MedTech Europe
from diagnosis to cure

MedTech Europe IVDR & MDR Survey Results 2024

Report Highlights

01/2025

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Executive Summary

Since the last MedTech Europe surveys conducted in 2022[1,2], three amending regulations have been published, providing extended time under conditions for devices to transition to either *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) and Medical Devices Regulation (EU) 2017/745 (MDR). These measures have helped sustain device availability on the market by enabling a phased transition, yet manufacturers of IVDs and MDs continue to face challenges around the predictability, transparency and high cost of the CE-marking system for their devices.

The regulatory burden and cost on manufacturers has grown under IVDR and MDR compared to the medical devices directives[3]. Unclear clinical evidence 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 and including documentation requirements, streamlining the time and costs 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 pathways and policies into the regulatory system also are needed.

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

Respondents & Methodology

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

- 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).

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.

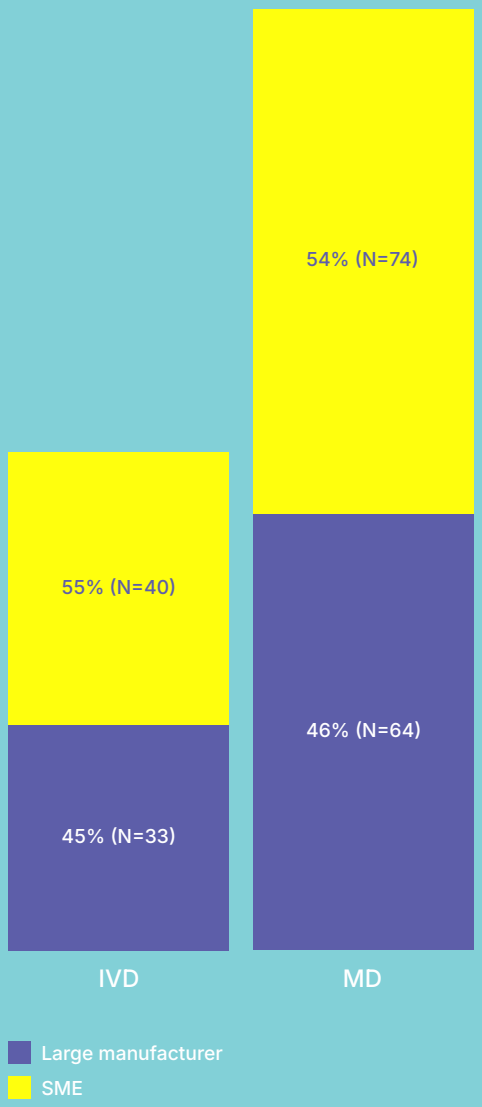
Where appropriate, this survey report compares the results with recent findings of European Commission surveys run by GÖG (Gesundheit Österreich GmbH).[5,6]

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

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

Survey Respondents per company size



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.

The majority of 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. The typical respondent, therefore, already has a Notified Body agreement as well as devices certification under either IVDR or MDR.

7) MedTech Europe Facts & Figures 2024: https://www.medtecheurope.org/wp-content/uploads/2024/07/med-tech-europe--facts-figures-2024.pdf

Key Findings

Certification 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.

Certification challenges (Regulatory Complexity)

- Top answers to *What would help you most to transition to MDR?* indicate the need for:

  1)'Aligned and clear requirements from within the NB and among NBs',

  2)'Predictability of timelines'

  3) 'Structured dialogue'

- Structured dialogue pre-submission as well as during conformity assessment is further highlighted as top tool to help MDR transition

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.

Costs

The financial burden on manufacturers has increased under the IVDR and MDR regulations, with substantial rises in clinical evaluation, Post-Market Surveillance (PMS), and certification costs. Of the total manufacturers' costs for obtaining and maintaining certification related to either IVDR or MDR for the first year:

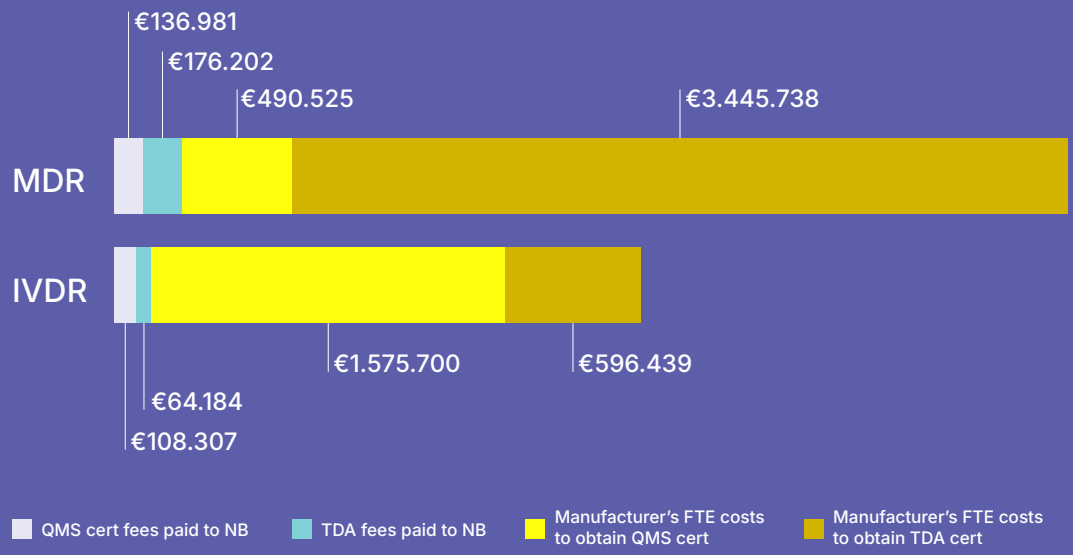
90% is spent on personnel costs to complete QMS and TD processes and documentation

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. Maintenance and re-certification costs are expected to exceed initial certification fees, with IVD manufacturers likely to spend 70% more and MD manufacturers 50% more over the five-year certification cycle.

Certification



Note: the overall average (3.4mil) is heavily influenced by the variation and outliers in the data. Outlier values have not been adjusted for. Interpret this datapoint with caution due to the sample size (n=26).

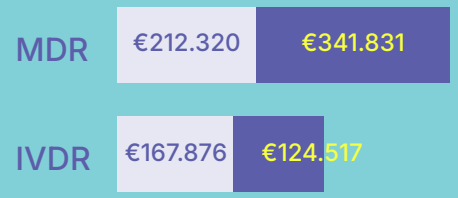
For more detailed information (e.g. sample size) please see section on IVD and MD Costs in the full survey report.

Maintenance

SIMULATION: maintenance costs accumulated after 5-years certification cycle (per device):

- average IVDR yearly costs 61,907 € x 5
- average MDR yearly costs 99,648 € x 5

Re-certification

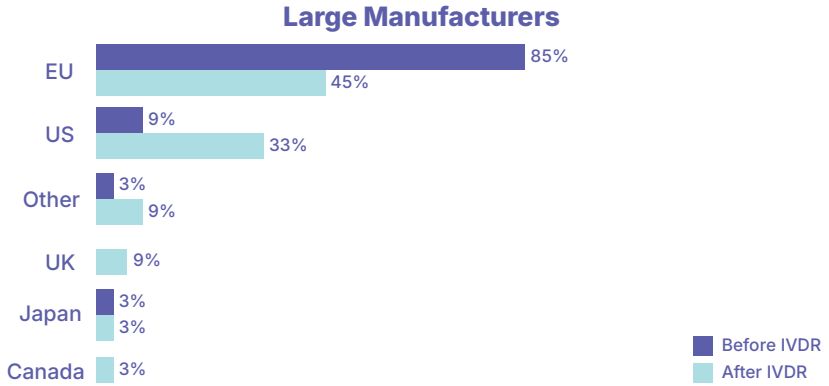


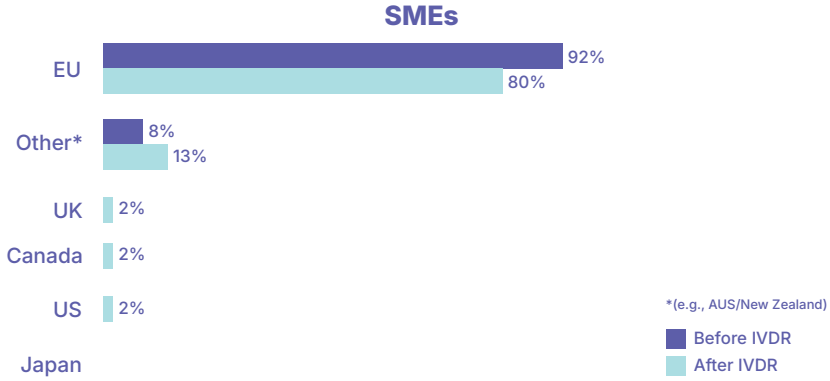
SIMULATION: QMS re-certification fees paid to NB: 55% increase of fees paid to NB for initial QMS certification

SIMULATION: TDA re-certification fees paid to NB: 94% increase of fees paid to NB for initial TDA certification

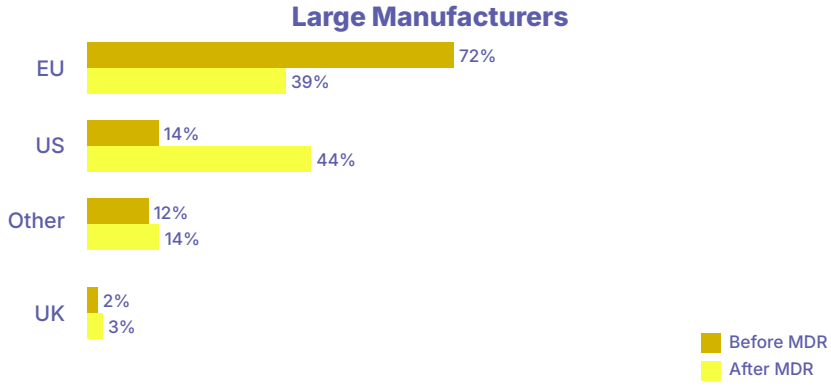
Innovation

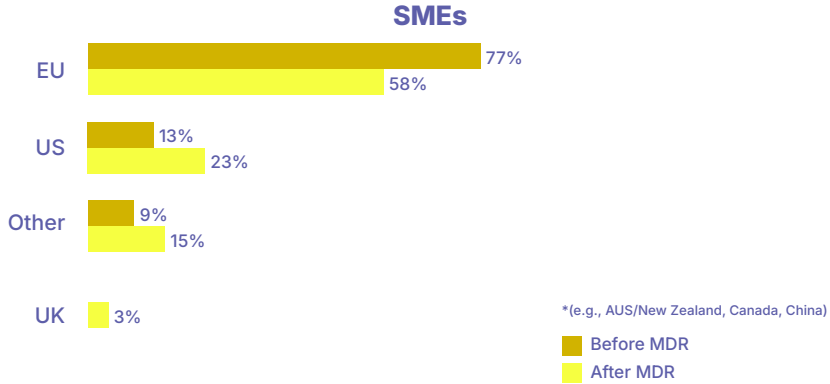
Since the IVDR and MDR dates of application, the manufacturer's choice of the EU as the first launch geography has dropped by **40% for large and 12% for SME IVD manufacturers**;





In the MD sector choice of the EU as the first launch geography has dropped by **33% for large and 19% SME manufacturers**:





- Furthermore, 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.
- 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.

Other challenges

The MedTech Europe 2024 survey also collected information regarding other areas such as:

1) Orphan Devices

- **53.3%** of IVD 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 only **less than 5%** of their portfolio of orphan devices.
- **52%** of MD respondents that produce orphan devices indicate they will transfer all their orphan devices to the MDR. However, **29%** indicate they will transition only **less than 5%** of their portfolio of orphan devices.

2) Resources for regulatory compliance:

It is a challenge to find staff to employ in the area of regulatory affairs, particularly for MD manufacturers:

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

26.6% IVD Manufacturers transitioning <5% of OD portfolio.

29% MD Manufacturers transitioning <5% of OD portfolio.

Conclusion

Shifting Priorities

While finding a Notified Body is no longer a major concern, uncertainty around timelines, costs, and predictability has become **a significant challenge for CE marking and maintaining devices on the market**.

Conformity Assessment Delays

Over 50% of the total conformity assessment time is spent on activities outside the review phase, i.e. the pre-review and certificate issuance phases. Streamlining these administrative processes could significantly reduce overall assessment time.

Increased Costs

The financial burden on manufacturers has increased under the IVDR and MDR regulations, with substantial rises in clinical evaluation, Post-Market Surveillance (PMS), and certification costs.

Long-Term Financial Strain

Maintenance and re-certification costs are expected to exceed initial certification fees, with **IVD manufacturers likely to spend 70% more and MD manufacturers 50% more over the five-year certification cycle**.

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