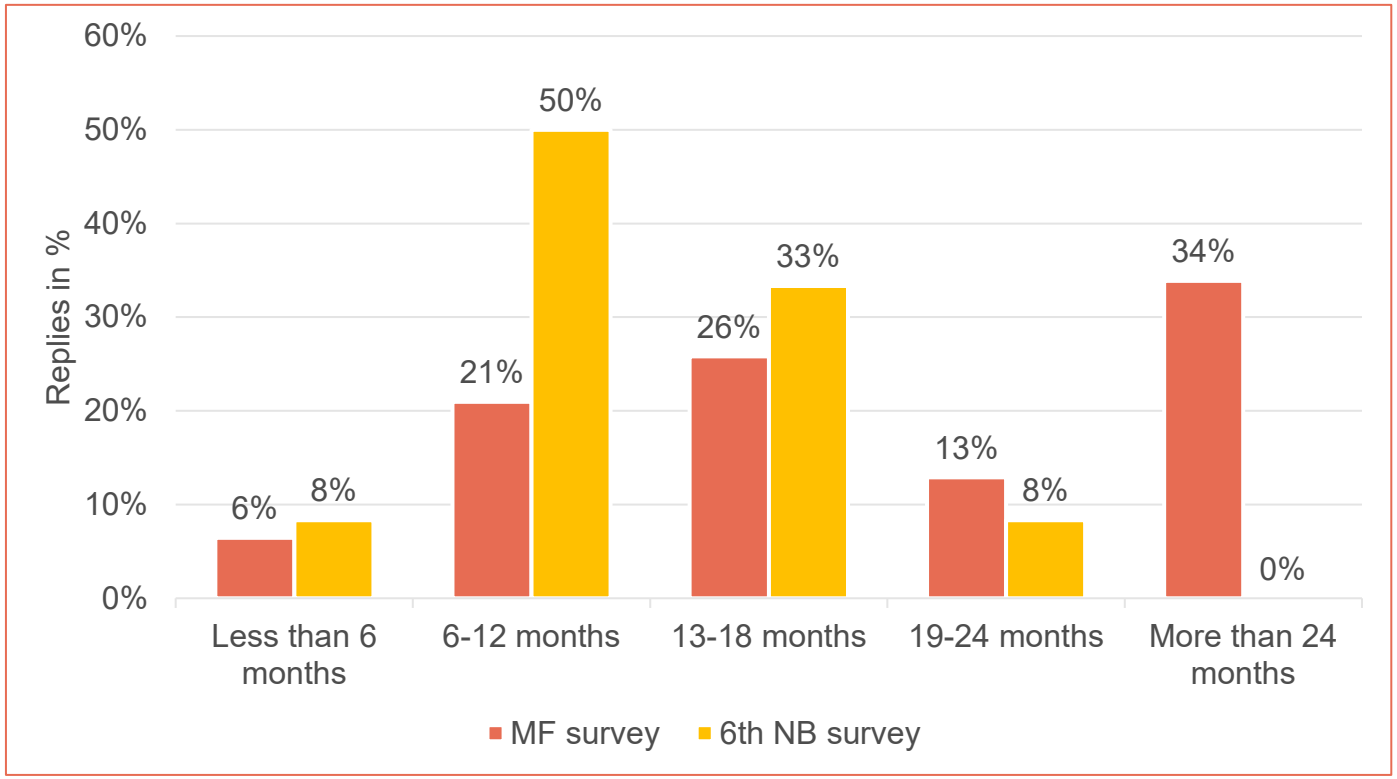
European Commission

IVD

Timelines

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

Total responses from MFs for IVDs: 130



Notes:
- Replies of 62 IVD MFs; 68 MFs indicated 'no information available'
- For comparison data of the 6th NB survey (covering the same data period until 31/10/2023): data of 12 notified bodies

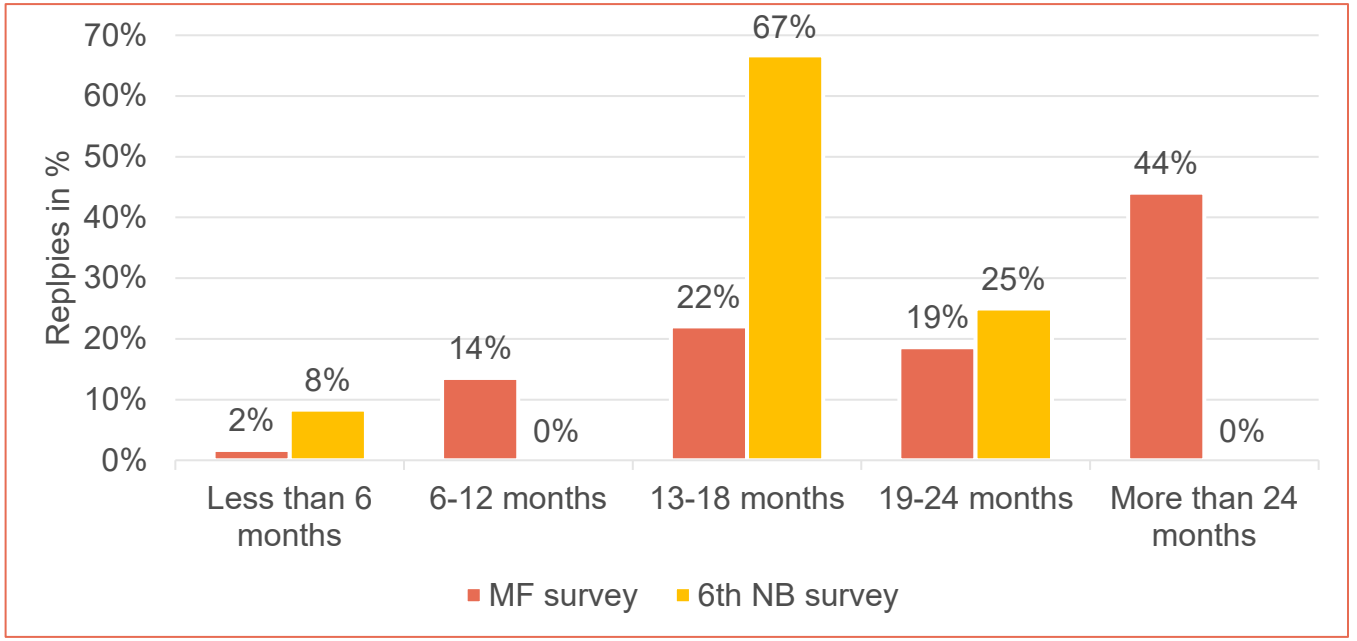
European Commission

IVD

Timelines

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

Total responses from MFs for IVDs: 130



Notes:
- Replies of 59 IVD MFs; 71 MFs indicated 'no information available'
- For comparison data of the 6th NB survey (covering the same data period until 31/10/2023): data of 12 notified bodies

European Commission

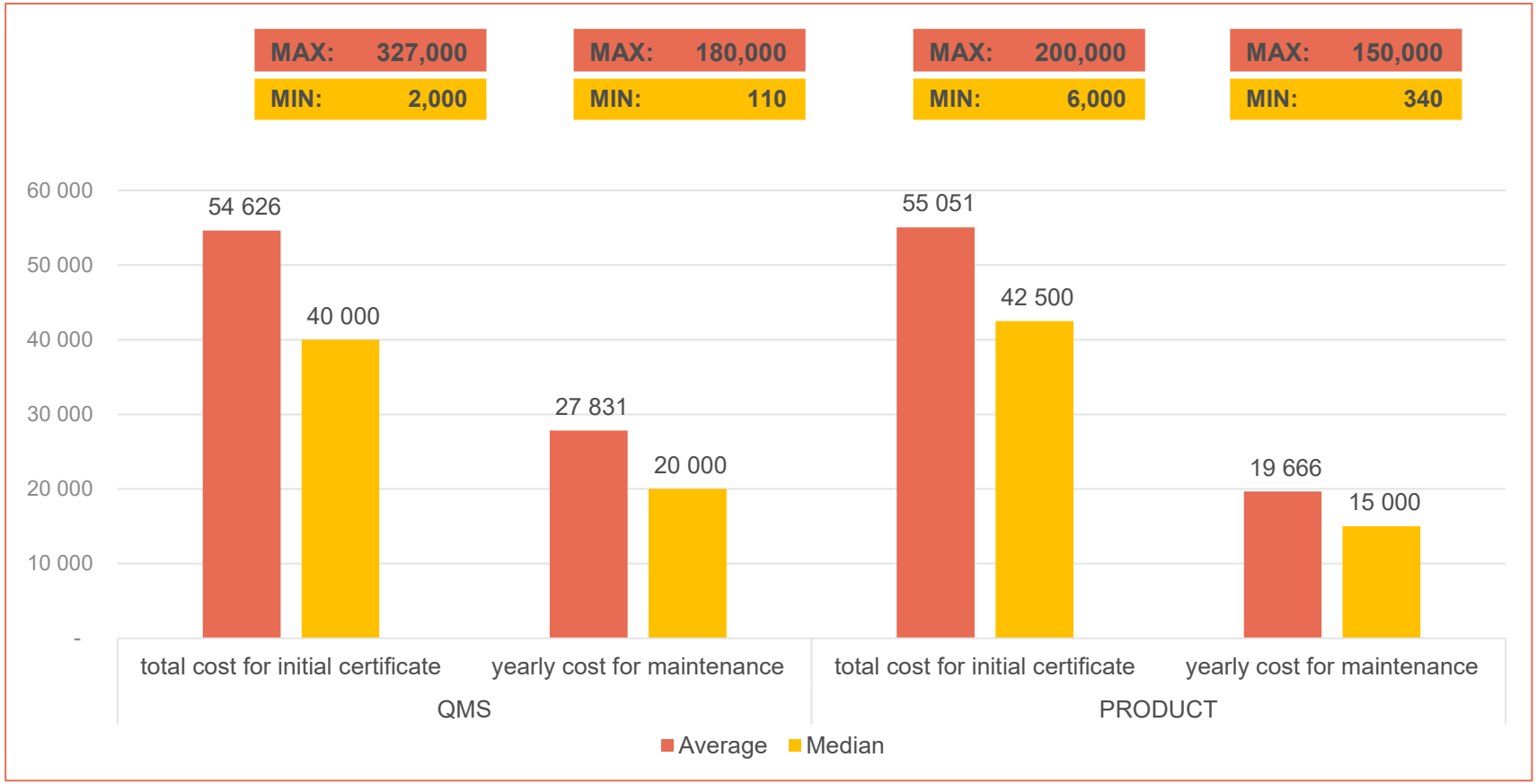
IVD

Estimates

IVD

Costs for IVDR certification

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



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

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

- QMS: estimations of costs for initial certificate by 54 MFs; for maintenance: 51 MFs taken into account with responses >0.
- Product: estimations of costs for initial certificate by 34 MFs; for maintenance: 29 MFs taken into account with responses>0.

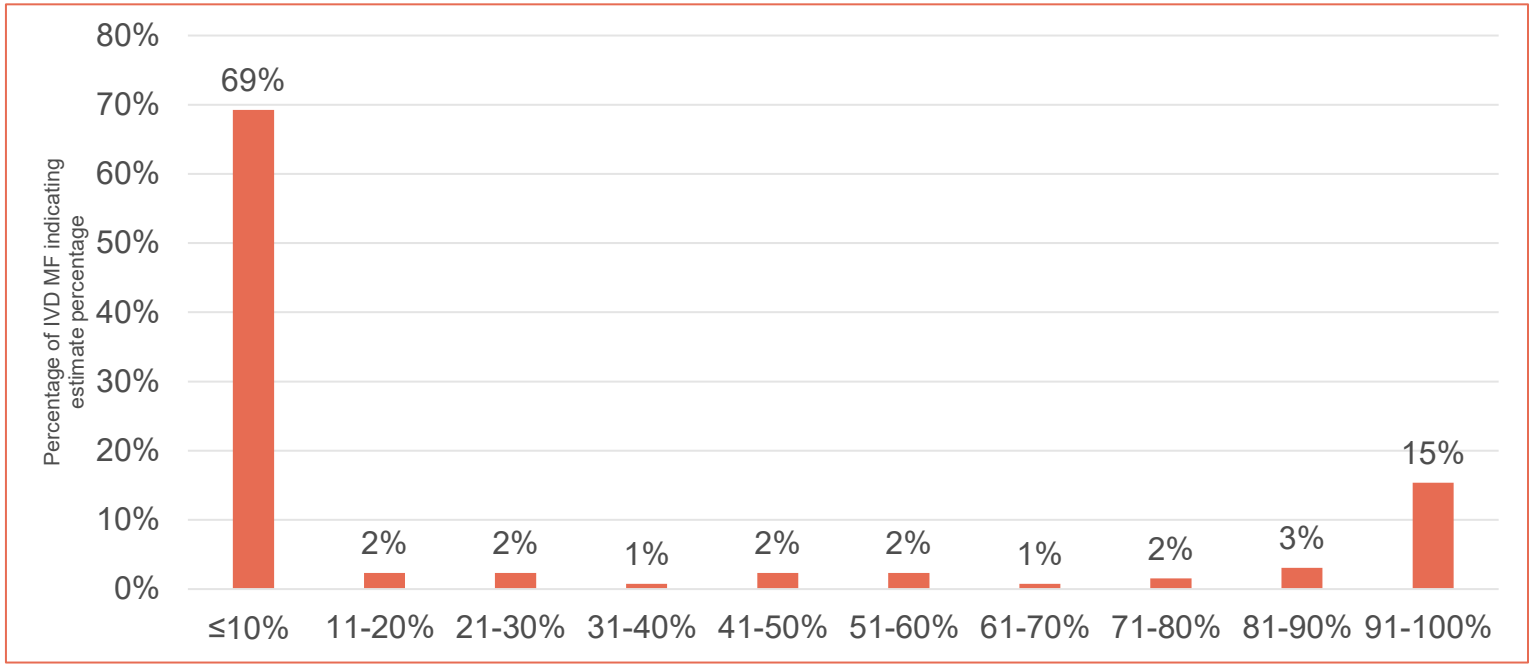
European Commission

IVD

Transition completion status

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

Total responses from MFs for IVDs: 130



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

European Commission

IVD

New devices

Estimate number of new devices (which have never been certified before) for which applications will be submitted to a NB in the next 12-18 months:

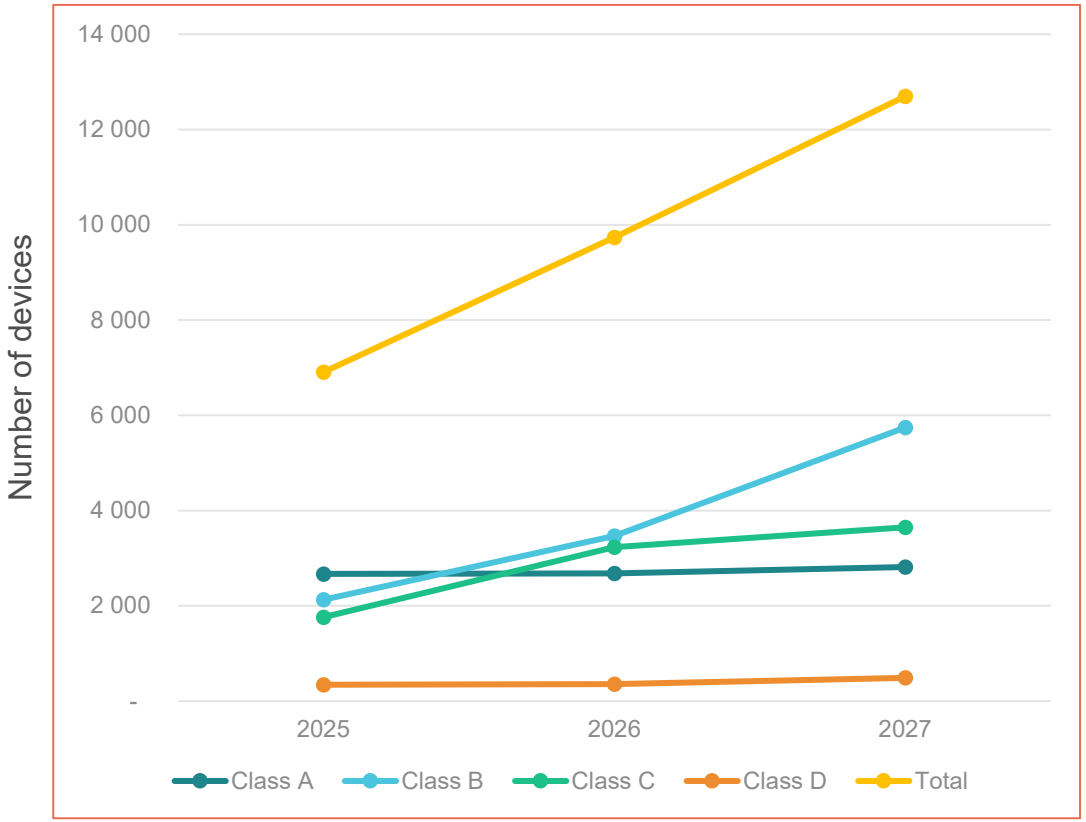
2,203 new devices (sum)

(Note: n=64 companies)

IVD

Future projections

Estimate number of IVDR devices per class placed on the market at the end of the transitional period (2025, 2026 or 2027) (n=130)



Notes:

- No information available for two IVD MF, for one further IVD MF selected information not available.
- Some actors have entered the same data for 2025, 2026 and 2027. For actors that entered data for the year 2025 and "0" for 2026 or 2027 the same data as for 2025 was taken for 2026, 2027.

Estimate number of IVDR certificates per annex by the end of the applicable transitional period (2025, 2026 or 2027) (n=130)

Notes:

- No information available for two IVD MF, for one further IVD MF selected information not available.
- Some actors have entered the same data for 2025, 2026 and 2027. For actors that entered data for the year 2025 and "0" for 2026 or 2027 the same data as for 2025 was taken for 2026, 2027.

IVD

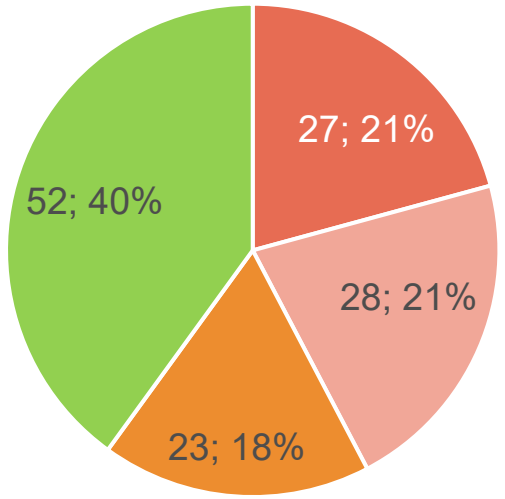
Discontinued in vitro diagnostic medical devices

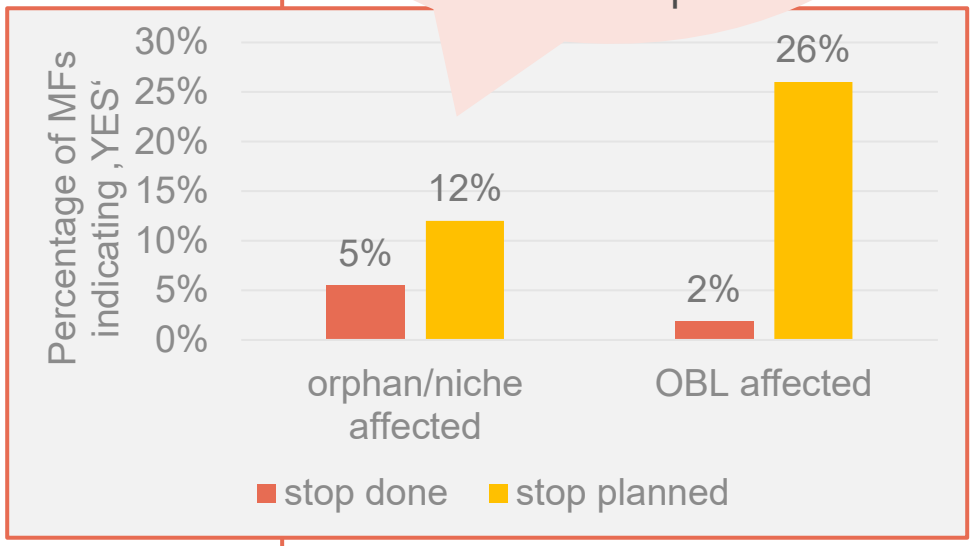
IVD

Discontinuation of IVDs (1)

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

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

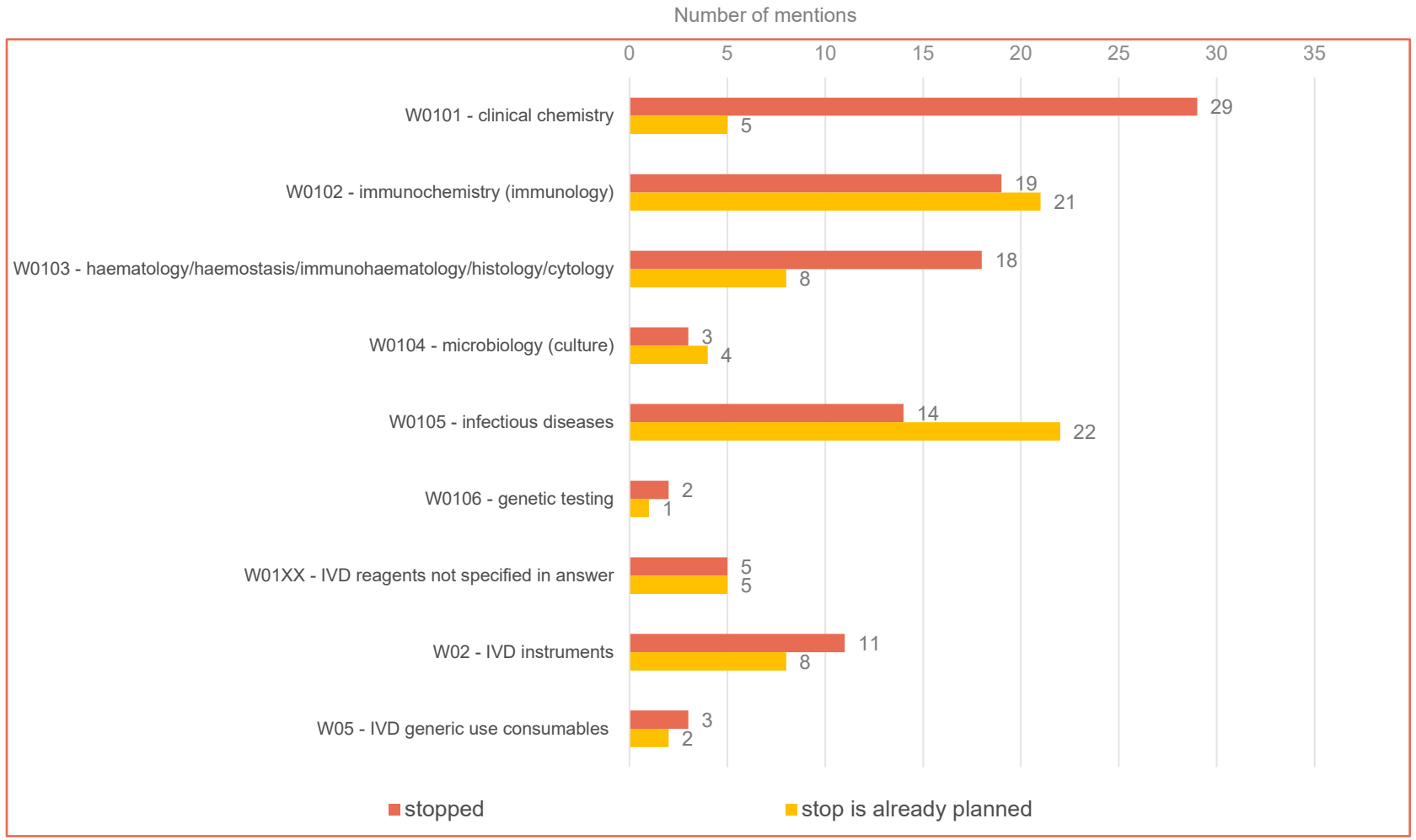




- Some devices stopped already, other discontinuations planned
- Some devices stopped already, no further discontinuations planned
- Production/marketing/supply stop planned, but not implemented yet
- No product discontinuations realised nor planned

European Commission

Discontinuation of IVDs (2)

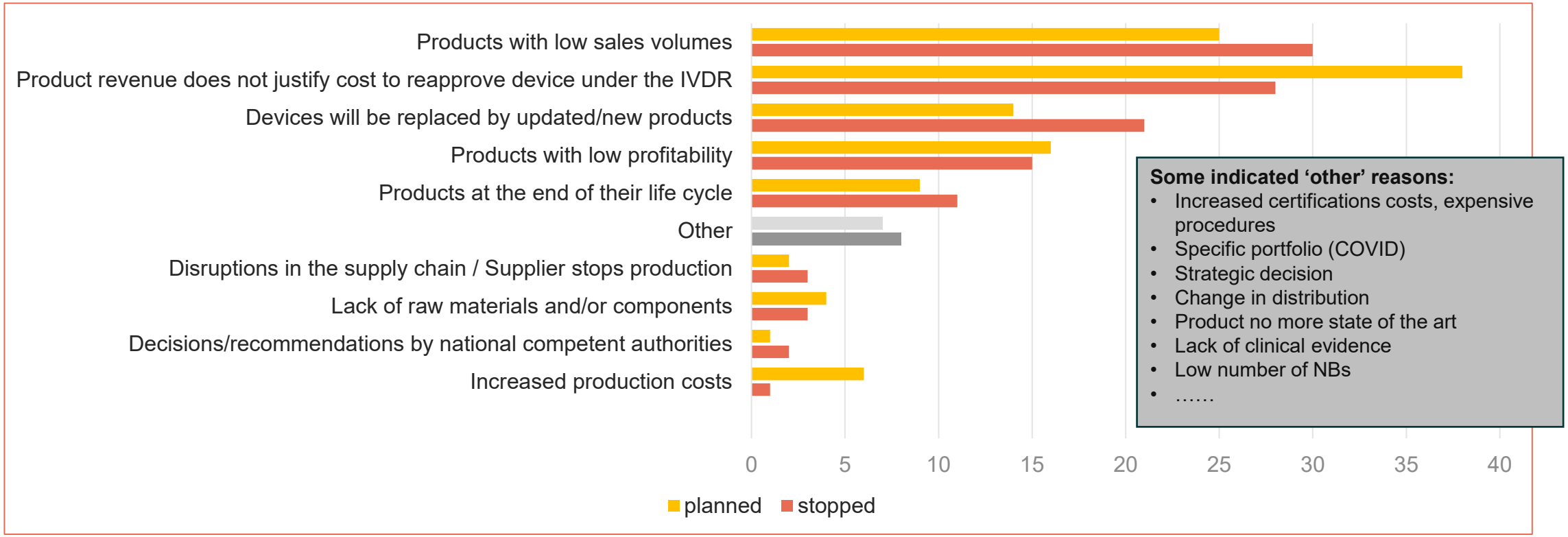


Types of IVDs (by EDMN code) stopped or "stop is already planned" (top mentions in comment section)

IVD

Discontinuation of IVDs (3)

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; 55 MFs having stopped and 50 MF planning to stop participated in this survey question.

European Commission

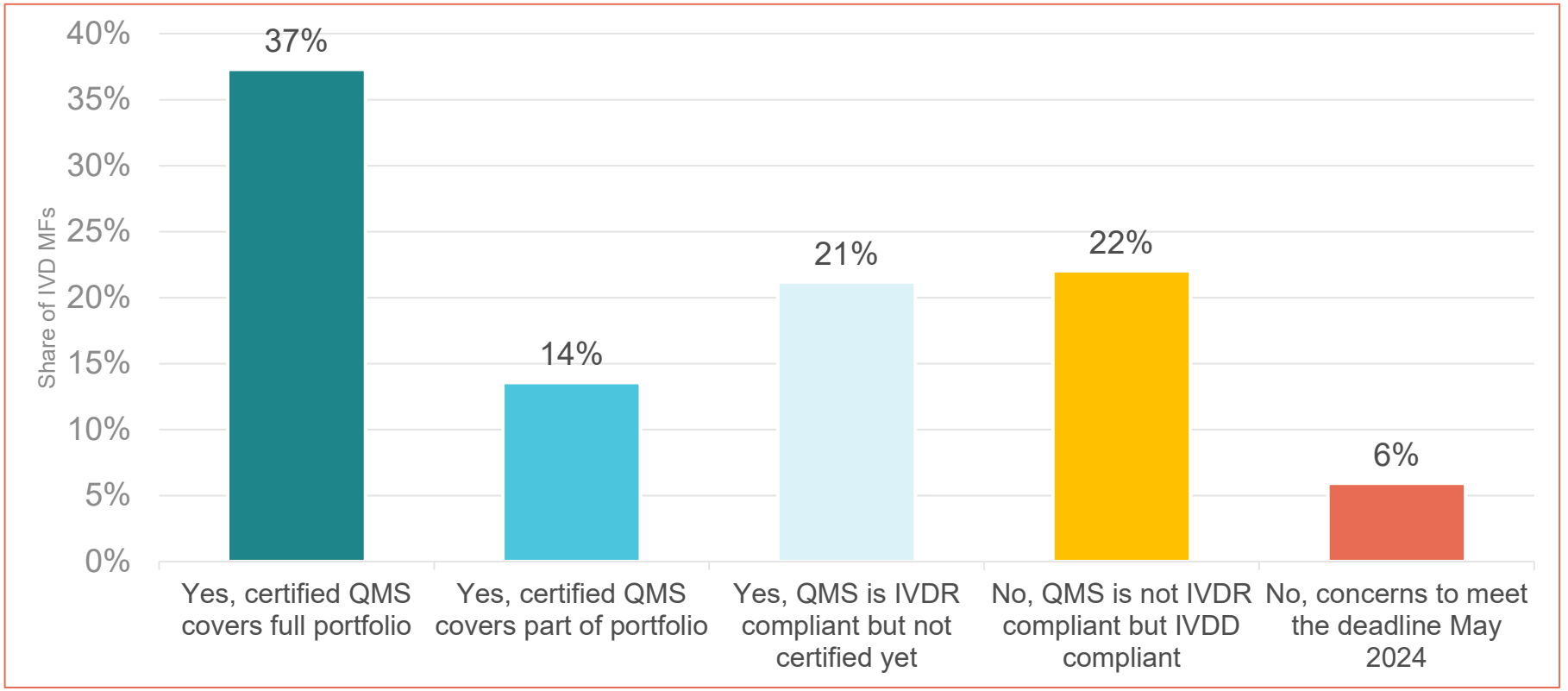
IVD

Preparedness of manufacturers

IVD

Preparedness of manufacturers (1)

Share of IVD MF with IVDR compliant QMS (n=130)

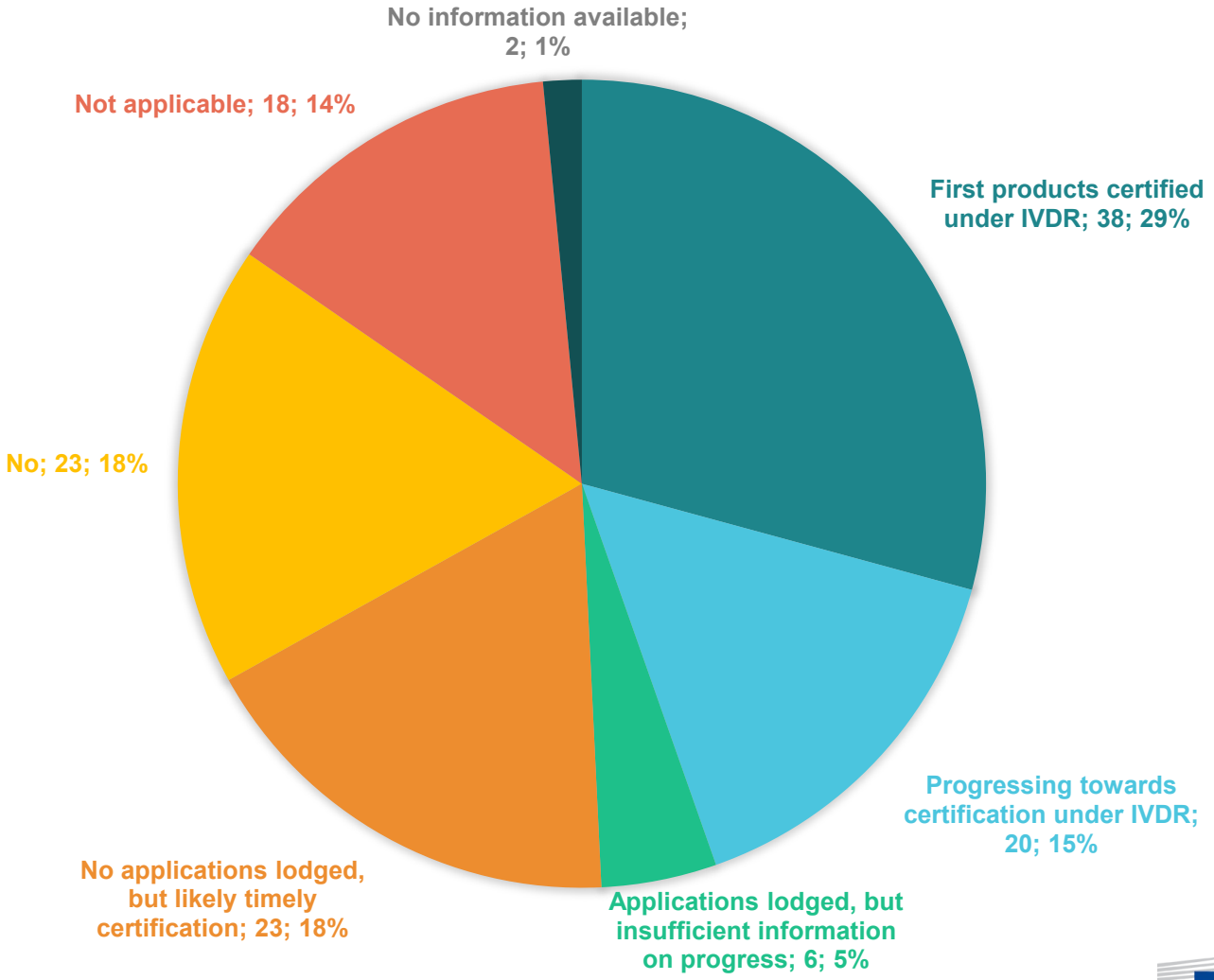


Note: Category 'not applicable' selected by 12 companies is not included in this graph (e.g. their products are not available yet)

European Commission

Preparedness of manufacturers (2)

Share of IVD MF having transferred products/ technical documentation to the IVDR (n=130)



AR

2.4. Survey results for authorised representatives

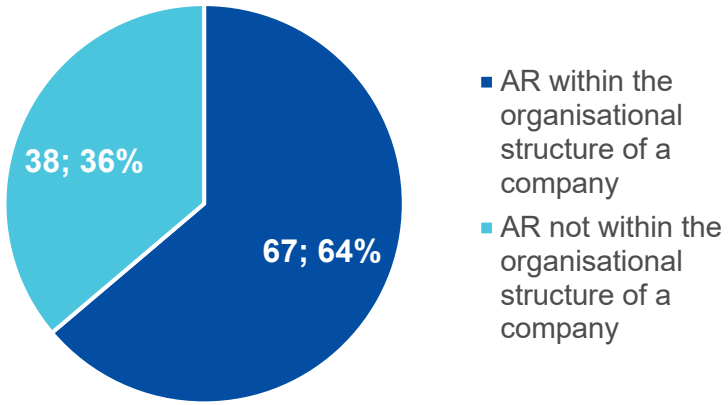
Questionnaire part 2.4. including questions 50 to 53

Authorised representatives (1)

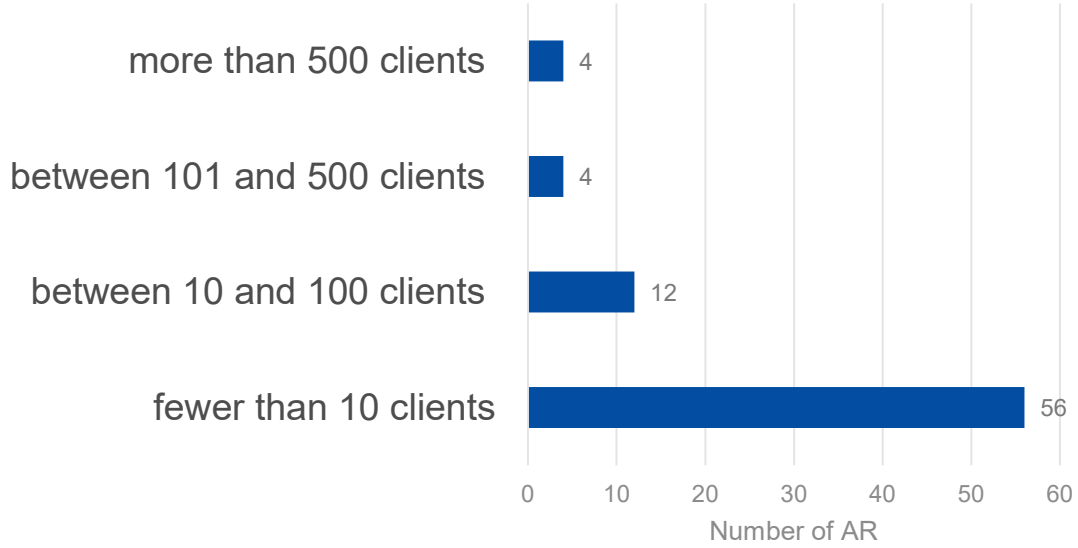
AR

Total responses from ARs: 105

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



Number of companies represented by authorised representatives



Note: 29 ARs indicated 'not applicable' as they mostly operate within the organizational structure of the legal manufacturer

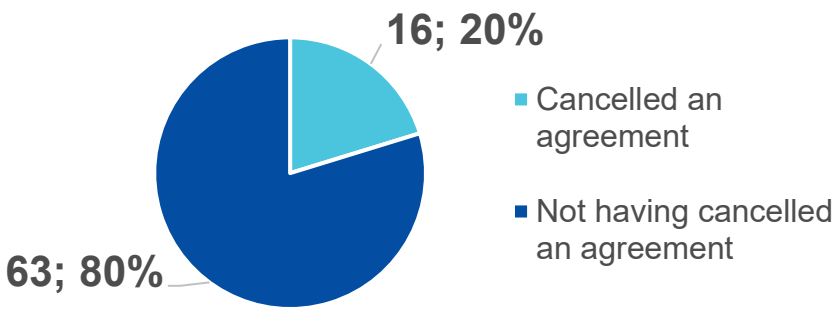
European Commission

Authorised representatives (2)

AR

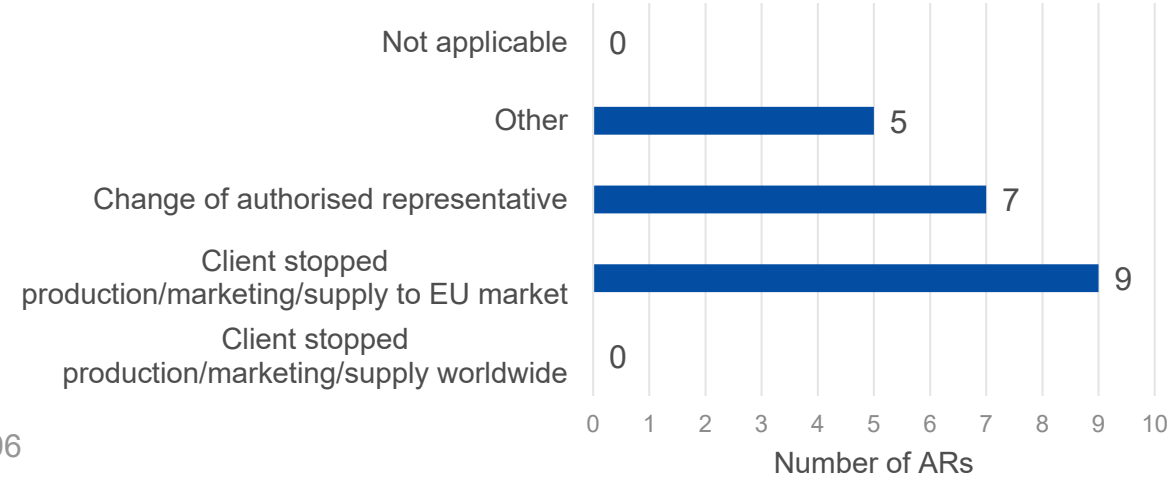
Total responses from ARs: 105

Number of AR with clients having cancelled an agreement for some MDs/IVDs since 2021



Note: 26 ARs indicated 'I don't know / not applicable'.

Reasons for cancellation of agreements for some MDs/IVDs since 2021



Percentage of clients having cancelled an agreement for some MDs/IVDs since 2021: **on average 21%**

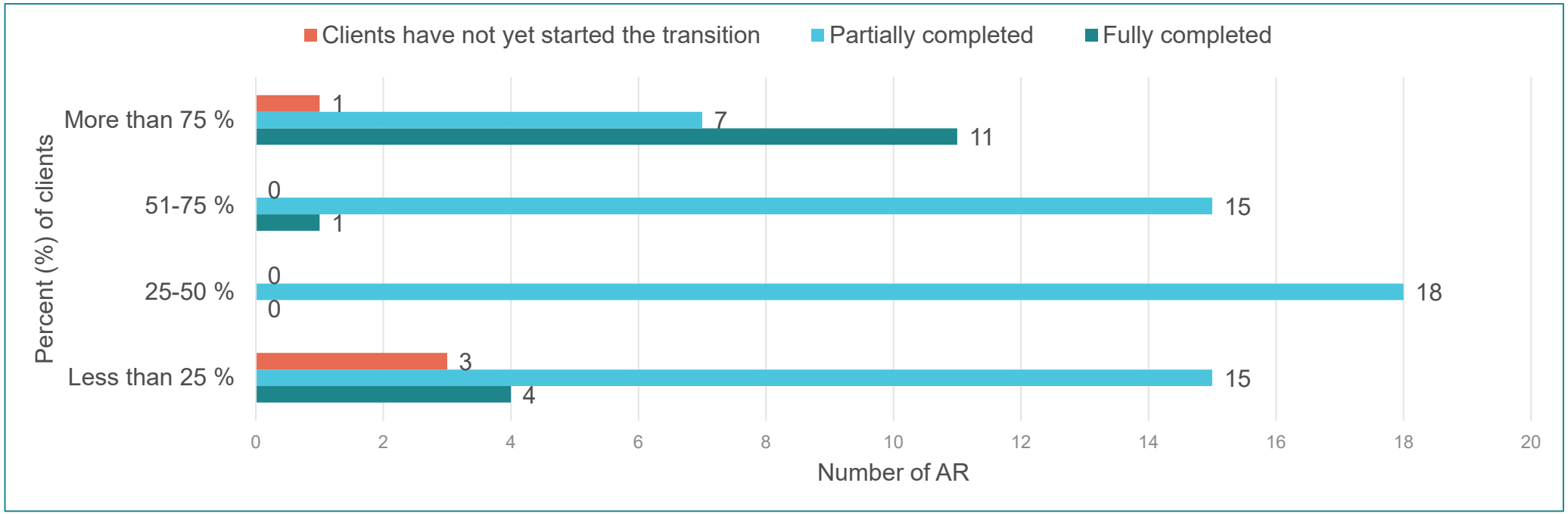
European Commission

Authorised representatives
Legacy devices transition

AR MD

Total responses from ARs: 105

Estimate number of legacy devices completely transitioned to MDR/IVDR



Note: 36 AR indicated 'I don't know / not applicable'.

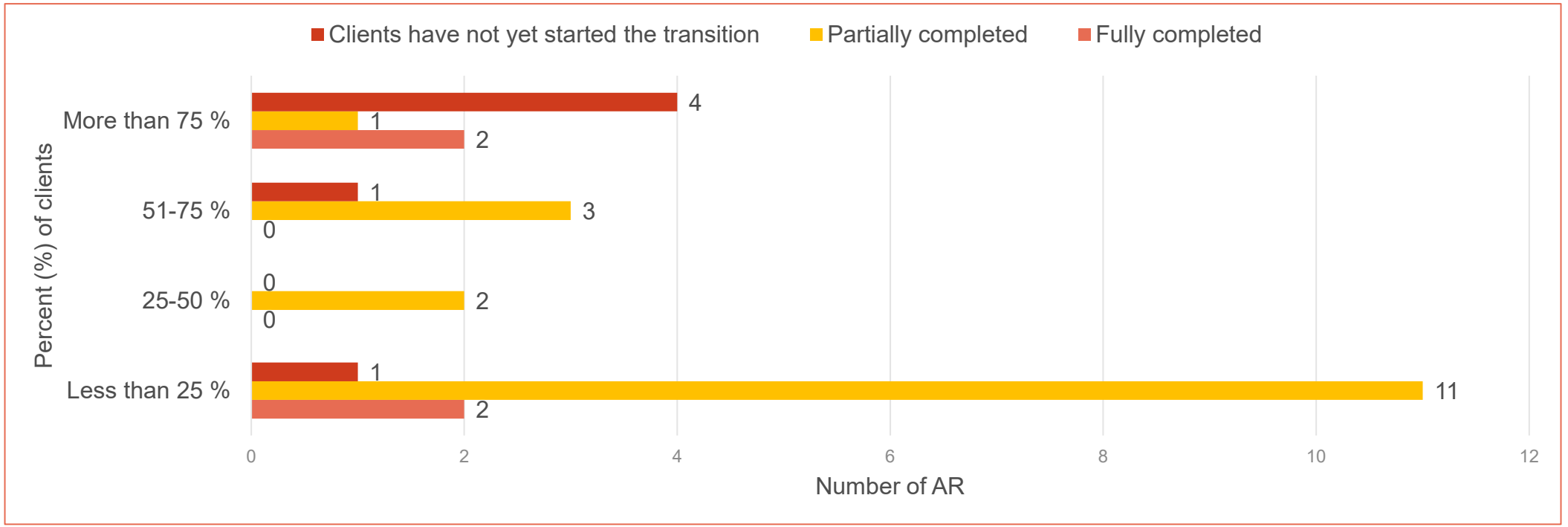
European Commission

Authorised representatives Legacy devices transition

AR IVD

Total responses from ARs: 105

Estimate number of legacy devices completely transitioned to IVDR



Note: 81 AR indicated 'I don't know / not applicable'.

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Thank you

Contact for questions: medical.devices@goeg.at

European Commission