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 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 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.

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.