Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Appendix 1 – Symptom checkers

Independent software intended for use by lay users. The user manually enters details/symptoms and the software algorithm matches these with conditions. There are many on the market, some using AI chatbots to interact with the user.

Outputs can include:

- A list of all matching conditions, likely conditions, most likely condition etc.
- An indication of seriousness – e.g. 'Red flag'.
- Recommended treatments.
- Triage 'signposting' of next steps, e.g. visit GP, go to A&E.

Examples that may be devices include:

- Software intended to output a subset of those medical conditions that match the input symptoms.
- Software that indicates the likelihood of a match.
- Software that provides treatment recommendations for listed conditions, e.g. first aid treatment.
- Software that offers filters by red flag/severity/probability of a match.

Examples that are unlikely to be devices include:

- Software that offers only reference information about the conditions listed.
- Software intended to list all matching conditions that fit the symptoms input where the order is independent of likelihood, e.g. in alphabetical order.
- Software that only signposts the user to suitable care e.g. see your GP, go to A&E.

Symptom checker devices will be class I unless considered to 'allow direct diagnosis', in which case they will be class IIa.

A device is considered to "allow direct diagnosis" when

- it provides the diagnosis of the disease or condition by itself,
- it provides decisive information for making a diagnosis, or
- claims are made that it can perform as, or support the function of, a clinician in performing diagnostic tasks.

For devices intended to be used by lay users, provision of an indicative diagnosis may be enough to imply that the device is allowing direct diagnosis.

Indicative words and phrases:

Triage
Self assessment
Medical Information
Health Information
Working diagnosis
Differential diagnosis

Appendix 2 – Clinical calculators

Many clinical calculators meet the definition of a medical device but not all of them need to be UKCA marked. MEDDEV 2.1/6 allows some discretion for software performing **a simple action**.

Calculators linked to specific devices/drugs are likely to qualify as devices whatever the complexity of the calculation.

Calculators where the calculation/result can be easily verified are unlikely to be devices:

1. Calculators without a medical purpose
General purpose tools for analysing clinical data e.g. statistical analysis. These are not medical devices.

2. Simple scores
Points given for listed symptoms e.g. ABCD² Score for TIA. The calculation is just simple addition of the integer scores, usually, these can be easily verified. More complex scoring tools may be considered to be devices.

3. Simple calculations
Contains a few variables and a simple calculation using basic functions available on a simple calculator. (+, -, ×, ÷) e.g Parkland Formula for Burns. These are usually easily verified.

Calculators for "educational purposes only" do not need to be able to perform the calculation but can provide examples.
Providing the calculation is likely to qualify the tool as a device.

Calculators where the calculation/result cannot be easily verified are likely to be devices:

4. Intermediate calculations
Contains a few more variables and a more complex calculation but can be calculated using the functions available on a simple calculator. [+, -, ×, ÷, (,)] e.g. Aminoglycoside Clearance Estimate.
Not always easily verified.

5. Complex calculations
Contains a complex calculation using functions available only on a scientific calculator or spreadsheet. These are not easily verified. E.g. Complex cardiovascular disease risk scores.

6. Calculators with linked lookup tables
The calculator uses linked data that is not displayed and the result cannot be verified.

Calculators pulling data from fields in an electronic patient record are likely to be devices if the simple calculation or the data used cannot be easily verified.

Indicative words and phrases:

Equation
Risk score
Formula
Algorithm

Take into account the intended user's numeracy level. If the calculation cannot be easily verified by the intended user then it is likely to be a device. You will need evidence to show that the user can verify the calculation (user studies).
You should always provide details of the formula used and details of the source research for any calculator.

Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Appendix 3 – 'drives or influences the use of a device'

The term "*drives a device or influences the use of a device*" can include anything from direct control of a device to just selecting a device. This must be an intended action by the manufacturer of the software and not just an accidental influence on use of a device.

Annex IX, implementing rules:
2.3. Software, which drives a device or influences the use of a device, falls automatically in the same class.

Examples:

Third party software that uses patient CT images and stent sizes from published data to help a clinician select the best implant for a patient. It is a new product.

The stent manufacturers do not specifically recommend stent sizing by this method (the use was not prohibited as they didn't know about this product)

Software is influencing the use of a device outside its intended purpose. Software will take the classification of the device.

Third party software that sends insulin dose values via Bluetooth connection to any compatible insulin pump.

The pump manufacturer allows Bluetooth communication but ONLY from its dedicated software.

Software is influencing the use of a device outside that mentioned in the IFU. Software will take the classification of the device.

Any interactions should be considered under the post-market surveillance plans of the software and device manufacturers.

Third party dental image PACS that can be connected to a digital detector to acquire images. It doesn't control/drive/influence the performance of the x-ray source but does influence the use of the detector.

Some digital detectors allow connection to third party systems but only if the listed standards are met. Others specify OEM connection only.

This software states that is can be used with ALL detectors.

Software is influencing the use of those devices that do not mention this use in their IFUs. Software will take the classification of the detector.

Third party software that makes recommendations about choices of contraceptive devices/medications.

The app decision process follows national prescribing recommendations and not the contraceptive device's IFU (some contraindications are not considered by the app).

Software is influencing the use of a device outside that mentioned in the IFU. Software will take the classification of the device.