

# MedTech Denmark's Consultation Response Regarding the European Commission's Proposal to Revise the Regulations for Medical Devices (MDR) and In Vitro Diagnostic Medical Devices (IVDR)

April 13<sup>th</sup>, 2026

## Summary

Since the adoption of the MDR and IVDR in 2017, the Danish and European medical device industry has been seriously set back in global competition due to an unpredictable, costly, and unnecessarily bureaucratic regulatory regime. This has resulted in existing products not being maintained on the European market, while new health technology solutions are often launched in the USA and Asia rather than in the EU. The consequence is that patients, citizens, and clinicians in Denmark and Europe have missed out on a wide range of modern health technologies.

Therefore, it is very positive that the European Commission has launched a draft revision of the MDR and IVDR, aiming to ensure greater proportionality, remove unnecessary administrative burdens, and promote innovation – thereby supporting the availability and patient safety of innovative medical devices in Europe.

Specifically, MedTech Denmark supports the revision proposal to remove the maximum validity period of five years for certificates across all risk classes, increased harmonization of notified bodies, strengthened use of clinical equivalence, better opportunities for structured dialogue, reduction of the fee level as part of the certification process, removal of unnecessary bureaucracy in areas without implications for patient safety, introduction of a fast track for breakthrough devices, more accurate risk classification of products, strengthened market surveillance, as well as better alignment between the AI Act and the MDR and IVDR.

However, MedTech Denmark is deeply concerned about the proposals relating to increased powers for healthcare institutions to develop medical devices in-house. MedTech Denmark is also highly skeptical regarding Article 17 of the proposal, which introduces a reversed burden of proof for manufacturers of single-use devices and encourages the reprocessing of such devices, which will compromise patient safety. Furthermore, MedTech Denmark finds it inadequate that the revision proposal does not address the inefficient approval process associated with integral drug-device combination products, cf. Article 117.

## Introduction

As the industry association representing manufacturers and suppliers of medical devices, MedTech Denmark brings together the Danish medtech sector and has therefore followed at very close range the development, adoption in 2017, and subsequent implementation challenges of the MDR and IVDR.

With more than 240 member companies, close member engagement through the association's 22 expert groups, and strong involvement in the European industry association MedTech Europe, the medical device regulation is one of MedTech Denmark's key focus areas.

Against this background, MedTech Denmark very much welcomes that the European Commission has now presented its proposal to revise the MDR and IVDR, which points towards more competitive regulatory conditions and strengthened patient safety in Europe.

With a long-awaited revision proposal from the European Commission now on the table, there is a real opportunity to future-proof European patients' access to innovative medical devices while supporting one of Europe's key life science strengths. In the following, MedTech Denmark provides a structured review of the European Commission's proposal and highlights the most important elements included in the updated regulatory framework.

### **A brief overview of medical device regulation – and the need for revision**

The medical device sector is essential to Europe's healthcare systems, patient safety, and the EU's competitiveness. The sector delivers critical health technologies from early detection and diagnosis to treatment in hospitals, to follow-up care at home, including through greater use of elderly tech. At the same time, the industry contributes to employment, research and development, and innovation in the EU: the sector employs more than 930,000 people and accounts for approximately 15,000 patent applications annually.

The current regulatory framework – the MDR and IVDR adopted in 2017 – has strengthened requirements for clinical evidence, safety, and post-market surveillance. However, it has also created significant regulatory challenges. Insufficient notified body capacity, unpredictable conformity assessment processes, and disproportionately burdensome requirements mean that many manufacturers – especially small and medium-sized enterprises (SMEs) - either withdraw critical medical devices from the EU market or refrain from launching new health technologies in the EU altogether.

As a result, patients risk losing access to necessary – and in some cases vital – medical devices. The repeated extensions of the transitional periods for the two regulations, which for certain devices run until 2028 depending on risk class, have provided only temporary emergency relief to prevent critical devices from leaving the market in the short term. They have not addressed the underlying problems of an overly complex, burdensome, and bureaucratic regulatory framework. A revision of the medical device and in vitro diagnostic medical device regulatory framework is therefore necessary to safeguard continued access to devices in Europe, foster innovation, and maintain a high level of patient safety across European healthcare systems.

In its resolution P10\_TA(2024)0028, “Urgent need to revise the medical devices regulation”, adopted on 23 October 2024, the European Parliament underscored the urgent need to revise the medical device Regulations so that it becomes attractive again to develop, manufacture, and place innovative medical devices on the market in Europe – benefiting European patients, healthcare systems, and the EU’s competitiveness in the medtech sector.

EU Commissioner for Health and Animal Welfare Olivér Várhelyi has likewise stated that a revision of the MDR and IVDR is critical. When the European Commission’s European life science strategy was published on 2 July 2025, the medical device sector was highlighted as one of the areas where Europe is at greatest risk of losing competitiveness to other regions – particularly due to regulatory challenges.

At the same time, the Danish Government has on several occasions advocated an innovation-driven revision of the MDR and IVDR, including in connection with the national Agreement on the Life Science Strategy (November 2024), where the Government and the agreement parties agreed that Denmark should work to revise the MDR and IVDR so that it becomes attractive again for manufacturers to develop and launch innovative medical devices in Europe. The Danish Life Science Council has likewise pointed to the need for a more modern medical device regulatory framework in Europe.

Below follows a systematic review of the European Commission’s revision proposal, as set out in the table on pages 12-20 of document COM(2025) 1023 final of 16 December 2025.

## **Simplification and proportionality**

### **Person responsible for regulatory compliance (PRRC) (MDR: Article 15; IVDR: Article 15)**

*The proposal replaces the detailed qualification requirements for the PRRC with a requirement for "requisite expertise" in the relevant field.*

MedTech Denmark supports the European Commission's proposal to replace the detailed qualification requirements for the person responsible for regulatory compliance (PRRC) with a requirement for "requisite expertise" in the relevant field.

In MedTech Denmark's assessment, this change – together with the proposal that micro and small enterprises will only need to have a PRRC available rather than continuously and permanently accessible – will make it easier for companies to meet the administrative requirements on the pathway to CE marking.

This is one of several proposed changes intended to improve conditions for micro and small enterprises in line with the principle of proportionality. MedTech Denmark considers this highly positive, as the development of new technologies and innovative products in Europe's medtech sector is primarily driven by smaller companies.

### **Validity of certificates and recertification requirements (MDR: Artikel 56, IVDR: Artikel 51)**

*The maximum validity period of five years for certificates is removed. Instead, notified bodies shall perform periodic assessments proportionate to the device's risk level for as long as the certificate remains valid.*

Medical devices on the European market are, due to the general requirements in the MDR and IVDR, subject to stringent ongoing oversight, including annual audits, vigilance/safety reporting, clinical evaluations, and extensive post-market surveillance mechanisms such as Periodic Safety Update Reports (PSURs), Post-Market Surveillance Reports (PMSRs), Post-Market Clinical Follow-up (PMCF), and incident reporting obligations.

These measures, introduced in the current Regulations, ensure that medical devices on the European market are closely monitored after certification. In addition, the notified bodies overseeing the devices may at any time suspend or withdraw certificates on the basis of relevant evidence.

Despite the close post-market oversight, it is currently a requirement that all medical devices be recertified every five years. This stems from the fact that certificates issued by notified bodies typically have a five-year validity. These five-year recertification

requirements constitute an unnecessary and bureaucratic regulatory measure that does not enhance patient safety but merely makes the conformity assessment process unnecessarily costly and thereby reduces manufacturers' incentives to both maintain existing medical devices on the European market and to launch new health technology solutions in the EU.

MedTech Denmark therefore welcomes the European Commission's proposal to remove the maximum five-year validity period for certificates across all risk classes. As part of the work towards the revision of the MDR and IVDR, MedTech Denmark has clearly highlighted the need - across all risk classes – to abolish the five-year recertification requirement, which is one of the most problematic elements of the current regulatory framework.

The reason why the current medical device regulatory framework includes recertification requirements is rooted in the legislation that preceded the two regulations, namely the Medical Devices Directive (MDD) and the In Vitro Diagnostic Medical Devices Directive (IVDD). Under those directives, certificates also had limited validity.

However, the transition from directives to regulations represents a fundamental change in the approach to oversight of devices on the European market. It can therefore be viewed as an error that these requirements were not already removed when the MDR and IVDR were adopted.

Under the directives, the technical documentation was to some extent static, and periodic recertification was therefore an appropriate measure to help ensure patient safety. By contrast, the current regulations are based on the principle of continuous reassessment of safety and performance, with robust mechanisms already providing notified bodies with routine, detailed, and ongoing visibility into conformity throughout the product lifecycle.

In the draft revision of the MDR and IVDR, the European Commission also introduces a new possibility to designate reference laboratories, which currently exist only for IVDs. One potential task for such reference laboratories is to provide scientific and technical assistance to competent authorities in connection with market surveillance and investigations of vigilance cases, cf. Article 106a described below. This strengthens market surveillance, as an independent actor can support authorities in assessing the incident investigations carried out by the manufacturer. MedTech Denmark welcomes this, as it provides an additional rationale for why the market surveillance system - including the vigilance reporting system - constitutes a sufficient safeguard for patient safety.

With the current regulatory framework and the measures included in the draft revision to further strengthen market surveillance, the five-year recertification requirement therefore appears not only unnecessary, but also directly burdensome and strongly innovation-inhibiting for manufacturers of medical devices.

For example, it is a fact that the recertification requirement has led companies to discontinue products from the European market because it is not economically viable to maintain existing products in Europe.

At the same time, the recertification requirement - with its high compliance costs and administrative complexity - has the undesirable effect of making the EU less attractive as a market overall, which can reduce companies' incentives to launch new and more innovative products in Europe at all.

Both aspects have direct implications for patients' access to existing as well as new health technology solutions. The recertification requirement thereby undermines patient safety for citizens and patients in Europe because it impedes patients', citizens', and clinicians' access to the latest and best medical technologies.

A major study prepared by Ernst & Young for the European Commission's Directorate-General for Health and Food Safety (DG SANTE) ahead of the 2025 draft revision also clearly points out that recertification requirements are among the most significant barriers to a well-functioning internal market for medical devices in Europe.<sup>1</sup>

In that study, 60% of respondents indicate that the MDR and IVDR are innovation-inhibiting and have forced European medtech companies to certify and launch innovative medical devices in markets other than the European one, particularly in the United States.

The figure may appear striking, but it aligns with several other studies in the area. For example, according to a 2022 report by the University of California and Boston Consulting Group, 89% of large medtech companies state that, going forward, they prefer to launch new, innovative medical devices in the United States rather than in the EU due to the regulatory challenges that have followed in the wake of the MDR and IVDR.<sup>2</sup> These findings are supported by a survey among MedTech Europe's members, where approximately 50% of companies expect to deprioritise the European market in the future.<sup>3</sup>

Figures from the German market show a similar pattern. Data from the German Chamber of Industry and Commerce indicate that both large and small medtech companies have been forced to discontinue the marketing of products on the European market. Among

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<sup>1</sup> Ernst Young (EY) for DG Sante, Study on Regulatory Governance and Innovation in the field of Medical Devices, Executive summary, 2025, p. 7

<sup>2</sup> Boston Consulting Group & University of California, Interstates and Autobahns Global Medtech Innovation and Regulation in the Digital Age, 2022: <https://web-assets.bcg.com/8c/f0/06744e8848ea9654bbd0765bf285/bcg-interstates-and-autobahns-mar-2022.pdf>

<sup>3</sup> MedTech Europe, MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation, 2022: <https://www.medtecheurope.org/wp-content/uploads/2022/07/medtech-europe-survey-report-analysing-the-availability-of-medical-devices-in-2022-in-connection-to-the-medical-device-regulation-mdr-implementation.pdf>

micro-enterprises with up to nine employees, 67% state that they have chosen not to transition at least one product to the MDR. For larger companies with more than 250 employees, this applies to 48% of companies. The implication is fewer medical technologies in Europe overall, but also far fewer niche products, which can have significant consequences for public health.<sup>4</sup>

A further key argument for removing the recertification requirement is that - besides not contributing to improved patient safety and instead weakening access to innovative health solutions in Europe - the requirement itself creates bottlenecks in the conformity assessment process. In the first years after the MDR and IVDR entered into force, there were severe bottlenecks that meant critical medical devices were at risk of falling off the market. This was one of the most important reasons why the transitional periods for the two regulations have been extended on several occasions.

Today, notified body capacity is better than it was a few years ago. However, data from Gesundheit Österreich (2025) illustrate that the current recertification requirements may lead to renewed bottlenecks, again threatening the availability of solutions on the European market more broadly, because - if maintained - the current requirements can be expected to create cyclical bottlenecks every five years.<sup>5</sup>

Overall, MedTech Denmark therefore assesses that the recertification requirement - together with a generally bureaucratic regulatory regime - plays a central role in explaining why Europe is losing ground in global competition, including why products are either not launched or not maintained in the EU.

This would also align with the very clear recommendations made by the Danish Life Science Council in the preparatory work for the European life science strategy, where the Council recommended that, as part of the revision of the MDR and IVDR, the mandatory five-year recertification requirements for medical devices across all risk classes should be removed.<sup>6</sup>

In this context, MedTech Denmark notes that a number of Danish manufacturers are, during these months and years, facing recertification of their devices for the first time under the MDR and IVDR. This is partly because Danish medtech companies have been "first in class" in the transition period by investing heavily and early in moving from the

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<sup>4</sup> German Convergence Centre and Industry, Current assessment of the German medical device manufacturers of the effects of the EU Medical Device Regulation (MDR) – Unsolved problems weaken Germany and the EU as health and innovation locations, 2023:

[https://www.spectaris.de/fileadmin/Content/Pressemitteilungen/2024/Medizintechnik/DIHK\\_MedicalMountains\\_SPECTARIS\\_MDR\\_Survey\\_2023.pdf](https://www.spectaris.de/fileadmin/Content/Pressemitteilungen/2024/Medizintechnik/DIHK_MedicalMountains_SPECTARIS_MDR_Survey_2023.pdf)

<sup>5</sup> Gesundheit Österreich GmbH, 2025, Evaluation of the implementation of the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR) – 2nd European Operators Survey

<sup>6</sup> The Danish Life Science Council, Recommendations for a European Life Science Strategy, 2025, p. 15-16: <https://www.em.dk/Media/638781413079014720/Life%20Science%20rdets%20anbefalinger.pdf>

MDD and IVDD to the MDR and IVDR. As a result, a number of Danish medical device manufacturers will be hit particularly hard if the political process to reach agreement on the revision of the MDR and IVDR drags on, because they will remain subject to the recertification requirements.

The European Commission's proposal states that, instead of the recertification requirement, there should be periodic assessments proportionate to the device's risk level for as long as the certificate remains valid. MedTech Denmark points out that ongoing surveillance of medical devices is already part of the current market surveillance mechanisms. It is therefore crucial that no new requirements are introduced "through the back door" that, in practice, are as burdensome as the current recertification requirements. MedTech Denmark recommends that clear guidance be developed on the scope of notified bodies' activities to avoid divergent practices across notified bodies and over-implementation of specific market surveillance requirements.

**Clinical evidence, non-clinical data and clinical data (MDR: Article 2(48), Article 61, Annex II; equivalence under Article 61(5) and Annex XIV; MDR Article 82)**

*A broader spectrum of data can now qualify as clinical data, and reliance on data from an equivalent device is made more flexible. The device's safety and performance may be demonstrated solely using non-clinical data, and the use of new methods such as real-world data and in silico testing becomes possible.*

MedTech Denmark supports that a broader spectrum of data can now be used as clinical data - for example, in silico evidence and "real-world data" are mentioned. It should, however, be emphasised that the data used as clinical documentation must always be scientifically robust, and it will remain a case-by-case assessment where the notified body verifies whether the level of clinical evidence is sufficient considering the product's risk profile. Especially within digital medical devices, this represents a significant modernisation, which MedTech Denmark supports.

Regarding the use of "real-world data", MedTech Denmark's members highlight it as positive that such data can be used in other jurisdictions outside Europe. The revision proposal also provides that Article 82 of the current MDR be deleted. Article 82 concerns clinical investigations that are not conducted to demonstrate conformity with the requirements of the Regulation. These are often early tests with medical devices - for example prototypes - that cannot be defined as clinical investigations of devices under Article 62(1), but rather serve to generate more knowledge about a given technology.

MedTech Denmark observes that many member companies make use of this type of clinical investigation, which in Denmark is applied for only with the Research Ethics

Committee and not with the Danish Medicines Agency. It is unclear to MedTech Denmark why this Article is proposed to be deleted, and MedTech Denmark therefore requests that Article 82 be retained.

Under Article 61(5) of the current Regulation, it is required that a clinical investigation be performed for all implantable class IIb devices and all class III devices. Certain exceptions apply: if the device is a modification of a previous device from the same manufacturer and is considered equivalent by the notified body; or if the device is equivalent to another manufacturer's device and the manufacturer has a contract with that other manufacturer granting full access to the technical documentation, and the clinical evaluation has been conducted in accordance with the requirements of the Regulation.

In the European Commission's proposal, the requirement for full contractual access to the technical documentation is removed. This is a very significant and positive change, which MedTech Denmark fully supports. It was precisely the narrowed equivalence principle that caused several products to leave the European market. At the same time, since it is maintained that the clinical evaluation must be carried out in compliance with the Regulation's requirements for clinical evaluation, MedTech Denmark considers that this change will not be detrimental to patient safety. In this context, it is noted that EU medicinal product regulation similarly operates with a comparable equivalence concept, and that this also applies in the United States, where the FDA allows a manufacturer to prepare its clinical documentation by referencing an existing product - a so-called "predicate device" - which does not need to be the manufacturer's own.

In Annex XIV, regarding the biological and clinical characteristics of devices, the wording is supplemented with "similar" instead of only "same" as in the current MDR. This likewise increases the possibility of applying the equivalence principle, which is highly positive and should be preserved during the negotiations. It has proven very difficult to document that a modified material has the "same" clinical and biological profile; therefore, the insertion of the word "similar" constitutes a clear improvement and will mean that equivalence can, in practice, be applied within medical devices.

**Well-established Technologies (WET) (MDR: Article 2(72), Article 18, Article 32, Article 52, Article 61, Article 86)**

*A definition of 'well-established technology device' is introduced for devices which will be subject to more proportionate requirements, replacing the lists of devices in the current Articles 18(3), 52(4) and 61(6)(b) MDR.*

When the current Regulation was negotiated, there was, as such, no possibility for well-documented legacy devices with a long, safe history on the European market (so-called

“well-established technologies”) to remain on the market without meeting the new requirements of the Regulation - so-called “grandfathering”. However, as it became apparent already during the negotiations that, for example, sutures, osteosynthesis products, etc. would risk disappearing from the European market, Article 61(6)(b) was amended to include a list of devices - such as sutures, staplers, dental fillings, orthodontic devices, osteosynthesis products, etc. - that were exempt from the requirements of Article 61(4).

At the same time, Article 61(8) included a delegation to the European Commission to expand the list in Article 61(6). Unfortunately, due to workload, the Commission only began work on expanding the list in paragraph 6 in 2025, and this possibility has therefore not yet been used - greatly to the detriment of a number of Danish device manufacturers whose products, like those listed in Article 61(6), have a long and safe market history but were simply not mentioned. In part for this reason, the MDR has been postponed several times, as there would otherwise have been a risk that critical medical devices would leave the European market. The challenge for these products is that it is very difficult to conduct new clinical investigations of old technology. It is difficult to find clinicians (investigators) willing to carry out such studies precisely because the technology is well known. There is also an important ethical consideration in subjecting participants to potentially invasive investigations with significant discomfort solely for regulatory reasons when the risk profile and performance of these products are well established and unchanged.

It is therefore appropriate that the European Commission proposes that the Regulation’s provisions on clinical evidence no longer refer to specific products but instead define the concept of “well-established technologies” in Article 2(72). This proposal reflects the definition in the relevant MDCG guidance, MDCG 2020-6, which is positive. Overall, these changes will ensure that the scope for these well-known and safe legacy devices is broadened, so that more devices are subject to much more proportionate requirements than under the current rules. This change will also help ensure that important medical devices can remain available on the European market.

### **Repackaging and labelling (MDR: Article 16, IVDR: Article 16)**

*The requirements for notified body certificates for relabelling and repackaging, as well as the prior notification obligation, are removed.*

In the revision proposal, the requirements are removed for distributors or importers who translate information supplied by the manufacturer or repackage devices - provided the device’s original condition is not affected - to notify the manufacturer or the Member State in which the device is made available. In addition, the requirement that these specific activities must be covered by a certificate issued by a notified body is removed.

MedTech Denmark is, in principle, positive towards the proposal to remove the requirement that repackaging activities must be certified by a notified body, as this administrative burden is assessed not to contribute to increased patient safety.

However, MedTech Denmark is concerned that the information/notification obligation is proposed to be removed. In MedTech Denmark's view, it can be highly problematic if the manufacturer is not informed in cases where distributors translate or otherwise modify the information accompanying products for which the manufacturer ultimately bears responsibility. The notification obligation ensures that the manufacturer has awareness of - and the ability to intervene in - situations where, for example, mistranslations or inadequate instructions for use may occur, which could affect the safe and correct use of the product. In the worst case, MedTech Denmark considers that this amendment could compromise patient safety. MedTech Denmark also points out that the proposal would weaken traceability of the individual products.

Overall, MedTech Denmark therefore recommends the proposal that repackaging activities should no longer need to be certified by a notified body, while maintaining the notification obligation in connection with repackaging of the product.

### **Classification (MDR: Annex VIII)**

*Annex VIII has been adjusted and several rules have been amended, resulting in lower risk classes for certain devices such as reusable surgical instruments, accessories for active implantable devices, and software.*

In the European Commission's proposal, a number of classification rules are to be adjusted so that they better reflect the device's actual risk. This will result in lower risk classes for a range of devices, including certain types of reusable surgical instruments, accessories for active implantable devices, and some forms of software.

In the run-up to publication of the revision proposal, MedTech Denmark has argued that there are classification challenges in the current system, where very simple medical devices have inappropriately been classified as high-risk devices.

As a result, it is currently disproportionately costly to place this type of solution on the European market, and there are limited incentives to make minor updates to simple and well-established devices because the conformity assessment process has been too heavy, bureaucratic, and resource intensive. Ultimately, the current regulatory framework has therefore meant that patients and clinicians have missed out on products and updates that are otherwise available in other regions.

MedTech Denmark therefore considers the proposal to adjust the classification rules to be a highly sensible measure that will increase proportionality, strengthen incentives to

update these types of devices, and ultimately ensure that patients in Europe have access to a broader range of medical devices.

The current wording means, in practice, that devices such as pacemaker screws or scalpels used in cardiac or neurosurgery are placed in the highest risk class, with the legislation's strictest requirements for clinical evidence, scrutiny, and notified body review/approval - even though the devices themselves are relatively simple. Under the revision proposal, these wordings are amended, and the pathway to market is therefore eased.

With regard to the proposed amendments on software classification, MedTech Denmark has, ahead of publication of the revision proposal, emphasised that there are classification challenges in the current system. MDR Rule 11 may, in some situations, lead to over-classification of low-risk medical device software (MDSW). In this context, MedTech Denmark's initial assessment is that the proposed amendments primarily align the wording with guidance from the International Medical Device Regulators Forum (IMDRF), but do not entail major changes to how software is classified today. However, the practical implications will depend on the specific wording in the relevant MDCG guidance.

Overall, MedTech Denmark is very positive about the European Commission's proposal to adjust a number of the classification rules, as this will, in practice, ensure that classification aligns much better with the device's risk profile. This will reduce the workload for both notified bodies and manufacturers and lower disproportionate administrative costs associated with certification of this type of device.

MedTech Denmark therefore unequivocally recommends that the European-Commission actively works to preserve this amendment. Without this adjustment, launching—or even making minor updates to—simple and well-established devices will remain unattractive on the European market, which does not benefit patient safety.

## **Reduction of administrative burdens**

### **Summary of Safety and Clinical Performance, SSCP (MDR: Article 32, IVDR: Article 29)**

*The requirement for manufacturers to draw up a Summary of Safety and (Clinical) Performance is limited to devices for which a notified body must perform a technical documentation assessment. Separate validation by the notified body is no longer required.*

Under the current Regulation, all devices in risk class IIa, IIb and class III are required to be accompanied by a Summary of Safety and Clinical Performance (SSCP). The SSCP must meet a number of requirements, including that it must be written in language understandable to a lay person and translated into all languages relevant to the Member States where the devices are marketed.

In the European Commission's revision proposal, the requirement is narrowed so that an SSCP is no longer required for class IIa devices, and only where the device is intended to be used by the citizen or patient themselves must the SSCP be drafted in a lay-person-friendly manner. Finally, the manufacturer will be able to upload the SSCP to EUDAMED themselves, rather than - as today - having this handled by the notified body.

MedTech Denmark strongly supports these amendments, as they will make the rules more proportionate and workable—without affecting patient safety or impacting those who use the devices—because the notified body will still verify the relevant documentation as part of its periodic surveillance of the manufacturer's documentation.

### **Periodic Safety Update Report (PSUR) (MDR: Article 86, IVDR: Article 81)**

*The frequency of PSUR preparation is reduced. Notified bodies will assess PSURs as part of their surveillance activities.*

When the current Regulations were adopted - drawing inspiration from the medicinal product legislation - requirements were introduced for manufacturers of medical devices to prepare a Periodic Safety Update Report (PSUR), and for class I devices to prepare a Post-Market Surveillance Report (PMSR).

These documents provide an important overview of the device's safety and performance, and the introduction of PSUR/PMSR therefore significantly strengthened post-market surveillance of medical devices as part of the transition from the MDD and IVDD to the MDR and IVDR.

The frequency for preparing these reports follows the device's risk class. Under the current Regulation, PSURs must be prepared annually for class IIb and class III devices, every two years for class IIa devices, while class I devices require a Post-Market Surveillance Report (PMSR) as needed.

The European Commission now proposes to reduce the frequency of PSUR preparation, so that for class IIb and class III devices the PSUR must be prepared in the first year and thereafter every two years or as needed - for example if significant changes to the device's risk profile are introduced. The PSURs will also no longer be subject to a specific, stand-alone audit, but will instead be reviewed as part of the ongoing and routine surveillance carried out by notified bodies.

MedTech Denmark assesses that these changes will reduce the administrative burden for medical device manufacturers while maintaining the strong focus on device safety and performance. MedTech Denmark therefore supports these amendments, which reflect a more proportionate approach to post-market surveillance of medical devices without having implications for patient safety.

### **Incident reporting (MDR: Article 87, IVDR Article 82)**

*Manufacturers now have 30 days (previously 15) to report serious incidents that are not related to a serious public health threat, death, or serious deterioration in a person's state of health.*

In the current Regulations, the reporting deadline for serious incidents that are not related to a serious public health threat, death, or serious deterioration in health was shortened from 30 days to 15 days. The proposal now extends this deadline back to 30 days.

As these are incidents that do not involve a serious public health threat, death, or serious deterioration in health, MedTech Denmark considers this a very positive change that has the potential to reduce administrative burdens for both competent authorities and manufacturers.

In practice, these incidents can rarely be sufficiently assessed within 15 days, which has therefore led to almost all incidents being reported regardless of whether they are actually reportable. Most initial reports are then followed by a final report once the investigation concludes that the incident was not reportable.

This change will therefore save both the competent authorities and manufacturers time, while patient safety is, in reality, strengthened because the large volume of non-reportable incidents in the current set-up puts pressure on the system and, in the worst case, can

divert both authorities' and manufacturers' focus from cases that genuinely require corrective and preventive actions.

By extending the deadline to 30 days for reporting serious incidents that are not related to a serious public health threat, death, or serious deterioration in health, a more efficient and patient-safe system is ensured, with better possibilities to allocate time and resources to cases that truly require attention.

### **Change handling (MDR: Bilag VII, IVDR: Annex VII)**

*Notified bodies must distinguish between changes that manufacturers may implement without prior notification, without prior approval, or only after approval. Where necessary, a predefined change control plan (Pre-determined Change Control Plan, PCCP) shall be agreed.*

The proposal clarifies that notified bodies must clearly distinguish between changes that manufacturers may implement without prior notification, changes that require notification but not prior approval, and changes that may only be implemented after approval. At the same time, it becomes possible for the manufacturer and the notified body to agree on an advance assessment of planned changes to the device where relevant, so that such changes can be implemented without the notified body needing to be informed and reassess the changes again, through a so-called Pre-determined Change Control Plan (PCCP).

MedTech Denmark's clear assessment is that these proposals will significantly reduce the workload for both manufacturers and notified bodies, while also harmonising the often divergent practices among notified bodies in their handling of changes. In the run-up to the Commission's revision proposal, MedTech Denmark has therefore actively argued that current practice should be changed, as inconsistent handling of changes has created substantial opacity, unpredictability and unequal conditions for manufacturers, and has furthermore delayed patients' access to updated devices.

Overall, MedTech Denmark therefore strongly supports these amendments, which will ultimately help ensure that patients and citizens benefit from up-to-date, technology-enabled support as part of their treatment and care.

In this context, MedTech Denmark finds it important to note that this revision proposal does not change the fact that notified bodies must assess changes that affect the device's performance, intended purpose, or otherwise may impact the device's risk profile. The proposal will therefore not weaken patient safety, but instead support a more up-to-date supply of medical devices in Europe.

Finally, MedTech Denmark also finds it important to point out that the revision proposal includes amendments to Annex XII regarding the content of certificates. For example, in Chapter I, 4(b), it is proposed that manufacturing sites be included on the certificate, as was the case under the MDD. This was removed with the implementation of the MDR. While it is appropriate for notified bodies to know all manufacturing sites, there is no wish from industry to reintroduce this on the certificate itself, as it would trigger an unnecessary need to issue new certificates whenever manufacturing sites change. In addition, there is a rewording of Chapter II, point 10, in the revision proposal which could be interpreted as requiring common specifications and harmonised standards to be included on the certificate.

As certificates often cover many different devices, this must be an error, as it would both make certificates very long and add a significant and unnecessary workload to keep certificates updated – also impacting international registrations that rely on recognition of the CE mark. MedTech Denmark therefore recommends that Chapter I, 4(b) remains unchanged, while Chapter II, point 10 is deleted entirely. This will ensure that issued certificates can maintain their validity for longer, without patient safety implications, as notified bodies already have this information available.

**No longer required: prior authorisation of performance studies is unnecessary for IVD devices where the investigation involves routine blood sampling only (IVDR: Article 58)**

*Performance studies that involve routine blood sampling only do not require prior authorisation, and the notification requirement for performance evaluations of companion diagnostics using left-over specimens is removed.*

MedTech Denmark considers this proposal highly positive, as performance studies for IVD devices that involve routine blood sampling only will no longer require a prior application and authorisation by the competent authority and an ethics committee in those cases where participants are not subjected to anything beyond the standard diagnostics or treatment they already receive.

## **Innovation and availability of devices for specific patient groups or situations**

### **In-house devices (MDR: Article 5(5); IVDR: Article 5(5))**

*The conditions for manufacturing and use within health institutions are made more flexible, including the possibility to transfer to other health institutions where required for patient safety or public health. Under the IVDR, the requirement that no equivalent devices are available on the market is removed, and central laboratories using tests for clinical trials are included within the scope of the exemption.*

When the MDR and IVDR were adopted in 2017, an exemption was introduced allowing a health institution to manufacture a medical device itself and use it within its own institution, provided that a thorough prior market investigation demonstrates an unmet clinical need. This can be compared to the extemporaneous (magistral) preparation of medicinal products.

In the European Commission's proposal, these powers are expanded in several respects, which MedTech Denmark considers highly problematic. The proposal could have significant implications for the medtech industry in a country such as Denmark, which has a predominantly publicly funded healthcare system. Below, MedTech Denmark sets out key concerns in relation to the MDR and IVDR respectively:

### **Under the MDR**

Under the European Commission's revision proposal, the possibility to share in-house developed devices is expanded so that - unlike today - it will no longer be only the institution that manufactures the device that may use it. In addition, health institutions are given the possibility to manufacture and use such devices for up to ten years.

In Denmark, it remains an issue that health institutions themselves wish to develop medical devices, particularly in the software area. In repeated political agreements, including most recently the 2024 Healthcare Reform, there has been a misguided focus on new solutions being developed within the healthcare system itself.

It is therefore deeply problematic that the proposal would allow in-house developed devices to be shared across health institutions and used for up to ten years, because this removes incentives for medtech companies to innovate in these fields, as the market becomes limited and effectively reserved for in-house devices.

In Denmark, the public healthcare system procures medical devices through tendering under the EU public procurement directives, and these contracts typically have a duration of two years with an option to extend for a further two years. In MedTech Denmark's

view, giving the public sector the ability to reserve the market for in-house developed devices for up to ten years therefore goes far beyond what is reasonable.

In this connection, MedTech Denmark notes that, as regards magistral (extemporaneous) preparation of medicinal products, the Danish Pharmacy Act (Apotekerloven) sections 13(2) and 56(6) provide that if an equivalent medicinal product is manufactured by parties other than pharmacies or hospital pharmacies respectively, then pharmacies/hospital pharmacies may no longer manufacture it.

It would therefore be a peculiar legal situation - and would significantly harm the medical device market - if, in the medtech field, it becomes possible to develop and use in-house devices for up to ten years, while magistral preparation of medicinal products must cease when a commercially developed alternative exists.

MedTech Denmark therefore clearly and unequivocally urges the European Commission to seek removal of the possibility for health institutions to share in-house devices across institutions. In addition, MedTech Denmark recommends that the permitted period during which in-house devices may be used is reduced to only one year. This would give the public healthcare system a reasonable timeframe to run a tender for the relevant device, without undermining the market for innovative medical devices through public-sector activity.

MedTech Denmark also notes that healthcare capacity in Denmark and many other European countries is under severe strain in these years, inter alia due to the double demographic pressure. In a time when shortages of healthcare professionals are repeatedly highlighted as one of the greatest challenges to future healthcare provision, it appears incongruous that healthcare systems on the one hand are struggling to reduce waiting lists, while on the other hand they would be granted powers to spend resources developing medical devices themselves when a large private market already exists.

## **Under the IVDR**

Under the European Commission's revision proposal for IVDR, it is suggested that the approach goes even further by removing the condition that in-house development of tests may only take place where no commercially available equivalent test exists.

MedTech Denmark strongly opposes this, for the same reasons described above under the MDR. In MedTech Denmark's view, it is not reasonable that the public healthcare system should operate activities involving manufacturing and supplying in-vitro diagnostic medical devices competing with medtech companies on unfair market terms.

MedTech Denmark also notes that, in particular within the IVD area, there are areas of tests for which no commercial market exists. Against that backdrop, this amendment appears odd and unjustified, as the current Regulation already allows for in-house production to develop such tests as the market does not provide them.

MedTech Denmark therefore strongly advises against removing, as part of the MDR/IVDR revision, the current condition that in-house development is permitted only where there is a need that cannot be met by the market.

## **General remarks**

Regarding the proposed amendments to MDR and IVDR Article 5(5), MedTech Denmark considers it important to point out that there are significant differences in the oversight and control applied to in-house devices compared to devices placed on the market by commercial manufacturers. This is most clearly reflected in the fact that in-house devices are not subject to notified body oversight, regardless of the device's risk class.

By proposing, under the MDR, that in-house devices may be shared across health institutions and used for up to ten years, while under the IVDR going even further by removing the condition that in-house development of tests is only permitted when no commercially available equivalent test exists, the proposal opens the door for patients in public healthcare systems such as Denmark's to increasingly be treated with medical devices subject to substantially weaker oversight than devices placed on the market by private actors. In MedTech Denmark's view, this represents a serious failure of the patient safety objective that the regulatory framework is intended to protect.

## **Interruption or discontinuation of supply of certain devices (MDR: Article 10a, IVDR: Article 10a)**

*A central IT tool for reporting and information exchange will be made available via EUDAMED or an interoperable system. The EMA will develop methods and lists for the reporting obligations.*

In the current MDR, Article 10a was inserted in June 2024, obliging manufacturers to report to the national competent authorities if, within a six-month period, certain products are expected to be subject to supply problems.

MedTech Denmark was critical of this new obligation, because in Denmark it is not the competent authority - the Danish Medicines Agency - that has an overview of the supply situation in the Danish healthcare system. Consequently, it will also not be the Danish Medicines Agency that in Denmark can assess alternative products to those discontinued;

instead, this will be for the actors within the healthcare sector – in Denmark this is regions and municipalities. Typically, this is something that is already regulated through contractual provisions between the healthcare actors and the medtech companies who supply the healthcare system, and there is currently no national reporting system in place in Denmark for such notifications, only the European template and the adherent Q&A.

MedTech Denmark anbefalede derfor, at man i stedet indfører en europæisk indberetning til EUDAMED. Derfor kan MedTech Denmark også støtte, at man i Europa-Kommissionens forslag til ny Artikel 10a i begge forordninger nu foreslår, at der enten rapporteres til EUDAMED eller et andet, interoperabelt system til EUDAMED, så man samler disse indberetninger på europæisk og ikke nationalt niveau.

MedTech Denmark therefore recommended instead introducing EU-level reporting to EUDAMED. MedTech Denmark can therefore also support that, in the European Commission's proposal for a new Article 10a in both Regulations, reporting is now proposed to take place either via EUDAMED or another system interoperable with EUDAMED, thereby consolidating these notifications at European rather than national level.

Since the European Medicines Agency (EMA) already has tasks related to the Health Emergency Preparedness and Response (HERA) framework, including certain tasks aimed at defining critical medicinal products and critical medical devices, and since EMA is developing the ATHINA platform to host intelligence on public health and resilience, MedTech Denmark recommends that EMA is given responsibility for this area.

Furthermore, Medtech Denmark finds it imperative that this new European reporting requirement is aligned with EUDAMED and integrated with EUDAMED as medtech companies are investing heavily in getting into compliance with EUDAMED.

For completeness, it should nevertheless be noted that MedTech Denmark's overall view remains that this reporting obligation is, in practice, entirely unnecessary for the Danish market, since security of supply is already covered by the contracts suppliers enter with actors in the healthcare system. During the COVID-19 crisis, it was precisely the Danish regions and municipalities that worked to manage the supply situation for medical devices - and not the Danish Medicines Agency in its role as competent authority.

### **Conformity assessment procedures for 'breakthrough devices' or orphan devices (MDR: new Article 52a; IVDR: new Article 48a)**

*Criteria for breakthrough and orphan devices are introduced. After designation by an expert panel, these devices undergo prioritised and continuous assessment, and manufacturers gain access to expert panel advice.*

For a long time - and in the run-up to the European Commission's revision proposal for the MDR and IVDR - MedTech Denmark has argued for the need to introduce a dedicated fast-track procedure in the EU for so-called breakthrough devices.

Today, Europe has no dedicated regulatory approval pathway for the most innovative health technology solutions. In reality, this means that a truly novel and innovative solution that can meet clinical needs, which today are not sufficiently addressed faces the same slow, resource-intensive conformity assessment procedures as other medical devices.

This differs from the fast-track systems implemented in the European Union for medicinal products and advanced therapies, positioning the EU notably behind other regions in the medtech sector - including the United States, Japan, and Australia – all of which have established dedicated expedited pathways for breakthrough innovation in medical devices.

From a health policy perspective, the lack of fast-track measures implies that the newest innovations are launched later in Europe than in other markets, and European patients therefore gain access later. From an industrial policy perspective, it has also made Europe a less attractive region for launching new and modern health technology solutions.

MedTech Denmark therefore very much welcomes that the revision proposal introduces the possibility of a dedicated regulatory pathway for breakthrough devices. In practice, this means that health technology solutions that can meet clinical needs not sufficiently addressed today gain access to a prioritised and more interactive process with notified bodies. The effect of the proposal will be faster access for healthcare systems to these solutions - and thus that patients in Europe can benefit from the newest health technologies earlier than is the case today.

The European Commission's proposal provides that, in specific cases, these selected solutions may be allowed to be placed on the market on the basis of limited clinical evidence, where earlier market access is assessed to outweigh the risk - on the condition that the limitations are addressed through early post-market surveillance. A pilot project is already planned, and the proposal introduces a legal basis for this in the Regulation.

In MedTech Denmark's assessment, the European Commission's proposal to introduce a dedicated fast-track procedure for breakthrough devices is crucial to make certain that European healthcare systems gain rapid access to innovative medical devices. MedTech Denmark also considers that the proposal can help ensure that companies increasingly have an incentive to launch their newest solutions in the EU, where they have previously prioritised markets such as the United States, Japan and Australia. MedTech Denmark therefore clearly recommends that the Danish Government actively works to ensure that this proposal becomes a reality in the final revision of the MDR and IVDR.

In addition, the proposal will make it more attractive to develop devices for the treatment of conditions where the affected patient population is so small that, from a commercial perspective, it is typically difficult to prioritise such development. This underscores the need to implement the proposal in its current form.

**Derogations in Public Health Emergencies, Disasters, or Crises (MDR: Article 59, new Article 59a; IVDR: Article 54, new Article 54a)**

*The European Commission may authorise the placing on the market of devices in emergency situations. National competent authorities may grant derogations in cases of serious cross-border health threats, disasters, or crises.*

MedTech Denmark supports that, where national competent authorities grant permission to place non-CE-marked devices on the market in emergency situations, the revision proposal provides a legal basis for the European Commission to extend such derogations to apply across the entire EU. This methodology was implemented during the COVID-19 crisis, and MedTech Denmark believes it is prudent to create a permanent legal foundation for its continuation within the Regulation.

MedTech Denmark further advises that Denmark should endorse the proposal allowing the European Commission, acting independently and in consultation with the Medical Device Coordination Group (MDCG), to grant such exemptions under highly exceptional circumstances, including public health emergencies at the Union level.

In this context, however, MedTech Denmark considers it essential to emphasise that, for reasons of patient safety, such derogations should only be used in truly exceptional situations - exactly as the revision proposal also envisages.

**Regulatory sandboxes (MDR: new Articles 59b and 59c; IVDR: new Articles 54b and 54c)**

*Member States and the European Commission may establish regulatory sandboxes to address the needs arising from new technologies.*

According to the European Commission's proposed revisions, Member States and the Commission would have the option to create regulatory sandboxes. These frameworks are intended to address particular requirements related to the development and implementation of emerging and innovative technologies.

The introduction of such regulatory sandboxes is new in the context of the MDR and IVDR. However, the concept was introduced in the AI Act with the aim of creating a controlled regulatory environment in which companies can test and further develop new solutions under the supervision of authorities.

MedTech Denmark welcomes the objective to facilitate conformity assessment for devices with otherwise uncertain regulatory pathways.

## **Reprocessing of Single-Use Devices (MDR: Article 17)**

*Manufacturers will be obliged to provide a justification for a 'single-use' claim. All devices that are not intended for single-use can be reprocessed in accordance with the instructions provided by the manufacturer. A person who fully refurbishes a single-use device will be the manufacturer of the fully refurbished device. The provision will become applicable five years after entry into force.*

### **Regarding justification for a "single-use" claim**

The revised wording of Article 17 is a significant sticking point in an otherwise well-balanced revision draft of the MDR and IVDR – and the challenges within Article 17 therefore require considerable attention.

First of all, the revised wording establishes a reversed burden of proof, requiring manufacturers to demonstrate why a device cannot be used beyond its stated purpose. This is a paradoxical requirement, as it is difficult to document the purposes the device does *not* have, including what it is not designed for. Normally, the medical device regulation sets out requirements for what a device *can* do. With this rewording, it effectively becomes a requirement to document what the material and design cannot do, which is not appropriate.

This is analogous to obliging a manufacturer of equipment designed specifically for cardiac surgery to provide evidence explaining why it is inappropriate for use in the central nervous system.

Furthermore, the rewording may create uncertainty regarding what constitutes a sufficient level of evidence, potentially placing manufacturers of single-use devices in an unreasonable market situation where they are disproportionately required to document aspects that fall outside the device's intended purpose. MedTech Denmark furthermore emphasizes that an appropriate justification for single-use based on the risk-management file of the device is already called for in Annex I, 23.4(p).

In this context, MedTech Denmark considers it crucial to emphasize that no additional requirements that could distort competition should be placed on companies marketing single-use devices in comparison to those offering devices intended for multiple use. Single-use devices represent an equally vital component of an effective and patient-safe healthcare system as their reusable counterparts.

## **Regarding the responsibility of the reprocessor of single-use devices**

Further, a notable development is that the revised proposal for Article 17 no longer explicitly assigns national authorities the responsibility to determine whether single-use devices may be reprocessed and under which conditions. At present, fewer than half of Member States permit this practice nationally, and MedTech Denmark maintains its established policy that, in the interest of patient safety, the systematic off-label use of medical devices by re-use of single-use devices should be approached with considerable caution.

Medical devices designated for single use are designed and validated under the presumption that they will be utilized only once. The reprocessing and reuse of such devices on patients introduces an inherent risk of infection, thereby elevating the potential for cross-contamination between individuals. Despite thorough cleaning and sterilization procedures, some microorganisms may persist, posing significant health risks.

Moreover, it is essential to verify that the reprocessed and re-sterilized device maintains equivalent functionality to the original product, as the chemicals and procedures involved in reprocessing can impose considerable stress and wear on materials and design.

MedTech Denmark expresses significant concern regarding the amendment to Article 17 referenced in Recital 21. Among the justifications provided is the intention to make the reprocessing of single-use devices commercially viable for businesses in this sector.

Should the proposal be enacted, MedTech Denmark observes that it would effectively establish a similar legal environment, whereby the reprocessor is regarded as the manufacturer of the reprocessed device. In Denmark, health authorities have undertaken an extensive review that has resulted in permitting the reprocessing of single-use devices. Under this framework, the entity responsible for reprocessing assumes the full obligations of a manufacturer for each newly reprocessed device.

In addition to ensuring that the reprocessed device retains the same functionality as the original product, it is also crucial that the device can be traced on the market, which requires labeling and UDI, as with all other medical devices.

In the revision proposal, the requirement (Annex I, 23.2(o)) that it must be indicated on the labeling if the device is a reprocessed single-use device is removed. This is highly problematic, especially for market surveillance, as it may result in the device being misleadingly presented as the original single-use device, thereby causing uncertainty about the responsible company – whether it is the original manufacturer or the reprocessor of the single-use device.

In the current version of Article 17, paragraph 3(a) includes a reference to a number of the requirements set out in Article 5.5, which concerns in-house production of medical

devices. These references have been removed in the proposal. Article 5.5 establishes clear requirements for in-house manufactured medical devices, including requirements for a quality management system, a declaration that the device conforms to the general safety and performance requirements, for device identification and notification obligations. Without these references between article 17 and 5.5, in-house reprocessing of single-use devices will be subject to full compliance with article 10 (general obligation of manufacturers), which we welcome for the sake of patient safety and a level playing field for different actors of medical devices.

### **Regarding sustainability considerations**

Recital 21 cites sustainability considerations, which, in MedTech Denmark's assessment, are misinterpreted.

MedTech Denmark supports efforts to decarbonize the healthcare system; however, it is imperative that patient safety is not compromised, which the current proposal may potentially affect. Additionally, reprocessing single-use devices may not always result in greater sustainability, as many of the processes and chemicals involved can be environmentally burdensome. Consequently, there is insufficient evidence to suggest that sustainability is enhanced by re-use of single use devices.

### **General remarks**

Overall, it is therefore MedTech Denmark's clear recommendation that the revision proposal concerning Article 17 be subject to a thorough rewrite, with a view to ensuring a balanced approach to the use of single-use devices and re-usable device designed and developed for reprocessing. In this context, it is crucial to fundamentally consider whether it is indeed appropriate for the current revision proposal to encourage systematic off-label use of medical devices, which risks both compromising patient safety in Europe and weakening the competitiveness of the medical device industry.

### **Kits (IVDR: new Article 19a)**

*Clarity is provided regarding the composition of kits as defined in Article 2(11) IVDR.*

MedTech Denmark supports this clarification.

## **'Grandfathering' of Existing Orphan Products (MDR: Article 120, IVDR: Article 110)**

*Existing orphan products with CE marking under the previous directives may continue to be marketed beyond the transition period, provided orphan status is confirmed by an expert panel and subject to certain conditions.*

The European Commission's revision proposal stipulates that existing orphan products, which are CE-marked in accordance with the previous directives, may continue to be marketed after the expiry of the transition period, provided this is confirmed by a relevant expert panel and a number of specific conditions are met.

MedTech Denmark regards this as a prudent approach intended to maintain the availability of existing medical devices within the European healthcare system. This measure is particularly significant for products serving small patient populations, where manufacturers may find it challenging to allocate and justify the resources necessary for compliance with MDR requirements.

If this amendment is not included in the final revision, MedTech Denmark assesses that there will be a significant risk that some equipment of great importance to a very small patient population will disappear from the European market, potentially leaving vulnerable patient groups without essential devices.

## **Nanomaterials (MDR: Annex I, Annex VIII)**

*The outdated nanomaterial definition in Article 2 MDR is removed and replaced by a reference to the European Commission's Recommendation of June 10, 2022, which is incorporated into Annex I and Annex VIII.*

MedTech Denmark supports replacing the nanomaterial definition in Article 2 MDR with a reference to the European Commission's Recommendation of June 10, 2022, which is incorporated into Annex I and Annex VIII instead of the current outdated definition of nanomaterials.

## **Predictability and cost-efficiency of certification**

### **Structured dialogue (MDR: Annex VII; IVDR: Annex VII)**

*A legal basis is introduced allowing notified bodies and manufacturers to conduct structured, documented dialogues both before and after device submissions.*

Under the current Regulations, there is very limited scope for dialogue between manufacturers and their notified bodies. This is highly problematic and leaves especially small manufacturers with the experience that conformity assessment processes is a “black box” process - trying to hit the target without any ability to gauge whether they are aiming in the right direction. MedTech Denmark has therefore, in the run-up to the European Commission’s revision proposal, highlighted that structured dialogue between companies and notified bodies should be significantly strengthened in Europe. For example, MedTech Denmark has pointed to the need to establish an EU version of the U.S. “Pre-Submission Program”, where a manufacturer may request feedback from the FDA, which authorises medical devices in the United States.

Early dialogues - before submission of an application and supporting documentation - are crucial to calibrate the appropriate level of clinical evidence and documentation. There should therefore be a focus on ensuring that such dialogue can take place very early in the conformity assessment process. This is not clearly reflected in the proposal, which uses a more vague term (“before” the time of application) without specifying how early. This detail - timing of the dialogue - will be decisive for the practical usefulness of the early dialogue option.

The inclusion of an explicit legal foundation for structured dialogue with notified bodies represents a significant advantage in the proposal. Previously, such communication was disjointed and subject to the discretion of each notified body and its designating authority, determining whether and how the notified body could participate in structured discussions with manufacturers.

Considering the complexity and unpredictability of the current certification process, it is beneficial for manufacturers to engage in constructive communication with their notified bodies. This interaction should be conducted with due regard for the notified body's obligation to remain impartial and refrain from offering consulting services while carrying out its assessment responsibilities.

Dialogue has always been possible. MedTech Denmark believes that inconsistent management of dialogue by notified bodies needs harmonisation, which the proposal now provides with a clear legal foundation for structured communication.

MedTech Denmark therefore supports all elements that move in the direction of increased dialogue - within the limits of the division of roles set out in the legislation, as described above - because this will help ensure a much smoother certification process. MedTech Denmark's clear recommendation is that the Danish Government supports this amendment; however, it should be made more explicit what the possibilities are with regard to early dialogue, as this is a crucial need for a more efficient certification process, which is one of the main objectives of revising the MDR and IVDR.

**Conformity assessment procedures (MDR: Article 52, Annex IX, X, XI; IVDR: Article 48, Annex IX, X, XI)**

*Notified body involvement is relieved for devices classified as low or medium risk (class IIa, IIb; IVDR class B and C). Technical documentation assessments are conducted for representative devices for ongoing surveillance. Virtual audits are permitted, and biennial audits may be acceptable when appropriately justified. Unannounced audits are carried out exclusively on a "for-cause" basis.*

A study by Ernst & Young for the European Commission's Directorate-General for Health and Food Safety (DG SANTE), prepared Prior to the 2025 revision proposal, points out that certifying medical devices in Europe often creates costs and administrative burdens that seem excessive compared to the potential benefits for patient safety.<sup>7</sup> This aligns with MedTech Denmark experience.

It is therefore positive that, with the revision proposal, the European Commission specifically addresses several of these challenges, including by introducing wording to ensure the principle of proportionality, so that low- and medium-risk devices are subject to a less detailed assessment and a lower audit frequency where this can be justified on the basis of a low level of incidents that could affect patient safety.

As a follow-up to reducing the audit frequency for certain types of devices, the European Commission also proposes that the mandatory five-year unannounced audit cycle is replaced by a "for-cause" approach. This means that notified bodies are empowered to carry out unannounced or short-notice audits where this is deemed justified by findings from other post-market surveillance activities.

MedTech Denmark considers these amendments extremely important and very positive, as they enable notified bodies' resources to be prioritised in areas where patient safety is most critical - based on a risk-based approach and the principles of proportionality. While

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<sup>7</sup> Ernst Young (EY) for DG Sante, Study on Regulatory Governance and Innovation in the field of Medical Devices, Executive summary, 2025, p. 8

manufacturers can likewise allocate their resources more efficiently from a business perspective.

MedTech Denmark assesses that these are highly important measures that can remove unnecessary administrative burdens and thereby contribute to strengthening the competitiveness of the European medtech industry, while keeping patient safety at the forefront.

MedTech Denmark notes that these sections include several amendments, providing significant clarifications to promote consistent conditions for manufacturers across notified bodies. For instance, the phrase "at least one" has been revised to "one," and the proposed changes allow for virtual or remote audits, which were previously subject to varying procedures depending on the authority responsible for designating each notified body.

Although these adjustments may appear small, MedTech Denmark believes they will promote clearer processes, increased transparency, and more consistent market conditions - especially given the current differences manufacturers and stakeholders face among various notified bodies. For this reason, it is essential that these updates are incorporated into the final versions of the MDR and IVDR.

### **Consultation timelines with medicinal product and SoHO authorities are reduced**

MedTech Denmark welcomes that the interaction between notified bodies and the competent authorities responsible for assessing medicinal products and "substances of human origin or their derivatives" (SoHO) is clarified in the revision proposal - and that the timelines for the relevant authorities' assessments are shortened.

MedTech Denmark considers that this will help shorten the time from product development to market access, thereby strengthening competitiveness and making Europe a more attractive market for these products - benefiting both patients and healthcare systems.

### **The 'scrutiny procedure' (MDR: Article 54), performance evaluation, and early advice (IVDR: Article 48, new Article 56a)**

*The scope of the 'scrutiny' / Clinical Evaluation Consultation Procedure is limited to class III implantable devices, with the possibility for the European Commission to extend the scope via a delegated act. The Performance Evaluation Consultation Procedure (PECP) is removed and replaced by early expert panel advice for class C and D IVDs.*

When the current MDR was negotiated, the introduction of the scrutiny procedure in Article 54 was a new element, applicable to certain class IIb and class III devices. The idea was that, for these devices, the notified body would submit the manufacturer's Summary of Safety and Clinical Performance (SSCP), after which the European Commission could select a device for scrutiny (the 'Scrutiny' / Clinical Evaluation Consultation Procedure). If a device was selected for scrutiny, it would be assessed by the relevant expert panel composed of clinicians within the relevant device area.

The introduction of this scrutiny procedure created significant unpredictability since manufacturers could not anticipate whether their devices would be chosen for review. As a result, MedTech Denmark is pleased that this special process applies exclusively to the highest-risk medical devices, specifically class III implantable devices.

This is of particular relevance for many Danish companies, because in practice it means that, for example, drug-delivery systems such as pen injectors are no longer within scope, as these products are typically classified as class IIb devices. MedTech Denmark therefore considers this amendment to be of particular importance for the Danish medtech sector, but also for a number of Danish pharmaceutical companies that develop and manufacture, for example, pen injectors (note that this concerns non-pre-filled pens only, as pre-filled pens are, from a regulatory perspective, medicinal products).

MedTech Denmark also finds it worth highlighting that the proposal empowers the European Commission, via a delegated act, to expand the scope again if deemed necessary. This empowerment serves as an additional safeguard: if it turns out that limiting scrutiny to implantable class III devices goes too far, the scope can be adjusted through a delegated act. This means that the strong focus on patient safety that underpinned the introduction of the scrutiny procedure - and the involvement of clinical expert panels designated by Member States - can, in practice, be maintained.

### **Notified body fees (MDR: Article 50)**

*Fee reductions are introduced for micro and small manufacturers as well as orphan devices. The European Commission will set the level and structure of notified body fees.*

Unlike the pharmaceutical industry, the Danish and European medical device industry primarily consists of small and medium-sized enterprises. European data show that 90% of the more than 38,000 companies in the European medtech sector are SMEs, most of which have fewer than 50 employees.<sup>8</sup> The same pattern is seen in Denmark, where the

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<sup>8</sup> MedTech Europe, Facts and Figures 2025, p. 16: <https://www.medtecheurope.org/wp-content/uploads/2025/09/medtech-europe-facts-and-figures-2025-digital-1.pdf>

vast majority of the Danish medtech sector's 30,000 employees are also employed in SMEs.<sup>9</sup>

This strong predominance of SMEs is important for understanding the medtech sector and the impact that a costly, unpredictable, and bureaucratic certification process has on the many smaller actors that often deliver specialised medical devices for individual patient needs.

In the Ernst & Young study prepared for the European Commission's Directorate-General for Health and Food Safety (DG SANTE) ahead of the 2025 draft revision, one of the conclusions is that the very high costs associated with certification of medical devices – combined with massive administrative burdens – are among the most important reasons why 57% of medtech companies in the survey have reduced their product portfolio in the EU, and why 17% have entirely ceased manufacturing for the EU market.<sup>10</sup> A similar conclusion is found in figures from the German Chamber of Industry and Commerce, which also illustrate that SMEs are particularly hard hit by the high costs associated with the certification process.<sup>11</sup>

In the period leading up to publication of the revision proposal, MedTech Denmark has actively argued that the certification process itself should be faster, more efficient and predictable, and less costly for all companies in the sector, especially SMEs. MedTech Denmark has also highlighted the need for a revision of the MDR and IVDR to address the major differences in costs and timelines across notified bodies.

It is therefore positive that, in its revision proposal for the MDR and IVDR, the European Commission proposes fee reductions for micro and small manufacturers and for orphan devices. Overall, the Commission's proposal embraces the recognition that compliance costs are generally disproportionate and should be reduced, and it points out that the disproportionate cost level is a particularly significant challenge for SMEs in the sector.

Specifically, the European Commission proposes that notified bodies establish lists of their fees for the conformity assessment activities they perform and make those lists publicly available. Notified bodies are also required to notify the European Commission of these lists, after which the Commission shall make references to the lists publicly available on a

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<sup>9</sup> Erhvervsministeriet, LIFE SCIENCE-INDUSTRIENS ØKONOMISKE FODAFTRYK, 2025, p. 8:

<https://www.em.dk/Media/638790174888015216/Life%20science-industriens%20konomiske%20fodaftryk%202025.pdf>

<sup>10</sup> Ernst Young (EY) for DG Sante, Study on Regulatory Governance and Innovation in the field of Medical Devices, Executive summary, 2025, p. 7

<sup>11</sup> German Cgnver ig Cnnerce and Industry, Current assessment of the German medical device manufacturers of the effects of the EU Medical Device Regulation (MDR) – Unsolved problems weaken Germany and the EU as health and innovation locations, 2023:

[https://www.spectaris.de/fileadmin/Content/Pressemitteilungen/2024/Medizintechnik/DIHK\\_MedicalMountains\\_SPECTARIS\\_MDR\\_Survey\\_2023.pdf](https://www.spectaris.de/fileadmin/Content/Pressemitteilungen/2024/Medizintechnik/DIHK_MedicalMountains_SPECTARIS_MDR_Survey_2023.pdf)

dedicated website. Increased transparency regarding notified bodies' fee levels is important, as there is currently significant uncertainty and a lack of transparency in this area. The proposal is therefore crucial to creating a market characterised by greater transparency and competition – and thereby lower costs associated with the certification process.

At the same time, it is proposed that notified bodies apply a fee reduction of 50% for manufacturers that fall within the definition of micro-enterprises under Commission Recommendation 2003/361/EC, while small enterprises should receive a minimum fee reduction of 25%. Both are concrete and positive proposals that the Danish Government should clearly support to ensure the availability of innovative medical devices and niche products in Europe and to foster an innovative industry characterised by SMEs.

It is also stated that the European Commission, in consultation with the Medical Device Coordination Group (MDCG), may adopt implementing acts to determine the structure and level of notified body fees, taking into account the need to establish and maintain high standards of device quality and safety, ensure availability of devices, protect the interests of micro, small and medium-sized enterprises, and support innovation and competitiveness.

MedTech Denmark has strongly argued for the need for a more predictable and less costly certification process, as the current regulatory framework has significantly increased certification costs and substantially extended time-to-market. Specifically, MedTech Denmark has highlighted the need to introduce a cap on fees charged by notified bodies to ensure proportionality and reduce burdens for manufacturers of medical devices – while, of course, taking into account the type and extent of tasks that notified bodies perform.

It is therefore also positive that the European Commission's proposal would influence the fee level not only for micro-enterprises and small actors, but also – at a general level – through the ability to set fee levels. MedTech Denmark therefore clearly supports that the European Commission, in cooperation with the Medical Device Coordination Group (MDCG), can set the specific structure and level of notified bodies' fees.

In this context, it is important to highlight that fee levels should not be reduced only for micro, small and medium-sized enterprises, but for the sector overall. The cost of reducing fees for smaller actors must not be shifted onto the largest medtech companies as an extra bill. If this is not addressed, it will be directly reflected in the number of new and innovative health solutions on the European market and will thereby hinder patients' and clinicians' access to modern medical technologies.

It is a general experience in the market – both for smaller and larger actors – that since the introduction of the MDR and IVDR, resources and financial means have been invested

in compliance, while innovation, research and development have had to be deprioritised. If fee reductions apply only to smaller actors, this trend risks continuing, which will only weaken European competitiveness and patients' access to modern medical devices.

It also follows from the European Commission's revision proposal that notified bodies must process any request for conformity assessment activities from a manufacturer and, within 15 days of receiving the request, inform the manufacturer accordingly. It is also emphasised that the authority responsible for notified bodies will, under the proposal, have powers to require a notified body to accept a manufacturer's request for conformity assessment activities that fall within that notified body's scope of designation, where this is duly justified on grounds of public health or patient health or safety.

MedTech Denmark strongly supports both proposals. It is a well-known problem that SMEs in particular may face major challenges in obtaining access to a notified body – or risk being placed at the back of the queue because their ability to pay is lower than that of larger actors.

In this context, the strengthened powers of the competent authority (in Denmark, the Danish Medicines Agency) will help ensure that patient considerations carry greater weight than notified bodies' commercial interests. MedTech Denmark also notes that the proposal fully supports the generally high patient safety requirements that apply in the EU in the medical device area, because it merely ensures that devices that might otherwise end up at the back of the queue are assessed – not that devices are inappropriately certified.

## Coordination within the decentralised system

### **Regulatory status of products and device classification (MDR: Article 4, new Article 4a, new Article 51a, new Article 51b; IVDR: Article 3, new Article 3a, new Article 47a, new Article 47b)**

*Coordination between competent authorities on device qualification and classification (the "Helsinki procedure") is codified, including the possibility to obtain opinions from expert panels.*

It is not uncommon for manufacturers, notified bodies and competent authorities to face both uncertainty and disagreement as to whether a product qualifies as a medical device and, if so, which risk class it falls under. Similarly, it may be clear that the product is a medical device within the meaning of Article 2, but the classification remains uncertain.

Such cases can take a disproportionately long time to resolve, which is extremely burdensome for manufacturers and also means that devices that could be of significant value to a patient group are unnecessarily delayed.

Under the current Regulations, such cases may be referred to the so-called Helsinki procedure, under which a Member State or the European Commission may raise these questions.

Under the proposal, it will become possible to consult expert panels where there is doubt about a product's regulatory status. At the same time, the proposed new Article 4a enables actors other than Member States and the European Commission to trigger a process to determine which legislation a product falls under, and - where it is considered to be a medical device - what risk class it has. The relevant expert panel may also be consulted under Article 4a.

MedTech Denmark supports the proposal, which lets medical device makers request clarity on regulatory status and engage expert panels - an option not currently available. MedTech Denmark stresses that the objective of this amendment also should help reduce time and delays in borderline cases.

### **Designation and surveillance of notified bodies (MDR: Articles 36–44; IVDR: Article 31 with reference to the MDR provisions)**

*Streamlined assessment and designation of notified bodies involves joint teams from national authorities, experts designated by the European Commission and experts from other Member States (Joint Assessment Teams). Audits of notified bodies take place at*

*least every two years. The requirement for full re-designation every five years is removed. The European Commission sets fees and reimbursable costs for designation and audits.*

The proposal introduces amendments aimed at ensuring that notified bodies possess the relevant clinical and technical competencies needed to carry out assessment and certification activities. At the same time, the proposal places greater emphasis on continuous surveillance, thereby enabling the removal of the five-year re-designation cycle for notified bodies.

It is also important to note that the revision proposal clarifies and emphasises that notified bodies perform a delegated authority task and, in exercising their role, must act in the public interest. In addition, it provides a legal basis for the European Commission to adjust requirements for notified bodies in order to adapt the legislation to new technologies or international developments.

MedTech Denmark considers it positive that the legislation is adjusted to reflect the technological and regulatory reality for medical devices and the sector's actors, while also clarifying that notified bodies act on behalf of the European Commission and the authorities that have designated them. This clarification is important, as it is necessary to underline that notified bodies also bear responsibility for ensuring European patients' timely access to innovative and safe medical devices.

In line with the measures proposed for other actors to remove administrative burdens that do not increase patient safety, it is positive to see that such measures also extend to the proposal to abolish the requirement for five-year re-designation of notified bodies. MedTech Denmark assesses that this change will make it possible to prioritise more time for value-creating tasks benefiting patients and healthcare systems, rather than unnecessary bureaucracy.

De ændringer, der er indeholdt i revisionsforslaget ses i forlængelse af den igangværende gennemførelsesforordning vedrørende MDR/IVDR Bilag VII, hvor MedTech Denmark støtter den retning, Europa-Kommissionen har valgt. Gennemførelsesforordningen indeholder vigtige præciseringer og operationelle bestemmelser, som har potentiale til markant at forbedre forudsigelighed, gennemsigtighed og ensartethed i anvendelsen af MDR- og IVDR-rammerne.

The amendments included in the revision proposal are seen as a continuation of the ongoing implementing regulation regarding MDR/IVDR Annex VII, which MedTech Denmark supports as the right direction chosen by the European Commission. The implementing regulation contains important clarifications and operational provisions that have the potential to significantly improve predictability, transparency, and consistency in the application of the MDR and IVDR frameworks.

**'Dispute Settlement Mechanism' between manufacturers and notified bodies (MDR: Article 35; IVDR: Article 31 with reference to the MDR provisions)**

*The national authority responsible for notified bodies assumes an ombudsman role in disputes between manufacturers and notified bodies.*

Under the current Regulations, there is no formal complaints mechanism for manufacturers in the event of disputes between manufacturers and notified bodies. Instead, this is treated as a matter between the notified body and the national competent authority that has designated the notified body.

Some notified bodies' standard terms and conditions governing the contract between the notified body and the manufacturer include guidelines and provisions on how such disputes are handled. MedTech Denmark has experienced that, in specific cases, manufacturers have been placed in a very disadvantaged position. In practice, manufacturers have been at the mercy of the notified body, and from the manufacturers' perspective there has been little to no legal certainty.

With the European Commission's revision proposal for the MDR and IVDR, it is proposed that the national authority responsible for notified bodies should assume an ombudsman role in disputes between manufacturers and notified bodies. In MedTech Denmark's view, this process has the potential to provide a greater degree of legal certainty for manufacturers, which MedTech Denmark strongly supports, as such an option does not exist in the current system.

**Coordination of notified bodies (MDR: Article 49; IVDR: Article 31 with reference to the MDR provisions)**

*Notified bodies' obligation to participate in NBCG-Med is strengthened, and NBCG-Med reports to the MDCG.*

MedTech Denmark considers it positive that, through the revision proposal, the European Commission strengthens the wording on notified bodies' obligation to participate in coordinating groups that ensure knowledge sharing and the development of common guidance and templates to harmonise practices across notified bodies, and that these coordinating groups are accountable to the Medical Device Coordination Group (MDCG).

MedTech Denmark assesses that this measure, along with others in the proposal, will contribute to more harmonized conditions and increased predictability for manufacturers across Europe.

## **Strengthened role for external expertise in the regulatory system (MDR: Article 106, new Article 106a; IVDR: Article 100)**

*The role and composition of expert panels are expanded to cover assessment of regulatory status and device classification, as well as provision of scientific, technical, clinical and regulatory advice to the European Commission, Member States, the MDCG, notified bodies and, in certain cases, manufacturers. The EMA continues as the secretariat. Expert laboratories are clarified in a dedicated provision.*

### **Early advice from the expert panels, cf. Article 106**

MedTech Denmark considers it very positive that, under the European Commission's revision proposal, all actors are given the opportunity to obtain advice from the expert panels on classification as well as scientific, technical, clinical and regulatory matters.

MedTech Denmark's focus is naturally on the possibility for manufacturers to seek early advice from the relevant expert panel for their device, and this represents a clear strengthening for the sector. This possibility also mitigates potential uncertainties given that, as commented upon earlier, the European Commission has reduced the scope of the scrutiny procedure to cover only implantable class III devices.

As described above, this is important because, under the current rules, it is extremely difficult for manufacturers to obtain dialogue with their notified body, and this opportunity is therefore very welcome.

Early dialogue is crucial for quality assurance and alignment of expectations. MedTech Denmark assesses that the proposal will ease work for both manufacturers and notified bodies, as an opinion from an expert panel with appropriate clinical expertise available there will carry significant weight when the notified body subsequently reviews the manufacturer's documentation. Early dialogue is therefore essential to support innovation in medical devices.

As secretariat for the expert panels, the EMA has run a number of pilot projects for high-risk devices, and these have so far shown positive results.

### **Designated expert laboratories, cf. Article 106a**

As a new element, the proposal includes the possibility for the European Commission to designate expert laboratories under the MDR, as has been the case since adoption of the current IVDR.

As described above, the expert laboratories can assist competent authorities with independent scientific and technical investigations as a supplement to the current handling of reportable incidents. This is a clear strengthening of market surveillance, and MedTech Denmark strongly supports it.

MedTech Denmark observes that this proposal offers further justification for eliminating the existing five-year recertification requirement, as suggested by the European Commission. This is due to the fact that market surveillance systems increasingly are being enhanced through the measures outlined in the proposal.

### **Support from the EMA for coordination of competent authorities (MDR: new Article 106b)**

*The EMA provides scientific, technical and administrative support for coordination among national competent authorities, including on borderline products and classification, multinational clinical studies, derogations, vigilance and market surveillance. The EMA also provides support to SMEs.*

For a long time, and in the run-up to the European Commission's draft revision of the MDR and IVDR, MedTech Denmark has advocated for a single, dedicated governance structure to oversee and administer the regulatory system for medical devices, including designation and surveillance of notified bodies, with authority to take decisions at system level. MedTech Denmark's experience is that the current system lacks consistency in the guidance and interpretations that medtech companies and notified bodies must follow, which creates uncertainty and contributes to an inefficient certification process.

From the industry's perspective, the vision is to create future-proof regulatory framework conditions for medtech companies in Europe. MedTech Denmark therefore considers that there is a strong need for a central mechanism that can ensure an efficient and predictable CE-marking system, so that the newest innovations reach European healthcare systems and patients first - rather than, as is often the case today, being launched outside the EU first.

It goes without saying that such a dedicated mechanism must have the necessary medical device expertise and be allocated the resources required to carry out the tasks assigned to it.

In proposed Article 106b, the role that the European Medicines Agency (EMA) already has today within the medical device framework is expanded. The EMA already provides the secretariat for the expert panels, and the EMA also plays a significant role within the HERA framework, including regarding the list of critical medical devices and the ATHINA platform.

In the European Commission's revision proposal, the EMA is assigned additional tasks - for example relating to the new process for uncertainty about classification, national and Union-level derogations, the coordinated process for performance study applications under the IVDR, and reporting related to IVD devices. The EMA is also assigned a role in the new regulatory sandboxes proposed by the European Commission, and finally the EMA is envisaged to have a role in the new dedicated support regime targeted at SMEs.

Provided that the EMA will be equipped with the right medical device competencies and is allocated the necessary resources and full-time equivalents to handle the new tasks described above, MedTech Denmark considers it meaningful to leverage the expertise and credibility the EMA has today for the benefit of the entire medical device ecosystem.

However, it is also clear that the European Commission's proposal does not meet the clear requests MedTech Denmark has put forward regarding building a dedicated structure to strengthen the overall governance system for medical devices.

The proposal contains nothing on designation and surveillance of notified bodies or on a structure for issuing authoritative guidance documents. These are all important measures that MedTech Denmark has called for, because the regulatory system for medical devices in Europe is highly fragmented.

MedTech Denmark's overall assessment is therefore that the changes proposed to strengthen the governance of the MDR and IVDR are a step in the right direction. At the same time, MedTech Denmark recommends that, as part of the upcoming negotiation process, options will be explored for establishing a dedicated body that can contribute to designation and surveillance of notified bodies and ensure a more uniform and streamlined structure for issuing authoritative guidance documents.

## Further digitalisation

### **Digitalisation of compliance tools (MDR: Article 19, new Article 110a, Annex I, Annex VI; IVDR: Article 17, new Article 103a, Annex I, Annex VI) & Digitalisation of conformity assessment (MDR: new Article 52b; IVDR: new Article 48b)**

*The EU declaration of conformity may be provided digitally. Future rules may allow certain labelling information to be provided digitally. Manufacturers of near-patient tests may provide electronic instructions for use. Manufacturers may prepare technical documentation, reports and other documents in digital form. All MDR/IVDR submissions will be electronic, and economic operators must register digital contact details in EUDAMED.*

With its revision proposal, the European Commission sets out a significant expansion of the use of digital solutions to meet MDR and IVDR requirements, including digital provision of conformity assessment-related documentation and technical documentation.

MedTech Denmark supports a more modern and resource-saving approach by allowing digital solutions for declarations of conformity, technical documentation, and information provided to users and patients. This will increase the availability of information to third parties and thereby reduce workload across competent authorities, notified bodies, and economic operators.

MedTech Denmark also considers that it will ensure that updated information becomes available more quickly to relevant stakeholders, and will, in general, be a significant benefit to the sustainability agenda.

In this context, it is important to emphasise the need for transitional arrangements to allow sufficient time for adaptation - along with guidance and harmonisation across, for example, submissions to notified bodies - so that economic operators are not forced to juggle different formats depending on the preferences of each individual notified body.

### **Online sales (MDR: Article 6; IVDR: Article 6)**

*Necessary information on device identification and instructions for use must be made available in the context of online sales.*

Compared with the current wording of Article 6, the proposal clarifies that for online sales of medical devices - including digital medical devices such as apps - appropriate labelling information must be available, so that the following details are clearly provided: the device name, the intended purpose, the name of the manufacturer and, where the manufacturer

is not established in the EU, the name of the authorised representative. In addition, devices sold online must be accompanied by instructions for use. Finally, the proposal also provides that a Member State may require online sales to be stopped on public health grounds.

MedTech Denmark supports this protection of patients and consumers, which we assess that the proposal provides.

**UDI and EUDAMED (MDR: Articles 27–33, Annex VII; IVDR: Articles 24–30, Annex VII)**

*Provisions on UDI assignment and registration in EUDAMED are clarified. Certain electronic systems may be established outside EUDAMED.*

In the European Commission's revision proposal, it is suggested, that certain electronic systems may be established outside EUDAMED.

In MedTech Denmark's view, it is a very positive change that electronic systems established outside EUDAMED must be interoperable with EUDAMED. This means that the IT system for reporting interruptions or cessation of supply of medical devices will be integrated with, or at a minimum interoperable with, EUDAMED, and that national distributor databases must, going forward, enable direct retrieval of product information from EUDAMED. Taken together, these measures strengthen transparency, efficiency, and cooperation across the EU medical technology sector.

## **International cooperation**

### **International cooperation and reliance mechanisms (MDR: new Articles 108a and 108b)**

*A new section strengthens global regulatory convergence and international cooperation, including participation in IMDRF and MDSAP.*

This section introduces provisions that strengthen the European Commission's mandate to promote international cooperation and bilateral relations with regulators outside the EU. As part of the revision proposal, the European Commission is empowered to enter into arrangements that make it easier to exchange information, share experiences and coordinate joint actions such as inspections and surveillance.

These initiatives support the implementation of regulatory reliance, including recognition of CE marking in third countries and participation in multilateral programmes such as MDSAP and the WHO. The European Commission is thereby enabled to engage in international harmonisation projects outside the EU, including with support from experts from the Member States and EU funding.

MedTech Denmark appreciates these initiatives, as they not only promote international cooperation, but also help make the EU an attractive market for medical devices, because a CE mark may provide access to more markets than "only" the European one—thereby strengthening European companies' competitiveness on the international stage. By ensuring mutual recognition and harmonisation of standards, both innovation and export opportunities for the industry are supported. These measures meet the industry's wish for greater cooperation and trust in the regulatory sphere, thereby promoting harmonisation of international standards and strengthening confidence in regulatory processes.

## Interaction with other EU legislation

### **Combined studies involving medicinal products, medical devices and/or IVDs (MDR: new Article 79a; IVDR: new Article 75a)**

*Sponsors of combined studies may submit a single consolidated application, triggering a coordinated assessment under Regulation (EU) No 536/2014 on clinical trials, as adapted via the Biotech Act.*

MedTech Denmark has expressed its full support for the EU project COMBINE. The initiative is logical, as it enables sponsors to submit a single application when, for instance, a medicinal product contains a medical device component or requires an IVD test, such as a companion diagnostic.

MedTech Denmark therefore fully supports this proposal. MedTech Denmark also supports that these products can be handled in the CTIS system used for medicinal products, and that the EMA - pursuant to proposed Article 106b - has a role to play in the clinical assessments of these combined IVD performance evaluations and clinical studies of medicinal products.

### **Interaction between pharmaceutical legislation and MDR (EU) 2017/745 Article 117**

In this consultation response, MedTech Denmark would also like to draw attention to the acute need for a transparent, streamlined and centralised EU regulatory framework for integral drug-device combination products (iDDCs) pursuant to Article 117 of Regulation (EU) 2017/745 (MDR).

This is an area that the European Commission does not address in its revision proposal for the MDR and IVDR, which is deeply concerning and contrasts with the remarks made by the EU Commissioner for Health, Olivér Várhelyi, in connection with the launch of the European life science strategy on 2 July 2025. The Commissioner pointed out that the approval process for this type of combination product should be made more efficient.<sup>12</sup>

Specifically, based on input from a dedicated working group on drug-device combination products, MedTech Denmark calls for the designation of a single responsible authority with overarching responsibility for both the medicinal product and device components, in order

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<sup>12</sup> European Commission, 2025: Press remarks by Commissioner Várhelyi on the EU Life Science Strategy: [https://ec.europa.eu/commission/presscorner/detail/en/speech\\_25\\_1716](https://ec.europa.eu/commission/presscorner/detail/en/speech_25_1716)

to improve the approval process and ensure faster patient access to innovative treatments.

Key recommendations include establishing an integrated framework for market access and post-market surveillance, access to scientific advice, harmonisation of the requirements for General Safety and Performance Requirements (GSPR), consistent procedures for change management throughout the product lifecycle, and introducing a platform approach for medical devices. These measures should reduce regulatory burden, shorten time-to-market, and restore the EU's competitiveness for the launch of iDDCs.

The current EU regulatory framework for iDDCs is fragmented, with shared responsibility between the EMA, national competent authorities and notified bodies. This results in inefficiency, unpredictable outcomes and delayed patient access. The lack of harmonised guidance and standardised processes leads to inconsistent interpretations, particularly regarding GSPR compliance and change control.

To address these challenges, MedTech Denmark proposes that the following changes should also be addressed in the European Commission's work on revising the MDR:

- Designation of a single responsible EU entity for iDDCs that coordinates assessment and oversight
- Opportunity for joint scientific advice covering both the medicinal product and device components
- Issuance of formally recognised GSPR guidance for iDDCs
- Implementation of clear, consistent procedures for change management and
- Introduction of platform-based design solutions to minimise repeated assessments of similar device components across products

Immediate action is needed from the European Commission and regulatory authorities to align EU practice with global standards, promote transparent cooperation, and re-establish Europe as the preferred region for launching innovative, patient-centred health solutions.

### **Cybersecurity (MDR: new Article 87a, Annex I; IVDR: new Article 82a, Annex I)**

*Serious incidents reported under the MDR/IVDR that also constitute cybersecurity vulnerabilities or serious incidents under Regulation (EU) 2024/2847 are shared with national CSIRTs and ENISA. Manufacturers must report actively exploited vulnerabilities and serious incidents that do not qualify as "serious incidents" under the MDR/IVDR to CSIRTs and ENISA via EUDAMED. Cybersecurity is explicitly referenced in the General Safety and Performance Requirements in Annex I to the MDR/IVDR.*

MedTech Denmark views the ambition to consolidate reporting of serious incidents and cybersecurity-related incidents in EUDAMED positively and understands the desire for a more coherent reporting structure.

However, not all cybersecurity vulnerabilities or cybersecurity incidents will necessarily constitute a serious incident within the meaning of the MDR/IVDR or entail a direct risk to patient safety. Conversely, certain serious incidents under the MDR/IVDR may also be subject to reporting obligations to national CSIRTs and ENISA under Regulation (EU) 2024/2847.

This complexity underscores the need for clear, detailed and harmonised guidance that precisely delineates which incidents must be reported where, when, and under which legal framework.

MedTech Denmark is therefore, at this stage, not yet clear on how this amendment can be implemented and function in practice.

### **AI Act: MDR & IVDR moved from Annex I, Section A to Section B**

Moving of medical devices from Section A to Section B means that the MDR and IVDR regulated devices will not be subject to the AI Act in full. Instead, software incorporating an AI system will be regulated primarily under the MDR/IVDR rules for medical device software, and only those provisions of the AI Act will apply that are not already covered by the MDR/IVDR.

In the Ernst & Young study prepared for the European Commission's Directorate-General for Health and Food Safety (DG SANTE) ahead of the 2025 draft revision of the MDR and IVDR, one conclusion is that, in several areas, there is insufficient alignment between horizontal EU legislation and the sector-specific regulatory framework constituted by the MDR and IVDR - particularly for devices incorporating artificial intelligence, where the interaction between the AI Act on the one hand and the MDR/IVDR on the other is materially inadequate.<sup>13</sup>

Prior to the proposed revision, MedTech Denmark has emphasised the considerable complexity arising from the interplay between the AI Act and MDR/IVDR. In particular, MedTech Denmark has underscored the importance of implementing a framework that permits notified bodies designated under MDR/IVDR to also be designated under the AI Act for the evaluation of additional AI-specific requirements. Such an approach would prevent the need for dual assessment bodies, mitigate the risk of divergent conformity

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<sup>13</sup> Ernst Young (EY) for DG Sante, Study on Regulatory Governance and Innovation in the field of Medical Devices, Executive summary, 2025, p. 10

evaluations, and reduce duplication of effort - thereby optimising resource utilisation, fostering innovation, and supporting timely deployment of AI-enabled medical devices to patients, citizens, and clinicians.

MedTech Denmark therefore welcomes that the European Commission recognises this challenge and proposes to move the MDR and IVDR from Section A to Section B in the AI Act. This would create greater legal clarity that medical software containing an AI component - and which falls within the definition of a medical device - should be regulated primarily under the MDR/IVDR, i.e., the medtech sector's legislation.

The practical implication would be that notified bodies designated to certify medical device software would remain the bodies involved in CE marking, thereby avoiding two assessment bodies, two potentially divergent conformity assessments, and costly duplication of work.

MedTech Denmark notes in this context that the change does not mean that medical devices will be entirely exempt from the AI Act, as certain additional requirements will still apply to the medtech sector where those elements are not already covered by the MDR/IVDR. MedTech Denmark therefore assesses that this simplification will not result in less oversight of medical software containing an AI component, but rather strengthen patient safety, because enforcement will clearly sit with the health authorities within the established regulatory track for medical devices.

Before the Commission's revision proposal, MedTech Denmark called for delaying the AI Act's application date for medical technology solutions until proper infrastructure was established for a smooth transition. Now that MDR and IVDR are expected to shift from Section A to Section B in the AI Act, this concern is resolved. Nevertheless, it is still crucial - if the Commission's proposal is accepted as it stands - to allow enough time for all medical devices with AI components to be assessed under MDR/IVDR. This also assumes that notified bodies have sufficient capacity within the required timeframe.

At the same time, MedTech Denmark draws attention to the fact that a number of member companies are already developing medical devices that incorporate an AI component. MedTech Denmark therefore focuses on the extent to which this change means that companies that have taken the lead in implementing the AI Act in their organisations would now need to roll this back. MedTech Denmark also notes the need for clarity for companies seeking to place new solutions on the market while the MDR/IVDR revision is still under negotiation, as they are looking ahead to a future regulatory framework that is expected to change the legal situation.

Ahead of the MDR/IVDR revision proposal, MedTech Denmark also argued that clarification was needed that medical devices involving an AI component undergoing clinical investigations or IVD performance studies should not require CE marking, as this is

not permitted under the MDR/IVDR, whereas it had been a requirement under the AI Act. That requirement was inappropriate, as it created uncertainty about how new AI-based medical devices could be developed in practice. Moving the MDR and IVDR from Section A to Section B in the AI Act, as proposed, resolves this challenge, because the MDR/IVDR requirements will apply in this area.

MedTech Denmark urges the Danish Government to back the European Commission's proposal to shift MDR and IVDR from Section A to Section B in the AI Act. This move clarifies that medical software with AI, classified as a medical device, falls under MDR/IVDR, ensuring proper assessment through qualified notified bodies. Ultimately, it will make approval of safe, innovative AI-enabled medical devices in Europe more straightforward and benefit patient care.

## Concluding remarks

The sector-specific regulation of medical devices in Europe in the form of the MDR and IVDR is a decisive framework condition for the Danish and European medtech industry. MedTech Denmark therefore, as the dedicated industry association for manufacturers and suppliers of medical devices in Denmark, maintains a strong focus on this area and a continuous, close dialogue with its members.

MedTech Denmark therefore looks forward to contributing to the forthcoming political negotiations on the European Commission's revision proposal for the MDR and IVDR, as the result of the negotiations will directly affect citizens', patients' and clinicians' timely access to medical devices, as well as the competitiveness of the medtech industry in Europe.

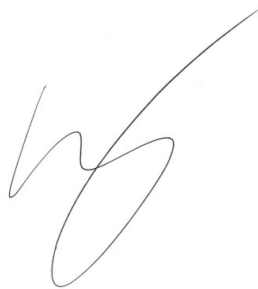
For this very reason, MedTech Denmark considers it to be in the interest of both patients, healthcare systems, and industry alike that members of the European Parliament, national governments, and the European Commission work in close collaboration to ensure a fast revision of MDR and IVDR, which addresses many of the challenges currently hampering the regulatory system for medical device

MedTech Denmark remains available to elaborate further on the above views and recommendations as set out in this consultation response.

Yours sincerely,



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