



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 2.1/5 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.

