First assessment of the German manufacturers of medical devices after the EU Medical Devices Regulation (MDR) came into force

Many problems still unsolved

DIHK Association of German Chambers of Commerce and Industry

SPECTARIS German Industry Association for Optics, Photonics, Analytical and Medical Technologies

MedicalMountains

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Many problems still unsolved

Results of a national survey of companies by the Association of German Chambers of Commerce and Industry (DIHK), the MedicalMountains cluster initiative and the German industry association SPECTARIS.

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Content

1. Introduction

Modern medical devices are a fundamental pillar of our healthcare system. The product range extends from dressings such as compresses and plasters, to medical aids, surgical instruments, medical software, endoscopes, implants and devices for diagnostics and intensive care – to name but a few.

A CE marking is a prerequisite for medical devices to be permitted on the market in Germany and the EU. Therefore, manufacturers must demonstrate that the products meet basic safety and performance requirements (conformity).

The applicable law in this regard is Regulation (EU) 2017/745 on medical devices (Medical Device Regulation; MDR for short), which has been mandatory for manufacturers of medical devices in the EU and in Germany since 26 May 2021. This date marks a milestone for the European medical device industry, as the MDR replaces decades-old directives and processes for the marketing and supply of medical devices.

The goal of the MDR, i.e. to ensure that medical devices are both safe and reliable, is appropriate and important. The implementation of the new legal requirements, though, is associated with major challenges for all partaking stakeholders and especially for the manufacturers of medical devices. In numerous areas, the requirements placed on processes and documentation have become significantly more detailed. In addition, structural prerequisites for a functioning MDR system are not in place yet.

These include the state-authorised so-called "Notified Bodies", which oversee the process of conformity assessment of medical devices by the manufacturers. The Notified Bodies lost their previously valid authorisations on the date of application of the MDR and must undergo a complex and lengthy new designation procedure in order to be allowed to operate under the new legal framework. At the time of the survey, less than half[1] of the former 59 Notified Bodies across the EU had been notified for the certification of medical devices under the MDR.

Not all medical devices require the involvement of a Notified Body for their conformity assessment procedure. Accordingly, medical devices solely of risk class I with a low risk for the patient (e.g. bandages) are exempt. However, according to the MDR, significantly more device groups (e.g. reusable surgical instruments or medical software) must be assessed by a Notified Body than was the case according to the previous directives.

In this nationwide survey by the Association of German Chambers of Commerce and Industry (DIHK), MedicalMountains GmbH and the industry association SPECTARIS, German manufacturers of medical devices were interviewed on numerous individual aspects in the course of the implementation of the new regulation, six months after the MDR came into force.

The survey results give answers to questions such as: Where does the industry stand six months after the MDR came into force? Which central issues exist in the implementation of the regulation? What is the impact of the MDR on the innovation activities of companies? Are well-established technologies being withdrawn from the market due to the MDR such that they become unavailable to patients?

Even though the survey results are from Germany, they can be understood to at least be indicative of trends for the entire medical device industry in the EU: German companies account for 41 per cent of the industry turnover generated in the European Union[2].

[1] Status April 2022: 28

[2] Source: EUROSTAT, SPECTARIS, Jahrbuch Medizintechnik 2021/22 (Yearbook Medical Technology 2021/22)

2. Key findings

The results of the survey show that, from the manufacturers' perspective, the MDR is not practicable in many aspects. For example, there are clear effects on the time needed and financial expenditure for market access – both for legacy devices and well – established technologies as well as innovative medical devices. In addition, there are operationally unsolvable obstacles for companies, for example, when Notified Bodies either do not react at all or reject their applications, or when clinical studies cannot be conducted for ethical reasons.

This results in portfolio adjustments, in some cases even complete product discontinuations, by the companies as well as negative effects on the innovative strength of the industry and thus on the availability of well-established and innovative medical devices in the EU.

2.1. According to manufacturers, numerous medical devices are being taken off the market due to the MDR

The survey results show that the variety of existing and niche products in Europe might decrease significantly.

Numerous existing products are being taken off the market – in each and every single one of the 21 application areas surveyed. In 16 application areas or product groups, at least half of the companies active in these areas are discontinuing individual products, entire product lines or even their entire product portfolio. Product discontinuations are made by companies of all sizes alike.

A total of 78 percent of the manufacturers active in the application area of dentistry are discontinuing products. The same is true of 77 percent of the companies in the field of visceral surgery and 74 percent of the companies producing medical aids. The application areas of surgical instruments (69 percent) as well as orthopaedics, traumatology, rehabilitation and rheumatology (68 percent) are also particularly strongly affected by product discontinuations.

According to the participating manufacturers, in many cases there are no alternatives to their own discontinued products available on the market. According to the survey results, this particularly concerns products in paediatrics (30 percent)[3], followed by medical aids (28 percent)[3], urology (21 percent)[3], orthopaedics, traumatology, rehabilitation and rheumatology (20 percent)[3] and obstetrics/gynaecology (19 percent)[3]. Paediatric surgery (15 percent)[3] and cardiology (ten percent)[3] are also affected.

Examples of discontinued medical devices cited by respondents include baby stents or radiofrequency perforation catheters for stuck heart valves in newborns. These are niche products, i.e. products whose intended purpose is associated with only a small number of applications. Other examples mentioned include various surgical instruments, electrodes, catheters, endoscopes, implants as well as X-ray tables, sit-to-stand beds or electrical stimulation devices.

2.2. Most legacy devices have not yet been transitioned to the MDR

By the third quarter of 2021, the Notified Bodies supervised more than 25,000 CE certificates issued under the previous directives[4]. This is evident from a survey[5] by Team NB[6] and the European Commission. According to these results, the vast majority of valid directive certificates expire in the first five months of 2024. In order for the corresponding products to continue to be available on the market, their currently valid certificates must be completely replaced by MDR certificates before their expiry date, but no later than by the end of the transition period on 26 May 2024.

The results of the company survey show that, on average for all risk classes considered, less than ten percent of the existing products that require involvement of a Notified Body in the scope of the conformity

[3] This is the number of respondents who indicated that there are no equivalent alternatives to their discontinued products on the market.
[4] This refers to certificates that were legally issued under the previously valid EU directives AIMDD (Active Implantable Medical Device Directive) and MDD (Medical Device Directive).
[5] https://www.team-nb.org/wp-content/uploads/2021/04/Team-NB-MD-Sector-Survey-PressRelease-20210414.pdf
[6] Team NB is the European association of Notified Bodies for medical devices.

assessment procedure are certified according to MDR. In risk class III, this drops to below six percent.

The survey results also indicate significantly longer conformity assessment procedures involving a Notified Body – again across all risk classes. On average, procedures take at least 45 percent longer than previously under the directives. In risk class III, the duration of conformity assessment procedures has more than doubled (101 percent).

In consequence, this means: In the time remaining, certification according to the MDR requirements by a Notified Body – which, on average, also needs significantly longer than before for the conformity assessment procedures – is still pending for a large part of the legacy devices that are to be transitioned to the new regulation.

Against this background, a clear capacity issue is evident at the Notified Bodies. This is consistent with the statements of the Notified Bodies[7] in their position paper of December 2021[8].

And there is another aspect: Almost every other company (48 percent) that has to conduct a clinical trial for transitioning its legacy devices to the MDR has great difficulties in being able to even conduct the necessary clinical trials. For example, there is a lack of investigators or there are negative rulings from the ethics committee. A total of 63 percent of these companies also state that financing such studies is quite a strain on them.

Overall, it must be assumed that a large fraction of the legacy devices cannot be transitioned to the MDR in time. Consequently, the industry is forced to prioritise its own products.

2.3. MDR has a negative impact on the industry's innovative strength and on the availability of innovative medical devices in the EU

A total of 83 per cent of the companies responding state that they have not yet certified innovative new products according to MDR.

The survey results show that the MDR has a negative impact on the general innovation activity of the companies. Accordingly, innovation projects are on hold due to the MDR in almost every other company (46 percent). In the field of paediatrics, the figure is as high as 74 percent of the companies. The figures are also very high for paediatric surgery (67 percent) and pneumology, anaesthesia and intensive care medicine (62 percent).

In addition, 43 percent of all companies no longer make any changes or optimisations to legacy devices due to the MDR. This being the case because so-called step innovations on legacy devices can lead to their existing directives certificates becoming invalid prematurely.

Where innovations are being developed, more than half of the responding companies (51 percent) expect a delay in the market launch in Europe due to the MDR. Among those companies, which, in their own assessment, need to conduct a required clinical trial within the next five years, this figure is even higher at 80 percent. In turn, 65 per cent of these companies expect an average delay in excess of 12 months.

A total of 19 percent of the companies are currently working on innovations, but intend to have them certified in other markets first due to the MDR. In the free-text answers, it is often stated that future product certifications are primarily envisaged in the USA or Asia. If innovations are certified primarily in other markets, it may have an impact on clinical research and development (R&D) in Europe if, e.g. clinical data collection and studies are also shifted to the countries of first certification. Moreover, five percent of the companies indicated that they are planning to relocate their R&D department abroad in the medium to long term due to the MDR.

2.4. There are many issues with the implementation of the MDR: From high costs and bottlenecks at Notified Bodies, to legal and planning uncertainties and the difficulties in generating clinical data

Various issues come into play, especially in regards the necessary cooperation with the Notified Bodies in the course of implementing the MDR. The certification

[7] Quote from the Position paper of Team-NB of December 2021:"These circumstances are inevitably leading to an extreme bottleneck in the processing of MDR/IVDR certification by NBs, which will increase towards 2024 proportionally to the amount of expiring Directives certificates and will most probably prevent a large number of devices currently certified under Directives from timely transitioning by 26 May 2024."

[8] https://www.team-nb.org/wp-content/uploads/2021/12/Team-NB-PositionPaper-on-MDR_IVDR-Implementation-V3.pdf

costs are a major problem for the companies. For 58 percent, the certification costs are associated with large or very large problems. This was indicated by an even higher number of 72 percent of small and medium sized companies with up to 49 employees.

The significant increases in certification costs upon involvement of a Notified Body in the conformity assessment procedure are being experienced across all risk classes. The lowest average cost increase, still amounting to 38 percent, is in risk class Is. The highest average increase in certification costs is seen in risk class III, with costs almost doubling (99 percent).

In addition, 59 percent of the companies indicated that they have no real planning certainty with regard to the fees (lack of cost transparency). For companies with up to 49 employees, the figure is 67 percent. The lack of certainty in their planning means that only at a very late stage do companies have a reliable basis available to them to even be able to assess the economic viability of their products.

In addition to increased costs and longer certification times, a lack of capacity at the Notified Bodies is cited as a major challenge with regard to cooperation. Around two thirds of the companies have great difficulties with these scarce capacities. Almost half of the companies (43 percent) also receive late or no deadlines for product file reviews by the Notified Body. Companies also report that their current Notified Body has not yet been notified according to the MDR or that they cannot find a Notified Body in general. Furthermore, 52 percent of the companies complain about the lack of binding deadlines for performance of the necessary assessments by the Notified Bodies. This contributes to the companies' planning uncertainty. To make matters worse, ambiguity regarding the requirements in the absence of pertinent guidelines is a major problem for 49 percent of the companies.

Likewise, the inconsistent interpretation of the MDR requirements by the Notified Bodies and the companies also leads to difficulties in the MDR certification process as indicated by 52 percent of the companies. A total of 43 percent of the manufacturers surveyed also state that the existing clinical data is not considered sufficient by the Notified Bodies.

In addition, there is a plethora of additional challenges. For example, 45 percent of the companies experience large difficulties finding qualified personnel for implementation of the increased regulatory requirements. The increased requirements for post-market clinical surveillance are also particularly problematic for 46 percent of the companies. In addition, the new requirements not only place obligations on manufacturers of industrially manufactured medical devices, but also on manufacturers of custom-made devices, such as medical supply stores. Here, too, the clinical evaluation and clinical post-market surveillance place a heavy burden on the companies. Some 79 percent of the manufacturers of custom-made devices find it difficult to implement both.

The greatest challenges in implementing the new requirements for manufacturers of Class I devices, which can declare conformity without the involvement of a Notified Body, are the preparation of the technical documentation (57 percent) and the clinical evaluation (56 percent). Risk class I includes, e.g. wheelchairs and nursing beds. For 45 percent of manufacturers of class I devices the post-market surveillance requirements are a major challenge.

3. DIHK/MedicalMountains/SPECTARIS requests and proposed solutions

The central goal is to ensure the long-term supply of safe, effective and innovative medical devices to patients in Germany and Europe. In addition, the MDR emphasises time and again that the concerns and interests of the many small and medium-sized enterprises in the medical technology sector, which are the backbone of this industry, must be taken into account and safeguarded[9]. In order to be able to provide healthcare with safe and innovative medical devices in Germany and Europe beyond 2024, there is an urgent need for action by the lawmakers in the industry's point of view.

3.1. Resolve the certification backlog and capacity bottleneck at Notified Bodies

Resolving the certification backlog at Notified Bodies in due time must be a central goal for the legislator:

- In order to prevent a scenario, in which valid certificates for legacy devices cannot be transitioned to the MDR in time before their expiry or the expiry of the transition period on 26 May 2024, these certificates should be extended in a pragmatic and non-bureaucratic way. This is the only way to quickly ensure that these products will still be available after 26 May 2024.
- At the same time, it must be ensured that the existing sales-off restriction for these products is lifted[10]. Extending the validity of certificates makes little sense if these medical devices can no longer be sold afterwards or if any stocks would even have to be destroyed.

Further, the capacity bottleneck at Notified Bodies needs to be remedied:

- This could be achieved by shortening the designation period for Notified Bodies, streamlining the procedures for ongoing designations and thereby also creating incentives for new applications for designation.
- Another option is that bodies that are still in the application procedure are already allowed to accept and examine applications for MDR certifications despite the fact that their notification is still pending. Manufacturers could thus be provided with the opportunity to work and rework at an early stage without further loss of time.

3.2. Make more efficient use of existing resources of Notified Bodies

The scarce resources currently available must be used reasonably:

- A better allocation of resources and consequently a balancing of processing times could be provided by granting Notified Bodies and manufacturers more flexibility within the framework of the conformity assessment procedure. In addition to allowing remote audits, this also includes the possibility of step-by-step filing of the required documents and modular processing and examination of these documents by the Notified Bodies.
- It should also be made possible to issue certificates subject to conditions after an appropriate risk assessment.
- Repeated reviews, e.g. of legacy devices that are not conducted as a result of significant changes such as modifications affecting the safety, function or usability of the product, should be omitted.

3.3. Create sustainable solutions for legacy devices and niche products

It is important that legacy devices and niche products that have proven themselves over many years continue to be available on the market:

- A significant contribution might be made if the requirements for the collection of clinical data for legacy devices were adapted and if these were exempted from the requirement to conduct additional clinical studies, especially if these are not possible from an ethical point of view. Instead, existing market data (e.g. data from post-market

[9] See, for example, Recital 2, Article 15 (2), Article 106 (14), Annex VII 1.2.8

[10] Art. 120(4) MDR: "Devices lawfully launched into the market before 26 May 2021 in accordance with Directives 90/385/EEC and 93/42/EEC and devices launched into the market from 26 May 2021 in accordance with paragraph 3 of this Article may continue to be made available on the market or put into service until 26 May 2025."

surveillance, health insurance data, registry data) as well as r data of the kind that existed according to the previous directives – should be recognized in principle.
- This also includes using the method of equivalence possible again in a practical way – without the need for a contractual agreement with competitors.
- In addition, separate requirements for niche products must be developed in order to ensure their continued availability.

It is essential that the respective solutions be developed at EU level through the involvement of all relevant stakeholders.

3.4. Preserveinnovation and research in Europe

Value creation and jobs by means of innovations must continue to be preserved in Europe. This will also benefit healthcare. The legal framework must therefore be designed appropriately such that the innovative strength of the medical technology industry in Europe is maintained:

- Clinical research should be reinforced, for example, by shortening processing times for the approval of studies and expanding the necessary infrastructure for conducting clinical studies in European hospitals.
- Companies should also be given legally secure access to healthcare data and be able to use this data more extensively so that innovations can be developed more quickly and existing products can be improved more rapidly.
- In addition, it is important that pragmatic and realistic requirements are set for initial feasibility studies and clinical data for CE certification of innovative medical devices.

3.5. Ensure a transparent and predictable certification system

Uniformity, transparency and predictability in the market access process must also be ensured in order to safeguard the competitiveness of medical technology companies in the EU.

- This includes ensuring that interpretative documents on the MDR (including MDCG guidelines) are developed in a transparent procedure and a clearly defined process involving experts from all relevant stakeholder groups.
- It must, by all means, be made sure that ongoing conformity assessment procedures are not adversely impacted by newly published guidelines – especially in view of the current capacity bottlenecks and the impending threat of a certification backlog.
- It is also important to make sure that the MDR is interpreted and enforced uniformly across the EU. Special and differing national paths and regulations (such as in the application of remote audits or the use of the European database EUDAMED) must be avoided in the future.

Moreover, it is of fundamental importance for companies in the medical device industry to have planning certainty in their work with Notified Bodies:

- Uniform assessment standards should be created between and within Notified Bodies concerning the interpretation of MDR requirements.
- Furthermore, a binding way of handling the processing times for assessments by the Notified Bodies is necessary by means of binding clauses in the contracts that take into account the available resources of the Notified Bodies.
- The determination and presentation of fees for the activities of the Notified Body in the scope of the conformity assessment should become more transparent. This must go beyond the simple disclosure of standard fees as done currently. It must be possible to calculate the expected total expenditure from the fees in order to be able to determine the economic viability of the products in good time and to minimize the entrepreneurial risk.
- In particular, the interests of small and medium-sized enterprises must be adequately taken into account when setting fees[11].
- There is an urgent need for a solution for companies that can demonstrate that they cannot find a Notified Body.

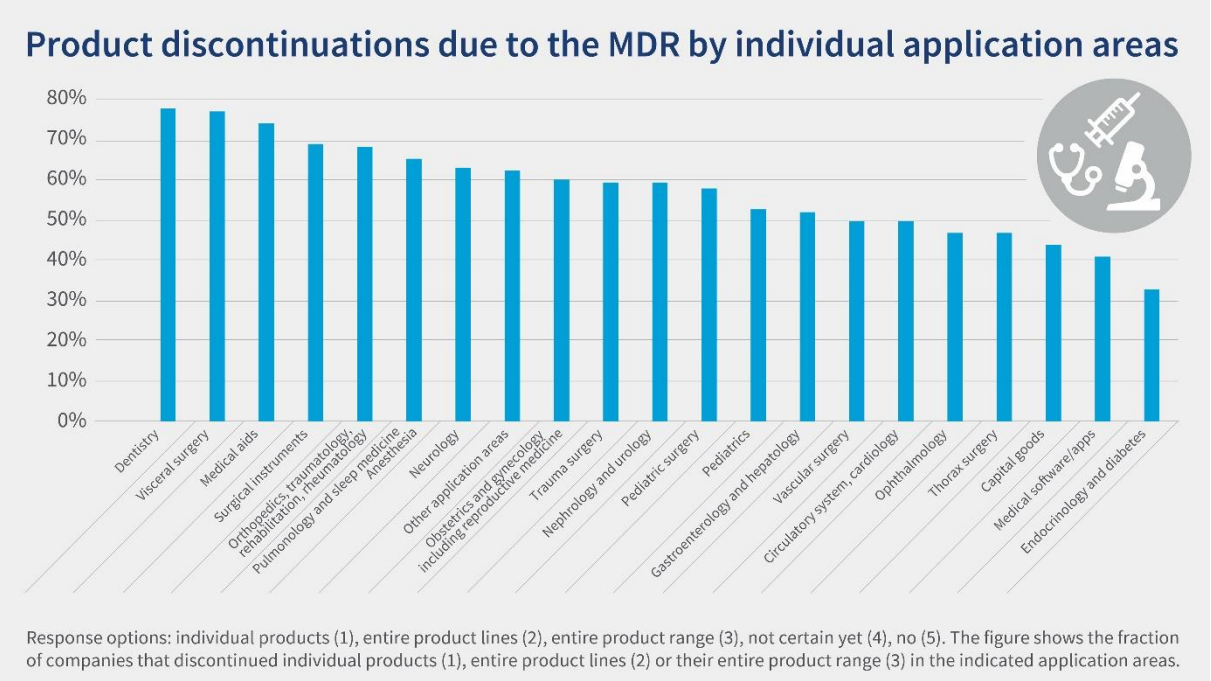
[11] Also see explicitly on this issue Annex VII item 1.2.8 MDR.

4. The results in detail

4.1. In almost all application areas, manufacturers are taking individual products, product lines, and in some cases entire product portfolios off the European market

This result is seen independent of the company size of the responding medical device manufacturers. Product discontinuations are made throughout – regardless of whether the company has no more than nine or over 250 employees.

Question: Are you taking products off the market because of the MDR?



Response options: individual products (1), entire product lines (2), entire product range (3), not certain yet (4), no (5). The figure shows the fraction of companies that discontinued individual products (1), entire product lines (2) or their entire product range (3) in the indicated application areas.

Figure 1

One in six companies that participated in the survey is active in the "Dentistry" application area, among others. A total of 78 percent of these companies are certain that product discontinuations will take place in the dental area. This concerns entire product lines in 23 percent of these companies, individual products in 72 percent, and the entire product portfolio in four percent.

According to free-text responses, most of the discontinuations concern implants, drills, abutments and components for dental implantology. Jaw fracture plates and various special dental instruments were also mentioned several times by the responding manufacturers.

Likewise, many product discontinuations are also expected in the field of **visceral surgery**. A total of 77 percent of the companies serving the "visceral surgery" field are certain that product discontinuations will take place. These discontinuations concern entire product lines in 38 percent of cases and individual products in 62 percent of cases.

For example, discontinuations of accessories and spare parts for high-frequency surgical equipment are evident from the free-text responses. Devices can no longer be repaired or enhanced if the corresponding accessories are lacking. TIPS were also mentioned, e.g. cannulation instruments for transjugular intrahepatic portosystemic shunts. TIPS is a method of relieving excess pressure in the portal vein leading to the liver by creating a "bypass" in the liver.

Furthermore, the survey results reveal many product discontinuations in the **medical aids** field. One in ten companies responding to this survey manufactures such "aids," among other products. A total of

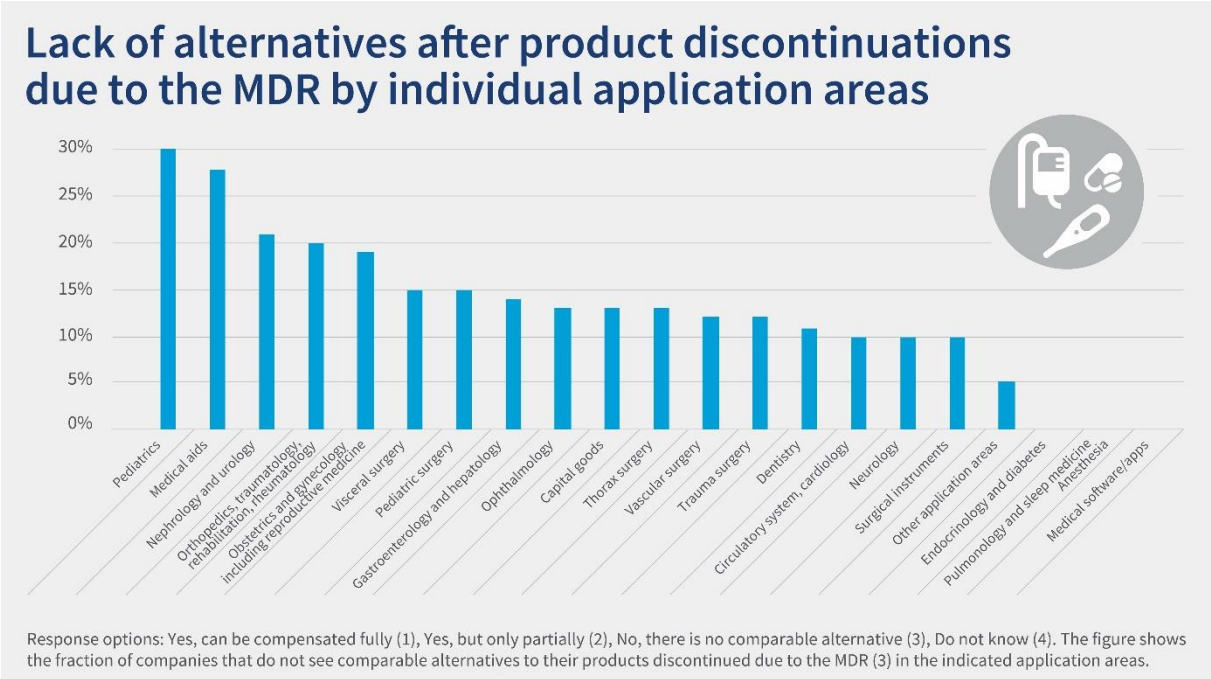
74 percent of these companies are certain that product discontinuations will take place. In 12 percent of these companies, this concerns the entire product portfolio. A total of 27 percent of these companies are discontinuing entire product lines, and 62 percent are abandoning individual products. Respiratory home therapy products, visual and hearing aids and medical care products are mentioned frequently in the free texts as products that companies will no longer market in Europe. The respondents also named therapeutic devices for home care, such as walkers or sports wheelchairs, as well as sit-to-stand beds, for example, for ALS patients, ventilated home care patients and/or people with a high level of paraplegia.

"**Surgical instruments**" is another large product group that is subject to product discontinuations. One in three companies responding in the survey manufactures surgical instruments. A total of 69 percent of these companies are certain that product discontinuations will take place. This concerns the entire product portfolio in 14 percent of these companies, whereas entire product lines and individual products are affected in 39 percent and 47 percent, respectively. According to free text responses, the discontinuations will concern, for example, instruments for special patient populations such as children, as well as other special instruments from the niche sector.

The top five of these application areas include the field of **orthopaedics, traumatology, rehabilitation, rheumatology**. About one in three surveyed companies is active in this area. A total of 68 percent of these companies are certain that product discontinuations will take place. This concerns the entire product portfolio in 12 percent of these companies, whereas entire product lines and individual products are being discontinued in 25 percent and 64 percent, respectively. Products in this application area include, for example, spinal implants and implant systems, epidural catheters for pain management, endoscopic catheters for spinal pain management, mesh finger splints or skeletal implants (screws, plates, nails, wires).

According to the manufacturers, there are no alternatives for many of the products that are being taken off the market. According to the survey results, this concerns, in particular, products in paediatrics (30 percent), followed by medical aids (28 percent), urology products (21 percent), products for orthopaedics, traumatology, rehabilitation and rheumatology (20 percent) and obstetrics/gynaecology (19 percent). Paediatric surgery (15 per cent) and cardiology (ten per cent) are also affected.

Question: Are there any alternatives to the products you are discontinuing available in the market?



Response options: Yes, can be compensated fully (1), Yes, but only partially (2), No, there is no comparable alternative (3), Do not know (4). The figure shows the fraction of companies that do not see comparable alternatives to their products discontinued due to the MDR (3) in the indicated application areas.

Figure 2

Examples of such product discontinuations without alternatives cited by respondents include baby stents or radiofrequency perforation catheters for stuck heart valves in newborns but also endoscopy products for special applications or electrostimulation devices, to name just a few examples. Often – but not always – these are niche products, i.e. products whose intended use has only a small number of applications.

4.2. Most legacy devices have not yet been transitioned to the MDR

An average of only less than ten percent of legacy devices requiring involvement of a Notified Body as part of the conformity assessment process have been certified under the MDR at the time of the survey - and only six percent of the products in the highest risk class III, which have the most comprehensive product certification requirements. This means that the vast majority of legacy devices that are to be transitioned to the new regulations by the manufacturers, have their certification in accordance with the MDR requirements by a Notified Body still pending. This concerns companies of all sizes equally.

More than half of the companies (59 percent) have indicated that they still have to submit up to ten product files by 2024 in order to actually be able to make all products planned for transition to MDR available on the market in due time according to MDR. For 22 percent of the firms, this concerns between ten and 29 files, and 13 percent of the companies still need to submit more than 30 files. Around six percent of the companies are not aware of their status.

Moreover, 40 percent of the companies indicated that existing certificates for their products are becoming invalid prematurely due to significant changes being made to these products. This concerns an average of 20 percent of these companies' legacy devices. However, it may well be that significantly more existing certificates lose their validity, as more than 60 percent of the companies responding to this question indicated that they do not yet know whether existing certificates for their products will become invalid prematurely.

4.3. Biggest problems for market access: Capacities of the Notified Bodies and duration and costs of certification

Some 66 percent of the companies stated that a lack of capacities at the Notified Body is a particular problem to them. The certification costs are another major problem for the companies. For 58 percent, this is associated with large or very large problems. This was indicated by an even higher number of 72 percent of the companies with up to 49 employees.

Question: As of today, what are your biggest challenges in the course of transitioning products to MDR?

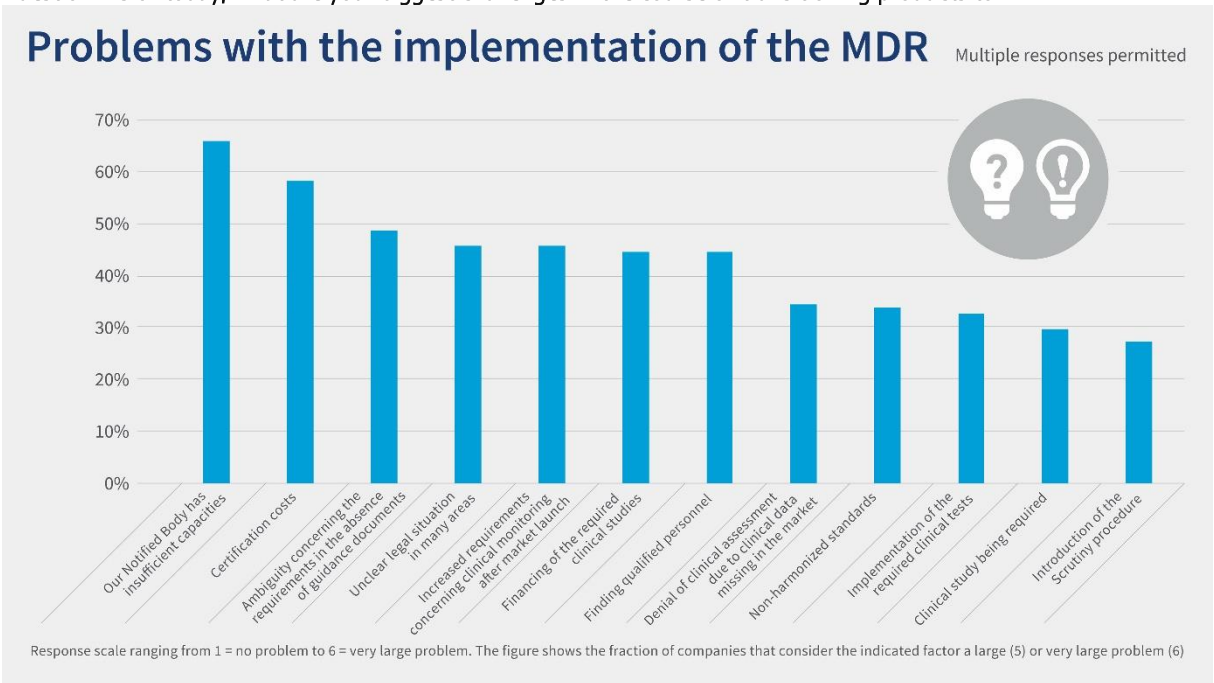


Figure 3

Significantly increased costs in the scope of the conformity assessment procedure involving a Notified Body can be seen across all risk classes (average increase of at least 38 percent), with the highest increase in risk class III where costs almost double (99 percent).

The duration of conformity assessment procedures involving a Notified Body has also increased considerably across all risk classes. On average, there has been an increase of at least 45 percent in each risk class, whereby the average increase in the duration of the conformity assessment procedure in risk class III more than doubled (101 percent).

Average increase of the duration and costs of the conformity assessment of medical devices upon involvement of a Notified Body according to the MDR as compared to MDD

Class of medical device*	Average increase of costs, in %	Average increase of duration, in %
Im	72.0	84.5
Is	38.8	45.4
Ir	84.7	77.9
IIa	73.0	77.5
IIb	82.0	82.5
III	98.5	101.5

*MDR defines different medical device classes based on the function of the devices and their potential risk for the patient. Class III is the highest risk class.

Figure 4

In addition, 59 percent of the companies indicated that they have no real planning certainty with regard to the fees (lack of cost transparency) (Figure 6). For companies with up to 49 employees, the figure is 67 percent. The background being that the total costs incurred usually cannot be deduced from the standard fees disclosed by the Notified Bodies. This means that only at a very late stage do companies have a reliable basis available to them to even be able to assess the economic viability of their products.

Some 52 percent of the responding medical device manufacturers criticize the lack of binding deadlines for the necessary assessments on the part of the Notified Bodies (Figure 6). Start-ups criticize this particularly often (71 percent).

Some 43 percent of the companies complain about late or no deadlines for product testing (Figure 6). However, 35 percent of these companies still have to submit at least ten product files by 2024 in order to actually be able to make all products planned for transition to MDR available on the market in due time according to MDR.

However, to the knowledge of the companies, binding review dates from the Notified Body are only available for an average of 54 percent of the pending product files for being able to make these products available on the market in accordance with the MDR in time before 2024. Another two percent of companies indicated that they only had deadlines beyond 2024 offered to them.

Companies also report that their current Notified Body has not yet been notified according to the MDR or that they cannot find a Notified Body in general.

4.4. Biggest difficulties in the MDR certification process: different interpretations of the MDR requirements, lack of standard file structure and existing clinical data

With regard to devices that require the involvement of a Notified Body in their conformity assessment, particularly the following difficulties in the direct processing procedure of the certification are seen by the responding manufacturers:

1. Different interpretation of MDR requirements by Notified Bodies and companies (52 percent). This concerns, in particular, class IIb manufacturers (58 percent).
2. Different expectations of auditors within a Notified Body and between different Notified Bodies regarding the standard structure for setting up the technical documentation (44 percent). This is particularly evident in Class Is (50 percent).
3. The existing clinical data is considered insufficient (43 percent). This issue concerns, in particular, class III manufacturers (53 percent).

Providing clinical data is a particular challenge for manufacturers. The rejection of the clinical evaluation by the Notified Bodies in the scope of the certification process due to a lack of clinical data is a particular issue for 35 percent of the companies (Figure 3).

Studies are needed for many legacy devices as well. Thirty percent of all companies, regardless of risk class, indicated that they will need to conduct clinical studies for legacy devices in the next five years to allow the products to still be marketed in the future. Of these, almost one in two (48 percent) companies has great difficulties in even being able to conduct the necessary clinical trials, e.g. due to a lack of investigators or negative decisions from the ethics committee. A total of 63 percent of these companies also state that financing such studies is quite a strain on them. Nearly 30 percent of all companies do not yet know whether or not they will have to conduct studies for existing products. Consequently, the burden on trial centres and clinics cannot yet be assessed conclusively.

Question: Which of the following difficulties were / are particularly evident to you during the MDR certification process?

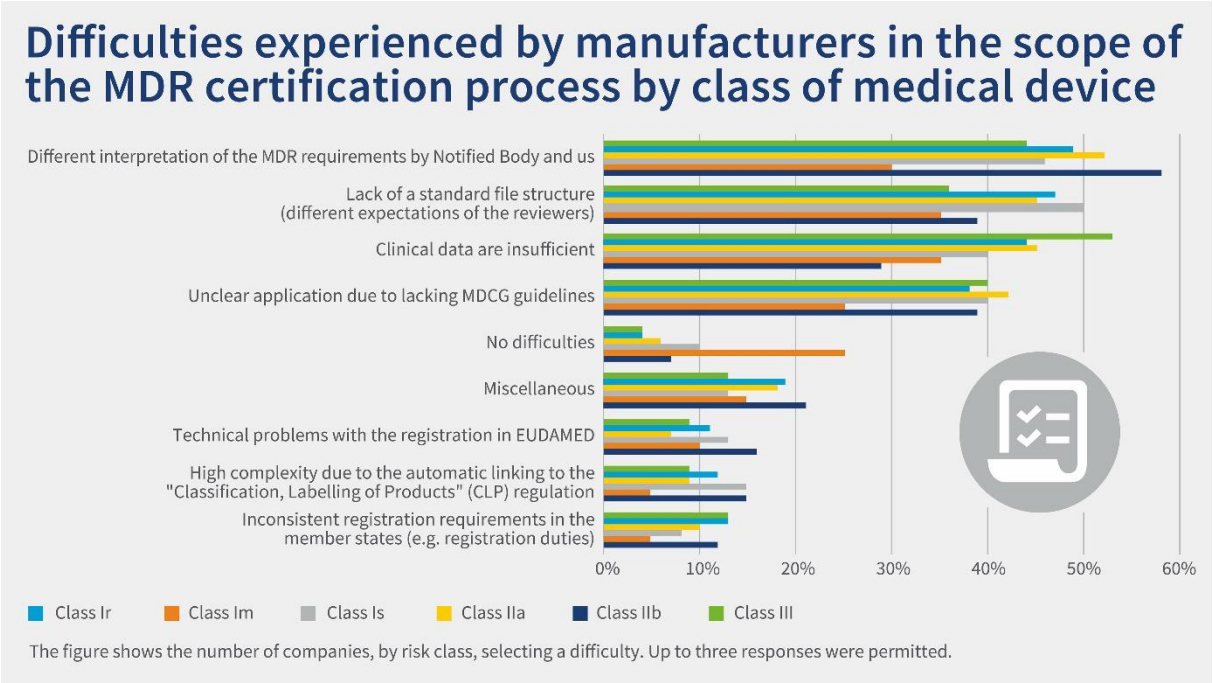


Figure 5

Across all risk classes, 46 percent of companies report different interpretations of identical MDR requirements by different Notified Bodies (Figure 6). According to the free-text responses of the survey respondents, ambiguous interpretation also extends to different demands being made by the Notified Body and the authority, which are often not in agreement. Uncertainties within Notified Bodies with regard to their own new processes are also mentioned in the free text. Accordingly, time and again reviewers from the same Notified Body hold different views. In all cases, such differences in interpretation lead to time losses,

uncertainties and further cost increases due to the increased workload and time expenditure experienced by the companies.

Question: What challenges does your company face in working with Notified Bodies?

Figure 6

4.5. Companies indicate further major challenges and problems: Legal uncertainties, shortage of skilled workers, and clinical surveillance

Separate from the challenges in the work with Notified Bodies, the companies face a variety of other problems. For example, 45 percent of the companies experience major difficulties in finding qualified personnel for implementation of the increased regulatory requirements (Figure 3). In addition, the legal situation being ambiguous in many areas poses major challenges for 46 percent of companies. In particular, respondents take issue with many standards not yet being harmonized under the MDR (34 percent). The increased post-market surveillance requirements are also particularly difficult for 46 percent of the companies. Moreover, 27 percent of the companies report major difficulties in introducing the Scrutiny procedure – an additional testing procedure at EU level for specific medical devices of higher risk classes (Figure 3).

In addition, the following issues are mentioned several times in the free text:

- The creation and reorganization of content of product files (technical documentation) as well as a lack of internal resources for file processing.
- Difficulty with obtaining necessary data and information from suppliers for the technical documentation of the products.
- The requirements concerning the usability and documentation of software developments.
- The fact that the common specifications to be drawn up by the European Commission for certain products, which have no medical purpose, but resemble medical devices, are still not available. These are the basis for the conformity assessment of these products. Until they are available, no applications for certification are accepted by the Notified Bodies.

However, even without involvement of a Notified Body, companies are facing major challenges: More than half of the companies responding to this survey also have risk class I products in their product portfolio and at least some of these are already on the market in accordance with the new requirements. In order to place products in this risk class on the market, the involvement of a Notified Body for the conformity assessment procedure is not required but companies can declare conformity with the MDR requirements

independently. This risk class includes, e.g., wheelchairs and nursing beds. According to the results, the greatest challenges in implementing the new requirements are the preparation of the technical documentation (57 percent) and the clinical evaluation (56 percent).

Also for 45 percent of the manufacturers of class I devices, the post-market surveillance requirements pose major challenges for the companies.

4.6. Almost every other company puts innovation projects on hold

A total of 83 per cent of the responding companies indicate that they have not yet certified innovative new products according to MDR.

The MDR has a considerable impact on the innovation activities of companies. Accordingly, innovation projects are on hold due to the MDR in almost every other company (46 percent). In the field of paediatrics, this concerns as many as 74 percent of the companies. The figures are also very high for paediatric surgery (67 percent) and pneumonology, anaesthesia and intensive care medicine (62 percent).

Some 13 percent of all companies are reducing their research and development budgets.

A total of 43 percent of companies are no longer making any changes or optimizations to legacy devices as a result of the MDR. This is the case because so-called step innovations on legacy devices can lead to their existing certificates becoming invalid prematurely. Previous certificates being valid always presupposes that no circumstance has arisen that is to be classified as a "significant change" – this includes, e.g., a change in the intended purpose of the product, such as new indications or new user groups.

A total of 19 percent of the companies are currently working on innovations, but intend to have them certified in other markets first due to the MDR. In the free-text answers, it is often stated that future product certifications are primarily envisaged in the USA or Asia. Moreover, five percent of the companies indicated that they are planning to relocate their R&D department abroad in the medium to long term due to the MDR.

More than half of the companies (51 percent) indicated that they expect a delay in the launch of their company's innovative medical devices in Europe due to the MDR. A total of 80 percent of the companies required to conduct clinical trials for innovative products expect a delay in the introduction of their products in Europe. Some 65 percent of them envision average delays in excess of 12 months in this context.

4.7. A special case – custom-made devices: Difficulties especially in clinical evaluation and post-market surveillance

The new requirements place obligations not only on manufacturers of industrially manufactured medical devices, but also on manufacturers of custom-made devices, such as medical supply stores. A custom-made device is a product that is specifically made in accordance with a written prescription, such as patient-specific prostheses. Nearly 80 percent of custom-made device manufacturers have indicated that clinical evaluation and post-market surveillance are difficult to implement. Also custom-made devices must undergo evaluation, which requires, for example, a critical examination of the relevant current scientific literature on the safety, performance, design characteristics, and intended use of the device. The mandatory risk management system presents difficulties in practice for half of the companies. The companies need to establish an appropriate system that requires updating throughout the entire life cycle of a product. Moreover, the post-market surveillance of the product is associated with difficulties for 46 percent of the companies. Manufacturers must plan, establish, document, apply and keep up to date a post-market surveillance system for each product.

5. Methodology

This survey by the Association of German Chambers of Commerce and Industry (DIHK), MedicalMountains GmbH and SPECTARIS was designed to gather data on various aspects related to the implementation of the MDR six months after the MDR came into force, providing insights into the difficulties and impact of the new EU regulation. Only manufacturers of industrial medical devices or custom-made devices were surveyed.

DIHK made the anonymous survey available to the 79 chambers of industry and commerce (IHKs), which in turn were able to send an Internet link to the online survey to their member companies. SPECTARIS and MedicalMountains GmbH in turn informed their member companies or networks. A total of 378 companies responded and completed the questionnaire in full or in part.[12]

The participating companies are active in different product areas and application fields. Nearly 30 percent of the companies surveyed manufacture surgical instruments. A total of 28 percent of the companies are active in the field of "orthopaedics, traumatology, rehabilitation, rheumatology." Another 17 percent are active in dentistry and 13 percent in ophthalmology. Ten percent of the companies indicated that they produce medical aids (e.g., respiratory home therapy, visual or hearing aids, medical care aids, etc.). Another nine percent produce capital goods (e.g. hospital and nursing beds, large and small sterilizers, imaging equipment).

Almost half of the participating companies are from Baden-Wuerttemberg, where large clusters of medical device companies reside. There were many respondents from Bavaria (13 percent) and NRW (12 percent) as well. Around four percent of the companies each reside in Berlin, Hesse, Schleswig-Holstein and Thuringia.

The responses can be broken down by company size as follows: Almost 80 percent of the companies have fewer than 249 employees, and more than half have fewer than 50 employees. A total of 19 companies classify their company as a start-up.

With regard to the products made by the surveyed companies, all possible risk classes of medical devices according to MDR are represented: Some 36.5 percent have Class I products in their product portfolio. Class IIa medical devices are the most common, at 64.3 percent, followed by Class IIb products at 47 percent. Class III products are being manufactured by 19.3 percent of the respondents.

The survey was conducted in December 2021 and January 2022 and the analysis was done from February to April 2022.

[12] In Germany, 1,446 companies with more than 20 employees each are active in the medical technology sector. (EUROSTAT, SPECTARIS from SPECTARIS Yearbook Medical Technology 2021/22) Note: excluding custom manufacturers of medical devices.