

Safe Medical Devices Rest In Paperwork.



Responding to the „Call for evidence“
Targeted revision of the EU rules for medical devices

Executive summary

Since 2014, the German medical technology and medical devices industry has lost 10,000 micro and small enterprises, according to the findings of a recent study entitled ‘The Medical Technology and Medical Devices Industry in Germany in Light of the Medical Device Regulation’ – a special study commissioned by the Federal Ministry for Economic Affairs and Energy (BMWE)¹ (German Language only).

SMEs are the backbone of Europe's medical innovation, but they are currently facing disproportionate recertification costs and regulatory hurdles that have already led and will continue to lead to the discontinuation of essential medical devices until the end of the transition period (2027/2028).

This means, that thousands of well-established and safe medical devices, such as dental materials, have been lost due to the high costs of recertification. The introduction of the EU Medical Device Regulation (MDR) has placed immense pressure on micro- and small -sized enterprises (SMEs) in the medical device sector, threatening the safety and well-being of patients across Europe.

The COVID-19 epidemic has shown how important it is to have a functioning local production of medicines, disinfectants and medical devices in times of crisis. Excessive regulation has driven pharmaceutical production out of Europe. This mistake is now being repeated in the medical device industry, an economic sector in which Europe was leading until now and which was not (!) dependent on subsidies.

At the same time, there are distributors of medical devices who are not registered as economic operators anywhere in Europe. These distributors are not under surveillance and currently pose a risk for the distribution of certified products falling into the wrong hands, as well as for the distribution of non-conforming, unsafe products.

This document provides evidence of the adverse effects that small and medium-sized enterprises (SMEs) in the medical device industry are being exposed to as a result of the MDR 2017/745. The evidence relates to Germany and, in particular, the German dental industry. Not only do we report on the harmful effects, we also provide the ingredients for remedy: Three key proposals for a targeted revision.

Three ad-hoc MDR Corrective Actions:

- Reclassification of unobtrusive legacy devices (old products certified under MDD) with well-established technologies (WET) into a new risk class: **Class I legacy**
 - exempting them from re-certification by Notified Bodies (grandfathering)
 - subjecting them to the monitoring carried out by National Competent Authorities CAMDs
- Utilizing Article 97 MDR to provide alternative pathways in particular for SMEs for the transitional period to ensure continued product availability
- Central registration of distributors as economic operators in EUDAMED for the sustainable improvement of patient safety

¹ Federal Ministry for Economic Affairs and Energy (2025), FORSCHUNGSBERICHT Medizintechnik- und Medizinproduktebranche in Deutschland im Zeichen der Medical Device Regulation Sonderstudie im Auftrag des Bundesministeriums für Wirtschaft und Energie (BMWE), August 2025 ([BMWE](#) accessed on 01.10.2025) p. 32

Micro, small and medium-sized enterprises in the European medical device industry

Small and medium-sized enterprises (SMEs) are of central importance to the economic and social fabric of Europe. 24 million European SMEs make up 99% of all companies in the EU, account for two thirds of private sector jobs in the EU and are deeply rooted in local communities, especially in rural areas.

They account for more than half of the value added in the EU's non-financial corporate sector, and they are the breeding ground for innovation, diversity and equality in Europe.

SMEs are crucial for the green and digital transition in Europe and for its long-term prosperity².

- *European Charter for Small Enterprises "General Affairs" Council, Lissabon on 13 June 2000.*

Definition³ SME:

Micro, small and medium-sized enterprises are being distinguished:

Micro-enterprises: fewer than 10 employees and an annual turnover (the amount of money earned in a given period) or annual balance sheet total (assets and liabilities of a company) of less than 2 Mio.

Small enterprises: fewer than 50 employees and an annual turnover or annual balance sheet total of less than EUR 10 million.

Medium-sized enterprises: fewer than 250 employees and an annual turnover of less than EUR 50 million.

NEW: Small Mid-Caps⁴

companies that are not small or medium-sized but are not large enterprises either

fewer than 750 employees and an annual turnover of less than Euro 150 Mio

99.4% of the companies in the German medical device and medical technology industry are SMEs, which accounted for 75.8% of turnover (2014 data)⁵; 82% of these were micro-enterprises.

During the period of the first BMW study (2011–2014), there was a steady increase in the number of companies in the medical industry sector; from 24,300 in 2011 to 25,000 in 2014 .

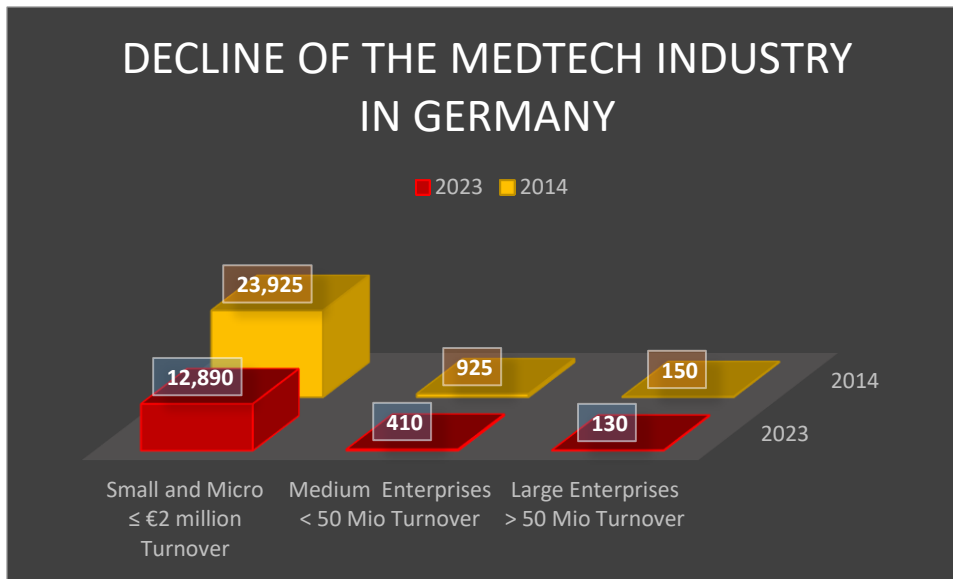
² COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS, Strasbourg, 12.9.2023

³ https://single-market-economy.ec.europa.eu/smes/sme-fundamentals/sme-definition_en

⁴ COMMISSION RECOMMENDATION (EU) 2025/1099 of 21 May 2025 on the definition of small mid-cap enterprises accessed 06.10.2025

⁵ Federal Ministry of Economics (2016), Gesundheitswirtschaft Fakten und Zahlen Sonderthema Medizinprodukte und Medizintechnik. <https://tinyurl.com/BMWE2016MD>

Since 2014, the industry has lost a total of 11,600 companies⁶

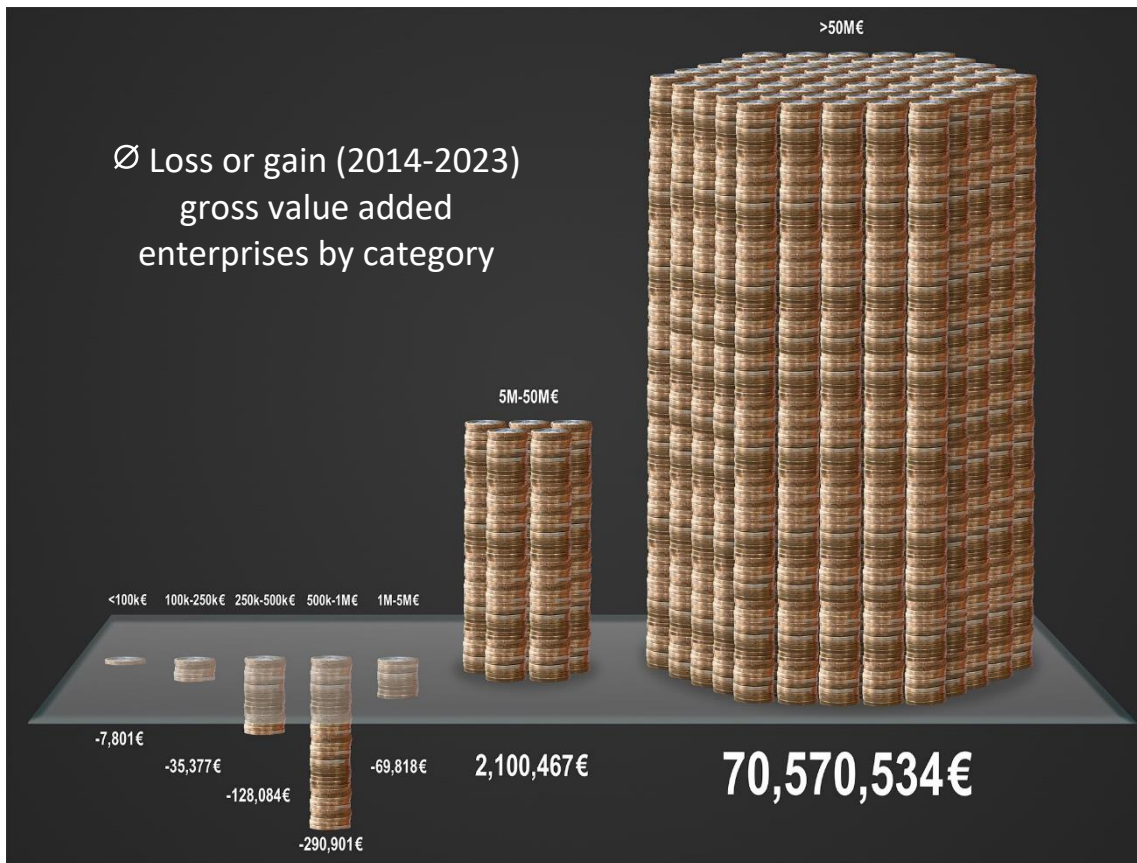


The new BMW study makes it clear that the majority of companies ceased operations in the period up to 2020. Hence it is **not an effect of the pandemic**. For the period from 2020 to 2023, the number of companies that went out of the medical industry were just 220. The loss of more than 10,000 manufacturers must be attributed to the challenges posed by the MDR. 2020 was the year when the transition period was supposed to end. In the light of the pandemic the transition period was prolonged for another year.

In 2013, small and medium-sized enterprises generated 75.8 % of the sector's turnover. Currently, only 36.1 % of turnover is attributable to micro, small and medium-sized enterprises, which make up the vast majority of the business landscape with a share of around 99.0 %. Fewer large enterprises now account for 63.9 % of turnover.

The share of turnover accounted for by large companies has grown at the expense of micro and small enterprises according to 2023 data. Unfortunately, the new group of small mid-caps cannot be identified. Neither their number nor share of turnover.

⁶ Own illustration based on Federal Ministry for Economic Affairs and Energy (2026) Note: 925 medium-sized enterprises is not accurate, as it still includes some small businesses.



The table above illustrates the extent of the shift in market share. A few large companies (130 instead of 150 previously) achieved a tremendous disproportionate increase in gross value added.

The fewer micro and small enterprises (- 11,000 manufacturers) suffered losses of 26 to 51 per cent on average. Only the group of small enterprises on the borderline with medium-sized enterprises was able to hold its ground, but still lost.

Medium-sized companies achieved a significant increase of 60 per cent and large companies on average quadrupled their share.

Four out of five medical device manufacturers are discriminated against by MDR 2017/745.

In terms of effort, intensity and costs, small and micro manufacturers are overburdened by the recertification requirements. They are systematically discriminated against.

Certification Product testing 100 % vs. 5 %

Medical devices are not licensed in the same way as medicinal products. Medical devices are placed on the market through a combination of company and product certification and additional monitoring by national authorities. Unlike licences, these certifications must be renewed regularly.

During an MDR certification cycle (every 5 years), 15 % of a company's products are to be randomly tested (sampling) by the Notified Bodies. In the initial 5-year cycle, the scope of the products tested may even be reduced to 5 %⁷. Only large companies benefit from this sampling.

As SMEs produce only a few medical devices, sometimes even just one, this means that SMEs with one or a just a few products often have to have 100 % of their products certified in one cycle (if not one year).

According to verbal reports, there are Notified Bodies that review the same file every year after a product has been recertified in accordance with the MDR. This file is then reviewed in full every year at the corresponding cost.

As a result, the effort and costs for a large corporation in connection with the review of product files are only 5-15 % of the costs for a micro-enterprise.

However, large companies (according to the SME definition) are not necessarily corporations. In the dental industry in particular, sales is generated with many small specialised products.

Mark Pace, Chairman of the Association of German Dental Manufacturers, illustrates this problem very clearly in his article 'The impact of bureaucracy on the German dental industry'⁸. With 600 employees and a turnover of 68 million euros, Dentaureum is a small mid-cap enterprise according to the new category for Small Mid-Caps (SMCs). Turnover is achieved with a total of around 8,500 products. Less than 10 per cent of these products achieve a turnover of more than 100,000 euros per product. According to Dentaureum, it has taken 1,000 products from the market due to the MDR in the last two years.

While small Mid-Caps and large enterprises "only" cancel product lines, micro and small enterprises have closed down (or moved to another less regulated sector) on a large scale and the remaining are acutely threatened with closure – with potentially fatal consequences for patients⁹.

Audit times for micro-enterprises 16,000 times higher than for large enterprises

The disparity is even greater when it comes to audit times. The IAF Mandatory Documents¹⁰ define time periods according to which the Notified Bodies determine the time and effort required for auditing management systems. For the smallest size category with 1-5 employees, at least three days of audit time are allocated for initial certification. An organisation with 10,700 employees is audited for a maximum of 25 days.

For micro-enterprises, the audit time is therefore 4.8 hours (288 minutes) per employee, compared to only 0.018 hours (1.8 minutes) per employee for large enterprises. If large companies then artificially reduce their size by certifying only a sub-organisation in accordance with MDR, the disparity becomes even greater.

The importance of distributors for the supply of medical devices and for patient safety

Article 14 of the MDR explicitly lays down the general obligations of distributors. Distributors fulfill important functions in controlling the conformity of devices before they are made

⁷ MDCG 2019-13 Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation (p. 5)

⁸ Pace, Mark (2/2024) Quintessenz Das Magazin Sonderdruck, Berlin: Quintessenz Verlag

⁹ Widman, Marc. (2024) [Suddenly a hole in a child's heart - because a part is missing for a few Euros, Die Zeit No 25](#)

¹⁰ IAF MD 1:2023 IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization, Annex D (aufgerufen am 01.10.2024)

available to users and consumers. Although intensive controls are the responsibility of the Notified Bodies and the competent authorities, distributors have a key control function in the daily marketing of goods.

Surprisingly, however, there is only an optional provision for the registration of distributors. According to Article 30 (2), Member States may introduce a register for the registration of distributors operating on their territory.

„Member States may maintain or introduce national provisions on registration of distributors of devices which have been made available on their territory.“

This is only taking place to a very limited extent, if at all. Germany, for example, has not currently provided any registration¹¹. Austria, on the other hand, has introduced a registration requirement for distributors who have their registered office in Austria.¹² However, this does not by any means include all distributors who offer medical devices in Austria.

Cross-border trade

In fact, trade in medical devices is no longer limited to local markets, but is increasingly taking place across borders within the European single market via web shops and online portals.

These companies, whether small or large, can choose where to establish their headquarters – in particular with regard to tax and regulatory considerations.

Amazon EU S.à r.l., based in Luxembourg, for example, operates Amazon.de Marketplace. In Germany, medical devices are offered on Amazon.de by dealers from all over Europe and even outside Europe. Although the distributors agree to comply with all European laws vis-à-vis Amazon, all kinds of medical devices are offered that are not safe. This may be because products are sold that are not CE marked, or because products are offered that are only intended for professional use but can nonetheless be purchased by laypersons via the marketplace. Amazon is just only one example of such a marketplace.

A central registration requirement for all distributors would be an important step towards better control of this market. In fact, the effort required to achieve this would be minimal. EUDAMED would only have to create a new serial number range. The module for registration of economic operators in accordance with Article 31 has been fully operational for four years. Manufacturers, authorized representatives and importers are already registered there centrally.

¹¹ In a European context, the MDR and IVDR allow the member states to adopt national rules for the registration of distributors (including pharmacies). In a national context, the German Medical Device Law Implementation Act (MPDG) authorises the Federal Ministry of Health to adopt corresponding rules in an ordinance (Section 88 (1) no. 9 MPDG). Such an ordinance has not yet been published (as of August 2024). Source: <https://www.bfarm.de/EN/Medical-devices/Tasks/DMIDS/node.html>

¹² Source: <https://medizinproduktregister.at/node/197>[German only]

Three ad hoc actions to alleviate the burden of MDR and to increase patient safety

1. WET legacy devices regrouping all into a new Risk — CLASS I LEGACY

Legacy devices with well-established technologies shall be grouped into a new Class I Legacy, provided they fulfil certain requirements:

Suggested prerequisites for regrouping/medical device profile:

- With a long history of use at least 10 years legally on the market under MDD
- Based on proven technology (WET) such as dental filling materials¹³
- No serious incidents within the meaning of MDR 2017/745 Art. 2 (65)
- No PBT and vPvB substances according to Annex XIV REACH (EC) 1907/2006
- Manufacturers with physical production in the territory of the EU who can claim the preferential origin of their products in accordance with EU Regulation 2015/2446¹⁴
- Manufacturers based in closely linked European economies, i.e. EFTA plus UK (incl. British Crown Dependencies) with physical production in the territory of their country analogous to EU manufacturers (see above) with mutual recognition of authorisation

Justification for this risk-based approach and the reclassification to CLASS I LEG:

Every proven WET legacy device that is withdrawn from the market causes new health risks simply due to unforeseen changes in the treatment method of practitioners.

Notified Bodies ignore the exceptions for WET-legacy devices laid down in the MDR. We are currently experiencing that tooth filling materials, liquids for impregnating retraction sutures, etc. are being recategorised into the highest risk category Class III by Notified Bodies.

WET legacy devices – especially dental materials – are safe. A total of 24 risks were reported to the Federal Office for Drugs and Medical Devices (BfArM) for dental materials in the period 2013 - 2024 (across all brands) (see Annex I). None of these reports were serious incidents or posed a risk to public health.

Products therefore do not have to be recertified like new products. However, all post-market surveillance requirements must be fully met. The only difference is that these activities are not monitored by Notified Bodies, but by the competent authorities

As the sole monitoring institution for class I devices, competent authorities primarily focus on public health and the availability of medical devices and not on their own economic interests.

Advantages of CLASS I LEG:

- Proven products that have already been discontinued can be brought back
- Prevention of further discontinuation of medical devices
- Ensuring the availability of medical devices within the EU
- Stopping the decline of the (dental) medical device industry in the EU

¹³ Article 18 (3), Article 52 (4), Article 61 (6)b, Chapter III Regulation 7 und Regulation 8

¹⁴ Otherwise, competent national authorities will find it difficult to ensure monitoring.

- Capacities of Notified Bodies are freed up for new products, especially for novel and innovative medical devices
- Risk-based approach
- Reducing the bureaucratic burden to a sensible level
- Reducing costs for medical device-manufacturers, especially for small and micro enterprises will lead to lower costs for the healthcare system/the general public
- The surveillance of Class I devices is the responsibility of the Competent Authorities of Medical Devices (CAMD). This will strengthen the position of CAMDs and may lead to a more robust market surveillance system at EU level in the medium and longer term, especially when EUDAMED is fully operational.

2. Article 97 in particular for SMEs

The following statement in the Q&A document¹⁵ should be revised and cancelled by the European Commission:

6.1. Does a national derogation granted after 20 March 2023 in accordance with Article 59 MDR or the application of Article 97 MDR lead to an extension of the transitional period?

No. If, after 20 March 2023, a competent authority has granted a derogation in accordance with Article 59 MDR or has obliged a manufacturer in accordance with Article 97 MDR to carry out the applicable conformity assessment procedure, the condition referred to in Article 120 (2), point (b) of the MDR is not fulfilled. Therefore, an expired certificate is not considered valid and the extended transition period according to Article 120 (3a) MDR does not apply.

Our proposal

YES. A derogation under Article 59 MDR or Article 97 MDR after 20 March 2023 should also trigger the extension of the transitional period. This applies in particular to SMEs (definition according to Commission Recommendation 2003/1422) that manufacture medical devices in the territory of the European Union and can claim preferential origin for their products within the meaning of Article 37 of Regulation (EU) 2015/2446.

Rationale

The sole decision on the continued existence of a medical device manufacturer must not be left to a small group of Notified Bodies – for reasons.

There must therefore be an alternative approach to the transitional provisions as originally laid down in Regulation 2023/607 of the European Parliament and of the Council. CAMDs, unlike Notified Bodies, are not driven by financial interests, but solely serve public health. It can be assumed that they have a great interest in keeping safe medical devices – incl. WET legacy – available. SMEs predominantly report positive results from inspections by competent authorities. The advantage in this context is that, should disputes arise, there are established appeal procedures that offer enterprises legal protection.

¹⁵ European Commission (July 2024) Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 [...] Rev. 2 ([mdr_proposal_extension-q-n-a.pdf](#) aufgerufen am 01.10.2024)

3. Centralised registration of distributors as economic operators in EUDAMED for the sustainable improvement of patient safety

Measure

A central registration obligation for all distributors of medical devices in accordance with Article 31, as it exists for other economic operators such as manufacturers, authorised representatives or importers, should be made mandatory within 12 months.

Rationale

A central registration requirement for all distributors would be an important step towards better control of this market. In fact, the effort required to achieve this would be minimal. EUDAMED would only have to create a new serial number range. The module for registration of economic operators in accordance with Article 31 has been fully operational for four years. Manufacturers, authorized representatives and importers are already registered there centrally.

Conclusion

The proposed measures, if implemented, will provide the urgently needed short-term relief to maintain established and safe medical devices, while helping to preserve micro and small enterprises in Europe. The conditions for SMEs must be improved if Europe wants to maintain its innovative strength. It may come as a surprise that the measures cost almost nothing but bring quick returns.

These proposals were drawn up by

Yvonne und Tobias Hoffmann

(3rd generation family entrepreneurs of what is currently a micro-enterprise)



Hoffmann Dental Manufaktur GmbH, founded in 1892, has survived two World Wars, the Great Depression, Oil shocks, Financial Crisis and the Coronavirus Pandemic and is now acutely threatened by the MDR.

These proposals are supported by



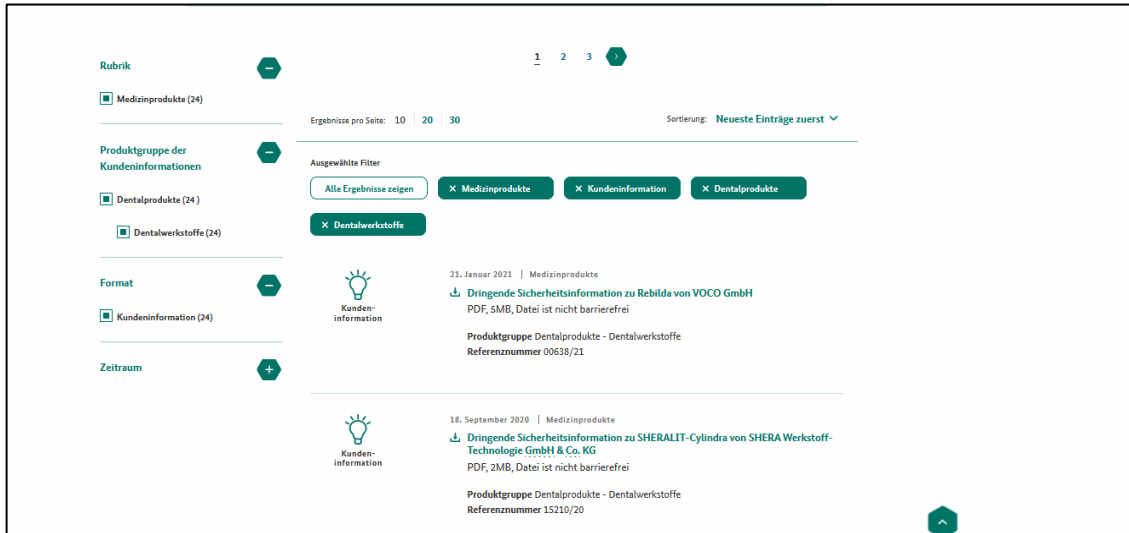
ADDE, The Association of Dental Dealers in Europe represents the interests of a total of more than 960 dental dealer organisations in Europe.



BVD, Bundesverband Dentalhandel represents 130 members from the dental trade, manufacturers who mainly supply through retailers and are expressly committed to this cooperation (cooperative members), and mail order companies in Germany.

Appendix I

Reported risks of BfArm Germany Dental materials all (2013-2024) → total 24



The time is right to get these or similar amendments through. There was a debate in the EU Parliament in October.

Transcripts:



Videos:



A resolution on 23 October 2024 demanding short-term changes from the Commission:



And a related newspaper-article in the „Zeit“:



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