Targeted revision of EU MDR Rule 11 for medical device software

COCIR Position Paper

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35, Square de Meeûs - 1000 BRUSSELS – Tel: +32 (0) 2 895 36 01
http://www.cocir.org/
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1. About COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT, and electromedical industries. It advocates a regulatory framework that protects patients while enabling innovation, legal certainty, and timely access to safe technologies across Europe.

2. Executive Summary

MDR Classification Rule 11 on software has been revised in response to numerous implementation challenges over the past years. In December 2025, the European Commission proposed a revised version of Rule 11, however, several key terms (inform, drive, risk of causing) remain too open to interpretation, creating legal uncertainty and reducing predictability for both manufacturers and authorities. COCIR therefore proposes alternative wording that addresses these challenges, considering international convergence and following a risk-based approach, while supporting the Commission's objective of simplification without compromising patient safety.

The targeted revision of Rule 11 should be assessed against a clear legislative benchmark: whether it enables classification outcomes that are sufficiently predictable, proportionate, and operational for manufacturers, notified bodies, and competent authorities to apply consistently in practice. A revision that leaves the decisive policy choices to later guidance or case-by-case interpretation would not fully achieve the Commission's stated objectives of simplification and legal certainty.

COCIR recommends a simplified rule that preserves the healthcare-situation reflected in the Commission's proposal but removes the concept of "confers a clinical benefit," and the distinction between "inform/drive clinical management" distinction and adds the dimension of "healthcare professional oversight". This approach is intended to make the rule more operational and reduce possible

divergent interpretations. In particular, COCIR considers healthcare professional oversight to be a more reliable legal discriminator than the distinction between software that merely "informs" and software that "drives" clinical management, because oversight more directly reflects residual risk in the real conditions of use.

Variant I.

Software which is intended to generate an output that is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation, or alleviation of a disease or condition is classified as class **I**, unless:

- the output is intended to be used without healthcare professional oversight, for a disease or condition 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**;
- the output is intended to be used without healthcare professional oversight, for a disease or condition in a serious situation with a risk of causing a serious deterioration of a person's state of health, in which case it is classified as class **IIb**;
- the output is intended to be used with healthcare professional oversight, for a disease or condition in a critical situation with a risk of causing death or an irreversible deterioration of a person's state of health, or for a disease or condition in a serious situation with a risk of causing a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class **IIa**.

Variant II. – without Class III

Software that is intended to generate an output that is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation, or alleviation of a disease or condition is classified as class **I**, unless if it is intended to be used in a situation with a risk of causing death, an irreversible or serious deterioration of a person's state of health, in which case it is class **IIb**, except if it is used with healthcare professional oversight, in which case it is class **IIa**.

3. Intro to software classification and its manufacturer impact

MDR classification Rule 11 is not used in isolation. Software classification is conducted in consideration of the Annex VIII implementing rules and other applicable classification rules.

MDCG 2019-11[1] identifies the most relevant classification rules for software as Rules 11 (software), 15 (applies to contraception apps, class IIb), and 22 (applies to therapeutic software with an integrated or incorporated diagnostic function that significantly determines the patient management by the device, class III).

Though implementing Rule 3.3 software that drives or influences the use of a hardware device inherits the device's classification, unless, through implementing Rule 3.5, another rule applies that leads to a higher class. For example, a software that drives or influences the use of a surgical robot inherits the surgical robot's class, which is classified as class IIa or IIb under Rule 9 or Rule 10.

The general safety and performance requirements apply to all medical device software, regardless of its class. Only the class I devices are self-certified. Higher-class medical device software requires the involvement of a notified body. The class affects the frequency with which the notified body must sample the technical documentation (see Figure 1) and the frequency with which the manufacturer must report (see Figure 2). Class III devices and Class IIb implantable devices require a clinical investigation, with some exceptions, such as when an existing CE-marked device is modified, and equivalence is demonstrated.

In a risk-based regulatory framework, classification should reflect not only the seriousness of the relevant disease or condition, but also the extent to which reasonably foreseeable risk is reduced through the actual conditions of use. For software, that includes whether the output is acted on directly or instead remains subject to meaningful review, supervision, or intervention by a qualified healthcare professional **to ensure appropriate patient management** is taken. This is important because software-related harm is often indirect and mediated through subsequent clinical or user action.

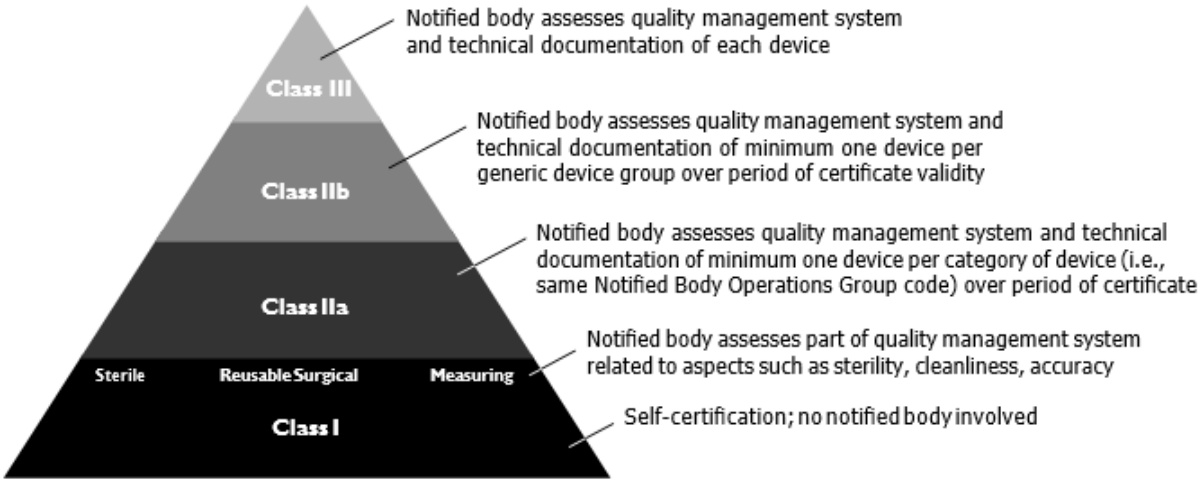

Figure 1 Illustration of the Extent of Notified Body Review for Increasing Device Classification

[1] MDCG 2019-11 Rev.1, Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR, June 2025.

	Class I	Class I Measuring, Sterile, or Reusable Surgical	Class IIa	Class IIb	Class III
CER Clinical Evaluation Report	Update after receiving PMS information with potential to change current evaluation. Class III: Submit to notified body via EUDAMED. Other classes: Keep available for notified body and competent authority.				
PMS Report Postmarket Surveillance	When necessary	N/A	N/A	N/A	N/A
PSUR Periodic Safety Update Report Evaluation Report	N/A	When necessary and at least every two years		At least annually	At least annually (upload to EUDAMED)
PMCF Postmarket Clinical Follow-Up	When needed and according to PMCF plan				At least annually
SSCP Summary of Safety and Clinical Performance	N/A	N/A		At least annually (for implantable products only)	At least annually

Figure 2 The Type and Frequency of Reporting to Competent Authorities Based on Risk Class in the EU

4. Challenges with the current MDR 2017/745 Rule 11

The current interpretation of Classification Rule 11 is rife with ambiguities, leaving very little room for class I and, consequently, significantly impacting the attractiveness of the EU for innovation and market authorization of medical device software. The Commission's staff working document[2] noted that many stakeholders underlined challenges in software classification. It identified a need to simplify, clarify, and make conformity assessment procedures more predictable and proportionate, without affecting patient safety. To mitigate, it suggests reclassifying medical device software commensurate with actual risk and technological maturity, clarifying the boundaries between classes, reducing interpretative divergences among manufacturers, notified bodies, and competent authorities, while aligning internationally via IMDRF N81[3]. COCIR supports a targeted revision of Rule 11.

[2] European Commission. (2025). Commission staff working document (SWD(2025) 1050).
[3] International Medical Device Regulators Forum, Characterization Considerations for Medical Device Software and Software-Specific Risk (IMDRF/SaMD WG/N81FINAL:2025)

5. European Commission's proposed Rule 11

The Commission's targeted revision proposes the following revised Rule 11. Highlighted aspects are discussed in this paper.

> Software which is intended to generate an output that confers a clinical benefit and is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation or alleviation of a disease or condition is classified as class I, unless the output is intended for a disease or condition:
>
> – 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.

6. Challenges with the Commission's proposed Rule 11

The proposal remains vulnerable to divergent downstream guidance

Because the key terms (inform, drive, risk of causing) are contestable, much of the real policy choice would be pushed from the legislature into later guidance and case-by-case interpretation. That would recreate the very problem the targeted revision was supposed to address: insufficient legal certainty, uneven application, and limited predictability for manufacturers and authorities alike. That would be problematic not only as a matter of implementation, but also as a matter of legislative design. Where a targeted legislative amendment is intended to simplify classification and improve legal certainty, the key risk discriminators should be sufficiently clear in the legal text itself and should not depend on later guidance to supply the operative content.

The proposal does not reliably create more Class I software

The Commission's text opens with Class I as the default, but its subsequent sub-rules drive software into Class IIa, IIb, or III depending on the nature of the situation and the significance assigned to the software output. In particular, the third indent appears to capture software intended to be used for a disease or condition in a non-serious situation and classifies it as Class IIa, thereby making it difficult to see any remaining room for a Class I. In addition, the subrules overlap, and because implementing Rule 3.5 requires one to consider all subrules with the highest applicable class to prevail, the promised expansion of Class I does not materialize. On the contrary, Class I appears not possible following the proposed rule. The result is a legal text that looks more permissive than it may operate in reality.

The proposal departs from the best route to international alignment

The Commission places value on convergence through IMDRF and suggests in its staff working document to align with IMDRF N81[4], published in 2025. The Commission's proposal, however, aligns with the older IMDRF N12[5], published in 2012. International alignment should be measured against today's direction of travel, not against the least stable concepts in older guidance. The point is not that Union law must replicate IMDRF documents verbatim. Rather, where the Commission expressly relies on international convergence as a policy rationale for reform, the resulting legal text should reflect the most current internationally agreed regulatory thinking, especially where newer concepts offer more operational and robust risk discriminators than older terminology. IMDRF N12 used categories such as "inform clinical management" and "drive clinical management", categories most international legislators have avoided or abandoned, and ads "surgical intervention", a term not leveraged by IMDRF, whereas IMDRF N81 places less weight on those categories and more on practical control and oversight dimensions. Rule 11 should align with the latest internationally agreed regulatory science and risk logic of IMDRF N81, rather than selectively reusing outdated terms.

The phrase "confers a clinical benefit" unnecessarily broadens Rule 11

The phrase "confers a clinical benefit" suggests that Rule 11 should also reach software accessories whose main role is to drive or influence medical device hardware. But software accessories that drive or influence hardware are already addressed through the implementing rules, notably Rule 3.3. Keeping such software accessories within Rule 11 duplicates existing logic from other classification rules, complicates scope, and creates risks classification overlap. The cleaner approach is to delete the phrase "confers a clinical benefit", thereby narrowing the rule to independent medical device software that genuinely needs a dedicated software rule. Removing the phrase reduces overlap and makes the scope easier to explain and interpret.

The proposal relies on unstable "inform" and "drive clinical management" concepts at the Class I boundary

The distinction between software that "drives clinical management" and software that merely "informs clinical management" has long been difficult to apply with confidence[6]. Those terms are not robust enough to sit on the legal boundary between Class I and higher classes. Their IMDRF definitions[7] are overlapping,

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[4] IMDRF, Characterization Considerations for Medical Device Software and Software-Specific Risk (IMDRF/SaMD WG/N81FINAL:2025)

[5] IMDRF, Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations (IMDRF/SaMD WG/N12FINAL:2014).

[6] The "Inform clinical management" definition suggested by IMDRF N12 requires the software to "Aggregate information" and "Provide options". It is unclear whether the criteria are cumulative or alternative. In practice, software often outputs a single conclusion that does not present multiple "options" in the IMDRF sense. So, if regulators interpret the criteria strictly (all conditions must be met), then most current software "drives" clinical management. Class I becomes exceptional rather than common.

[7] **To drive clinical management**

Driving clinical management infers that the information provided by the SaMD will be used to aid in treatment, aid in diagnoses, to triage or identify early signs of a disease or condition will be used to guide next diagnostics or next treatment interventions:

- To aid in treatment by providing enhanced support to safe and effective use of medicinal products or a medical device.
- To aid in diagnosis by analyzing relevant information to help predict risk of a disease or condition or as an aid to making a

contestable, and heavily guidance-dependent.

Under the current framework, that ambiguity was tolerable because both categories usually led to notified-body oversight. Under a revised Rule 11, however, the same distinction would determine whether software remains in Class I or is upclassified. That would create avoidable disputes, inconsistent interpretation, and commercial uncertainty. It would turn a soft guidance concept into a hard legal fault line. A revised Rule 11 should not hinge on vague fault lines inviting disputes, guidance battles, and divergent interpretations. Class I software should not be uncertain.

Regardless of how guidance defines these concepts, manufacturers remain free to draft the intended purpose of their device as "informing clinical management" rather than "driving". Because implementing Rule 3.1 makes the intended purpose determinative for classification, a revised Rule 11 would allow the Class I boundary to turn on discretionary wording choices rather than stable legal criteria. That creates obvious scope for strategic positioning, inconsistent classification of functionally similar software, and prolonged disputes over drafting rather than substance. A legal threshold of this importance should not depend on terminology so easily shaped by the manufacturer's own characterization.

The "risk of causing" formula is open to serious over-interpretation

The proposal does not make sufficiently clear whether the relevant risk attaches to the output, the disease or condition, the surrounding situation, or the chain of use. For software, harm is usually indirect: it depends on subsequent action or inaction by a professional, a patient, a medicine, or a hardware device. A vague "risk of causing" threshold, therefore, invites divergent approaches. If interpreted too broadly, even remote or highly atypical scenarios could trigger systematic upclassification. A more proportionate and operational approach would focus on the foreseeable patient risk arising from the software's intended purpose under reasonably foreseeable conditions of use, taking account of whether the output remains subject to meaningful healthcare professional oversight before patient-impacting action is taken.

Bottom Line

- The Commission promised simplification, legal certainty, proportionality, and stronger uptake of international guidance.
- Its software proposal does not yet meet that benchmark because the central interpretive difficulty is not removed; it is moved to the Class I boundary,

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definitive diagnosis.
  - To triage or identify early signs of a disease or conditions.

To Inform clinical management

Informing clinical management infers that the information provided by the SaMD will not trigger an immediate or near-term action:

  - To inform of options for treating, diagnosing, preventing, or mitigating a disease or condition.
  - To provide clinical information by aggregating relevant information (e.g., disease, condition, drugs, medical devices, population, etc.)

where the consequences are greater.
- Minor textual tinkering is unlikely to solve a structural design problem.

7. COCIR proposal

COCIR proposes a simpler rule that preserves the healthcare-situation dimension found in the Commission proposal, but removes "confers a clinical benefit," collapses the unstable "inform/drive clinical management" distinction, and offsets it against software intended to "diagnose or treat" patients without healthcare professional oversight. This makes the rule more operational and less semantically fragile than the "inform/drive" dichotomy.

The advantage of healthcare professional oversight as a classification criterion is that it can be practically assessed. Authorities and economic operators can ask concrete questions: whether a qualified healthcare professional reviews the output before action is taken, whether that professional can reject, override, or supplement the output (professional-in-the-loop), whether that professional monitors the performance, use, and misuse of the device over time (professional-on-the-loop), and whether the oversight is clinically meaningful rather than merely formal.
This makes oversight a more stable and auditable risk-control concept than the semantic distinction between software that "informs" and software that "drives" clinical management.

The human oversight concept is derived from IMDRF N81 and the EU Artificial Intelligence Act (AIA)[8]. It resonates with the broader European regulatory vocabulary around human oversight in AI-enabled systems, better reflects real-world risk control, is easier to explain, and gives a more credible pathway to additional Class I software while keeping higher classes for higher-risk uses.

COCIR does not suggest that the MDR should import the legal framework of the Artificial Intelligence Act (AIA) into device classification. The relevance of the human oversight concept is instead that it reflects a familiar and coherent European regulatory vocabulary for the management of technology-enabled risk, while also corresponding more closely to how software-related risk is controlled in clinical practice.

COCIR proposed text for revised Rule 11

Software which is intended to generate an output that is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation, or alleviation of a disease or condition is classified as class I, unless:

– the output is intended to be used without healthcare professional oversight,

[8] European Parliament and Council of the European Union. (2024). *Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act)*.

for a disease or condition 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;

- the output is intended to be used without healthcare professional oversight, for a disease or condition in a serious situation with a risk of causing a serious deterioration of a person's state of health, in which case it is classified as class IIb;
- the output is intended to be used with healthcare professional oversight, for a disease or condition in a critical situation with a risk of causing death or an irreversible deterioration of a person's state of health, or for a disease or condition in a serious situation with a risk of causing a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIa.

Reference matrix

	Critical	Serious	Non-serious
No healthcare professional oversight	III	IIb	I
Oversight healthcare professional oversight	IIa	IIa	I

Comparing Commission's proposal with COCIR proposed improvement (Rule 11)

Software which is intended to generate an output that confers a clinical benefit and is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation or alleviation of a disease or condition is classified as class I, unless the output is intended for a disease or condition: – 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;	Software which is intended to generate an output that ~~*confers a clinical benefit and*~~ is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation, or alleviation of a disease or condition is classified as class I, ~~*unless the output is intended for a disease or condition*~~: – ***the output is intended to be used without healthcare professional oversight, for a disease or condition*** 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; – ***the output is intended to be used without healthcare professional oversight, for a disease or condition*** 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 case it is classified as

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.	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.*~~ – *the output is intended to be used with healthcare professional oversight, for a disease or condition in a critical situation with a risk of causing death or an irreversible deterioration of a person's state of health, or for a disease or condition in a serious situation with a risk of causing a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIa.*

8. Discussion of the COCIR proposal

How does this proposal provide for patient safety?
The EU MDR's general safety and performance requirements apply to all medical device software, regardless of its class. The question is not whether safety matters, but whether the chosen risk discriminator is a sound one, i.e., whether it leads to a more proportionate risk class. In COCIR's view, healthcare professional oversight is relevant precisely because it can materially reduce the probability that a software output will translate into patient harm without review or correction. Based on the risk-based approach, COCIR proposes a text that classifies software into several classes depending on the risk profile of the software. The amendment provides for a proportionate approach, reflecting elements of international convergence and considering the most recent internationally aligned regulatory science published by the IMDRF in 2025, while safeguarding the robustness of EU MDR classification rules.

How does this proposal provide for innovation and competitiveness?
The current Rule 11 has almost eliminated class I software and is rife with interpretation issues. COCIR's proposal is simpler, preserves a high-risk pathway, creates a meaningful Class I space, and replaces an unstable semantic distinction with a more operational one. The reduction in legal uncertainty incentivizes investment and enhances innovation and competitiveness.

What medical device software is Class I?
Under the COCIR proposal and given its low risk profile, software used for non-serious situations (e.g., seasonal allergies) would remain Class I, regardless of whether it is used under 'healthcare professional oversight'. The policy rationale is that, in non-serious situations, the residual risk associated with software output is

generally lower and can be addressed through the MDR's baseline safety and performance requirements without automatically requiring notified-body involvement. The proposal, therefore, restores a meaningful Class I space without removing the safeguards applicable to all medical devices. In addition, the proposal provides legislators and authorities with a clearer way to identify genuinely lower-risk software without forcing them into artificial debates over whether the software merely informs or instead drives clinical management. The practical result is a broader, more dependable Class I space for independent medical device software use in non-serious situations, which, according to the IMDRF, includes software for migraine risk prediction, nystagmus and other eye movement disorder detection, and cholesterol management.

What does "healthcare professional oversight" mean?
In this context, it means that a qualified healthcare professional remains able, in a timely and clinically meaningful way, to review the relevant output, understand its role in the decision-making process, and, as appropriate, accept, reject, override, reverse, or supplement that output (professional-in-the-loop), or otherwise to exercise effective supervisory control over its use and misuse (professional-on-the-loop). Oversight should be real and effective, not merely nominal or retrospective. This criterion is more operational than the distinction between "informing" and "driving" clinical management because it turns on assessable features of workflow and control rather than contested linguistic categories.

E.g., a doctor who needs to accept/reject every medication dose calculated by the software, or every rehabilitation exercise suggested by the therapeutic software, is in the loop. A doctor is on the loop when not having to confirm each software output, but by monitoring safety and performance over time, for example, by using performance drift detection dashboards.

Note that the AIA requires all providers of high-risk AI systems to provide human oversight capabilities and imposes obligations on professional deployers of such systems, e.g., healthcare professionals. The AIA allows both human-in-the-loop (approval before action) or human-on-the-loop (supervisory control). The AIA allows patients to deploy high-risk AI systems for their own healthcare without obligating them to ensure human oversight, e.g., by a healthcare professional. Consequently, a patient may use a high-risk AI system without healthcare professional oversight, which warrants a higher risk class.

What medical device software is Class IIa or IIb?
The distinction between class IIa and class IIb in the COCIR proposal reflects whether the seriousness of the situation is mitigated by meaningful healthcare professional oversight. The classification outcome therefore turns on a combination of clinical context and risk control, rather than on unstable distinctions about whether software output merely informs or instead drives clinical management.

Software for critical or serious healthcare conditions or situations that provides healthcare professional oversight is class IIa. Software for serious healthcare situations without healthcare professional oversight is class IIb.

IMDRF N12 examples that lead to class IIa *include software intended for healthcare professionals to predict sepsis based on information from the electronic patient file, assist in the reading of computed tomography images for the purpose of detecting lesions indicative of colon cancer, or to detect stroke using magnetic resonance images.*

IMDRF N12 examples that lead to class IIb *include software intended for patients or their layman caregivers to predict asthma episodes or cardiac risk, provide exercise-based treatment for cardiac rehabilitation of patients, detect heart arrhythmia using electrocardiograms from wearables, or calculate insulin dosages based on among others the blood glucose reading,* unless healthcare professional oversight is provided, in which case the software classifies as class IIa.

What medical device software is Class III?
Software intended for use by patients or layman caregivers to *detect stroke or melanoma through smartphone images without healthcare professional oversight is class III. If the software provides healthcare professional oversight, it is class IIa.*

9. A simpler fallback variant without Class III

Should class III really be included?
COCIR includes Class III in its main proposal for pragmatic reasons: it closely mirrors the Commission's architecture to facilitate legislative negotiation and demonstrates that COCIR is not advocating indiscriminate deregulation. But the substantive case for Class III independent medical device software is weak. COCIR nevertheless includes Class III in its primary drafting proposal as a pragmatic compromise designed to facilitate legislative negotiation. As a matter of policy substance, however, COCIR considers that a no-Class-III model for independent medical device software is the more proportionate and conceptually coherent end-state.

This alternative has the additional advantage of legislative economy. It reduces the number of thresholds that must be interpreted, keeps the main operational distinction that matters in practice, and avoids creating a highest-risk category for independent software where the substantive justification remains limited and where other MDR rules already address the most extreme cases.

At the time of publication, EUDAMED contains only three class III software items, all intended for programming active implantable neurostimulators, i.e., software that drives or influences the use of an implant, and which, following

implementation Rule 3.3 in combination with Rule 8, are class III, rather than class IIa through Rule 11.

Software harm is typically indirect, and COCIR is not aware of an established market for independent medical device software whose intrinsic risk is comparable to that of the highest-risk implantable hardware. Furthermore, if software incorporates a diagnostic function and provides cognitive-behavioral therapy for critical mental illnesses, it is already classified as class III under Rule 22.

The class III melanoma and stroke detection software discussed earlier would, following MDR Article 61(4), require a clinical investigation, which is often ill-suited and disproportionate for diagnostic software, where robust retrospective evidence may be scientifically stronger and ethically preferable. Furthermore, if the diagnosis of melanoma or stroke were not performed through software, but through hardware instead, the applicable hardware rules would only lead to class IIb (Rule 10).

For those reasons, as a matter of substance, a software rule that includes Class III is not the most suitable and proportionate.

A variant without class III

Once the weak substantive case for Class III is acknowledged, the rule can be simplified further. A variant without Class III is not only more proportionate; it is visibly simpler for legislators, authorities, and manufacturers to apply. It keeps the core policy distinction that matters in practice: higher classification for serious or critical contexts, and a lower class where healthcare professional oversight reduces the residual risk.

Variant 2 (without Class III)

Software that is intended to generate an output that is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation, or alleviation of a disease or condition is classified as class **I**, unless if it is intended to be used in a situation with a risk of causing death, an irreversible or serious deterioration of a person's state of health, in which case it is class **IIb**, except if it is used with healthcare professional oversight, in which case it is class **IIa**.

Reference matrix

	Critical or Serious	Non-serious
No healthcare professional oversight	IIb	I
Healthcare professional oversight	IIa	I

Comparing Commission's proposal with COCIR proposed improvement without Class III (Rule 11)

Software which is intended to generate an output that confers a clinical benefit and is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation or alleviation of a disease or condition is classified as class I, unless the output is intended for a disease or condition: – 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.	Software ~~*which that*~~ is intended to generate an output that ~~*confers a clinical benefit and*~~ is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation, or alleviation of a disease or condition is classified as class I, ***unless if it is intended to be used in a situation with a risk of causing death, an irreversible or serious deterioration of a person's state of health, in which case it is class IIb, except if it is used with healthcare professional oversight, in which case it is class IIa.*** ~~*the output is intended for a disease or condition*~~: ~~– *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.*~~

10.COCIR recommendations

- Do not settle for minor drafting edits to the Commission text if the underlying interpretive fault line remains intact.
- Delete "confers a clinical benefit" so that Rule 11 focuses on independent medical device software rather than duplicating rules for software accessories.
- Avoid "inform clinical management" and "drive clinical management" at the Class I boundary.

- Ensure that the revised Rule 11 uses risk discriminators that are observable in practice, sufficiently clear in the legal text itself, and closely linked to residual patient risk under the intended conditions of use (i.e., use healthcare professional oversight as the more operational risk-control concept).
- Keep international convergence real by drawing on current IMDRF thinking, not only older software-risk labels.
- Consider the no-Class-III variant as the more proportionate and visibly simpler end-state for independent medical device software.

In short, the legislature has room to improve the software proposal while staying fully aligned with the Commission's stated objectives of simplification, proportionality, and international convergence. The COCIR text offers a more coherent route because it replaces unstable semantic distinctions with a more operational and auditable risk-control concept. The no-Class-III variant offers an even simpler and more proportionate end-state for independent medical device software if policymakers want maximum clarity and practical applicability.