MedTech Europe
from diagnosis to cure

MedTech Europe IVDR & MDR Survey Results 2024

Public Report December 2024

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Executive Summary

More than seven years following the publication of the *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) and Medical Devices Regulation (EU) 2017/745 (MDR), manufacturers of IVDs and MDs continue to face challenges around the predictability, transparency and high cost of the CE-marking system for their devices.

Since the last MedTech Europe surveys conducted in 2022[1] [2], three amending regulations[i] have been published, providing extended time under conditions for devices to transition to either IVDR or MDR. These measures have helped sustain device availability on the market by enabling a phased transition, yet further steps are needed to fully address the underlying root cause issues which led to the need for additional transition time.

The regulatory burden and cost on manufacturers has grown under IVDR and MDR compared to the medical devices directives[3]. Unclear clinical expectations, extensive documentation requirements, varying interpretation of compliance requirements and rising costs have reached a level that is significantly impacting the availability of devices and hampering innovation. Certification and maintenance costs under IVDR/MDR have escalated up to 100% (or more) compared to previous directives and require a critical amount of personnel resources from the manufacturer. Costs throughout the regulatory lifecycle remain unpredictable for many manufacturers, causing budget uncertainty.

The resulting impact on innovation activities is significant. Since the application of the Regulations, less respondents are choosing Europe as the place to first-launch their devices compared to the situation under the medical devices directives. Moreover, the ability to invest in research activities has dropped in many cases as resources likely are being diverted to manage regulatory compliance under IVDR or MDR.

These survey findings highlight the need to optimise certification timelines, bring efficiencies across the regulatory system and reduce associated costs. Adding clarity to conformity assessment application and other documentation

[1] MedTech Europe Survey Report – Analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation
[2] Transition to the IVD Regulation - MedTech Europe Survey Results for October 2022 - MedTech Europe
[3] Active Implantable Medical Devices Directive 90/385/EEC; IVD Directive 98/79/EC; Medical Devices Directive 93/42/EEC

requirements, streamlining the time and costs for both pre- and post-market activities, can help both large and small manufacturers to plan resources more effectively and increase investment in research and development. Improved predictability is essential to restoring innovation capacity. Embedding innovation-friendly pathway and policies into the regulatory system also are needed.

Key Findings

Timelines

Quality Management Systems (QMS) and Technical Documentation Assessment (TDA)

- For IVD manufacturers, the total average time for both Small Medium Enterprises (SMEs) and large companies to complete QMS or TDA certification each is ~18 months.
- For MD manufacturers, the average time for QMS assessment is 19.5 months, and 21.8 months for TDA
- Of the total time spent on conformity assessments for both IVDs and MDs, >50% is spent in the "pre-review" and "certificate issuance" phases, while only ~50% is used to the actual review of documentation.
- Following first QMS certification, manufacturers report no significant improvement in duration for subsequent QMS applications, meaning that experience does not translate into gain in efficiency.
- Following first TDA certification, 77% of respondents observe increased speed in conformity assessment for subsequent TDA certification.

Costs

Of the total manufacturers' costs for obtaining and maintaining certification related to either IVDR or MDR for the first year:

- 90% is spent on personnel costs to complete QMS and TD processes and documentation
- 7% is spent on Notified Body fees to complete certification
- 3% is spend on yearly regulatory maintenance costs per device.

Each year, maintenance costs per device accumulate. After a 5 year cycle, recertification costs come on top of these.

Total average Notified Body fees for IVDR QMS and TDA certification are 108,307€ and 64,184€ respectively, while for MDR QMS and TDA certification they are 136,981€ and 176,202€ respectively.

Innovation

- Since the IVDR and MDR dates of application, the manufacturer's choice of the EU as the first launch geography has dropped by:
  - 40% for large and 12% for SME IVD manufacturers;
  - 33% for large and 19% SME MD manufacturers.
- Both IVD and MD manufacturers have experienced a significant decline in innovation activities, particularly in new device development, with more companies reporting decreases than increases.
- In both sectors, SMEs report higher declines in key innovation areas compared to large companies.

- IVD and MD manufacturers have increased R&D spending, but it remains uncertain whether these investments will lead to market innovations or be hindered by regulatory barriers.

- Both sectors show reluctance to modify IVDR and MDR CE-marked devices, raising concerns about the long-term availability of innovative devices.

Orphan Devices

- An astonishing 26.6% of IVD manufacturers will transition only less than 5% of their portfolio of orphan devices.

- Over 52% of MD respondents that produce orphan devices indicate they will transfer all their orphan devices to the MDR. However, 29% indicate they do not plan to transfer any of their current Orphan devices to the MDR.

Resources for Regulatory Compliance

- It is a challenge to find staff to employ in the area of regulatory affairs. This is a challenge for each sector, more so for MD manufacturers:

  - 86% large and 91% SME MD manufacturers and find it difficult to secure qualified regulatory affairs employees;

  - 30% large and 38% SMEs IVD manufacturers find it difficult to secure regulatory affairs employees.

Regulatory Complexity

- When responding to the question 'What would help you most to transition to MDR?'
  - 28 out of 96 MD respondents mentioned 'Aligned and clear requirements from within the NB and among NBs'
  - 27 out of 96 MD respondents required 'Predictability of timelines'
  - 19 out of 96 MD respondents mentioned 'Structured dialogue'
  - 'Leverage evidence' and 'Increased NB capacity' were each chosen by 18 respondents

Performance Evaluation/Clinical Evaluation

- For 30% of IVD and 50% of MD respondents, at least one certificate was significantly delayed or closed negatively because its Performance Evaluation or Clinical Evaluation was challenged by the Notified Body.

- The top obstacle for those respondents was lack of clarity about clinical evidence expectations.

Post Market Surveillance (PMS) Reports

- 70% of IVD and MD manufacturers require up to four months to update PMS reports under IVDR and MDR, indicating this is a time-consuming activity.

Introduction and Methodology

MedTech Europe, the European trade association representing manufacturers of medical devices, diagnostics and digital health, conducted a survey with the aim of collecting data on timelines and cost for certification and certification maintenance under IVDR/MDR, as well as the associated impact on innovation in the EU.

The survey was conducted between 5 April and 3 May 2024. The target group was IVD and MD manufacturers placing devices on the Union market either based in or outside of Europe. The main areas surveyed included on:

- **Certification timelines and challenges:** Quality Management Systems (QMS) and Technical Documentation Assessment (TDA), Performance/Clinical Evaluation, post-market surveillance (PMS).
- **Costs[4]:** An overview of trends for certification & maintenance costs from manufacturers who have obtained IVDR or MDR CE-marking for their devices.
- **Innovation:** The impact of IVDR and MDR on the availability of innovative devices on the European market and on R&D activities (e.g. first regulatory approval, optimisation of existing devices and new devices).

Respondents also were asked questions outside of the above areas, including about the state of their transition to either IVDR or MDR, devices discontinuations, orphan devices and challenges with the transition.

The survey was administered in English language. Alchemer online survey platform was used to collect the data. The survey was designed by using advanced logic, allowing the respondent to skip certain questions not relevant to them based on previous responses (e.g. the respondents who indicated that they do not have IVDR/MDR Notified Body were not provided questions related to Notified Bodies, Post-Market Surveillance and most cost questions). Due to this logic the sample size per question may differ.

To highlight potential differences based on company size, the results were analysed separately for larger companies and SMEs (where possible). SMEs were defined as companies that employ fewer than 250 persons and which have an annual turnover not exceeding 50 million euro, and/or an annual balance sheet total not exceeding 43 million euro (in line with European Commission Recommendation 2003/361/EC).

To address potential antitrust risks, where the number of respondents was not high enough to guarantee anonymity, responses were either consolidated for the IVD

[4] For cost data the exchange rates used are from the 31st of December 2023 (USD-0,90595; DKK-0,13413; GBP-1,15278)

and MD sector or the questions and data were excluded altogether (especially in the costs part). In addition, in some cases the outliers were removed for data accuracy, with clarity provided about outliers as appropriate.

MedTech Europe's survey complements existing European Commission surveys focusing on the state of the transition, by providing granular information on costs and timelines as well as impact of IVDR and MDR on innovation. Where appropriate, this survey report compares the results with recent findings of European Commission surveys run by GÖG (Gesundheit Österreich GmbH). [5,6]

When making comparisons, certain factors must be noted and due caution taken. One is that the MedTech Europe and GÖG surveys occurred at different timeframes: the GÖG survey run with manufacturers represents the situation in December 2023/January 2024 while the snapshot of the MedTech Europe's survey represents the situation in April 2024. GÖG Notified Body surveys have occurred at regular intervals over the past two years, the recent available data dates from October 2024. There also are important differences in the pool of respondents that participated in three surveys: GÖG Notified Bodies October 2023, GÖG manufacturers December 2023/January 2024, and MedTech Europe survey of manufacturers April 2024:

- In MedTech Europe's 2024 survey, the typical respondent already has a Notified Body agreement as well as devices certification under either IVDR or MDR for at least part of their portfolio. The GÖG manufacturers' survey represents a larger spread of manufacturers including a proportion of respondents that do not yet have an agreement in place.

- The GÖG manufacturers' survey comprises more participants. It should be noted that GÖG surveyed legal manufacturers (parent companies) whereas MedTech Europe surveyed at the level of the manufacturer organisation (some of which may include two or several legal manufacturers), which reduced the sample size but may give a clearer picture of the results.

[5] 10th notified bodies survey on certifications and applications (MDR/IVDR) link: NBs survey on certifications and applications (MDR/IVDR) 30 October 2024

[6] Study supporting the monitoring of the availability of medical devices on the EU market, Study overview and survey results of the 1stMF/AR survey with data status 31 October 2023, 25 September 2024, accessed at: https://health.ec.europa.eu/document/download/71bc3a23-1ace-4e42-a1f3-ea1e40cece40_en?filename=md_availability_study_presentation.pdf

Abbreviations

GÖG:	Gesundheit Österreich GmbH
MDCG:	Medical Devices Coordination Group
IVD:	*In Vitro* Diagnostic Medical Device
IVDD:	*In Vitro* Diagnostic Medical Devices Directive 98/79/EC
IVDR:	*In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746
LC:	Large Company
MD:	Medical Device
MDD:	Medical Devices Directive 93/42/EEC
MDR:	Medical Devices Regulation (EU) 2017/745
MNF	Manufacturer
MTR:	Manufacturer's Trend Report
NB:	Notified Body(ies)
PSR:	Periodic Summary Report
PSUR:	Periodic Safety Update Report
PMSR:	Post-Market Surveillance Report
RWD:	Real-World Data
RWE:	Real-World Evidence
QMS:	Quality Management System
TDA:	Technical Documentation Assessment
SME:	Small- and Medium-sized Enterprises

In this report 'directives' refer to the Active Implantable Medical Devices Directive 90/385/EEC; IVD Directive 98/79/EC; and Medical Devices Directive 93/42/EEC; 'regulations' refer to IVDR/MDR; unless otherwise specified.

Results

About the respondents

A total of **73 IVD** and **138 MD manufacturer organisations** participated in the survey with an almost equal distribution between large companies and SMEs. Based on the European revenue provided in this survey and the MedTech Europe European medical technology market size estimate[7], this survey covered around 50-70% market share for the IVD sector and around 35-40% for the MD sector. Most respondents report direct **experience of undergoing IVDR or MDR certification**, with 79% of IVD and 93% of MD respondents having transitioned at least part of their portfolios to IVDR or MDR respectively. By the same measure, the responses will not be representative of manufacturers which have not yet engaged in transitioning devices to the Regulations.

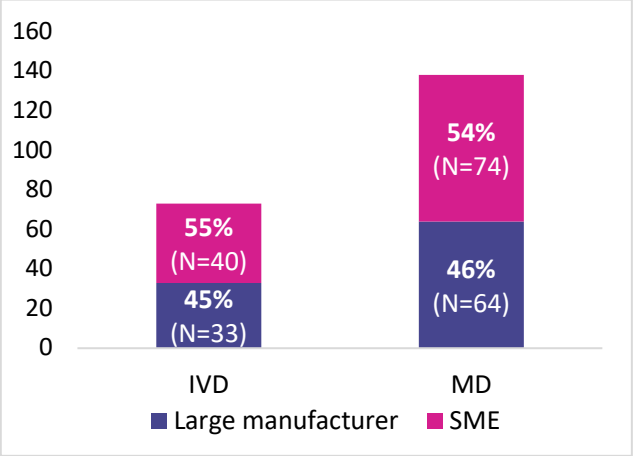

Figure 1: Survey respondents per company size

The respondents that submitted input into the survey results are covered by:

- **6 IVD Notified Bodies (out of 12 designated at that time[8])**
- **18 MD Notified Bodies (out of 43 designated at that time)**

Therefore, a relevant but not fully comprehensive proportion of Notified Bodies are reflected in the results.

[7] MedTech Europe Facts & Figures 2024: https://www.medtecheurope.org/wp-content/uploads/2024/07/medtech-europe--facts-figures-2024.pdf

[8] 8th notified bodies survey on certifications and applications (MDR/IVDR) Survey results of the 8th NB survey with data status 29 February 2024 (small and medium dataset) 17 May 2024, accessed at: https://ppri.goeg.at/system/files/inline-files/2024-02_8NBSurvey_MD_IVD_MDAvailabilityStudy_20240517.pdf

IVD and MD: Access to a Notified Body

Obtaining an agreement with the Notified Body is a crucial step for manufacturers to begin the transition to the Regulations. Without an established agreement, manufacturers cannot start their conformity assessment. However, an agreement might not cover the full range of products in manufacturer's portfolio. Here it should be noted that the survey only asked if the manufacturer had at least one agreement in place: a positive response to this question does not guarantee full coverage of the manufacturer's portfolio. The manufacturer will need more than one agreement if they plan to operate with more than one Notified Body.

IVD: Access to a Notified Body and IVDR transition

Compared to the MedTech Europe survey of 2022[9], the percentage of IVD manufacturers having at least one agreement with a Notified Body, remains high for large companies. In 2024, only 9% report they do not yet have a Notified Body agreement.

The number of SMEs who have a contract with a Notified Body has increased significantly. The percentage of SMEs not having an agreement in place reduced from 53% in 2022 to 37.5% in 2024. Although the trend is positive, differences between SMEs and large companies persist; significantly more SMEs report not having an agreement compared to large companies.

By comparison, the GÖG report[10] providing data from Notified Bodies for October 2023 highlights that 42% of manufacturers (small and large combined) do not have an agreement with a Notified Body.

From the **respondents without a Notified Body**:

- 50% indicated that they would engage with an already-designated IVDR Notified Body;
- 11% are waiting for their Notified Body to be designated;
- 11% were not able to sign with a currently designated body;

[9] Transition to the IVD Regulation - MedTech Europe Survey Results for October 2022 - MedTech Europe
[10] Study supporting the monitoring of the availability of medical devices on the EU market, Study overview and survey results of the 1stMF/AR survey with data status 31 October 2023, 25 September 2024, accessed at: https://health.ec.europa.eu/document/download/71bc3a23-1ace-4e42-a1f3-ea1e40cece40_en?filename=md_availability_study_presentation.pdf

- 28% had "other reasons" for not proceeding (such as insufficient clinical evidence for older devices, site acquisition, or changes in the legal manufacturer).

From the **respondents with an agreement with a Notified Body**, 71% already obtained their QMS certificate and 44% certified more than half of their devices under the IVDR.

The three main reasons given for not starting with conformity assessment are:

- Option for staggered approach for the transition of IVDs to IVDR;
- Insufficient performance evaluation data;
- Insufficient expertise / personnel within the company.

For additional information about the proportion of IVD devices transitioned, see Annex III.

Interestingly, these reasons for not starting conformity assessment only partly overlap with the GÖG-report[11], where the main reasons for not starting conformity assessment are either low product revenue, and the IVD will be updated/replaced and the length of certification time.

Moreover, many manufacturers will not transition all their devices to IVDR. Examples given of IVD devices that will not be transitioned include reagents for infectious diseases, immunochemistry, haematology, histology, cytology, genetic testing and instrumentation for chemistry, haematology, histology and cytology. Unfortunately, these results signal a potential reduction of the availability of IVDs on the market for niche indications in the future unless special considerations or incentives can be offered to these companies.

MD: Access to a Notified Body and MDR transition

In 2022, MedTech Europe's survey[12] reported that around 85% large companies and 60% of SMEs still have no agreement with an MDR-designated Notified Body. Since then, the number of companies having at least one Notified Body agreement

[11] Study supporting the monitoring of the availability of medical devices on the EU market, Study overview and survey results of the 1stMF/AR survey with data status 31 October 2023, 25 September 2024, accessed at: https://health.ec.europa.eu/document/download/71bc3a23-1ace-4e42-a1f3-ea1e40cece40_en?filename=md_availability_study_presentation.pdf

[12] MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation https://www.medtecheurope.org/wp-content/uploads/2022/07/medtech-europe-survey-report-analysing-the-availability-of-medical-devices-in-2022-in-connection-to-the-medical-device-regulation-mdr-implementation.pdf

has increased. The 2024 survey indicates that overall 89% of MD manufacturers have an agreement with a Notified Body.

Access to Notified Bodies remains an issue for some SMEs. 13 SME respondents compared to only 2 large company respondents reported not having an agreement. Moreover, an agreement in place does not necessarily translate into having a QMS certification; the majority, however not all, of respondents with a NB agreement have at least one QMS certification. Again, SMEs are more affected: 95% of manufacturers with a NB agreement also have QMS certification while only 34% of SMEs have both the Notified Body agreement and QMS certification. This large disparity highlights the challenges faced by SMEs, possibly exacerbated by difficulties such as finding or retaining qualified regulatory affairs employees, having financial means to engage a Notified Body, or simply being less aware of deadlines and the complexity of the MDR system.

It should be noted that this survey was conducted from April until early-May 2024, in other words just before the 26 May 2024 deadline for manufacturers to file applications with their Notified Body for conformity assessment under the MDR. It is concerning that at this late stage, a small proportion (11%) of MD manufacturers still reported not having a NB agreement in place.

From respondents with a MDR QMS certificate, 51% have certified more than half of their devices under the MDR. The number of large manufacturers that have certified more than half of their portfolio is 38.8% which is significantly higher when compared with 12% of SMEs.

Manufacturers that have not yet started conformity assessment report three main reasons for not doing so:

- Choosing a staggered approach for the transition to MDR
- High certification costs
- Other reasons, which include all submissions already made and staggered approach/ prioritization/ sequential planning.

For additional information about the access to NB and the proportion of MD devices transitioned, but also the devices which will be discontinued, see Annex IV.

As noted earlier for IVDs, these main reasons only partly overlap with the main reasons presented in the GÖG-report[13]; low product revenue, the MD being replaced with a more innovative product and the length of certification time. This disparity could be due to the fact that, as mentioned in the 'About respondents' section, the respondents to the MedTech Europe survey form a specific group of manufacturer organisations that mostly are well advanced in the transition to the regulations. Hence, the response to the MedTech Europe survey may represent the approach of manufacturers with experience of transitioning under MDR.

Although MDCG Guidance 2022-14[14] outlines measures that Notified Bodies can implement to support the transition to the Regulations, these are not adopted consistently. Notably, in the MD sector, 23% of respondents report that their Notified Body has not introduced any supportive actions. Among the measures, *"Leveraging evidence as per MDCG 2022-14"* and *"Certificates under conditions"* are the least frequently used. In contrast, structured dialogues are cited by 58% of MD respondents as being available, while pre-submission dialogues were mentioned by 41%. This further creates an uneven level playing field and fragmentation in the system.

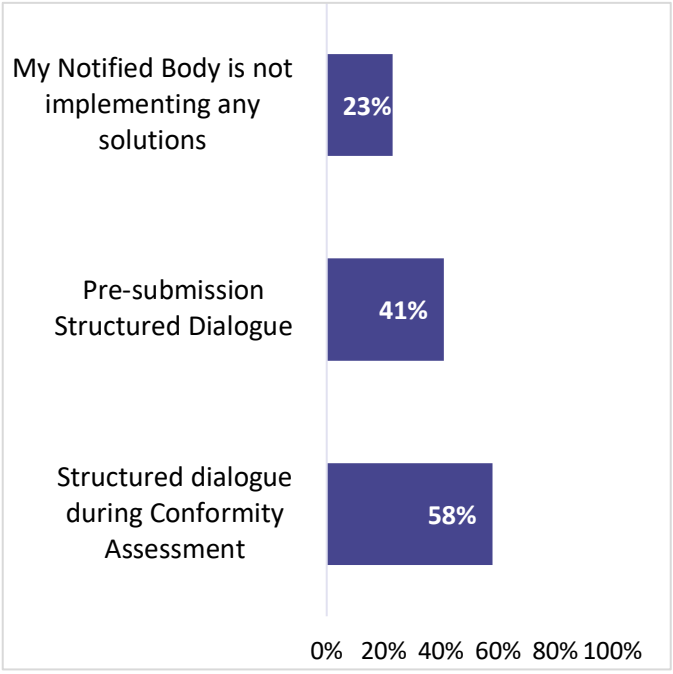

Figure 1.1: solutions implemented by NB to help MD manu-facturers to help MD manufacturers transition to MDR

When asked, 'What would help you most to transition to MDR?' Most respondents indicated improvements in the in processes and working of Notified Bodies as shown in the figure below 1.2. These solutions reflect the critical role that Notified Bodies play in facilitating a smooth and efficient transition.

[13] Study supporting the monitoring of the availability of medical devices on the EU market, Study overview and survey results of the 1stMF/AR survey with data status 31 October 2023, 25 September 2024, accessed at: https://health.ec.europa.eu/document/download/71bc3a23-1ace-4e42-a1f3-ea1e40cece40_en?filename=md_availability_study_presentation.pdf

[14] MDCG 2022-14 "Transition to the MDR and IVDR - Notified body capacity and availability of medical devices and IVDs" (link)

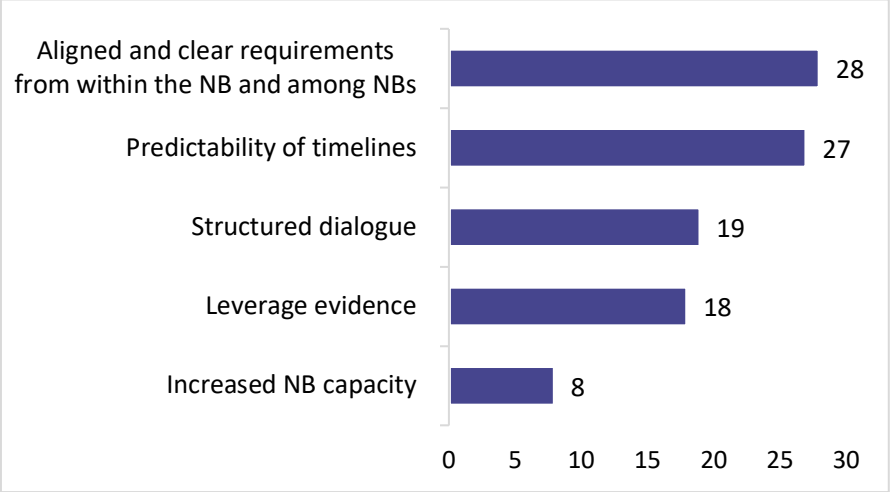

Figure 1.2: TOP 5 measures that would help manufacturers to transition to MDR

Although data for the IVD sector is unavailable due to the small sample size, it is reasonable to assume that the IVD sector shares similar views regarding the importance of cooperation with Notified Bodies (NB) and the critical role they play in the transition process.

IVD and MD: Orphan devices

Manufacturers face several challenges with bringing orphan devices through the regulatory system in Europe. Firstly, clinical evidence may be difficult to generate for orphan devices due to small patient populations. The cost of generating clinical data and obtaining certification can be disproportionally high compared to the low sales volume and especially the investment needed to CE-mark under the IVDR or MDR. Finally, there often are additional regulatory and ethics considerations because of vulnerable target patient populations, like paediatric.

IVD: Orphan devices

Orphan device production is concentrated among a small number of companies – 80% of manufacturers do not have any orphan devices in their entire portfolio.

Overall, 53.3% of the total respondents that produce orphan devices indicate they will transfer all their orphan devices to the IVDR. An astonishing 26.6% of IVD manufacturers will transition less than 5% of their portfolio of orphan devices.

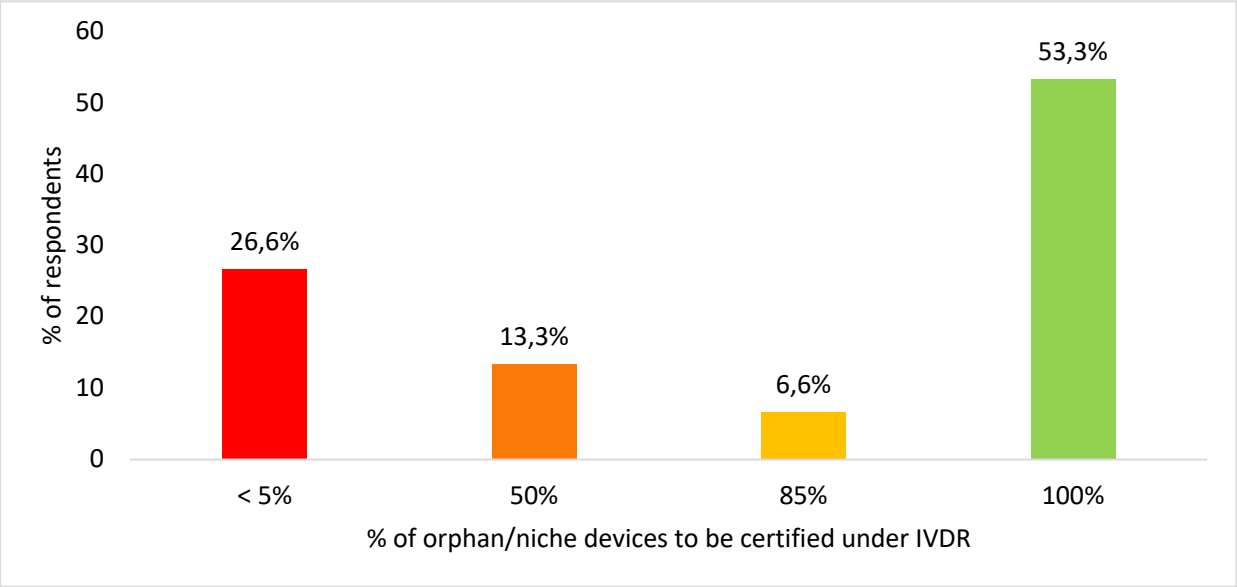

Figure 1.3: The percentage of orphan/niche IVDs that manufacturers are planning to certify under IVDR (out the manufacturers that do have orphan devices)

MD: Orphan devices

Orphan devices represent a specific segment of the MedTech industry and their production is concentrated among a smaller number of manufacturers, as MedTech Europe data indicates (15% of the total MD respondents). Also, the percentage of orphan devices ranges from 1% to 100% of the manufacturer's portfolio and their proportion to the whole portfolio tends to differ between SMEs and large manufacturers.

Overall, a little over 52% of respondents that produce orphan devices indicate they will transfer all their orphan devices to the MDR. However, 29% indicate they will transfer only less than 5% of orphan devices to the MDR - a potential significant loss in the European market - which will negatively impact European patients, unless a sustainable pathway is put forward quickly.

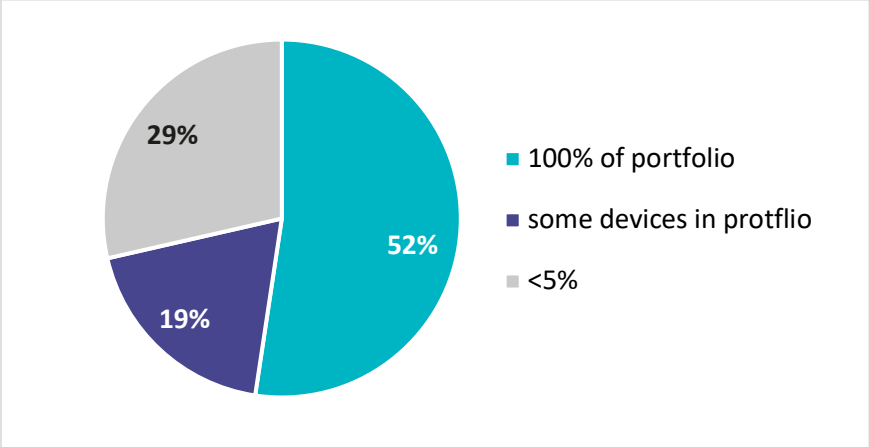

Figure 2: The proportion of manufacturers that plan to transition all of their orphan devices and the ones that will transition only part of their portfolio

under MDR

The recently published MDCG 2024-10 guidance[15] offers a pragmatic approach to clinical evaluation for orphan medical devices. While broad adoption of this guidance marks an important first step in addressing the unique regulatory requirements and challenges associated with MD orphan devices, additional measures are essential to ensure their continued availability. These include establishing dedicated regulatory pathways, providing targeted incentives, and fostering a supportive environment for innovation in this critical group of products. As IVDs are outside the scope of MDCG 2024-10, a practical approach to performance evaluation for orphan IVDs also is needed. Finally, regulators and the European Commission should consider providing EU-wide derogations from conformity assessment for the purpose of maintaining critical orphan devices on the European market.

Note: the survey was conducted before the release of MDCG 2024-10 in June 2024, which provides clarification and guidance on the clinical evaluation of orphan medical devices. It remains to be seen if this guidance document will have an impact on the ability of orphan device manufacturers to market their products.

IVD and MD: Resources for Regulatory Compliance

One in three IVD manufacturers have challenges in finding qualified regulatory affairs employees. This percentage is slightly higher for SMEs (37.5% versus 30.2% for large companies). Notably, for the same question, 65% of MD SME respondents find it highly difficult to secure qualified regulatory affairs employees. While this survey did not ask respondents to provide more information, it can be speculated that this may be in part due to limited expertise in the system when faced with the complex regulatory framework. Some SMEs may have difficulty in providing competitive compensation packages to attract qualified personnel. This highlights a need for regulators and trade associations to support SMEs in pooling expertise for navigating the complexities of the regulatory system. Training provided by regulators, trade associations and NBs also are important.

IVD and MD: Performance & Clinical Evaluation

MDR and IVDR have increased clinical evidence expectations for IVDs and MDs to be certified under these regulations. The present MedTech Europe survey aimed to

[15] MDCG 2024-10 "Clinical evaluation of orphan medical devices June 2024" (link)

evaluate, if the change in expectations have led to challenges – for both legacy and new devices – which could impact the availability of the devices on the market.

A comprehensive strategy for the generation of clinical data – both for new and legacy devices – is key for a successful conformity assessment and hence bringing medical devices and IVDs to the European market. Therefore, the expectations regarding what is 'sufficient clinical data', acceptance of real-world evidence collected during the port-market phase and feeding into performance and clinical evaluation, need to be clear well before submission of an application for conformity assessment. This would help avoid lengthy reviews and multiple deficiency rounds which add to both timelines and costs for the certification process.

IVD: Performance Evaluation

When asked whether a Notified Body challenged their Performance Evaluation which led to the certification either incurring slight delays or threatening to fail, most IVD manufacturers (71%) state not having faced such challenges. Despite this majority, there is still a large proportion of manufacturers (29%) which report being challenged on their performance evaluation for at least one device in their portfolio. This resulted in either a significant delay in their certification process or threatened to fail their certification.

Only those respondents who stated that their Performance Evaluation was strongly challenged were asked to provide reasons for those challenges. The following reasons were provided:

- No clear definition of sufficient clinical evidence
- Difficulty in running performance studies
- Difficulty in agreeing on an appropriate Post-Market Performance Follow-Up Plan with the Notified Body
- Justification of PMPF omission was not accepted.

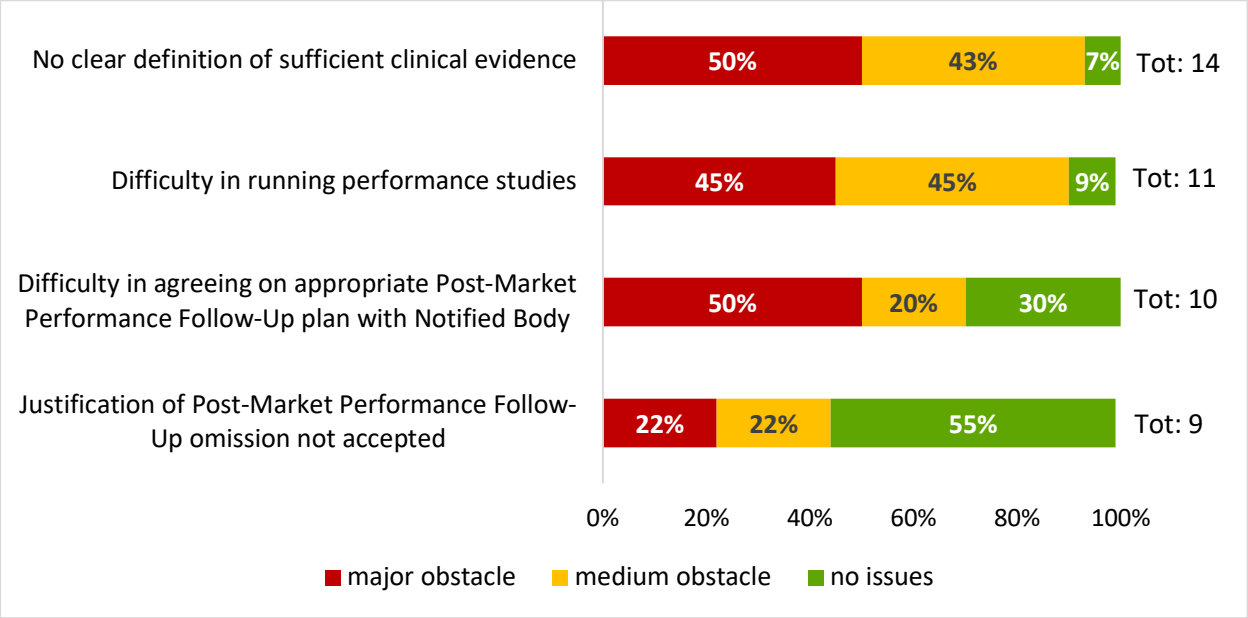

Figure 3: IVD Performance Evaluation – obstacles for legacy devices
The figure illustrates the major obstacles encountered by IVD manufacturers in their performance evaluation, ranked from most challenging to least challenging. The ranking is based on the number of participants (indicated in green) who reported no issues.

50% of respondents found an unclear definition of sufficient clinical evidence represented a 'major obstacle' during their IVDR certification process. However, 43% of respondents indicated that this was only a 'medium obstacle' and 7% indicated that it was not an issue.

Regarding difficulties with conducting performance studies, an equal split of responses (45%, respectively) is observed for those who considered it a 'major obstacle' and those who considered it a 'medium obstacle'. No issues were reported from 9% of respondents.

An equally high number (50%) found a 'major obstacle' was agreeing on an appropriate Post-Market Performance Follow-Up Plan with the Notified Body. 20% reported this as a 'medium obstacle' while 30% reported it did not represent an issue. Justifying the omission of Post-Market Performance Follow-Up was the least reported obstacle, 55% rated this as causing no issues.

Overall, these responses highlight an urgent need to put in place concrete actions to equip manufacturers with a better understanding of the evidence required well in advance of needing to submit applications. The level of clinical evidence required should be clear before performance studies are conducted. Structured dialogues, less administrative burden and facilitation for performance studies, including

sourcing of samples, could provide the transparency, predictability and additional support needed to ensure that applications meet Notified Body expectations. Based on these observations, a more pragmatic approach should be considered, to ensure that a greater number of devices successfully and efficiently obtain certification.

MD: Clinical Evaluation

1. Challenges

Clinical evaluation remains a complex part of MDR implementation. 50% of respondents indicated that their clinical evaluation for at least one application, was significantly challenged by their Notified Body. Note that this does not mean that all applications for those respondents were significantly challenged. It is possible that some respondents who indicated no significant challenges with clinical evaluation have not yet made that experience with their Notified Body (the survey question did not contain a Non applicable option).

Only those respondents who stated that their Clinical Evaluation was strongly challenged, were asked to provide reasons for those challenges. The 3 top ones are:

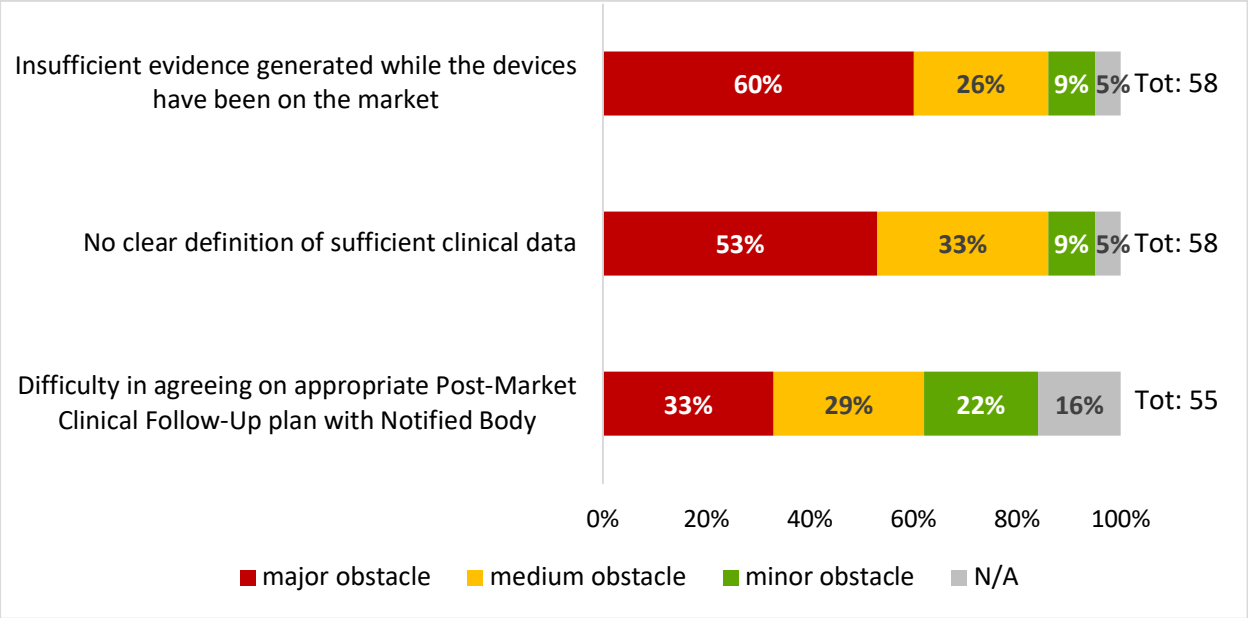

Figure 4: MD Clinical Evaluation – obstacles for legacy devices

These top 3 challenges were closely followed by 'Well established Technologies (WET) definition in MDCG 2020-6 not being sufficiently used by NBs' to incorporate further kinds of devices that thus may be required to perform clinical investigations even though they are in fact WET. Some of these challenges may be addressed via upcoming MDCG guidance on clinical evaluation, however, that takes time to develop and should involve all stakeholders in order to be fit for purpose.

Currently, without a **pre-submission dialogue** between NB and manufacturer, a clinical strategy is applied by the manufacturer which may be later challenged by the NB after the manufacturer has applied it for months or even years of documentation development. In addition, the absence of common specifications or the possibility to consult the expert panels as per MDR Art.61.2 (since it runs in pilot phase for a limited scope of devices) creates further uncertainties. The current situation represents significant costs, resources deployment but most importantly a delay in product availability for the European patient.

Therefore, it is **absolutely crucial for manufacturers to be able to discuss their clinical strategy at an early stage** (pre-submission in addition to dialogue during conformity assessment) with their Notified Body. Structured dialogue is also recognised by MDCG 2022-14 as one of the urgent solutions, yet 2 years after the publication its implementation is not complete and situation remains fragmented with some NBs offering structured dialogue (before or during conformity assessment), while others do not.

Note on clinical investigations of new MDR Devices

Only a relatively small number of respondents (25) were able to provide feedback on the following optional question: *What are the major obstacles (if any) for clinical investigations under the MDR for new devices?* The key obstacle is the associated costs. Timelines is the second biggest obstacle, followed by the diverging requirements (between Member States) and significant clinical investigation documentation requirements.

Even though the feedback is limited, it indicates complexity in running clinical investigations in the EU and identifies the key obstacles which should be addressed to support Europe's attractiveness as a location for running clinical investigations.

2. Real World Data (RWD) & Real World Evidence (RWE)

RWE acceptance for Post-market clinical follow-up (PMCF)

It is widely acknowledged that RWE can be a valuable source of clinical data but may have shortcomings with regards to gathering data on performance, particularly over a long-term period. The MedTech Europe survey shows significant discrepancies exist among NBs regarding the acceptance of Real-World Evidence (RWE)[16] as clinical data during Post-Market Clinical Follow-Up (PMCF).

[16] Real-World Evidence is evidence derived from the analysis of RWD *(Real-world evidence provided by EMA Support for regulatory decision-making; 10 April 2024; EMA/152628/2024; European Medicines Agency)*

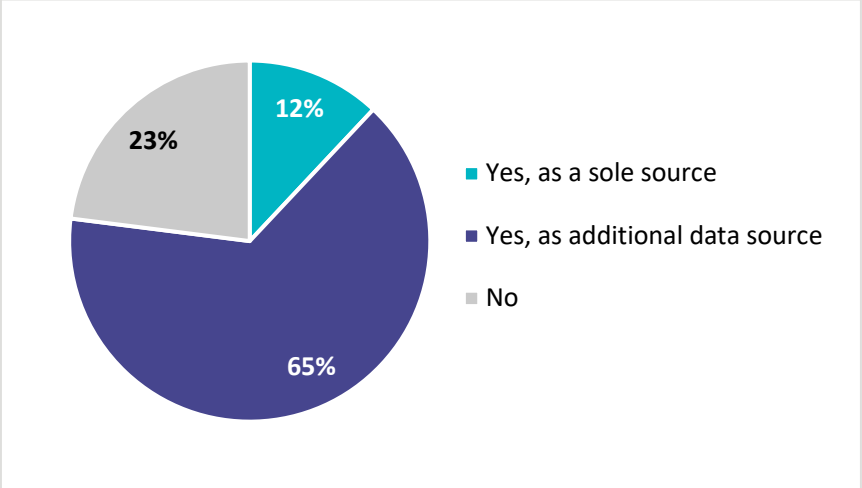

Figure 5: The % of Notified Bodies that accept RWE as a source of PMCF data

Real World Evidence (RWE) is somewhat accepted by Notified Bodies: 65 % of respondents report that their NB does accept RWE as additional source of Post Market Clinical Follow Up. This number, however, falls to a little over 12% for RWE being the sole source of PMCF data and 23% report their NB does not accept RWE at all for PMCF. In order to realise the full potential of RWE, industry needs more clarity on its acceptability for different types of devices ideally with concrete examples. Such clarifications will benefit both NBs and manufacturers.

In principle, RWE should be accepted as data that can support the sufficiency of clinical data during PMCF and for CE marking (e.g., RWE collected outside of the EU could be used for expanding indications).

Sources of RWD most accepted by Notified Bodies
Unsurprisingly, registries are the most accepted source of real world data (RWD) by Notified Bodies, as can be seen in the following graph. The significantly lower score (than registries) of many sources, such as health service administrative records, social media and wearables indicate that improvements are needed in terms of their quality and reliability. Note that the survey questions did not inquire about the reasons for why some sources are preferred over others, yet, it is likely related to the quality and reliability of data sources.

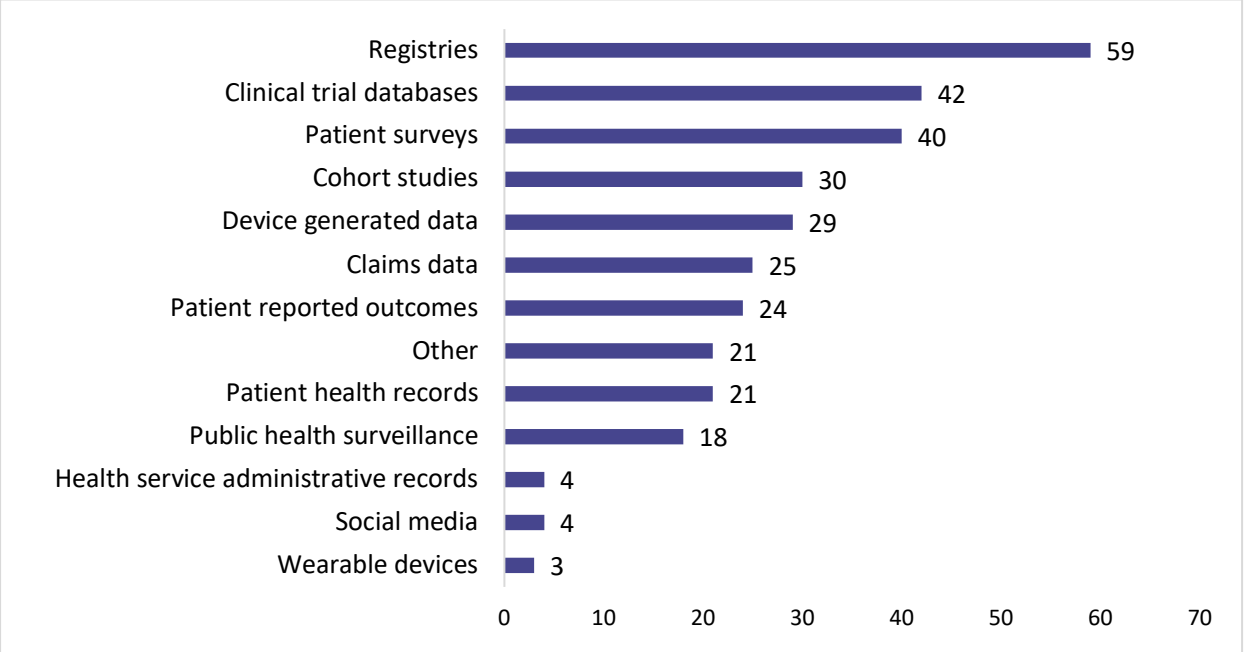

Figure 6: Sources of RWD accepted by the respondent's Notified Body (multiple choice question)

Even for registries a substantial amount of work lies ahead in terms of alignment on collection of core data sets so that the information is comparable and can be effectively used. Initiatives already exist to align on the minimum data set that registries should collect. Such initiatives should be supported.

Several initiatives would be helpful for supporting an improved, more transparent and predictable system for clinical evaluation, for example:

1) Fit for purpose Medical Devices Coordination Group (MDCG) guidance on clinical evaluation

2) Fit for purpose update to MDCG 2019-6 that will:
   a) clarify that structured dialogue before submission can include clinical strategy

   b) outline the framework and rules for such discussion while ensuring NB independence.

3) Define examples/benchmarks for RWE acceptance and support alignment efforts among registries

IVD and MD: Conformity Assessment timelines

Although there is still considerable variability in responses regarding the IVDR certification processes (both QMS and TDA certification), feedback from MD manufacturers to the survey shows more consistency. Interestingly, the overall

certification time is similar between the two device groups. At the same time, the timelines can vary widely for SMEs versus larger companies.

Overall situation for IVD certification

- The total average time for both SMEs and large companies to complete either the QMS or TDA certification is around 18 months for each.

- The Notified Body spends >55% of the total average time from application to certificate issuance of the QMS outside of the Review phase (Pre-review + Certificate issuance)

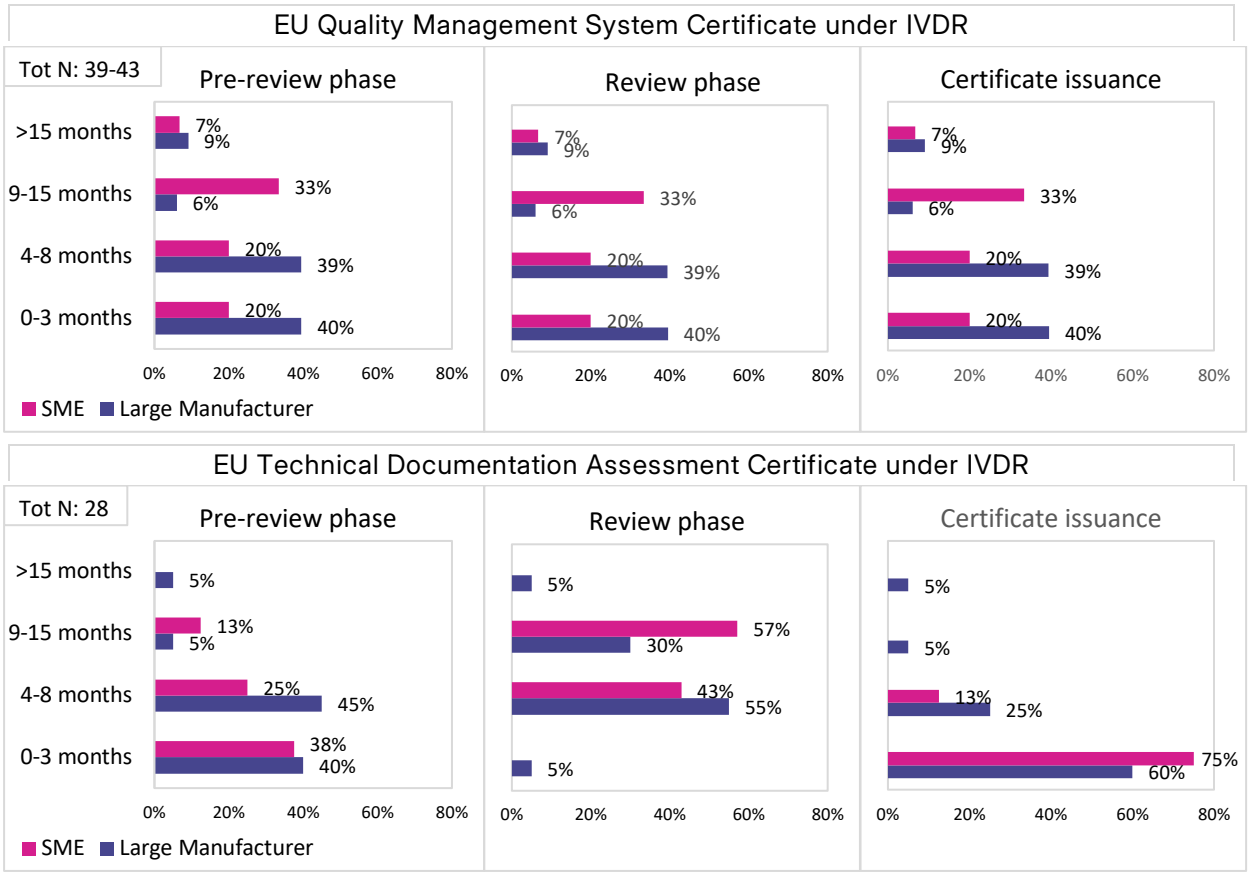

Figure 7: Certification Timelines under IVDR per different phase

Overall situation for MD certification

- The average time for SMEs and large companies to complete the QMS certification is approximately 19.6 months.

- The overall TDA timelines for SMEs and large companies are similar at 22 months. The only difference is in the pre-review phase, where it takes on average, 50% less time for SMEs to complete than large companies.

- The Notified Body allocates over 50% of the total time from application to QMS certificate issuance to phases outside the Review phase (Pre-review and Certificate issuance); this is 42% in case of TDA.

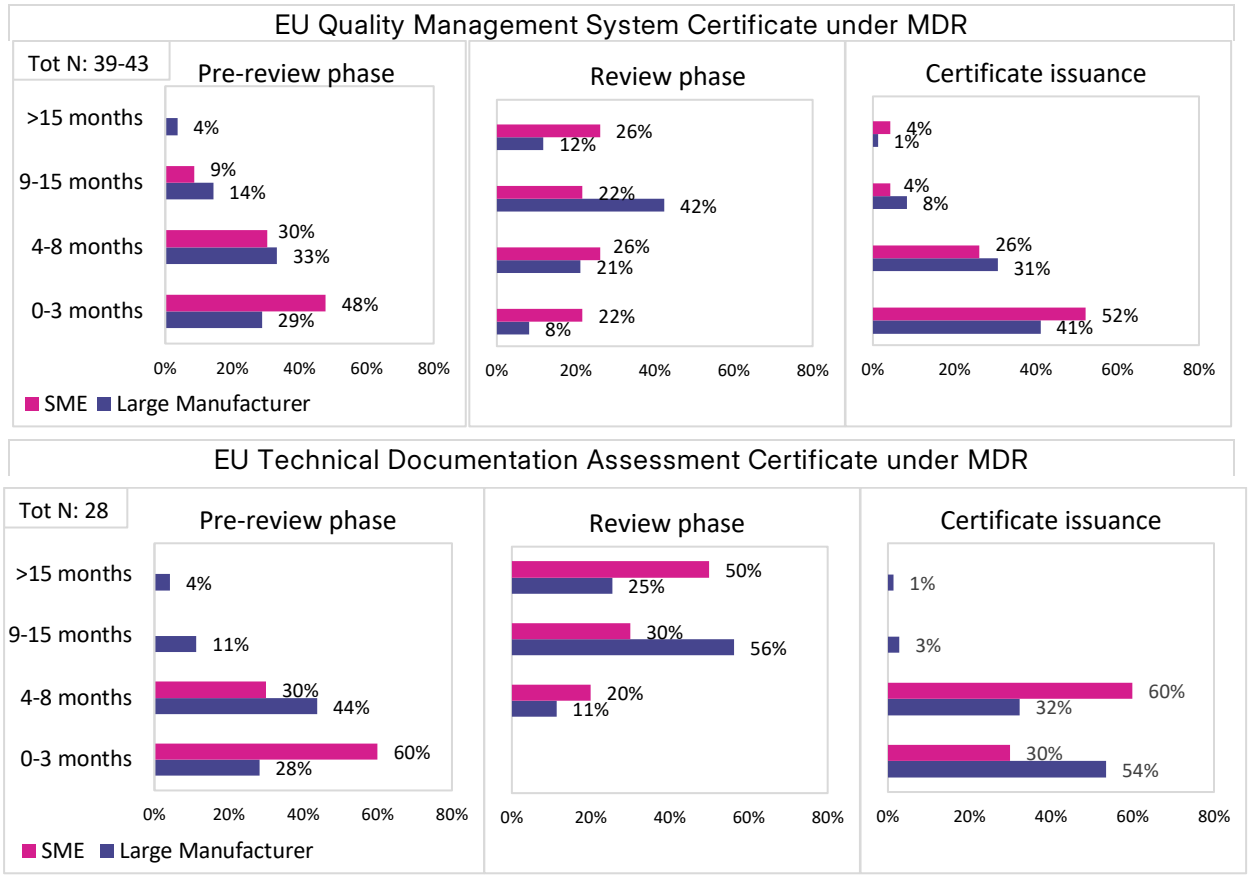

Figure 8: Certification timelines under MDR per different phase

A significant amount of time is now spent during the pre-review and certificate issuance phases which together often require upwards of 6 months. Independent of company size and Regulation, an analysis of the different duration times shows that activities other than the actual review process take at least half of the total time from the manufacturer sending their submission to receiving their certification.

When comparing the manufacturer information with data provided from the Notified Bodies and presented in the 2024 GÖG NB report[17], QMS certification times (from initial agreement to certificate issuance) for MDs and IVDs seem to be slightly higher compared to the certification times provided by Notified Bodies. The

[17] 8th notified bodies survey on certifications and applications (MDR/IVDR) Survey results of the 8th NB survey with data status 29 February 2024 (small and medium dataset) 17 May 2024, accessed at: https://ppri.goeg.at/system/files/inline-files/2024-02_8NBSurvey_MD_IVD_MDAvailabilityStudy_20240517.pdf

difference may be due to how the certification start and end is perceived. MedTech Europe's survey asked respondents for timelines from the sending of their submission to receiving their certification. It is entirely possible that Notified Bodies would calculate conformity assessment timelines differently.

Furthermore, when calculating how long it will take to bring a device through the regulatory pathway, the actual time for the manufacturer to prepare for the application needs to be added to the overall timelines described above. While this survey did not ask respondents about time for preparation, according to the 2024 GÖG Manufacturer report[18], 43% of files need between 6 and 12 months for preparation.

QMS Conformity Assessment for IVD manufacturers

Feedback on the timeline assessment for IVDR QMS Review was based on information from 43 respondents in total.

- The median time for the Notified Body **Pre-Review Phase**, i.e. the time from submission of the application to review start, depends on several factors, such as the completeness of the documentation and the scheduling times of the Notified Bodies. The median time for large companies is shorter at 5.4 months compared to 8.8 months for SMEs.

  There is a positive trend towards a shorter pre-review time, especially for large companies, compared to the MedTech Europe IVDR survey in 2022 when 38% reported 7-9 months and 37% >10 months of pre-review time.

- However, the median **Review time**, i.e., the time from the start of the application review to the certification, is similar between large companies (8 months) and SMEs (7.2 months). This only slight difference is somewhat surprising considering that large companies might be expected to have more manufacturing sites and devices covered by the QMS conformity assessment than SMEs.

  The median **Certificate issuance time**, i.e. the time from positive recommendation to certificate issuance, is 4.9 months for large companies and 2.8 months for SMEs. Of note, all SMEs indicated that they received their certificate within eight months, whereas more than 10% of large companies waited nine months or longer. Interestingly, the IVD sector

[18] Study supporting the monitoring of the availability of medical devices on the EU market, Study overview and survey results of the 1stMF/AR survey with data status 31 October 2023, 25 September 2024, accessed at: https://health.ec.europa.eu/document/download/71bc3a23-1ace-4e42-a1f3-ea1e40cece40_en?filename=md_availability_study_presentation.pdf

reported longer issuance timelines than for larger companies in the MD sector, which was around 4 months.

TDA Conformity Assessment for IVD manufacturers

The information on certificate issuance of IVD manufacturers is based only on 28 respondents. This may reflect the current situation where many IVD manufacturers are still undergoing TDA conformity assessment for their devices.

- The median lead time for the Notified Body **Pre-Review Phase** for large companies is 4.6 months and 4.5 months for SMEs. This phase covers the time from submission of the application to review start, and may be influenced by several factors, such as the completeness of the documentation and the scheduling times of the Notified Bodies.

- The median **Review time**, i.e. the time from application review start to certification is also similar between large companies (with 8.3 months) and SMEs (with 9.3 months), with a somewhat larger variability for large companies.

- The median **Certificate issuance time**, i.e. the time from positive recommendation to certificate issuance is 4.9 months for large companies and 2.8 months for SMEs. However, 28% of the SMEs could not provide an estimate or replied "N/A".

The total average time for both SMEs and large companies to complete either QMS or TDA certification is around 18 months for each.

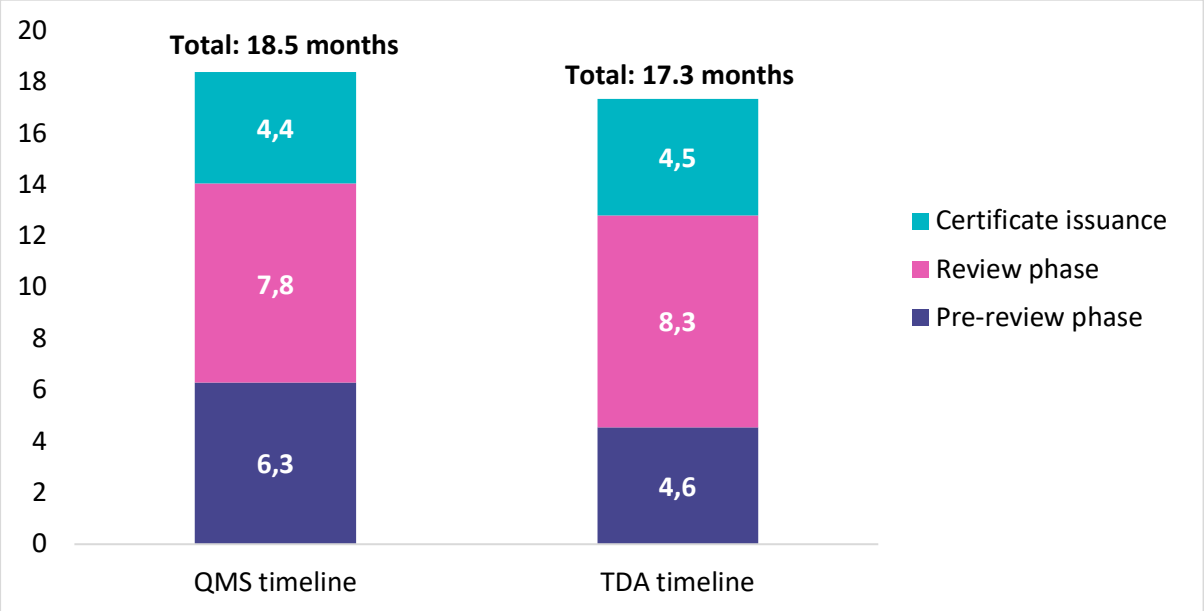

Figure 9: Average IVD certification time – QMS and TDA

QMS Conformity Assessment for MD manufacturers

The feedback on the timeline assessment for QMS was based on information from 88 MD manufacturers.

- The median lead time for the Notified Body **Pre-Review Phase** is 6 months for large companies and 4 months for SMEs.

- The median **Review time** is more similar between large companies (10.5 months) and SMEs (10 months). This only slight difference is somewhat surprising considering that large companies might have more manufacturing sites and devices covered by the QMS conformity assessment than SMEs. There is a difference in median review time to the IVD sector, which is around two months shorter.

- The median **Certificate issuance time** is 4.6 months for large companies and 4 months for SMEs. While nearly 50% of the manufacturers received their certificate within 3 months, nearly 10% had to wait 9 months or more.

TDA Conformity Assessment for MD manufacturers
The feedback on the timeline assessment for TDA Review for Medical Device companies was based on the information from 80 manufacturers.

- The median time for the Notified Body **Pre-Review Phase** is 6 months for large companies and 3 months for SMEs.

- The median **Review time** is similar between large companies (13.7 months) and SMEs (14.3 months), with a significantly higher number of SMEs experiencing >15 months of review time compared to large companies.

- The median **Certificate issuance time** is 3.75 months for large companies and 4 months for SMEs.

The total average time for SMEs and large companies to complete the QMS and TDA conformity assessment is around 20 months. This is higher than the average 13 - 18 month time-to-certification that was reported in the 2022 survey across manufacturers of all sizes.

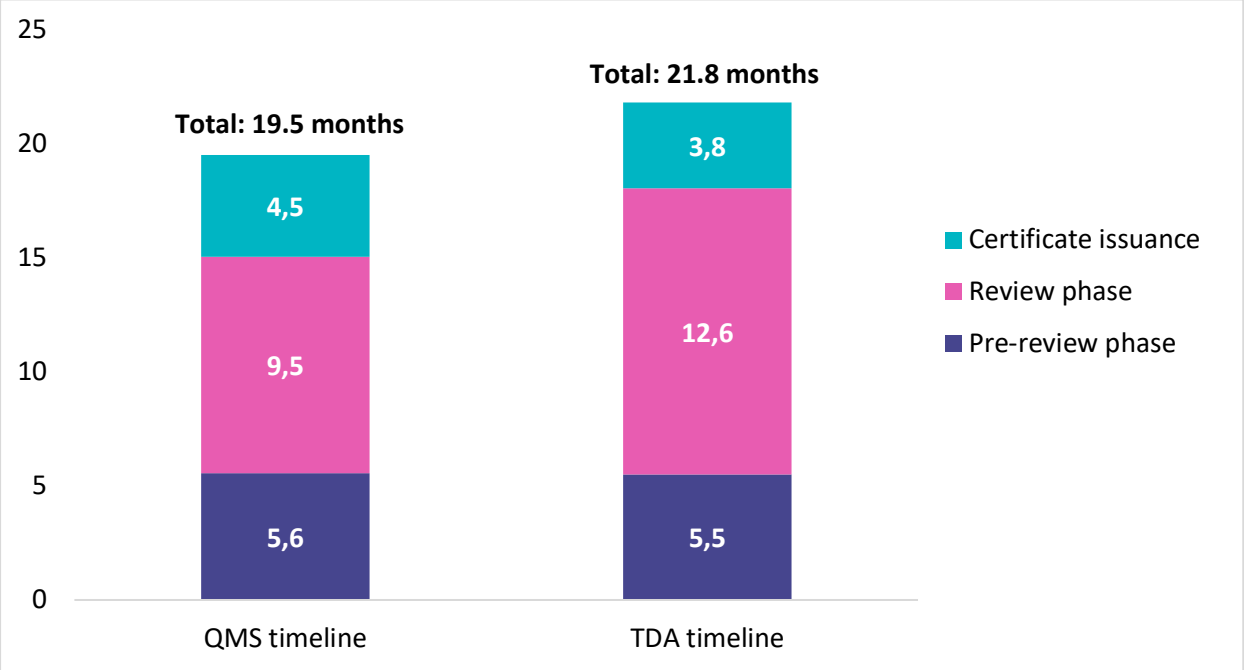

Figure 10: Average MD certification time – QMS and TDA

Improvement on subsequent Notified Body conformity assessment

Manufacturers for IVDs and MDs with more than one QMS / TDA certification were asked for potential improvements in the conformity assessment process. 36% of IVD and 50% of MD respondents answered this question.

IVD

- With respect to **QMS certification**, there is no significant improvement in duration of conformity assessment following the initial process (either for subsequent submissions or for surveillance audits).
- With respect to **TDA certification**, there is a significant improvement, with 77% of respondents noting a positive impact on the timeline.

MD

- There is room for improvement in **QMS certification** and **QMS surveillance audits**, as only 37% and 23% of manufacturers note improvements in these processes, respectively.
- In **TDA certification**, approximately 60% of respondents note reduced timing, indicating a steady learning curve among manufacturers and Notified Bodies.
- For **re-certification**, 30% of respondents report an increase in time against the initial certification, while 70% observe no change in timing.

IVD and MD: Post-Market Surveillance

The requirements for Post-Market Surveillance have increased significantly from the medical devices directives to IVDR/MDR. The regulations introduced obligations for data collection, evaluation, documentation and reporting to increase patient safety through early identification of potential safety issues and to confirm long-term efficacy of the devices.

Respondents were asked to report the average time needed to update applicable PMS reports under IVDR/MDR per different device class[19]. For both MD and IVD sectors, 70% report needing up to 4 months to update their PMS reports. However, for some respondents (~30%) it may take up to 12 months and, in some cases, 20 months or more.

While there seems to be no prominent difference between different class devices among MD manufacturers, a minority of IVD manufacturers report that updating PMS reports for Class B devices requires more time compared to other IVD classes. For ~13% of IVD manufacturers it takes 20 months or more to update the PMS reports under IVDR as compared to ~8% for class A, ~3% for class C and none for class D devices. A minority of class C manufacturers also indicate taking between 5 to 8 months or more. This may, in part, result from the lack of experience because most class B and C devices are expected to have Notified Body certification for the first time. In contrast, only ~3% of MD respondents report that they need 20 months or more to complete PMS reports for class I and class II devices, and none report 20 months or more for class III devices.

The MD sector's experience with Notified Bodies under (AI)MDD may effectively explain less time needed for PMS reports under MDR as compared to IVD sector. Nonetheless, a minority of MD manufacturers did report needing more than 5 months with some stating they even need up to 12 months or more for development of PMS reports. This indicates that many manufacturers continue to struggle with PMS reporting.

[19] Applicable PMS reports per class:
- For IVD class C & class D devices, and MD class II & class III devices: Periodic Safety Update Report (PSUR)
- For IVD class A & B devices, and MD class I devices: Post-Market Surveillance Report (PMSR)
- All devices: Manufacturer's Trend Report (MTR)
- All devices: Periodic Summary Report (PSR)

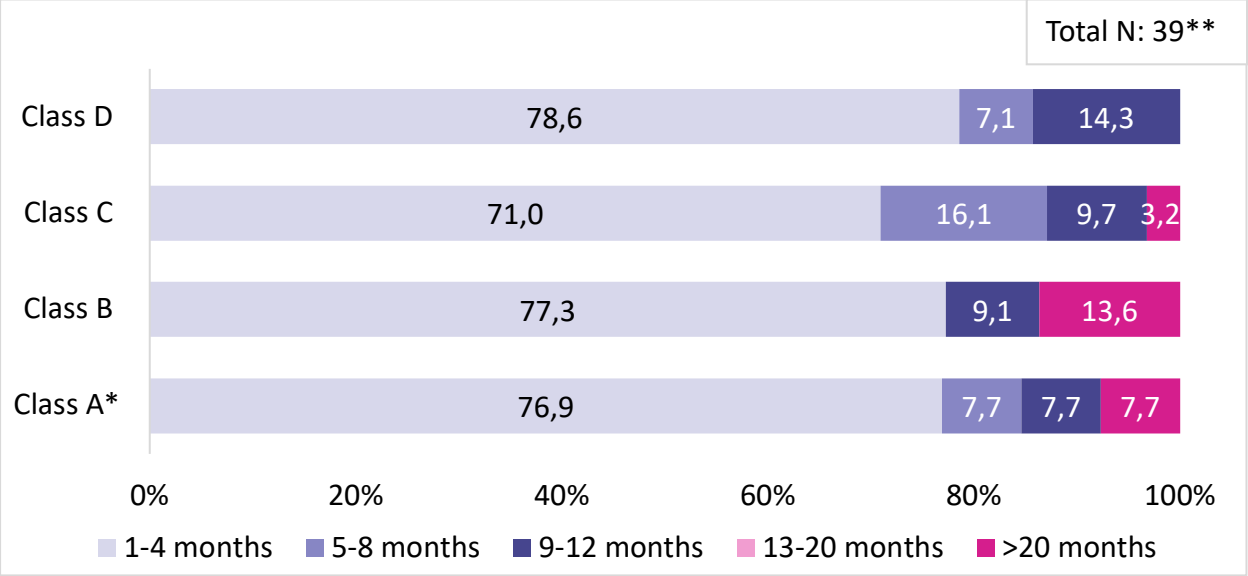

Figure 11: Average time needed to update the Post-Market Surveillance reports under IVDR (% of total per class)

** Data for class A sterile was excluded due to only one response providing data and most responses indicating N/A.*

*** In total, 39 respondents provided data on this question. Number of responses per class differ as some respondents either did not have some of the class devices in their portfolio or could not provide accurate estimates*

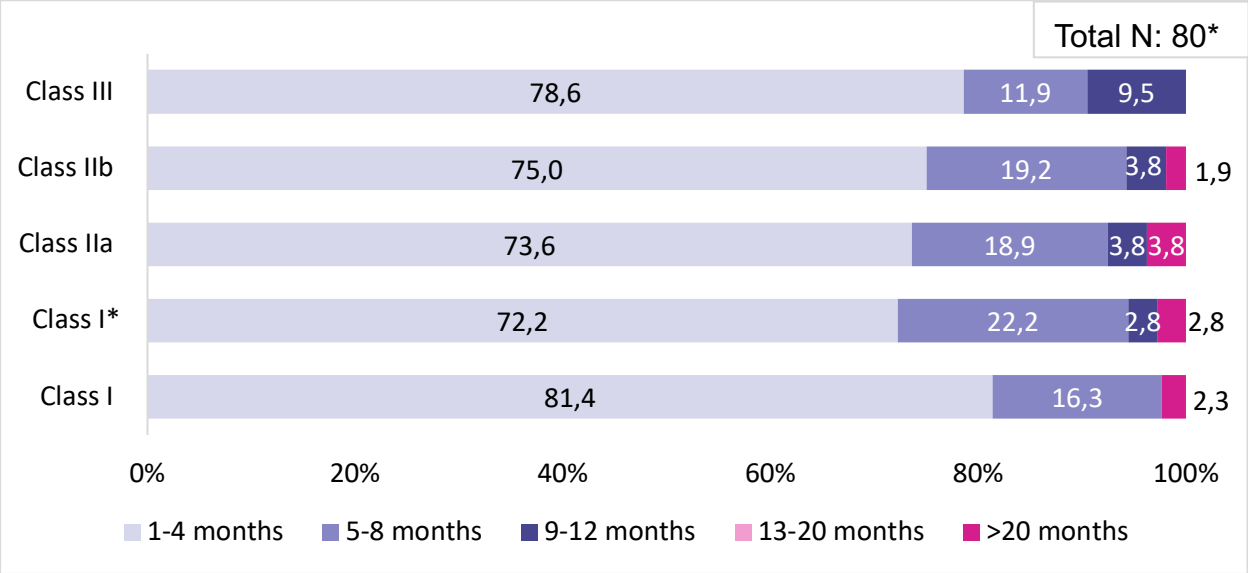

Figure 12: Average time needed to update the Post-Market Surveillance reports under MDR (% of total per class)

** In total, 80 respondents provided data on this question. The number of responses per each class differ because some of the respondents either did not have some of the class devices in their portfolio or couldn't provide accurate estimate.*

Interestingly, it seems that completing PMS reports for lower class devices does not take less time as compared to higher class devices for both IVD and MD

manufacturers, which does not seem to follow a risk-based approach (i.e. time needed for PMS reports would vary by risk class).
There are several factors that could explain this similarity across different classes, for example, the PMSR (reports for lower class devices)[19] often include several devices (grouping of device) which increases the time needed to write these reports.

Overall, manufacturers report that IVDR/MDR post-market surveillance requirements need increased time for completing PMS reports as compared to the medical devices directives (IVDD and (AI)MDD). This is not surprising given more detailed requirements under the regulations and divergent Notified Body 'expectations' that add to the overall lead time. Some of the factors contributing to increased time spent on PMS reports could evidently qualify as an unnecessary administrative burden, such as duplication of information across different reports (e.g. the same basic device information). Repetition of basic information is less valuable than essential content related to product safety and performance, especially for well-established devices with stable PMS data. In addition to increased requirements, manufacturers also seem to be struggling with strict deadlines for data collection which often are difficult to meet and interfere with a proactive and streamlined PMS approach.

IVD and MD: Costs

The IVD and MD sectors are experiencing considerable changes in costs during the transition to the IVDR and MDR. The data of this survey provides a deeper look at and a more granular analysis of overall regulatory costs under IVDR/MDR, including changes in costs under regulations as compared to the medical devices directives, visibility of costs, and certification as well as maintenance costs. Furthermore, this section presents an outlook at IVDR/MDR costs from a product life cycle's perspective which offers a more comprehensive view of the direct and indirect costs needed to place and maintain devices on the EU market.

Changes in costs under the regulations as compared to the directives

Respondents were asked to rate the level of changes in costs for performance/clinical evaluation, PMS, and conformity assessment. For nearly all respondents the costs under the regulations as compared to the medical devices directives are increasing by up to 100% and, in some cases, more.

For IVD manufacturers the spike in costs is most significant for TDA. More than half of all respondents indicate that the costs are increasing by 100% or more. IVDR

QMS certification costs are also greatly impacted with over half of manufacturers reporting an increase of up to 99% or more compared with the IVD Directive. Here it should be considered that an increase in certification costs for the IVD sector could be related to the increased number of devices subject to Notified Body certification under IVDR. The least prominent, albeit still stunning, increase in costs for the IVD sector seems to be for performance evaluation where 94% of respondents report a rise in costs of up to 49% or more (see figure 13).

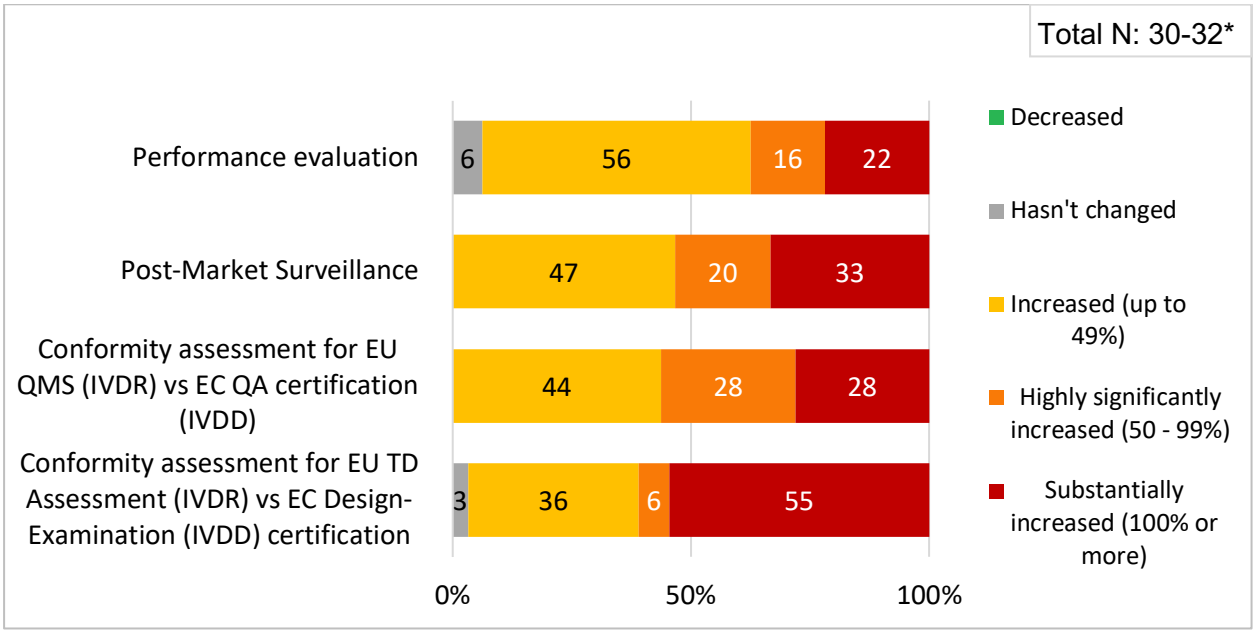

Figure 13: Changes in the IVDR costs as compared to IVDD (% of total per area)

** The number of respondents per each area is between 30-32 respondents of those who were able to answer this question.*

Changes in costs for MD sector are seeing even more drastic increases under MDR as compared to (AI)MDD, with the costs for clinical evaluation experiencing the highest increase of any category surveyed. 70% of MD manufacturers report an outstanding increase in costs of 100% or more for clinical evaluation, followed by a startling spike in PMS costs where roughly half of respondents report that the costs have more than doubled and a third report increases of up to 100%. While certification costs for the MD sector seem to be less impacted than for the IVD sector, the financial impact, especially for TD assessment, for MD manufacturers is very high: for half of respondents, EU TDA costs are doubled or more (see figure 14).

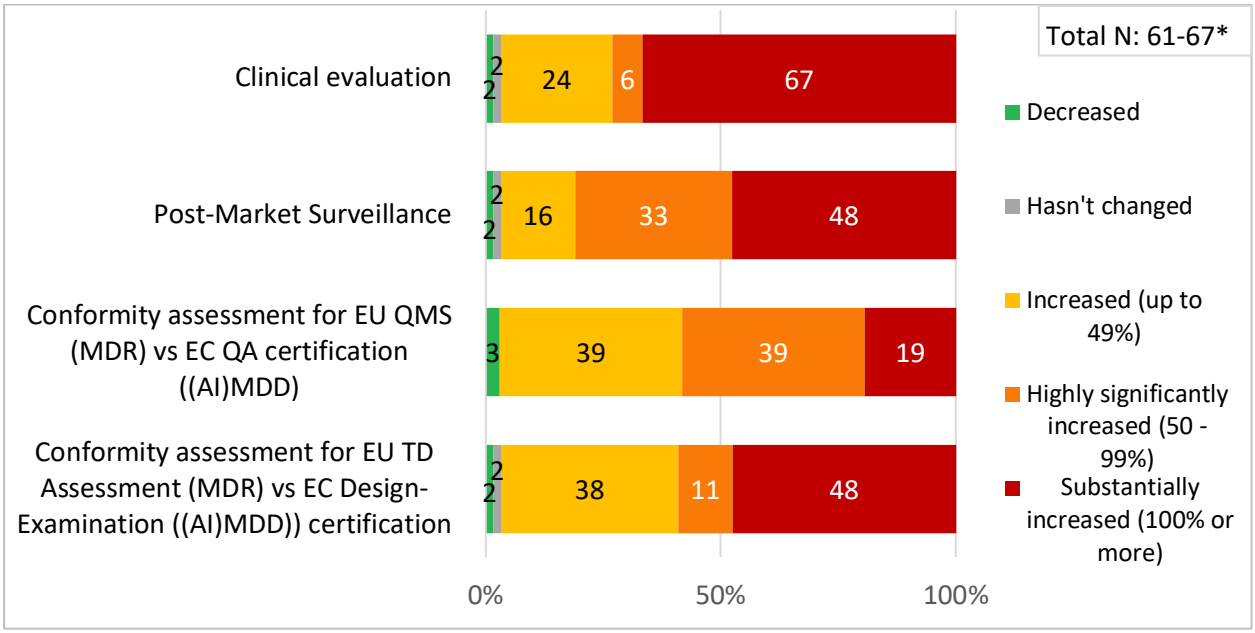

Figure 14: Changes in the MDR costs as compared to MDD/(AI)MDD (% of total per area)
** The number of respondents per each area is between 61-67 respondents of those who were able to answer this question.*

These results of MedTech Europe survey corroborate with the results reported by a Confindustria Dispositivi Medici (CDM) survey, which show that most respondents (40%) are experiencing an increase in certification costs of 75% or more for MD and IVD manufacturers and other economic operators who market their products in Italy[20].

There can be multiple reasons that have impacted such a rise in costs, such as few considerations for legacy devices versus new devices, unpredictable or long time to certification, additional or unclear PMS and clinical/performance evaluation requirements, administrative requirements, etc.

It is interesting to note that while there are more safety and information requirements implemented through the regulation, such as transparency and oversight requirements, the devices themselves have not necessarily changed. Under the regulations as compared to the directives there have been few changes in the general safety and performance requirements ('essential requirements' under the directives) with some notable exceptions, for example for software, certain labelling requirements, and (for MDs) in the area of substances. While the costs have increased significantly across all risk classes, the quality of the products has remained largely the same. Administrative areas which are leading to unnecessary

[20] Confindustria Dispositivi Medici (CDM) Survey Report on the critical issues of the certification process of MD & IVDs (2024) (link)

bureaucracy and not impacting on safety and performance of devices should be identified and addressed.

Cost visibility

Respondents were asked if they have visibility over the costs which they need to spend the following year on certification and maintenance under the regulations. Overall, the findings show that manufacturers perceive their cost visibility as relatively low. This shows a critical need for increasing transparency and predictability in Notified Body fees, to support a sustainable and competitive medical technologies industry which can make informed investment decisions.

Of the 26% of IVD respondents and 27% of MD respondents which do have high cost visibility, these are more likely to be SMEs. While the survey did not investigate reasons for cost visibility, it is possible that some SMEs may have a higher cost visibility due to low complexity in their device portfolios (see figure 15).

Taken together, roughly half of IVD and MD respondents (both large and smaller manufacturers) indicate that they do not have visibility over certification and maintenance costs for the next year.

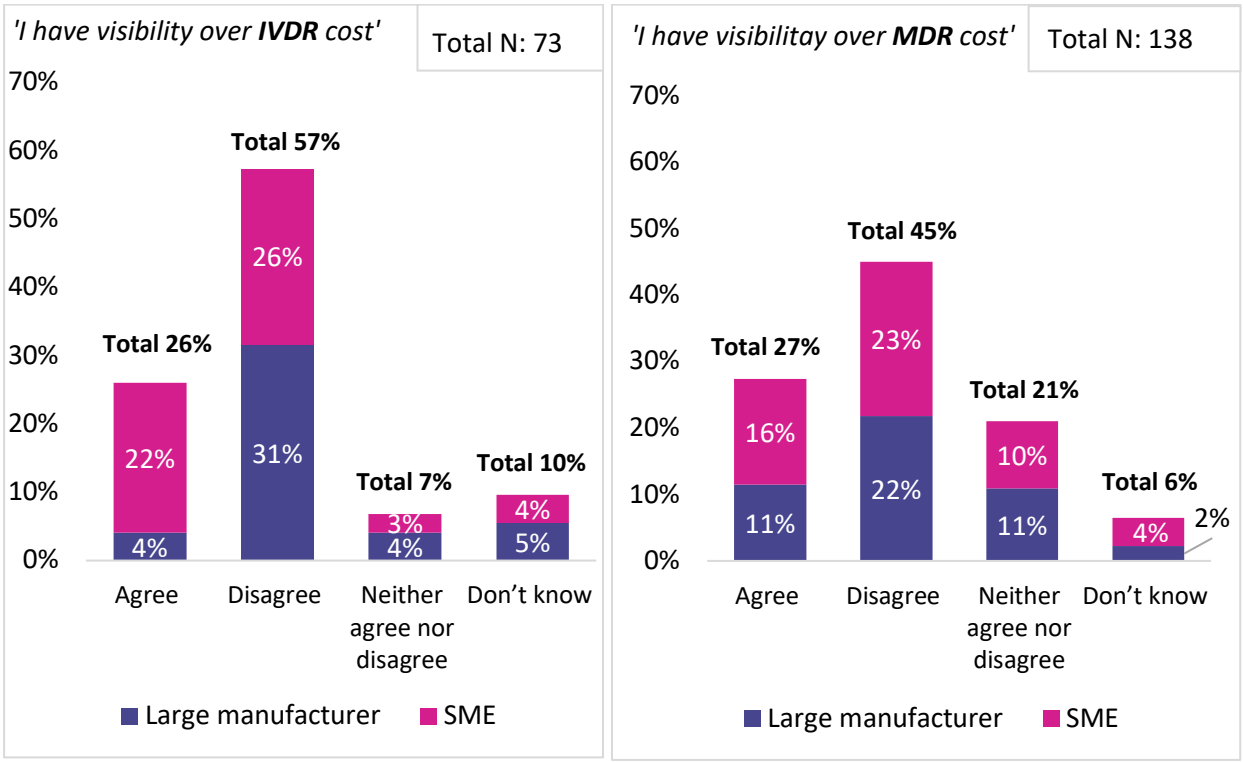

Figure 15: Manufacturers' visibility over certification and maintenance costs for the next year (% of total)

However, there is a clear sectoral difference: more IVD respondents (57%) than MD respondents (45%) report a lack of visibility over the regulatory costs they would need to spend for the next year. Furthermore, 21% of MD manufacturers neither agree nor disagree that they have visibility over costs for next year. While this difference could be related to the major shift of IVD manufacturers to Notified Body assessment for devices that previously did not require certification, the fact that a large minority of MD manufacturers also have low visibility of costs shows that cost uncertainty is not merely related to a lack of experience with the Notified Body system. MD manufacturers have plenty of experience in working with Notified Bodies, yet their visibility over costs under MDR also is relatively low.

There are certainly many reasons that may impact the cost planning of manufacturers for both sectors, the lack of predictability being probably the main one. The current system allows Notified Bodies high flexibility to set up their fee structures. They may change their cost structure not only based on inflation but other internal factors where costs may be passed on to manufacturers. While costs are required to be made publicly available by Notified Bodies with a 'fee per hour', the total costs to be paid for conformity assessment and for maintenance activities remain unclear. Many manufacturers have contracts with a duration shorter than the five-year certification cycle which leads to yearly or bi-yearly budget discussions. Together with the calculation of hourly fees with Notified Bodies, this results in budgeting uncertainties for the manufacturers, even for those which already went through successful certification under IVDR or MDR.

The IVDR and MDR do require transparency and documented details from Notified Bodies about the fees which they charge. While existing MDCG guidance[21] stipulates how standard fees may be set out and published, a revision of such guidance should be considered to provide improved transparency and predictability, for example by asking for Notified Bodies to provide ex post reports of their total costs per device type and per overall process (e.g. entire cost to reach certification, conduct annual surveillance, review Summary Safety & (Clinical) Performance, etc.).

Manufacturers require accurate budget planning internally which is key to external investment and to secure funding in order to maintain devices or bring new devices to the market. Therefore, the regulatory system should provide transparency and predictability on costs to enable manufacturers to place and keep medical devices and IVDs on the EU market.

[21] See MDCG 2023-2 MDR form; MDCG 2023-2 IVDR form

Certification costs

To compile a picture of total certification costs for IVDR and MDR, the survey asked for information on both external costs (Notified Body fees) and internal costs (manufacturer's full-time equivalent (FTE)/personnel costs). The survey asked for the cost for one certificate per type: the analysis provided here therefore is based on actual individual examples provided by respondents. Respondents were asked to provide the total cost for one certificate, the number of devices it covered, the number of manufacturing sites (for EU QMS certificates), the total manufacturer FTE cost and (where available) the cost for recertification of that certificate. Interestingly, in the IVD sector, QMS certification appears costlier than TDA certification, while the opposite holds for the MD sector.

Certification costs depend heavily on a multitude of influencing factors, and they cannot (and should not) be viewed in isolation. Therefore, in this cost analysis we present certification costs by taking into account some of these factors, such as fees paid to the Notified Body, manufacturer FTE costs, the number of devices and sampling parameters.

External/internal certification costs

There is a remarkable difference in external and internal certifications costs between IVD and MD sectors, as well as between QMS and TDA costs. The below breakdowns and explanation of external and internal costs are based on the overall averages taken between the certificate costs provided (per sector, per certificate type). While considering average costs is of interest, variables such as number of devices covered by the QMS certificate should be considered. It also should be noted that there is high variability in the certificate costs provided which are analysed in the section following this one.

External costs (fees paid to Notified Body)

Certification costs paid to Notified Bodies are markedly higher for MD manufacturers than for IVD manufacturers. In addition, it appears that IVD manufacturers are spending more on QMS certification as compared to technical documentation assessment certification, while for the MD manufacturers the technical documentation assessment is more expensive than QMS assessment (see figure 16).

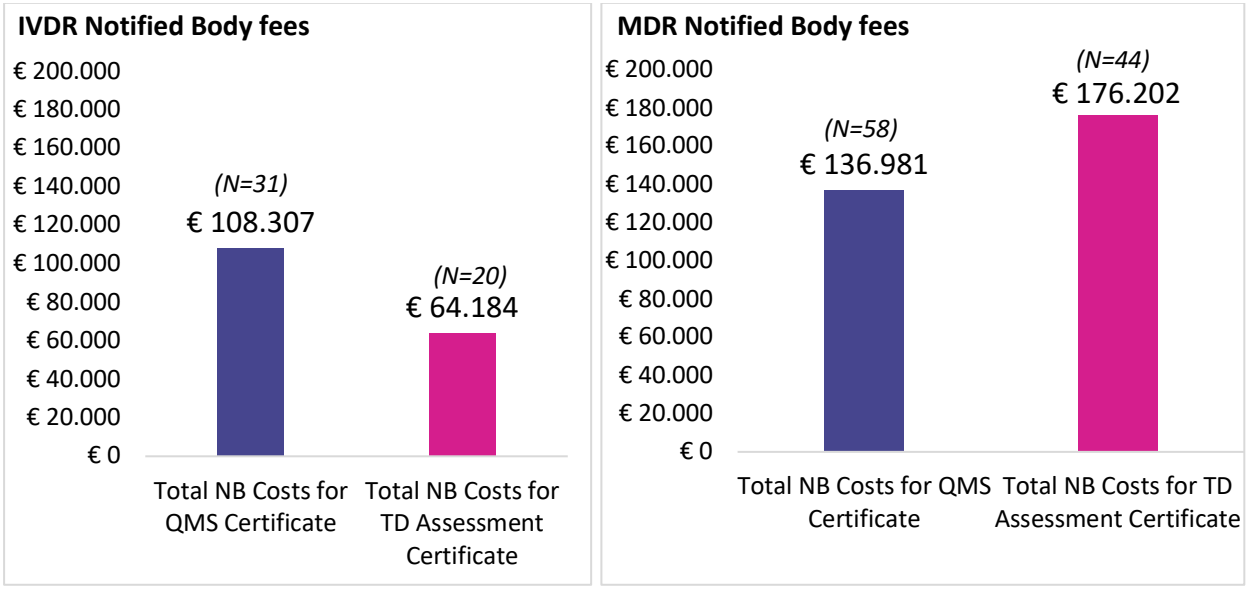

Figure 16: Average costs paid to Notified Body for QMS & TDA Certificate

Internal costs (manufacturer's FTE costs): Similarly for external costs, the internal costs are notably higher for MD manufacturers than for IVD manufacturers. The IVD sector invests more FTE to complete QMS certification, while MD sector invests more FTE on TDA certification. There is a striking difference between QMS and TDA FTE costs spent by manufacturers: for the IVD sector, the QMS assessment is nearly 3 times higher than TDA, while the MD sector on average spends 7 times more on TDA as compared to QMS assessment (see figure 17).

There is a weak positive correlation between the Notified Body fees for certification and the FTE costs manufacturers are investing to complete it. This is to be expected, since one factor driving higher Notified Body fees is more hours spent on certification (most Notified Bodies charge per hour) which in consequence the manufacturer's will need to assign its own FTE to follow.

It is important to note that FTE costs reported as being spent on the completion of certification may overlap with FTE costs spent on other areas (e.g. maintenance activities) therefore this data needs to be interpreted with caution.

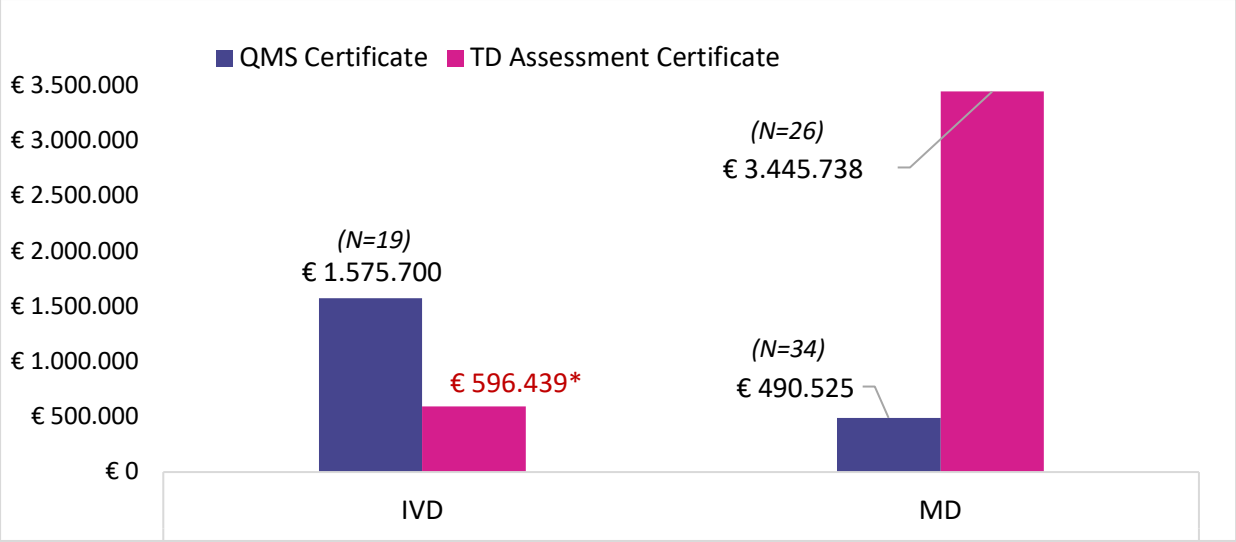

Figure 17: Average manufacturer's FTE (personnel) costs to complete certification
** The total number of responses for total manufacturer's FTE (personnel) cost to complete TD certification under IVDR is less than 15 therefore the data must be interpreted with caution.*

The data showcased above demonstrate that bringing IVDs (especially lower risk class IVDs) under IVDR has become more costly in particular due to higher QMS certification costs. For bringing higher risk class MDs under MDR, costs are driven by high TDA cost.

In addition, there is an apparent difference between IVD and MD sector costs (the latter being significantly higher). Such sectorial difference may be due to multiple factors including the complexity and novelty of the technology at hand, the length of time the review takes and the cost to the Notified Body in hiring the needed reviewers. For example, in the case of certain MD assessments, reviews by several experts, e.g., clinical or biocompatibility experts, might be necessary, thus generating additional costs. Reviews of higher risk MDs might take reviewers longer than they would spend on a class D IVD or near-patient test. It also is possible that employing clinical experts such as orthopaedic or cardiac surgeons to review implantable devices may be more costly for the Notified Body than employing for example, clinical laboratory experts to review IVDs. It may be possible to reduce Notified Body reviewer costs in the IVD sector by reducing the number of scope designation codes applicable for IVDs.

Certification cost variability and influencing factors

There is a substantial variability in Notified Body fees paid to complete IVDR and MDR certification across both sectors. These costs range from > € 50K to < € 100K for a QMS certificate and from > € 50K to < €150K for TD assessment certification.

Overall, the respondents provided the QMS certification costs within a variety of cost ranges which clearly indicates outstanding variability in Notified Body fees required to complete EU QMS certification under current regulations (see figure 18).

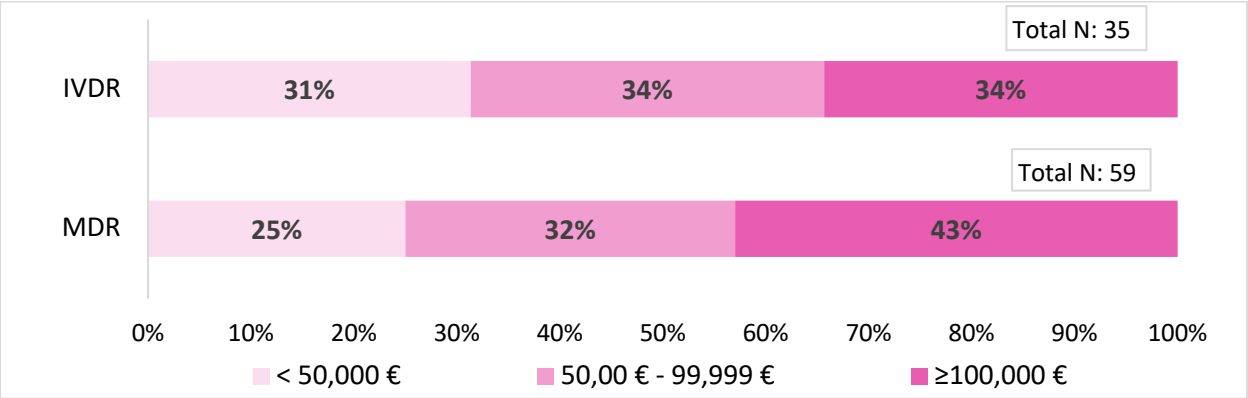

Figure 18 Variation in average QMS certificate costs paid to Notified Body

High certification cost variability also is observed in EU TDA certification costs. Although TD assessment costs also vary profoundly, in 65% of cases, TDA certification costs fall either in the lowest (< €50,000) or the highest (≥ €150,000) cost range. This indicates a slight disparity in Notified Body fees for assessing TDA as compared to QMS assessment and the fees are likely to be either very low or very high[22] (see figure 19).

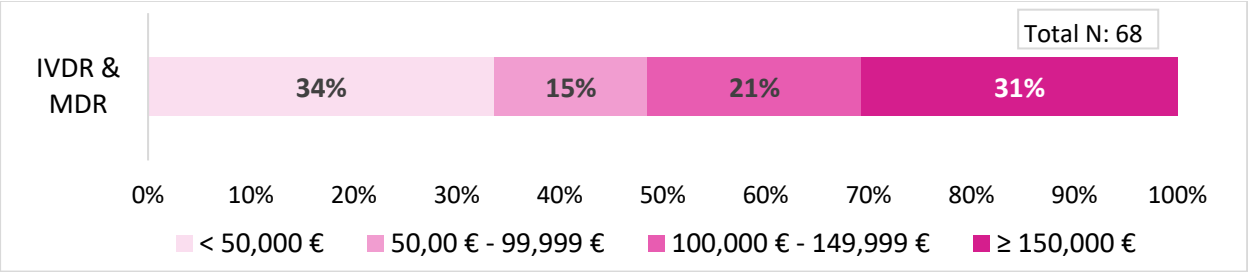

Figure 19: Variation in average TDA certificate costs paid to Notified Body

The above presented variability is not surprising given the many influencing factors that affect these costs. Based on data collected in this survey, the below listed factors are associated, albeit weakly, with the costs manufacturers pay for Notified Bodies for certification and they can at least partially explain the variation in IVDR/MDR certification costs:

[22] Note, IVD and MD sector differentiation for variation in average TD assessment certificate costs could not be included in this report due to low sample size. Therefore, it could be that the disparity in TD assessment certification costs is related to strong difference between IVD and MD sectors, as presented under external/internal certification costs section of this report.

- **The number of devices covered by a certificate**: the more devices a QMS certificate covers – the more costly the Notified Body fees are (weak positive correlation R=0.023) (see figure 20). The same is true for TDA costs (weak positive correlation R=0.046), even though the TDA certificate usually cover less devices than the QMS certificate[23]. It is, however, important to note that the rate of increase in costs is rather slow with the increasing number of devices on a certificate, potentially (in case of QMS certificates) due to sampling of device categories and generic device groups. Thus, the more devices the certificate covers – the cheaper the Notified Body certification fees per device are.

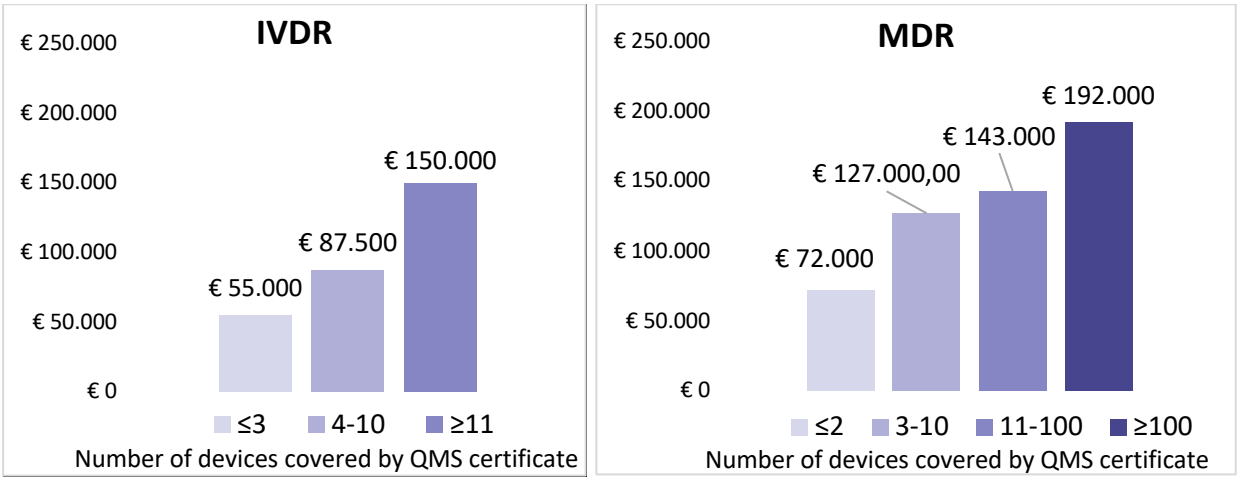

Figure 20: The impact of the number of devices covered by one QMS certificate on the costs paid to Notified Body for the QMS assessment

- **The costs paid to Notified Body for the assessment of one technical file for sampled devices**: costs for sampling one technical file seem to be substantially higher for MD sector (~ € 60K) than for IVD sector (~ € 38K) (see figure 21). The costs for the assessment of one technical file for sampled devices also seem to have an impact on Notified Body certification fees: the higher the sampling cost – the higher the overall Notified Body certification fees for QMS certificate (weak positive correlation R=0.285).

[23] The number of devices covered by technical documentation certificates reported for this survey vary from >3 to ≥30 devices per certificate. Most certificates (37%) had >3 devices covered under TD assessment certificate, 22% covered up to 7 devices, 15% up to 30 devices and 26% - 30 devices or more.

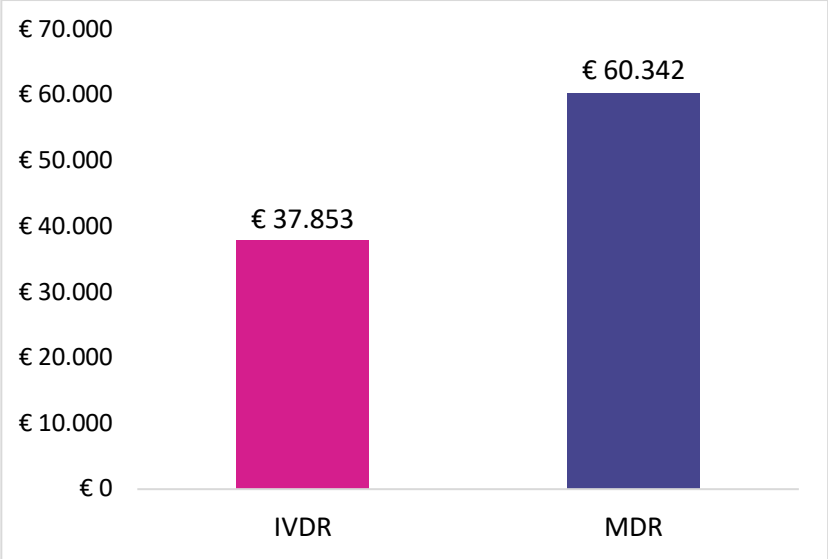

Figure 21: Sampling costs
The average costs paid to Notified Body for the assessment of one technical file for sampled devices

- **The numbers of samples taken for technical file assessments**: On average, the number of samples taken for technical file assessment is higher under IVDR (5.2) as compared to MDR (2.5). This difference could result from the current sampling criteria[24]; also the Notified Body scope designation codes are more extensive for IVDs than for medical devices and the way groupings are done may result in more categories for IVDs. Similarly to previously discussed factors, the number of samples taken for technical file assessments for QMS certificate also have an impact on Notified Body fees: the more samples taken – the higher the overall Notified Body fees for QMS certificate (weak positive correlation R=0.101). This indicates a need to consider reducing the number of scope designation codes applicable for IVDs.

While the above discussed influencing factors clearly have an impact on the variability of Notified Body certification fees and partially explain the significant variations in costs, one would expect that the correlations should be stronger given the level of variability in costs (especially for the numbers of devices covered by a certificate which is weak). It is, therefore, evident that there are other factors not covered by this survey at play which contribute to the variability in QMS and TD assessment certification fees.

[24] MDCG 2019-13 Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation December 2019

Some of other possible areas of influence could be the manufacturer's size, the number of days required for the audit, the number of auditors involved, and different device technologies, their complexity and novelty (for technical documentation certificate costs). Furthermore, cost variability is highly likely to be impacted by the rounds of questions asked by the Notified Body, long certification timelines and the costs of the reviewers to ensure access to the required expertise for the conformity assessment. Finally, individual Notified Bodies may simply have different pricing strategies.

Maintenance costs

'Maintenance costs' can be understood as the costs invested by the manufacturer to remain in compliance with the IVDR or MDR following CE-marking of the device. This is a significant area of investment for the industry: costs for post-market surveillance under IVDR and MDR have increased by at least half (or more) since the medical devices directives, for almost all respondents of this survey. In this section, we look more closely at these increased maintenance costs with the focus on the vigilance fees paid to Notified Body, the costs for yearly surveillance audits and the costs needed for continuous update of required documentation during the lifecycle of the device.

Overall, medical devices and IVDs in higher-risk class categories usually have higher costs of maintaining the technical documentation than those of lower-risk classes which seems to be confirmed by the results of this survey (see figure 22). Although the sample size of the data provided for the IVDs is lower, the costs provided per Class B and Class C devices seem roughly consistent with those provided for medical devices of the different risk classes. These costs include a rough estimate of all regulatory costs following CE-marking, such as post-market surveillance and vigilance costs, annual surveillance costs, audits, and external (Notified Body) costs. Many respondents did not include internal costs (employee costs) because it was too difficult to calculate them. However, some respondents noted that the salary for one employee for maintenance may cost the same or more as the average maintenance costs reported for this survey.

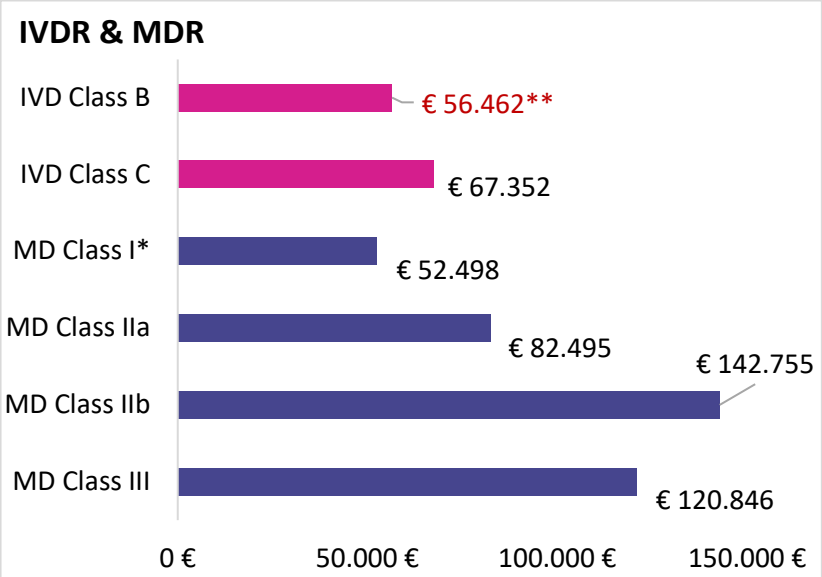

Figure 22: Average yearly IVDR/MDR certification maintenance costs per class (per one device)

** Class I sterile, measuring, reusable*

*** Total number of responses for average yearly costs for Class B devices is less than 15 therefore the data must be interpreted with caution. There were insufficient numbers of responses for Class A and Class D to be aggregated.*

Vigilance costs

On average, manufacturers pay 285 € to the Notified Body per one vigilance case under IVDR & MDR. Most of the respondents (57%) indicated that they pay above 200 € and the costs can reach up to 600 € per vigilance case. However, some respondents confirmed that they have been charged substantially higher than 600 € per one vigilance case (see figure 23).

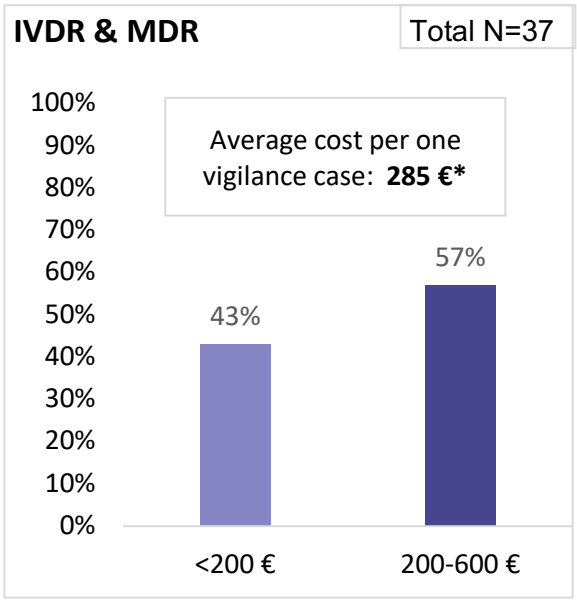

Figure 23: Costs paid to Notified Body per single vigilance case (average cost and cost variation)

**Please, note that some substantial outliers above the highest value in this average (max 600 €) have been removed for data accuracy.*

The yearly costs for vigilance depend on the size of the manufacturer, number of vigilance cases submitted, and the amount charged by Notified Bodies per case. Based on a very conservative estimate, the simulation in the table below shows that yearly costs for vigilance could be as low as 10K € and as high as 600K € per year, based on number of cases per year (see figure 24).

Table 24 Simulation of yearly vigilance costs based on costs paid to Notified Body per single vigilance case for different cost categories

Example yearly vigilance case numbers	Cost category 1: *NB charge 200 € per vig. case*	Cost category 2: *NB charge 600 € per vig. case*
1,000 vigilance cases per year	Total yearly cost **200,000 €**	Total yearly cost **600,000 €**
500 vigilance cases	Total yearly cost **100,000 €**	Total yearly cost **300,000 €**
50 vigilance cases	Total yearly cost **10,000 €**	Total yearly cost **30,000 €**

This is a significant increase in costs given that the manufacturers were not charged for single vigilance case reviews by Notified Bodies under the directives. In fact, under the directives, single vigilance case reviews were solely the responsibility of Competent Authorities, while Notified Bodies would review relevant vigilance data as part of certification process. It is noteworthy that these costs represent a significant and unnecessary administrative burden since the regulations have not established responsibility for vigilance case review for Notified Bodies: this role is held by Competent Authorities. The role of Notified Bodies remains defined in terms of the review of vigilance data which could have an impact on IVDR/MDR certification as part of annual surveillance[25]. Moreover, given that the number of vigilance cases per year are not predictable, these additional costs being paid to Notified Bodies constitute a considerable unforeseeable financial burden, and the manufacturers often need to find extra budget to pay these costs. The roles of Competent Authorities versus Notified Bodies in vigilance case reviews should be clarified to reduce costs, avoid duplication of review and better manage the limited resources of all actors in the regulatory system.

Costs for yearly surveillance audits

The average Notified Body surveillance costs for IVD and MD manufacturers are nearly half the average costs paid to Notified Bodies for initial QMS certification, which on average are 41,396 € for IVDR audits and 52,463 for MDR audits. These numbers are impressive given that the QMS initial certification costs are paid only once while the surveillance costs are paid every year to maintain the obtained

[25] Per IVDR/MDR the Notified Body is responsible for assessing in depth the manufacturer's PMSV system on a regular basis as part of the certification audit process which include the review of vigilance data as per MDR/IVDR Annex VII section 4.10(3): *"to review vigilance data <...> in order to estimate its impact, if any, on the validity of existing certificates."*

certification. These annual surveillance costs after 5 years accumulate to costs that are almost twice as high as fees paid for initial QMS certification (see figure 25).

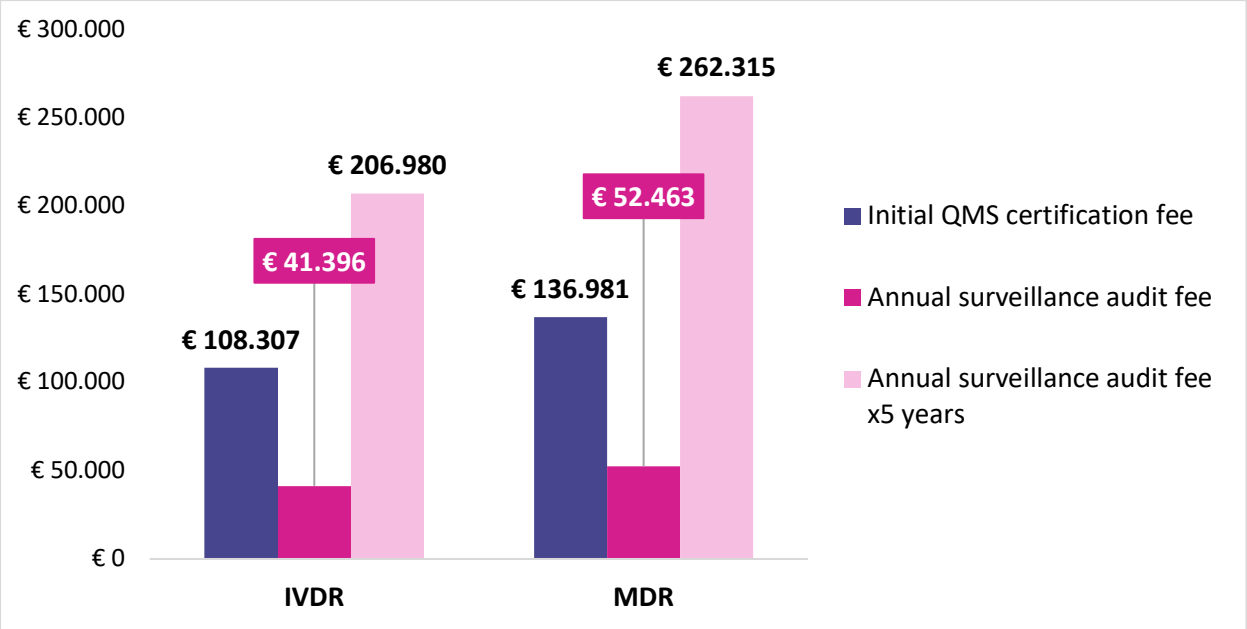

Figure 25: Average annual surveillance audit fees in comparison to initial QMS certification fees paid to Notified Body and average annual surveillance fees accumulated after 5 years (x5)

In addition, it is interesting to note that while the average certification costs for the IVD sector are less than for the MD sector, the annual surveillance audit costs are almost as high as those for the MD sector. This is also true with regards to how the surveillance costs are distributed across different cost ranges: the majority (~ 60%) of IVD and MD manufacturers pay 25K € or more for the annual surveillance audit and the remaining 30-40% less than 25K €.

There could be several explaining factors that at least partially justify the height and variability of annual surveillance costs, such as the size of the manufacturer, the auditing days, number of sites, critical suppliers etc. Nevertheless, in comparison to the initial certification costs, annual surveillance is rather expensive, especially considering the long-term costs which after 5 years surpasses the costs for initial certification.

Documentation maintenance costs

The regular update of several reports – depending on the risk class, mainly the Periodic Safety Update Report (PSUR), Post-Market Performance (Clinical) Follow-Up (PMP(C)F) and Summary of Safety (and Clinical) Performance (SS(C)P) adds significantly to total IVDR and MDR maintenance costs. Together the average maintenance fees paid to the Notified Body for the evaluation of these three

documents mount to ~16K €, with the PSUR evaluation report being the most expensive (6,427 €) (see left graph in figure 26).

Most important, the data from this survey shows that there is a great variation in costs being paid to Notified Body for the evaluation of these documents: the costs range from less than 1,000 € to more than 5,000 € (see right graph in figure 26). This variability shows the lack of alignment of current Notified Body fees and practices for evaluating these reports. Given that these documents are relatively recently established through the regulations, it may be that many Notified Bodies have not yet established their practices as to how these reports need to be evaluated. Similarly, many manufacturers also may still be working on establishing their own experience on the type and extent of information needed in these reports. Lack of alignment and experience may lead to questions or excessively complex documents being developed (and requested) with repetitive information which contributes to the administrative burden both on the side of the Notified Body and the manufacturer.

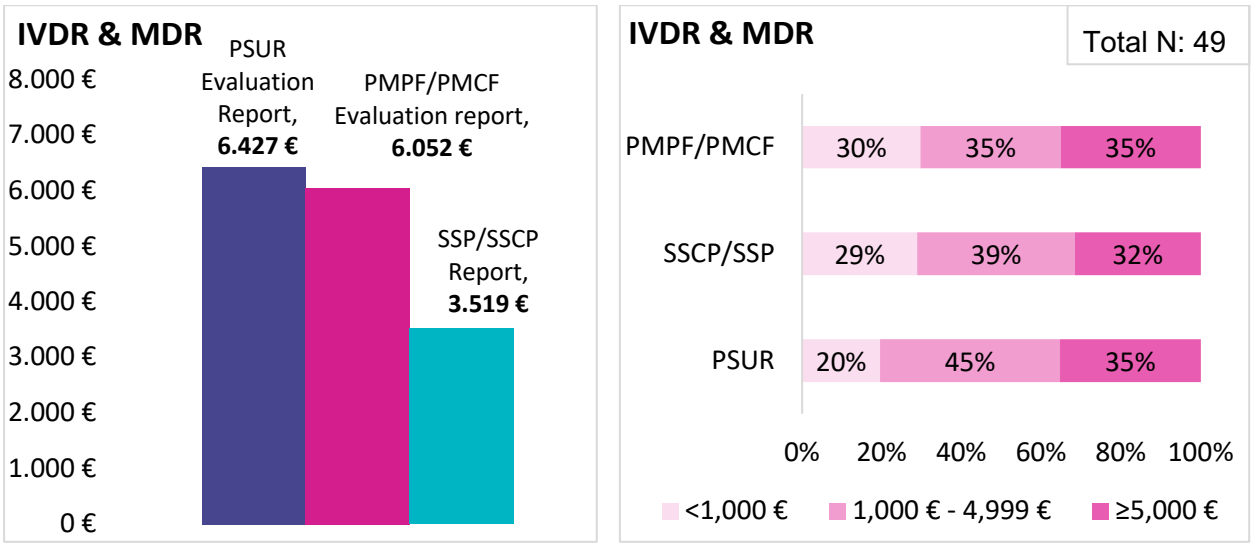

Figure 26: Average costs (left) and variation in costs (right) for PSUR, SSP/SSCP & PMPF/PMCF (evaluation) reports paid to Notified Body (per one report)

Lifecycle costs

While there is a great deal of discussion ongoing with regards to Notified Body fees related to the initial IVDR/MDR certification, the underlying manufacturer's internal and maintenance costs are often overlooked. Yet based on the results of this survey, those place an outstanding additional cost burden on manufacturers which should be considered as part of any policy consideration seeking to reduce the complexity and burden of the IVDR and MDR.

After 5 years of certification, the total regulatory costs (certification, maintenance and re-certification costs together) for IVDR add up to an average of ~2.9mln €. For MDR this total average cost is ~4.8mln €. Of these total amounts, ~6% is spent on Notified Body fees for QMS and TDA certification, ~73-74% spent on manufacturer's FTE costs to complete certification, ~9-11% on maintenance costs (per device) and ~11-10% on re-certification fees. While Notified Body fees for EU QMS and TDA certification have increased by almost 100% under IVDR/MDR, these constitute only 7% compared to the manufacturer's FTE costs required to complete it. An overwhelming 93% of total manufacturer's initial certification costs are spent on personnel required to complete it.

Interestingly, some manufacturers report re-certification fees which are higher than initial certification fees. Re-certification costs after 5-years for QMS assessment were reported to be on average ~ 55% higher and for TD assessment – ~94% higher than the initial certification fee (see figure 27). Please note that the re-certification costs presented in this report need to be treated with caution given the small sample size and high variability in initial certification costs which were used to calculate possible re-certification costs.

Please also note that costs for maintenance were calculated per device, whereas certification costs were calculated per certificate. Given that one certificate may (and usually does) cover more than one device, the total costs to maintain one certificate may be substantially higher than presented below.

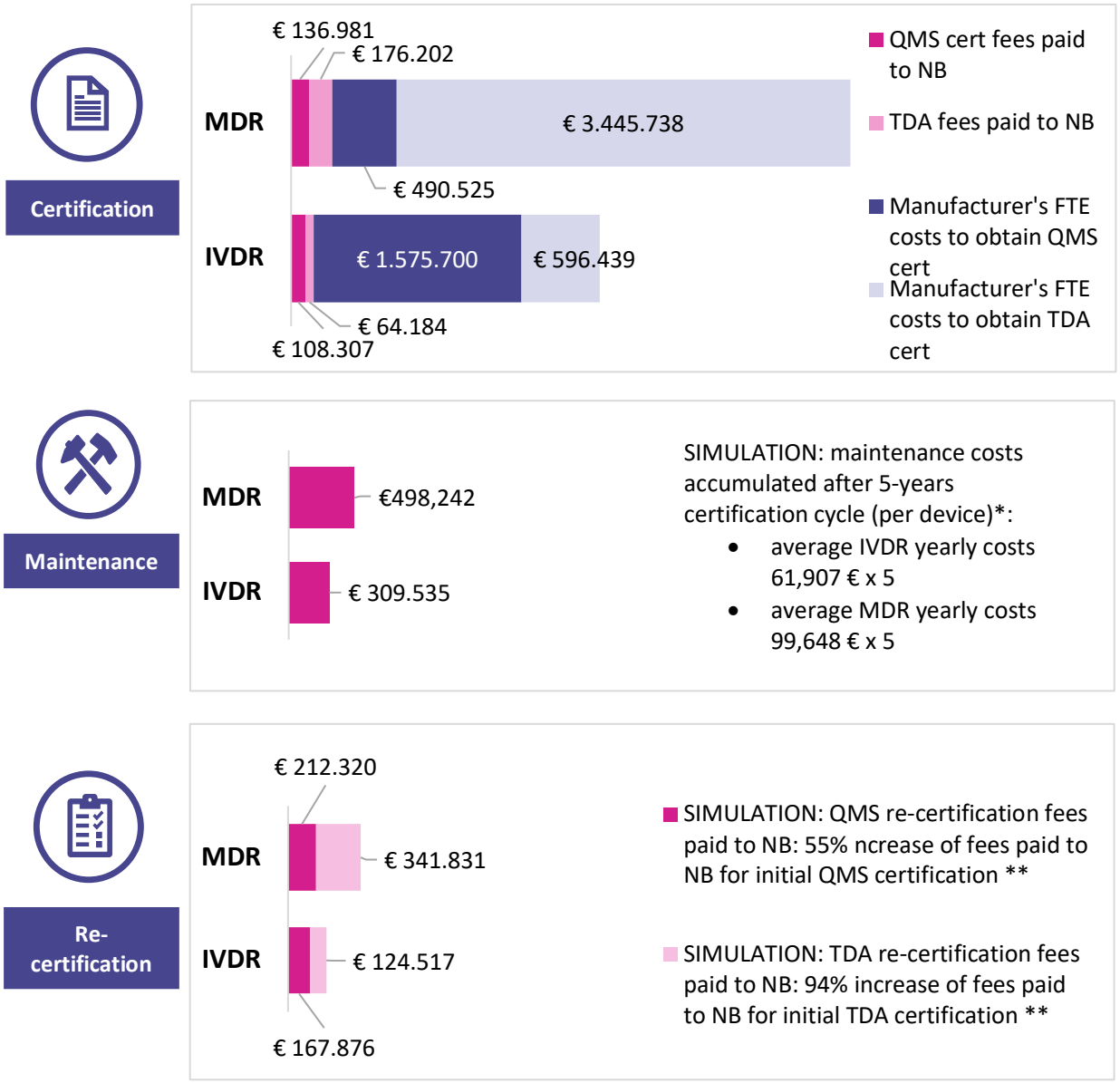

Figure 27: Total regulatory costs to place and maintain medical devices and IVDs on the EU market throughout the device life-cycle

** This data was calculated based on the average of maintenance costs per different class devices. For IVDs, only the average of class B and class C devices are included; the number of responses for class A and class D were insufficient to be aggregated. Note, most IVD & MD respondents excluded internal manufacturer's costs (e.g. employee costs) from maintenance costs because it was too difficult to calculate.*

*** The IVD and MD respondents have reported that on average the QMS re-certification costs for IVDR/MDR have increased 55% and TDA re-certification costs - 94% as compared to initial certification (total N of respondents >15, therefore the data must be treated with caution). The QMS and TDA re-certification costs in this figure were calculated by adding 55% and 94% increase in the average costs reported for initial certification respectively.*

The data of this survey reveals the device life-cycle costs that are often not visible and not accounted for in the total regulatory costs required to place and maintain

medical devices and IVDs on the EU market. The initial certification fees paid to Notified Bodies are high compared to the previous directives, but they are only the 'tip of the iceberg', with manufacturer's internal (FTE), maintenance and re-certification costs adding significantly to the total cost package over the certificate lifetime. It is noteworthy that the higher the Notified Body fees, the higher the manufacturer's internal costs to complete certification which may be related to the long certification timelines and associated administrative burden. Moreover, high maintenance and re-certification costs show that when considering product's revenue in relation to costs, the manufacturers should not only account for regulatory costs needed to obtain certification, but they must also bear in mind the costs needed to maintain that certificate, which are considerable for all devices.

Moreover, besides the Notified Body fees (which are considerable compared with fees paid under the medical devices directives), recurring maintenance and internal personnel costs present a significant burden on manufacturers which should not be overlooked.

IVD and MD: Innovation

Future innovations in medical technologies can help relieve health systems and workforce burden, prevent more effectively, diagnose better and earlier, treat to save more lives, and relieve financial strains on public health and social welfare. Such innovations can appear through optimisation of existing technologies as well as through groundbreaking, breakthrough and disruptive technologies. As such, it is important that Europe has strong investment in R&D, has a robust innovation pipeline and offers an attractive market for medical technologies.

The survey questions for this section, focus on whether the IVDR and MDR have a positive, neutral or negative impact on manufacturers' R&D and innovation activities and on the availability of first-in-class devices for the European market.

The first part of the findings show that the regulations are affecting the location where companies choose to launch innovative products first.

Respondents were asked to indicate their preferred geography for the first regulatory approval of a device, both before and after the IVDR/MDR came into application.

IVD: Preferred geography for initial placing on the market

IVDR – is affecting the choice of the EU as the primary market option for first regulatory approvals in particular for large manufacturers. A shift away from Europe as the first place of choice by 40% and 12% has been observed since the IVDR date of application for large companies and SMEs, respectively.

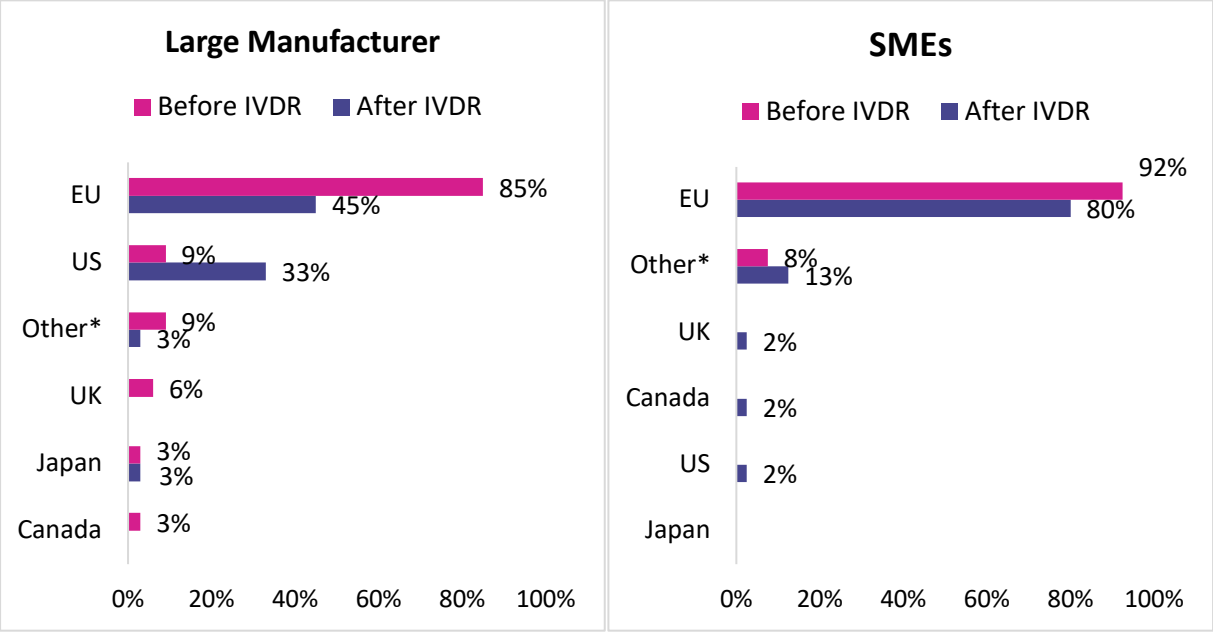

Figure 28: Preferred geographical regions for initial regulatory approval before and after the implementation of IVDR
** Other, e.g., Australia/New Zealand*

For larger companies, the most popular areas of choice include US, UK, Japan and Canada. While a significant shift away from Europe is observed, it should be noted that 45% of large manufacturers maintain Europe as their region of first launch. This is a larger percentage than for MD large manufacturers, only 39% of which now prioritise Europe (see the graphs below). It is unknown if this percentage of IVD large manufacturers will remain stable or decrease as the IVD sector faces the transitional deadlines arriving in 2025, 2026 and 2027.

For those SMEs who are shifting away from Europe, their choice of regions for first regulatory approvals are similar to those of larger manufacturers, but with far less emphasis on the US market. Overall, although there is a small shift away from Europe as region for first regulatory approvals, the majority of SMEs indicate that they will stay in Europe. This may indicate a lack of choice on the part of most SMEs to pick their region of first launch as they may have less ability to commercialise successfully overseas compared to larger manufacturer counterparts.

MD: Preferred geography for initial placing on the market

MDR – Compared to the situation under the MD Directive, EU is now less attractive for the initial regulatory approval for first launches of new products. A decrease of 33% (large companies) and 19% (small companies) for the EU as choice for initial market is reported since the MDR date of application. The effect is most stark when looking at large manufacturers, only 39% of which would prioritise the EU over other markets, whereas 58% of SMEs indicate they consider the EU as the first marketing option.

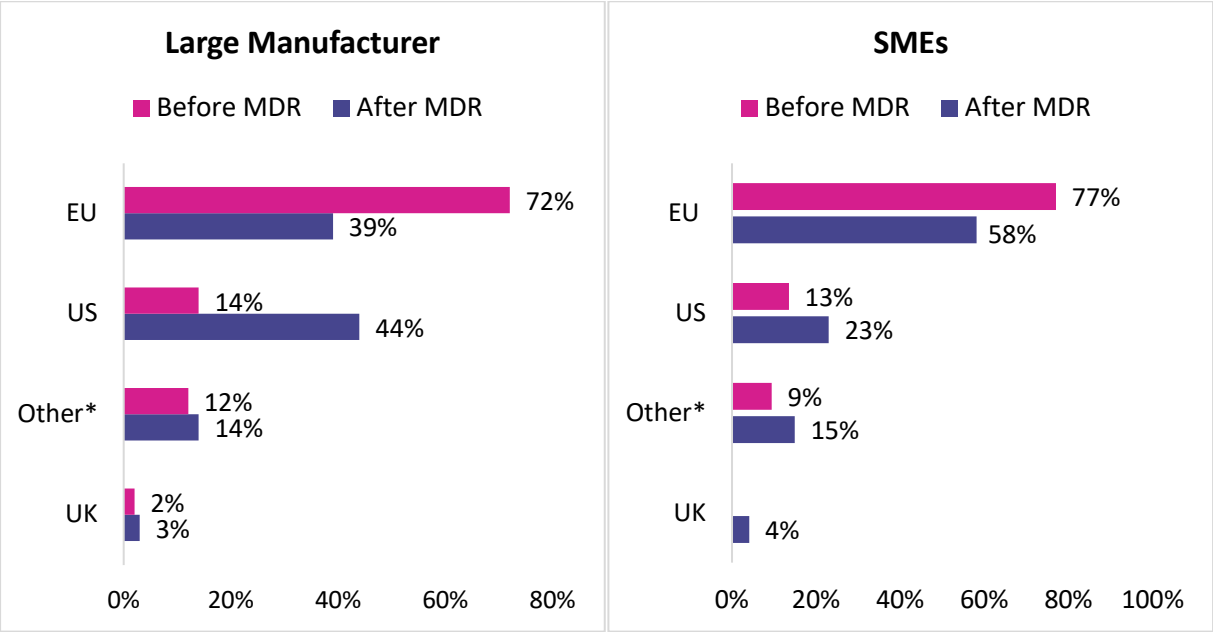

Figure 29: Preferred geographical regions for initial regulatory approval before and after the implementation of MDR.
** Other, e.g., Australia/New Zealand, Canada, China*

There is a significant shift from the EU to the US for large manufacturers whereas other markets see a slight increase in preference. A significant difference can be observed for the MD SME sector when compared with the IVD sector, where 80% of IVD SMEs maintain Europe as their first region for regulatory approvals. Far more MD SMEs than IVD SMEs are penetrating the US market and Asia-Pacific region. Overall, while Europe remains the preferred market for SMEs seeking initial regulatory approval for their devices, it no longer holds this position for larger MD manufacturers, the majority of whom now choose the US.

IVD and MD: Conclusion on preferred geography for initial placing on the market

The observed decline in companies choosing Europe for a first regulatory approval is particularly notable, given that CE-marking currently acts as a complete or partial

passport to over 100 jurisdictions around the world. Some regions such as Switzerland, Brazil, UK and Australia are reviewing their policies in terms of allowing devices with regulatory decisions from other jurisdictions such as the US, to access their markets.

Europe remains the preferred market for IVD/MD SMEs and also for large IVD manufacturers. However, this trend may be changing as there is a noticeable shift toward the US jurisdiction among large MD manufacturers.

Here there surely are many factors arising from IVDR or MDR, which may explain this decline, including:

- The length, cost and unpredictability of conformity assessment, which could act as deterrents for manufacturers and their financers to bring new products to Europe particularly if these elements are seen as significant business risks.
- A lack of clarity around the level of evidence expected at the time that the manufacturer is developing their application for conformity assessment.
- The lack of swift and clear regulatory pathways for CE-marking breakthrough innovations or for specific device types such as orphan, niche and paediatric.

Each of these areas should be addressed for Europe to regain the competitive edge it has lost since the IVDR and MDR. Solutions here include bringing transparency into the total time and cost for conformity assessment, reducing assessment timelines, bringing predictability around clinical evidence expectations through early, structured dialogues and putting in place accelerated regulatory pathways for breakthrough innovations, orphan, niche and paediatric products.

IVD and MD: Impact on Innovation Projects

Next, survey questions investigated the impact of IVDR/MDR on innovation activities being carried out or planned by manufacturers. This includes research and development projects for developing new devices and optimizing existing ones. Respondents were asked to rank the impact of IVDR and MDR on these activities using a scale from 5 (overwhelmingly positive) to -5 (overwhelmingly negative).

IVD: Impact on Innovation Projects

Below, we compare the number of manufacturers reporting decreases to those reporting increases in each area of innovation since the application of the IVDR. (For a detailed graph representing the increases, decreases, and manufacturers reporting no change in activity related to IVDR, see Annex I):

- **Innovation projects to develop new IVD devices** (devices that have never been CE-marked) decreased for 43.75% of large IVD manufacturers and 59% of IVD SMEs.
- **Activities to optimise/improve devices marketed under IVDD** decreased for 37.5% of large companies and 54% of SMEs.
- **Budget for R&D projects** decreased for 24% of large companies and 34% of SMEs.
- **Activities to optimise/improve IVDR devices** decreased for 15.15% of large companies and 22.5% of SMEs.

At the same time, IVD manufacturers reported increases as follows:

- **Innovation projects to develop new devices** increased for 9.40% of large IVD manufacturers and 10.2% of IVD SMEs. In contrast to the decreases mentioned above, only a modest number of manufacturers reported an increase in this area. This is the area where the difference between positive and negative trends is most significant, with the negative trend prevailing. Four to five times more companies reported a decrease in the development of new IVD devices across the industry due to the impact of IVDR.
- **Activities to optimise/improve devices marketed under IVDD** increased for 34.4% of large companies and 23% of SMEs. Among large manufacturers, a similar number of companies reported either an increase or a decrease. However, an astonishing finding is that twice as many SMEs experienced a decrease as those reporting an increase in this type of IVDD modernization activity. This trend indicates that SMEs are particularly struggling to improve and modify existing IVD devices CE-marked under the Directives, preferring not to make changes, which suggests that optimization efforts are being discouraged.
- **Budget for R&D projects** increased for 42% of large companies and 37% of SMEs.
  This suggests that both large companies and SMEs are boosting their investment in R&D activities. The number of manufacturers increasing R&D resources exceeds those reducing investment. However, it's crucial to track the progression of this investment to determine whether it leads to the development of innovative devices or if it is hindered by regulatory obstacles. The key question remains: Does this increased investment result in a greater number of innovative devices entering the market?
- **Activities to optimise/improve IVDR devices** increased for 18.2% of large companies and 10% of SMEs. Here, we observe that challenges are more pronounced for SMEs in the IVD sector. Twice as many SMEs are not

optimizing IVDR devices compared to those who are improving the devices they have CE-marked under IVDR.

MD: Impact on Innovation Projects

Below, we compare the number of manufacturers reporting decreases to those reporting increases in each area of innovation since the application of the MDR. (For a detailed graph representing the increases, decreases, and manufacturers reporting no change in activity related to IVDR, see Annex II):

- **Innovation projects to develop new MD devices** (devices that have never been CE-marked) decreased for 47.6% of large manufacturers and 54.4% of SMEs.
- **Activities to optimise/improve devices marketed under the Medical Devices Directives** decreased for 51% of large companies and 47.2% of SMEs.
- **Budget for R&D projects** decreased for 18% of large companies and 33% among SMEs.
- **Activities to optimise/improve MDR devices** decreased for 31.7% of large companies and 25% of SMEs.

At the same time, MD manufacturers reported increases as follows:

- **Innovation projects to develop new devices** increased for 19% of large manufacturers and 13% of SMEs. In contrast to the decrease mentioned above, only a modest number of manufacturers reported an increase in this area. This negative trend is very similar to the IVD sector.
- **Activities to optimise/improve devices marketed under the Medical Devices Directives** increased for 20% of large companies and 18% of SMEs.
- **Budget for R&D projects** increased for 39% of large companies and 41% among SMEs.
  Despite declines in certain innovation activities, a notable proportion of MD manufacturers reported increases in R&D spending. This indicates that, although innovation activities have been impacted, manufacturers are still investing in R&D. Similarly to the IVD sector, the key question remains whether these investments are translating into tangible benefits, particularly in terms of new devices available on the European market.
- **Activities to optimise/improve MDR devices** increased for 14.2% of large companies and 11.11% of SMEs. The number of large MD manufacturers making changes to devices CE-marked under MDR is half the number of those not making changes. This negative trend mirrors observations in the IVD sector. Overall, there is limited willingness to modify devices already

placed on the market under MDR, indicating a reluctance to make adjustments due to the burdensome regulatory process required for such changes.

SMEs are facing particularly severe challenges for innovation activities under MDR, with more SMEs reporting decreases across all categories compared to their larger counterparts. While some SMEs have increased their R&D budgets, these positive changes are not enough to offset the broader negative trend.

IVD and MD: Conclusion Impact on Innovation Projects

- **Overall negative impact on innovation**: Both IVD and MD manufacturers have experienced a notable decline in innovation activities since the introduction of IVDR and MDR. A significant number of manufacturers in both sectors reported decreases in key innovation areas such as new device development, optimisation of existing devices, and activities to improve devices marketed under the Directives. The negative trends are particularly prominent in new device development, with a higher proportion of manufacturers reporting declines than those reporting increases.
- **Challenges for SMEs**: SMEs in both sectors are facing greater difficulties than larger manufacturers. In the IVD sector, twice as many SMEs report decreases in optimising IVDR devices compared to larger companies. In the MD sector, SMEs report greater declines in key innovation activities, highlighting the heavier regulatory burden on smaller companies.
- **R&D investment increase**: Despite declines in innovation, both IVD and MD manufacturers increase their R&D spending, signalling ongoing investment in future device development. However, it remains uncertain whether these investments will lead to actual market innovations or if they are hindered by regulatory barriers.
- **Reluctance to modify existing devices under the Regulations**: Both sectors show reluctance to modify CE-marked devices already placed on the market under IVDR and MDR. While R&D investments are increasing, they are not necessarily leading to immediate innovation. The slow pace of device development and reluctance to modify existing devices raise concerns about the long-term availability of innovative devices on the European market. This suggests that investment is being diverted away from innovation and device improvement to regulatory tasks.
- **Impact of compliance costs**: A large part of the innovation impact may be attributed to the significant cost and resources manufacturers invest in supporting IVDR and MDR compliance. This may explain the decline in

optimisation activities for legacy devices, as such devices can only benefit from extended transition periods if they undergo no significant changes. While R&D budgets may have increased, resources may have been redirected towards transitioning legacy devices, shifting investment away from innovation towards administrative and compliance tasks.

Conclusion

The survey results indicate a shift in the challenges faced by manufacturers transitioning to the IVDR and MDR, compared to surveys conducted by MedTech Europe in 2022. While finding a Notified Body is no longer a primary concern, it is now clear that areas such as costs, timelines, and predictability deserve attention and regulatory system improvement. Manufacturers report significant uncertainty regarding the timelines and costs associated with obtaining and maintaining IVDR/MDR certificates, contributing to a growing sense of unpredictability and deprioritisation of the European market especially for first-launch devices. It is clear that these areas need to be tackled to ensure a sustainable system for medical technologies.

Remarkably, the Notified Body spends over 50% of the total conformity assessment time for procedures outside the review phase, namely during pre-review phase and for issuance of the certificate. Optimising the pre-submission phase alone could reduce the total time for conformity assessment by over 30%. The pre- and post-review phases can be considered mainly administrative and should be made more efficient and predictable.

The cost burden for IVD and MD manufacturers is significantly increased under the regulations compared to the directives. Clinical evaluation or performance evaluation, Post-Market Surveillance (PMS), and certification costs, all have risen substantially while national reimbursement for medical technologies have not. For over half of IVD manufacturers, costs associated with TDA have doubled, while clinical evaluation costs similarly have increased for MD manufacturers. Furthermore, significant variability in these costs exists, likely due to differing practices across Notified Bodies. This variability, in turn, impacts the overall cost structure for manufacturers. The issues are particularly accentuated for SMEs and again for orphan devices (although any type device could be impacted by the cost and timelines complexity).

Perhaps most concerning is the additional burden of internal costs, maintenance, and re-certification. These costs, accumulated over the course of a device's life cycle, outweigh the initial certification fees. By the end of the five-year certification cycle, IVD manufacturers are likely to spend approximately 70% more, while MD manufacturers will spend 50% more on maintenance and re-certification, not including full-time equivalent (FTE) costs. This financial burden, exacerbated by inefficiencies and administrative complexity, places undue strain on manufacturers without clear patient benefit. Furthermore, the financial and regulatory burden extends beyond Europe, potentially affecting global markets that rely on European certification.

Overall, significant challenges remain and should be tackled in the areas of predictability, transparency, costs, and innovation, amongst others. Should these

challenges be addressed, this would significantly increase Europe's attractiveness and support the competitiveness of the medical technologies sector which delivers the medical devices and diagnostics that underpin our healthcare systems in Europe and also globally.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
www.medtecheurope.org.

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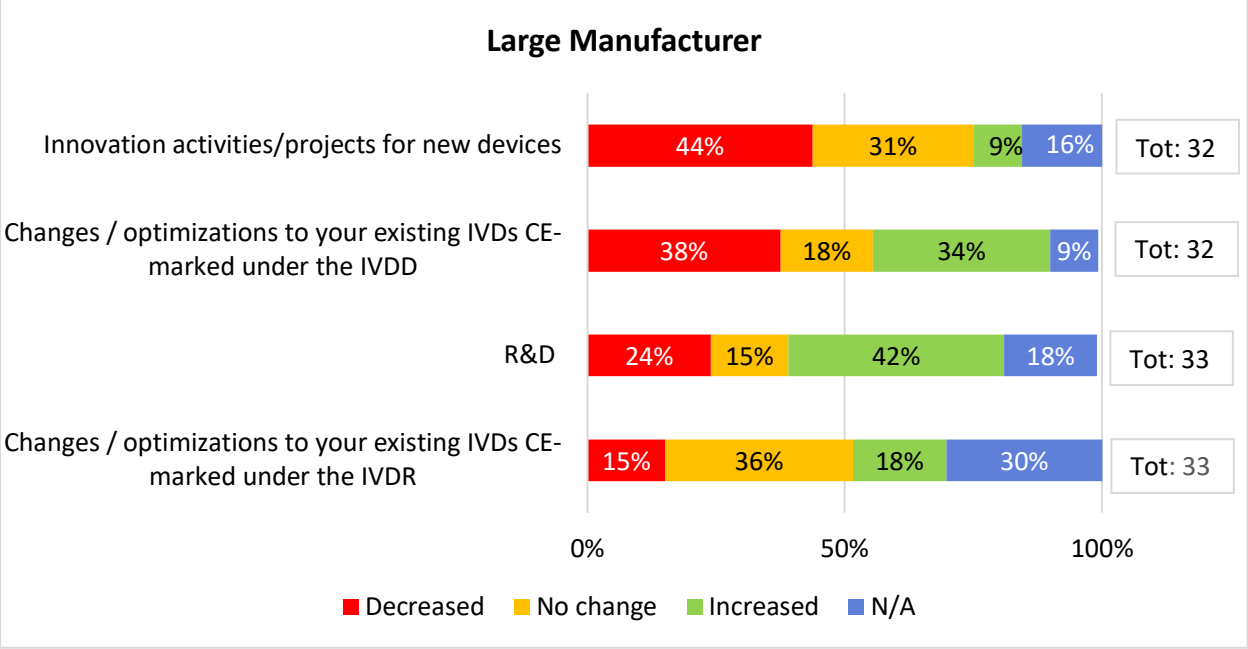
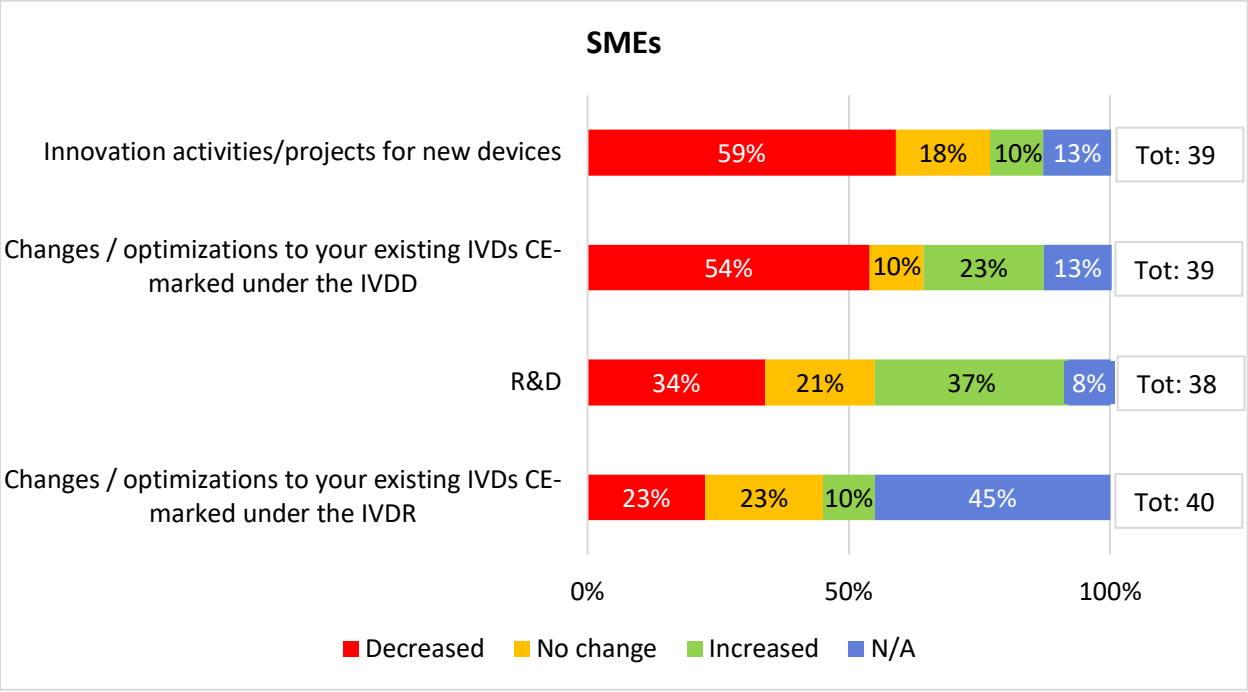
Annex I – Innovation IVD

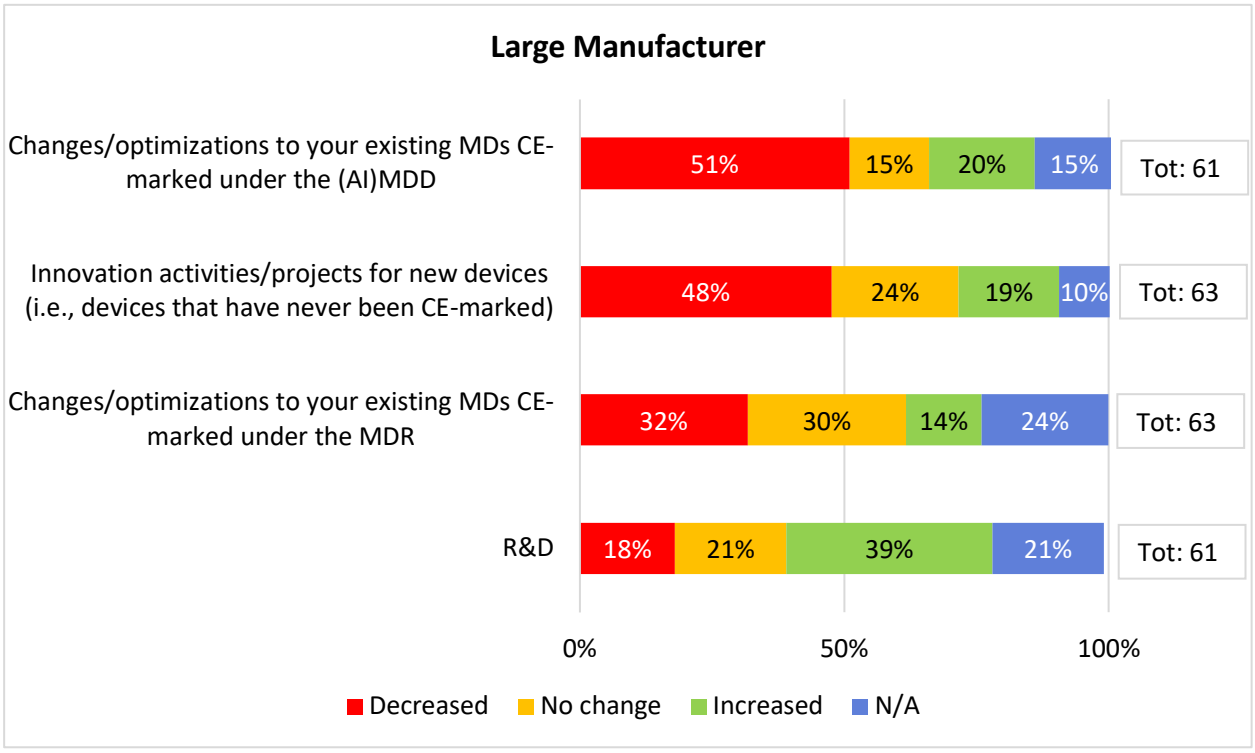
The impact of IVDR on innovation areas

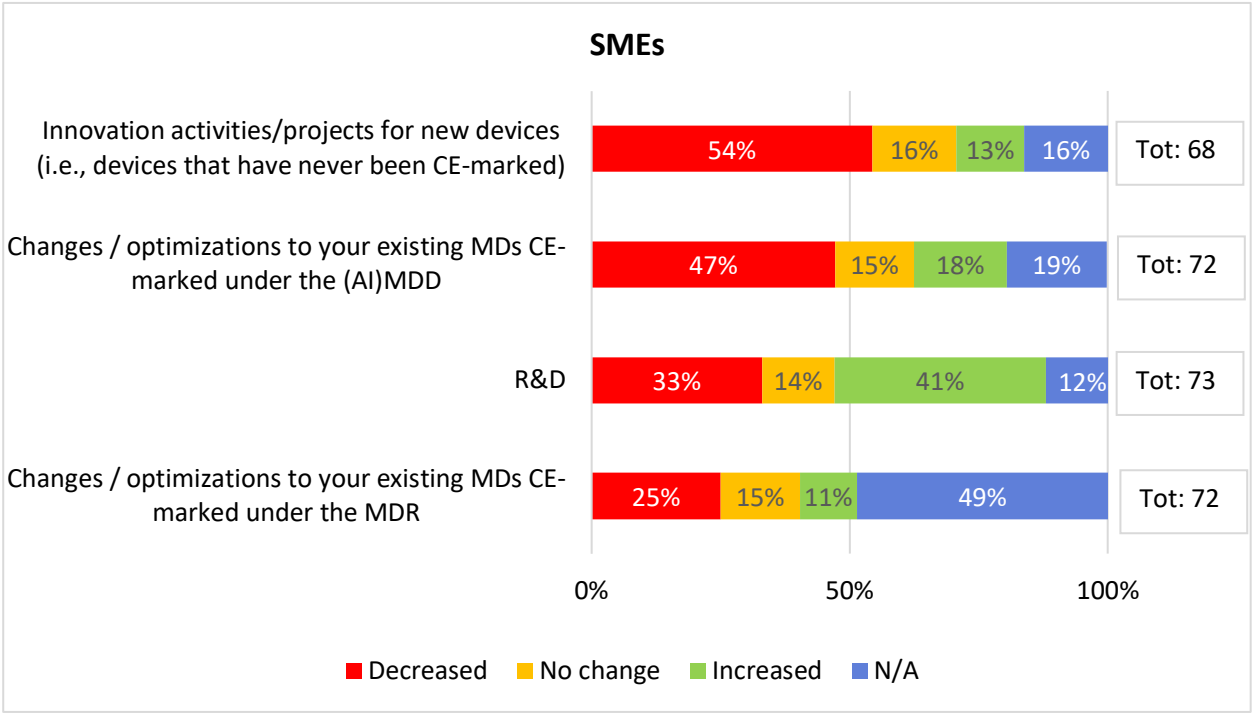




Annex II – Innovation MD

The impact of MDR on innovation areas



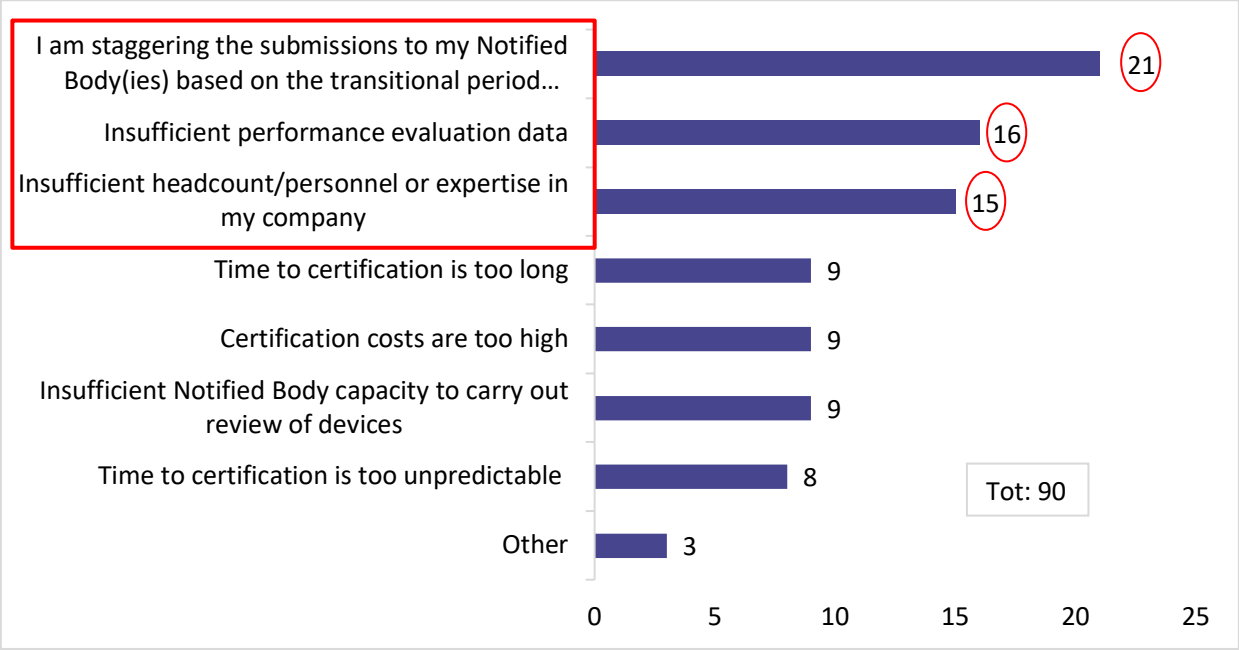


Annex III – Transition to IVDR

Progress of manufacturers towards IVDR certification

Out of a total of 39 respondents that already have an agreement with a Notified Body under IVDR: *What percentage of IVDs have already received an IVDR certificate?*	
< 10%	33,3% of respondents
Between 10% and 50%	23,1% of respondents
> 50%	43,6% of respondents

What prevents MNFs from starting conformity assessment for other devices?

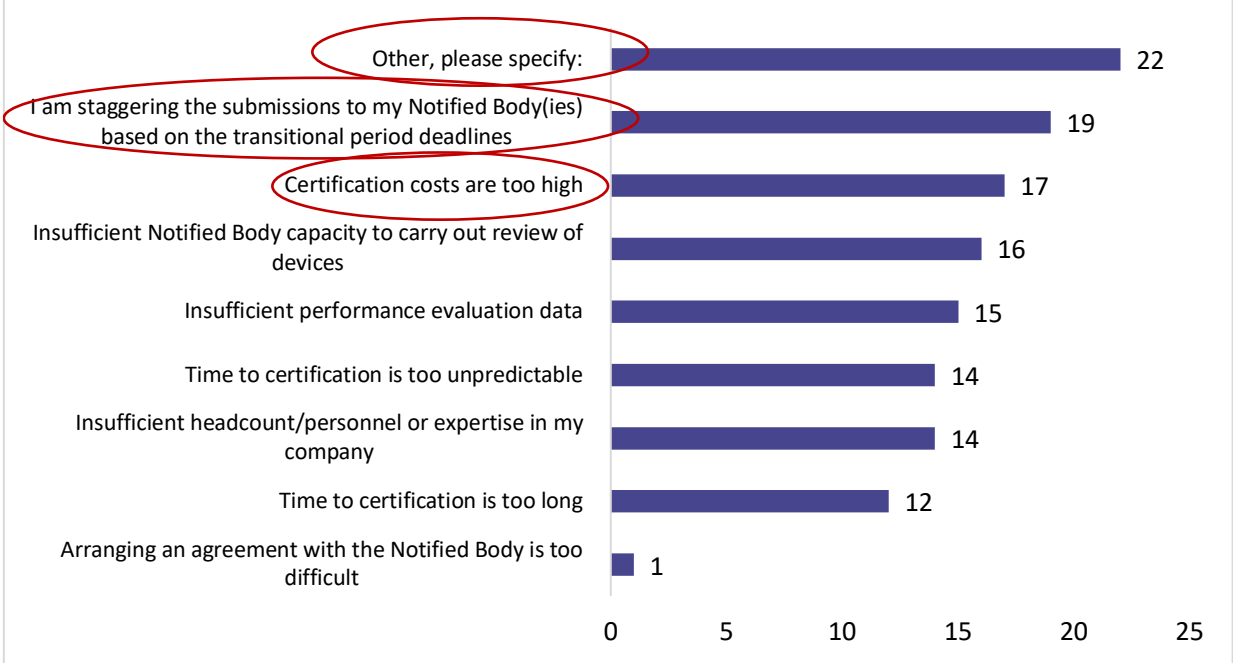


Annex IV – Transition to MDR

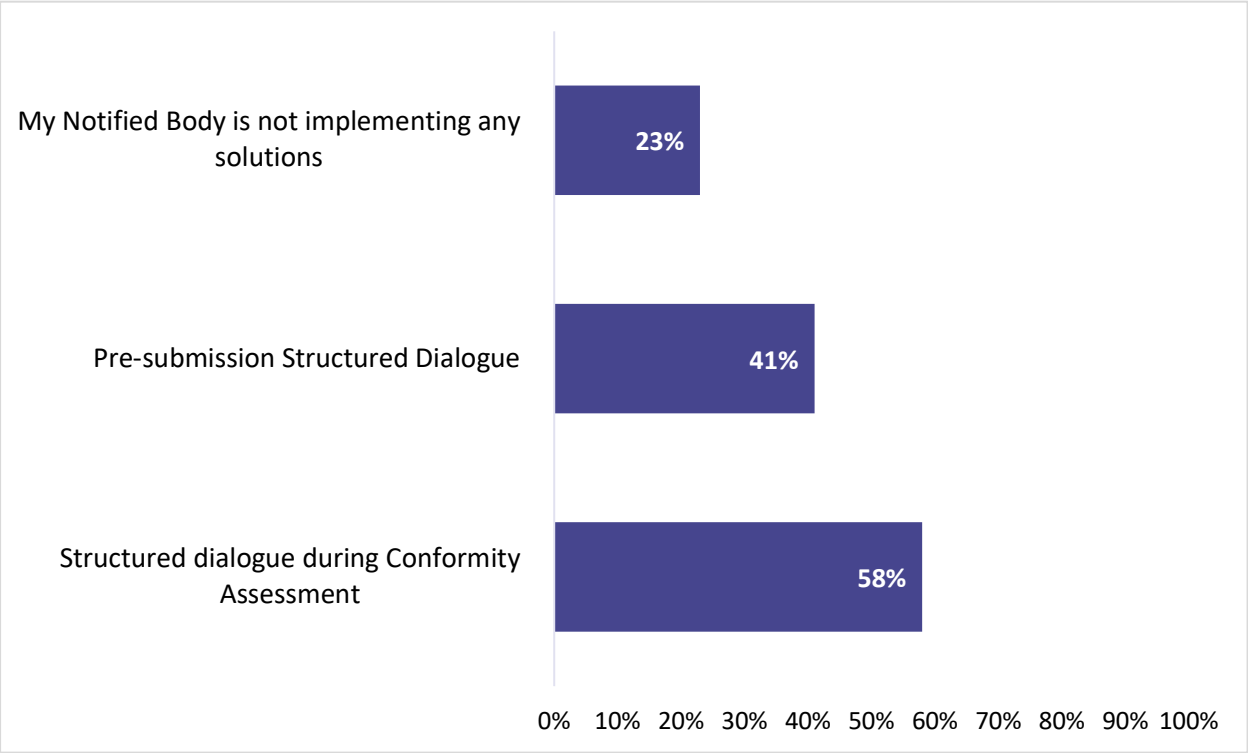
Progress of manufacturers towards IVDR certification

Out of a total of 80 manufacturers that already have an agreement with a Notified Body under MDR and an MDR QMS: *What percentage of MDs have already received an MDR certificate?*	
< 10%	6% of respondents
Between 10% and 50%	43% of respondents
> 50%	51% of respondents

What prevents MNFs from starting conformity assessment for other devices that do not yet have MDR certification?



What solutions does your Notified Body implement to help MDR transition?

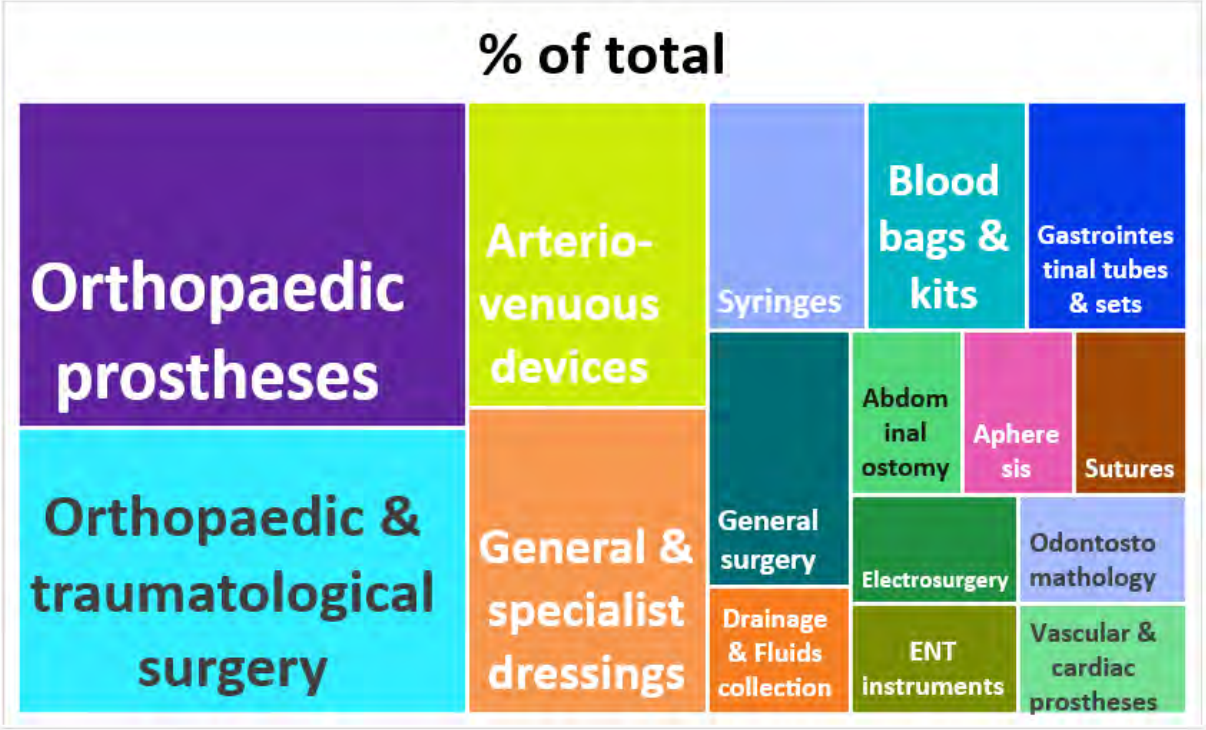


TOP answers:

1. *Structured dialogue during Conformity Assessment (*chosen 47x*)*
2. *Pre-submission Structured Dialogue (*chosen 33x)
3. *My Notified Body is not implementing any solutions* (chosen 19x*)*

- multiple-choice question (graph **does not add to 100%)**
- 'Leveraging evidence as per MDCG 2022-14' and 'Certificates under conditions' scored low (chosen 16x and 10x respectively), indicating that these solutions are less seldom employed.

Examples of orphan MDs which will be discontinued mainly due to the cost/burden of MDR (% of total)



[i] 2022: Regulation (EU) 2022/112[i] of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and the deferred application of conditions for in-house devices (Text with EEA relevance)
Introduced a staggered extension of the IVDR transition periods for all IVD classes and deferred the application of conditions for in-house devices. Additionally, certain legacy devices already on the market were permitted to remain available under conditions and if they met safety standards, even if not yet certified under IVDR. These changes were introduced to address the shortage of Notified Bodies and to give manufacturers more time to transition to the new, stricter IVDR requirements.

2023: REGULATION (EU) 2023/607[i] OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices
Similarly, this Regulation extended the original MDR compliance deadlines for medical devices under MDD (Directive 93/42/EEC) or AIMDD (Directive 90/385/EEC). Devices with certificates expiring before the new deadlines now have more time to meet MDR requirements. The transitional period for Class III and Class IIb devices has been extended to December 31, 2027, and for Class IIa and Class I devices that require the involvement of a Notified Body to December 31, 2028.

2024: Regulation (EU) 2024/1860[i] of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices (Text with EEA relevance)
This Regulation has further extended the transition period for IVDs until 31 December 2027 (for class D devices), 31 December 2028 (for Class C) and 31 December 2029 (for Class B and A sterile).

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