Impact of EU Regulations MDR (2017/745) and IVDR (2017/746) on innovation, competitiveness and security of supply in the EU – Results of an industry survey 2025

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Results of an industry survey carried out in Germany, Austria and Switzerland (DACH).

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As of: October 2025

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1. Introduction

Regulations (EU) 2017/745 on medical devices (MDR) and (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) were adopted with the aim of establishing a robust, transparent, predictable and sustainable regulatory framework that ensures a high level of safety and health while supporting innovation (MDR/IVDR, Recital 1).

However, since their entry into force in May 2021 (MDR) and May 2022 (IVDR), it has become clear that implementation poses considerable challenges for the entire sector – with noticeable adverse effects on innovation, product availability, competitiveness and the resilience of the European healthcare industry[1]. The European Parliament, several Member States, as well as industry associations, including the publishers of this report, have repeatedly called for simplification and modernisation of the two legal frameworks.

In this context, the European Commission has brought forward the targeted evaluation of the two regulations. The results of this review are expected to be translated into concrete legislative proposals. In particular, the aim is to reduce bureaucracy, speed up processes, increase predictability and cost efficiency, and secure the future viability of Europe as a location for medical devices and in vitro diagnostics.

The Commission's initiative has three core objectives:

- Strengthening the competitiveness of the European single market and in global competition
- Promoting innovation and reducing dependencies
- Ensuring patient safety and care in a proportionate regulatory system.

In an effort to gather further evidence in support of a revision proposal BVMed, MedicalMountains, SPECTARIS and VDGH conducted a comprehensive survey of manufacturers in the D-A-CH region in the summer of 2025. The aim was to provide an overview of the current situation regarding the impact of the MDR and IVDR on innovation, competitiveness, resilience, product availability and the special situation of orphan devices.

The results provide empirical evidence that a swift and targeted revision of both regulations is urgently needed.

The authors of this report have published proposals for solutions, addressing many of the issues identified with the regulations in separate papers and statements that have not been included in this report.

[1] This is confirmed, among other things, by data from previous industry surveys in Germany on the impact of the MDR, most recently from 2023: Current assessment by medical device manufacturers of the impact of the EU Medical Device Regulation (MDR) by DIHK, Medical Mountains and SPECTARIS.

2. Methodology

The online survey took place from 15th June to 31st August 2025. A total of 267 companies from the D-A-CH region took part, including 245 manufacturers whose responses were included in the evaluation.

78 % produce medical devices and/or their accessories within the meaning of the MDR (including products listed in Annex XVI of the MDR), 10 % produce in vitro diagnostic medical devices in accordance with the IVDR, and 12 % are manufacturers under both regulations.

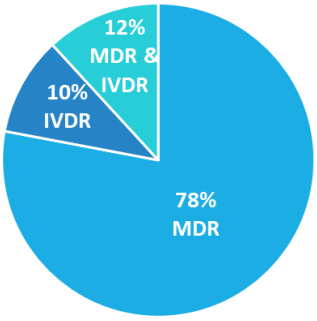
The headquarters of 209 manufacturers are located in Germany, with other participants coming from Switzerland (11), Austria (5) and other EU and non-EU countries (20).

The spectrum ranged from micro-enterprises (<10 employees, 9 %), small enterprises (10 to 49 employees, 23 %) and SMEs (up to 249 employees, 31 %) to small and mid-cap companies (up to 750 employees, 13 %) and large enterprises (>750 employees, 24 %).

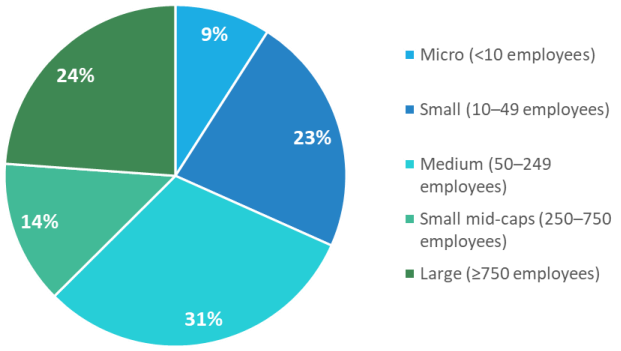
84 % of the participating companies have been active in research and development (R&D) over the past ten years. 91 % operate at least one production site in the EU. This means that the results are highly significant for the European market.

Since German manufacturers hold a disproportionately large market share of around €60 billion – almost half of the EU-wide industry turnover – the results should be largely indicative of trends across the entire European medical technology industry.[2]

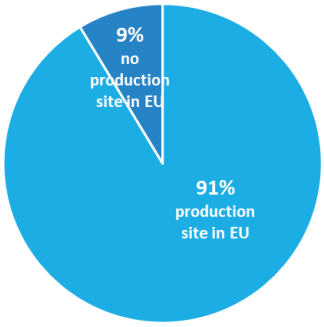
Regulatory Categorization of the Surveyed Manufacturers



Company Size



Production sites in the EU



[2] SPECTARIS Yearbook "The German Medical Technology Industry 2025/26"

3. Key findings

The survey data shows clear indications that the MDR and IVDR are having a negative effect on the innovative power and competitiveness of companies and the market availability of products in Germany and the EU.

Decline in research and development
53 % of respondents report a reduction in their R&D projects over the last five years due to the MDR/IVDR. 46 % of these companies have seen a decline of over 75 %. In addition, 20 % of the responding companies have reduced their R&D staff. The decline particularly affects in vitro diagnostics. Despite these setbacks, R&D continues to take place predominantly within the EU.

Shift in the market launch of innovations to non-EU countries
More than 40 % of the responding companies have not launched innovative products in the EU. Over half of these innovations entered other markets instead – primarily the United States, followed by Asia, South America, and Canada.

Special national requirements as a barrier within the EU single market
38 % of respondents state that they have products that have not been placed on the market in all EU Member States due to special national regulatory rules (e.g. language requirements, national databases) – especially affected are Slovakia, Hungary, Croatia and Romania.

Decline in patent applications
22 % of respondents reported a decline in patent applications in the EU. Cited reasons included prolonged development and approval processes, rising costs and a significant shift of resources to regulatory activities.

Production sites in the EU under pressure
Around one third of the companies that responded are planning to relocate some or all of their production outside the EU. The decisive factors include rising energy costs, a shortage of skilled workers, high labour costs, regulatory burdens and increasing bureaucracy.

Unstable supply chains
Almost three-quarters of respondents report disruptions in their supply chains over the past five years. In addition to global factors such as raw material shortages and trade tariffs, regulatory requirements in the EU are also cited as a key burden.

Orphan devices particularly at risk
Of the manufacturers that produce orphan devices, 64 % stated that they had already discontinued products due to the MDR/IVDR. This threatens to create significant supply gaps for particularly vulnerable patient groups.

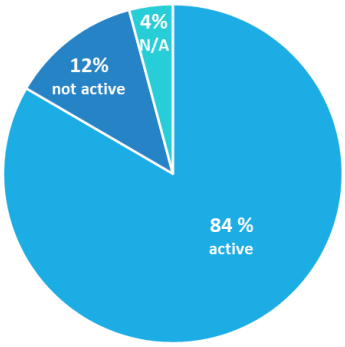
4. Results in detail

The following chapters provide more detailed information on the results in the individual subject areas.

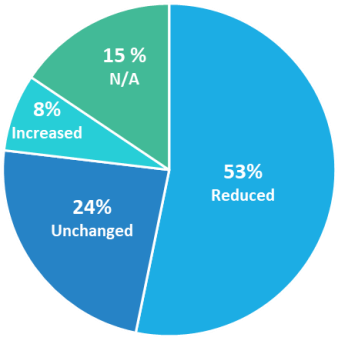
4.1 Research and development

84 % of companies have conducted research and development (R&D) in the past ten years – but more than half (53 %) report a reduction in projects in the last five years due to the MDR/IVDR. Manufacturers of in vitro diagnostics (70 %) are particularly affected.

Activity in R&D in the last 10 years



Change in R&D Project Numbers Over the Past 5 Years as a Result of MDR/IVDR



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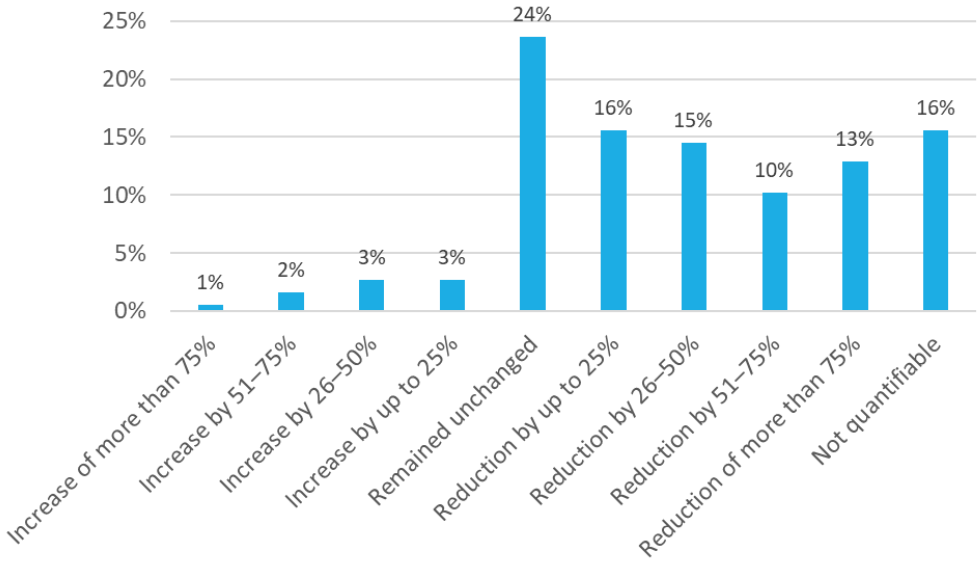
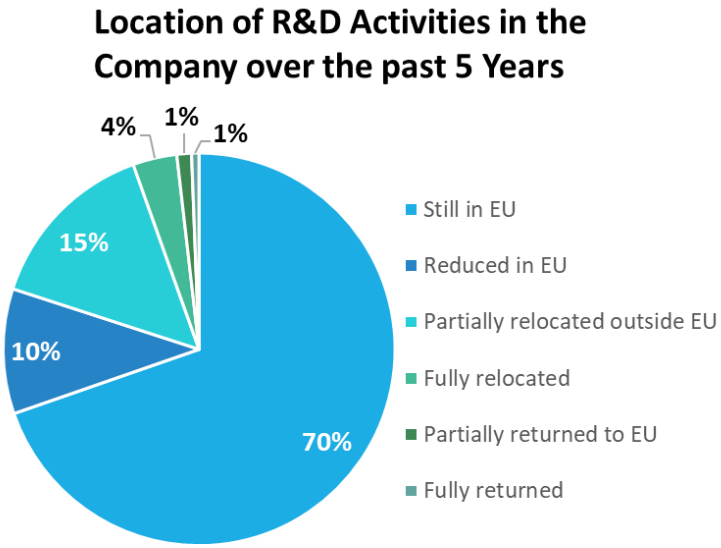
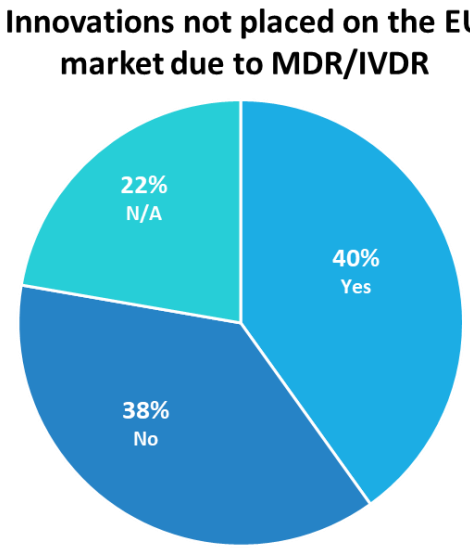


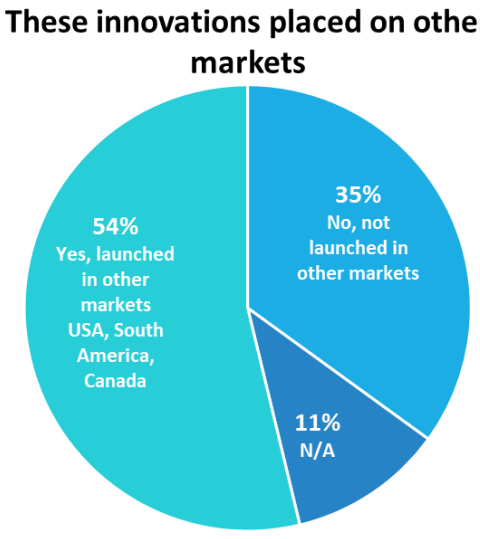
Although almost 70 % of the responding companies continued to conduct their R&D activities in the EU over the past five years, almost one-fifth reported a shift to non-EU countries – almost 15 % partially and almost 4 % completely. In contrast, only 2 % reported a shift back to the EU – slightly more than 1 % partially and less than 1 % completely.



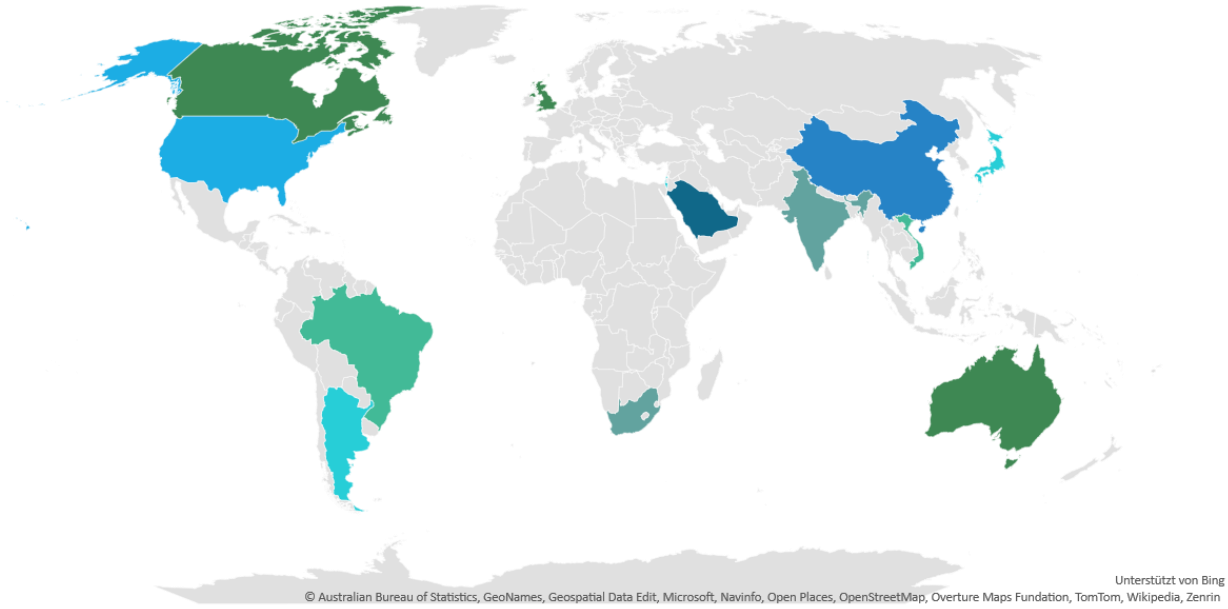
4.2 Placing products on the market

40 % of the responding manufacturers no longer place innovations on the market in the EU due to the MDR/IVDR. More than half of these companies place them on the market in other markets instead, most frequently in the USA, followed by Asia, South America and Canada.



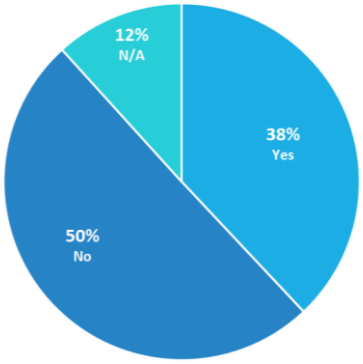


First markets for innovations

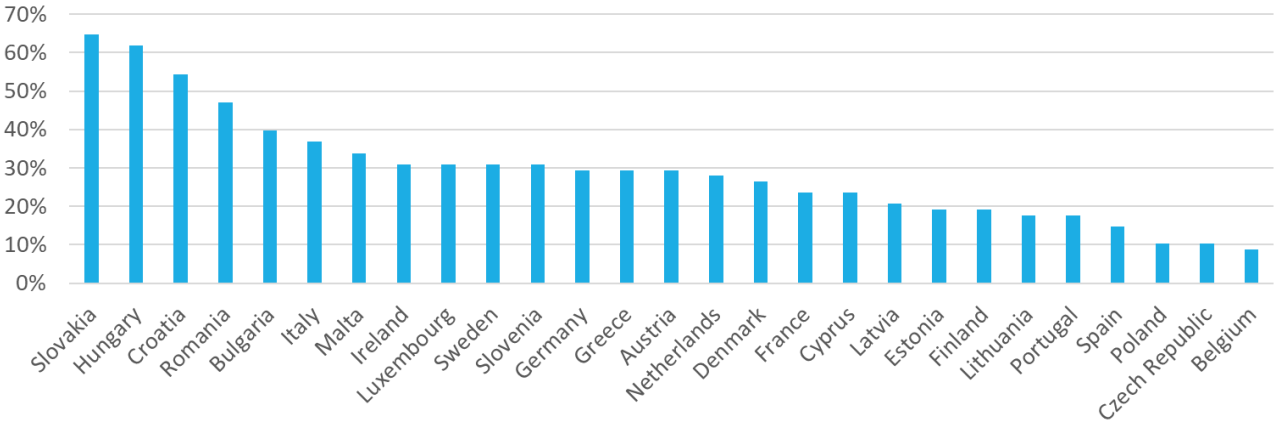


Regulatory requirements also lead to differences in supply within the EU. 38 % of the companies that responded stated that they do not market certain products in all EU Member States due to special national regulatory requirements (e.g. language requirements and national databases), particularly in Eastern European and Baltic countries.

Products were not placed on the market due to national special requirements

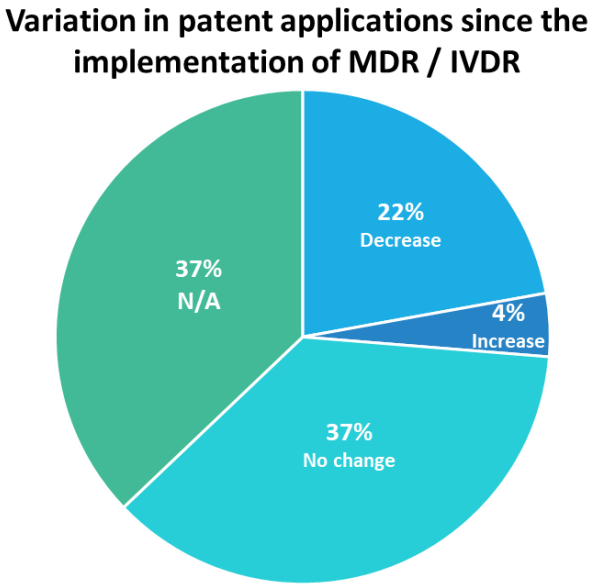


Affected countries



4.3 Patent applications

22 % of respondents report fewer patent applications since the introduction of the IVDR/MDR – only 4 % report an increase.



The reasons given in the free-text responses for the decline are varied, but they are all interrelated. Many companies are postponing or halting innovation projects because the increased requirements of the MDR/IVDR significantly increase development efforts. In addition, there has been a shift in resources: instead of investing in R&D, human and financial resources are increasingly being used for regulatory documentation requirements.

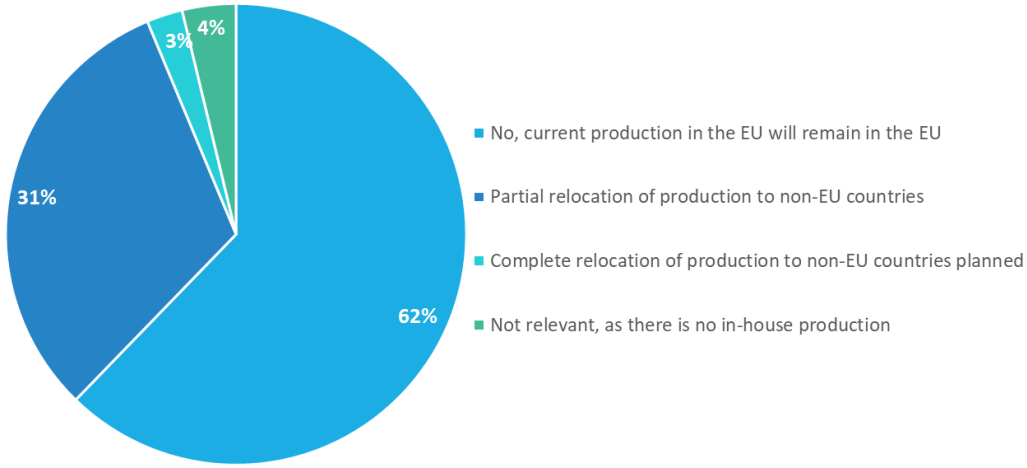
One problem are the extended development times. Since processes from the initial idea to market readiness often take five to eight years, the economically profitable time-frame where patent protection is in place, has drastically reduced – of the original 20 years, often only around 12 years of effective market use remain. This development exacerbates the already high-cost intensity: patent procedures are expensive, and the additional MDR/IVDR-related expenses mean that companies are having to weigh up the costs, benefits and risks more and more carefully. Many are therefore foregoing new patents altogether.

Furthermore, the benefits of patents are increasingly being called into question, as they do not offer sufficient protection against imitators despite their high costs. In the free-text responses, several companies called for the introduction of a compensation mechanism – comparable to the supplementary protection certificates (SPCs) in the pharmaceutical industry.

4.4 Production location in the EU

91 % of survey participants stated that they operate production sites in the EU. 34 % of these companies – one third of MD manufacturers and one fifth of IVD manufacturers – are planning a partial or complete relocation to non-EU countries. 62 % state, that they will maintain their production in the EU.

Planned relocation of production sites outside the EU

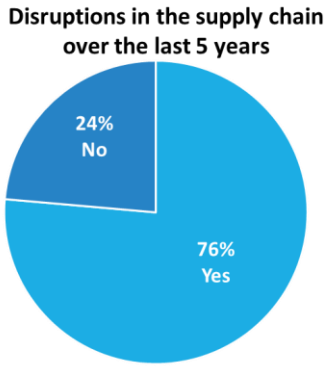


In addition to rising costs and energy prices, many participants cite growing bureaucracy and regulatory requirements (not only due to the MDR, but also other EU regulations such as the PFAS restriction) as decisive factors in their free-text responses. However, the availability of skilled workers, their high wage costs and increased sick leave also play a key role. Additional personnel expenses due to extensive labour and safety regulations, for example in the areas of fire protection, air freight safety, occupational safety, hazardous goods management, or export safety, are also mentioned. International markets are also increasingly being served from outside the EU, as non-EU locations often offer cost advantages and a faster time-to-market.

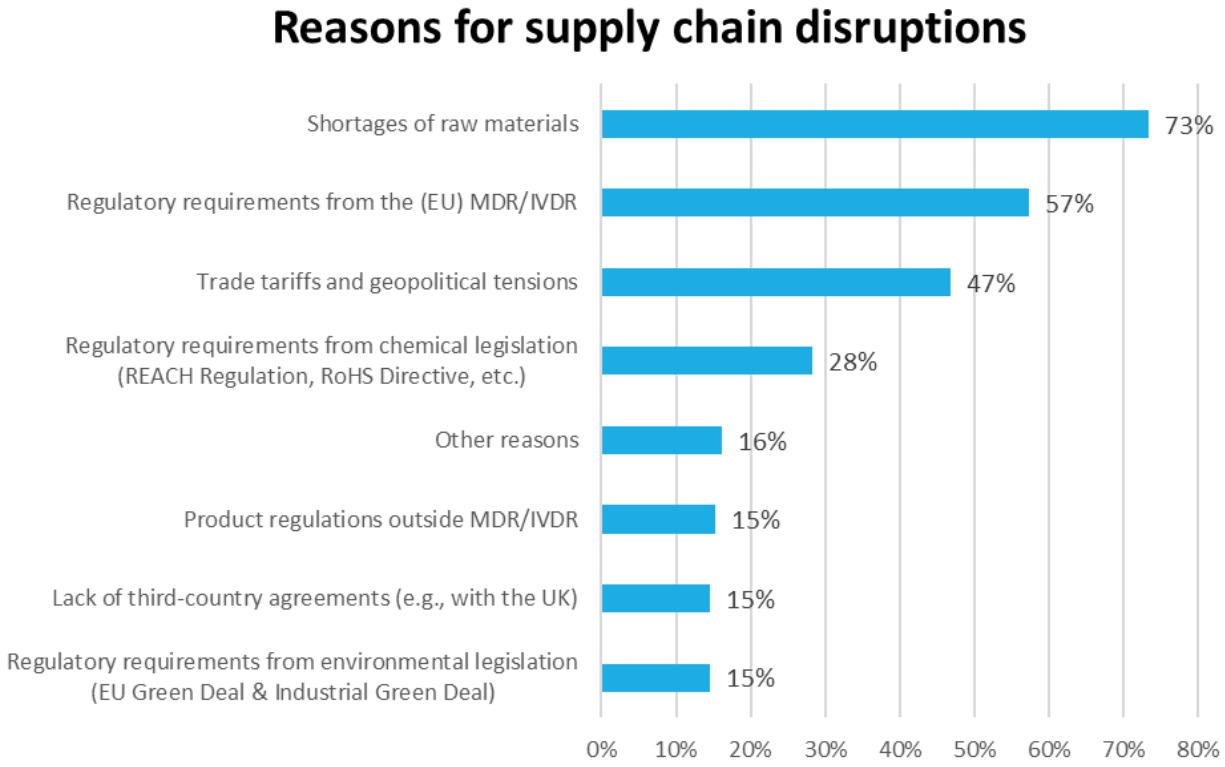
Numerous products are already being purchased outside the EU because they are no longer manufactured here – a development that has intensified since the MDR and IVDR came into force.

4.5 Supply chain

Three-quarters of respondents reported supply chain issues in the past five years.



In addition to global factors such as raw material shortages and customs duties, respondents cited regulatory requirements in the EU as a major burden. Many companies are trying to minimise customs risks and reduce their dependence on European production sites.



External influences also played a role: the COVID-19 pandemic led to massive supply bottlenecks, transport disruptions and production stops among suppliers. Further burdens arose from geopolitical crises such as the blockade of the Suez Canal, attacks by Houthi rebels in the Red Sea, the war in Ukraine and ongoing conflicts in the Middle East.

Furthermore, quality problems, such as defective packaging materials, and logistical bottlenecks in container availability further exacerbated the situation. Structural factors such as company bankruptcies, product discontinuations or the cessation of business activities by individual suppliers led to abrupt

supply shortages in some cases. Finally, certification problems also played a role – for example, when subcontractors lost their ISO 13485 certification and could no longer be used as qualified suppliers.

Overall, it is clear that supply chains are not only affected by external crises, but increasingly by regulatory conditions. This weakens the resilience of European medical device production and jeopardises the long-term security of supply in the healthcare sector.

4.6 Availability of orphan devices

The results in the area of orphan devices are particularly alarming. Only 22 companies were able to answer in the affirmative when asked whether they currently carry or have carried orphan devices[3] in their portfolio. However, this small sample size can be explained by the naturally small number of suppliers of such highly specialised products. It does not diminish the relevance of the results.

Of these 22 companies, 14, or 64%, stated that they had already discontinued orphan device products due to the MDR/IVDR – including one manufacturer of in vitro diagnostics.

Since orphan devices are often indispensable for very specific and particularly vulnerable patient groups, discontinuations pose an immediate threat to security of supply. In most cases, the shortfalls cannot be compensated for in the short term or replaced by alternative products. There is an urgent need for action, particularly in the IVD sector, as the existing MDCG guideline on so-called "orphan devices" applies exclusively to medical devices. Without timely regulation, there is a risk of losing important diagnostic tests, for example in the field of transplant preparation, which would then no longer be available.

5. Conclusions

The results clearly show that the MDR and IVDR have not achieved their original goals in regard to safety, transparency and innovation.

Instead of promoting innovation, the current regulations are leading to

- a massive decline in research and development activities,
- the relocation of innovation and, in some cases, production abroad,
- a shift in value creation and know-how to other jurisdictions – primarily America and Asia
- a loss of competitiveness and location attractiveness,
- endangered supply chains and impending supply shortages – especially for orphan devices.

[3] A medical device or accessory falls under the term "orphan devices" if it is specifically intended to help patients in the treatment, diagnosis or prevention of a disease that affects no more than 12,000 people in the European Union per year. In addition, there must be no adequate alternative, or it must offer an expected clinical benefit compared to available alternatives (cf. MDCG 2024-10).

Europe is thus in danger of permanently losing its leading role as a medical device location and jeopardising patient safety and security of supply in the EU.

A targeted revision of the MDR and IVDR is therefore essential.
Procedures need to be simplified, requirements need to be proportionate and (small and medium) enterprises are in need of relief, so that we can strengthen competitiveness, promote innovation and guarantee the security of supply in the long term.

It is important to adopt and implement the necessary adjustments in a timely manner in order to set the course for a regulatory system that enables innovation, ensures long-term competitiveness and, at the same time, guarantees a high level of patient safety.