LFH REGULATORY
Regulation Made Simple

A Free Regulatory Guide to Bringing Your Medical Device to the EU Market

A ‘Regulation Made Simple’ Series Guide 1.0

Version 1.0

LFH REGULATORY
Regulation Made Simple

Contents

Introduction 3
What is a medical device and does my product fall under this definition? 3
How to classify your medical device? 5
Quality Management System (QMS) 6
Technical Documentation 9
Risk Management 12
Clinical Evaluation 13
Post Market Surveillance 14
Post Market Clinical Follow-up 15
Route to market & Approval 16
Class I 16
Class IIa, IIb & III 16
Conclusion 17
Appendix 1 – Classification Rules 18

LFH REGULATORY
Regulation Made Simple

Introduction

You have produced an innovative idea that could change the MedTech market but wonder where you go from there, and what red tape you might encounter to bring your device to market. Worry not, this step-by-step guide will walk you through the regulatory 'hurdles' and make the **regulation simple** so you can easily understand what happens at each stage and what you need to do.

This guide covers topics that are necessary to understand the main areas of bringing a medical device to EU market and be submission ready.

What is a medical device and does my product fall under this definition?

Firstly, we need to ensure that the product we have, is indeed a medical device.

In Article 2 of the EU Medical Device Regulation 2017/745, also referred to as the MDR, a 'medical device' is defined as:

Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
- *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
- *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- *devices for the control or support of conception;*
- *products specifically intended for the cleaning, disinfection or sterilisation of devices*

The first step is to determine whether your device falls within the definition of a medical device and the easiest way to do that is to break it down into bite-sized chunks. This is how we do this:

Answer the questions in the following steps regarding the target device:

Step 1

Is your device an instrument, apparatus, appliance, software, implant, reagent, material or other article?

If so, move onto the next step.

Step 2

It is time to move on to the next part of the definition and it is important to look at whether your device:

diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease

OR

diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability

OR

investigation, replacement or modification of the anatomy or of a physiological or pathological process or state

OR

providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations

If you have answered yes to one of the above, then you need to move on to the next step.

Step 3

The next part of the definition states:

...and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

This means that your device cannot achieve its principal intended purpose by pharmacological, immunological, or metabolic means but does not rule out secondary action e.g. bone cement which contains antibiotics such as gentamicin; the cement's primary intended purpose is to hold the joint implant in place with the secondary intention to reduce the infection if present.

Step 4

At this point, you should have confidence in whether your product falls under the definition of a medical device. For software, this may be a little trickier as some modules may fall

under medical devices whereas other modules could be deemed to be health tech dependent on their functionality and intended purpose.

If you are still unclear if your product falls under the definition of a medical device, it is worthwhile engaging with an expert to help. Reach out to our team to see how we can help you with classifying your product.

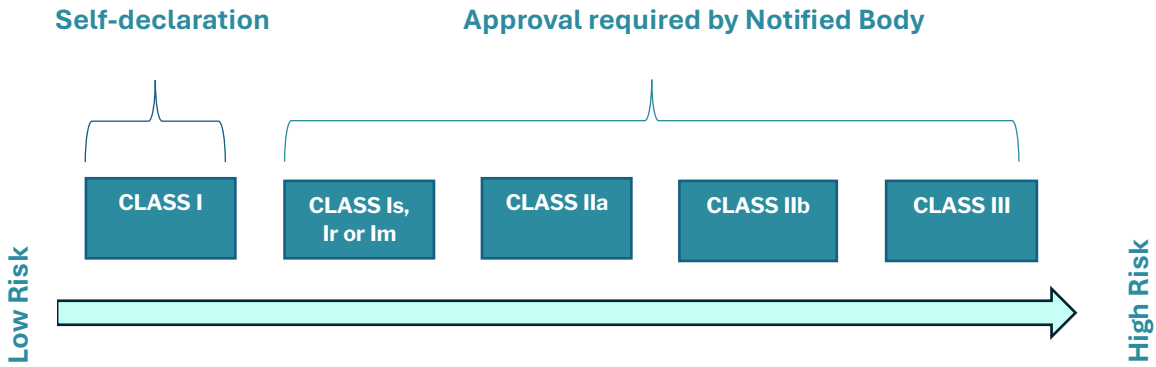
How to classify your medical device?

When you have determined that your product is a medical device, you will then need to determine the classification of your device.

Classification of medical devices are risk-based that take into consideration the vulnerability of the user/human body and the potential risks associated with the device. It considers:

1. Duration of use
2. Contact with the body including the invasiveness
3. Whether the device is active and depends on a source of energy.

There are four classifications classes under which devices shall be divided considering their intended purpose and associated risks. The four classifications are:



Class I can be further sub-divided into 3 categories:

- Class Is – devices placed on the market in sterile condition
- Class Ir – is reusable surgical instrumentation
- Class Im - devices with a measuring function

Class I is the lowest risk with the risk increasing and class III being the highest risk medical devices. The classification rules are set under Annex VIII of the MDR and there are currently 22 rules set under this Annex. They are broken down and split into 4 different categories:

- Non-invasive devices (Rule 1-4)
- Invasive devices (Rule 5-8)
- Active devices (Rule 9-13)
- Special rules (Rules 14-22)

If you believe your device could fall under 2 different classification rules, you need to apply the highest risk classification rule to your device.

Determining the classification of a device is vital to your route to market and can have negative consequences if wrongly classified, such as removal from the marketplace with significant loss of revenue.

For a further breakdown and a detailed overview of the classification rules, see Appendix 1 – Classification Rules.

The Medical Device Coordination Group (MDCG), a European Commission Group that provides medical device guidance, published a useful article in 2021 on the classification rules using product examples; see MDCG 2021-4 Guidance on classification of medical devices

Quality Management System (QMS)

Once you have established the classification for your medical device, you to need consider the quality requirements that manufacturers adhere to.

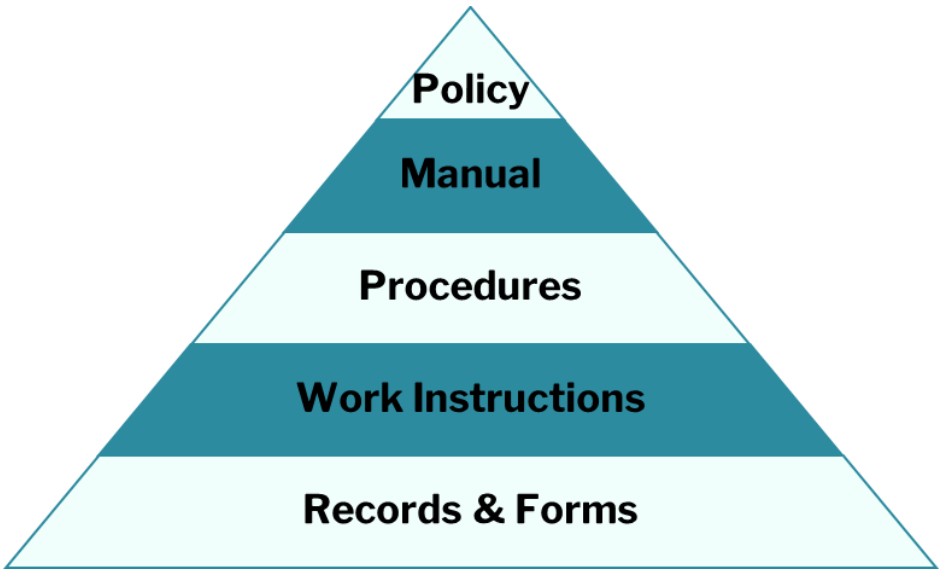
Article 10 – General Obligations of a Manufacturers and Annex IX, chapter 1 of the MDR, it states:

> *The quality management system shall cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation.*

The article outlines the basic requirements that a manufacturer must adhere to. The general rule to demonstrate that you comply with this area of the regulation is to follow standard *ISO 13485 – Medical devices – Quality Management Systems- Requirements for Regulatory Purposes*. Which is an international standard that outlines the requirements for a quality management system (QMS), within the medical device industry. It also covers the entire life cycle of a device from design and development to production, installation, servicing, and post-market activities.

There is also ISO 13485:2016 - Medical Devices - A Practical Guide, which expands the clauses of the standard and gives substance to what is required for each clause.

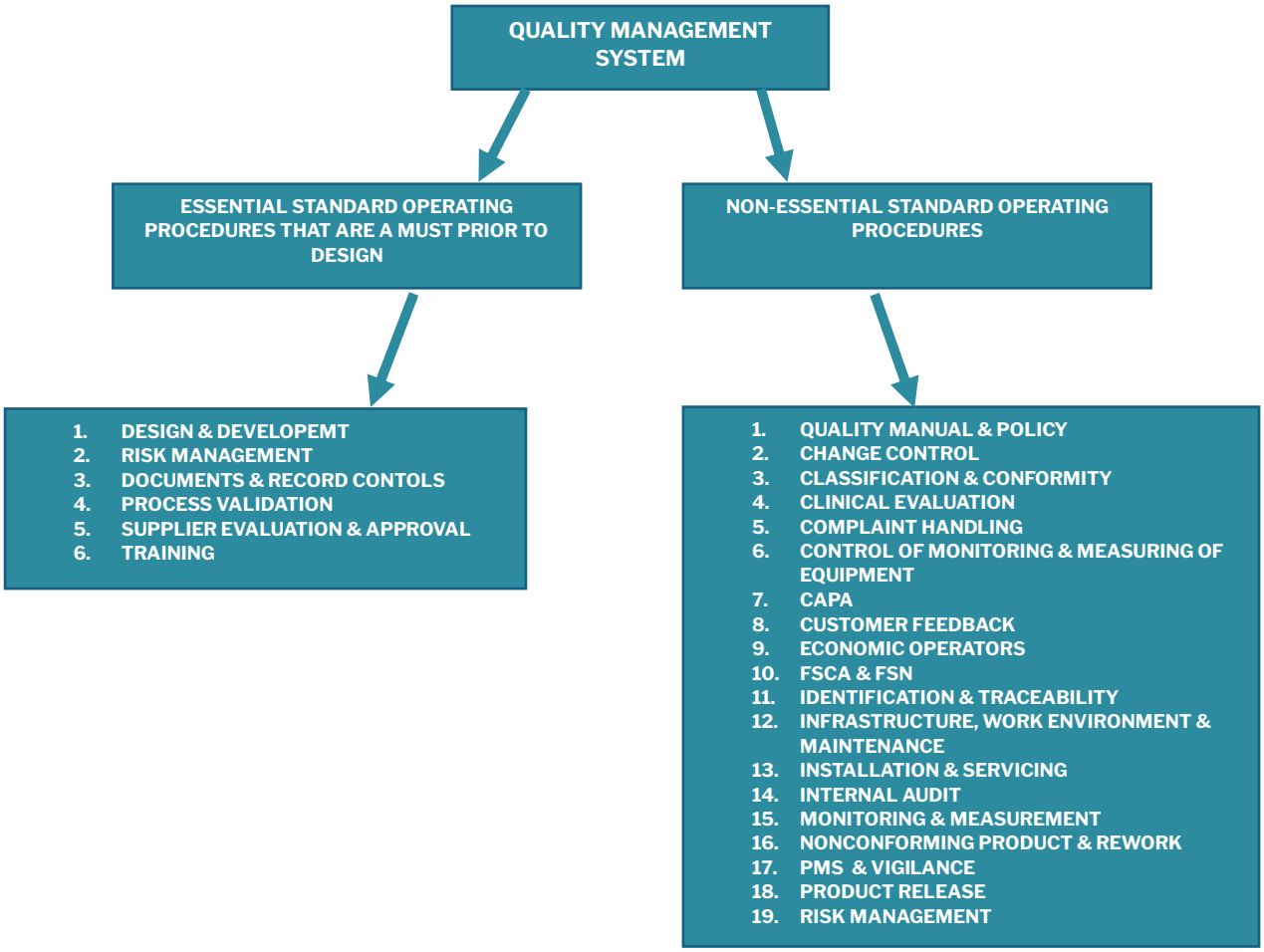
It is worth noting what the QMS documentation structure and hierarchy consists of:



As a consultancy, we work with many start-up companies and appreciate the financial constraints during the initial stages of setup. It is not unusual for a start-up medical device company to have started designing their device and making prototypes before initiating any type of QMS.

Implementing a full, robust, and effective QMS can come at a cost but is essential in future-proofing your device and preventing remediation activities.

The diagram below names the essential procedures required prior to design activities taking place and non-essential procedures which can be implemented late on;



As stated before, the procedures documented above are a starting point. You should implement the required processes as they arise and certainly make sure you have a fully functioning QMS prior to the launch of your device.

At LFH Regulatory, we believe in taking a strategic approach to creating and implementing an effective QMS to suit our client's needs: see our Quality Management System services to see how we can help simplify your QMS implementation.

Technical Documentation

Annex II of the MDR states that the technical documentation shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include elements listed in the Annex.

The Annex goes on to list what information needs to be presented in technical documentation, this includes:

Technical documentation section	Further information
Device Description and Specification, including Variants and Accessories	Device description and specification including things such as: • Product/trade name • UDI-DI • the intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings • Principle operations and mode of action • Rationale for qualification as a device • Classification of device with classification rule • Explanation of novel features • A description of any accessories • Description or complete list of the various configurations/variants of the device • General description of the key functional elements • Description of the raw materials • Technical specifications Reference to previous or similar generations of the device.

Technical documentation section	Further information
Information to be Supplied by the Manufacturer	A complete set of labels for the device needs to be available including labels on the device, sales packaging, transport packaging (where applicable). Instructions for use (IFU) also need to be included. Labelling and IFU's will need to be available in the languages accepted in the countries that the device will be sold. The European Commission has published MDR - Language requirements for manufacturers that documents the language requirements of each state.
Design & Development Information	Information to allow the design stages applied to be understood. Complete information and specifications which include the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. All sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.
General Safety & Performance Requirements	The General Safety & Performance Requirements (GSPRs) are under Annex I of the Regulation and are used to demonstrate how you meet the requirements of the regulation. You will need to document the GSPRs that are applicable to your device and provide evidence along with any standards that are relevant. For any GSPRs that are not applicable, you will need to justify the reasons why.
Benefit-Risk Analysis & Risk Management	This will be demonstrated by following ISO 14971 Medical Devices – Application of Risk Management to Medical Devices. You should compile a risk management file in line with the requirements of ISO 14971 including Risk Management Plan, Annex A Checklist, Risk Assessment and Risk Management Report.
Product Verification & Validation	The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

Technical documentation section	Further information

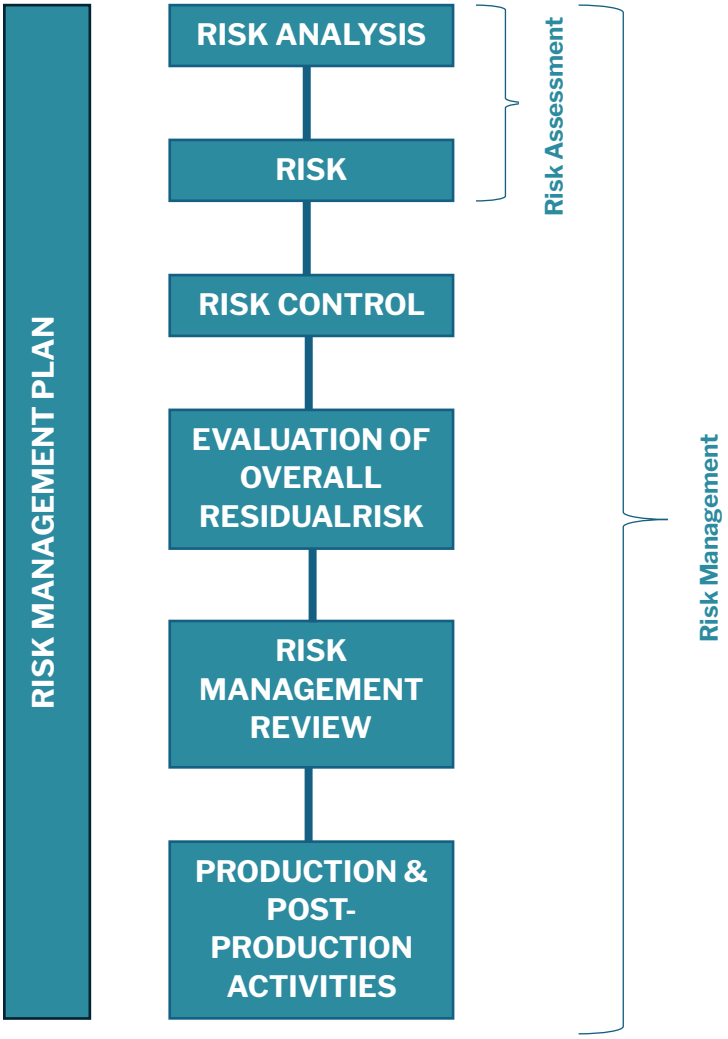
	Pre-clinical and clinical data such as;
	• results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications;
	• detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular:
	  ○ Biocompatibility including biological evaluation
	  ○ Physical, chemical and microbiological characterisation
	  ○ Electrical safety and electromagnetic compatibility
	  ○ software verification and validation
	  ○ Stability testing including the shelf life
	  ○ Performance and safety
	• Clinical Evaluation Plan and Report
	• Post Market Clinical Follow Up (PMCF) Plan and Report. If not PMCF is required, a justification as to why it is not applicable.

Additional information required in specific cases	There are special cases where additional information will need to be included, these are; • Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product including a medicinal product derived from human blood or human plasma. • A device is manufactured utilising tissues or cells of human or animal origin, or their derivatives. • Devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body. • Devices containing CMR or endocrine-disrupting substances. • Devices placed on the market in a sterile or defined microbiological condition. • Devices placed on the market with a measuring function. • Device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration.

Risk Management

There is a strong emphasis on risk management within the MDR regulation. It is mentioned a whopping 243 times!. That is because risk management plays a crucial role in the medical device product development lifecycle. It ensures the reliability of the product, its proper functioning, and the safety of patients, operators, and the environment. The risk management cycle aims to create dependable medical devices by minimising the likelihood of failures.

The General Risk Management Process to follow is ISO 14971, presented in a flowchart below.



The general process of Risk Management under ISO 14971 should ideally be part of the initial stages of any project, but we have seen that it has not always been considered.

To achieve the best practices in medical device development, you should correlate design control with risk management. When identifying hazards or hazardous situations early on, feed them into your design controls, user needs, and design inputs.

By evaluating the risk and putting risk control measures in place e.g. design verification/validation can assist with mitigating the risk to an acceptable level.

Risk management is not only an early-stage requirement but should be reviewed and updated throughout the lifetime of your medical device periodically, or when it becomes available that there is a new risk and/or risk that needs reevaluating.

Conducting risk management activities correctly is crucial for ensuring MDR compliance of your medical device and following the correct requirements and updating your documentation is crucial for remaining compliant.

We are here to help create or navigate you to implement an effective risk management file.

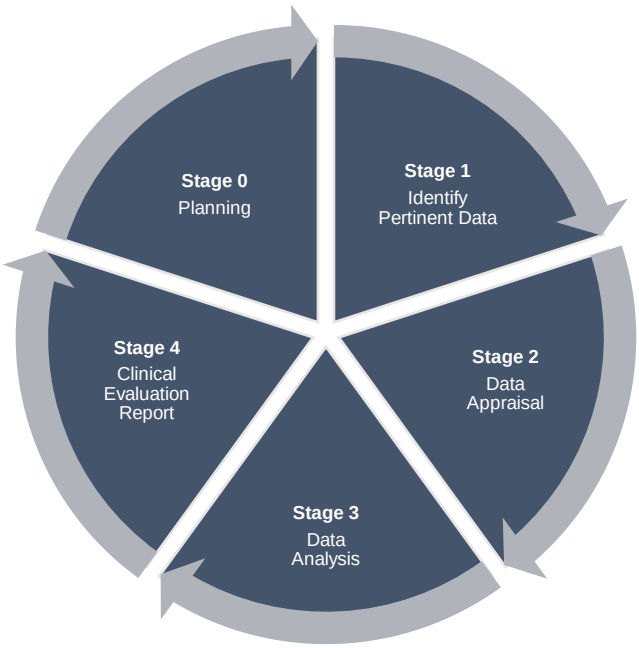
Clinical Evaluation

Clinical evaluation is a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device to verify the safety and performance. It includes the in-direct or direct clinical benefits of the device when used as intended by the manufacturer and is expected to identify any relevant clinical data that may impact the benefit risk ratio. It is conducted throughout the life cycle of a medical device, as an ongoing process.

Clinical evaluation is necessary; it ensures that the evaluation of safety and performance of the device is based on sufficient clinical evidence for the lifetime that the medical device is on the market. This ongoing process that enables manufacturers to provide notified bodies and competent authorities with sufficient clinical evidence for demonstration of conformity of the device with the General Safety and Performance Requirements throughout its lifetime (for example for CE marking, fulfilment of post-market surveillance and reporting requirements, or during surveillance procedures).

The clinical evaluation is first performed during the development of a medical device to identify data needed for market access (i.e. CE marking) and it must be actively updated thereafter.

There are stages for performing a clinical evaluation:



As the clinical evaluation can be a complex and time-consuming set of documents to create, it should be conducted by a suitably qualified individual or team. At LFH Regulatory, we offer a flexible solution option through our Clinical Evaluation Services where our experts can deliver your clinical documentation needs.

Post Market Surveillance

Post Market Surveillance (PMS) comes under Article 83 & Annex III of the MDR which describes what needs to be drawn up as part of the technical documentation. PMS can be defined as:

> *All activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.*

Manufacturers of class I devices need to prepare a PMS report from data gathered in accordance with the PMS plan. There is no specified timeframe for updating, with the MDR stating the report is to be updated when necessary or upon the request of the competent authority.

For Class II, III Devices:

Article 86 of the MDR discusses the requirements for Periodic Safety Update Report (PSUR).

For class IIa, IIb and III devices, a more detailed PSUR must be produced. The PSUR for class IIa device will need to be updated when necessary but at least every 2 years. For class IIb and III devices, the PSUR will need be updated at least annually.

Post market can be classified as reactive or proactive and both approaches should be taken. The following table gives examples of the types of post-market activities that should be carried out but are not limited to:

Reactive Post Market Data	Customer complaints Vigilance including adverse events, serious incidents & Field safety corrective actions (FSCA)
Proactive Post Market Data	Customer Surveys and Feedback Literature Searches: Systematic literature searches and/or review for a particular product, material used in a product or clinical procedure which may be conducted. Post-market Clinical Follow Up

Post Market Clinical Follow-up

Post Market Clinical Follow-up (PMCF) is a continuous process in which a manufacturer proactively collects and evaluates clinical data about how their device is used within its intended purpose.

Annex XIV, Part B of the MDR sates that what activities should be conducted to fulfil these requirements. The aim of the PMCF plan is:

- Confirming the safety and performance, including the clinical benefit if applicable, of the device throughout its expected lifetime.
- Identifying previously unknown side-effects and monitor the identified side-effects and contraindications.
- Identifying and analysing emergent risks based on factual evidence.
- Ensuring the continued acceptability of the benefit-risk ratio.
- Identifying possible systematic misuse or off-label use of the device, to verify that the intended purpose is correct.

A PMCF plan shall specify the methods and procedures to proactively collect and evaluate clinical data from the use in or on humans of a CE-marked medical device, placed on the market or put into service within its intended purpose.

There is no specific format for a PMCF study and because of this, it can be concluded that numerous options are acceptable, including formal clinical studies, systematically curated evidence available in literature and surveys to generate feedback from medical experts and patients.

It is not surprising that you might find post-market activities confusing. At LFH Regulatory, we can help you navigate the complexities of post-market activities including PMCF.

Route to Market & Approval

So, you've carried out the above, but where do you go next? You will need to understand whether your device is a self-declared product or whether you will need to go through a review and approval process.

Class I

Class I devices are self-declared products which means they will not be required to go through a review and approval process by a Notified Body. Although there is no review process, you will still be required to demonstrate that you mean the requirements of the MDR and sign off on your technical documentation with your Declaration of Conformity (DoC).

Once you have signed off on the technical documentation with your DoC, you will be able to register with your competent authority e.g. Medicines Healthcare Product Regulatory Agency (MHRA) in the UK. If you are based outside the EU, you will need to appoint an EU Authroised Representative to do this on your behalf.

You will also need to have a QMS implemented and for good practice audited. This will consist of a 2-stage approach with the 1st stage reviewing procedures to make sure they meet the requirements of the standard and any regulatory requirements. The 2nd stage will review that you are adhering to your procedures and will want to witness evidence.

Class IIa, IIb & III

Class IIa, IIb and III will be required to go through a review and approval process with a Notified Body. Generally, they will review your technical documentation and QMS to ISO 13485 for the purposes of CE marking.

There are different stages/audit involved which consist of but are not limited to;

1. Technical documentation – review of the complete full technical file including performance data. If you have more than 1 technical file, the notified body made carry out a sampling plan of your technical documentation.
2. QMS audit – This consist of a 2-stage approach with the 1st stage reviewing procedures to make sure they meet the requirements of the standard and any regulatory requirements. The 2nd stage will review that you are adhering to your procedures and will want to witness evidence.

Should you require your medical device to be certified, it is advisable that you communicate with your preferred notified body early on to understand they have the required approval codes and the timeframes for certification (this may vary between notified bodies).

Conclusion

This step-by-step guide has taken you through the main requirements of CE marking your medical device under the MDR.

Any new product must be determined whether it is defined as a medical device and if so, this needs identification is followed by the product risk classification to understand your route to market and to streamline this process to make it as efficient as possible.

The QMS is not a checkbox exercise and is instrumental in facilitating design control practices throughout the development of your device.

Although we have discussed the PMS, Risk Management, and Clinical Evaluation as separate points, it should be noted that these all encompass important inputs into the Technical Documentation and in demonstrating compliance with the MDR.

To discuss any requirements you may have around CE marking your device or the EU MDR, please feel free to contact us for an informal chat.

Tel: +44(0) 1484 662575

Email: info@lfhregulatory.co.uk

Appendix 1 – Classification Rules

Category	Classification Rule	Device Types Covered
Non-invasive devices	Rule 1	All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies.
	Rule 2	All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class IIa: • if they may be connected to a class IIa, class IIb or class III active device; or • if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags; blood bags are classified as class IIb. In all other cases, such devices are classified as class I.
	Rule 3	All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body are classified as class IIb, unless the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas, heat, in which case they are classified as class IIa. All non-invasive devices consisting of a substance, or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken from the human body or used in vitro with human embryos before their implantation or administration into the body are classified as class III.
	Rule 4	All non-invasive devices which come into contact with injured skin or mucous membrane are classified as: • class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates; • class IIb if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and

Category	Classification Rule	Device Types Covered
		• class IIa if they are principally intended to manage the micro-environment of injured skin or mucous membrane; and • class IIa in all other cases. This rule applies also to the invasive devices that come into contact with injured mucous membrane.
Invasive devices	Rule 5	All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as: • class I if they are intended for transient use; • class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity, in which case they are classified as class I; and • class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are classified as class IIa. All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to a class IIa, class IIb or class III active device, are classified as class IIa.
	Rule 6	All surgically invasive devices intended for transient use are classified as class IIa unless they: • are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III; • are reusable surgical instruments, in which case they are classified as class I; • are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III; • are intended to supply energy in the form of ionising radiation in which case they are classified as class IIb; • have a biological effect or are wholly or mainly absorbed in which case they are classified as class IIb; or

Category	Classification Rule	Device Types Covered
		• are intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are classified as class IIb.
	Rule 7	All surgically invasive devices intended for short-term use are classified as class IIa unless they: • are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III; • are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III; • are intended to supply energy in the form of ionizing radiation in which case they are classified as class IIb; • have a biological effect or are wholly or mainly absorbed in which case they are classified as class III; • are intended to undergo chemical change in the body in which case they are classified as class IIb, except if the devices are placed in the teeth; or • are intended to administer medicines, in which case they are classified as class IIb.
	Rule 8	All implantable devices and long-term surgically invasive devices are classified as class IIb unless they: — are intended to be placed in the teeth, in which case they are classified as class IIa; • are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III; — have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III; • are intended to undergo chemical change in the body in which case they are classified as class III, except if the devices are placed in the teeth; • are intended to administer medicinal products, in which case they are classified as class III; — • are active implantable devices or their accessories, in which cases they are classified as class III; • are breast implants or surgical meshes, in which cases they are classified as class III; • are total or partial joint replacements, in which case they are classified as class III, with the exception of ancillary components such as screws, wedges, plates and instruments; or

Category	Classification Rule	Device Types Covered
		• are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments.
Active devices	Rule 9	All active therapeutic devices intended to administer or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with 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 classified as class IIb. All active devices intended to control or monitor the performance of active therapeutic class IIb devices or intended directly to influence the performance of such devices are classified as class IIb. All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb. All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III.
	Rule 10	Active devices intended for diagnosis and monitoring are classified as class IIa: • if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, in which case they are classified as class I; • if they are intended to image in vivo distribution of radiopharmaceuticals; or • 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 and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as class IIb.

Category	Classification Rule	Device Types Covered
		Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.
	Rule 11	Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause: — death or an irreversible deterioration of a person's state of health, in which case it is in class III; or — a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb. Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb. All other software is classified as class I.
	Rule 12	All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are classified as class IIa, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are classified as class IIb.
	Rule 13	All other active devices are classified as class I.
Special Rules	Rule 14	All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the devices, are classified as class III.
	Rule 15	All devices used for contraception or prevention of the transmission of sexually transmitted diseases are classified as class IIb, unless they are implantable or long-term invasive devices, in which case they are classified as class III.
	Rule 16	All devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses are classified as class IIb.

Category	Classification Rule	Device Types Covered
		All devices intended specifically to be used for disinfecting or sterilising medical devices are classified as class IIa, unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing, in which case they are classified as class IIb. This rule does not apply to devices that are intended to clean devices other than contact lenses by means of physical action only.
	Rule 17	Devices specifically intended for recording of diagnostic images generated by X-ray radiation are classified as class IIa.
	Rule 18	All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non- viable or rendered non-viable, are classified as class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are devices intended to come into contact with intact skin only.
	Rule 19	All devices incorporating or consisting of nanomaterial are classified as: • class III if they present a high or medium potential for internal exposure; • class IIb if they present a low potential for internal exposure; and • class IIa if they present a negligible potential for internal exposure.
	Rule 20	All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation are classified as class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life- threatening conditions, in which case they are classified as class IIb.
	Rule 21	Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as: • class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose; • class III if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;

Category	Classification Rule	Device Types Covered
		• class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and • class IIb in all other cases.
	Rule 22	Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.