



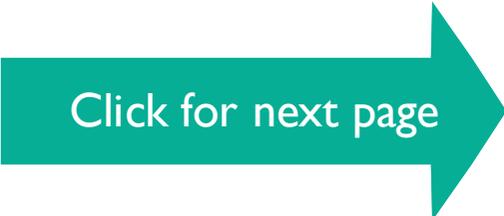
Guidance:

Medical device stand-alone software including apps (including IVDMDs)

Application of this Guidance

This guidance is applicable to standalone software and apps placed on the Great Britain market. Great Britain is England, Wales and Scotland. The UKCA (UK Conformity Assessed) mark is used for certain goods, including medical devices, being placed on the Great Britain market. This guidance gives examples of software and apps which meet the definition of a medical device and it outlines requirements for UKCA marking of medical devices. Please note that CE marked devices will continue to be recognised on the Great Britain market until 30 June 2023.

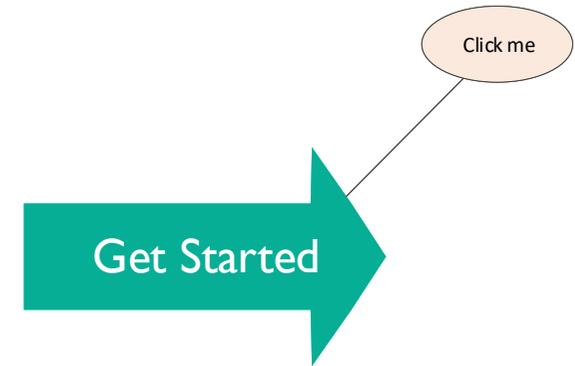
For Northern Ireland, different rules apply to those in Great Britain. Please review our [published guidance](#) for further information on the different rules which will apply and our guidance on [applying the MDR and IVDR](#).



Click for next page

For full functionality, this document is best viewed in Acrobat reader.

- This document is intended to be viewed on screen rather than printed.
- Please use the in-document [links](#) to navigate through this document for further information on the UKCA mark process.
- At the bottom of each page you will find a navigation pane with quick links to the start of the main sections.



Indicative words and phrases box:

Words and phrases listed in this box are all likely to contribute to a determination by the MHRA that the app they were associated with is a medical device.

See:
[MHRA Guidance Note No. 8 – A guide to what is a medicinal product](#)
and
[Guidance on legislation, Borderlines with medical devices.](#)



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Introduction

This guidance document replaces the previous MHRA guidance titled “medical device standalone software, including apps”.

As well as medical device apps becoming a growth area in healthcare management in hospital and in the community settings, the role of apps used as part of fitness regimes and for social care situations is also expanding.

However, in the UK, standalone software and apps that meet the definition of a medical device are still required to be UKCA marked in line with the Medical Device Regulations 2002 (as amended) (UK MDR 2002) in order to ensure they are regulated and acceptably safe to use and also perform in the way the manufacturer/ developer intends them to.

But how do developers and users of this software decide whether apps qualify as medical devices and which are for health and fitness purposes?

This guidance uses **examples within flowcharts** to show which standalone software and apps meet the definition of a [medical device, an in vitro diagnostic device or active implantable medical device](#) and are required to be UKCA marked, and those which do not.

For developers of software, including apps, we are also including information on classification, suggestions on how to address the main aspects of the UKCA marking process and responsibilities for reporting and correcting when things go wrong.

For users we offer a few tips on how to decide if the app or software device you are using is a medical device and if so how to ensure it is appropriately marked along with how to report problems

This guidance is to be used in addition to MEDDEV 2.1/6 and is the UK’s interpretation of the guidance.

For Governance and regulatory requirements for decision supporting and making software in the NHS and Adult Social Care see “Clinical Safety Guidance”:

<https://digital.nhs.uk/services/solution-assurance/the-clinical-safety-team/clinical-safety-documentation>

Developers and
manufacturers

Users

The manufacturer is defined as:

“the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.”

Guidelines on the qualification and classification of stand alone software used in healthcare within the regulatory framework of medical devices





Software users – professional and lay

How do I know if my app is a medical device?

If you are using an app for yourself or if you are using an app and you are not a trained healthcare professional, then this advice is for you. If the app you are using has a medical purpose it is important that it is UKCA or CE marked. There is a [legal definition of a medical device](#) but here are some practical examples;

Depending on information you enter about yourself

- Those which calculate medicine doses for you to take /inject
- Those that tell you that you have a medical condition or disease or give you an individual percentage risk score of having one.

Before you choose a medical device app - is it the right app for me?

You should think about what you will do with the results and the information that the app is giving you. If the app is giving you significant health information then be sure you will understand the result and you know what you need to do when you get the result. When an app developer applies a 'UKCA or CE mark' they are claiming that the app is fit for the purpose it claims and it is acceptably safe to use. The UKCA or CE mark should be visible on the app when you are looking at it in the app store or on the further information or 'landing' page. This information should also tell you what the app can be used for and how to use it.

If you can't see these details or are unsure we suggest you contact the developer to ask and in the meantime that you don't use it. **Please use only medical device apps that are UKCA or CE marked.** If you see a medical device app that does not have a UKCA or CE mark, then you can [report it to MHRA](#).

Once you have started using the medical device app

Once you are sure the app is right for you and it is UKCA or CE marked then you should follow the instructions carefully. Be honest with the information you put into the app. If you enter wrong information about yourself, the app may not give you the right result.

Ensure that you always update the app to the newest compatible version.

After using the medical device app

If you are in doubt about the information that the app has given you or you are concerned about your health then you should consult a healthcare professional (a pharmacist, health visitor, practice nurse or GP)

If you have any problems with the app not working as stated e.g.

- If the instructions aren't clear or the app is difficult to use
- If the app isn't giving you the results that you expected
- If you have concerns over the safety of the app or the information that it provides

Tell the MHRA about these problems. You can do this by going to our reporting page on the website <https://yellowcard.mhra.gov.uk/>.

You should also contact the developer/owner of the app to tell them.

Personal data and security

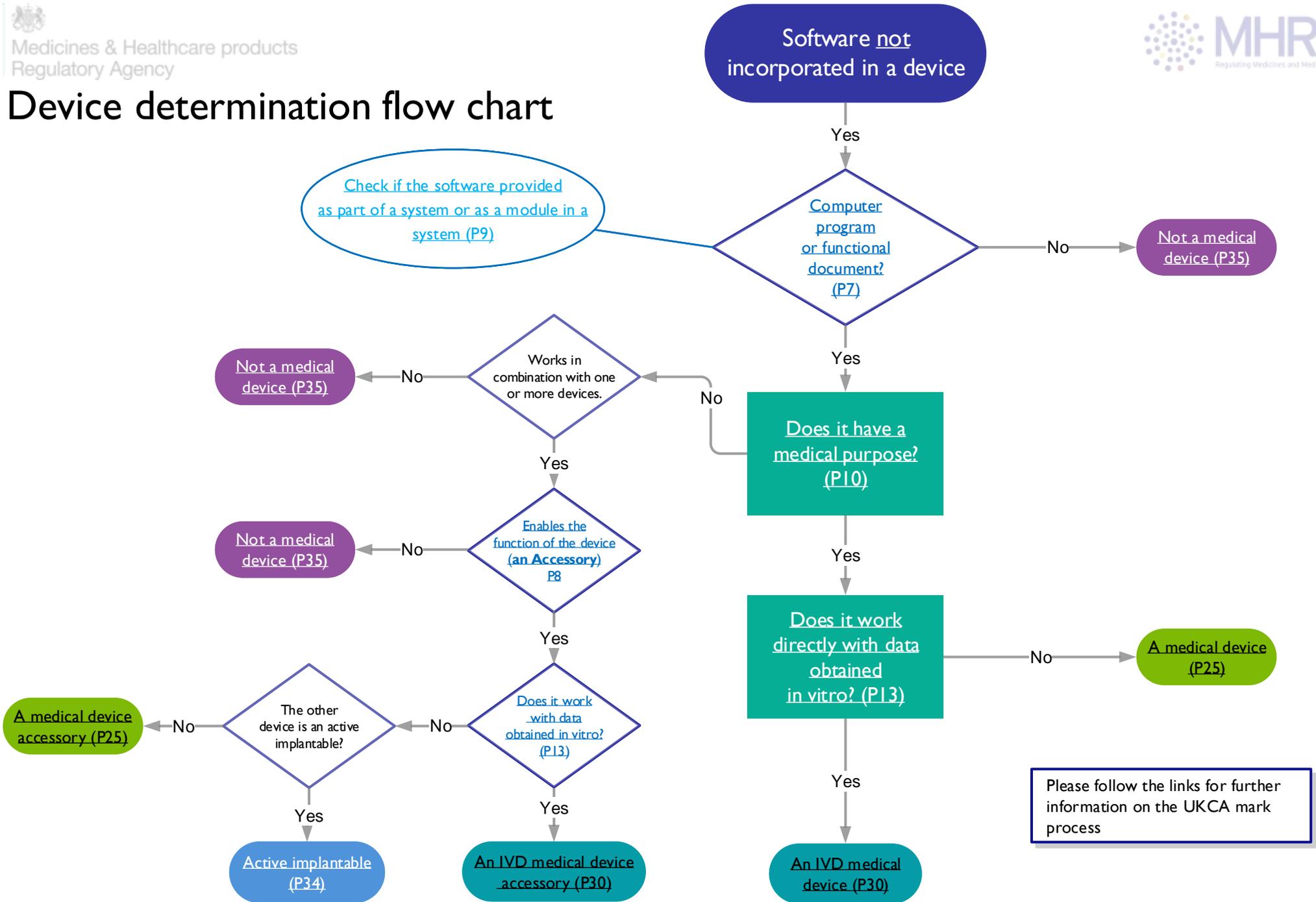
It is very important that you have read the small print to understand what personal data you may have agreed to share with the developer by signing up to the app and how they might store or use your data or share your information with third parties. This includes information about you such as your name, address, date of birth and information about your health.

Additional sources of information:

RCP guidance on medical Apps: <https://www.rcplondon.ac.uk/guidelines-policy/using-apps-clinical-practice-guidance>



Device determination flow chart



Please follow the links for further information on the UKCA mark process



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.

MEDDEV 2.1/6 - 2016

“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;

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.

Indicative words and phrases:

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





Accessories

An accessory is a product intended to enable a medical device to fulfil its intended function and it will be treated as a device under the UK MDR 2002.

E.g. Software on a mobile device linked wirelessly to a monitoring device to record data.

Please Note:

Apps acting as accessories to physical medical devices such as in the measurement of temperature, heart rate, blood pressure and blood sugars could be a medical device as are programmers for prosthetics and active implanted devices.

If an app is the only way of interacting with a physical device then it may be considered to be a component of the device e.g a physical clinical thermometer with no display that links to an app on a mobile device by wireless link. The app displays, stores and analyses the data.

MEDDEV 2. 1/1 has this to say about spare parts (= software components):

“Spare parts supplied for replacement of existing components of a device, the conformity of which has already been established, are not medical devices. If spare parts, however, change significantly the characteristics or performances of a device with regard to its already established conformity, such spare parts are to be considered as devices in their own right.”

MEDDEV 2. 1/1

“The definition of "accessory" requires that the accessory is specifically intended by the manufacturer of the accessory to be used together with a device. The intended use of the accessory must be such as to enable a device to be used in accordance with its intended use. Therefore a product can only become an accessory to a medical device if the manufacturer of such a product establishes an intended use in conjunction with one or several medical devices.”

Indicative words and phrases:

Can be used with..
Helps...



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Systems and modules

Systems

Medical devices

There is no definition of a 'system' in the UK MDR 2002 but there are specific requirements for products placed on the market **together** that combine UKCA/CE marked devices and non-UKCA/CE marked products.

e.g. a combination of laptop (not a medical device), software (a medical device) and heart monitoring hardware (an accessory) is considered to be a 'system' if these are placed on the market together.

MEDDEV 2.14/1 revision 2
"a 'kit' consists of more than one component that are made available together and intended to be used to perform a specific IVD examination."

In-vitro diagnostic medical devices

Where the software is provided as part of an IVD system (or IVD kit) it should be treated as an IVDMD.

Modules

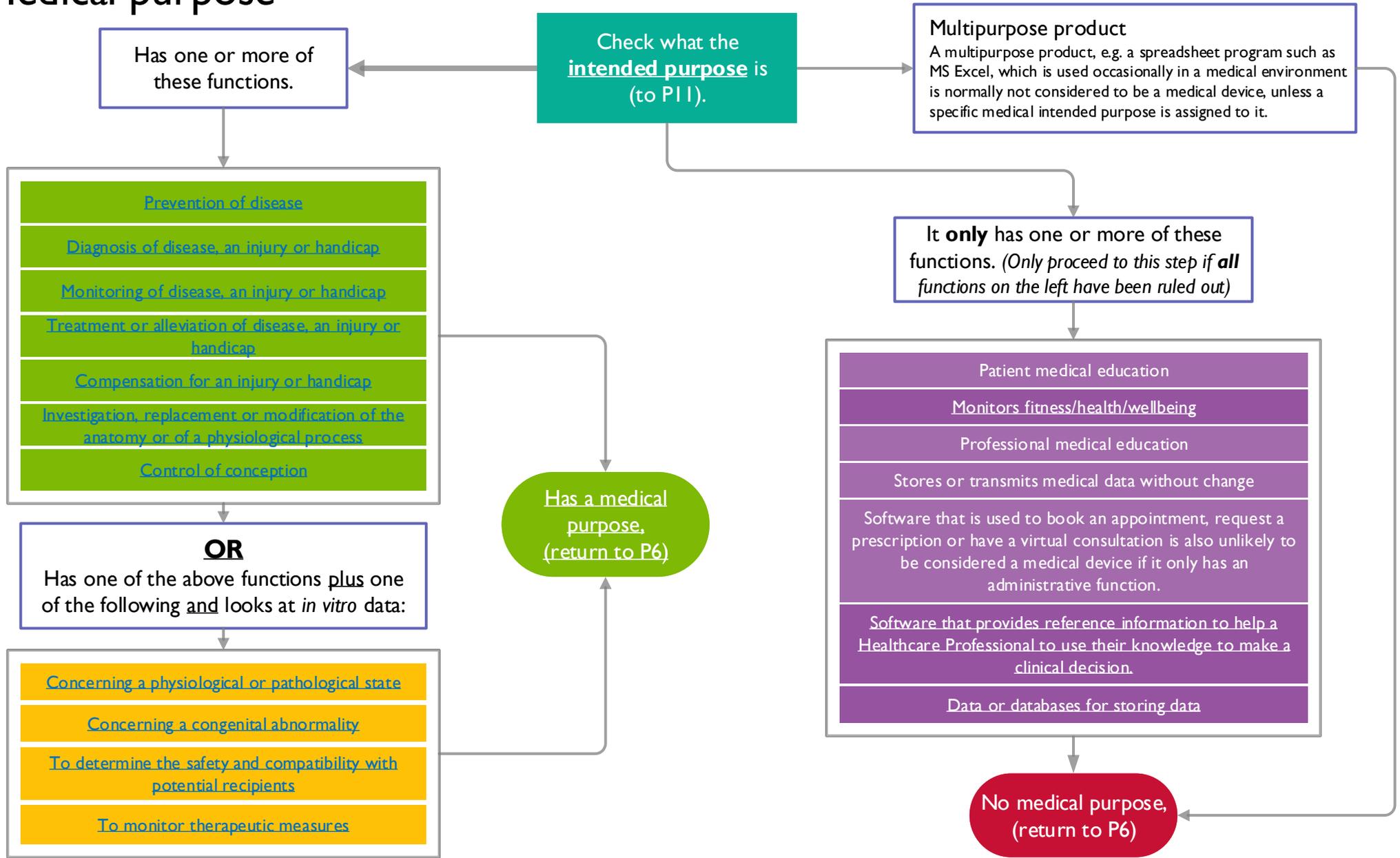
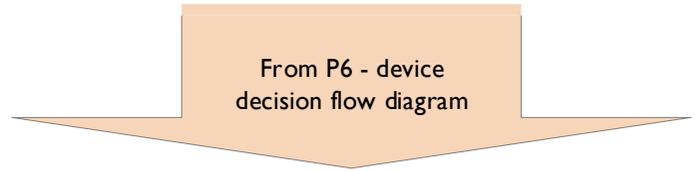
In complex systems it may be appropriate to UKCA mark only those functions/modules that meet the definition of a device rather than UKCA marking the whole product.

Examples that may be devices include:

- Clinical systems that include modules that are intended to indicate the risk that a specific patient has of developing a disease based on entered data for that patient.



Medical purpose





Intended purpose

A **medical purpose** is determined by what the manufacturer states in the device's labelling, instructions for use and any promotional materials.

Examples of promotional materials include:

- Adverts
- App store description and category
- The landing page
- The manufacturer's social media channels

Notes:

- Care should be taken with the description of what the software is intended to be used for. Simple changes to the description make the difference between a product being considered a device or not.
- A number of apps have a disclaimer saying "for information only" or "for research use only" or other statements that try and reduce the responsibilities of the manufacturer. However, if an app qualifies as a medical device and is placed on the market for a medical purpose, it will still need to comply with UK MDR 2002.
- General disclaimers (for example 'this product is not a medical device') are not acceptable if medical claims are made or implied elsewhere in the product labelling or associated promotional literature.
- Anecdotal quotes and testimonials are considered to be implied claims by the manufacturer if they are repeated in product literature.
- Use of a product for a medical purpose does not make it a medical device. See MHRA guidance on [off-label use of a medical device](#).

MEDDEV 2.1/1.1.1b) medical purpose

"Medical devices are defined as articles which are intended to be used for a medical purpose. The medical purpose is assigned to a product by the manufacturer. The manufacturer determines through the label, the instruction for use and the promotional material related to a given device its specific medical purpose."

Indicative words and phrases:

Clinical Trials Evidence...
Clinically proven...
Medical research...



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Non medical functions

Monitors fitness/health/wellbeing

The monitoring of general fitness, general health and general wellbeing is not usually considered to be a medical purpose – see [monitoring](#).

Decision support

Software is unlikely to be a device if:

- It just reproduces a paper document in digital format. - It is down to the health care professional to make the decisions based on the advice displayed.
- It just follows the path of a procedure/treatment - there are no decisions - may provide information.
- It has decision points, options may be explained but the health care professional decides which path to take.
- It offers only lifestyle treatment choices or referral advice (e.g. see your GP).

Software is most likely to be a device if:

- It is linked to a specific medicine/device (is likely to be an accessory).
- It is intended to influence the actual treatment - dose, size of implant, time of treatment etc.
- It results in a diagnosis or prognosis - provides future risk of disease

Decision support software is usually considered a medical device when it applies automated reasoning such as a simple calculation, an algorithm or a more complex series of calculations. For example, dose calculations, symptom tracking, clinicians guides to help when making decisions in healthcare. This is likely to fall within the scope of the UK MDR 2002.

Some decision support software may not be considered to be a medical device if it exists only to provide reference information to enable a healthcare professional to make a clinical decision, as they ultimately rely on their own knowledge. However, if the software/ app performs a calculation or interprets or interpolates data and the healthcare professional does not review the raw data, then this software may be considered a medical device. Apps are increasingly being used by clinicians who will rely on the outputs from this software and may not review the source/raw data.

Databases

MHRA do not generally regulate data, databases or analytical services, but if you are analysing or processing data for a medical purpose, then the software that you are using may be covered by the regulations (e.g. analysing imaging or genomic data to determine treatment)

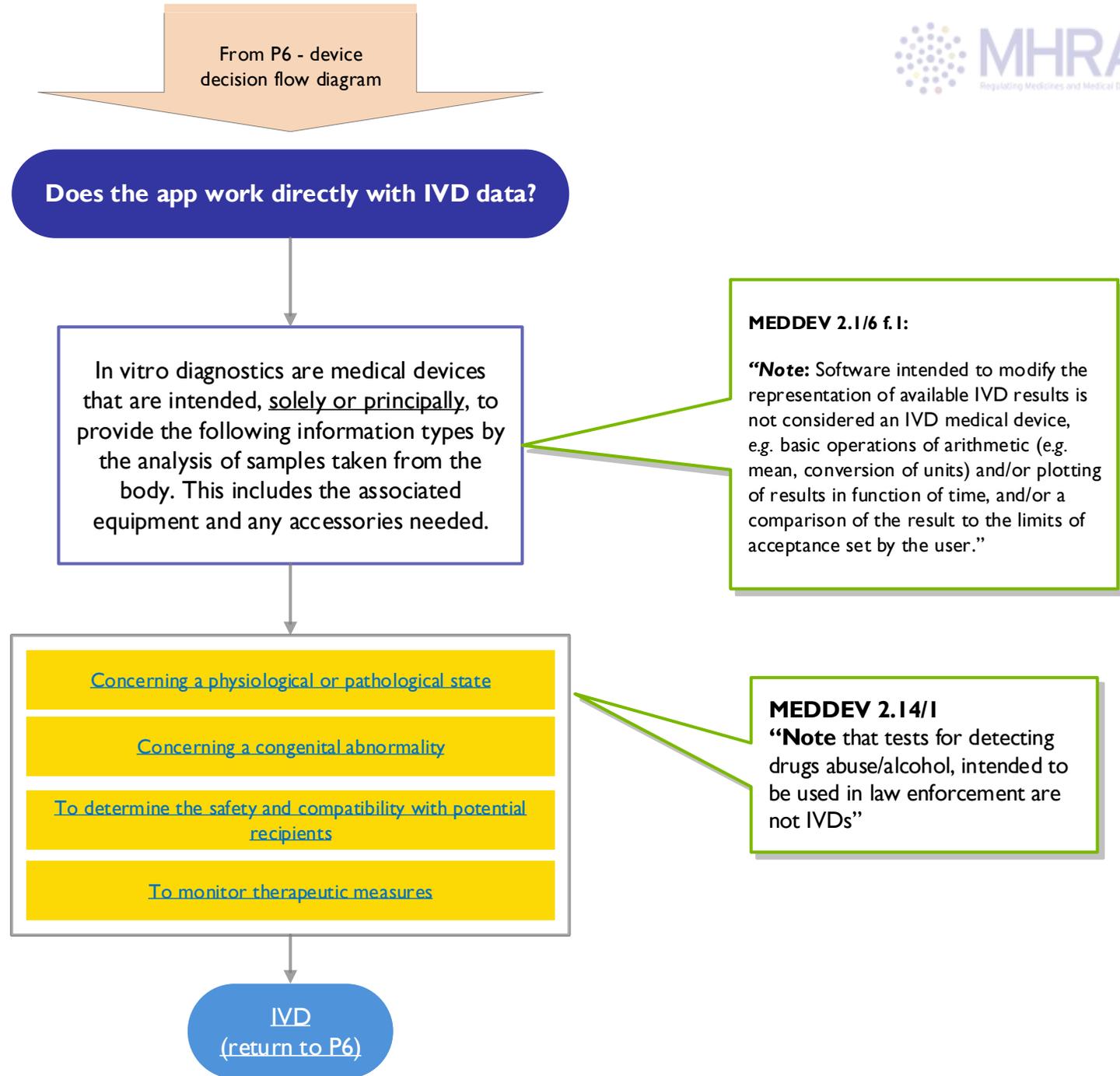
MEDDEV 2.1/6 gives examples of databases that are and are not considered to be medical devices.

Where you are using software to process or analyse data you may need to set criteria around the data that you are analysing - for example data security (hacking, integrity); ethics of data collection (informed consent etc); data quality (was the data produced within a recognised QMS, what was the performance of the test/equipment used to create the data etc)





In vitro diagnostics





Concerning a physiological or pathological state

Software that gives information about a condition or disease from results generated by an IVD. Results may be quantitative or qualitative and can be entered manually by the user or automatically from the IVD

Examples that may be devices include:

- Apps and software that are intended to diagnose
- Apps and software that are intended to calculate clinical risk
- Apps and software that are intended to provide clinical decisions

Indicative words and phrases:

Marker
Prognosis
Indicates





Concerning a congenital abnormality

Software that gives information about an acquired or inherited condition or disease from results generated by an IVD. Results may be quantitative or qualitative and can be entered manually by the user or automatically from the IVD.

Examples that may be devices include:

- Apps and software that are intended for detecting and interpreting mutations in DNA
- Apps and software that are intended for determining risk of trisomies

Indicative words and phrases:

DNA
Genomics
Data analysis
Big Data
Next Generation sequencing...





To determine the safety and compatibility with potential recipients

Software that gives information about the compatibility of blood, tissues, organs or cells donated for transplant or transfusion from results generated by an IVD. Results may be quantitative or qualitative and can be entered manually by the user or automatically from the IVD

Examples that may be devices include:

- Apps and software that are intended for matching organ donors with recipients.

IVF use

Software intended to analyse blastocysts for reintroduction into the body are not considered to be IVDs:

An IVD is used in vitro for the examination of a specimen derived from the human body and where such specimen is never reintroduced into the body. Without a containable specimen derived from the human body, the product will be a medical device and not an IVD. The blastocyst is intended to be reintroduced into the body and is therefore not a specimen for examination. Software for the examination of a blastocyst is therefore a medical device and not an IVD.

Indicative words and phrases:

HLA/ Human Leucocyte Antigen
testing/ typing
ABO/ blood grouping
Tissue typing
Alleles
Lymphocyte cross-matching
Antigen
Antibody
Immunogenetics
Histocompatibility





To monitor therapeutic measures

Software that gives information about the presence or amount of a pharmaceutical or other therapeutic measure from results generated by an IVD. Results may be quantitative or qualitative and can be entered manually by the user or automatically from the IVD

Examples that may be devices include:

- Apps and software that are intended to provide information for the calculation of drug dose (utilising IVD data e.g. blood sugar, creatinine, genomic variant)
- Apps and software that are intended for therapeutic drug monitoring
- Apps and software that are intended to monitor blood glucose, prothrombin time or coagulation

Indicative words and phrases:

Pharmacokinetic





Prevention of disease

Prevention of disease - includes software that claims to be able to prevent specific diseases. It does not include products that claim to prevent injury or handicap.

There needs to be a link to specific disease/s to qualify as a device.

Examples that may be devices include:

- Apps and software that claim that the output from the physical device can prevent disease.

Examples that are unlikely to be devices include:

- Apps and software that just provide tips or advice on prevention.

Prescribing interaction alerts:

Software, of which at least one of the functions makes it possible to use patient-specific data for the purposes, inter alia, of detecting contraindications, drug interactions and excessive doses, is, in respect of that function, a medical device within the meaning of those provisions, even if that software does not act directly in or on the human body.

Indicative words and phrases:

Avoids...
 Can benefit those who suffer from...
 Combats...
 Controls...
 Protects against...
 Stops...





Diagnosis

Diagnosis – includes devices that supply information for detecting, diagnosing as well as those that perform diagnosis independently.

This includes software that claims that the sensors from the physical device can be used for diagnosis.

Examples that may be devices include:

- Apps and software that are intended to be used to diagnose/assess/monitor the skin by use of images taken by/imported into the app.
- Apps and software that provide medical condition advice based on user entered data.
- Apps and software that are intended to indicate the risk that a specific patient has of developing a disease based on entered data for that patient, e.g. *people with the same risk factors as you have a X% chance of heart disease.*

See Appendix I – symptom checkers

Examples that are unlikely to be devices include:

- General purpose apps and software that are intended to record images. Subsequent review by a clinician will not necessarily make it a device.
- Apps and software that are intended to make general recommendations to seek further advice.
- Apps and software that are intended to indicate the risk that a broad group of the population has of developing a disease, e.g. *males aged over 50 have X% chance of heart disease.*

Indicative words and phrases:

Spots...
 Detects...
 Finds...
 Prognosis
 Screening
 Symptom Checker
 Triage
 Risk of...
 Measures...
 Predicts





Monitoring

Monitoring - includes devices that monitor the progress or severity of disease, an injury or handicap.

This includes software that claims that the sensors from the physical device can be used for monitoring.

Examples that may be devices include:

- Apps and software that are intended to allow remote access to information on physical monitors and applies user-defined filtering rules to any alarms generated by the original device.
- Apps and software that monitor a patient and collects information entered by the user, measured automatically by the app or collected by a point of care device may qualify as a medical device if the output is intended to affect the treatment of an individual.

Examples that are unlikely to be devices include:

- Apps and software that simply replace a written diary/log of symptoms that can be used when consulting with the patient's doctor. However, the addition of features that enhance the data presented may bring it into the remit of the UK MDR 2002.
- Apps and software for monitoring sport or fitness purposes, e.g. heart rate, are not considered to be medical devices. However, in some specific cases, where the intention is to investigate the physiological processes they may be.

There needs to be a link to a specific disease, injury or handicap.

See Borderline manual I.17 – 9.6
Classification of software for information management and patient monitoring

Indicative words and phrases:

Check
Alarms





Treatment and alleviation

Treatment - includes devices that provide information that can be used to enable treatment to be performed or claim that the output from the physical device can be used to treat.

There needs to be a link to a specific disease, injury or handicap.

Alleviation - includes devices that reduce symptoms or severity of a disease, injury or handicap.

Examples that may be devices include:

- Apps and software that are intended to calculate the dose of a insulin a diabetic needs to treat their diabetes based on carbohydrate in a meal.
- Apps and software that are intended to automate the treatment pathway for an individual patient.
- Apps and software that are intended for the treatment of neurotrauma, neurodegenerative and neuropsychiatric conditions.

See Borderline manual 1.17 – 9.5

Examples that are unlikely to be devices include:

- Apps and software that are intended to treat non-medical conditions e.g non-specific stress.
- Apps and software that are intended to just provide tips or advice or link to support groups.
- Apps and software that are intended to remind users that medicines are taken.

Indicative words and phrases:

Calculates...
 Can benefit those who suffer from...
 Clears...
 Combats...
 Controls...
 Counteracts...
 Cure/cures...
 Eliminates...
 Fights...
 Heals...
 Help/help with...
 Reduce pain





Compensation

Compensation - includes software that the manufacturer claims can compensate for an injury or handicap or claims that the sensors and output from the physical device can be used for this purpose. It doesn't include those products that are intended for general use but can be used to compensate for an injury or handicap.

There needs to be a link to a specific injury or handicap.

Examples that may be devices include:

- Apps and software that are intended to magnify text specifically for people with visual impairment.
- Apps and software that are intended to amplify sounds for people with reduced hearing.

Examples that are unlikely to be devices include:

- Apps and software that are intended to magnify text but there is no mention of visual impairment in the manufacturer's claims.
- Apps and software that are intended to amplify sounds but the manufacture's claims do not mention reduced hearing ability.

Indicative words and phrases:

Corrects
Helps





Investigation, replacement or modification

Investigation, replacement or modification of the anatomy or of a physiological process includes devices that claim to be able to investigate, replace or modify the anatomy or a physiological process.

Examples that are unlikely to be devices include:

- Educational anatomy and physiology apps and software.

Indicative words and phrases:





Control of conception

Control of conception - includes devices that claim to be directly able to make pregnancies more likely or to be able to prevent pregnancy.

Examples that may be devices include:

- Apps intended to facilitate conception and enable contraception based on basal body temperature
- Stand-alone software application for conception and contraception purposes using data entered by the patient

See Borderline manual 9.9-9.11

Examples that are unlikely to be devices include:

- Apps and software that just track or display data related to a woman's menstrual cycle to aid in ovulation prediction.
- Apps and software that just provide tips or advice.

IVF use

Software intended to analyse blastocysts for reintroduction into the body are not considered to be IVDs:

An IVD is used in vitro for the examination of a specimen derived from the human body and where such specimen is never reintroduced into the body. Without a containable specimen derived from the human body, the product will be a medical device and not an IVD. The blastocyst is intended to be reintroduced into the body and is therefore not a specimen for examination. Software for the examination of a blastocyst is therefore a medical device and not an IVD.

Indicative words and phrases:

Fertility
Ovulation
Menstruation
Contraception
IVF





Medical device & accessories.

For all software and apps that meet the definition of a medical device, the following guidance is given to aid some key requirements of UKCA marking.

Classification

Manufacturers of 'general' medical devices will need to determine the classification of their products to determine the route to compliance, this is done by the use of the classification rules in the regulations. There are four classes as follows:

- Class I - generally regarded as low risk
- Class IIa - generally regarded as medium risk
- Class IIb - generally regarded as medium risk
- Class III - generally regarded as high risk

This guidance lists rules that are likely to apply to software and apps.

Essential requirements

The software must meet all of the [general essential requirements](#) and the relevant [design and construction essential requirements](#) contained in the regulations. This guidance lists those essential requirements that are likely to apply to software and apps.

Where available, relevant [designated standards](#) may be used to demonstrate how many of the requirements have been met.

Post market Surveillance

Once a medical device has been placed in the UK market, the manufacturer is responsible for monitoring the product and reporting serious adverse incidents to the MHRA. See [guidance on reporting adverse incidents](#) for information on how to do this. This ensures the device is acceptably safe to use for as long as it is in use.

Note

Accessories are treated as if they are medical devices and all the relevant requirements will apply.

For more detail see MHRA guidance:
[Medical devices: conformity assessment and the UKCA mark](#)

[Classification rules](#)

[General essential requirements](#)

[Design and Construction essential requirements](#)

[Post market surveillance](#)

In-house manufacture

Certain requirements don't apply if your device is only being used for patients within the institute it was made. See:

[In-house manufacture of medical devices](#)

Manufacturers must also consider the requirements of the [General Data Protection Regulation](#) and [Privacy and Electronic Communications Regulations](#).





Medical device classification

Advice on classification is given for general medical devices but for software, an active device, the following existing classification rules are most applicable:

- Implementing rule 2.3 - Software, which drives a device or influences the use of a device automatically falls into the classification of that device.
- Rule 9 - All active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in Class IIb.
All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices are in Class IIb.
- Rule 10 - Active devices intended for diagnosis are in Class IIa:
 - if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum,
 - if they are intended to image in vivo distribution of radiopharmaceuticals,
 - if they are intended to **allow direct diagnosis** or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in Class IIb.
 Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.
- Rule 12 - All other active devices are class I.
- Rule 14 - All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in class IIb.

While compliance of class I devices is based on self-declaration by the manufacturer, all other UKCA marked devices require use of an [UK approved body](#) to assess compliance (if the device is CE marked, an EU NB will be needed).

All devices placed on the Great Britain market must be [registered with MHRA](#).

Clinical data is required for all medical devices and for some novel software [clinical investigations](#) may be needed.

Software that directly modifies the state/action/use of another device is considered to be driving that device.
Software which produces data that is intended to be manually fed into a device, thereby modifying the state/action/use of the device, is considered to be influencing that device.

Active therapeutic device:
“Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.”

Active device for diagnosis:
“Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.”

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.

For general advice on classification see [MEDDEV 2. 4/1 Rev. 9 June 2010 - Classification of medical devices](#).





Medical device essential requirements - general

The following apply to all devices:

1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of the patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

This shall include:

- reducing as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and
- consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

- eliminate or reduce risks as far as possible (inherently safe design and construction),
- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
- inform users of the residual risks due to any shortcomings of the protection measures adopted.

3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in UK MDR 2002 - Part I Section 2(1), as specified by the manufacturer.

4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.

5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.

6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.

6a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.

The benefits of your app need to outweigh any risks from use of the app.

The user interface needs to be consistent, graphics and text need to be clear and readable.

Your app needs to be designed with safety in mind. You should initially aim to design out risks.

You need to have the evidence that the app does what you say it does. This may be gathered through clinical evaluation.

6a You must perform a clinical evaluation of your app. See [MEDDEV 2.7/1 Clinical evaluation: Guide for manufacturers and notified bodies](#)





Design and construction essential requirements

The manufacturer will need to determine which apply to their software by reviewing Regulation 9 of UK MDR 2002. The following are likely to apply to software devices:

9.1. If the device is intended for use in combination with other devices **or equipment**, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.

12.1. Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.

12.1a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.

12.4 Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm system to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

12.9.1. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

13.1 Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.

This information comprises the details on the label and the data in the instructions for use.

13.3 [The label must bear the following particulars.](#)

13.6. Where appropriate, the instructions for use must contain the following particulars:

(c) if the device must be installed with or connected to other medical devices **or equipment** in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;

d) all the information needed to verify whether the **device is properly installed** and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;

The following are possibly applicable to software devices:

10.1. Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.

10.2. The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.

10.3. The measurements made by devices with a measuring function must be expressed in legal units conforming to the Units of Measurement Regulations 1986.

The regulations require that the whole system to be safe. This is particularly pertinent to stand alone software, where the manufacturer must demonstrate compatibility with the recommended hardware platforms.

Validation of your app is a requirement before placing on the market.

The instructions should contain all the information needed to verify whether the device is properly installed and can operate correctly and safely. These can be provided in electronic form if they are packaged with the software and the risk of doing so is less than providing IFU in paper form. These are not needed for Class I and IIa devices if they can be used safely without any such instructions.

See page on labelling.

This may include details of validated operating systems, hardware and other running software such as anti virus.

i.e. metric units.





Medical device post market surveillance.

Manufacturers have a responsibility to implement an effective post-market surveillance system to ensure that any problems or risks associated with the use of their device once freely marketed are identified early, reported to competent authorities, and acted upon. This is known as the medical devices vigilance system.

For software, a system of registration / activation may aid the manufacturer trace devices that have been distributed by third party distributors or by app stores. This is important when undertaking any field safety corrective action.

Adverse Incident Reporting

Manufacturers should follow the guidance for [reporting adverse incidents](#) and field safety corrective actions to MHRA.



MORE: Manufacturers' Online Reporting Environment

Manufacturers are encouraged to use the Manufacturer's On-line Reporting Environment to submit Vigilance reports to the Agency





In vitro diagnostic medical devices & accessories.

For all software and apps that meet the definition of an in-vitro diagnostic medical device, the following guidance is given to aid some key requirements of UKCA marking.

Categories

Manufacturers of in-vitro diagnostic medical devices will need to determine which category of product the software is to determine the route to compliance. There are four categories as follows:

- general IVDs
- IVDs for self-testing
- IVDs in List A
- IVDs in List B

Essential requirements

The software must meet all of the [general essential requirements](#) and the relevant [design and manufacturing requirements](#) contained in the UK MDR 2002, Annex I (as modified by Part 3 of Schedule 2A to the UK MDR 2002). This guidance lists those essential requirements that are likely to apply to software and apps.

Where available, relevant Designated standards ([external link](#)) may be used to demonstrate how many of the requirements have been met.

Post market Surveillance

Once an in-vitro diagnostic medical device has been placed in the UK market, the manufacturer is responsible for monitoring the product and reporting serious adverse incidents to the MHRA. See [guidance on reporting adverse incidents](#) for information on how to do this. This ensures the device is acceptably safe to use for as long as it is in use.

Note

Accessories are treated as if they are medical devices and all the relevant requirements will apply.

A prospective buyer should be able to identify that the app meets the relevant essential requirements prior to purchase. As such, a developer may wish to display the UKCA mark on the primary landing page.

See [guidance on UKCA marking of in vitro diagnostic medical devices](#) for details of the requirements for displaying the mark. Details on how to reproduce the UKCA mark is given here:

<https://www.gov.uk/guidance/using-the-ukca-mark-from-1-january-2021>

For more detail see MHRA guidance:
[In vitro diagnostic medical devices: guidance on legislation](#)

[Essential requirements](#)

[Design and Manufacturing requirements.](#)

[Post market surveillance](#)

In-house manufacture

Certain requirements don't apply if your device is only being used for patients within the institute it was made. See:

[In vitro diagnostic medical devices: guidance on legislation](#)

Manufacturers must also consider the requirements of the [General Data Protection Regulation](#) and [Privacy and Electronic Communications Regulations](#).



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IVD essential requirements - general

The following apply to all devices:

1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise, directly or indirectly, the clinical condition or the safety of the patients, the safety or health of users or, where applicable, other persons, or the safety of property. Any risks which may be associated with their use must be acceptable when weighed against the benefits to the patient and be compatible with a high level of protection of health and safety.

The benefits of your app need to outweigh any risks from use of the app.

2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

Your app needs to be designed with safety in mind. You should initially aim to design out risks.

- eliminate or reduce risks as far as possible (inherently safe design and construction),
- where appropriate take adequate protection measures in relation to risks that cannot be eliminated,
- inform users of the residual risks due to any shortcomings of the protection measures adopted.

3. The devices must be designed and manufactured in such a way that they are suitable for the purposes referred to in UK MDR 2002 Part I Section 2(1), as specified by the manufacturer, taking account of the generally acknowledged state of the art. They must achieve the performances, in particular, where appropriate, in terms of analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference, and limits of detection, stated by the manufacturer.

You need to have the evidence that the app does what you say it does.

The traceability of values assigned to calibrators and/or control materials must be assured through available reference measurement procedures and/or available reference materials of a higher order.

4. The characteristics and performances referred to in sections 1 and 3 must not be adversely affected to such a degree that the health or the safety of the patient or the user and, where applicable, of other persons, are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use. When no lifetime is stated, the same applies for the lifetime reasonably to be expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.

5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under storage and transport conditions (temperature, humidity, etc.) taking account of the instructions and information provided by the manufacturer.





IVD design and manufacturing requirements.

In addition to the general requirements there are a series of specific design and manufacturing requirements. The manufacturer will need to determine which apply to their software by reviewing Regulation 35 of the UK MDR 2002.

1. Chemical and physical properties
2. Infection and microbial contamination
3. Manufacturing and environmental properties
4. Devices which are instruments or apparatus with a measuring Function
5. Protection against radiation
6. Requirements for medical devices connected to or equipped with an energy source
7. Requirements for devices for self-testing
8. Information supplied by the manufacturer





IVD medical device post market surveillance.

Manufacturers have a responsibility to implement an effective post-market surveillance system to ensure that any problems or risks associated with the use of their device once freely marketed are identified early, reported to competent authorities, and acted upon. This is known as the medical devices vigilance system.

For software, a system of registration / activation may aid the manufacturer trace devices that have been distributed by third party distributors or by app stores. This is important when undertaking any field safety corrective action.

Adverse Incident Reporting

Manufacturers should follow the guidance for [reporting adverse incidents](#) and field safety corrective actions to MHRA.



MORE: Manufacturers' Online Reporting Environment

Manufacturers are encouraged to use the Manufacturer's On-line Reporting Environment to submit Vigilance reports to the Agency





Active implantable medical device & accessories.

Accessory software for an Active implantable Medical device should be treated as an Active implantable Medical device. Further guidance is provided in guidance [MEDDEV 2. 1/2 rev 2](#).

A prospective buyer should be able to identify that the app meets the relevant essential requirements prior to purchase. As such, a developer may wish to display the UKCA mark on the primary landing page. See [guidance on UKCA marking of medical devices](#) for details of the requirements for displaying the mark. Details on how to reproduce the UKCA mark is given here:
<https://www.gov.uk/guidance/using-the-ukca-marking>

In-house manufacture

Certain requirements don't apply if your device is only being used for patients within the institute it was made. See:

[In-house manufacture of medical devices](#)

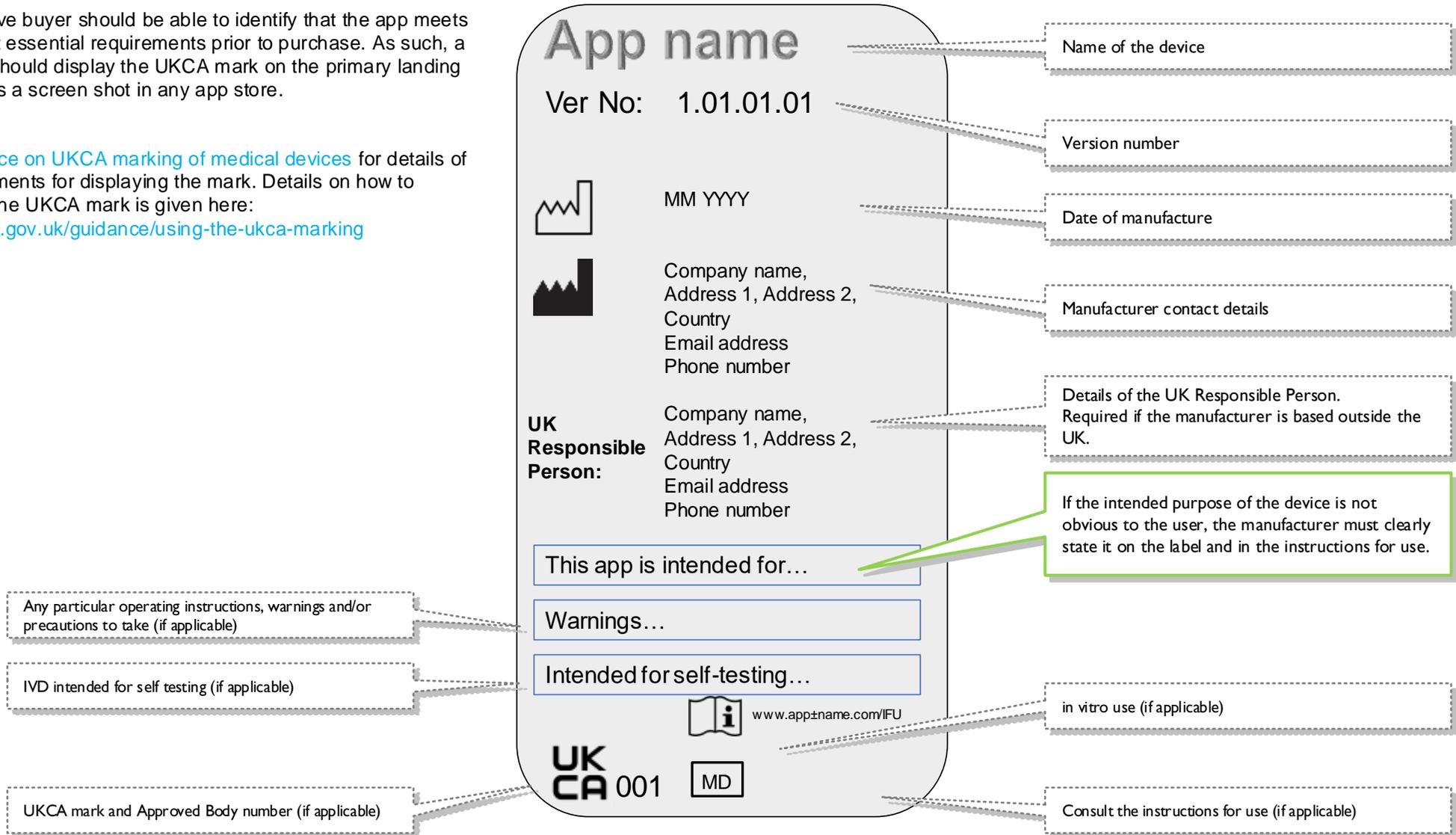
Manufacturers must also consider the requirements of the [General Data Protection Regulation](#) and [Privacy and Electronic Communications Regulations](#).

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App labelling – displaying the UKCA mark

A prospective buyer should be able to identify that the app meets the relevant essential requirements prior to purchase. As such, a developer should display the UKCA mark on the primary landing page and as a screen shot in any app store.

See [guidance on UKCA marking of medical devices](https://www.gov.uk/guidance/using-the-ukca-marking) for details of the requirements for displaying the mark. Details on how to reproduce the UKCA mark is given here:
<https://www.gov.uk/guidance/using-the-ukca-marking>





Not a medical device

Other UK legislation may apply such as the General Product Safety Regulations:

<https://www.gov.uk/product-safety-for-manufacturers>

<https://www.gov.uk/product-liability-and-safety-law>

Manufacturers must also consider the requirements of the [General Data Protection Regulation](#) and [Privacy and Electronic Communications Regulations](#).



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References

The following documents provide useful information to help software developers understand regulations for medical device software:

- [MEDDEV 2.1/1 Definitions of "medical devices", "accessory" and "manufacturer"](#)
- [Manual on borderline and classification in the Community Regulatory framework for medical devices](#)
- [Team NB FAQ on Implementation of EN 62304:2006 with respect to MDD 93/42/EEC.](#)
- [MHRA Borderlines with medical devices](#)

Standards

EN 62366 - Medical devices - Application of usability engineering to medical devices

EN 62304 - Medical device software -- Software life cycle processes

EN ISO 13485 - Medical devices - Quality management systems - Requirements for regulatory purposes

EN ISO 14971 - Medical devices. Application of risk management to medical devices

BSI PAS 277: 2015 Health and wellness apps. Quality criteria across the life cycle. Code of practice

PD IEC/TR 80002-1 - Medical device software Part 1: Guidance on the application of ISO 14971 to medical device software

Other national / international guidance (in English)

Sweden: [Guidance for qualification and classification of Medical Information Systems.](#)

Germany: [Guidance on "Medical Apps"](#)

IMDRF: [Software as a Medical Device \(SaMD\): Key Definitions](#)





Appendix I – 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 2.1/5 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.





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.

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.

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 it 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.

Annex IX, implementing rules:

2.3. Software, which drives a device or influences the use of a device, falls automatically in the same class.

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



Revision history

Version	Date	Changes
I.07	Nov-20	Updates for The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020
I.06	May-20	New - Appendix 2 - Clinical calculators New - Appendix 3 - 'drives or influences the use of a device' Clarification on interpretation of direct diagnosis. Addition of new indicative words P16 - IVF products for selection of blastocysts P18 - ECJ Case C-329/16 P24 - Control of Conception updated - new Borderline entry
I.05	Jun-18	Addition of Appendix 1 - Symptom checkers P19 - Diagnosis page updated. Links updated for GDPR. P4 - updated.
I.04	Sep-17	Added page on labelling Updated P 12 & 26
I.03	Apr-17	Update link on P5 & link to the CE mark
I.02	Oct-16	Format background colour of examples Change words and phrases boxes Clarification on P10 & 12 - decision support
I.01	Sep-16	Link (P1) and YellowCard graphic updated

