

Position on Annex VIII Classification Rule 11 of the Proposal for a Regulation amending Regulation (EU) 2017/745 as regards the simplification and reduction of regulatory burdens for medical devices (COM(2025) 1023 final)

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While the European Commission's proposal to amend Classification Rule 11 with the intention of assigning lower risk classes to software is a positive development, the proposed revision fails to meet its simplification objectives. Instead, it introduces significant legal uncertainty, which may inadvertently stifle innovation in digital health solutions within the EU. Furthermore, the amendments outlined in the European Parliament's Committee on Public Health Draft Report (Amendments 117 ff.) similarly fail to uphold the necessary principles of simplification and proportionality.

Commission Proposal	Draft Report of the Committee on Public Health of the European Parliament	Rule 11
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Original Text	Amendments 117, 118, 119 and 120	Proposed Change
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	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	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

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;

as class I, unless the output is intended for a disease or condition:

- in **treat or diagnose 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 **treat or diagnose 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 **of a disease or condition** in a critical situation in which cases it is classified as class IIb;
- in **treat or diagnose a disease or condition** in a non-serious situation, or to drive clinical management **of a disease or condition** in a serious situation or to inform clinical management **of a disease or condition** in a critical or serious situation in which case it is classified as class IIa;

class I, unless the output is intended for a disease or condition to:

- **treat or diagnose 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;
- **treat or diagnose 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 **of a disease or condition** in a critical situation in which cases it is classified as class IIb;
- **treat or diagnose a disease or condition** in a non-serious situation **where clinical management is required**, or to drive clinical management **of a disease or condition** in a serious situation, or to inform clinical management **of a disease or condition** in a critical or serious situation, in which case it is classified as class IIa.

Justification

The Commission's proposal to introduce a default class I classification under the revised Rule 11 is welcomed, as it aims to introduce greater proportionality for clinical benefit software.

However, we would like to draw attention to one aspect of Rule 11 that, in its current drafting, may not yet deliver the intended effect.

The opening sentence sets class I as the default classification for clinical-benefit software. However, this default no longer applies once the output is intended for a disease or condition in one of the three situations listed in the indents that follow:

- a critical situation
- a serious situation
- a non-serious situation.

These three situations cover every possible case; no fourth category exists. The final indent assigns even the mildest of the three, the non-serious situation, to class IIa. As a result, every clinical-benefit software output falls into one of the three situations, and none of them currently leads to class I in practice.

We would therefore welcome a clarification ensuring that the class I pathway set out in the opening sentence retains a genuine scope of application.

Illustrative examples that would currently suffer from the current proposal include:

- Dyscalculia exercise applications → Class IIa
- Motion sickness exercise applications, guiding lay users through standardised breathing and gaze-stabilisation exercises → Class IIa

Neither example concerns a critical or serious situation, and neither requires clinical management in the sense of ongoing monitoring, dose titration, or a change in a healthcare professional's treatment decision: both generate a tailored treatment (e.g. clinically well-established exercises), intended for direct use by lay users without the need of a healthcare professional. Yet under the current wording of Rule 11, both default to class IIa.

This approach results in trivial, low-risk software tools being placed in the same risk class as genuinely medium- or high-risk devices, such as ECG analysis software. Consequently, such devices would be subject to conformity assessment procedures involving a notified body, leading to disproportionate time and cost burdens. Low-risk and non-critical products should be made available to patients and users without unnecessary regulatory obstacles.

For these reasons, we believe the proposed revision of Rule 11 for software does not yet fully achieve its stated objective of simplification and proportionality, and risks discouraging investment in digital health solutions within the EU.

Our proposition restores a genuine class I pathway for low-risk treatment software that neither relates to critical or serious conditions nor requires clinical management, consistent with the default classification rule in Annex I, point 6.6(g). The proposed approach ensures that low-impact treatment-support software is not subject to disproportionate regulatory requirements, while preserving a cautious classification in line with established risk-based classification principles, including the IMDRF framework. The proposal is largely inspired by the amendments of the Draft Report of the Committee on Public Health of the European Parliament.