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## Urgent technical adjustment to MDR Annex VIII, Rule 11 Ensuring a genuine "Risk-Based Approach"



As a German manufacturer of software as a medical device (SaMD), we expressly support the objective of the European Commission to reclassify "devices in a way that saves time and effort and is more proportionate to their inherent risk". A risk-based classification is essential to ensure patient safety while simultaneously strengthening innovation capacity and security of supply within the European healthcare sector.

However, with regard to the proposed revision of Rule 11, a certain inconsistency emerges between the stated political ambition and the current regulatory design. **While Class I is formally defined as the standard, broadly framed exemption clauses nullify its practical accessibility.** As a result, the intended relief, particularly for SMEs and low-risk digital solutions, will not be fully realised.

This interpretation creates tension with core principles of the MDR. Recital 5 explicitly calls for international harmonisation, taking into account the IMDRF guidelines on risk-based classification of SaMD. Deviations from these principles may hinder the global interoperability of European innovations and weaken Europe's competitive position. Likewise, Recital 58 requires a proportionate classification reflecting the actual vulnerability of the human body. In the case of software, risk is primarily indirect and highly context-dependent, an aspect that is not yet sufficiently differentiated in the current proposal.

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To ensure a functional subdivision into four risk classes, **Rule 11 should therefore be further specified so that Class I remains genuinely accessible for low-risk software**, in line with the IMDRF framework. This requires clear and legally robust categorization criteria, as well as up-to-date examples - such as those provided through an updated MDCG guidance - that adequately reflect current technological developments and clinical practice.

Proposal	Proposed Solution	Rationale
<p>(6) Annex VIII is amended as follows:</p> <p>(a) [...]</p> <p>(g) Section 6.3 is replaced by the following: '6.3 Rule 11</p> <p>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:</p> <ul style="list-style-type: none"> <li>in a critical situation with a risk of causing death or an irreversible deterioration of a person's state of</li> </ul>	<p>(6) Annex VIII is amended as follows:</p> <p>(a) [...]</p> <p>(g) Section 6.3 is replaced by the following: '6.3 Rule 11</p> <p>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 <del>to for a disease or condition:</del></p> <ul style="list-style-type: none"> <li><b>treat or diagnose a disease or condition in a critical situation with a risk of causing death or an</b></li> </ul>	<p>"Default Class I" for all SaMD: This ensures that SaMD with low risk potential to patient health, based on the significance of the software output and the healthcare situation, are classified as Risk Class I.</p> <p>Exception 1: Ensures that SaMD with very high risk potential to patient health, based on the significance of the software output and the healthcare situation, are</p>

<p>health, in which case it is classified as class III;</p> <ul style="list-style-type: none"> <li>• 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;</li> <li>• 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.';</li> </ul>	<p><del>irreversible deterioration of a person's state of health</del>, in which case it is classified as class III;</p> <ul style="list-style-type: none"> <li>• <b>treat or diagnose a disease or condition</b> in a serious situation <del>with a risk of causing a serious deterioration of a person's state of health or a surgical intervention</del>, or to drive clinical management <b>of a disease or condition</b> in a critical situation in which cases it is classified as class IIb;</li> <li>• <b>treat or diagnose a disease or condition</b> in a non-serious situation, or to drive clinical management <b>of a disease or condition</b> in a serious situation, or to inform clinical management <b>for a disease or condition</b> in a</li> </ul>	<p>classified in the highest risk category (Class III).</p> <p>Exception 2: Ensures that SaMD with high risk potential to patient health, based on the significance of the software output and the healthcare situation, are classified as Risk Class IIb.</p> <p>Exception 3: Ensures that SaMD with moderate risk potential to patient health, based on the significance of the software output and the healthcare situation, are classified as Risk Class IIa.</p>
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	critical <del>or serious</del> situation in which cases it is classified as class IIa.';	
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Without this technical correction, the reform risks becoming a "paper tiger" for SaMD and digital therapeutics (DTx). The proposed amendment consistently implements the "Risk-Based Approach," relieving the system of unnecessary certification burdens for low-risk tools without compromising patient safety in critical applications.

### Rule 11 (Proposal)

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.';

State of Healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	III	IIb	IIa
Serious	IIb	IIa	IIa
Non-serious	IIa	IIa	IIa

### Rule 11 (Proposed Solution)

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 to:

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

State of Healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	III	IIb	IIa
Serious	IIb	IIa	I
Non-serious	IIa	I	I

Kind regards,



Dr. med. Mario Weiss

CEO

## About us

DTx stands for “Innovation Made in Europe”. GAIA was a pioneer and is now a leader in the development of DTx. As a medium-sized R&D company with around 300 employees based in Hamburg, Germany, we set global standards in patient care with over 20 years of experience, clinically proven efficacy, and more than 70 developed products, including eight prescription DTx (so-called DiGA) in Germany. As a research-based public health company, we combine scientific, technological, and therapeutic expertise under one roof to sustainably improve people’s health. In addition to many BMBF, EU, and US research funding programs, we were also awarded the German Federal Government Research Grant (BSFZ) in 2024 for our research and development achievements.