Current assessment of the German medical device manufacturers on the effects of the EU Medical Device Regulation (MDR)

Unresolved problems weaken Germany and the EU as health and innovation locations

DIHK Deutsche Industrie- und Handelskammer
German Chamber of Commerce and Industry

MedicalMountains

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

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Results of a nationwide company survey by the German Chamber of Commerce and Industry (DIHK), the MedicalMountains cluster initiative, and the German industry association SPECTARIS.

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1. Introduction

Healthcare in Germany and the EU depends on safe, efficient medical devices that are available on the market. There are around 500,000 types of medical devices and in-vitro diagnostics available on the EU internal market.[1] Medical devices include products such as bandages, medical aids, surgical instruments, medical software, endoscopes, implants, pacemakers, hip prostheses, or devices for diagnostics (e.g., X-ray machines) and intensive care medicine (e.g., ventilators) – to name just a few.

The prerequisite for medical devices to be allowed onto the market in Germany and the EU is a CE mark. Manufacturers must, among other things, provide evidence that their products meet basic safety and performance requirements (conformity). The applicable law is Regulation (EU) 2017/745 on medical devices[2] (Medical Device Regulation; MDR), which has been mandatory for manufacturers of medical devices in the EU and Germany since May 26, 2021.

The objectives of the MDR are correct and important. It aims to create a solid, transparent, predictable, and sustainable legal framework for medical devices that ensures a high level of safety and health protection. At the same time, it should promote innovation and – based on a high level of health protection for patients and users – ensure a smoothly functioning internal market for medical devices, considering the small and medium-sized companies operating in this sector.

The realization and implementation of the new legal requirements have been a major challenge since the beginning for all those involved. On the one hand, there are significantly more detailed requirements for processes and documentation in numerous areas. On the other hand, structural problems in the implementation of the regulation make a functioning MDR system difficult.

This system also includes, among other things, the state-authorized "Notified Bodies," which control the process of conformity assessment of medical devices by manufacturers. At the time of the survey, between June and August 2023, 39 of the previously 59 Notified Bodies across the EU had been designated for the certification of products under the MDR. Today, there are 41 (as of November 24, 2023).

Not all medical devices require the involvement of a Notified Body for their conformity assessment procedure. Medical devices in pure risk class I with a low risk for the patient (e.g., bandages) are exempt from this. However, under the MDR, significantly more product groups (e.g., reusable surgical instruments or medical software) must be tested by a Notified Body than was the case under the previous directives.

The limited available capacities at the Notified Bodies have become a critical bottleneck in the implementation of the MDR. Due to the foreseeable situation that thousands of certificates could not have been issued in accordance with the MDR in time for May 26, 2024, and additional feedback on imminent shortages in the availability of medical devices, new transitional provisions for the MDR came into force in mid-March 2023 with Regulation (EU) 2023/607[3]. With this regulation, the transitional provisions for certain medical devices were adjusted so that they can still be placed on the market or put into operation beyond May 2024[4] in compliance with the previous directives 93/42/EEC[5] on medical devices and 90/385/EEC[6].

[1] https://health.ec.europa.eu/medical-devices-sector/overview_en

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0607

[4] The amending Regulation (EU) 2023/607 provides that certain MDD certificates have the following extended validity:
- Until May 26, 2026 Class III custom-made implantable devices
- Until December 31, 2027 Class III and Class IIb implantable devices (with the exception of sutures, staples, fillings, braces, dental crowns, screws, wedges, dental or bone plates, wires, pins, clamps and connectors)
- Until December 31, 2028 Products in classes IIa, IIb, Is and Im.
- Until December 31, 2028 Class I devices under the directives that have been classified higher by the MDR and therefore require the involvement of a notified body in the conformity assessment process (e.g. reusable surgical instruments class Ir)

In the present nationwide survey by the German Chamber of Commerce and Industry (DIHK), MedicalMountains GmbH, and the industrial association SPECTARIS, German manufacturers of medical devices were asked about numerous individual aspects in the course of implementing the MDR two years after the MDR came into force and almost half a year after the new transitional provisions came into force. The survey results provide answers to questions such as: What central problem areas currently exist in the implementation of the regulation? How does the MDR affect innovation in the industry? Will tried-and-tested medical devices be removed from the EU market so that they are no longer available for healthcare?

The main results are summarized in Chapter 2. In Chapter 3, these are explained in more detail with graphics and additional results. Chapter 4, "Methodology" provides information about the way the survey was performed and the participants.

Even though the survey results come mainly from Germany, they can be understood as a trend for the entire medical device industry in the EU: German companies account for around 50 percent of the industry's turnover in the EU[7].

- These time limit extensions for manufacturers of medical devices only apply if certain conditions are met in accordance with the amending regulation.

[5] Council Directive 93/42/EEC of June 14, 1993 concerning medical devices

[6] Council Directive 90/385/EEC of June 20, 1990 on the approximation of the laws of the Member States relating to active implantable medical devices

[7] Turnover in 2020 including small businesses. No figures available for Ireland and Malta. Source: Eurostat.

2. Key results

The survey results highlight that the implementation of the MDR has resulted in a complex and costly environment for medical device manufacturers to bring products to the EU market. This is reflected in the high expenditure of time and money for both established existing products and innovative new developments. Companies are also confronted with structural obstacles that they cannot solve on their own. The consequences of these challenges are diverse and range from companies stopping products to negative effects on innovation in the industry. This affects the availability of both proven and innovative products in the EU healthcare market.

2.1 Numerous medical devices are being withdrawn from the EU market due to the MDR

The survey results show a significant decline in the diversity of existing and niche products in the EU.

Across all 21 application areas and product groups surveyed, 53 percent of all product ranges have at least partially discontinued sales of products in the EU.

In this context, product ranges with “at least partial discontinuation” of sales mean that individual products (34 percent), entire product lines (13 percent), or even complete ranges (6 percent) are discontinued – a total of 53 percent.

Surgical instruments are particularly affected by discontinuations (70 percent[8]). Examples mentioned in the comments areas are surgical microinstruments such as scissors, needle holders, or tweezers. In addition, dentistry with 67 percent (e.g., orthodontic brackets and archwires), pulmonology and sleep medicine, anesthesia, intensive care medicine with 63 percent (e.g., ventilation stands, emergency ventilators and sleep diagnostic devices), thoracic surgery with 60 percent (e.g. high-frequency scissor clamps and scissor clamps), traumatology and accident surgery with 58 percent (e.g. bone plates and bone screws for osteosynthesis, endoscopes and instruments with special dimensions, oral and maxillofacial surgery implants) and radiology with 58 percent were heavily affected by product stops.

Many of the medical devices discontinued in the EU remain available to users and patients outside the EU. 58 percent of companies that discontinue products in the EU continue to sell them in countries outside the EU. The USA is at the forefront with a share of 59 percent.

According to the participating companies, in almost 20 percent of cases, there are no equivalent alternatives for the discontinued products on the market.

This means that one in five discontinued products is no longer available for patient care in the EU or is not of equivalent quality. According to survey results, another 45 percent of medical devices cannot be fully compensated for. According to the manufacturers, only 36 percent of the products discontinued because of the MDR can be fully compensated for and are generally still available for patient care. However, this assumes that competitors' products are also not discontinued and that they can compensate for market demand through increased production.

The application areas with the highest proportion of non-compensable products are medical software and apps (57 percent[9] [10]), products for the circulatory system and cardiology (33 percent), for neurology and neurosurgery (31 percent), and for pediatrics (pediatric surgery, pediatric cardiology, pediatrics) (29 percent). A well-known example of non-compensable products is heart biopsy forceps specially developed for children[11], which enable tissue samples to be gently removed from the

[8] 70 percent of companies that manufacture surgical instruments withdraw at least individual products from the EU market.

[9] 57 percent of companies active in the field of medical software and apps that are withdrawing at least one product from the market have stated that their product discontinuation cannot be compensated by competitors.

[10] Medical software is subject to a higher classification in the MDR and the increased requirements associated with it. Due to very individual product solutions, discontinued products are in particular without alternative.

[11] https://www.awmf.org/service/awmf-aktuell/default-621339d7bddc2836aa3ee72e8e84d4e7-11

heart after a heart transplant to detect a rejection reaction. Another example is baby stents.

Among niche products, the proportion of non-compensable products is particularly high at 38 percent.

Niche products are defined in the survey as products whose intended purpose is associated with a small number of use cases. The small number of use cases is due in particular to rare diseases, certain stages of the disease, age groups (especially in children), specific conditions (e.g., pregnancy), or physical characteristics (e.g., body size, disabilities), each alone or in combination.

Some product examples mentioned by the companies, such as cardiac catheters for newborns and children or neurosurgical instruments for brain operations, can be classified as niche products.

The main reasons for product discontinuation in the EU are certification costs (91 percent) and bureaucracy (74 percent).

But other reasons, such as a personnel/skilled labor shortage in their own company (28 percent), the fact that required supplier products have been discontinued due to the MDR (27 percent), and planning and legal uncertainties (16 percent) also cause companies to discontinue products in the EU.

2.2 Germany and the EU are being weakened as locations for innovation– and with it the entire region's strengths in research and health

The results show that the MDR has a negative impact on the industry's innovative strength and the availability of innovative medical devices.

77 percent of the responding companies reported negative effects of the MDR on their innovation activities.

More than half (54 percent) of the companies that report negative impacts say that their innovation projects are completely on hold. Here, the values are particularly high in ophthalmology (70 percent), visceral surgery, obstetrics, and gynecology, including reproductive medicine (64 percent each). In addition to the suspension of development projects, more than half of the negatively affected manufacturers (54 percent) are no longer making any changes or optimizations to existing products. Surgical instruments are particularly affected here (62 percent). If innovations are still being developed, they are often only available to care with a very long delay. 57 percent of companies that reported negative impacts on their innovation activities expect a delay of more than 12 months to introduce new medical devices into the EU market.

At 88 percent, the USA is the preferred market for initial approvals of innovations.

28 percent of the companies that report negative impacts are working on innovations but are not planning their initial approval in the EU, but rather are planning to introduce them in the USA. One reason is that the approval process in the USA offers companies more planning security. This applies not only to the costs and processing times involved but also to the specific regulatory requirements.

Initial approvals of innovations outside the EU also have an impact on the EU as a research location.

26 percent of companies planning initial approval outside the EU stated that they would relocate their R&D departments to countries outside the EU in the medium to long term – significantly more than the companies as a whole (11 percent). Initial approval of innovations outside the EU, therefore not only weakens the EU as a center of health innovation but also as a research location – because research and development tends to take place in the country in which the initial approval takes place. This applies equally to research and development in companies as well as associated infrastructure, such as the implementation of clinical studies and tests.

86 percent of responding companies must conduct at least one clinical trial within the next five years. This applies to both studies for innovative products, with a share of 79 percent of the companies affected, as well as studies for numerous existing products, with a share of 54 percent of these companies. The demand for studies for existing products is primarily due to higher classifications of products under the MDR and the elimination of the equivalence principle for numerous medical devices due to the MDR. Under the previous guidelines, manufacturers were able to use existing clinical data from another manufacturer based on the

equivalence principle. This method is no longer possible for many products. Existing data will no longer be accepted, and separate clinical studies must be performed.

According to the manufacturers, 70 percent of all required clinical studies will not be performed or only partially performed in the EU. In addition to the initial approvals outside the EU, the main reasons are the high costs of conducting studies (60 percent), long study durations (60 percent), and restrictive data protection (42 percent). Companies that do not conduct their clinical trials in the EU mainly choose the USA, India, and Europe outside the EU.

2.3 The big problems remain: high costs, long process times and difficulties in working with Notified Bodies

The implementation of the MDR continues to represent a significant challenge for companies. Only 3 percent of all companies say they have no problems with implementation. The three biggest challenges are the effort required to adapt the technical documentation (67 percent), the certification costs (59 percent), and the high complexity caused by the link of the MDR to other regulations, directives, and/or MDCG guidelines (58 percent).

The survey took a closer look at certification costs.

On average, the cost of creating technical documentation has increased by 111 percent.

This includes internal personnel costs as well as external expenses, for example for laboratory services, clinical assessments, or studies. For 66 percent of all companies, these costs have increased by more than 50 per cent. Of these companies, 23 percent indicate an increase of up to 100 percent, 22 per cent an increase of up to 200 percent and 21 percent a cost increase of more than 200 percent. The increase in documentation costs extends across all risk classes, although it is significantly greater in the higher risk classes.

For companies that have to involve a Notified Body in the certification process, the costs for certification by the Notified Body have increased by an average of 124 percent compared to the old directives.

For 73 per cent of all companies, these have risen by more than 50 percent. Of these, 22 percent say that costs have increased by up to 100 percent, while 27 percent report an increase of up to 200 percent. For 24 percent of companies, the increase is even more than 200 percent. The increase in certification costs by the Notified Bodies also extends across all risk classes but is also greater in the higher risk classes.

Along with the costs, the average duration of the procedure when involving a Notified Body also increases by 150 per cent.

The average duration of conformity assessment procedures under the MDR - from the submission of the application for certification to the issuance of the certificate by the Notified Body - has increased by more than half for around 83 percent of all companies compared to the procedure under the old directives. Over 62 percent of companies report an increase in the duration of the procedure by at least double, while 37 percent of companies even report an increase of over 200 percent.

Over 90 percent of companies also see the necessary cooperation in the conformity assessment process with the Notified Bodies as problematic.

In particular, the lack of capacity at the Notified Bodies (73 percent), their high certification costs (59 percent), and the different interpretation of the MDR requirements by Notified Bodies and companies (47 percent) are cited as problems.

2.4 Deficits in digitalization make companies' work even more difficult

The survey highlights significant potential for the further development of digital processes in collaboration with Notified Bodies and state authorities in order to increase the efficiency of the entire system. 76 percent of companies state that the certification process at the responsible Notified Body cannot be completed digitally or only in parts. The cooperation with the state authorities is even worse: for 89 percent of companies, necessary processes such as registrations or applications for free trade certificates cannot or can only partially be processed digitally. Expanding digitalization in these areas could lead to significant resource conservation for everyone involved – be it in terms of time, personnel, or paper – and thus

also contribute to financial savings. In addition, the survey participants would like to use the potential of digitalization to enable faster market access in the EU.

2.5 Small companies are particularly affected by the effects of the MDR

The recitals of the MDR expressly mention that the interests of small and medium-sized companies must be taken into account. However, the survey results show a different picture.

It is mainly smaller companies that stop selling their products in the EU. Of the micro-enterprises with up to 9 employees, 67 percent stated that they were withdrawing at least one product from the market. For larger companies with more than 250 employees, this affects “only” 48 percent. It is also the small companies that are mainly bringing niche products to the market, according to the survey results. 65 percent of manufacturers with up to 9 employees state that the products they sell are niche products. For companies with 10 to 49 employees, this proportion is 47 percent. In companies with up to 249 employees, 30 percent of the products discontinued are niche products.

The main reason for product discontinuations – as already described under 2.1 – is the certification costs with a total of 91 percent. However, among micro-enterprises with up to 9 employees, all companies (100 percent) indicate this reason. For comparison: among companies with more than 250 employees, 84 percent of companies stated this to be the problem.

If the cost situation does not change, not only numerous (niche) products from small companies but also many small companies themselves will disappear from the EU market.

3. The results in detail

3.1 Manufacturers are withdrawing numerous medical devices from the EU market in all areas of application

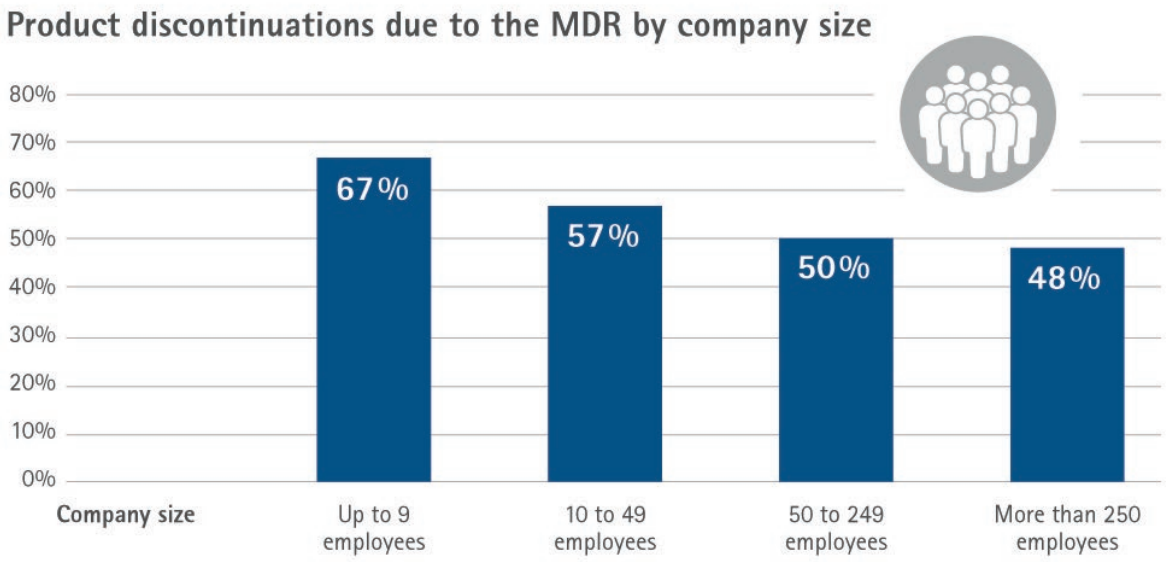
Across all 21 application areas and product groups surveyed, 53 percent of all product ranges have at least partially discontinued sales of products in the EU. In this context, product ranges with "at least partial discontinuation" of sales mean that individual products (34 percent), entire product lines (13 percent), or complete ranges (6 percent) are discontinued. For almost 10 percent of the manufacturers in the survey, a decision on whether to continue or discontinue further products is still pending. Without exception, all 21 application areas or product groups queried are affected by product discontinuations. However, the product group with the highest proportion of discontinued products is surgical instruments. Here, 70 percent of the companies that produce such products state that they are withdrawing at least some products from the EU market. In dentistry, it is 67 percent, in pulmonology and sleep medicine, anesthesia, and intensive care medicine 63 percent, in thoracic surgery 60 percent, in traumatology and accident surgery 58 percent and in radiology 58 percent of the medical device manufacturers active in the EU market.

Application area / product group	At least partial discontinuation of distribution
Surgical instruments	70%
Dentistry	67%
Pneumology and sleep medicine, anesthesia, intensive care medicine	63%
Thoracic surgery	60%
Traumatology, Trauma Surgery	58%
Radiology	58%
Neurology and neurosurgery	56%
Obstetrics and Gynecology, including Reproductive Medicine	53%
Orthopedics, rehabilitation, rheumatology	52%
Gastroenterology and Hepatology	52%
Vascular surgery	51%
Circulatory system, cardiology	50%
Pediatrics (pediatric surgery, pediatric cardiology, pediatrics, etc.)	47%
Nephrology and urology	47%
Visceral surgery	46%
Ophthalmology	40%
Medical software/apps	30%
Investment goods (e.g., beds, sterilizers, devices)	30%
Endocrinology and diabetes	25%
Medical supplies	25%
Digital health or care application (DIGA/DIPA)	11%

The table shows the proportion of the individual areas of application / product groups in which companies discontinue individual products (1), entire product lines (2) or complete product ranges (3).

Figure 1

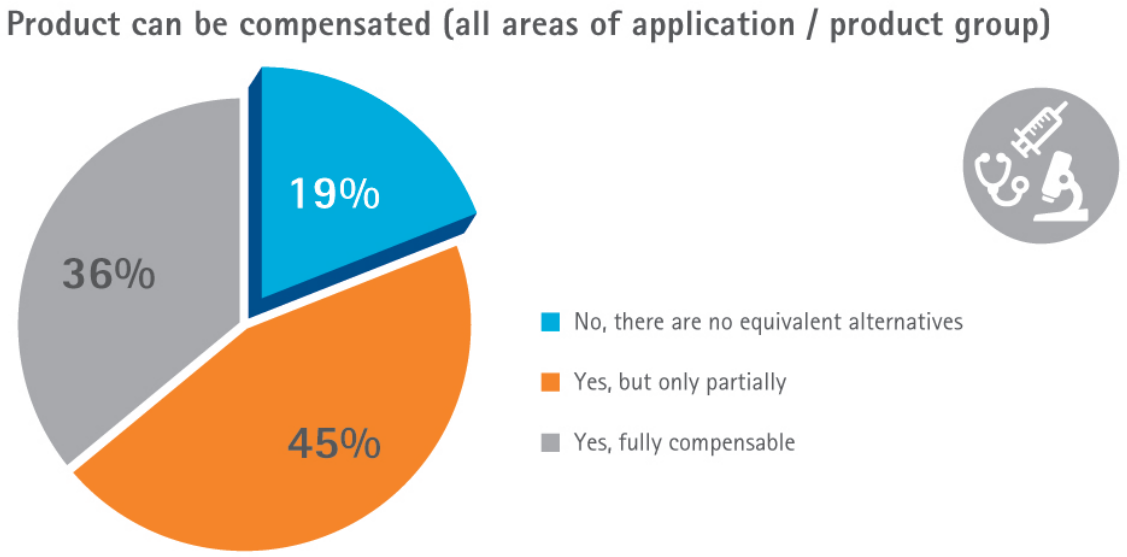
Above all, small companies are stopping sales of their products in the EU due to the MDR. Two-thirds (67 percent) of small companies with up to 9 employees report product discontinuations. However, almost half (47 percent) of larger companies with more than 250 employees also made the decision to withdraw products from the EU market as a result of the MDR.



The chart shows the proportion of product ranges in the companies in which individual products (1), entire product lines (2) or complete product ranges (3) are discontinued.

Figure 2

In almost 20 percent of cases, according to the participating companies, the products listed have no alternative or are not available on the EU market in equivalent quality. According to survey results, another 64 percent cannot be fully compensated for. This means that only 36 percent of the products that are discontinued on the EU market due to the MDR can, according to the manufacturer, be fully compensated for by competitors' products and are still available for patient care.



The data refer to companies that have discontinued products in at least one application area / product group.

Figure 3

The product group with the highest proportion of non-compensable products is medical software and apps. Here, 57 percent of the companies that are active in this area and are withdrawing at least one product from the market stated that their product discontinuations cannot be compensated for by the competition. This is followed by non-compensable discontinued products for the circulatory system and cardiology (33 percent), for neurology and neurosurgery (31 percent), and for pediatrics (pediatric surgery, pediatric cardiology, pediatrics) with 29 percent.

Application area / product group	Non-compensable
Medical Software / Apps	57%
Circulatory system, cardiology	33%
Neurology and Neurosurgery	31%
Pediatrics (pediatric surgery, pediatric cardiology, pediatrics, etc.)	29%
Thoracic surgery	26%
Traumatology, trauma surgery	25%
Visceral surgery	22%
Vascular surgery	21%
Pneumology and sleep medicine, anesthesia, intensive care medicine	20%
Radiology	20%
Orthopedics, rehabilitation, rheumatology	18%
Obstetrics and gynecology, including reproductive medicine	13%
Ophthalmology	13%
Surgical instruments	12%
Nephrology and urology	11%
Dentistry	9%
Gastroenterology and hepatology	7%

The information relates to the companies that have discontinued products in the respective application area / product group.

Figure 4

When it comes to niche products[12], the proportion of non-compensable products is particularly high at 38 percent. The survey results also show that niche products are more likely to be sold by small companies. 65 percent of manufacturers with up to 9 employees state that the products they sell are niche products. For companies with 10 to 49 employees, this proportion is 47 percent. For companies with up to 249 employees, 30 percent of the products discontinued are niche products, and for companies with more than 250 employees, 35 percent are.

The main reasons that lead companies to give up selling medical devices on the EU market are, at 91 percent, the high certification costs, according to MDR. This leads to the products being unprofitable, and 74 percent are deterred by bureaucratic effort. But other reasons, such as a personnel/skilled labor shortage in their own company (28 percent), the fact that required supplier products have been discontinued due to the MDR (27 percent), and planning and legal uncertainties (16 percent) also cause companies to discontinue products in the EU. Reasons added in the free text are problems with the Notified Body, missing clinical data, and difficulties due to missing documents for supplier products.

[12] In the survey, we define niche products as products whose intended use is associated with a small number of applications. The low number of use cases is due in particular to rare diseases, certain disease stages, age groups (especially in children), specific conditions (e.g. pregnancy) or physical characteristics (e.g. body size, disabilities), in each case alone or in combination. Other applications of a similar nature are possible.

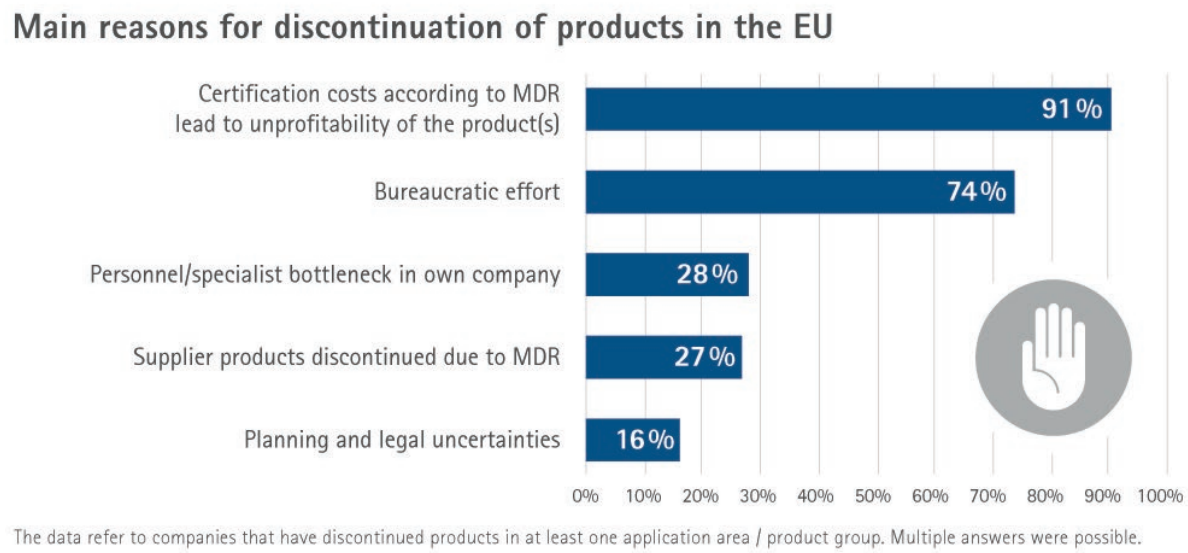


Figure 5

There are differences depending on company size in the 91 percent of companies that cite certification costs as the main reason for discontinuing products. All micro-enterprises surveyed (100 percent) stated that the high certification costs lead to the unprofitability of products and thus their withdrawal from the EU market. This applies to 84 percent of companies with more than 250 employees.

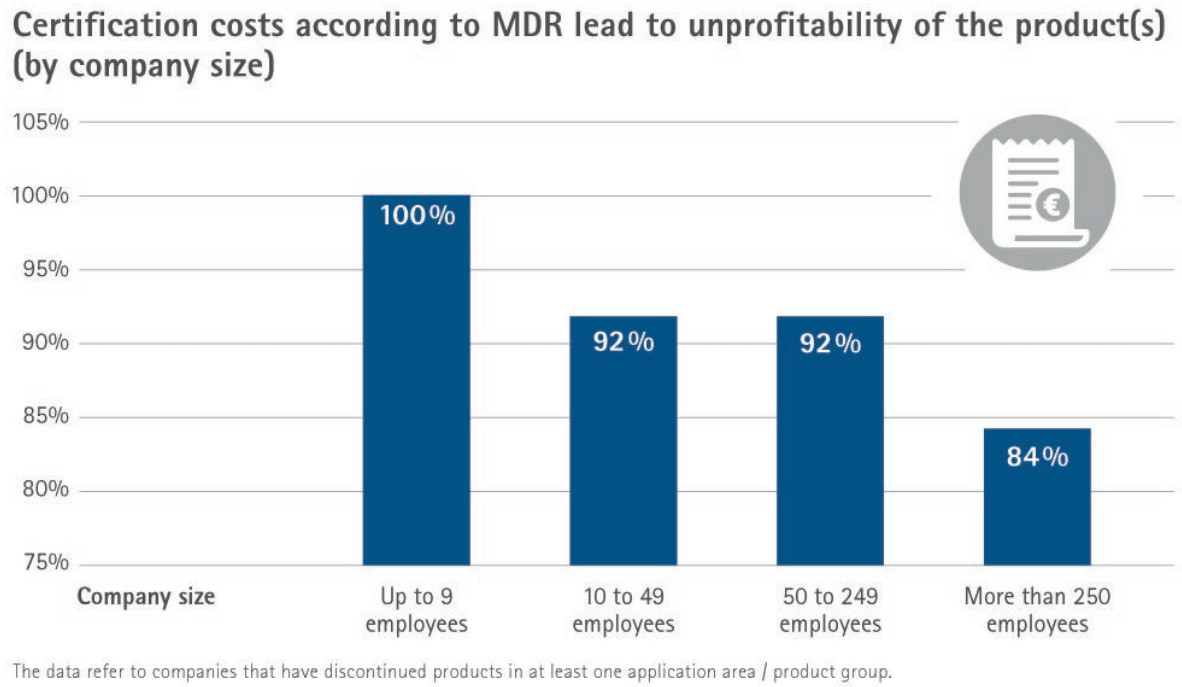


Figure 6

In many cases, users and patients outside the EU continue to benefit from medical devices discontinued in the EU. 58 percent of companies that discontinue their products in the EU continue to sell these products in countries outside the EU. The USA is at the forefront with a share of 59 percent, followed by Europe outside the EU with 52 percent. Also, in China (34 percent), India (31 percent) and Japan (29 percent), the medical devices are still in use. Other popular markets include Saudi

Arabia (26 percent), Turkey (25 percent), Russia (20 percent), Canada (20 percent), Australia (16 percent) and South Korea (11 percent). The manufacturers also specified South America, Africa, and other Asian countries.

3.2 A majority of companies report negative effects of the MDR on innovation

77 percent of the responding companies stated that the MDR had a negative impact on their innovation activities. 22 percent do not see their innovation activities being influenced. Only 2 percent see the MDR as having a positive impact on the topic of innovation.

More than half (54 percent) of the companies that report negative impacts on their innovation activities have innovation projects on hold. In addition to the suspension of development projects, more than half of the negatively affected manufacturers (54 percent) are no longer making any changes or optimizations to existing products, especially surgical instruments. The reason is that so-called step-by-step innovations in existing products can lead to old certificates becoming invalid prematurely and a completely new certification being necessary. The validity of old certificates always requires that no circumstance arises that can be classified as a "significant change" – this also includes, for example, a changed intended purpose of the product, such as new indications or new user groups. Comments from those surveyed state that further developments of existing products are technically possible and desirable, but only with a disproportionately high regulatory effort.

Where innovations are still being developed, they are often only available to care with a very long delay. 57 percent of companies that report negative impacts on their innovative activities expect a delay of more than 12 months to introduce innovative and advanced medical devices into the EU market. This particularly affects the following areas of application: traumatology, accident surgery (70 percent[13]), pulmonology and sleep medicine, anesthesia, intensive care medicine (70 percent), gastroenterology and hepatology (69 percent), circulatory system, cardiology (69 percent), neurology and neurosurgery (68 percent), thoracic surgery (68 percent) as well nephrology and urology (68 percent).

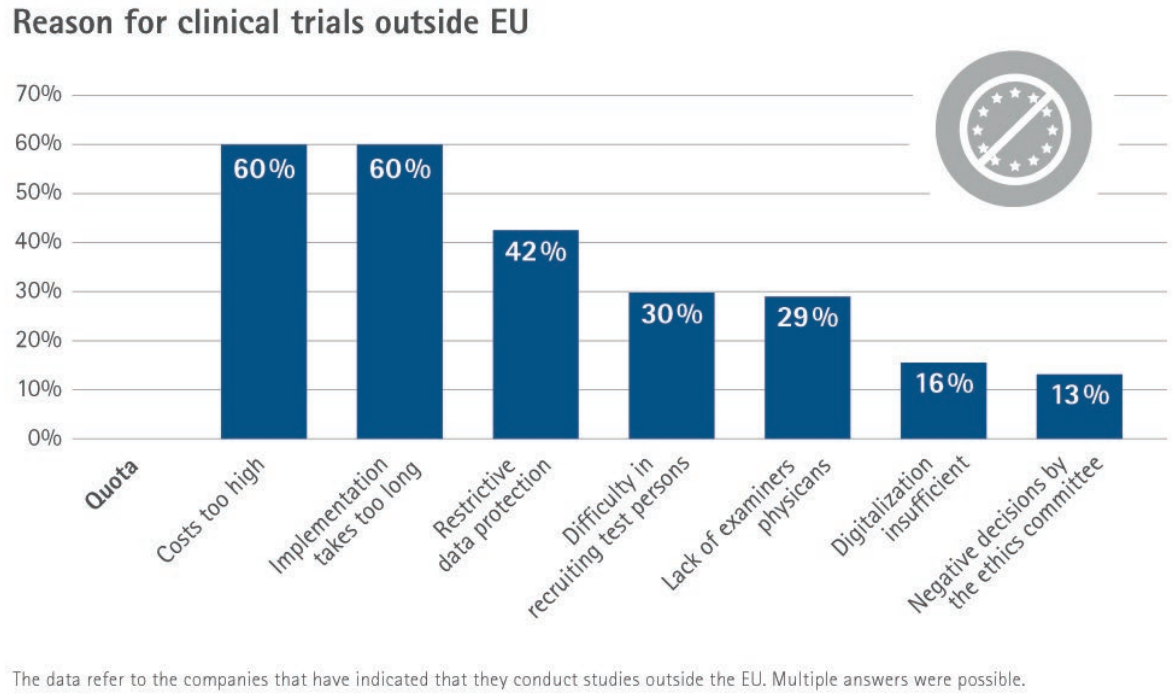
28 percent of companies that report negative effects of the MDR on their innovation activities also say that they are working on innovations but are not planning initial approval in the EU. The USA, in particular, is named by 88 percent of these companies as a market for initial registration, followed by Europe outside the EU (26 percent) and China (22 percent). Many reasons are given in the comments – particularly concerning the USA. In addition to faster approval procedures and an overall better ratio of costs and effort in relation to sales potential in the USA, many companies also mention planning security. The approval process in the USA is generally described as more predictable. This applies not only to the costs and processing times involved but also to the regulatory requirements, which are clearer when compared to the EU.

Initial approvals of innovations outside the EU also have an impact on the EU as a research location. 26 percent of companies planning initial approval outside the EU state that they will relocate their R&D departments to countries outside the EU in the medium to long term – significantly more than the companies as a whole (11 percent). Initial approval of innovations outside the EU, therefore, weakens the EU not only as a health location but also as a research location because research and development tend to take place in the country in which initial approvals take place. This applies equally to research and development in the company as well as the associated infrastructure, such as the implementation of clinical studies and tests.

86 percent of companies must conduct at least one clinical study within the next five years for approval of their products. 79 percent of the affected companies have to carry out such studies for innovative products, and 54 percent of the affected companies for existing products. The survey results now show that, according to manufacturers, 70 percent of the required clinical studies are not performed or only partially performed in the EU. The reason for this migration is not only the increasing number of first-time registrations outside the EU but also, in particular, high study costs (60 percent) and long study times (60 percent). The

[13] 70 percent of companies operating in the field of traumatology and trauma surgery have stated that they expect a delay of more than 12 months.

latter also includes the long procedural process - e.g., waiting for the necessary assessment by ethics committees and appeal procedures for any negative decisions. Other reasons cited for conducting clinical studies outside the EU include restrictive data protection within the EU (42 percent), difficult recruitment of test subjects (30 percent), a lack of investigators (29 percent), and inadequate digitalization when conducting studies (16 percent).



The data refer to the companies that have indicated that they conduct studies outside the EU. Multiple answers were possible.

Figure 7

Companies that do not conduct their clinical trials in the EU mainly choose the USA, India, and Europe outside the EU. In principle, clinical studies or clinical trials that are performed in the USA to determine the safety and performance of a medical device can also be used as part of CE certification in the EU and vice versa. However, the clinical trial must have been performed in accordance with basic quality standards. In the EU, the Notified Bodies check whether the test was properly approved (ethics, authority) and whether it was performed in accordance with ISO 14155:2021-05[14]. The US Food and Drug Administration (FDA) also takes these points into account. In addition, it can specify certain clinical endpoints for some medical devices, which must necessarily include the study.

In detail, however, it may also happen that certain studies from the USA or the EU cannot be adopted in the other regulatory regions if, for example, there are differences in standards of care or between European and other patient populations.

[14] DIN EN ISO 14155:2021-05: Clinical investigation of medical devices for human subjects - Good clinical practice;); German version EN ISO 14155:2020; The document sets out the formal requirements for conducting clinical investigations of medical devices.

3.3 EU market access under the MDR is associated with significantly higher costs and longer procedural times

The results of the survey show a significant increase in costs for manufacturers to gain market access for their products in the EU. This applies to innovations as well as the numerous existing products that manufacturers also sell in the EU market under the MDR – and, therefore, do not want to discontinue. The cost increases include, on the one hand, the internal and external costs that arise from the manufacturer as part of the necessary documentation for the product file and, on the other hand, the costs of the Notified Bodies, which the manufacturer must consult as part of the conformity assessment from Class I s, r, m. At the same time, the duration of the compliance assessment process is increasing across all risk classes.

In detail: According to the requirements of the MDR, medical devices are classified into different risk classes based on various factors, including the potential risk to patients and users as well as the intended uses of the product. They determine the requirements for conformity assessment, clinical evaluation, and regulatory processes that a manufacturer must go through in order to bring the product to market.

The MDR defines four main classes:

1. Class I: Low risk. This includes products such as bandages or disposable syringes. Part of this classification level is the division into:

1.1 Class Im: Medical device with or without measuring function
1.2 Class Ir: Medical device that counts as a reusable surgical instrument
1.3 Class Is: Sterile medical device [hereinafter referred to collectively as I*]

2. Class IIa: Low to moderate risk. These include products such as hearing aids, dental materials, or diagnostic ultrasound devices.
3. Class IIb: Medium to high risk. Examples include certain ventilators, dental implants, or pacemakers.
4. Class III: High risk. This includes products such as cardiac catheters, artificial joints, stents, active implantable medical devices, or heart valves.

Products with higher risk classes generally require more intensive testing and monitoring by the relevant supervisory authorities. The scope of the product file – the technical documentation – also varies depending on the risk class.

Technical documentation comprises extensive collections of documents and information that are carefully created and kept up to date by medical device manufacturers. This is necessary to demonstrate the compliance of their products to the requirements of the MDR and to ensure transparency and traceability of the products throughout their entire life cycle. They serve as evidence of the safety and effectiveness of the medical devices and are checked by the Notified Bodies as part of the approval and the responsible EU authorities as part of market surveillance. The MDR sets out clear requirements for the content.

According to survey results, the average costs for creating MDR-compliant technical documentation (excluding the costs of involving a Notified Body) have increased by 111 percent for manufacturers compared to the previous directives. These costs include internal personnel costs as well as expenses for laboratory services, and the preparation of clinical evaluations or studies.

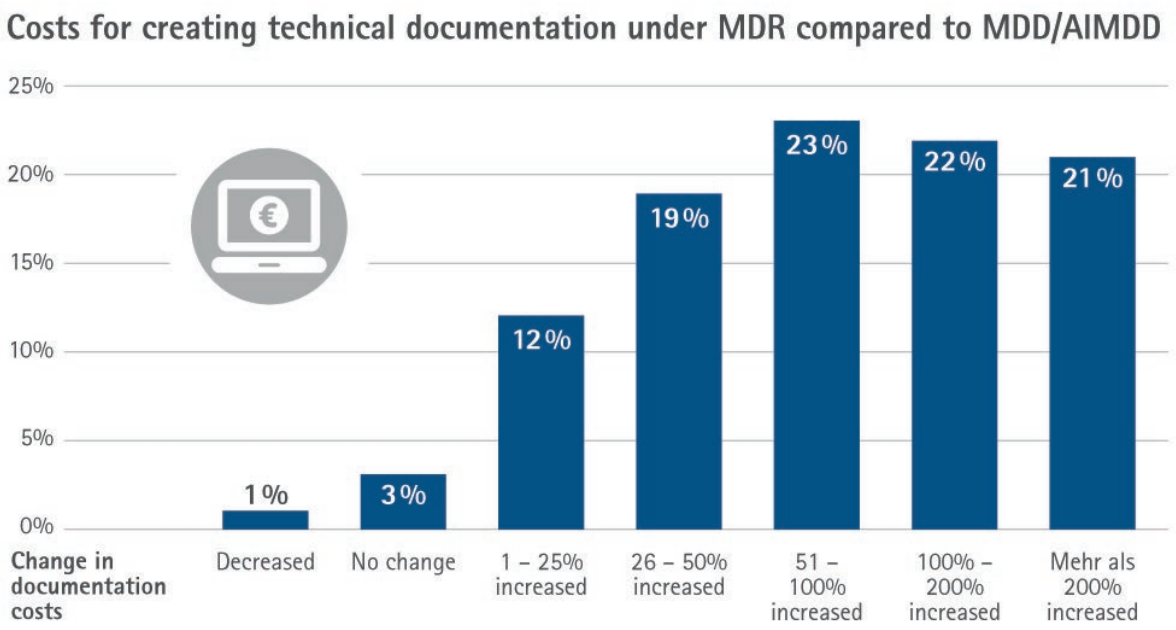


Figure 8

66 percent of all companies report an increase in costs of more than 50 percent for the creation of technical documentation. For 43 percent of all companies, costs have more than doubled. 21 percent recorded a cost increase of more than 200 percent.

The increase in documentation costs extends across all risk classes. However, it is significantly higher in the higher-risk classes: In classes IIb and III, 52 percent and 64 percent of companies, respectively, state that their costs for creating technical documentation have more than doubled.

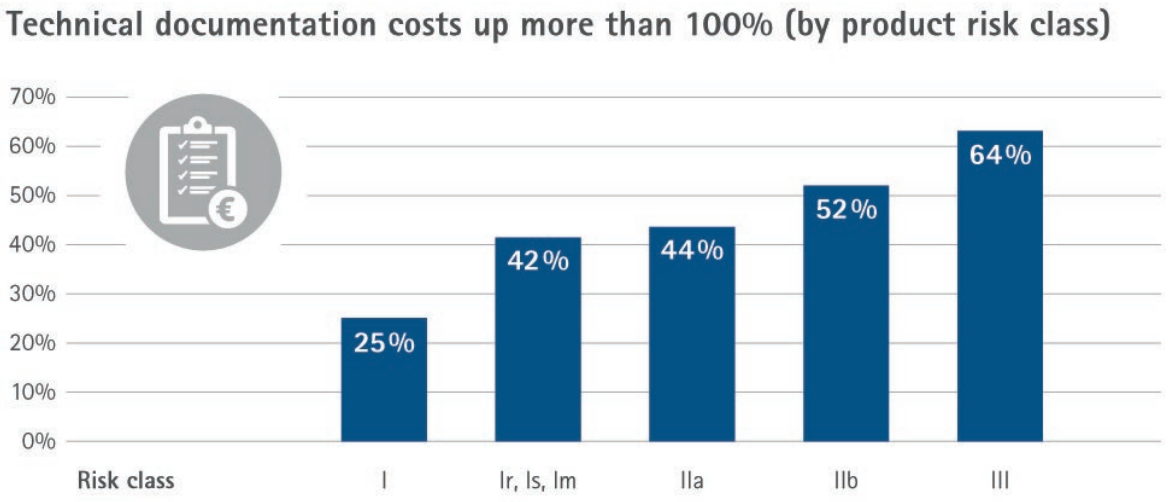


Figure 9

For risk classes from Class I* to Class III, the conformity assessment procedure also requires the involvement of a Notified Body. The body also charges costs. Here, too, there have been significant cost increases across all risk classes compared to the previous directives. These amount to an average of 124 per cent. For 73 percent of all companies, the costs for the certification process by the Notified Body have increased by more than 50 percent. 51 percent of all companies report an increase in costs for the Notified Body by more than 100 percent. For 24 percent of companies, the increase is already more than 200 percent.

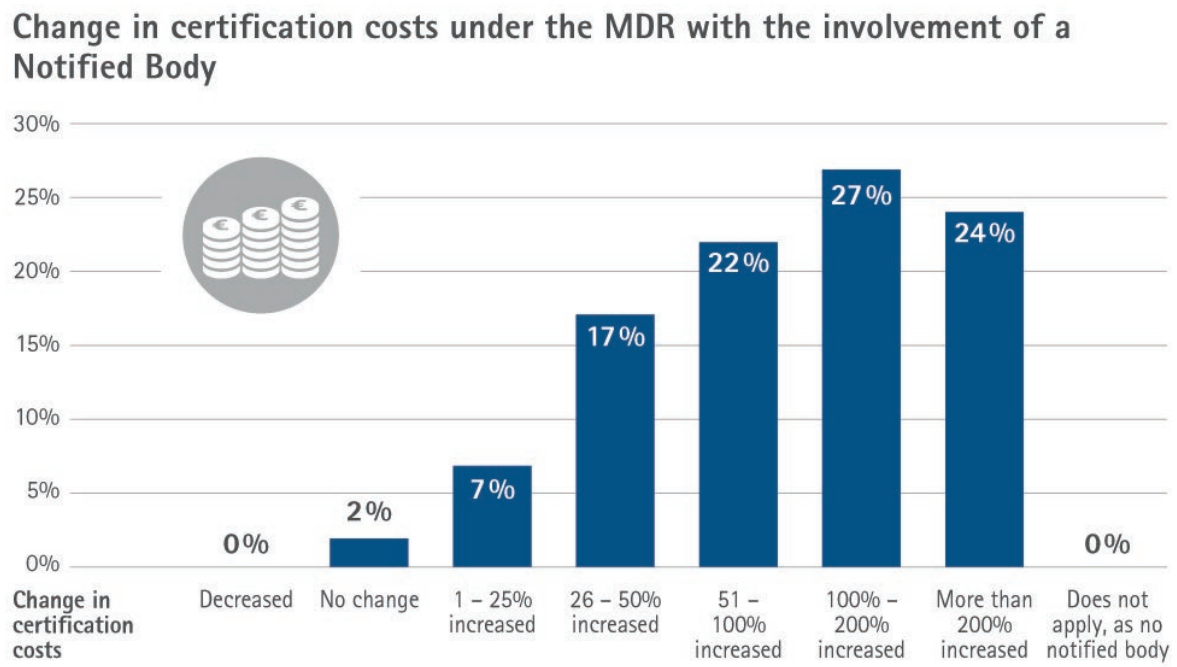


Figure 10

The increase in certification costs under the MDR when a Notified Body is involved also extends to all risk classes from class I* onwards (figure 11). However, the cost increases are even greater in the higher risk classes: In class IIb, 54 percent, and in class III, 70 percent of medical device manufacturers state that the certification costs with a Notified Body have more than doubled. An evaluation based on company size, therefore also shows that it is mainly larger manufacturers with more than 50 employees who implement the "more expensive" market access of the high-risk classes IIb and III in the EU.

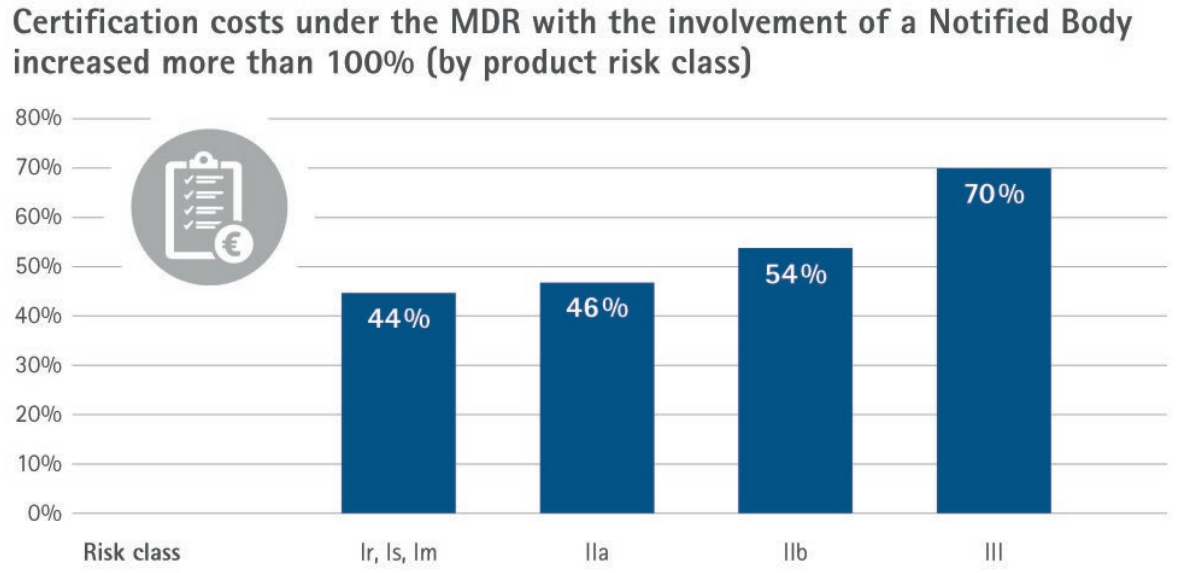


Figure 11

However, it is not only the costs that increase with the involvement of a Notified Body, but also the duration of the conformity assessment procedure under the MDR. The average duration of the conformity assessment procedure under the MDR – from the submission of the application for certifi-

cation to the issuance of the certificate by the Notified Body – has increased by 150 percent compared to the procedure under the old directives.

For around 83 percent of all companies, the duration has increased by more than half. Over 62 percent of companies have to accept that the certification procedures are now at least twice as long.

For 37 percent of companies, there is an increase of over 200 percent.

The increase in the duration of the certification procedure extends across all risk classes, as with costs. It is also higher in the higher-risk classes: In classes IIb and III, 67 percent and 71 percent of companies, respectively, report that their procedure times have more than doubled.

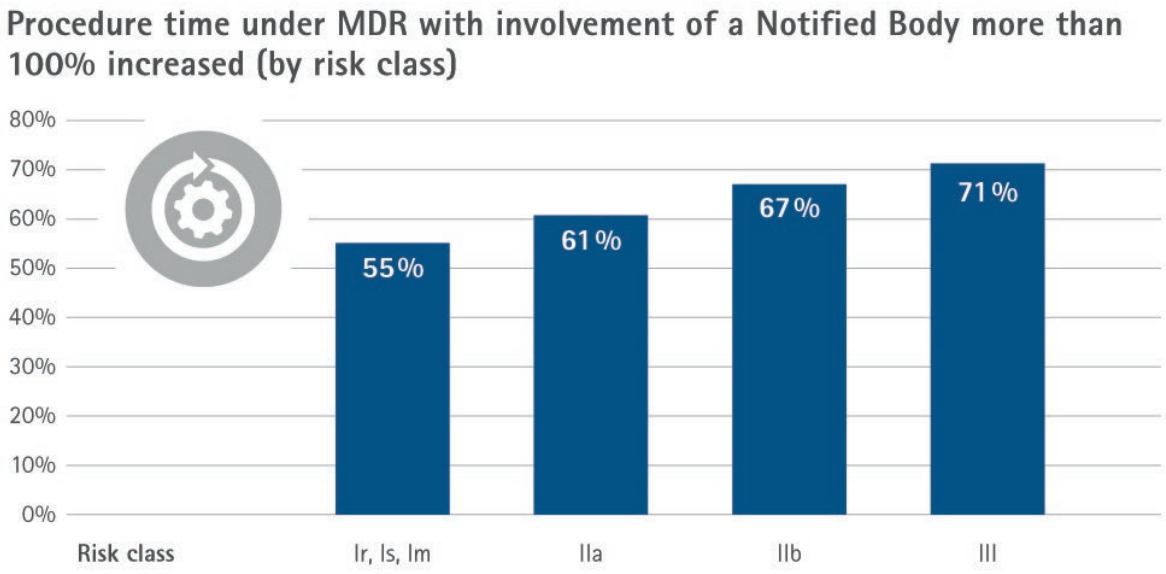


Figure 12

3.4 Certification costs, adaptation of technical documentation, and complexity are among the biggest problems in implementing the MDR

Implementation of the MDR presents companies with major challenges. Only 3 percent of all companies say they have no problems with this. However, the difficulties in implementation are manifold. 67 percent of the companies surveyed stated that the effort involved in making the necessary adjustments to technical documentation was particularly challenging. This is followed by total certification costs, which were cited as particularly problematic by 59 percent. 58 percent of companies are also concerned about the high level of complexity caused by the connection between the MDR and other regulations, directives, and/or MDCG guidelines.

Other problems include: finding qualified personnel for implementation and/or internal capacity problems (42 percent), the lack of planning security in terms of profitability and duration (38 percent), and cooperation with the Notified Bodies (36 percent). However, 33 percent of companies also see the creation of clinical evaluations based on non-existent clinical data as problematic. In addition, the different interpretation of the MDR requirements by the responsible authorities and companies (31 percent), the requirements for post-market monitoring (in interaction with dealers, users, etc.) (24 percent), and the implementation of the necessary clinical studies for existing products (19 percent) poses a problem for medical device manufacturers in the course of implementing the MDR. Also mentioned are the additional required registrations in individual EU countries (12 percent) and ambiguities regarding the new transitional provisions in accordance with Regulation 2023/607 (11 percent). There seems to be little difficulty in classifying the products. Other problems mentioned in the comments include the long time it takes for products to access the EU

market and necessary adjustments or renewals of product registrations in non-EU countries.

Implementation problem of the MDR	Nomination rate
Effort required to adapt the technical documentation	67 %
Certification costs	59 %
High complexity due to the link between the MDR and other regulations, directives, MDCG guidelines	58 %
Finding qualified personnel to implement the MDR / internal capacity problems	42 %
Lack of planning certainty in terms of cost-effectiveness and duration	38 %
Cooperation with the notified bodies	36 %
Preparation of clinical evaluation due to lack of clinical data	33 %
Differing interpretation of MDR requirements by the competent authorities and us	31 %
Requirements for post-market surveillance (in cooperation with distributors, users, etc.)	24 %
Conducting the necessary clinical studies for existing products	19 %
Additional registrations required in individual EU countries	12 %
Uncertainties regarding the new transitional provisions in accordance with Regulation 2023/607	11 %
Difficulties with the classification of products	5 %

Multiple answers were possible.

Figure 13

The weighting of the issues shown in Figure 13 varies depending on the size of the company. While the certification costs are stated to be the main problem for companies with up to 49 employees (70 percent), these are with 40 percent in fourth place for companies with more than 250 employees after (1) the effort required to adapt the technical documentation (72 percent), (2) the high complexity caused by the linking of the MDR to other regulations, directives, and MDCG guidelines (56 percent) and (3) the problem of finding qualified personnel to implement the MDR (46 percent).

There are currently also problems with the recognition of certificates for “legacy devices”[15] in numerous markets. 58 percent of the companies surveyed say that in many markets they have problems with recognition or the validity of certificates that were issued for their products in accordance with the previous guidelines and are making use of the new MDR transitional provisions related to “legacy devices”.

In detail: The conditions and deadlines for placing “legacy devices” on the market or putting them into service are set out in a document with corresponding flowcharts from the European Commission[16]. Companies have the following options to demonstrate compliance with the requirements:

- Manufacturer's declaration: The European medical device associations AESGP, COCIR, EuromContact, EUROM VI, and MedTech Europe have developed a template for manufacturers that any manufacturer can use freely. It can also be completed by the authorized representative on behalf of the manufacturer. How the manufacturer declares compliance with the applicable conditions will be disclosed by the manufacturer in the completed form[17].

- Confirmation letter from the Notified Body: The members of Team-NB[18] have agreed on a confirmation letter to be issued in accordance with Regulation 2023/607. This confirms to the manufacturer the status of a formal application, a written agreement, and appropriate monitoring within the framework of the MDR regarding the transitional provisions for certain medical devices with the Notified Body[19]

[15] Legacy devices are devices that were placed on the market after the date of application of the MDR and under certain conditions until May 26, 2024 in accordance with Article 120 (3) of the MDR. (MDCG 2021-25)

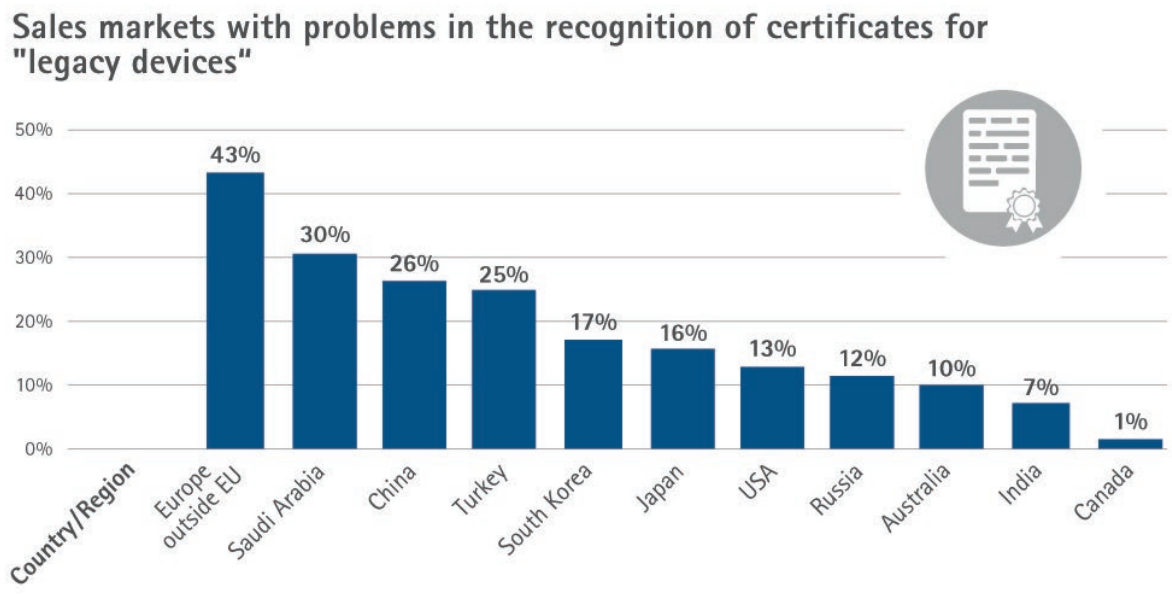
[16] https://health.ec.europa.eu/system/files/2023-08/md_devices-art120_flowchart_0.pdf

[17] http://eurom.org/wp-content/uploads/2023/06/230609-final_mdr_manufacturer-declaration.docx

[18] The European Association for medical devices of Notified Bodies

[19] https://www.team-nb.org/notified-body-confirmation-letter-eu-2023-607/

The countries where there are main problems with the recognition of legacy devices mainly include Europe outside the EU (43 percent), Saudi Arabia (30 percent), China (26 percent), and Turkey (25 percent). Important sales markets for German manufacturers of medical devices, such as Japan, with 16 percent, and the USA, with 13 percent, are also affected.



The information relates to the sales markets where companies are having problems in recognizing the validity of certificates issued under AIMDD or MDD for their products and are making use of the new MDR transitional provisions as a "legacy device". Multiple answers were possible.

Figure 14

3.5 Nearly all companies have problems working with Notified Bodies – from a lack of capacity, high certification costs and a lack of uniformity

Only 6 percent of all companies that involve a Notified Body as part of the compliance assessment process say they have no problems working with the Notified Body. However, 94 percent of companies have problems. According to the information provided by the manufacturers surveyed, the following difficulties in particular arise in the direct conformity assessment process for certification:

1. Lack of capacity of the Notified Body

This issue is particularly great for Class III manufacturers, 85 percent of whom complain about the lack of capacity of their Notified Body for their products. In addition, the lack of capacity is reported primarily by medium-sized companies with 50 to 249 employees (80 percent) and large companies with more than 250 employees (81 percent).

2. Certification costs too high

These are particularly problematic for smaller, medium-sized companies: 77 percent of micro-enterprises with up to 9 employees and 69 percent of companies with 10-49 employees cite this as a problem in working with the Notified Bodies.

3. Different interpretations of the MDR requirements by the Notified Body and the company itself

Further problems for companies in working with the Notified Bodies are the lack of binding deadlines set by the Notified Body within the certification process (44 percent) and a lack of planning security regarding fees or the lack of transparency in costs (37 percent). 35 percent of companies complain about a lack of a standard structure for file structure (reviewers have different expectations). 32 percent say that they do not receive any binding review appointments with their Notified Body.

The different interpretations of the same MDR requirements by different Notified Bodies are a

problem for over a quarter of companies (28 percent). 16 percent of those surveyed stated that there were difficulties in issuing the confirmation letter with regard to the new transitional provisions in accordance with Article 120[20] of the MDR by the Notified Body. 15 percent of companies have difficulties with the fact that there is no mutual recognition of assessments and/or certificates from different Notified Bodies in relation to suppliers. 9 percent of companies have the problem that there are too few Notified Bodies in the required product scope. Another 4 percent of companies still have difficulties finding a Notified Body at all. Comments the companies also contain information about problems such that already fixed dates are often postponed by the Notified Body or that the previous Notified Body can no longer handle the scope of the products.

Problem with the Notified Body	Nomination rate
Lack of capacity at our notified body	73%
Certification costs too high	59%
Different interpretation of the MDR requirements by the notified body and us	47%
We do not receive any binding deadlines from the notified body within the certification process	44%
We have no real planning security with regard to fees (cost intransparency)	37%
No standard structure for file structure (different expectations of reviewers)	35%
We do not have binding review dates with our notified body	32%
Different interpretations of the same MDR requirements by different notified bodies	28%
Problems in issuing the letter of confirmation with regard to the new transitional provisions by the Notified Body	16%
No mutual recognition of assessments and/or certificates from different Notified Bodies in relation to suppliers	15%
Too few Notified Bodies available in our product scope	9%
We cannot find a Notified Body	4%

Multiple answers were possible.

Figure 15

[20] On March 20, 2023, the Commission published the amending Regulation (EU) 2023/607, which extends the transitional provisions under Article 120 of the MDR for certain medical devices and under specific conditions. To prove compliance with the requirements, companies have the option of submitting a manufacturer's declaration or a corresponding letter of confirmation from the notified body. In July 2023, the European Commission also published a factsheet on the new transitional provisions of the MDR/IVDR for authorities in third countries.

3.6 Digitalization of internal processes and collaboration with authorities and Notified Bodies are not used enough

The digitalization of processes and documents in order to prove product compliance over the entire life cycle and to make QM and RA processes more efficient through electronic solutions is becoming increasingly important. It's about saving time, money, and, above all, scarce human resources in companies. The survey shows that there is still considerable potential for expansion in the implementation of digital processes in collaboration with the Notified Bodies and state authorities. For 76 percent of companies, the certification process at their Notified Body cannot be completed digitally or only in parts. Only 24 percent of companies can go through the process completely digitally, such as submitting applications, providing proof documents, etc.

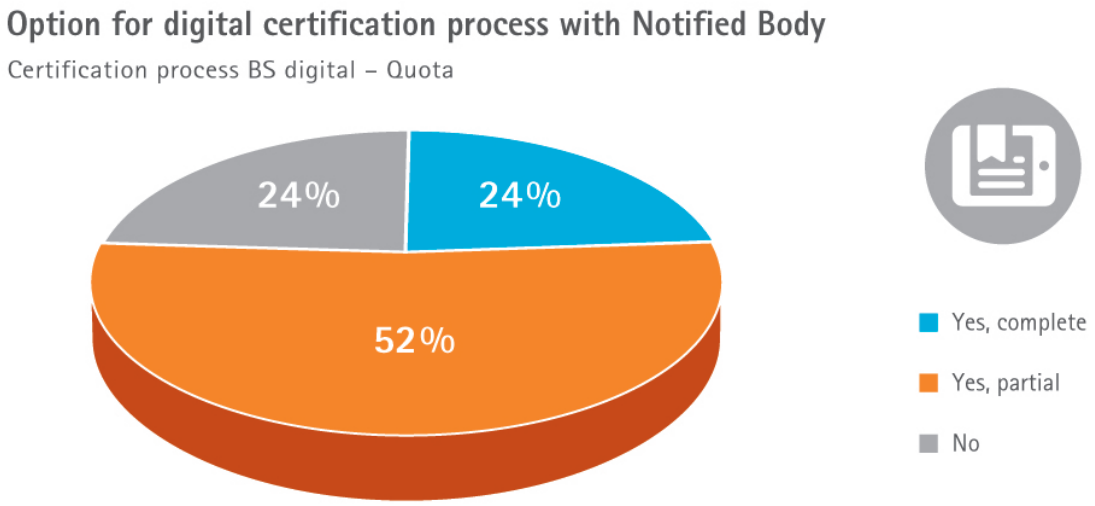


Figure 16

Cooperation with the state authorities is even worse: for 89 percent of companies, necessary processes with the state authorities, such as registrations or applying for a free trade certificate, cannot or can only partially be completed digitally. A completely digital process is possible for only 10 percent of the responding companies.

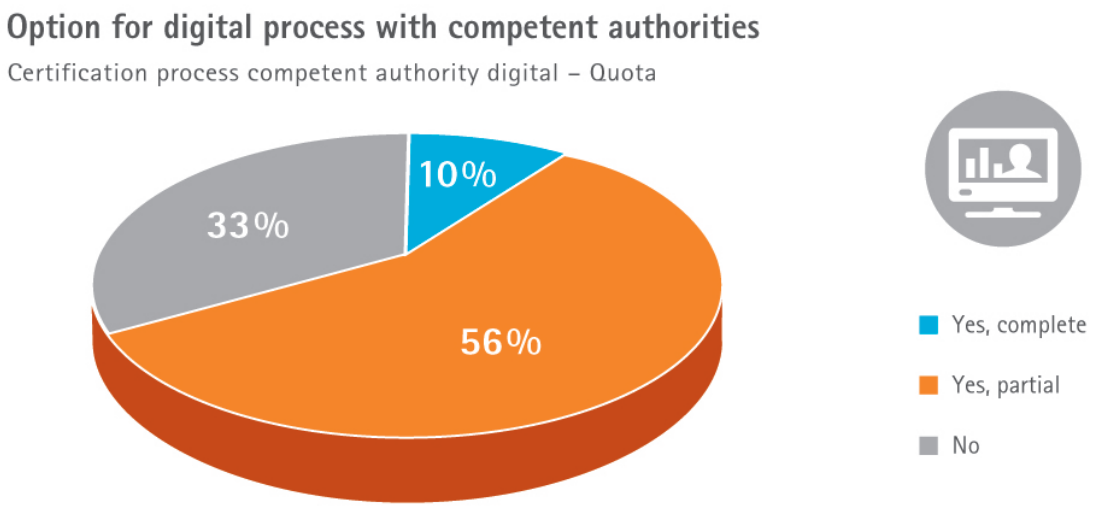


Figure 17

The survey also shows: to map internal processes from quality management or within the regulatory affairs department, 50 percent of companies already use software to digitalize these processes at least partially. Another 28 percent plan to do so.

The survey participants particularly want uniform and consistent digital processes in order to achieve a significant increase in efficiency in market access in the EU. This requires corresponding digital interfaces. The US FDA and the eSTAR program used there for submitting interactive PDF documents are often cited as a model.

When it comes to digitizing documents, respondents particularly often mention the introduction of electronic technical documentation (eTD) in a uniform format (e.g., STET), the basic ability to use electronic instructions for use for medical devices (eIFU), and the acceptance of digital signatures. The European database EUDAMED[21], which is still not fully functional and has been postponed again, is criticized as slowing down digitalization in the EU. This, in turn, creates unnecessary individual registrations by manufacturers in the individual EU member states and, consequently, avoidable additional effort that costs resources.

However, many participants see the problems with the digital implementation of the MDR not only in the slow digitalization itself but also in the legal text of the MDR. They doubt that the introduction of digital processes will help with the existing difficulties. (Quote from the comments: “If it is bad to begin with, digitizing it does not make it better.”)

[21] The date of full functionality of the EUDAMED database has already been postponed several times. The European Commission's current timetable does not expect it to be fully functional before Q2/2027.

4. Methodology

This survey by the German Chamber of Commerce and Industry (DIHK), MedicalMountains GmbH, and SPECTARIS collected data on various aspects relating to the implementation of the MDR two years after the MDR came into force and around half a year after the new transitional provisions came into force. Only manufacturers of industrial medical devices were surveyed.

The DIHK made the anonymous survey available to the 79 Chambers of Commerce and Industry (IHKs), which then sent an Internet link with the online survey to their member companies. SPECTARIS and MedicalMountains GmbH, in turn, informed their member companies and networks. 514 fully or partially completed questionnaires were included in the survey analysis[22]. Of these, 393 were from manufacturers within the meaning of the MDR. A further 121 respondents stated that they were not a manufacturer within the meaning of the MDR. Nearly 15 percent of these 121 companies stated that they had been manufacturers, according to the MDD before the MDR but had given up this role due to the MDR. These 121 companies were excluded from the other questions in the survey. The 393 manufacturers further surveyed in accordance with the MDR included smaller companies with 10 to 49 employees, medium-sized companies with 50 to 249 employees, and larger companies with more than 250 employees in roughly equal proportions of around 30 percent each. Only the proportion of micro-enterprises with up to 9 employees was lower at 13 percent. The answers from over 70 percent of the participants came from companies with fewer than 250 employees, and almost half (46 percent) from companies with fewer than 50 employees. The proportion of start-up companies in the survey that were founded within the last 5 years was 5 percent.

The participating companies are active in different product areas and areas of application. In many cases, the companies are active in several application areas or product groups. The proportion of surgical instrument manufacturers among all participants is almost 30 percent. Almost 26 percent work in the field of "orthopedics, rehabilitation, rheumatology". Further areas of application or product groups are: "Neurology and neurosurgery" (17 percent), dentistry, nephrology, and urology (15 percent each), and traumatology and accident surgery (13 percent). "Circulatory system and cardiology," vascular surgery, thoracic surgery, medical software/apps, and ophthalmology (between 11 and 13 percent each). Between 9 and 10 percent of the information relates to products for pediatrics (paediatric surgery, pediatric cardiology, pediatrics), for "pulmonology, sleep medicine, anesthesia & intensive care medicine", and for medical aids (e.g., respiratory home therapy, visual or hearing aids, medical nursing aids, etc.). Almost 9 percent work in gastroenterology and hepatology, and another 8 percent each in obstetrics and gynecology, including reproductive medicine and visceral surgery. The product groups radiology and capital goods (e.g., beds, sterilizers, devices) were each indicated at just under 6 percent. Further areas of application include digital health or care applications (DIGA/DIPA) and endocrinology and diabetes.

The products include all risk classes of medical devices according to the MDR: Class I products account for 53 percent. The proportion of classes Ir, Is, and Im is 34 percent. Products from class IIa make up the largest part, 63 percent. Also represented are Class IIb (44 percent) and Class III (21 percent) products.

Almost half of the participating companies come from Baden-Württemberg, where there are large clusters of medical device companies. Many companies also took part from Bavaria (14 percent), Hesse, and North Rhine-Westphalia (approx. 10 percent each). Around five percent of respondents each come from Schleswig-Holstein and Lower Saxony. Around three percent each from Hamburg, Thuringia, and Saxony. In total, answers are available from 15 of the 16 federal states. In addition, 19 companies from Austria, Switzerland, Denmark, and the Netherlands took part in the survey.

The survey was performed in June, July, and August 2023 and evaluated from September to November.

[22] In Germany, 1,470 companies with more than 20 employees are active in the medical technology sector. (SPECTARIS, Federal Statistical Office, from: SPECTARIS Medical Technology Yearbook 2023/24) Note: excluding custom manufacturers of medical devices.

5. Appendix 1 / Example overview of discontinued products

Disclaimer: The following table does not claim to be complete or to correctly assign the products to the corresponding application areas/product groups. It merely represents an overview of the additional information provided by the participants in the comments. Examples of product settings mentioned there are:

Field of use	Examples of discontinued products
Surgical instruments	- Surgical instruments for heart operations - Surgical instruments for brain operations - Neurosurgical micro-instruments such as scissors, needle holders, or tweezers - Surgical instruments used for rare cases (niches) - Trocars (3mm) for pediatric surgery - Suction cannulas - Haemostats - Aneurysm clips - Instruments with special dimensions
Dentistry	- Orthodontic brackets and archwires
Pulmonology and sleep medicine, anesthesia, intensive care medicine	- Endoscopic products - Ventilation stands - Sleep diagnostic devices - Emergency ventilators - Epidural anesthesia kits - Closed-loop intensive care ventilators - Sleep diagnostic devices - Resuscitator bags for children and adults
Thoracic surgery	- HF neutral electrodes non-sterile for reuse - HF scissors - HF scissor clamps
Traumatology, accident surgery	- Bone plates and bone screws for osteosynthesis - Atraumatic instruments - Endoscopes and instruments with special dimensions - Oral, jaw, and facial implants - Epitheses after surgical removal of facial parts - Trauma implants - HF neutral electrodes non-sterile for reuse - HF scissors - HF scissor clamps
Neurology and neurosurgery	- Neurosurgical micro-instruments such as scissors, needle holders or tweezers - Neurobiopsy products - Aneurysm clips - Serrated Spatulas (Skin Hooks for Dura) - Bipolar forceps - Spinal surgery plates - Engine systems - HF neutral electrodes non-sterile for reuse - HF scissors - HF scissor clamps
Obstetrics and gynecology, including reproductive medicine	- Endoscopic products

Orthopedics, rehabilitation, rheumatology	- Orthopedic implants - Osteosynthesis implants - Endoscopes and instruments with special dimensions - HF neutral electrodes non-sterile for reuse - HF scissors - HF scissor clamps - Spinal surgery plates - Medullary canal drill - Electrostimulation devices - UV heat lamps
Gastroenterology and Hepatology	- Endoscopic products - Reusable endoscopic therapy instruments - Salivary duct stents
Vascular surgery	- Surgical microinstruments such as scissors, needle holders, forceps
Circulatory system, cardiology	- Surgical instruments for heart operations - Endoscopes and instruments with special dimensions - Central venous catheters - Defibrillators
Pediatrics (pediatric surgery, pediatric cardiology, pediatrics, etc.)	- Cardiac catheter for newborns - Trocars for pediatric surgery - Drainage pumps - Baby stents
Nephrology and urology	- Endoscopic products - Microendoscopes - Microbiopsy devices - Minimally invasive kidney stone management system -
Ophthalmology	- Intraocular lenses in peripheral areas that are needed for rare cases - Microendoscopes - Microbiopsy devices
Medical software/apps	- Documentation aids for the treatment of rare chronic diseases
Medical aid	- Dressing materials - Sterile operating table covers