Software as a Medical Device (SaMD) Regulatory Pathway

NIHR | HealthTech Research Centre
Devices, digital and robotics

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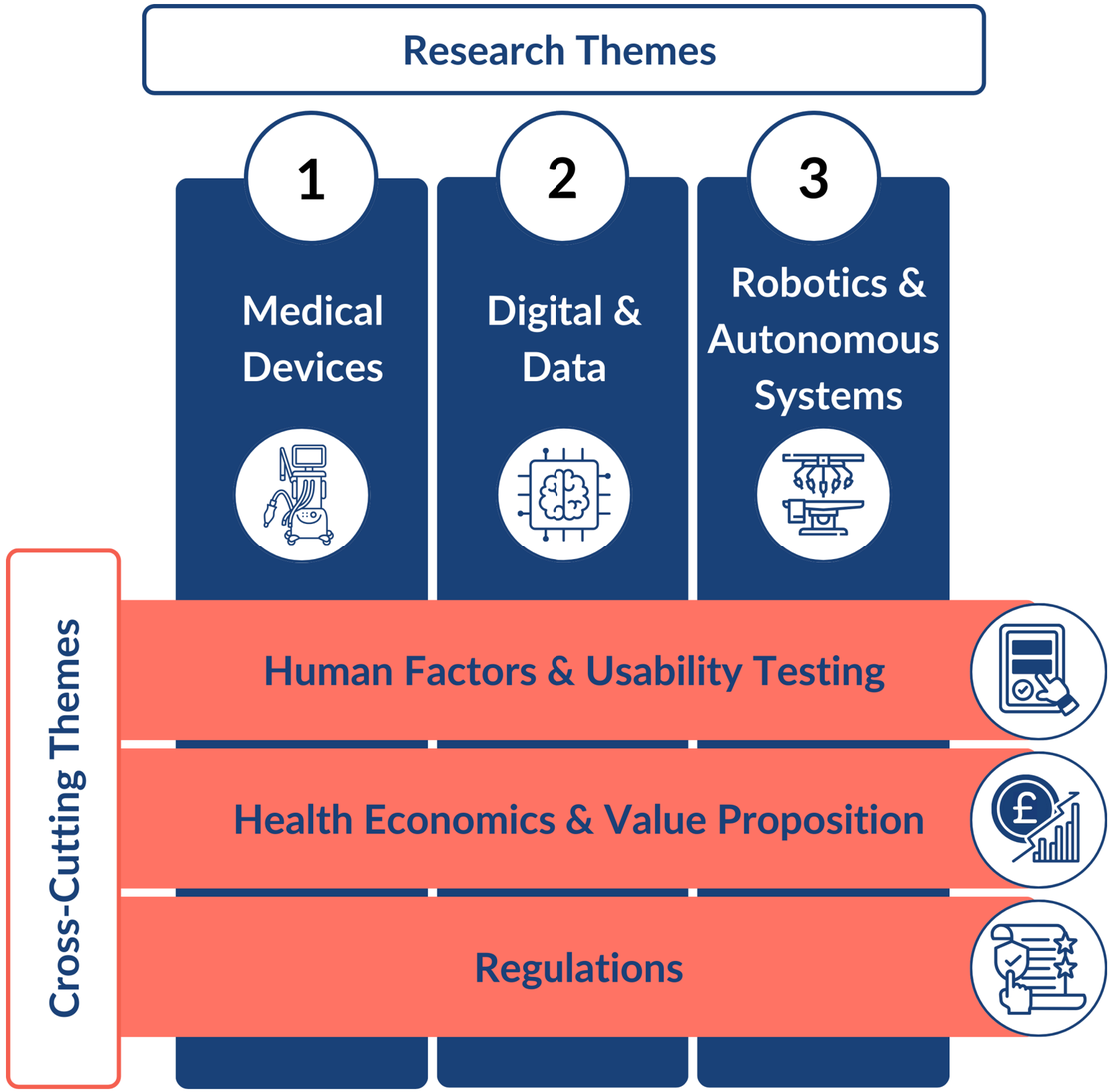
Who are the NIHR HealthTech Research Centre in Devices, Digital and Robotics?

The National Institute for Health and Care Research HealthTech Research Centre in Devices, Digital and Robotics (NIHR HRC-DDR) is one of fourteen HealthTech Research Centres (HRCs) in the UK.

The HRCs are funded to support safe, effective and efficient translation of new healthcare technologies into routine care for NHS patients and follow-on social care. The NIHR HRC-DDR is based at University Hospitals Birmingham NHS Foundation Trust (UHB). The remit of the NIHR HRC-DDR is to improve efficiencies, and rate of success, of HealthTech uptake into health and social care.

The NIHR HRC-DDR provides a national service supporting partners through the innovation ecosystem linking with expert academics and clinicians within our partner organisations and infrastructures, generating evidence to support uptake and adoption.



Aims and objectives

Outline the definition of a medical device and provide advice on which software is classified as a medical device

Provide advice on medical device classification for software

Outline the regulatory pathway for Software as a Medical Device (SaMD)

Outline processes involved in market access of software as a medical device

What is a medical device?

A medical device is defined as "an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which—

(a) is intended by the manufacturer to be used for human beings for the purpose of-

(i)diagnosis, prevention, monitoring, treatment or alleviation of disease,

(ii)diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

(iii)investigation, replacement or modification of the anatomy or of a physiological process, or

(iv)control of conception;

(b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means,"

[1]

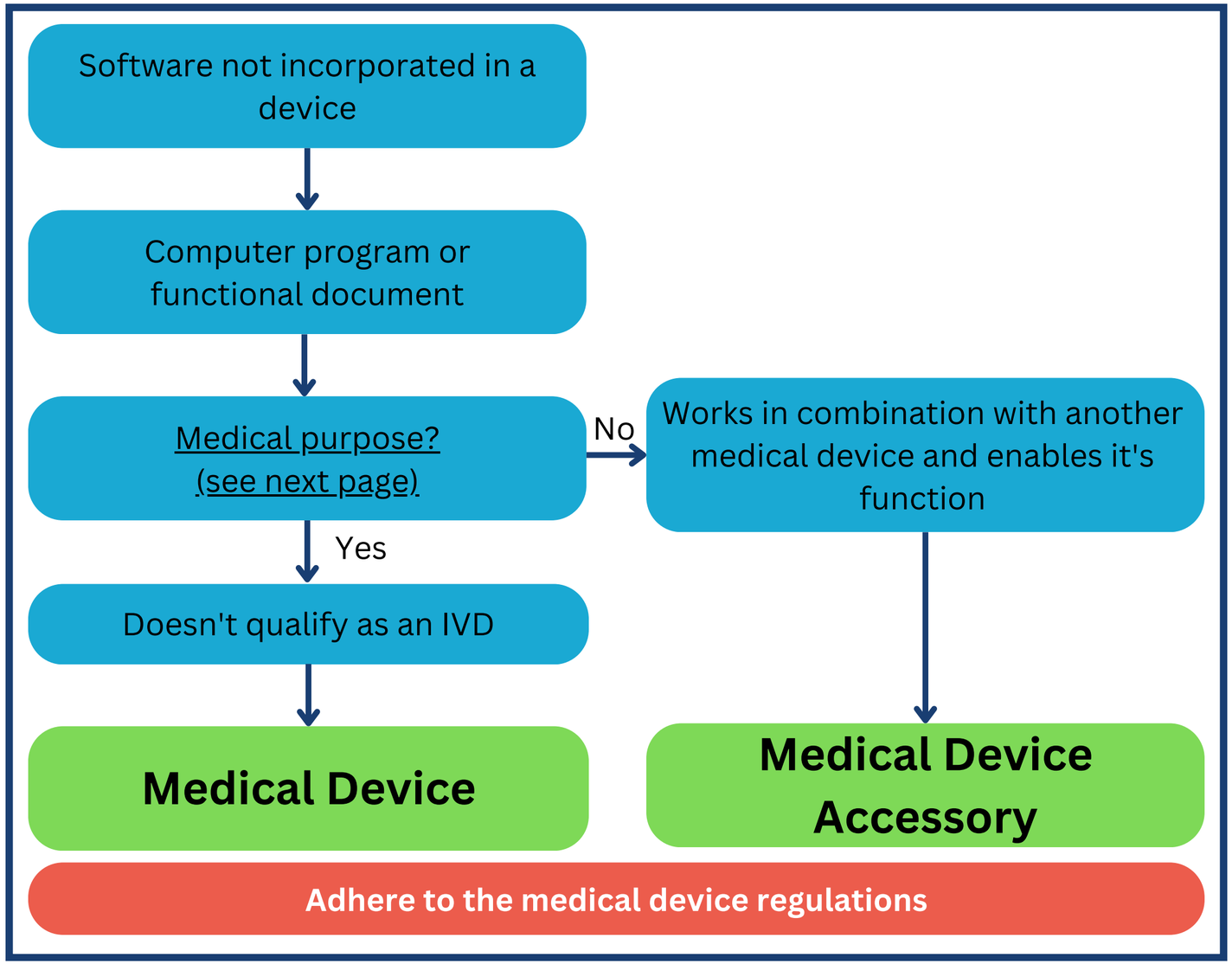
Is my software a medical device?

Medical devices do not need to be physical, but can also include software. This is called **Software as a Medical Device (SaMD)**. SaMD must adhere to the medical device regulations. Software that is stand-alone, and classified as a medical device, is termed an active medical device.

It it therefore important to determine whether or not the software is classified as a medical device; this is demonstrated in the simplified flowchart on the right.

If your software is not incorporated into a device, is a computer program or functional document, has a medical purpose and does not qualify as an In Vitro Diagnostic (IVD), then it **is** a medical device. Alternatively, if the software is not incorporated into a medical device, does not have a medical function but works in combination with one or more medical devices and enables their function, then this is a medical device accessory. Medical device accessory's need to undergo the same regulatory pathway.

If it is **not** a medical device or medical device accessory then it is not a legal requirement to adhere to the medical device regulations.



[2]

Is my software a medical device?

If the software or technology has one or more of the following functions listed on the right then it is classified as having a medical purpose, and may therefore be considered as a medical device.

Treatment includes information that can be used to enable treatment, or the output itself can be a treatment. However, this treatment needs to be linked to a specific disease or injury.

The software is **not** a medical device if it **only**:

- Is used for patient or professional medical education/ information.
- Monitors health, wellbeing or fitness.
- Stores or sends medical data without change or processing.
- Schedules or hosts appointments.
- Requests prescriptions.
- Provides reference information for healthcare professionals. to make clinical decisions.

- Prevention of disease
- Diagnosis of disease, injury or disability
- Monitoring of disease, an injury or disability, including where user-defined filtering rules are applied or the output is intended to impact an individual's treatment
- Treatment or alleviation of disease, an injury or disability
- Compensation for a specific injury/ disability
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception (not if simply logging cycle/ providing advice)

[2]

Is my software a medical device?

Software **only** storing and moving data

Software providing reference information for clinical decisions

Software providing information to be used to enable or change treatment

Software diagnosing disease, injury or disability

Is **Not** a Medical Device

- Software monitoring general fitness.
- App simply providing advice on preventing anxiety attacks.
- Software for patients to record the symptoms of their mental health condition.
- App signposting to information and support groups.

Is a Medical Device

- App leading to a diagnosis of a specific mental health condition, e.g. Post-Traumatic Stress Disorder (PTSD).
- App claiming that output will prevent anxiety attacks, or reduce PTSD symptoms.
- App collecting information on a patient's mental health condition symptoms which is used by a clinician to alter their medication, or calculating an individual's medication dose.

[2]

Medical Device Regulations

Medical devices must adhere to the medical device regulations and receive regulatory approval prior to being placed on the market.

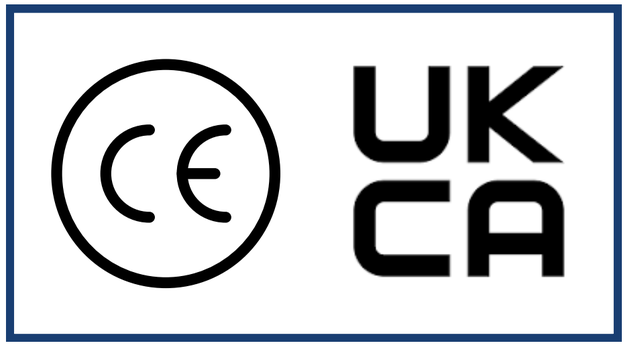
In Europe, medical devices require CE marking before being placed on the market. Following Brexit, the UK has introduced UKCA regulatory approval. The UK still currently accepts CE marking. The new UKCA regulations are under consultation and will be released during the transition period.

CE marking will be accepted for SaMD with a **EU Medical Device Directive (MDD)** certificate in the UK until the following dates:

- Class III - 31st December 2027
- Class I, IIa and IIb - 30th June 2028

CE marking will be accepted for software with a **EU Medical Device Regulation (MDR)** certificate in the UK until 30th June 2030.

Medical devices will not be accepted if the medical device's certificate expires prior to the accepted dates.



[3,4]

Medical Device Regulations

- CE marking accepted in Europe and the UK
- UKCA marking accepted in the UK

July 2028

- CE marking accepted in Europe and the UK for medical devices approved under the EU MDR
- CE marking not accepted in the UK for medical devices under the EU MDD
- UKCA marking accepted in UK

July 2030

- CE marking not accepted in the UK for medical devices approved under the EU MDR
- CE marking not accepted in Europe or the UK for medical devices under the EU MDD
- CE marking accepted in Europe under the EU MDR
- UKCA marking accepted in UK

Medical devices must have a technical file for regulatory approval, which contains all of the device's relevant information. Technical file requirements differ slightly between CE and UKCA marking, this document will focus on the technical file requirements for UKCA marking.

[3,4]

Medical Device Claims & Intended Purpose

Manufacturers must state the intended purpose of the medical device on the labelling and instructions. This must be clear, unambiguous and precise. This includes stating the condition, disease, or injury that the medical device treats, monitors or diagnoses. Using the device outside of the intended purpose may pose a safety risk.

Additional regulatory approval is required for a change in, or additional, intended uses. This may require an additional clinical investigation to be conducted. It's therefore important that the intended use of the medical device is well considered before applying for regulatory approval.

If medical claims are made, disclaimers cannot be added stating that the software is not a medical device. The device will still require regulatory approval. Additionally, any clinical claims must have supporting clinical evidence.

Further information on writing an intended purpose can be found here.

[2]

Medical Device Classification

Once it has been determined that the software is a medical device, it is then important to determine it's medical device classification. The classification will impact the required regulatory pathway.

The classification of a medical device is generally linked to its risk, with Class I being low risk, Class IIa and IIb being medium risk, and Class III being high risk. The classifications are shown on the right hand side.

If software drives or influences the use of a physical device then it falls into the respective device's classification. This includes if the software directly modifies the physical device's action or use (driving), or if the software data is fed manually into a device to modify its action or use (influencing).

Class I

Generally regarded as low risk

Non-invasive devices (if none other of the below rules are met)

Example: Software collecting and transmitting data for use by a clinician, but not to inform treatment.

Class IIa

Generally regarded as medium risk

Active therapeutic devices administering/ exchanging energy (unless involving the human body in a hazardous manner)

Active devices intended for diagnosis

Example: Software collecting and sending psychological symptoms to clinicians for use in diagnosis.

Class IIb

Generally regarded as medium risk

Active therapeutic devices administering/ exchanging energy involving the human body in a hazardous manner.

Devices intended for direct diagnosis of vital physiological processes where variations could result in immediate patient danger

Devices used for contraception or prevention of sexually transmitted diseases.

Example: Software providing direct diagnosis of sepsis.

Class III

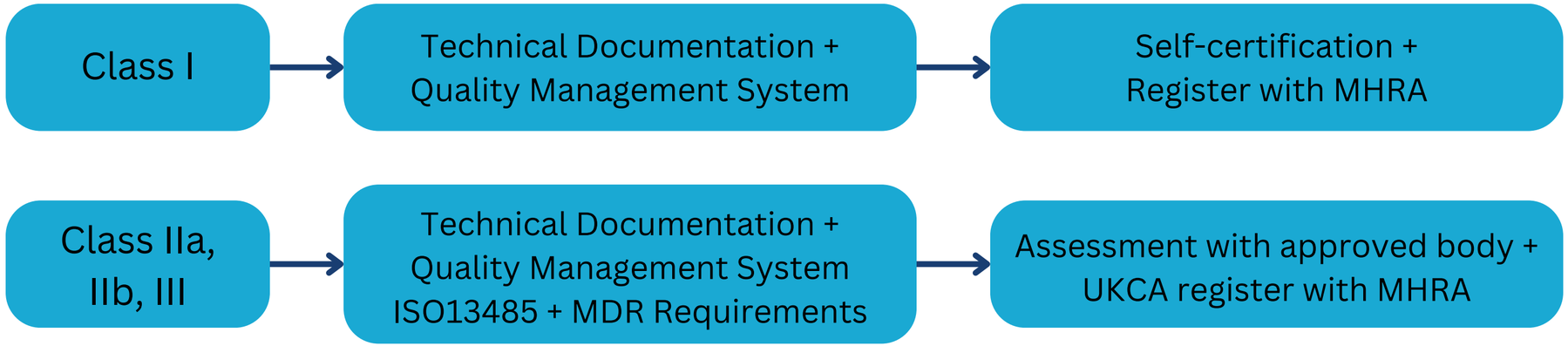
Generally regarded as high risk

Example: Software which drives the use of an implantable pacemaker.

[2,5]

Conformity Assessment Route

The software's medical device classification influences the conformity assessment route that is then required for regulatory approval. This is outlined very briefly below.



To view the associated regulatory pathway, please select the medical device classification.

Class I

Class IIa

Class IIb

Class III

Conformity Assessment Route - Class I

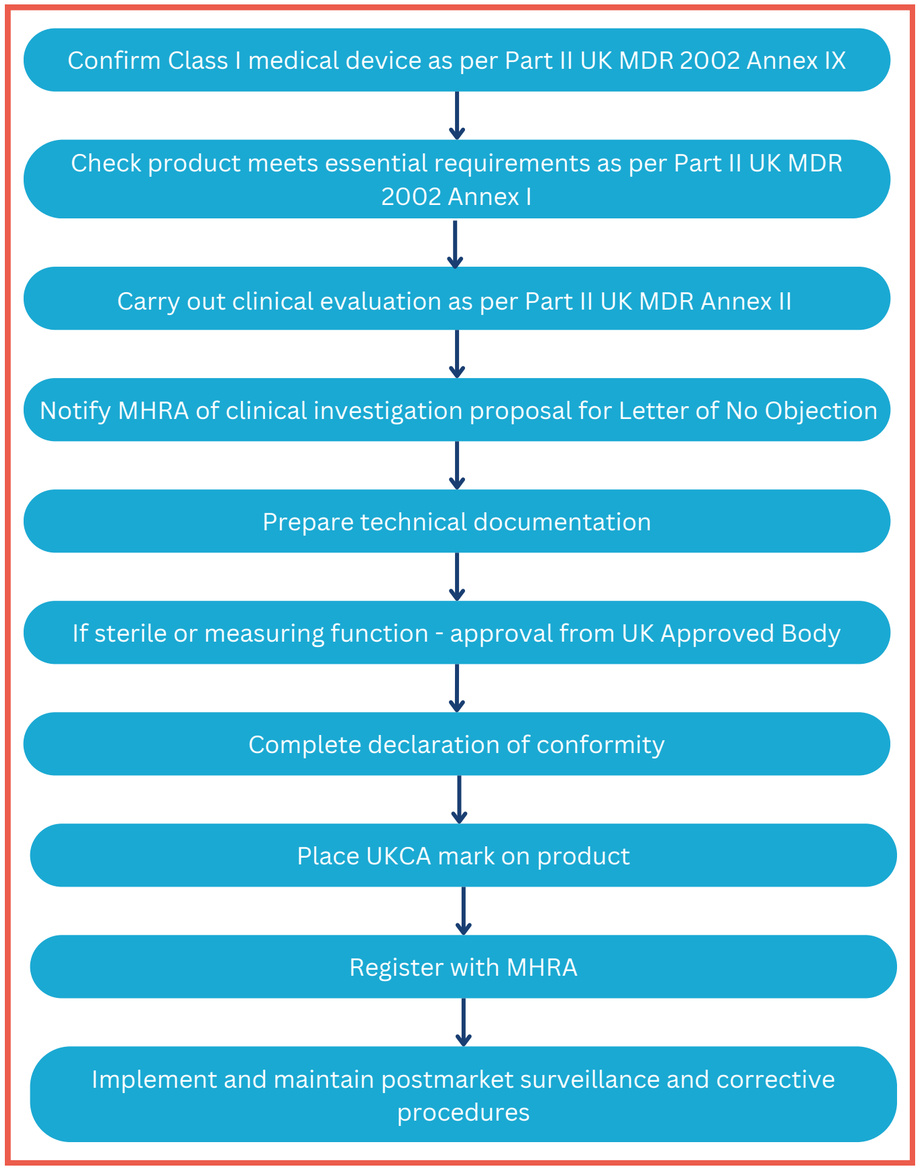
The outline conformity route for Class I medical devices is shown on the right.

If the device has a measuring function it does require approval from a UK approved body. The device has a measuring function if it provides a specific value in a unit of measurement appropriate to the intended purpose. The device is not considered to have a measuring function if a non-specific value is provided, or the value provided is not directly related to patient safety.

Manufacturers can self certify class I medical devices. This means that the manufacturer assesses the medical device's conformity, including preparing the technical file, completing a declaration of conformity and then applying the UKCA/ CE mark to the device. The European harmonized standards must be applied, as well as any other applicable legal frameworks.

All of the general essential requirements, and the relevant design and construction essential requirements must be met by the software.

Essential Requirements



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Conformity Assessment Route - Class IIa

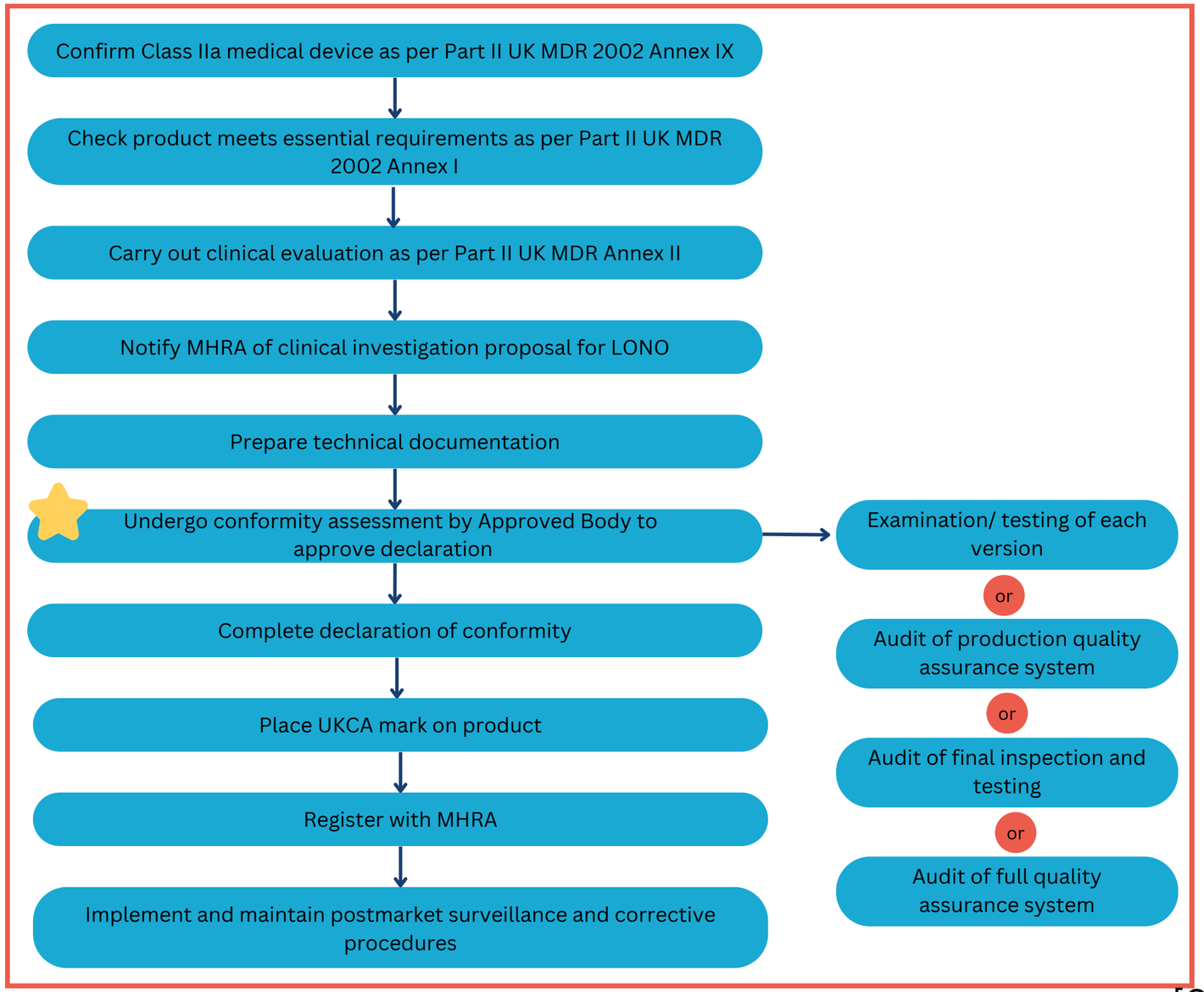
The outline conformity route for Class IIa medical devices is shown on the right.

Manufacturers must prepare a technical file. Class IIa medical devices require a conformity assessment by an approved body for UKCA marking. The technical documentation includes:

- The essential requirements detailed in Annex I.
- Technical documentation (Annex II)
- Declaration of conformity (Appendix IX).
- A risk management file. This is required to assess risk, and outline the risk analysis plan and processes.

Any other applicable legal frameworks must be applied. The approved body will approve the declaration of conformity, which subsequently allows the UKCA marking to be placed on the device and the device to be placed on the market.

Essential Requirements



[6]

Conformity Assessment Route - Class IIb

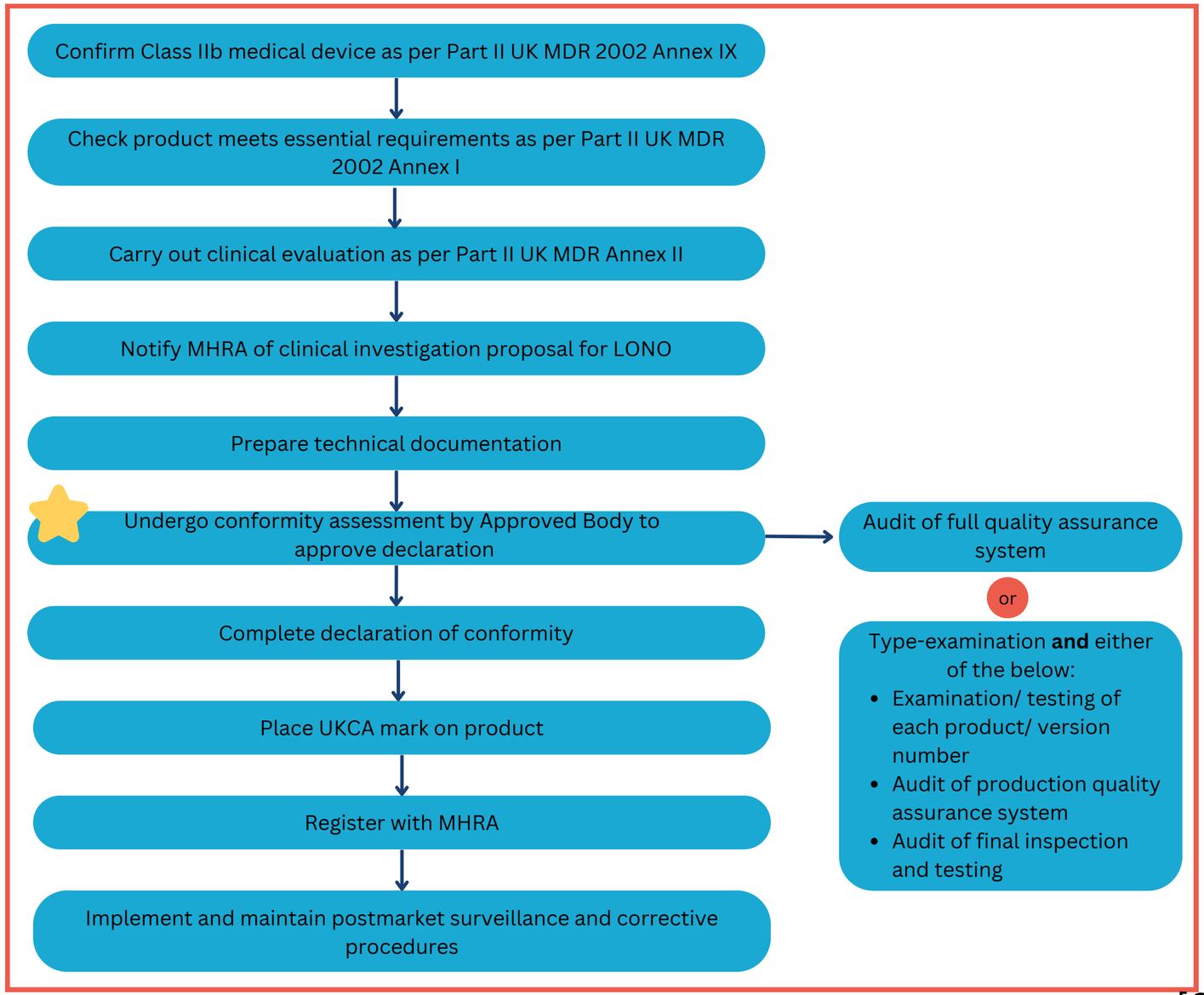
The outline conformity route for Class IIb medical devices is shown on the right.

Manufacturers must prepare a technical file. Class IIb medical devices require a conformity assessment by an approved body for UKCA marking. The technical documentation includes:

- The essential requirements detailed in Annex I.
- Technical documentation (Annex II)
- Declaration of conformity (Appendix IX).
- A risk management file. This is required to assess risk, and outline the risk analysis plan and processes.

Any other applicable legal frameworks must be applied. The approved body will approve the declaration of conformity, which subsequently allows the UKCA mark to be placed on the device and the device to be placed on the market.

Essential Requirements



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Conformity Assessment Route - Class III

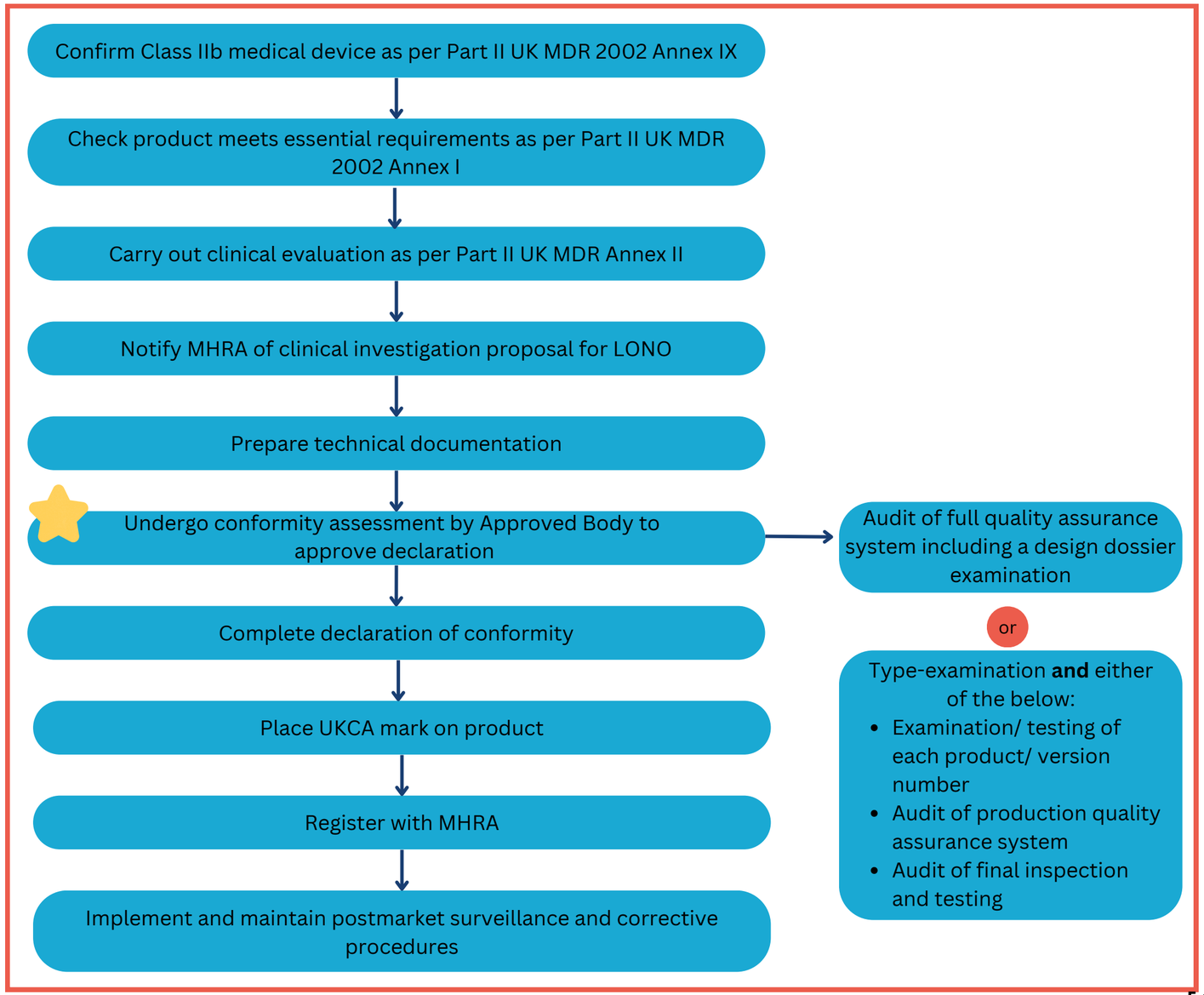
The outline conformity route for Class III medical devices is shown on the right.

Manufacturers must prepare a technical file. Class III medical devices require a conformity assessment by an approved body for UKCA marking. The technical documentation includes:

- The essential requirements detailed in Annex I.
- Technical documentation (Annex II)
- Declaration of conformity (Appendix IX).
- A risk management file. This is required to assess risk, and outline the risk analysis plan and processes.

Any other applicable legal frameworks must be applied. The approved body will approve the declaration of conformity, which subsequently allows the UKCA mark to be placed on the device and the device to be placed on the market.

Essential Requirements



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Conformity Assessment Route

Technical documentation must cover all of the below aspects.

- Product description: name, model numbers, variant information
- Final product documentation
- Packaging and labelling information
- Design verification: test and design calculations relevant to intended use
- Risk analysis: indicating compatibility with high-level protection of health and safety, in addition to risk versus benefit.
- Compliance with essential requirements
  - Part II MDR 2002, Annex I
- Clinical evaluation in accordance with Annex X
- Declaration of conformity

This documentation is required to be available for five years post the last device manufacture/ software release.

A UK Responsible Person is required if the manufacturer is not based in the UK; they must have a copy of all technical documentation available, in addition to the declaration of conformity, amendments and supplements.

Further information is available here.

Essential General Requirements

All of the general essential requirements, and the relevant design and construction essential requirements, must be met by the software.

This includes the following general essential requirements listed below:

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 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 Article 1 (2) (a), as specified by the manufacturer.

Essential General Requirements

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, 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 s**ubjected 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 a**cceptable 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.**

Requirements: Design and Construction Essential Requirements

Not all of the design and construction essential requirements will be relevant to the software, therefore the design requirements should be reviewed and those that apply to the software should be met. These can be reviewed here. Those likely to be relevant and applicable to software are listed below:

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.

12.1.a - 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 systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.**

12.9 - 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.

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;

[8]

Requirements: Design and Construction Essential Requirements

Medical devices must be labelled in a particular way. The label must bear the following particulars as applicable:

- The name or trade name and address of the manufacturer. For devices imported into the European Economic Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community;
- The details strictly necessary to identify the device and the contents of the packaging especially for the users;
- Where appropriate, the batch code, preceded by the word ‘LOT’, or the serial number;
- Where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;
- Where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community;
- If the device is custom-made, the words ‘custom-made device’;
- If the device is intended for clinical investigations, the words ‘exclusively for clinical investigations’;
- Any special storage and/or handling conditions;
- Any special operating instructions;
- Any warnings and/or precautions to take;
- Year of manufacture for active devices.

[8]

Standards: Meeting the Essential Requirements

The design and construction of the device must take account of the current state of the art, therefore the following standards are likely to be applicable and will assist in assuring the approved body that the software conforms to this essential requirement.

IEC 62304 - Medical device software — Software life cycle processes

IEC 82304 - Health software — Part 1: General requirements for product safety

IEC 80001 - Application of risk management for IT-networks incorporating medical devices

ISO 13485 - Medical devices

ISO 14971 - Medical devices — Application of risk management to medical devices

IEC 62366 - Medical devices — Part 1: Application of usability engineering to medical devices

[8]

Clinical Evaluations & Clinical Investigations

What is a clinical evaluation?

This is an evaluation of clinical data to prove the device's safety and functioning as per its intended use. This evaluation continues once the device is on the market, and will include post-market surveillance outcomes. MEDDEV2.7.1 (revision 4) provides guidance on how to conduct and document the clinical evaluation of a medical device.

What is a clinical investigation?

A clinical investigation may be required if there isn't sufficient published evidence/ literature to demonstrate that the essential requirements are met. Guidance on the requirements of a clinical investigation are documented in MEDDEV2.7/4.

Any medical device that has not received regulatory approval cannot be tested on humans without approval from the MHRA, therefore user testing requires a letter of no objection from the MHRA and needs to be conducted in accordance with ISO14155 (where relevant to SaMD). Clinical investigations are used to demonstrate the essential safety and performance of the device, including the analytical validity, the scientific validity and clinical performance for SaMD where appropiate.

In order to access patient data for evidence generation a letter of no objection from the MHRA is required and the research also needs to be conducted in accordance with ISO14155. Where confidental data is collected, patient consent is required.

[9,10]

MHRA Registration

Medical Devices must be registered with the MHRA before they can be placed on the market in Great Britain (England, Wales and Scotland). The following details must be included, and are not limited to:

- Manufacturer details
- Administrative contact
- Conformity certificates
- Applicable regulations
- Device classification and details
- UK approved body that the assessment was completed by

Post-market surveillance is then required, to gather data on the software's quality, performance and safety. Any serious adverse events must be reported to the MHRA.

Approved Bodies

Approved bodies are designated by the MHRA to assess medical device conformity to the Medical Device Regulations (2002). Approved bodies perform assessments, and if successful then issue certification allowing UKCA marking to be placed on the medical device, allowing medical devices to be placed on the UK market.

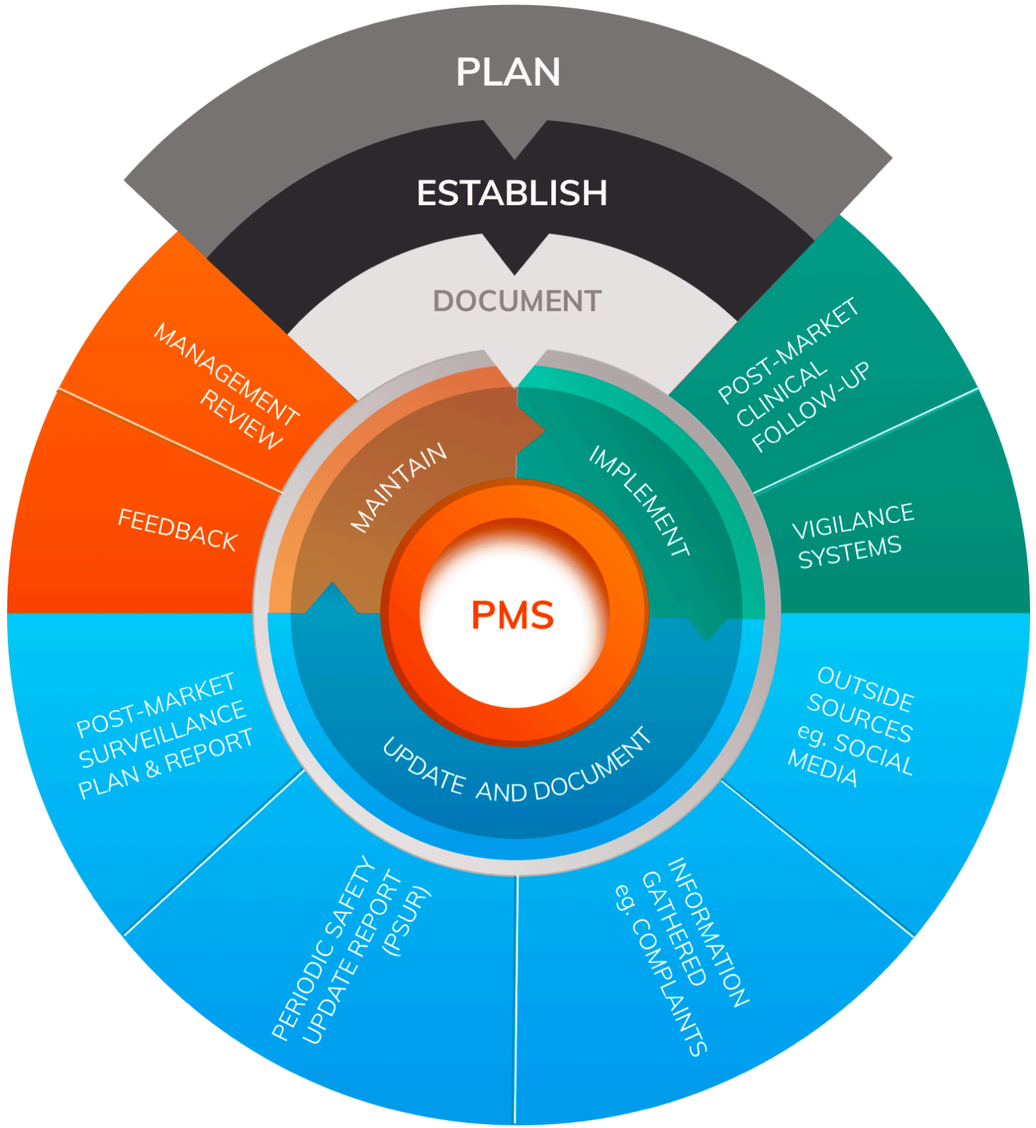
At the time of this document's publication there are four UK approved bodies, as shown below:

- BSI Assurance UK Ltd
- DEKRA Certification UK Ltd
- SGS United Kingdom Ltd
- UL International (UK) Ltd

For CE marking, the conformity assessment is undertaken by a notified body. CE marking will allow medical devices to be placed on the UK market until the dates shown here, after which all medical devices will require UKCA marking to be sold in the UK.

Post Market Surveillance

A post-market surveillance plan is required prior to placing a medical device on the market, and should then be implemented once the device has received UKCA marking. Proactive collection of experience from using/users of the medical device is required, as this ensures that the medical device is performing as intended and is safe to use. The post-market surveillance system must ensure that any device-related problems or risks are identified. These must then be reported to the relevant competent authority and corrective action must be taken (field safety corrective action). Any serious adverse events require reporting to the MHRA. This is the device's medical devices vigilance system. Additional information is also available here.



[11]

Market Access - The Digital Technology Assessment Criteria for Health and Social Care (DTAC)

The Digital Technology Assessment Criteria (DTAC) establishes good practice in key areas of digital technology development, including clinical risk management. It forms the new national baseline criteria for digital technologies entering the NHS and social care, combining legislation (Health and Social Care Act 2012) and good practice. Hence, meeting DTAC means your digital technology is meeting national baseline criteria. The DTAC is often used and referred to during NHS procurement. It's therefore helpful to refer to the DTAC during SaMD development to ensure that all of the standards (shown below) have been consideredduring the design process and prior to receiving regulatory approval.

- Clinical safety
- Data protection
- Technical security
- Interoperability
- Usability
- Accessibility

Further DTAC Information

[12]

Market Access - The Digital Technology Assessment Criteria for Health and Social Care (DTAC)

DCB0129 Standard

Compliance with DCB0129 (for manufacturers) and DCB0160 (for health and care organisations) is mandatory under the Health and Social care Act 2012. The DCB0129 standard is applicable to organisations responsible for the development of health IT systems. This standard requires you to detail and evidence/demonstrate that a clinical risk management system is in place. You must start your clinical risk management process at the earliest stage of your development lifecycle and continue to assess and gather evidence throughout development.

The standard is included as a part of a DTAC, where developers/ manufacturers are required to confirm the following:

- Clinical Risk Management activities have been undertaken in accordance with DCB0129.
- A Clinical Risk Management System is DCB0129 compliant.
- A Clinical Safety Case Report and Hazard Log is DCB0129 compliant.

The NHS will assess whether you have complied with DCB0129 before it will/ can adopt your technology

Market Access - Improving Uptake

Research has taken place to understand why uptake of software is low in the UK, particularly in relation to clinical decision support systems. The highest clinical concerns highlighted were the following:

- Accuracy of advice.
- Clinical effectiveness testing extensivity.
- The timeliness of the evidence base.

It's therefore important to inform clinicians on the following:

- Accuracy of the advice.
- The effectiveness of improving workflow and patient care.
- Whether or not the system advice matches the latest published guidance.

This highlights the need for evidence-based device development and user-centred design in improving device uptake. It is expected that the software has been designed with, and evaluated by, the intended users.

The UK Government advise the need for the elements shown on the right hand side, and note their importance in NHS procurement.

- Transparency
- Safety
- Equity
- Clear Market Fit
- Addressing an Unmet Need
- Effectiveness Evidence
- Cost-Effectiveness Evidence

Market Access - Evidence Standards Framework for Digital Health Technologies

NICE has developed the Evidence Standards Framework (ESF) for digital health technologies to help allow procurement teams to inform evaluation and identify digital health technologies which are likely to offer benefits. The ESF classifies digital health technologies, allowing application of proportionate evidence requirements. Most medical devices are Tier C as they fit within the following 4 groups.

- Inform clinical management
- Drive clinical management
- Treat specific condition
- Diagnose specific condition

This is therefore helpful for manufacturers to consider during the development of software, to help improve uptake. The ESF outlines standards which can be used by both developers and procurement teams to demonstrate the software's value. The ESF is frequently used by the NHS. Overall, there are 21 standards in 5 groups, as outlined below:

- **Design Factors - including safety and reliability.**
- **Describing Value - value proposition**
- **Demonstrating Performance - performance expectations**
- **Delivering Value - value for money**
- **Deployment Considerations - benefits in practice**

[14]

Data Protection

Software must comply with the relevant data protection acts. This includes being UK GDPR compliant and adhering to the the Data Protection Act 2018. This includes the key following points:

Lawfulness, fairness and transparency

Purpose Limitation

Data Minimisation

Accuracy

Storage Limitation

Integrity and confidentiality

Accountability

When NHS patient data is being accessed, the Data Security and Protection Toolkit must be completed. This allows assessment against the National Data Guardians 10 data security standards, shown on the right.

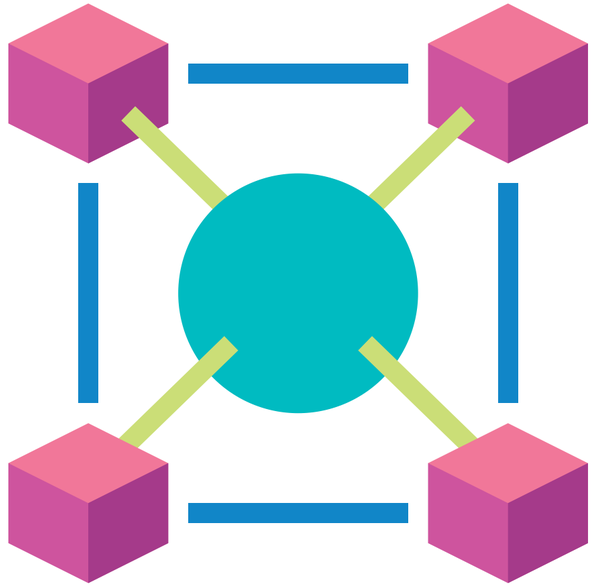
1. Secure data handling, storage and transmit.
2. All staff understand their responsibilities under the National Data Guardian's Data Security Standards, and their personal accountability for breaches.
3. Appropriate annual data security training for staff.
4. Personal confidential data is only accessible to staff who need it, and all access is attributable.
5. Processes are reviewed annually to identify and improve processes causing either breaches or near misses.
6. Cyber-attacks against services are identified and resisted and CareCERT security advice is responded to.
7. A continuity plan is in place to respond to data security threats.
8. No unsupported operating systems, software or internet browsers are used within the IT estate.
9. An IT System protection strategy is in place, based on a proven cyber security framework e.g. Cyber Essentials.
10. IT suppliers are held accountable via contracts for protecting the personal confidential data they process

[15,16]

Interoperability

It is important that technology can work together, therefore the following standards and tools are helpful in assuring others that software is compatible with existing systems, and that data can be shared between systems and organisations.

The NHS Interoperability Toolkit provides "a unified specification for system interoperability within the English NHS." This can be used by developers to create software which meets this specification. This may help to promote uptake into the NHS. Developers/ manufacturers can apply for conformance, by supplying all of the relevant information detailed here. Once approved as conforming, vendors and their systems are listed in a publicly accessible catalogue.



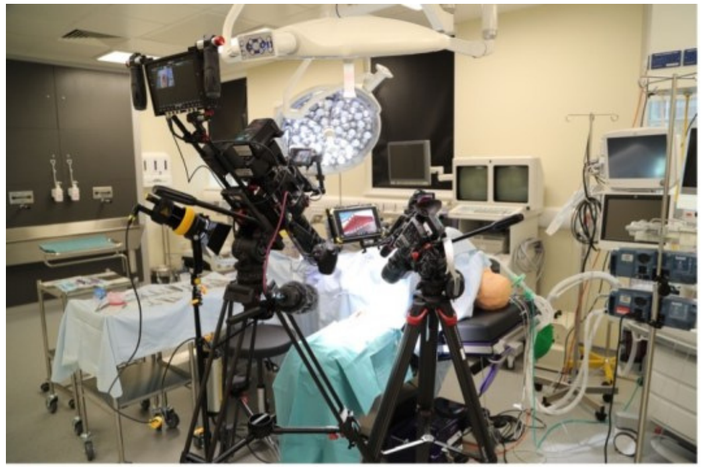
[17,18]

NIHR HRC-DDR

The NIHR HRC-DDR is funded to support the development of novel technologies and medical devices. As part of this, the NIHR HRC-DDR supports SME's, academics and clinicians to apply for grant funding. Additionally, the NIHR HRC-DDR works closely with the Medical Devices Testing and Evaluation Centre (MD-TEC). MD-TEC and the NIHR HRC-DDR are co-located within University Hospitals Birmingham NHS Foundation Trust (UHB). Aligned activity alongside the shared oversight of Clinical Director Professor Tom Clutton-Brock means that the HRC-DDR and MD-TEC are ideally placed to support SMEs navigate the complex journey of medical technology development.

The state of the art facility includes :

- a near replica operating theatre
- intensive care, emergency department, ward and clinic areas
- a simbulance and emergency medical equipment
- high fidelity patient simulators that manifest vital signs, clinical signs and symptoms



The NIHR HRC-DDR is able to support with the following activities:

- Usability studies in accordance with IEC 62366.
- Expert Reviews with clinicians in the relevant field.
- First in human clinical investigations, both preparation and delivery.
- Regulatory support.
- Patient and public involvement and engagement
- Health Economics

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