



NON-MEDICAL DEVICE STATUS DECISION FLOW CHART

Augmentia is not a medical device.

It is a back-office administrative tool designed exclusively for use by GP practice staff to track and manage compliance with QOF, DES, and LES frameworks. The system aggregates relevant patient surveillance data and presents it in a clear, structured dashboard, enabling users to identify completed tasks, monitor outstanding items, and support timely submissions for reimbursement claims. It effectively performs the secretarial task of consolidating the status of each patient, giving practices a comprehensive view of their progress.

The product does not perform any diagnostic, therapeutic, predictive, or preventive functions, and has no clinical decision-making capabilities. Its sole purpose is to streamline administrative processes related to framework reporting, and it operates entirely within a non-clinical, administrative context.

To validate this logic, MHRA's interactive guidance Device determination flow chart (p.6) can be followed:

1-The software is not incorporated with a device.

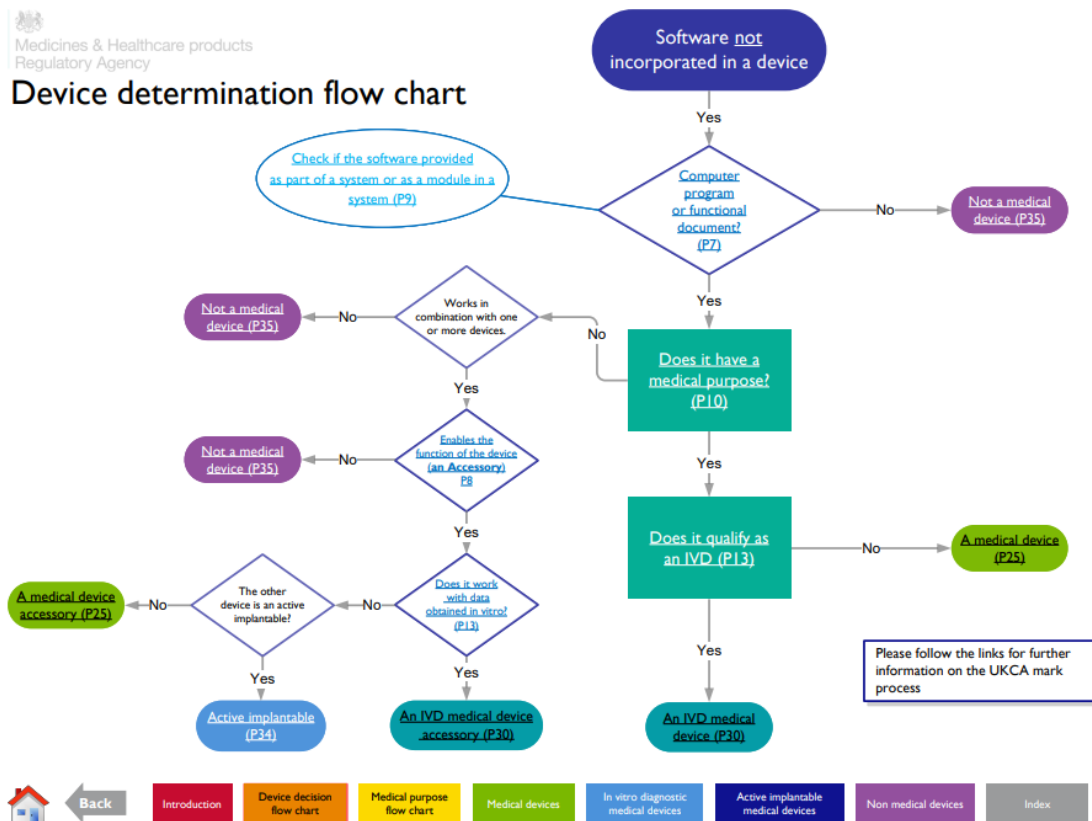
2-It is a computer program.

3-It does not have a medical purpose (It only has administrative function to oversee the progress in QOF-LES-DES framework surveillance.)

4-It does not work in combination with one or more devices; hence, it is not a medical device.



Device determination flow chart



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Definitions

Computer program

"syntactic unit that conforms to the rules of a particular programming language and that is composed of declarations and statements or instructions needed to solve a certain function, task, or problem"

[ISO/IEC 2382:2015\(en\)](#)

This includes:

- Un-compiled software - if all of the information is provided to install the software then the regulations may apply.
- Freeware / open-source software

Note

The regulations apply to all methods of software distribution. It applies to products that have been "placed on the market" rather than sold.

Functional document

Software that requires separate software to perform its function. Often this will be a general purpose application.

Examples include:

- A pdf that reproduces a treatment decision flow chart with logical links.
- Spread sheets - particularly if they provide complex functionality that is beyond that of existing paper charts e.g. an excel spreadsheet that calculates Glomerular filtration rate.
- Documents with macro or script enabled functions - complex medical applications can be written with languages such as visual basic
- Interactive web pages - these can utilise programming languages such as JavaScript to produce medical applications.

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"software" is defined as a set of instructions that processes input data and creates output data.

"placing on the market" means, in relation to a medical device, the first making available in return for payment or free of charge of a new or fully refurbished device, other than a device intended for clinical investigation, with a view to distribution, use, or both, on a relevant market

"putting into service" means:

- (a) in relation to an active implantable medical device, the making available of the device to a registered medical practitioner for implantation;
- (b) in relation to any other medical device, the first making available of the device in a relevant state to a final user, including where a device is used in a professional context for the purposes of medical analysis without being marketed;

Indicative words and phrases:

Software as a medical device
Standalone software
Medical apps
SaMD
Macro
Script



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Medical purpose

