

MDR Rule 11 Practical Decision Tree for CDSS Classification

A concise pathway from software qualification to clinical utility assessment

First determine whether the software qualifies as a medical device. Only then apply the MDR classification rules. Rule 11 addresses classification; it does not by itself establish real-world clinical utility.

1 QUALIFICATION Medical purpose under the MDR	2 CLASSIFICATION Applicable Annex VIII rule	3 RULE 11 Decision impact or monitoring	4 CLINICAL UTILITY Practice-oriented, structured evaluation
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Qualification and Rule 11 pathway

Decision point	If YES	If NO	Regulatory outcome
1 Does the software have an intended medical purpose under Article 2(1) MDR?	Proceed as Medical Device Software	Outside the MDR medical-device framework	Qualification result, not a risk class
2 Does it provide information used to take decisions with diagnosis or therapeutic purposes?	Assess the potential impact of those decisions	Proceed to physiological monitoring question	Rule 11, first paragraph
3 Could the decision cause death or irreversible deterioration of health?	Class III	Assess the next level of consequence	Highest decision-impact branch
4 Could the decision cause serious deterioration of health or require surgical intervention?	Class IIb	Class IIa	Decision-support branch
5 Is it intended to monitor physiological processes?	Class IIa; Class IIb if vital parameters could vary so as to result in immediate danger	Class I, unless another rule applies	Monitoring or residual branch

Interpretation note: “Not MDR” and “Class I” are not equivalent. “Not MDR” follows from qualification; Class I is a classification outcome for software that qualifies as a medical device but is not covered by a higher-class rule.

Beyond classification: Proposed 5-dimensional of clinical utility framework

REGULATORY COMPLIANCE Intended purpose, classification, conformity	CLINICAL VALIDATION Evidence, reliability, clinical relevance	PATIENT SAFETY Alert relevance, risk, unintended consequences	TRANSPARENCY Explainability, data provenance, limitations	WORKFLOW INTEGRATION Usability, alert burden, fit with care processes
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Classification identifies regulatory risk. The 5-dimensional framework asks the separate practical question: is the CDSS useful, safe and workable in everyday patient care?

Sources: Regulation (EU) 2017/745, Article 2(1) and Annex VIII, Rule 11; MDCG 2019-11 rev.1, Qualification and classification of software (June 2025). Educational decision aid only; classification must be assessed for the specific intended purpose and applicable rules.