

Classification Exercise Workbook

Apply the UK MDR Rule 10 direct diagnosis analysis and the EU MDR Rule 11 three-step severity test to each scenario. For UK classification, the key question is whether the product allows direct diagnosis under the MHRA three-part definition. For EU classification, apply the Rule 11 severity escalation steps. Work through each step before deciding the overall classification. This workbook is for self-study; answers are not provided.

Exercise 1 — Sleep coaching app

Scenario. A consumer sleep app delivers nightly personalised sleep-hygiene tips based on a user's wearable data. Users include adults with diagnosed insomnia and adults without any diagnosis. The tips include advice on caffeine, screen time, wind-down routines and breathing exercises. The app's terms of service state it is 'not a medical device'.

Step 1. UK MDR Rule 10: Does this product allow direct diagnosis — does it provide the diagnosis itself, provide decisive information for making a diagnosis, or claim to support clinician diagnostic function? **EU MDR Rule 11:** Does the software provide information used to take decisions with diagnosis or therapeutic purposes?

Step 2. Could an incorrect output directly cause death or irreversible deterioration of health?

Step 3. Could an incorrect output directly cause serious deterioration of health or surgical intervention?

Overall classification (UK MDR Rule 10 / Rule 12):

Overall classification (EU Rule 11):

Reasoning notes:

Exercise 2 — PHQ-9 administration tool

Scenario. A web app administers the PHQ-9 questionnaire to patients before a primary care consultation, calculates the total score using the validated algorithm, and displays the score and severity band to the GP in the consulting room. The GP uses the score alongside their own clinical assessment.

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Exercise 3 — Eating disorder companion

Scenario. A smartphone companion for adolescents recovering from anorexia nervosa offers daily meal-time prompts, a chat function staffed by an AI, and an emergency button that signposts to crisis services. The AI adapts its responses based on conversation history and food-log entries. The product is recommended by NHS clinicians as adjunct support between sessions.

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Exercise 4 — Pre-surgical anxiety module

Scenario. A module within a hospital's patient app delivers a four-session anxiety reduction programme to adults awaiting elective surgery. It includes a final-session questionnaire that produces a 'readiness score' shown to the anaesthetist, who uses it to decide whether to proceed with the planned anaesthesia plan or escalate to a pre-op review.

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Reasoning notes:

Exercise 5 — Carer escalation dashboard

Scenario. A dashboard for paid carers of people with severe mental illness aggregates the cared-for person's medication adherence, sleep, and self-reported mood. The system flags 'amber' or 'red' status. Carers are instructed to contact the community mental health team within four hours of any 'red' flag.

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