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# Position Paper

2026, April

# Medical devices and in vitro diagnostics – targeted revision of EU rules

## Summary

**Support for shifting MDR and IVDR to Annex I, Section B of the AI Act:** Bitkom supports the proposed transfer, as it can reduce duplicative regulation and avoid unnecessary double burden for AI-based medical devices. At the same time, further alignment is needed to ensure that AI medical devices are not still captured as high-risk systems under Article 6(2) and Annex III of the AI Act, which would undermine the objective of the reform.

**Rule 11 must ensure a genuine risk-based approach and prevent systematic up-classification**: The current regulatory design of Rule 11 risks undermining its intended risk-based approach. While Class I is formally defined as the default category for low-risk Software as a Medical Device (SaMD), broadly framed exemption clauses effectively eliminate its practical applicability. This creates legal uncertainty and leads to a systematic up-classification of software, including low-risk digital solutions.

**Human oversight must be properly reflected in the classification of software:** Software that supports healthcare professionals and remains subject to meaningful human oversight should not automatically be classified in a higher risk class unless its intended purpose justifies such classification. In particular, a clear and practical definition of "inform clinical management" is needed to ensure legal certainty and avoid unnecessary barriers for low-risk digital health solutions.

## Detailed Comments on the Commission's Proposal

### Shift of MDR and IVDR to Annex I, Section B (AI Act)

Under the current legal framework, the AI Act links the Medical Device Regulation (MDR) through No. 11 and the In Vitro Diagnostic Medical Devices Regulation (IVDR) through No. 12 of Annex I, Section A. Consequently, medical devices under the MDR and in vitro diagnostic

medical devices under the IVDR must, in principle, comply fully with the requirements of the AI Act, in particular with the substantive obligations applicable to high-risk AI systems. At the same time, it has been recognized that this may create a double regulatory burden.
Against this background, the proposed amendment in the context of the simplification of the MDR and IVDR consists in moving the MDR and IVDR from Annex I, Section A to Annex I, Section B of the AI Act. According to Recital 23 and the Commission's Digital Omnibus proposal, this shift would mean that the high-risk obligations of the AI Act would no longer apply directly based on Annex I, Section A. Instead, the relevant requirements need to be appropriately integrated into the MDR and IVDR framework. This approach is generally supportable, as it reflects a change in scope under Article 2(2) of the AI Act without, in principle, lowering the level of protection of fundamental rights. As has also been noted, including in assessments by the MDCG, the MDR already contains core mechanisms for safeguarding health, safety and fundamental rights. At the same time, the transition must be designed carefully to avoid regulatory uncertainty or temporary gaps in applicable requirements.
However, further amendments remain necessary in relation to the regulation of AI-based medical devices under the AI Act. In the future, AI medical devices in the healthcare sector may still be classified as high-risk AI systems in two different ways: first, under Article 6(1) in conjunction with Annex I of the AI Act where they are linked to the MDR or IVDR framework, and second, under Article 6(2) in conjunction with Annex III of the AI Act. In particular, the broad and open-ended definition in Article 6(2), Annex III, No. 5(a) should be clarified and supplemented to exclude AI medical devices from this category. One possible solution would be to add language such as "with the exception of health services or care services." Alternatively, certain organizational applications in the healthcare sector could be explicitly excluded, for example billing, inventory management or similar administrative processes. This would create legal certainty for the use of AI systems in hospitals that support operational processes such as bed allocation for potential patients or medication management, thereby enabling meaningful efficiency gains and cost savings in healthcare delivery.
Such clarification is also necessary from a systemic regulatory perspective. If the proposed shift from Annex I, Section A to Section B is based on the assumption that the MDR and IVDR already provide a sufficiently high level of protection for AI medical devices, that assessment is called into question if the same systems can still be classified as high-risk under Article 6(2) and Annex III of the AI Act. To avoid inconsistency, overlapping obligations and unnecessary legal uncertainty, the interaction between the AI Act and sector-specific medical device law should therefore be further aligned. The objective should be a coherent framework that preserves a high level of protection while preventing duplicative regulation and allowing innovation in the healthcare sector to develop within a clear and workable legal environment.

## Clarifying Rule 11 for Software Classification

The intention behind the proposed amendment to Rule 11, namely to enable a broader classification of software as Class I where appropriate, is appreciated. However, in its current form, the draft does not achieve this objective. While Class I is formally defined as the default category for low-risk Software as a Medical Device (SaMD), the broadly framed exemption clauses effectively deprive this category of practical relevance. As a result, even

low-risk software solutions are systematically driven into higher risk classes, creating legal uncertainty and undermining a proportionate, risk-based regulatory approach. Furthermore the reference to the IMDRF framework is, in principle, understandable, as it seeks to align the classification of software with an internationally recognised approach. At the same time, such alignment also carries risks. In particular, diverging definitions and regulatory concepts may create new uncertainties in the interpretation and application of the rules. For this reason, Rule 11 should not be maintained in its current form.

From our perspective, the classification framework should more accurately reflect the actual risk profile of SaMD, taking into account the intended purpose of the software, the clinical context in which it is used, and the significance of the information it provides for diagnosis or treatment decisions. In the case of software, risks to patients are typically indirect and highly context-dependent. A classification approach that does not adequately reflect these characteristics risks producing disproportionate regulatory outcomes. This issue is becoming even more important in light of the increasing integration of artificial intelligence into medical devices. As AI-based functionalities become more widespread, it is essential to ensure coherence between the MDR and the AI Act. Concepts such as human oversight play an important role in both frameworks and should be reflected in a manner that supports proportionate, risk-based regulation rather than creating additional uncertainty or unnecessary regulatory burden.

Should the current approach nevertheless be retained in principle, we would at least strongly recommend the following amendment:

*"Software which is intended […] .:*

- *in a critical situation with a risk of causing death or an irreversible deterioration of a person's state of health, in which case it is classified as class III;*
- *in a serious situation with a risk of causing a serious deterioration of a person's state of health or a surgical intervention, or to drive clinical management in a critical situation in which cases it is classified as class IIb;*
- ~~*in a non-serious situation, or*~~ *to drive clinical management in a serious situation or to inform clinical management in a critical* ~~*or serious*~~ *situation in which cases it is classified as class IIa;*

In addition, it is important to introduce a clear and practical definition of "inform clinical management". In our view, software should be considered to "inform clinical management" where its intended purpose fulfills all of the following criteria:

- the software is intended only to provide information, such as measurements, scores, risk estimates or suggested diagnostic or therapeutic options, in order to support a healthcare professional in making diagnostic or therapeutic decisions;
- the software is not intended to autonomously select, initiate or modify a diagnostic or therapeutic intervention;
- the software is not intended to be followed without further clinical judgment.

Such clarification is essential not only for legal certainty, but also from a fundamental rights perspective. Where medical decision-making remains under the responsibility of a qualified healthcare professional, the impact of software on patients is inherently mediated and context dependent. In such cases, the software does not independently determine clinical outcomes, which should be reflected in a proportionate classification. A more precise and

risk-based interpretation of Rule 11 would therefore support patient safety and regulatory clarity, while avoiding disproportionate classification outcomes for SaMD with a low-risk profile.

## Proportionate Rules on Surveillance and Unannounced Audits

We support the proposed amendment in "(c) Section 3.3", which provides that notified bodies shall continue to conduct surveillance audits and assessments every 12 months as a general rule, while allowing an extension to a 24-month interval where this is justified by the outcome of previous surveillance activities and where no concerns arise from post-market surveillance or vigilance data. This amendment introduces a more proportionate and risk-based approach without compromising the overall level of regulatory oversight. It appropriately reflects the compliance history of the manufacturer and the absence of relevant safety signals, while preserving annual surveillance as the standard rule.

We also support the proposed amendment in "(d) Section 3.4", in particular the clarification that additional audits may be carried out where justified on the basis of concerns related to post-market surveillance or vigilance data, or at the request of a competent authority. This change is welcome, as it better anchors additional supervisory measures in concrete and objective triggers. At the same time, it is important to ensure that the instrument of unannounced audits is applied in a targeted and proportionate manner. Under the previous legal framework, the conduct of unannounced audits by notified bodies was effectively required, which created a risk of overuse of this instrument. In order to prevent disproportionate application, we propose that notified bodies be required to provide reasonable written documentation explaining why an unannounced audit is necessary in the individual case. Such a requirement would strengthen transparency, enhance legal certainty and help ensure that unannounced audits remain an exceptional measure based on clear justification.

## Limiting Technical Documentation Assessments to Risk-Based and For-Cause Cases

We support the proposed amendment in "(e) Section 3.5", according to which, in the case of class IIa and class IIb devices, and of class III devices that are well-established technology devices, the notified body may, during the surveillance assessment, include a "for-cause" assessment of the technical documentation of representative devices where potential concerns have been identified. Based on our understanding, this amendment is a welcome step towards a more proportionate and risk-based approach. In particular, it appears to limit the continuous assessment of technical documentation by notified bodies more clearly to the actual risk profile of the devices concerned and to specific cases in which justified concerns arise.

From our perspective, the assessment of technical documentation should, as a general rule, be limited to situations in which a significant change has occurred or prior to the placing of a device on the market. A broader or routine reassessment outside such situations would create unnecessary regulatory burden without a corresponding benefit in terms of safety or

performance. Against this background, the proposed amendment can be supported insofar as it reinforces the principle that ongoing technical documentation reviews should not become a standard exercise, but should remain focused on higher-risk situations and exceptional cases, in particular with regard to class III devices.

At the same time, further clarification by the legislator is necessary regarding the meaning and intended scope of this clause. In particular, it should be specified more clearly under which conditions potential concerns are deemed to exist and how the “for-cause” assessment is to be understood in practice. Such clarification would be important to ensure a consistent application by notified bodies, to avoid unnecessary divergences in interpretation, and to provide greater legal certainty for manufacturers.

Bitkom represents more than 2,300 companies from the digital economy. They generate an annual turnover of 200 billion euros in Germany and employ more than 2 million people. Among the members are 1,000 small and medium-sized businesses, over 700 start-ups and almost all global players. These companies provide services in software, IT, telecommunications or the internet, produce hardware and consumer electronics, work in digital media, create content, operate platforms or are in other ways affiliated with the digital economy. 82 percent of the members' headquarters are in Germany, 8 percent in the rest of the EU and 7 percent in the US. 3 percent are from other regions of the world. Bitkom promotes and drives the digital transformation of the German economy and advocates for citizens to participate in and benefit from digitalisation. At the heart of Bitkom's concerns are ensuring a strong European digital policy and a fully integrated digital single market, as well as making Germany a key driver of digital change in Europe and the world.


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