

# Three-Step Test Reference Card

UK MDR 2002 (Rule 10 / Rule 12) direct-diagnosis analysis and EU MDR 2017/745 Annex VIII Rule 11 severity test — applied to SaMD.

## UK MDR 2002 — Rule 10 and Rule 12 (UK GB market)

The new UK classification framework is still being developed as of July 2025. The current framework applies EU MDD rules as carried forward into UK MDR 2002. Verify current MHRA guidance before relying on this card.

### Step 1 — Does the product allow direct diagnosis?

Apply the MHRA three-part test: does it provide the diagnosis itself; does it provide decisive information for making a diagnosis; or does it claim to support clinician diagnostic function? If none apply, Rule 10 does not engage — default to **Class I under Rule 12** unless Rule 9 applies.

### Step 2 — If Rule 10 engages, default is Class IIa.

Ask: could incorrect information cause immediate danger through variations in cardiac performance, respiration, or CNS activity? If yes → **Class IIb**. If no → **Class IIa**.

### Rule 9 note

If the product drives or controls a device delivering physical energy to the body (for example a tDCS app), Rule 9 applies separately. Class IIa unless the energy delivery is potentially hazardous, in which case Class IIb.

### Therapeutic software note

Therapeutic software such as CBT apps and AI therapy chatbots does not engage Rule 10 directly. It defaults to **Class I under Rule 12** unless it also performs a diagnostic function. Apply Rule 11 for EU MDR classification of therapeutic software.

## Rule 11 — EU MDR 2017/745 (CE marking, EU market and Northern Ireland)

### Step 1 — Diagnosis or therapeutic purpose?

Does the software provide information used to take decisions with diagnosis or therapeutic purposes? Therapeutic purposes are explicitly included.  
→ If yes, continue to Step 2.

### Step 2 — Death or irreversible deterioration?

Could an incorrect output directly cause death or irreversible deterioration of health?  
→ If yes → **Class III**. If no, continue to Step 3.

### Step 3 — Serious deterioration or surgical intervention?

Could an incorrect output directly cause serious deterioration of health or surgical intervention?  
→ If yes → **Class IIb**. If no → **Class IIa**.

### Two things the test does not do

It does not consider probability of harm. It does not credit disclaimers or design controls. Both are risk-management questions — not classification inputs.

## Serious deterioration in mental health — where is the line?

The serious deterioration boundary applies to the Rule 11 severity escalation analysis. It is not a UK MDR Rule 10 classification input.

Likely serious deterioration (IIb territory)	Probably not serious deterioration (stays IIa)
Suicide attempt resulting from delayed or incorrect intervention.	Slower symptom improvement than would have been achieved with optimal care.
Psychotic episode requiring emergency inpatient admission.	Missed opportunity for earlier intervention without a crisis event.
Relapse to substance use requiring medical detoxification.	Distress or discomfort from unhelpful or incorrect advice.
Self-harm requiring A&E attendance.	Need to try a different therapeutic approach after an ineffective one.
Significant loss of function (employment, housing) from an unmanaged crisis.	

## UK MDR vs EU MDR Rule 11 — representative product types

Product type	UK MDR Rule 10	EU MDR Rule 11
CBT skills app, fixed exercises	Class I (no direct diagnosis; defaults to Rule 12)	Class IIa (therapeutic purpose satisfies Step 1)
AI therapy chatbot, diagnosed depression	Class IIa if decisive information for clinical management; Class I if purely therapeutic with no diagnostic function	Class IIb minimum; Class III if crisis assessment in scope
PHQ-9 tool displaying score to GP	Class IIa (provides decisive information for diagnosis)	Class IIa
Relapse prediction algorithm	Class IIa (decisive information for clinical management)	Class IIb; worst-case argument to III