# The new EU Medical Device Regulations and CE Marking Medical Devices

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## 1 Introduction

The new EU Medical Device Regulations (MDR 2017/745) was formally published in May 2017 and comes into full force from 26 May 2021. The MDR consolidates and replaces the Medical Devices Directive (MDD) 93/42/EE and the Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC and is more strictly implemented, complex and comprises of 175 pages. There is no grandfathering of devices which means all existing devices will need to be assessed against the MDR and current standards and state of the art.

CE Marking provides access to the European Single Market comprising of 28 Member States, the European Economic Area (Iceland, Liechtenstein, and Norway) and, through bilateral treaties, Switzerland and Turkey. These 33 Markets mostly comprise of a wealthy, aging population of over 515 million consumers. In addition to the above markets, CE Marking can be leveraged to access other markets adding further to its importance.

The MDR takes a lifecycle approach similar in view to the US Food and Drug Administration (FDA) and has incorporated many elements of the current European guidance documents. Greater emphasis is placed on clinical data and evaluations both pre-market, and in alignment with the lifecycle approach, post-market and technical files have been bolstered to include post-market surveillance requirements.

A new regulatory body called the Medical Device Coordination Group (MDCG) has been created to foster harmonization efforts, foster cooperation and increase the Commission's power to act as needed.

As this goes into publication there are further areas that need to be clarified, developed or enacted as well as updates to guidance documents and standard harmonisation. Manufacturers will need to use the best information available at the time of CE Marking and then update their records as more information becomes available

Below is a summary of many of the key aspects as well as reference material. SEHTA also runs courses covering many of these requirements throughout the year.

The purpose of the regulations is to ensure that only safe devices that perform effectively are placed on the European market. To achieve this the regulation provides

a framework whereby a manufacture may show compliance to the regulation through the CE Marking of their devices. The starting point is setting out the devices ***Intended Use*** from which it can be determined whether it is a ***Medical Device*** and if it is, what the ***Classification*** is.

Once you have determined the ***Classification*** of your device it becomes clearer what conformity assessment routes are available for the manufacturer. ***Conformity Assessment*** is the process whereby the manufacturer demonstrates that they have fulfilled the requirements of the MDR. Manufacturers demonstrate conformity through their ***Technical Files*** and records, ***Quality Systems*** and ***Clinical Evidence***.

Once CE Marking has been achieved your CE certificate will be issued and uploaded onto the ***European Database of Medical Devices*** (EUDAMED).

### 1.1 Classification

Medical Devices are classified into **four** product classes. These classes are determined through the application of 22 classification rules that are based on the vulnerability of the human body and take into account the potential risks associated with the technical design and manufacture of the devices. The starting point for any classification is **Intended Use.**

- Is it a device?
- Where will the device be used e.g. central nervous system?
- Is it Invasive?
- How long will it be in contact with the patient: Transient, Short Term, Long Term?
- Is it an Implantable?
- Is it an Active device?

The four classification categories are class I, IIa, IIb and III with “III” being the highest risk devices and “I” the least. In addition to these categories Class I has three subclasses; I **s**terile, I **m**easuring and I **r**e-usable.

The 22 rules are divided into 4 groups

| | |
|---|---|
| Rules 1 – 4 | Non-invasive Devices |
| Rules 5 – 8 | Invasive Devices |
| Rules 9 – 13 | Active Devices |
| Rules 14 – 22 | Special Rules |

For those transferring from the MDD to the MDR the old rule 18 is now consolidated under rule 2 and four new rules have been added covering software, nano materials and invasive devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body.

Changes to the classification rules mean the following need to be self-certified (class I) or certified by a Notified Body according to the MDR by May 2020

- Class I self-certified devices

- Class I reusable surgical instruments
- Class III implantable custom-made devices
- Devices new to the MDR scope
- Devices without an intended medical purpose (Annex XVI e.g. non-prescription contact lenses, liposuction...)
- Devices up-classified from Class I self-certified

## 1.2 Technical Documentation & Records

The technical documents required to assess conformity are set out in the following three Annexes:

***Annex I*** - General Safety and Performance Requirements (SPR), previously known as the essential requirements);
***Annex II*** – Technical Documentation;
***Annex III*** – Technical Documentation on Post Market Surveillance.

### 1.2.1 Annex I – SPR

There are 23 SPR requirements in Annex I grouped in three sections:

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|---|---|
| 1. SPR 1-9 | General Requirements |
| 2. SPR 10-22 | Design and Manufacture |
| 3. SPR 23 | Information supplied with the device |

Every Medical Device no matter what class is required to complete and satisfy the General Safety and Performance requirements. SPR 23 on “information supplied with the device” is only one SPR but it has more than 70 sub-parts and it should not be underestimated.

### 1.2.2 Annex II – Technical Documentation

The technical documentation requirements closely resemble the Global Harmonization Task Force Summary of Technical Documentation format for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices often abbreviated to the STED format.

Technical documentation covers the following six areas;

| | |
|---|---|
| 1. Device Description and Specification including Variants and Accessories | Intended Use, how it works, product specification, materials, classification, conformity assessment route |
| 2. Information Supplied by the Manufacturer | Labels, IFU, promotional material, language requirements |
| 3. Design and Manufacturing Information | Design stages and further detail, manufacturing process, critical suppliers, product release process, address of manufacturing sites and certificates |

| | |
|---|---|
| 4. General Safety & Performance Requirements (Annex I) | EC Declaration of Conformity, product detail classification, completed General Safety and Performance Requirements document, list of applied standards |
| 5. Benefit-Risk Analysis and Risk Management | Risk analysis & control: ISO 14971:2012 - Summary of the risks identified, analysis of how the risks have been controlled and reduced, risk management plan. Importantly needs to incorporate PMS |
| 6. Product Verification and Validation | Verification and Validation: Summary of the results of verification and validation activities e.g. engineering tests, laboratory tests, biocompatibility data, medicinal substances, animal or human cells, tissues or their derivatives, sterilization, software verification and validation. Clinical evaluation & shelf life |

### 1.2.3 Annex III – Technical Documentation on Post Market Surveillance (PMS)

This is a new addition in the MDR and requires that the manufacturer has a documented post-market surveillance (PMS) system which collects and utilises all available information including publicly available information for other comparable devices.

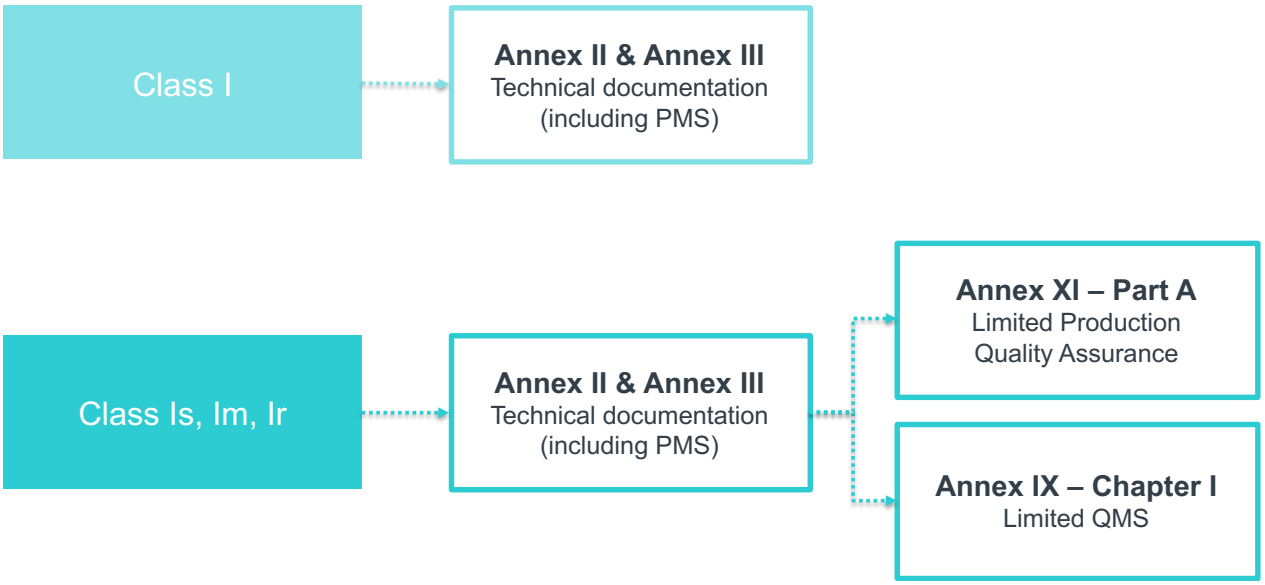
The MDR requires that the manufacturer shall proactively collect and evaluate clinical data with the aim of confirming the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence.

The manufacturer needs a proactive and systematic PMS plan, implementation of the plan followed by reporting of the information gathered in a post market surveillance report or periodic safety update report which also feeds into the manufacturer's risk assessment and ongoing clinical evaluation.

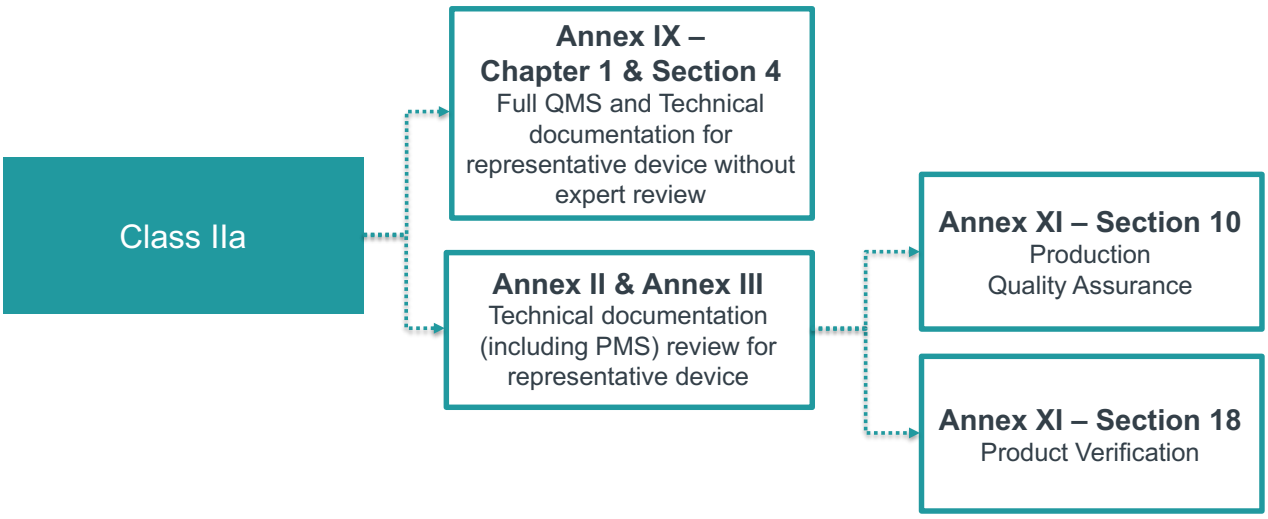
## 1.3 Conformity Assessment

The conformity assessment routes are set out in Annex IX, X and XI. All of these annexes require a technical file or documentation in compliance with Annex II (Technical Documentation) and Annex III (PMS Technical Documentation) and Annex II requires the completion of Annex I (SPR). The routes available to each device class are set out below.

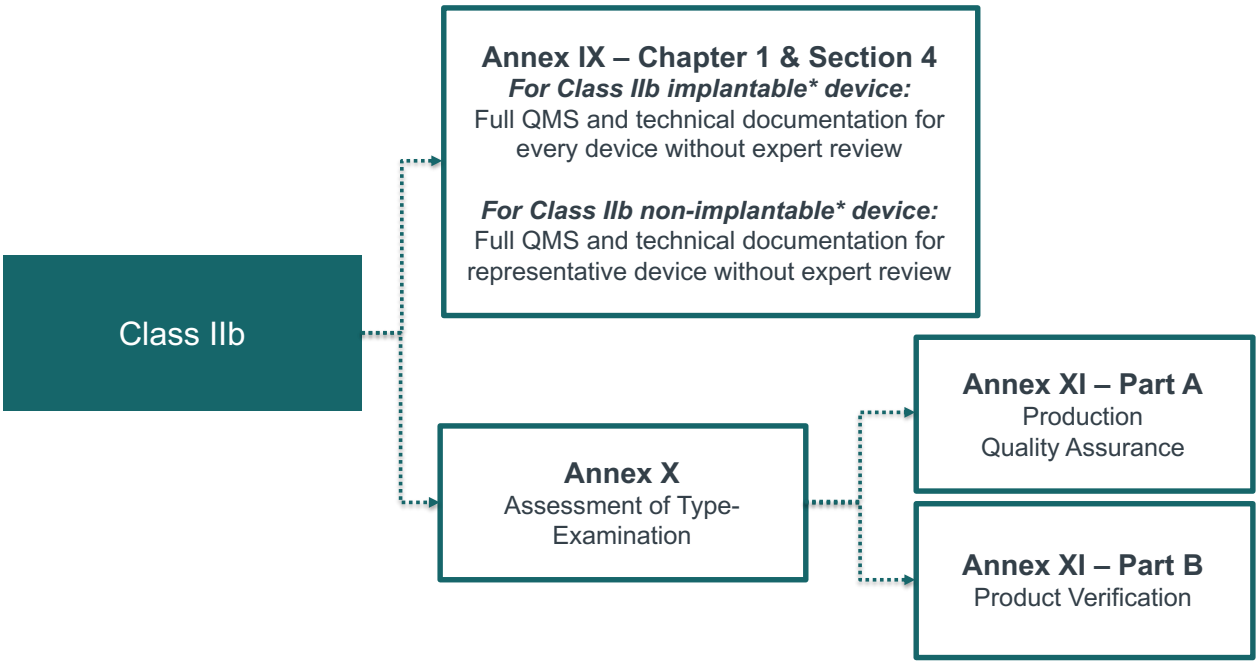
### 1.3.1 Routes for Class I Devices



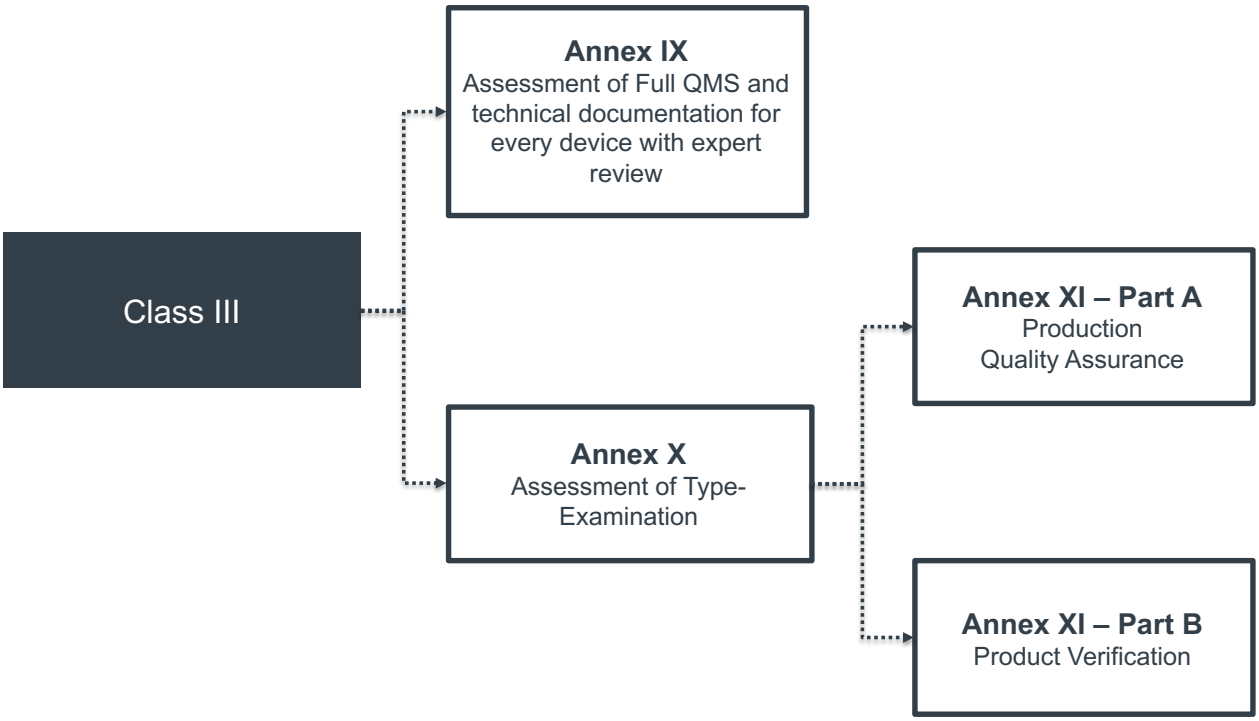

### 1.3.2 Routes for Class IIa Devices



### 1.3.3 Routes for Class IIb Devices




### 1.3.4 Routes for Class III Devices



Conformity assessment routes should be determined in conjunction with a regulatory specialist so that the best choice is made and understood for the required business objectives.

### 1.4 Clinical Evidence

Greater emphasis is placed on clinical data and clinical evaluations. The requirements for clinical evidence have increased substantially and extend over the whole lifecycle of the product.

The commonly used approach of claiming substantial equivalence to another device without clinical data on the manufacturer's own device will be much more challenging, and in many cases unlikely. Therefore, most products will require their own clinical data providing evidence of performance and safety. This topic is presently under detailed discussion at the European Competent Authorities level with guidance expected soon on what constitutes "sufficient clinical evidence" for devices affected by this new restriction.

The MDR has also introduced a new level of review of clinical evaluations for high risk products which is known as the Scrutiny Procedure. This procedure is a review by an Expert Panel, appointed by the European Commission, of the Notified Body's assessment of a manufacturer's clinical evaluation and associated clinical evidence. This Scrutiny Procedure may add both time to the CE Marking process and additional requirements to the clinical evidence required for Medical Devices deemed to be high risk. At present the exact nature of how this process will work is yet to be established. The introduction of the Expert Panel does bring with it a positive opportunity, though. That is, the chance to consult the Panel for a scientific opinion on the design of pre-market clinical investigations for novel devices. This should bring some additional clarity to the future clinical evidence requirements for Medical Devices, but again the exact working of the process is yet to be established.

A further item that the MDR brings in is the requirement for manufacturers of Class III and some Class IIb Medical Devices, to publish on EUDAMED a Summary of Clinical Safety and Performance (SCSP). This data summary is intended to provide users greater information on the clinical evidence supporting the CE Marking of a specific Medical Device to enable better patient and treatment selection. There are a number of activities ongoing at present to determine the likely format and content of the SCSP.

Then finally, the MDR introduces more detailed rules for the execution of, and the use of data resulting from, Post-Market Surveillance and Post-Market Clinical Follow-up.

### 1.5 UDI & European Database of Medical Devices (EUDAMED)

There is a requirement that devices are traceable by means of a Unique Device Identifier (UDI). Devices shall also be assigned to a "Basic UDI-DI". The "Basic UDI-DI" is a record key in the UDI database and connects devices with the same intended purpose, risk class and essential design and manufacturing characteristics and is separate from the packaging /labelling of the device. The "Basic UDI-DI" is referenced

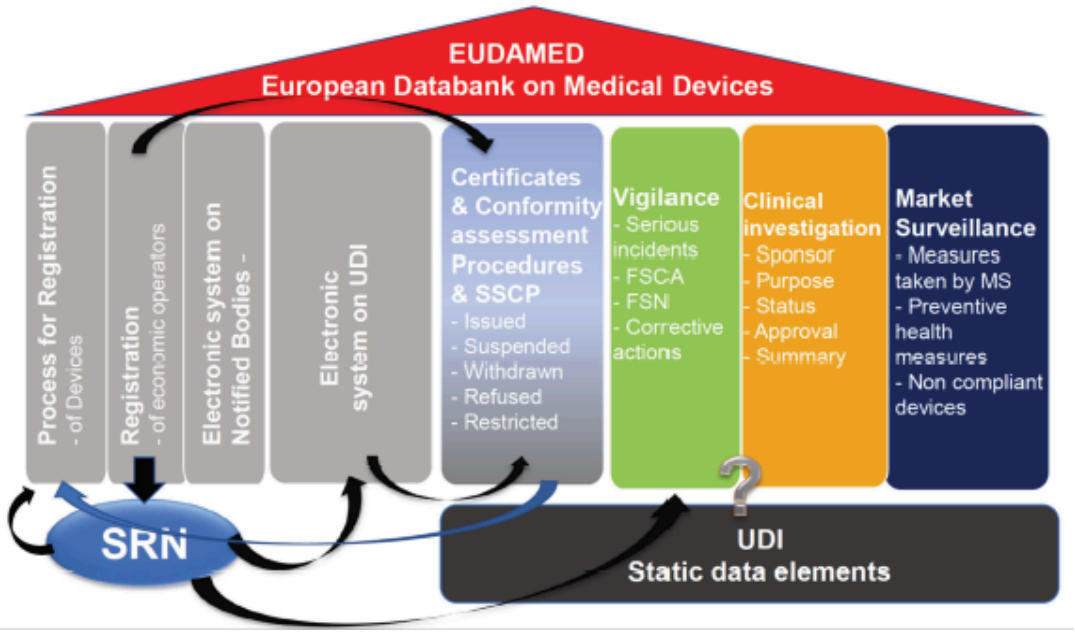
in regulatory documents such as the Technical Documentation, Declaration of Conformity, Notified Body Certificates and Post Market Studies.

The Commission also mandated that EUDAMED should be relaunched and include:

- An electronic system for registration of devices referred to in Article 29(4);
- A UDI-database referred to in Article 28;
- An electronic system on registration of economic operators referred to in Article 30;
- An electronic system for notified bodies and holding on certificates referred to in Article 57;
- An electronic system on clinical investigations referred to in Article 73;
- An electronic system on vigilance and post-market surveillance referred to in Article 92;
- An electronic system on market surveillance referred to in Article100.

This is an ambitious project and there may be some initial teething issues and delays. Should that happen then existing arrangement remain in place until EUDAMED becomes fully functional. The start of the whole process is the requirement for manufacturers to obtain a Single Registration Number (SRN) from their Competent Authority (MHRA in the UK). At this stage the most important action for a manufacturer is to ensure they meet the UDI labelling requirements, update existing labelling to meet MDR requirements and to keep a watching brief on EUDAMED progress and the issuance of SRNs.

Below is a representation of EUDAMED presented by the EU Commission & medtecheurope.org



## 2 Key Dates

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|---|---|
| March 2020 | Scheduled date for the European Database on Medical Devices (EUDAMED) to go live. There are provisions allowing for a delay. |
| May 2020 | MDR comes into force:<br>• All Class I, self-certified devices and custom-made devices (excluding Class III implantable) must be compliant to the MDR<br>• Class I reusable surgical instruments, Class III implantable custom-made devices, devices new to MDR scope, devices without an intended medical purpose (Annex XVI – contact lenses, liposuction, and devices up-classified from Class I self-certified must be certified by a Notified Body according to the MDR<br>• Combination products of a pharmaceutical and a medical device that are considered medicinal products must comply with the General Safety and Performance Requirements, with notified body involvement if applicable (MDR Article 117)<br>• Clinical investigations must comply with the MDR<br>• UDI must be added to technical documentation<br>• All PMS and PMCF requirements of the MDR apply, unless exempted by article 123 |
| May 2021 | UDI must be placed on the label of Class III devices that are MDR certified |
| May 2022 | Certificates issued in accordance with Annex 4 of AIMDD and Annex IV of MDD that have not yet expired will become void |
| May 2023 | UDI must be placed on the label of Class IIa and Class IIb devices that are MDR certified |
| May 2024 | Other certificates issued under current Directives that have not yet expired will become void |
| May 2025 | Devices that were CE marked under the MDD or AIMDD may no longer be marketed or put into service in Europe<br><br>UDI must be placed on the label of Class I devices |
| TBD | BREXIT– a transition period may start. Add key requirements and dates when agreed |

## 3 Structure of the MDR

When looking for key articles and sections it is useful to understand the structure as there is no index.

| | | |
|---|---|---|
| **Chapter I** | Art 1 - 4 | Scope & Definitions |
| **Chapter II** | Art 5 - 24 | Making Available on the Market |
| **Chapter III** | Art 25 - 34 | Identification and Traceability of Devices |
| **Chapter IV** | Art 35 - 50 | Notified Bodies |
| **Chapter V** | Art 51 - 60 | Classification and Conformity Assessment |
| **Chapter VI** | Art 61 - 82 | Clinical Evaluation and Clinical Investigations |
| **Chapter VII** | Art 83 - 100 | Post Market Surveillance, Vigilance & Market Surveillance |
| **Chapter VIII** | Art 101 - 108 | Cooperation between Members & Bodies |
| **Chapter IX** | Art 109 - 113 | Confidentiality and Data Protection |
| **Chapter X** | Art 114 - 123 | Final Provisions |

| | |
|---|---|
| **Annex I** | General Safety & Performance Requirements - SPR |
| **Annex II** | Technical Documentation |
| **Annex III** | Technical Documentation on Post Market Surveillance - PMS |
| **Annex IV** | EU Declaration of Conformity - DoC |
| **Annex V** | CE Marking of Conformity – CE Mark |
| **Annex VI** | Information to be Submitted – UDI+ |
| **Annex VII** | Requirements to be met by Notified Bodies |
| **Annex VIII** | Classification Rules |
| **Annex IX** | Conformity Assessment – QMS & Tech Docs |
| **Annex X** | Conformity Assessment – Type Examination |
| **Annex XI** | Conformity Assessment – Product Conformity |
| **Annex XII** | Certificates to be Issued by a Notified Body |
| **Annex XIII** | Procedure for Custom Made Devices |
| **Annex XIV** | Clinical Evaluation and Post Market Clinical Follow-up |
| **Annex XV** | Clinical Investigations |
| **Annex XVI** | Products without an Intended Medical Purpose |
| **Annex XVII** | Correlation Table |

# 4 Key Standards & Guidance

There are hundreds of standards covering the many thousands of medical devices. However, there are a core set of standards that are applicable to many devices which are listed below and would be in addition to any specific standards applicable to your device.

| | |
|---|---|
| **Quality Management:** | ISO 13485 |
| **Risk:** | ISO 14971 |
| **Clinical Evaluation:** | MEDDEV 2.7. Rev 4 + MDR Annex XIV |
| **Clinical Investigation:** | ISO 14155 |
| **Biocompatibility:** | ISO 10993 |
| **Software:** | EN 62304 |
| **Medical Equipment:** | EN 60601 |
| **Usability:** | EN 62366 and FDA Human Factor Analysis |
| **Symbols:** | ISO 15223 |

# 5 Next Steps

The new regulations are in place and whether you are developing a medical technology for the first time or you have a portfolio of devices actions need to be taken to ensure you know your route to compliance and how you are going to get there

## 5.1 New Devices

For new devices the first step is to develop a regulatory strategy based on the MDR with a clear understanding of intended use, device classification, conformity assessment route, Technical file requirements and an understanding of the clinical evidence strategy.

Once this has been determined engage with your chosen Notified Body at an early stage. This will establish an understanding of timing, costs and who your account manager is as well as confirming your device classification.

### 5.2 Existing Devices and Portfolio

For existing devices and portfolio, a business decision is required to determine which devices will be re certified to comply with the MDR at the appropriate time and which if any will be discontinued.

To understand the compliance effort the manufacturer will need to assess their portfolio and understand the size of the gaps and the resources that will be required to enable compliance by the date required.

The manufacturer will scope and plan the review with the objective of identifying the products that will be kept on the market after 2020 and of those products which can be maintained with no changes until their MDD CE certificate expires.

The analysis will identify gaps in technical files as well as process gaps such as the PMS requirements. The manufacturer also needs to identify which Notified Body will be able to assess which devices.

Once the review has been completed the manufacturer will have an understanding of the time, skill and people resources needed to achieve compliance. This will enable the organization to prioritise devices and identify where and how these resources will be obtained from within and outside the business.

This analysis can now be used to compile a compliance plan, actions, priorities and activities in alignment with overall business objectives.

## 6 Reference Sites

MHRA: https://www.gov.uk/government/latest?departments%5B%5D=medicines-and-healthcare-products-regulatory-agency

EU Commission: http://ec.europa.eu/growth/sectors/medical-devices_en

Copies of the MDR: http://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en

**About Psephos**

Psephos Biomedica was founded in 2001 and works with clients from around the world to help them bring medical technologies to market. A highly focused, experienced team Psephos only works with Medical Devices and Clients range from innovative start-ups to entrepreneurial corporations. The team has together more than 100 years Medical Device and IVD experience.

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