# Guide to obtaining the CE marking of an IT application based on AI

as a medical device in accordance with the European MDR/IVDR Regulations

Generalitat de Catalunya

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**AAMI**
Association for the Advancement of Medical Instrumentation, 16

**AEMPS**
Spanish Agency for Medicines and Health Products, 6

**CE**
Conformité Européene, 6

**CS**
Common Specifications, 14

**DHF**
Design History File, 10

**DMR**
Device Master Records, 10

**OJEU**
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**EDHS**
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**MS**
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**IT**
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**SOP**
Standard Operating Procedures, 17

**SOTA**
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**SOUP**
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**SSCP**
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**STRIDE**
Spoofing, Tampering, Repudiation, Information disclosure, Denial of service and Elevation of privilege, 24

**TD**
Technical Documentation, 10

**TIR**
Technical Information Report, 24

**TR**
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**EU**
European Union, 6

# 1

# Introduction.
# Purpose of the document

The Programme for the Promotion and Development of Artificial Intelligence (AI) in the Catalan Health System strives to create an environment that facilitates the development and implementation of AI solutions for the optimisation of processes in the Catalan healthcare system.

The TIC Salut Social Foundation has created this guide with the aim of supporting the parties involved in establishing the regulatory requirements for IT applications applied in the field of health, including cases with AI algorithms. In the event that the aim is to implement the AI solution on the market as a medical device (MDSW), the requirements of European AI legislation must be met, as well as the regulatory requirements applicable to medical devices, that is, the European MDR or IVDR regulations and the Spanish royal decrees on medical devices, in order to obtain **CE marking.**

CE marking is a mandatory symbol for many products, in accordance with the approach of the new European legislative framework, which allows their marketing in Europe and with which the manufacturer indicates, as the sole responsible party, that it has evaluated the product and guarantees that it meets the safety and efficacy requirements established by the EU.

The organisation responsible for the product and its introduction into the market is the one that must undertake these regulatory obligations. For example, a company's registered address is in Spain, it will need to obtain a licence to establish a manufacturing facility for healthcare products, issued by the Spanish Agency for Medicines and Healthcare Products (AEMPS).

**This guide provides information on the process that must be followed in order to be able to label a product with the CE marking, mandatory before its routine use with patients,** and which can be divided into five blocks:

| | |
|---|---|
| 1 | **Qualification and classification as a health product.** |
| 2 | **Drawing up of technical documentation.** |
| 3 | **Implementation of a quality system to ISO 13485 ISO 42001 and MDR/IVDR standards.** |
| 4 | **Conformity assessment.** |
| 5 | **Registration of products and operators in EUDAMED and AEMPS for access to the EU market.** |

# 2

# Regulatory context.
# Relevant legislation and guides

The innovation process of a medical IT application (MDSW) is, in many ways, similar to any other sector. However, the healthcare products sector is a regulated sector and applicable regulatory requirements must be included. **It is of utmost importance to consider the clinical, technical, regulatory and business aspects from the beginning of the project, assessing the risks of each in order to reduce uncertainty and increase the chances of success.**

Healthcare products encompass a wide variety, from medical software to active implantable products, as well as in vitro diagnostic products. The regulation of these products in Europe began in 1993 with European directives and their transposition into the legislation of each country.

It is also necessary to consider other regulatory requirements such as data protection, cybersecurity and other regulations applicable to both the product and the activity, also depending on the markets we want to target. Thus, for software with AI, the requirements of the European AI regulation must also be met, which establishes additional requirements to ensure safe and ethical use.

In 2017, two new regulations were enacted that replaced the previous European directives on medical devices. These regulations are:

- Medical Devices Regulation (EU) 2017/745, in effect since 26 May 2021 [1], hereinafter MDR.
- Regulation of in vitro diagnostic medical devices (EU) 2017/746, in effect since 26 May 2022 [2], hereinafter IVDR.

As they are regulations, they are directly applicable throughout the EU and do not require transposition into national legislation, as was the case with previous directives. Initially, the regulations established a limited time to complete the transition to the new requirements, but amendments to these transitional periods were published in Regulation 2023/607 [3] for the legacy products (those still on the market with CE marking complying with the previous directives). **This guide sets out the requirements applicable to new products, that is, products that have not yet been introduced on the market.**

The MDR and IVDR regulations establish the essential requirements for medical devices at an EU level, thus allowing the free movement of products that meet these requirements within the European Union and the European Economic Area (EEA). However, each country may add additional requirements in order to regulate specific aspects or areas not fully regulated by these regulations. Thus, in Spain, Royal Decree 192/2023, which came into force on 23 March 2023 [4], establishes requirements applicable to general medical devices. For example, the labelling and instructions for use are required to be in Spanish, and it is also required that manufacturers and importers of health products operating within Spain first obtain a licence from the Spanish Agency for Medicines and Health Products (AEMPS), which authorises the exercise of their activity and includes the appointment of a responsible technician who has the necessary skills and qualifications. It is also mandatory to register all variants of products marketed in the country in national databases.

Currently, work is underway on a draft of a new royal decree to specifically regulate medical devices for in vitro diagnosis (IVD) [5], which will complete the national requirements for this product category.

# 3

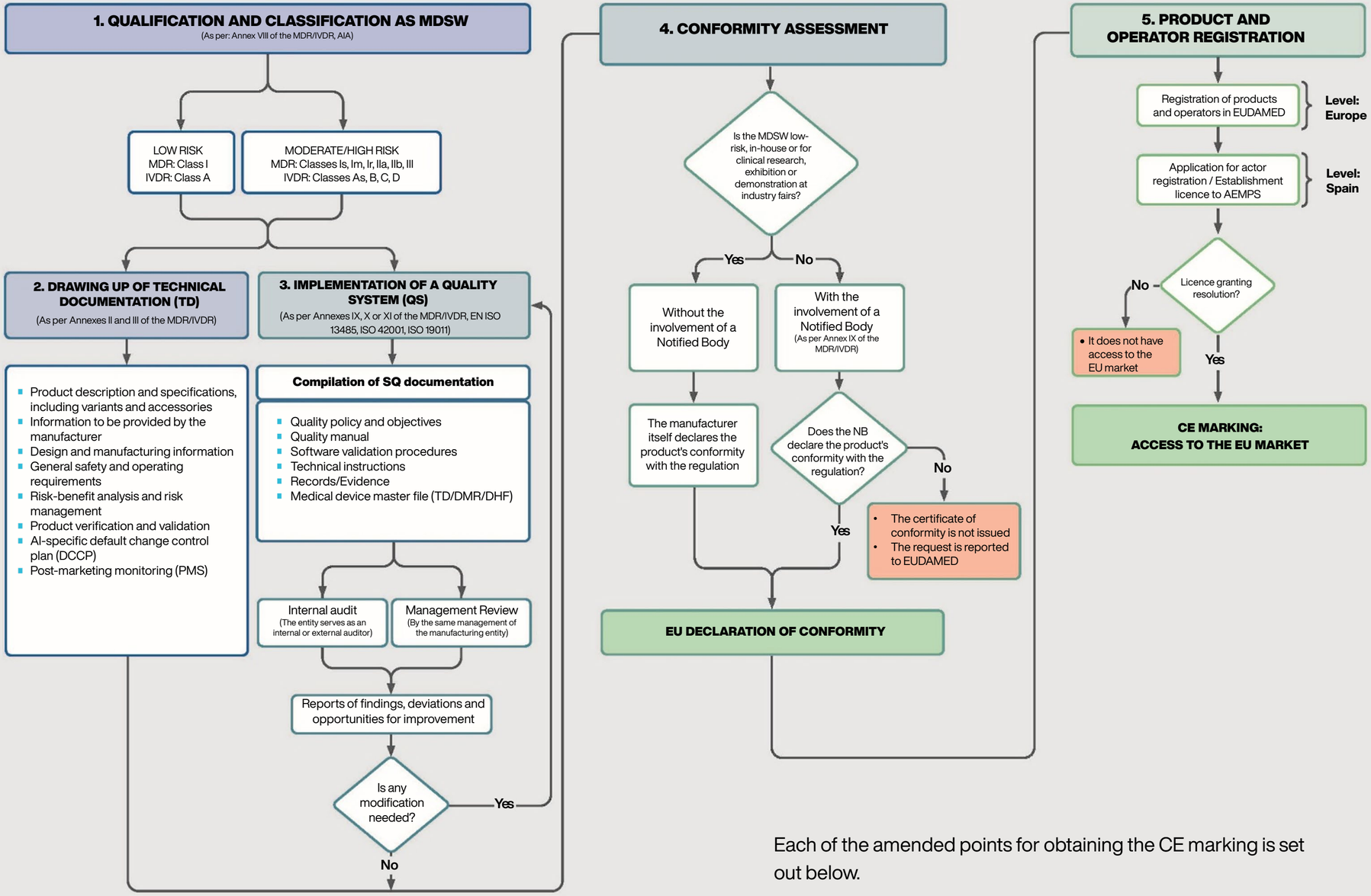
# Process for obtaining CE marking for a medical device

For healthcare products, including medical software (MDSW), the steps to obtain the CE marking in order to access the market are:

| | |
|---|---|
| 1 | **Qualification and classification as a health product.** |
| 2 | **Drawing up of technical documentation.** |
| 3 | **Implementation of a quality system to ISO 13485 ISO 42001 and MDR/IVDR standards.** |
| 4 | **Conformity assessment.** |
| 5 | **Registration of products and operators in EUDAMED and AEMPS for access to the EU market.** |

The general process for obtaining a CE marking, based mainly on the MDR and IVDR regulations, is shown in the following diagram:

## Process for obtaining the CE marking of an MDSW




Each of the amended points for obtaining the CE marking is set out below.

## 3.1 Qualification and classification as a health product

The qualification of a product consists of determining whether the requirements of the Medical Devices Regulation (MDR) or the In Vitro Diagnostic Regulation (IVDR) are applicable to the product in question, as defined within these regulations. This process is specific to each jurisdiction; for example, a product may be considered a medical device in Europe but not in the United States. It may also happen that the same algorithm is considered AI in Europe, but not necessarily in other countries. Furthermore, other situations and regulatory definitions must be taken into account, such as whether the product is listed in Annex XVI of the MDR or if it meets the definition of an accessory or in vitro diagnostic product.

### 3.1.1 Qualification and classification as an MDR/IVDR medical device

Once the qualification is complete, the next step is the **classification**, which determines the risk class of the product in accordance with the rules established in the MDR or IVDR. This stage is of utmost importance to define the specific requirements that the product must meet to obtain the CE marking and be marketed. Annex VII of both regulations establishes a risk-based classification.

Thus, for MDR we have products of class I, IIa, IIb and III;

| Classification | Comments | A notified body is involved |
|---|---|---|
| Class I* | Lower risk | No |
| Class IIa | Moderate to low risk | Yes |
| Class IIb | Moderate to high risk | Yes |
| Class III | Very high risk | Yes, and it is necessary to combine the quality management system certificate with an additional specific certificate of examination of the technical documentation. |

* Classes Is (sterile product) and Ir (reusable surgical instrument) do not apply to MDSW. Class Im (device with measurement function) could be applied in cases where the MDSW has a measurement function.

Thus, for MDR we have products of class I, IIa, IIb and III;

| Classification | Comments | A notified body is involved |
|---|---|---|
| Class A | Lower risk | No |
| Class B | Moderate to low risk | Yes |
| Class C | Moderate to high risk | Yes |
| Class D | Very high risk | Yes, and it is necessary to combine the quality management system certificate with an additional specific certificate of examination of the technical documentation. |

* Class As (sterile product) is not applicable to MDSW.

Not all computer applications used in a clinical setting are healthcare products, for example, big data processing applications broadly speaking, are not usually aimed at a specific individual patient, which means that they are not normally considered a medical device.

The application of these regulations is discussed in depth in the ***Guide for the qualification and classification of an IT application based on AI as a medical device in accordance with the European MDR/IVDR Regulations.***

### 3.1.2 Qualification and classification in accordance with Regulation (EU) 2024/1689 on artificial intelligence

The European regulation on artificial intelligence [6], was approved on 13 March by the European Parliament. This law classifies AI systems based on their risk and regulates them in accordance with a series of obligations and requirements. It establishes the following definition:

**Definition of artificial intelligence system in accordance with European Artificial Intelligence Regulation**

AI System: a machine-based system designed to operate with different levels of autonomy which can display adaptability after deployment and which, for explicit or implicit goals, infers from the input information it receives how to generate output results, such as predictions, content, recommendations and decisions, among others, that can influence physical and virtual environments.

The Artificial Intelligence Regulation came into force on 1 August 2024, and compliance therewith is mandatory from 2 August. However, some specific elements are applied in a staggered manner depending on the risk (six months for unacceptable risk systems and two years for high risk, limited risk and minimal risk).

Therefore, medical devices with AI must not only comply with the technical and safety criteria of the **MDR** or **IVDR** regulations, but must also follow the provisions of the artificial intelligence regulation and ensure compliance with the **data protection** rules of the GDPR. These regulations work together to ensure that AI applied to health is conducted in a safe, transparent and respectful manner with user rights.

## 3.2 Drawing up of technical documentation

Obtaining the CE marking requires the preparation of specific documentation for the product that one wishes to launch on the market. The **technical documentation** is set out in Annexes II and III of the MDR and IVDR regulations. Next we will see how the following documentation is applied to an MDSW.

**The minimum contents of the technical documentation in accordance with Annex II of the MDR and IVDR regulations are:**

a. Product description and specifications, including variants and accessories.
b. Information that the manufacturer must provide.
c. Design and manufacturing information.
d. General safety and operating requirements.
e. Risk-benefit analysis and risk management.
f. Product verification and validation.
   - Specific preclinical evaluation for MDSW incorporating AI/ML.
   - Specific clinical evaluation and research for MDSW incorporating AI/ML.

**The minimum contents of post-market technical documentation in accordance with Annex III of the MDR and IVDR regulations are:**

a. AI-specific default change control plan (DCCP).
b. Periodic safety reports and post-marketing surveillance (PMS).

A noteworthy new feature of the regulations is the establishment in Annex III of the minimum information that must be included in post-marketing follow-up.

This information must form part of the technical documentation, which must be continuously updated to ensure compliance with current regulations.

Below, we go into more detail on each of these points.

### 3.2.1 Product description and specifications, including variants and accessories

This **section includes the intended purpose, qualification and classification of the product**; the variants, accessories and products used in combination, such as computers and sensors; the operating principles of the device and its mode of action, scientifically proven where applicable (see the MDCG guide 2023-4) [7].

It is mandatory to include the **European Medical Device Nomenclature (EMDN) codes in the applicable documentation,** in accordance with MDCG 2021-12 [8]. Furthermore, **the unique identifier of the product family (basic UDI-DI)** must be added, which corresponds to section C of Annex IV and which the manufacturer has assigned to the product. The **product code and catalogue number** or another unambiguous reference that allows its traceability must also be included. **It is important that the version of the MDSW described within the scope of the technical documentation is also clearly identified.**

The general product description must make it possible to understand its basic design and main characteristics. Sufficient information must be provided to understand its intended purpose and functions. For example, the intended purpose should provide sufficient detail to explain the disease conditions, physiological or pathological conditions about which the program or application provides information. **Intended users must be identified** (i.e. medical professionals of a given specialisation, clinical nursing professionals, non-specialised individuals, etc.);

**the intended patient population; the diseases to be diagnosed, treated and/or controlled, and other considerations,** such as patient screening criteria, indications, contraindications, warnings, etc.

**The risk class** of the device and **the rationale for the classification rule or rules applied** in accordance with Annex VIII must be **specified**. The rationale must address each point of the selected classification rule. If multiple classification rules are applied, all of them must be identified and the strictest rules that result in the highest classification must be applied [9] [10]. There must be a rationale for why the software or application is considered a medical device. Often, it is **possible to divide the software into modules, so that some have a medical purpose and others do not.** Modules for medical purposes must meet the requirements of the MDR, must bear the CE marking and the safety of all modules as a whole must be validated. Also, it is necessary to indicate the software security classification in accordance with the EN 62304 standard on "software life cycle processes" and the rationale for it must be clearly identified.

In the case of innovative products (EU guide 2020/C 259/02 OJEU 7-8-2020) [11] **scientific evidence must be provided**, for example, clinical research with the product that demonstrates its functioning.

Furthermore, **a general description of the key functional elements of the product, for example, the structure of parts and components** (or architecture in the case of software) and the **functionality thereof must be included**. Typically, diagrams, photographs or schematics are provided, clearly indicating the different components of the product, as well as an explanation sufficient to understand this information. **Any accessories must be identified**: a second medical device or another type of product that is intended to be used in combination with the main product.

Finally, if necessary, reference must be made to **previous or similar generations** of the device, whether it has a sales history in different markets and whether similar products exist. In such a case, it is necessary to provide a comparison to show the main similarities and differences.

This section includes the information necessary to describe the characteristics of the product, including the purpose, qualification, classification, variants, accessories and products used in combination - such as computers and sensors - as well as the rationale to consider it a medical device in accordance with the MDR/IVDR regulations.

The technical documentation must include:

### 1 General description of the product and intended purpose

- **Trade name and general description**: provide the product's trade name, a general description of its basic design and its main features.
- **Intended purpose and users**: description of the intended purpose in sufficient detail to explain the physiological, pathological conditions or diseases that the device addresses or manages. Identify the intended users (medical professionals, clinical nursing professionals, non-specialists, etc.) and the patient population to be diagnosed, treated or monitored, also indicating selection criteria, contraindications and warnings, if applicable.

### 2 Identification and traceability

- **Nomenclature codes and identifiers:** the EMDN code of the medical device must be included as per MDCG 2021-12 [8], the unique identifier of the product family (basic UDI-DI), section C of Annex IV, and any other codes necessary for traceability, such as the product code or catalogue number. The MDSW version described in the documentation must be clearly specified.

### 3 Product classification

- **Risk class and rationale**: indicate the risk class of the device as per the MDR/IVDR and justify the rule or rules applied as per Annex VIII. If the product is classified by multiple rules, the most restrictive one applies.
- **Qualification as a medical device** provide clear rationale if the software or application meets the criteria to be considered a medical device in accordance with current regulations.

### 4 Software modularity and security requirements

- **Medical purpose and safety validation modules**: *Medical purpose and safety validation modules*: if the software is divided into modules, those that have a medical purpose must be identified and ensured that they comply with the MDR requirements (including CE marking). It must be verified that their safety as a whole meets the required standards.
- **Safety classification in accordance with EN 62304**: the software safety classification as per standard EN 62304 must be included, with clear rationale.

### 5 Innovative features and scientific evidence

- **Innovative features**: describe the innovative features of the device, if any, and provide scientific evidence of their functioning (as per the EU 2020/C 259/02 guideline) as a result of clinical research [8].

### 6 Functional elements and accessories

- **Description of key elements:** provide a description of the key components of the device (or architecture in the case of software) and its functionality, including diagrams, photographs or schematics to facilitate understanding.
- **Accessories and combined products:** identify any accessory or other product intended to be used in combination with the device.

### 7 Previous generations and similar products

- **Previous generations**: there must be a summary of previous generations of the product developed by the manufacturer, if they exist
- **Similar products**: provide a comparison with similar products available on the European Union market or other international markets.

## 3.2.2 Information to be provided by the manufacturer

This section describes the information that the product manufacturer must supply:

- **Labels that identify the product**: in the case of MDSW, the necessary information is typically included when the software is opened, when an option menu item is displayed, or in the dialogue "About this product..." or similar. Furthermore, the MDSW product labelling must comply with the requirements of Annex I, Chapter III of the MDR/IVDR regulations) and will include, whenever possible, symbols in accordance with the harmonised standard EN ISO 15223-1 "Symbols to be used with the information to be supplied by the manufacturer". The standard EN ISO 20417 "Healthcare products needs to be followed. Information to be supplied by the manufacturer" for the content of the product accompanying information. It is also necessary to ensure that any specific requirements of the relevant harmonised standards or any applicable common specifications (CS) are included in the labelling.
- **Instructions for use**: operating manual. In the case of software, Regulation 2021/2226 [12] applies; this establishes the rules for submitting the instructions for use to the user in electronic format "eIFU", complying with all additional aspects in order to guarantee access to updated information at all times.

## 3.2.3 Design and manufacturing information

In this section, first the **information needed to understand the different stages of product design and development** must be included, usually in accordance with the guidelines indicated in section 7.3 of the EN ISO 13485 standard "quality management system applicable to medical devices". In this way, information needs to be provided on the plan applied in the product development life cycle as well as the specific summarised information, which may be the following:

- The development plan.
- The baseline requirements.
- Information describing the development environment used (tools, elements, configurations, etc.).
- The schematic architecture of the development.
- The analysis and traceability of the requirements to the various risks identified and to the various tests and verification trials.
- Evidence of verification tests carried out, as appropriate, at a unitary function scale, integration of the various software components and system verification.
- Product usability validation test reports.
- Validation test reports that, under conditions that are representative of their use, achieve the declared intended purpose.
- List of known anomalies that remain in the released version with the assessment and rationale that they do not represent any significant risk to the user.
- Final review record and release of the specific version of the software to be deployed.

Information also needs to be included on the manufacture of the product which, in the case of an MDSW, will consist of the procedures related to the post-development stages of the product life cycle, which could be the following:

- Deployment and distribution of versions.
- Control tests carried out continuously.
- Problem management (bugs or anomalies).
- Change management.
- User service and assistance.

If tools or software are used to manage these processes, they must be duly validated. Furthermore, an installation and/or start-up process of the MDSW needs to be conducted at the user's location, information must be provided about the tests that shall be carried out.

Similarly, if subcontractors are used to carry out any process, they must be identified, indicating the addresses of the places where these tasks are carried out and providing copies of the service provision agreements and their EN ISO 13485 certificates or other relevant certificates, depending on the product or service they provide.

### 3.2.4 General safety and operating requirements

Annex I of the MDR/IVDR regulations includes a list of general safety and operational requirements (GDPR). Manufacturers have a legal obligation to declare (with signature and date) compliance with those provisions of the GDPR that are relevant and applicable to their product in order to declare compliance with the legislation.

The GDPR addresses general aspects of safety and performance for healthcare products and is expressed broadly speaking terms. In order to demonstrate and justify that the list of requirements is met and to fill it out more efficiently, **the relevant technical regulations of the state of the art (SOTA) and harmonised European regulations and/or common specifications must be applied, if applicable.** These regulations are more granular than the GDPR and are updated more frequently.

It should be noted that the MDR/IVDR regulations (Annex I, Chapter II) include the following general safety and performance requirements specific to MDSW:

- **(sec. 14.5/13.5)** Products intended to work together with other products or articles shall be designed and manufactured in such a way that interoperability and compatibility are reliable and safe.
- **(sec. 17/16)** Programmable electronic systems or products that incorporate programmable electronic systems and computer programs that constitute products in themselves.
- **(sec. 17.1/16.1)** Products incorporating programmable electronic systems, including computer programs, or computer programs that constitute products in themselves, shall be designed in such a way as to guarantee repeatability, reliability and operation in accordance with the intended use. In the case of first-failure conditions, appropriate measures shall be taken to eliminate or reduce the risks or the resulting deterioration in performance to the extent possible.
- **(sec. 17.2/16.2)** For products that incorporate computer programs, or for computer programs that constitute products in themselves, these shall be developed and manufactured based on the current state of the art, taking into account the principles of development life cycle, risk management, including information security, verification and validation.
- **(sec. 17.3/16.3)** The computer programs referred to in this section that are intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific characteristics of mobile platforms (for example, screen size and contrast ratio) and external factors related to their use (variable levels of light or noise in the environment).
- **(sec. 17.4/16.4)** Manufacturers must establish the minimum requirements relating to the physical medium, the characteristics of the computer networks and the computer security measures, including protection against unauthorised access, necessary to run the computer program as intended.
- **(sec. 23.4/20.4)** Information in the user manuals:
  - **Sec. 23.4 (f)** Where applicable, the necessary information that allows the healthcare professional to verify that the product is suitable and select the corresponding computer programs and accessories.
  - **Sec. 23.4 (a ter)** For products incorporating programmable electronic systems (including computer programs) or computer programs that constitute products in themselves, the minimum requirements relating to the physical support, the characteristics of computer networks and computer security measures (including protection against unauthorised access), necessary to run the computer program in the intended manner.

If one or more of the previous sections specific to MDSW apply to the product in question, a GDPR check-list has to be completed [13]. The following table is an example for an MD MDSW to which some sections apply, it may have the following configuration:

| **# GDPR**<br>*(Here are the sections applicable to the product, or not applicable and the rationale)* | **A/NA**<br>*(Whether the article applies to the product or not)* | **Rationale**<br>*(for NA)* | **Methods**<br>*(Here you can see what type of standards are used to prove compliance)* | **Standards, CS or other** | **ID Document**<br>*(Document of evidence of compliance with the GDPR that you provide)* |
|---|---|---|---|---|---|
| 17.1 Products [...] shall be designed in such a way as to ensure **repeatability, reliability** and operation in accordance with the intended use. In the case of first error conditions, **appropriate measures shall be taken to eliminate or reduce as far as possible the risks** or the consequent deterioration of operation. | A | - | Harmonised standard and state of the art (SOTA - current standards) | EN ISO 13485<br>EN 62304<br>EN 82304-1<br>EN ISO 14971 | TD Design chap.3<br>TD verification and validation report chapter 3 v |
| 17.2 The products [...] shall be developed and manufactured based on the current state of the art, taking into account the principles of development life cycle, risk management, including information security, verification and validation. | A | - | Harmonised standard and SOTA | EN 62304<br>EN 82304-1<br>EN ISO14971<br>EN 62366-1<br>AAMI 34971 | TD verification and validation report chapter 3 |
| 17.3 The programs [...] **intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific characteristics of mobile platforms** (for example, screen size and contrast ratio) and external factors related to their use (variable levels of light or noise in the environment). | A | - | Harmonised standard and SOTA | EN 82304<br>ISO 22989<br>IEEE11073-X | Verification and validation report Interoperability tests.<br>DT cap.3 |
| 17.4 Manufacturers will establish minimum requirements relating to the **physical medium, the characteristics of computer networks and computer security measures**, including protection against unauthorised access, necessary to run the computer program as intended. | A | - | Harmonised standard and SOTA | EN 82304<br>ISO 27799<br>ISO IEC 27002<br>MDCG 2019-16, EN 60601-4-5, FDA Guide, IG NB Guide | Verification and validation report<br>Data Integrity Tests.<br>Cyber Security Testing<br>DT chap.3 |

### 3.2.4.1 Applicable regulations

A list of harmonised standards for regulations is periodically published, and in special cases, common specifications are established (e.g. for Annex XVI products). When there is a harmonised standard specifically aligned to a GDPR requirement, its compliance grants a presumption of conformity (with the GDPR). Therefore, harmonised standards are essential tools for demonstrating regulatory compliance.

In order to maintain the state of the art (SOTA), the standards must be applied in the following order of priority:

- **Common Specifications (CS):** a set of technical and/or clinical requirements developed by the EC, other than a standard, that provide a means of complying with certain specific requirements of the MDR and IVDR regulations (for example: CS/EN ISO 18562-1, CS/EN ISO 20795-1).
- **Harmonised standards:** technical documents adopted by European standardization bodies to establish criteria for compliance with the GDPR. For example: EN ISO 13485, EN ISO 14971.
- **International standards:** standards developed by international organisations such as the ISO or the IEC, which establish requirements and practical improvements on a global scale. For example: ISO 9001, IEC 60601-1.
- **Local standards:** Standards applied at a national or regional level by standards bodies specific to a country or region. For example: UNE-EN ISO 10993-1, UNE-EN 1441.
- **Standards of good practice by sector:** standards that establish specific guidelines and requirements to ensure the quality and safety of a particular sector of the industry. For example: Good Distribution Practices for Medical Devices (GDPMD); good manufacturing practices for medical devices (GMP).
- **Own standards:** standards developed by a specific organisation to guide internal practices and ensure quality and consistency in processes. For example: standard operating procedures (SOPs); quality policies.

European technical standards include the **annexes Z,** which detail which points of the standard give presumption of conformity and which require additional evidence.

#### 3.2.4.1.1 The most relevant general rules are:

- EN ISO 15223-1 “graphic symbols for use on specific equipment”.
- EN ISO 20417 “healthcare products. Information to be supplied by the manufacturer”.
- EN ISO 14971 “risk management of medical devices”.
- EN 62366-1 “application of usability engineering to healthcare products”.
- EN ISO 14155 “Clinical research on medical devices for humans. Good clinical practices”.
- ISO/IEC 25010 “software systems and engineering - quality systems and software models".

#### 3.2.4.1.2 The most relevant technical standards are:

- ISO/IEC 62304 “Product life cycle processes” software” and, where appropriate, in combination with EN 60601-1 (chap.14) “general requirements for basic safety and essential performance” for electromedical equipment.
- IEC 82304-1 “health software safety” in combination with ISO/IEC 62304 for independent software.
- IEC 80001-1 “risk management for IT networks with MD”, which includes MDSW security, efficiency and data protection requirements.
- IEC TR 80002-1, which is the guide for the application of ISO 14971 (risk management) to software.

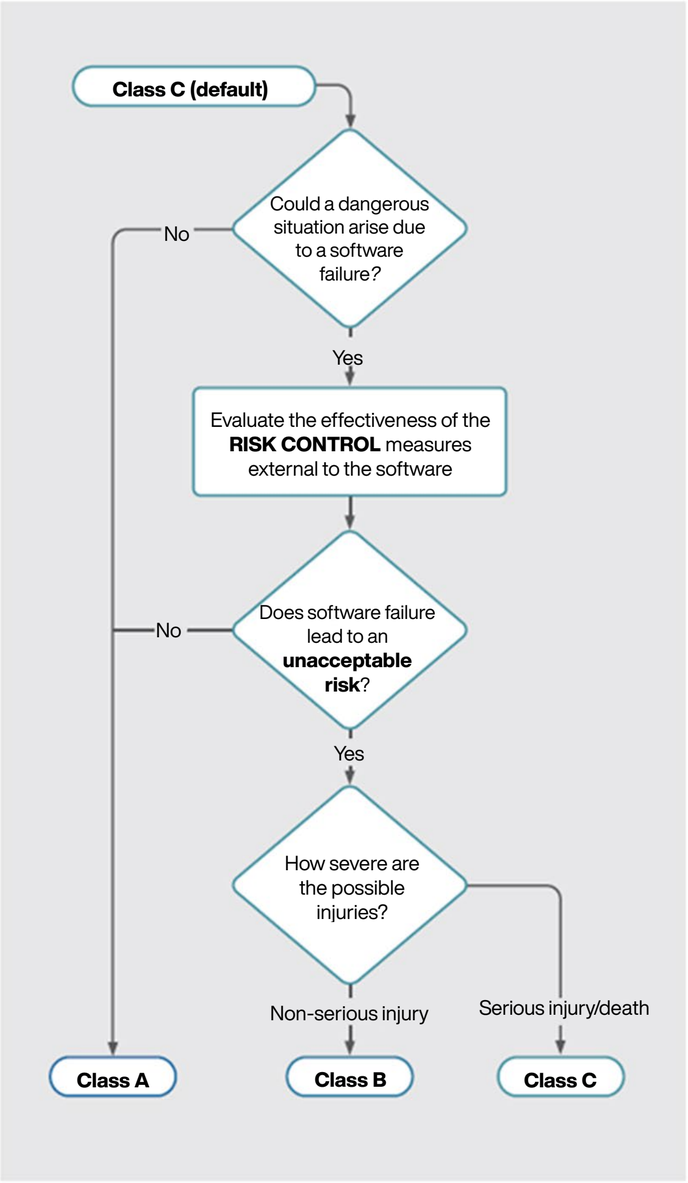
**The ISO/IEC 62304 standard applies to the entire software life cycle,** including development and maintenance processes; configuration management and troubleshooting [14].

A new development is that the rule makes a **security classification in accordance with risk level** (A, B and C), which allows one to modulate the requirements and necessary documentation of the device:

- **Class A:** the software cannot contribute to any hazardous situation; or it can only contribute to a hazardous situation that does not produce an unacceptable risk after considering risk control measures external to the software. *For example: an application that presents images on a backup screen.*
- **Class B:** the software may contribute to a hazardous situation that results in an unacceptable risk after considering risk control measures external to the software system, and the possible resulting harm is non-serious injury. *For example: an application that provides clinical decision support information - CDS.*
- **Class C:** the software may contribute to a hazardous situation that results in an unacceptable risk after considering risk control measures external to the software and the possible resulting harm is death or serious injury. *For example: an ICU monitoring application or a stroke diagnosis support program.*

Software security classification assignment

## Adaptation ISO/IEC 62304:2006. Software life cycle processes [14]

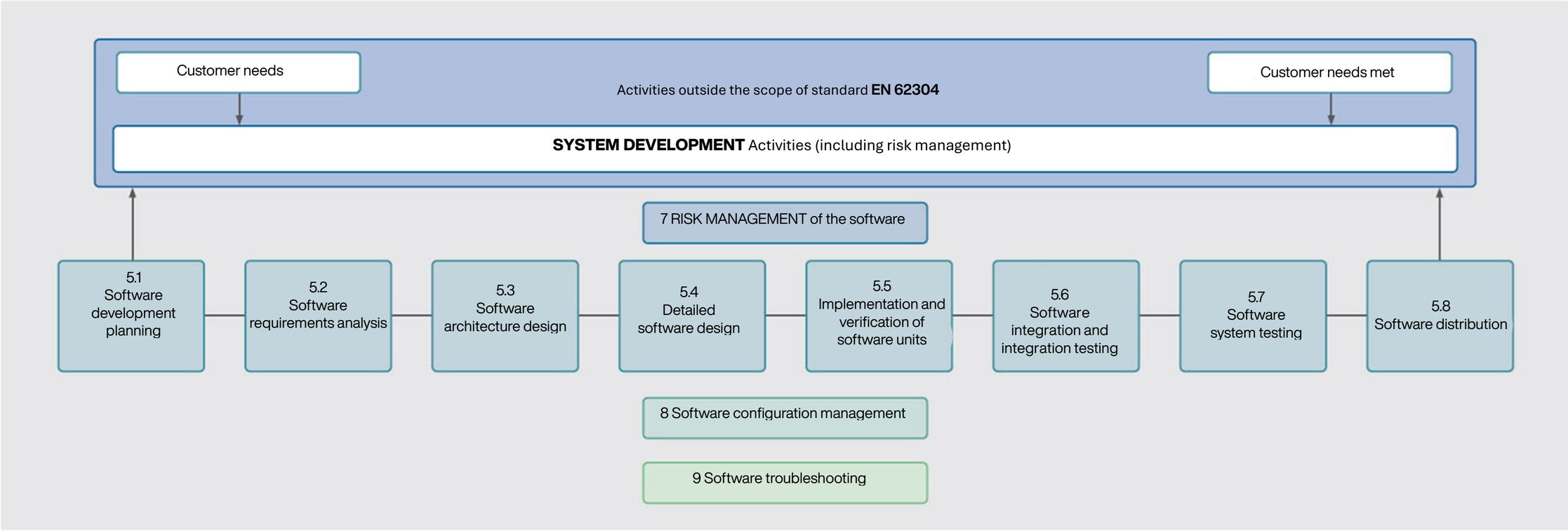



**This standard does not include the final validation of the medical device,** in other words, it does not include assurance that user specifications are met. Therefore, the scope of the standard extends to software verification. *For example: the software included in a blood pressure monitor designed as per the standard does not ensure that it correctly measures the patient's blood pressure. Additional testing and trials would be required with the final integrated product.*

The software development process as per ISO/IEC 62304 follows the following scheme:

## Adaptation ISO/IEC 62304:2006.

## *Medical device software. Software life-cycle processes*




A standards compliance check-list is recommended for requirements based on the software risk category. Direct references to where the technical file contains evidence of compliance with the requirements of the chosen standard should be present in any conformity check-list submitted.

If a standard other than the harmonised version has been used, a detailed document explaining how the requirements of the harmonised version have been met or exceeded must be provided together with the related evidence.

Thus, for example, this standard details the deliverable elements depending on the A, B or C classification of the application.

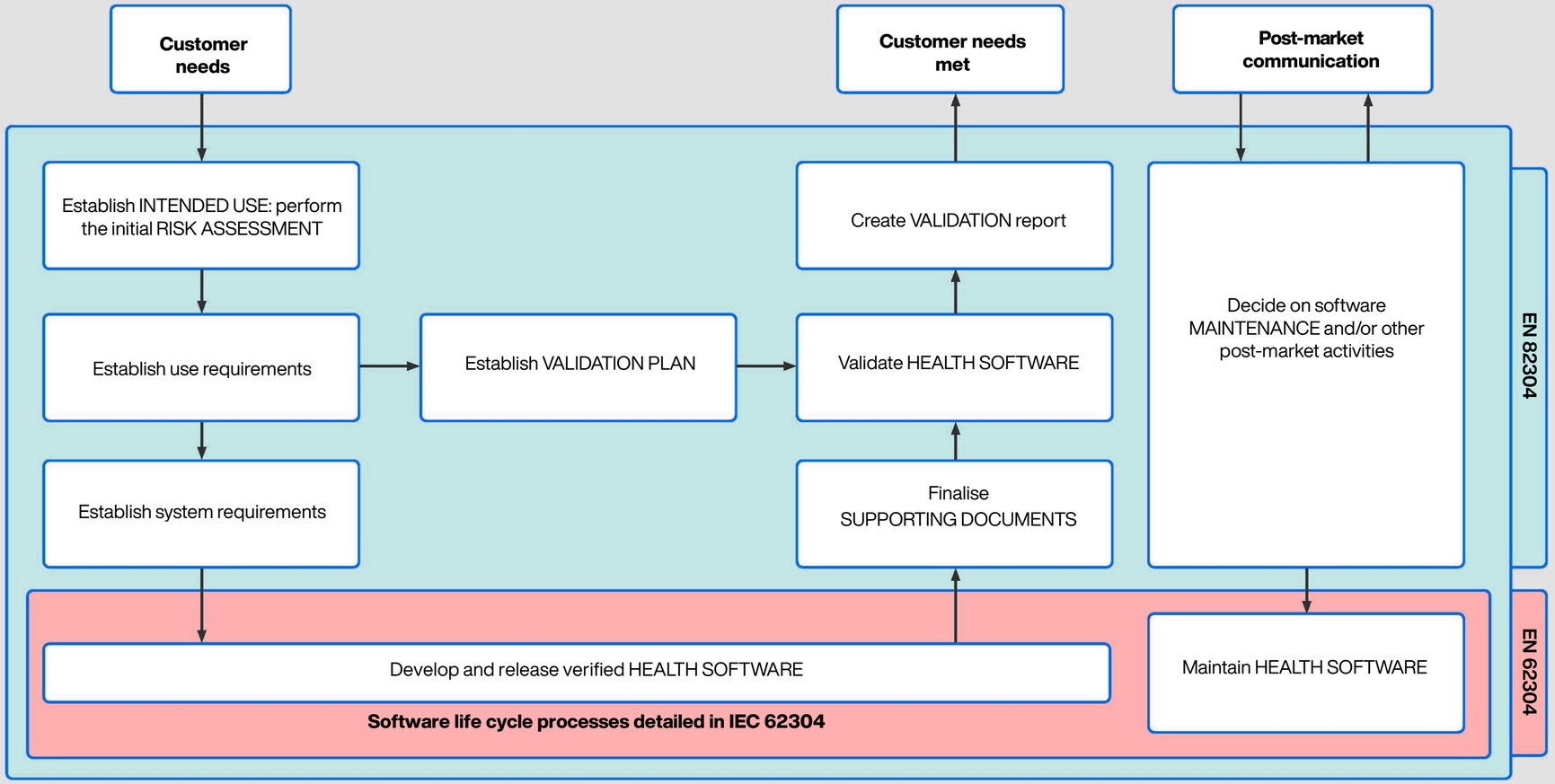
## Summary of requirements by software security class

Adaptation EN 62304:2006. *Medical device software. Software life-cycle processes.*

| Chapters and sections | | | Class A | Class B | Class C |
|---|---|---|---|---|---|
| Chapter 4 | All requirements | General requirements | X | X | X |
| 5.1 | 5.1.1, 5.1.2, 5.1.3, 5.1.6, 5.1.7, 5.1.8, 5.1.9 | Planning | | X | X |
| | 5.1.5, 5.1.10, 5.1.11 | Planning, tools, configuration | | X | X |
| | 5.1.4 | Standards, methods and tools | | | X |
| 5.2 | 5.2.1, 5.2.2, 5.2.4, 5.2.5, 5.2.6 | Requirements analysis | X | X | X |
| | 5.2.3 | Risk control measures | | X | X |
| 5.3 | 5.3.1, 5.3.2, 5.3.3, 5.3.4, 5.3.6 | Architecture | | X | X |
| | 5.3.5 | SW element segregation | | | X |
| 5.4 | 5.4.1 | Detailed design - SW units | | X | X |
| | 5.4.2, 5.4.3, 5.4.4 | Development and verification of SW units | | | X |
| 5.5 | 5.5.1 | Implementation of SW unit | X | X | X |
| | 5.5.1, 5.5.3, 5.5.5 | Procedure, adaptation and verification of SW unit | | X | X |
| | 5.5.4 | SW unit adaptation criteria | | | X |
| 5.6 | All requirements | SW integration and testing | | X | X |
| 5.7 | All requirements | SW system tests | | X | X |
| 5.8 | 5.8.4 | Release | X | X | X |
| | 5.8.1, 5.8.3, 5.8.5, 5.8.6, 5.8.7, 5.8.8 | SW verification and documentation | | X | X |
| 6.1 | 6.1 | SW maintenance plan | X | X | X |
| 6.2 | 6.2.1, 6.2.2, 6.2.4, 6.2.5 | Problem analysis | X | X | X |
| | 6.2.3 | Change request analysis | | X | X |
| 6.3 | All requirements | Implementation of SW modifications | X | X | X |
| 7.1 | All requirements | SW risk analysis | | X | X |
| 7.2 | All requirements | SW Risk control | | X | X |
| 7.3 | All requirements | SW risk verification | | X | X |
| 7.4 | 7.4.1 | SW security analysis and modification | X | X | X |
| | 7,4.2, 7.4.3 | Risk review and modifications | | X | X |
| 8 | All requirements | SW setting management | X | X | X |
| 9 | All requirements | SW troubleshooting | X | X | X |

EN 82304 applies to stand-alone software [15] and deals with the elements of the software environment, thus applying it in combination with EN 62304, as indicated in the following diagram:

## Adaptation. Software environment elements in combination with EN 62304



#### 3.2.4.1.3 AI/ML-based IT application standards are:

- ISO/IEC 42001: information technologies - artificial intelligence - management system.
- BS/AAMI 34971: application of ISO 14971 (risk management) to AI.
- ISO/IEC TR 24028 IT: artificial intelligence - overview of trust in artificial intelligence.
- ISO/IEC TS 4213 IT: Artificial intelligence - evaluation of machine learning classification performance.
- ISO/IEC 23894 IT: artificial intelligence - guidance on risk management.
- ISO/IEC 5338 IT - artificial intelligence - AI system life cycle processes.
- ISO/IEC 5339 IT: artificial intelligence - guidance for AI applications.
- ISO/IEC 5259-2 IT- AI: data quality for analytics and ML - data quality measures.
- ISO/IEC 5259-3 IT- AI: data quality for analysis and ML - data quality management requirements and guidelines.
- ISO/IEC 5259-4 IT-AI: data quality for analysis and ML - data quality process framework.
- ISO/IEC 12207: software systems and engineering - software life cycle processes.

#### 3.2.4.1.4 The most relevant general AI rules are:

**These standards are developed by the Joint Committee ISO/IEC JTC 1/SC 42, which continues to work on their evolution and expansion. Currently, there are several published standards in force such as:**

- ISO/IEC 22989: artificial intelligence. Concepts and terminology.
- ISO/IEC 4213: Information technology - Artificial intelligence - Machine learning classification performance evaluation.
- ISO/IEC TR 24027:2021: information technology - artificial intelligence (AI) - bias in AI systems and AI-assisted decision-making.
- ISO/IEC 38507:2022: information technology - IT governance - governance implications of the use of artificial intelligence by organisations.
- ISO-IEC 23053: for artificial intelligence systems using machine learning.
- ISO-IEC TR 24028: overview of reliability in artificial intelligence.
- ISO-IEC TR 24368 artificial intelligence - overview of ethical and social concerns.
- ISO-IEC TR 24030: Use cases.
- ISO-IEC TR 24029-1: assessment of the robustness of neural networks - part 1: overview.
- ISO-IEC TR 24372: overview of computational approaches for AI systems.
- ISO-IEC TR 29119-11: guide for testing AI-based systems.

It is necessary to stay up to date with the decisions of the ISO/IEC JTC 1/SC 42 committee and the harmonisation of standards with regulations.

### 3.2.5 Risk-benefit analysis and risk management

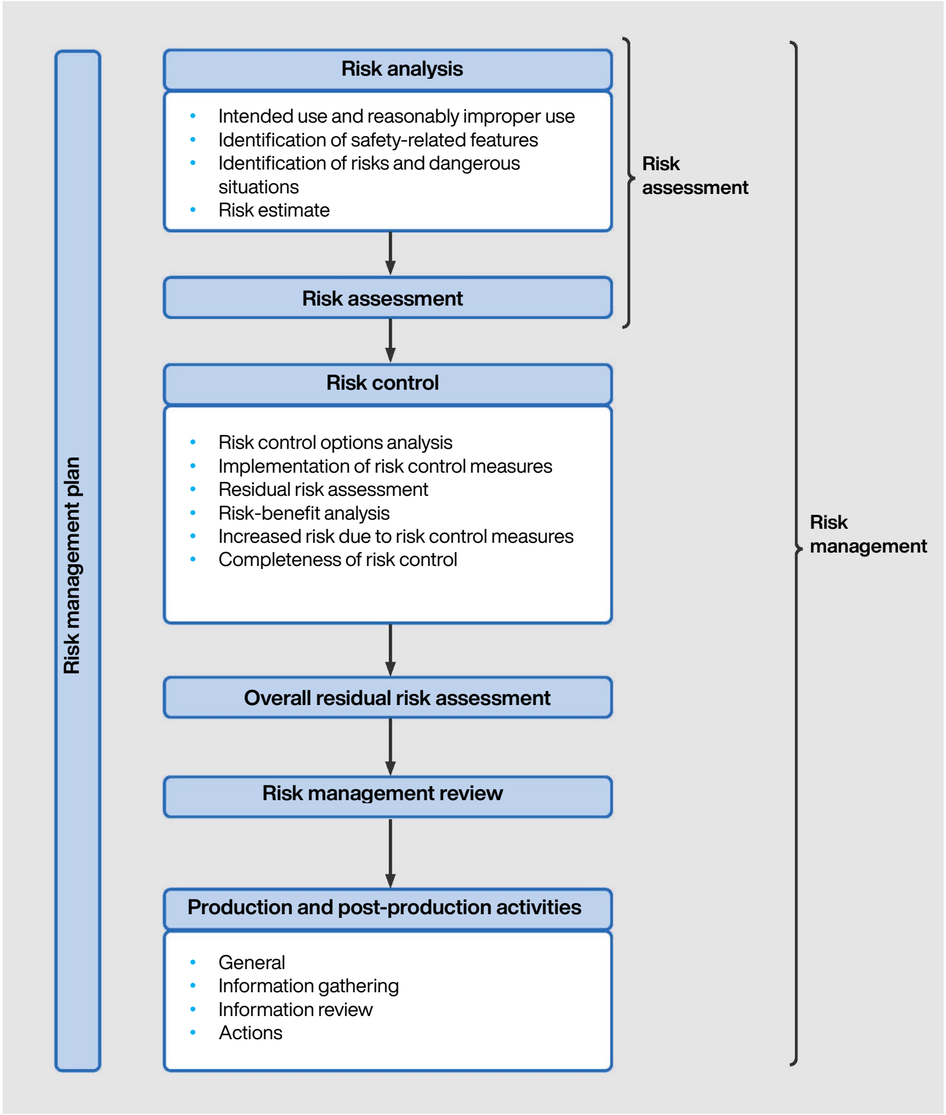
The regulations establish the need to include a **risk management system as part of the quality management system and associated with each product that you want to market.**

A specific plan must be established to manage the risks that may be associated with the product and the risk analysis must be included in the product's technical documentation. The procedure used to allow the correct application of the regulations to be evaluated must also be included.

The standard that generally deals with risk management is EN ISO 31000, but **when analysing risks related to medical devices, the EN ISO 14971 standard is the specific harmonised standard that must be applied.**

The risk management process as per EN ISO 14971 follows this flowchart:

**Adaptation. Risk management process as per EN ISO 14971.**



Furthermore, documentation must be submitted showing the **secure design and continuous maintenance of the healthcare product in terms of cybersecurity**. The manufacturer must clearly indicate the regulations used, aligned with the state of the art at all times and used to comply with the relevant GDPR.

It is necessary to be able to show that a security risk management system has been applied throughout the secure development lifecycle. Some examples include:

- Security risk management plan, security risk assessment and evidence of the incorporation of security risk controls as identified requirements and evidence of their subsequent verification and validation.
- Built-in protections for identified threats must align with the principles of confidentiality, integrity, and availability [16].
- Technical documentation that clearly identifies the method for identifying continuous monitoring of threats and vulnerabilities, as well as the methodologies used, for example, STRIDE, analysis of attack surfaces, data flows, etc. The documentation must show how cybersecurity is an active part of the device's ongoing post-market surveillance.
- Documented tests for monitoring the risks associated with vulnerabilities in software of unknown origin (SOUP) and their mitigation.

When necessary, **externally certified/accredited penetration testing** must be provided, including the certification data of the third party that carries them out as well as the relevant reports.

Furthermore, when using cloud-based software providers, it is necessary to document the activities and those responsible for monitoring and subsequent surveillance once the product is on the market as well as for the reporting of security issues.

It is also necessary to consider the specific content regarding MDSW risk management as per the IEC TR 80002-1 standard. “Guidance on the application of ISO 14971 to medical device software".

In the case of AI software, it is necessary to consider both ISO/IEC 23894 “Information technology - Artificial intelligence - Guidance on risk management”, which provides requirements in relation to the general process to be applied, as well as the **AAMI TIR 34971 “Application of ISO 14971 to AI”, which is specific to MDSW, based on AI/ML.**

The latter document, AAMI TIR 34971, addresses the following risks associated with data management, feature extraction, algorithm training, evaluation, bias, health inequality, security and cybersecurity:

**Data quality** (5.3.2.2 AAMI TIR 34971)

- Incorrect data
- Incorrect handling of outliers
- Incomplete data
- Subjective data
- Inconsistent data
- Atypical data

**Bias** (5.3.3.3 AAMI TIR 34971)

- Selection bias
- Confused variables
- Not normal
- Proxy variables
- Implicit bias
- Group attribution bias
- Experimental bias

**Data storage/security/privacy** (5.3.4.3 AAMI TIR 34971)

- Privacy failures
- Inability to contact the patient

**Overconfidence** (5.3.5.2 AAMI TIR 34971)

- Overconfidence
- Perceived risk
- User workload
- Self-confidence
- Variation in social confidence

**Adaptive Systems (continuous learning)** (5.3.6 AAMI TIR 34971)

- New low-quality data
- Change control
- Usage errors
- Validation maintenance
- Frequency of changes

**Other safety considerations** (5.3.7 AAMI TIR 34971)

- Lack of confidence
- Data drift (e.g. changes in clinical practice...)
- Excess data
- Fragmented data

To properly assess the specific risks of an MDSW with AI, it is of utmost importance to include qualified professionals, such as a clinical expert, in the development process. This will ensure that all relevant aspects of the design, development, production and clinical use of the product are covered. This participation will allow the risks identified in each phase of the product's life cycle to be mitigated and minimised, ensuring safe and effective application in the medical field.

The mitigation of risks related to use error must cover the requirements established in section 5 of Annex I of the MDR by applying a usability engineering process or "usability". For usability assessment, please refer to the MDR requirements indicated in Annex I, as well as the EN 62366-1 standard.

**Risk management should be understood as a continuous iterative process throughout the entire product life cycle and one that requires periodic systematic updating in order to allow for a continuous assessment of the product's benefit-risk relationship.**

### 3.2.6 Product verification and validation

Product verification and validation is a key requirement of technical documentation. This includes carrying out verification and validation tests and trials as well as the methods used that are established in the preclinical verification plan that must form part of the MDSW development plan. The technical documentation must provide the results and a critical evaluation of the verification and validation tests carried out. Linking them to the effectiveness of risk control measures and the general applicable safety and performance requirements.

A complete analysis of software requirements must be included, addressing:

- Functional and non-functional requirements (timing, emphasis, linguistic scalability, etc.).
- Requirements derived from possible software defects and information derived from previous designs.
- Requirements relating to the use of the device, for example, installation.
- Evidence that the requirements analysis considered Annex I Chapter II 17.4 of the MDR or Annex I Chapter II 16.4 of the IVDR, especially the hardware requirements, the characteristics of the computer network (if applicable) and the security requirements in relation to access control and unauthorised access.
- Evidence in the documentation of information relating to functionalities, capabilities, input data, output data, system interfaces, alarms, security requirements, cybersecurity requirements, user interface requirements, database requirements, installation requirements, requirements related to operation and maintenance methods, regulatory requirements, etc.

The architectural design must be represented graphically (for example, UML or block diagrams) and must include:

- The structure of the system elements and their internal and external interfaces.
- Externally sourced software components (SOUPs), with a tabular list that includes the name, version, developer and functional requirements.
- Segregation measures for risk control, when necessary, as per the software risk classification in accordance with **EN 62304.**

For MDSW classified as **B** or **C** in accordance with EN 62304, a refinement of the architectural design is required that describes in detail the software units, their functions and the associated interfaces. This should include information about inputs and outputs of each unit.

Regarding verification and validation, the technical documentation must include:

- Plans, protocols and reports of all tests carried out (internally, in simulated or real environments).
- Details about the testing environment, including the use of automated tests, test scripts and recorded results for unit, integration and full system tests.
- Evidence of the correct operation of the software on different verified machines and operating systems, as well as on mobile platforms, complying with GDPR 17.3.

For the final validation of the software, it is mandatory to provide tests that demonstrate compliance with its intended purpose as per **EN 82304-1**. Furthermore, traceability matrices are needed that relate specifications and tests, including verification of SOUP components.

Furthermore to individual reports, it can be very useful to present **a global summary report of all verification and validation trials** that identifies the following:

- The version of the verified/validated software.
- A summary of the results of the completed tests.
- Details of any unresolved defects or anomalies, with an assessment of their risk and a rationale for why they are acceptable.
- Conclusion on the acceptability of the final results.
- Details of the people who approve the summary.

Finally, the technical documentation must detail how the validated version of the software is created, published and distributed. This includes the procedures followed, the deployment environment, and the mechanisms for delivering the software to end users. This process is usually documented in the Release Notes.

#### 3.2.6.1 Specific preclinical evaluation for MDSW incorporating AI/ML.

For MDSW, including AI, we must establish additional verification and validation tests related to their specific risks and include them in the preclinical verification plan and the MDSW development plan. Some of the most important documents and regulations are listed below:

**Interoperability tests** (ISO IEC 22989 and the ISO/IEEE 11073 family of standards)

Interoperability allows different products to exchange information, communicate and work together as intended.

**Compatibility tests**

Compatibility is linked to different usage configurations and platforms, as well as maintaining compatibility with data from previous installations, allowing for joint operation as intended.

**Cybersecurity Testing** (MDCG 2019-16, IEC TR 60601-4-5, Guide IG NB, IEC 81001-5-1)

Cybersecurity review is performed with penetration and data integrity testing and must be maintained throughout the product lifecycle.

**Data Integrity Testing** (ISO 27799, ISO IEC 27002)

Data integrity review must be maintained in all processes associated with data communication and storage.

**Data protection tests**

Data protection is associated with the European requirements of high-risk personal data protection regulations, such as those associated with a person's health.

**For the MDSW with AI**, as per the IG-NB guide [17], additional requirements can be incorporated associated with the various development phases:

**Phase 1. Intended use and stakeholder requirements**

a) Intended use
b) Intended user, intended context of use
c) Stakeholder requirements
d) Inputs for risk management and clinical evaluation
   - Sufficiency of training, validation and test data (ISO/IEC 4213, AAMI 34971)
   - Data quality (population, user environment, etc.)
   - Explainability
   - Predictibility
   - Usage errors

**Phase 2. Software requirements**

a) Functionality and performance
b) User interface
c) Additional software requirements
d) AI Security Risks

**Phase 3. Data management**

a) Collection of training, validation and test datasets
b) Data tagging
c) Data (pre)processing procedure
d) Documentation and version control

**Phase 4. Model development**

a) Preparation
b) Training
c) Evaluation
d) Documentation

**Phase 5. Product development**

a) Software development
b) Supporting material
c) Usability validation
d) Clinical evaluation

**Phase 6. Product launch**

It is recommended to proceed in a similar way to incorporate the requirements for the subsequent development phases:

**Post-phase 1. Production, distribution, installation**

**Post-phase 2. Post-marketing surveillance**

**Post-phase 3. Uninstallation and cessation of use**

### 3.2.6.2 Specific clinical evaluation and research for MDSW incorporating AI/ML

The manufacturer must specify and justify the level of clinical evidence necessary to demonstrate compliance with the relevant general safety and performance requirements. This level must be appropriate taking into account the characteristics of the product as well as its intended purpose.

Therefore, manufacturers must plan, conduct and document a clinical evaluation in accordance with Part A and B of Annex XIV of the MDR and Chapter I and II of Annex XIV of the IVDR.

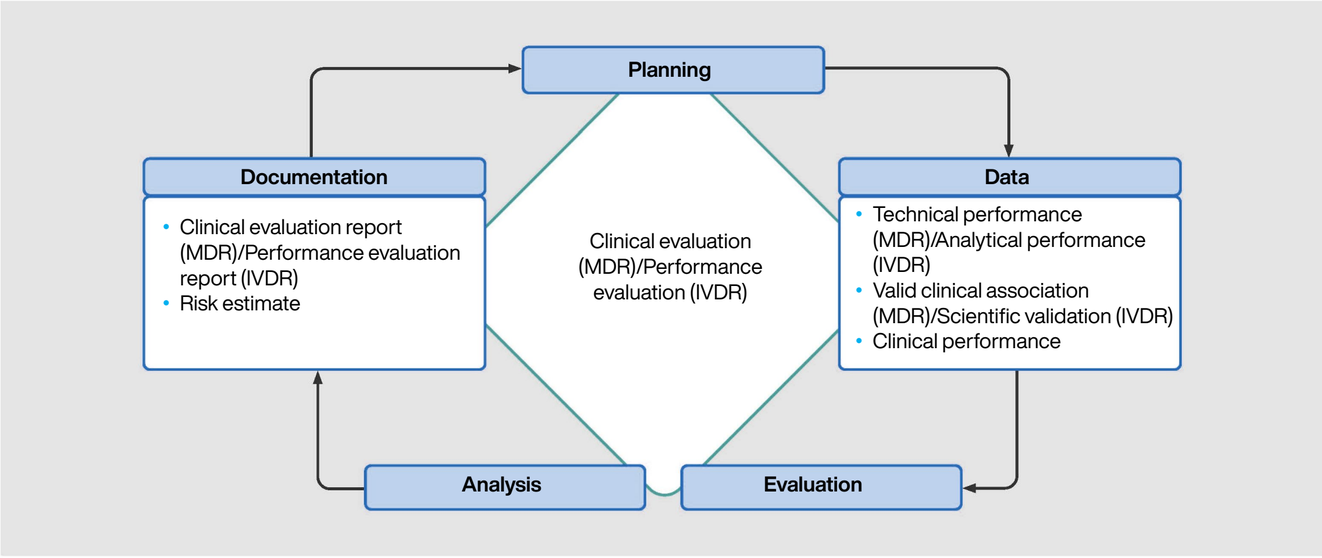
**For the assessment of the clinical evaluation, the following documents must be provided, providing a rationale, where appropriate, if there is any non-applicable element:**

- Clinical development strategy (**applicable only for high-risk products**);
- Clinical development plan (applicable when one or more clinical investigations have been carried out to validate the AI algorithm or model);
- Clinical evaluation plan for the device;
- Clinical evaluation report of the device;
- Post-market clinical follow-up plan (PMCF);
- PMCF evaluation report.
- Safety and Clinical Performance Summary Report (SSCP) **for MDSW class III (in accordance with Article 32).**

**The clinical evaluation of computer applications is conducted following the MDCG 2020-1 guide. *Guidance on clinical evaluation (MDR) / performance evaluation (IVDR) of medical device software.***

## Overview of the stages of CLINICAL EVALUATION (MDR) / PERFORMANCE EVALUATION (IVDR)

Adaptation of: *Medical Device Coordination Group. (2020). Guidance on Clinical Evaluation (MDR)/Performance Evaluation (IVDR) of Medical Device Software.*




In many cases, MDSWs propose innovative solutions to solve a specific clinical problem. Therefore, broadly speaking, it is necessary to establish clinical research in order to validate in a real-world use environment that the clinical indications of the MDSW described by its manufacturer are achieved. When the European Database Health Space (EDHS) is operational, the incorporation of data from this source could be considered.

**In the case of MDSW with AI/ML, the controlled test spaces (sandboxes) offer the possibility of using a controlled experimentation environment during development and before product commercialisation.**

In any case, the clinical evaluation plan must include all the strategies used to gather sufficient evidence and clinical tests that show that the specified intended purpose is achieved.

### 3.2.7 AI-specific default change control plan (DCCP)

In accordance with the European AI regulation, any change that could affect the compliance of a high-risk AI system with the regulation, such as a change in the operating system or software architecture, or a change in the intended purpose of the system, should be considered a "substantial amendment". This means that the AI system is considered new and undergoes a new conformity assessment. However, changes in the algorithm and operation of AI systems that continue to "learn" after their introduction to the market, provided that these changes have been predetermined by the supplier and assessed during the initial conformity assessment, shall not be considered substantial amendments.

### 3.2.8 Post-marketing surveillance (PMS)

The technical documentation must contain the following information on post-marketing monitoring:

- The post-marketing surveillance plan (PMS plan), in accordance with Article 84 of the MDR and 79 of the IVDR.
- The post-marketing surveillance report (PMS), in accordance with Article 85 of the MDR and 80 of the IVDR, is **specific for class I/classes A and B medical devices.**
- Periodic safety update report (PSUR), in accordance with article 86 of the MDR and 81 of the IVDR, **for medical devices in classes IIa, IIb or III/classes C and D.**
- PMCF post-marketing clinical follow-up plan (as detailed in Part B of Annex XIV), PMCF study protocols and PMCF assessment report (or, where applicable, a rationale as to why a PMCF is not applicable).
- A copy of the post-marketing monitoring procedure and the procedures established to ensure compliance with the obligations arising from the provisions on surveillance and incident reporting established by articles 87 to 90 and 92 of the MDR and 82 to 85 and 87 of the IVDR.

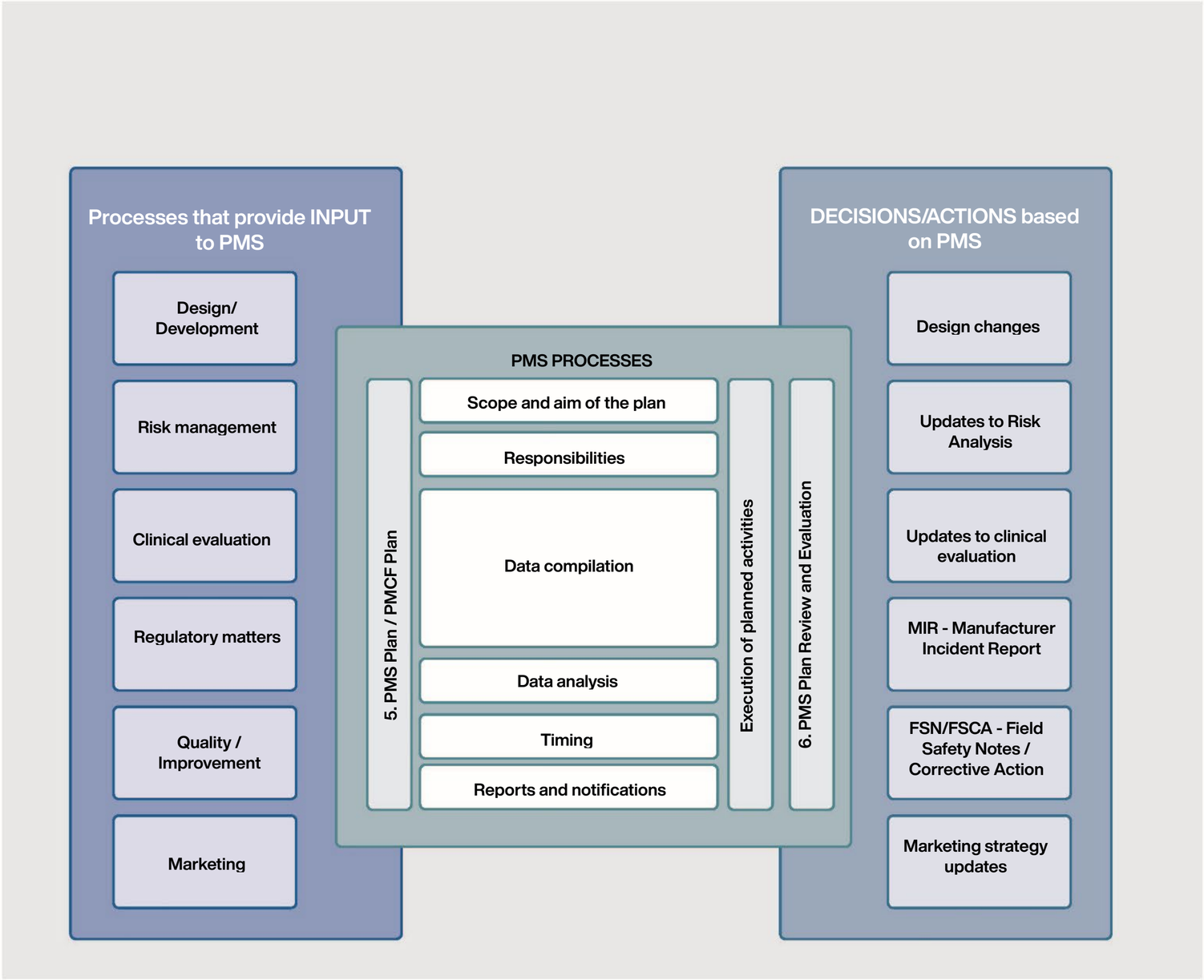
The manufacturer must also provide the following post-marketing surveillance data for the last five years:

- Market history.
- Sales volumes worldwide and in the EU.
- Complaints data and trend analysis of market feedback information.
- Surveillance data for serious incidents as well as trend analysis for non-serious incidents.
- Data from clinical studies, including post-marketing clinical monitoring, as well as registries and data from other PMS sources.
- Modifications made and/or corrective actions taken after reportable incidents as well as reviews made in the risk management file.

The reference document ISO TR 20416 of "post-market surveillance for manufacturers" **schematically describes the following post-marketing monitoring process,** with many sources of information input and providing information as output that serves to take actions and decisions in different organisational areas:

## PMS process

Adaptation of the ISO/TR 20416:2020. *Medical devices - Post-market surveillance for manufacturers.*



## 3.3 Implementation of a quality system as per ISO 13485 ISO/IEC 42001 and MDR/IVDR

One of the other foundations of the CE marking is the quality management system which provides a structure for managing the complete life cycle of the MDSW. Manufacturers of medical devices must provide comprehensive documentation as evidence of the safety of their products and the effectiveness of their quality processes.

### 3.3.1 Documentation as per ISO 13485 and ISO/IEC 42001

**The benchmark standard for quality systems for medical devices including MDSW is ISO 13485** of "Health products - quality management systems - requirements for regulatory purposes", which establishes the necessary elements of the system on a global scale. The requirements of each regulatory area or jurisdiction must be included, for example MDR/IVDR for Europe, those of the royal decrees for Spain and decrees for Catalonia (applicable to the distribution of products). The standard, in addition to constituting the requirements for the establishment, maintenance and improvement of the quality management system, details the roles and responsibilities of the management of the manufacturing entity and the management of resources for the operation of both the system and the production of the product itself.

**For quality systems associated with organisations that develop AI systems, the 2023 standard ISO 42001 "Information technologies - artificial intelligence - management system" must also be applied**. This addresses the unique challenges posed by AI, s uch as **ethical considerations, transparency and continuous learning.**

For organisations, it establishes a structured way to manage the risks and opportunities associated with AI and balance innovation with governance. For AI systems, it is also necessary to consider the IG-NB guide developed by the notified bodies of Germany, which establishes review criteria for AI systems.

The elements of the quality management system documentation are presented in the following hierarchy:

I. **Quality policy and objectives:** establishes the general principles and quality objectives that guide the organisation's quality management system. The quality policy defines the organisation's commitment to quality and customer satisfaction.

II. **Quality manual:** a document that summarises the key procedures and processes used to ensure the quality of products or services.

III. **Software validation procedures:** specific documents that describe the processes and requirements for validating the software used in the manufacture or quality control of medical devices.

IV. **Technical instructions:** specific technical details on how to conduct activities or processes within the organisation. They may include detailed information on equipment operation, test methods, safety requirements, etc.

V. **Records/evidence:** includes records that document the performance of activities and compliance with the requirements of the quality management system.

VI. **Medical Device Master File (MDF/ DMR/ DHF):** technical and design documentation associated with medical devices.

### 3.3.2 Implementation of a quality management system

In order to demonstrate the implementation of a quality system, **it is necessary to have evidence of the records of all relevant processes.** It is especially critical to have evidence of having applied a **design, development and deployment procedure** of the programs or applications with all related documentation. Also, for those post-marketing processes where evidence has not yet been collected (for example, complaints handling and surveillance) **simulations must be carried out to show that the process is defined** demonstrating that it shall be effective if applied.

It is also important to have defined performance indicators (KPIs), process indicators, and establish quality system improvement objectives.

Finally, an internal audit of all processes must be carried out as well as a quality system review report by the management of the manufacturing entity, before the ON audit.

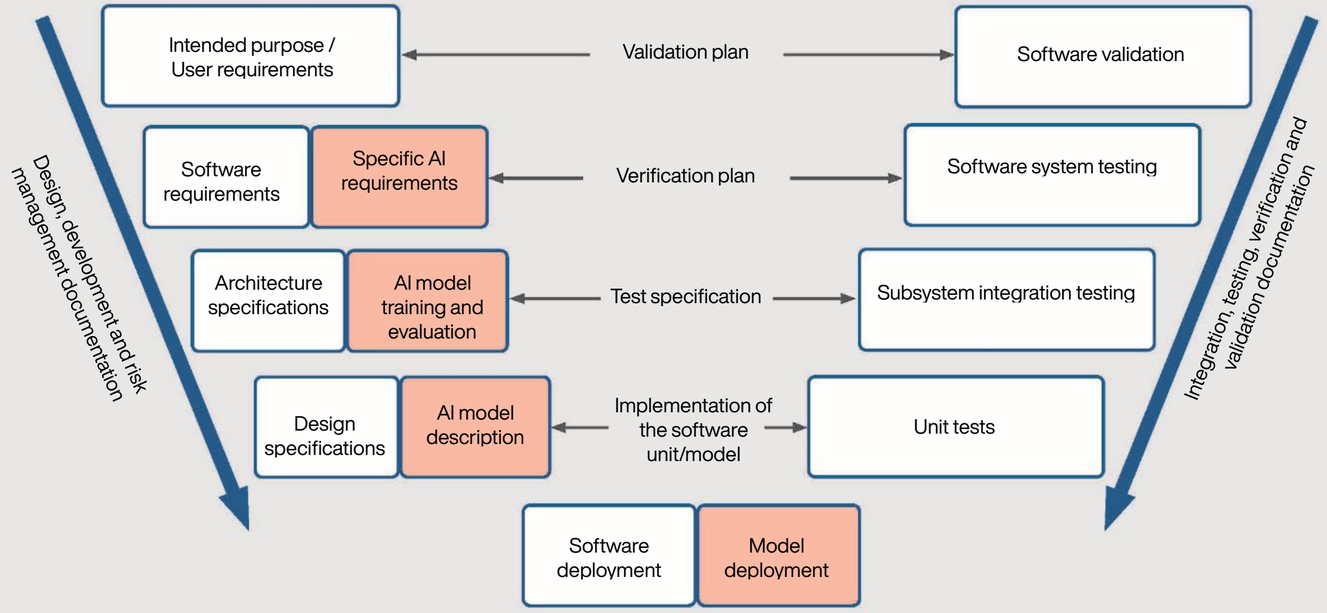
### 3.3.3 Software design and development procedure

The design and development process of an MDSW must include the requirements of the ISO 13485 quality standards, specific ones such as ISO/IEC 62304 and guides such as ISO TR 80002-3 of “Medical device software - part 3: reference model of life cycle processes of medical device software”. The possibility of iterative life cycle models is not excluded and, therefore, it can also fit with "AGILE" methodologies as long as the necessary evidence, documents and records are also generated to demonstrate that the regulatory requirements have been applied and met.

A possible approach is as per the following diagram of the design/development procedure:

## Software design and development procedure.

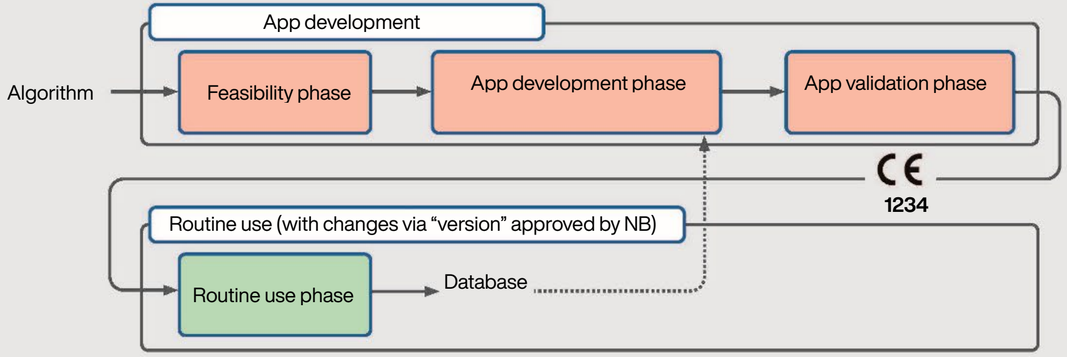
Adaptation of ISO/IEC 62304:2006 A1 2005.




At the end of the entire design procedure, it is necessary to have the technical documentation of the medical device with the minimum content in accordance with Annexes II and III of MDR/IVDR, as well as plans to maintain compliance with the standards throughout the life cycle of the MDSW.

On the one hand, the development of a Conventional MDSW can be summarised in the following general phases:

## Development phases of an MDSW



In contrast, the development of an MSDW with AI includes specific preliminary phases, such as the development of the algorithm, and also phases subsequent to obtaining the CE marking, such as the implementation of the product, and if applicable, the integration of default change control plans (DCCPs). These DCCPs allow us to anticipate possible modifications arising, for example, from self-learning, always within the validated conditions.

During the development phase, a clinical association is established between the algorithm output and the clinical or physiological condition of interest. This association can be obtained through retrospective data, scientific literature, etc. In parallel, the application development process follows the usual procedure to obtain the CE marking for an MDSW, in accordance with Regulation (EU) 2017/745 (MDR).

Once the MDSW with AI has obtained the CE marking, it is necessary to address the implementation phase, which includes:

- The adjustment or adaptation of user interfaces.
- Adaptation to the environment of use.
- The management of possible modifications not covered in the DCCP. In this case, a new conformity assessment by a notified body (NB) shall be necessary.

These phases are usually not included in the development of a conventional MDSW or with deterministic algorithms and pose an additional challenge in the process of assessing the conformity of MDSWs with AI.

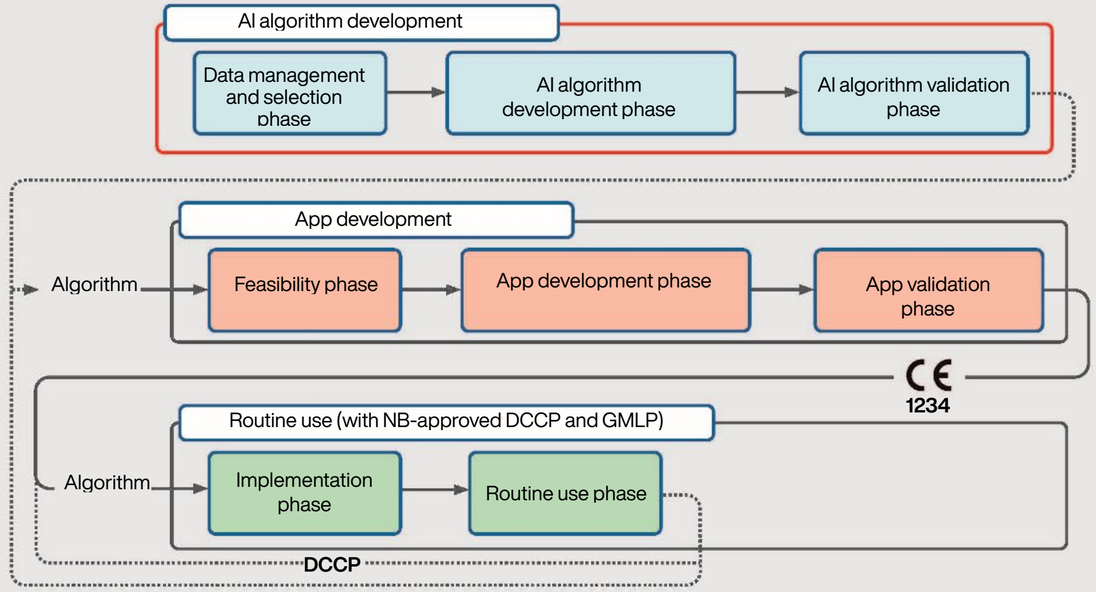
The Alliance of German Notified Bodies (IG-NB) has published guidelines that can be very useful in aligning the development process with the expectations of the NBs. These guidelines help ensure that the Technical Documentation, prepared in accordance with Annex II of the MDR, meets the regulatory criteria. Technical evaluation is necessary in most cases and depends on the case-by-case analysis of the ON.

MDSWs with AI/ML, which incorporate self-learning functionalities, can modify the algorithm, the output information or the results provided. If these changes are significant, it is mandatory to carry out a new conformity assessment before re-introducing the product to the market.

NBs do not consider products that "self-modify" in an uncontrolled manner to be certifiable. However, manufacturers can ensure product safety within the scope of validation by:

- The establishment of Default Change Control Plans (DCCP), which detail the conditions and limitations of the AI model.
- The application of control mechanisms that guarantee that changes do not exceed validated limits.

## Development phases of an MDSW



### 3.3.4 Internal Audit

Internal audit is the process whereby the organisation itself reviews compliance with quality regulations and regulatory requirements applicable to its processes.

**A procedure must be established for how to conduct these audits, their frequency and the requirements of the auditors**. It is advisable to use external consultants to avoid bias in the audit of our organisation. More detailed information regarding the authorship process can be found in the ISO 19011 standard "Guidelines for auditing management systems".

The results of this audit shall be compiled in a report with the findings and deviations that have been categorised as non-conformities: **major, if they are a serious breach of the rule or requirements, or minor, if it is a case of one-off non-compliance.** Also in internal audits, auditors can point out opportunities for improvement in the audited process.

### 3.3.5 Review of the quality management system by the management of the manufacturing entity

ISO 13485 requires that the entity's management review the quality management system at planned intervals (usually carried out annually), including system performance, the effectiveness of corrective and preventive actions, legal compliance and opportunities for improvement. This review should include aspects such as audits, customer feedback, process performance and possible changes that affect the system. It must be documented with the actions and decisions necessary to improve the system, and it must be planned, adapting the frequency to the needs of the organisation.

## 3.4 Conformity assessment

### 3.4.1 MDSW assessment without involvement of a notified body

In the case of **low-risk MDSW** (e.g. health product of the **class I without measurement function;** or medical product for in vitro diagnosis **class A), the involvement of a notified body is not necessary; it is the manufacturer itself who declares the product's conformity with the regulation**. It should be remembered that, although the involvement of a notified body is not necessary, it is necessary to have all the technical documentation for the product and apply a quality management system. Similarly, manufacturers based in Spain must have obtained the establishment licence for manufacturing health products from the AEMPS, passing inspection visits by the competent Health Authority.

For MDSWs that incorporate artificial intelligence, see the *Guide for the application of the European regulation on artificial intelligence in the field of health*. This guide will help you determine whether additional requirements specified in the European AI regulation are applicable.

#### 3.4.1.1 Exemption for "in-house" MDSW

In the case of MDSW for intra-hospital use (in-house), that is, they are manufactured[1] and are used[2] exclusively in the same healthcare centre established in the EU,[3] **the involvement of a notified body is not necessary and it is the hospital itself that declares compliance with the regulation, reporting to the AEMPS** that it performs this activity. In order to apply this exemption, several conditions established in Annex I (general safety and performance requirements) and in Article 5(5) of the MDR/IVDR regulations and those of national legislation RD 192/2023 must be met. These conditions include:

- The product cannot be classes IIb and III or implantable;
- Products cannot be transferred or sold to other legal entities;
  - The concept of legal entity may vary depending on the organisation of the healthcare systems of each member state. Three main situations can be distinguished:
    - A single hospital or health centre that constitutes its own legal entity.
    - A hospital with various legal entities, such as different health centres within the same hospital.
    - Several hospitals that belong to the same legal entity, considered part of a same health centre.
- The manufacture and use of the product must take place within the framework of an appropriate quality management system;
- It is necessary prove that needs cannot be met of the specific group of patients for whom the products are intended (or not with an adequate level of functioning) with no other equivalent product on the market;
- A public declaration must be made, which includes identifying the name and address of the manufacturing healthcare centre, the data to identify the products and the declaration that the products comply with the GDPR;
- Documentation must be prepared that explains the facility where production takes place, the production process itself, the design and operating data of the products, including the intended purpose, and that allows the competent authorities to establish that the applicable GDPR is effectively complied with;

[1] The "manufacture" of a product is defined in the MDCG 2023-1 guide as: (1) starting from raw materials, parts or components of a product, (2) combining products or (3) modifying an existing product to obtain a new product.

[2] The use of an in-house product can be physical or remote (as long as it is not made available to another legal entity).

[3] In Spain, only hospitals can carry out in-house manufacturing. See the definition of Hospital in Royal Decree 1277/2003 of October 10.

- Measures must be implemented to ensure that products are manufactured in accordance with the established design following the defined manufacturing process;
- It is necessary to review the experience gained with the clinical use of the products and take all necessary corrective measures;
- **Hospitals shall not be able to subcontract any of the manufacturing activities;**
- Hospitals shall appoint a person responsible for in-house manufacturing procedures and shall communicate their details to the AEMPS;
- Hospitals must inform the AEMPS prior to the start of the activity, providing the documentation indicated in Article 9.8 of RD 192/2023;
- Hospitals must report any modification of data or cessation of activity as per article 9.10 of RD 192/2023.

#### 3.4.1.2 Other exemptions for MDSW (research, fairs, etc.)

In the case of **MDSW for clinical research or exhibition or demonstration at trade fairs professionals in the sector, the product is exempt from compliance with the requirements of the regulation.** In any case, in order to be used on people for research purposes, it is necessary to request the approval of an Ethics Committee and, if it is considered a medical product without the CE marking, prior authorisation must be requested from the health authority of the countries where the research takes place (in Spain, the request is made to the AEMPS).

These products must be clearly identified so that the user can take into account the limitations of their use.

### 3.4.2 Evaluation as MDSW as per MDR/IVDR

Conformity assessment is the procedure whereby it is demonstrated whether a product meets the requirements of the MDR or IVDR regulation. This process is of utmost importance to guarantee the safety, efficacy and quality of products before they can be placed on the market or put into service within the EU. Depending on the product's risk classification, intended use and technical characteristics, the conformity assessment may vary in complexity and may require the intervention of a notified body, which is the entity designated to carry out the review and certification. Furthermore, it includes key elements such as the drawing up of the technical dossier, clinical or performance evaluation, the application of a quality management system and, in the case of certain products, the carrying out of audits or additional tests. This procedure ensures not only compliance with EU regulations, but also adequate protection for patients and users, following articles 2.40 of the MDR and 2.32 of the IVDR.

### 3.4.3 MDSW assessment by a notified body

In this assessment, the technical documentation (as per Annexes II and III MDR or IVDR), the quality management system (as per EN ISO 13485) and the registrations and licences (EUDAMED and national) are reviewed. For low-risk products (MDR class I or IVD class A), the reviews can be completed by the manufacturer itself. For all other cases, they must be conducted by a notified body (*for example, the Spanish CNCps 0318 [18]*). Depending on the product classification, different evaluation routes can be followed, but the most common is the procedure as per Annex IX (Chapter I and II) of the MDR/IVDR which includes product design information.

Annex IX: conformity assessment based on a quality management system and assessment of technical documentation.

- *IX Chap. I: Quality Management System*
- *IX Chap. II: Evaluation of technical documentation*

The following table shows the compliance requirements for MDSW by risk class and EU regulation.

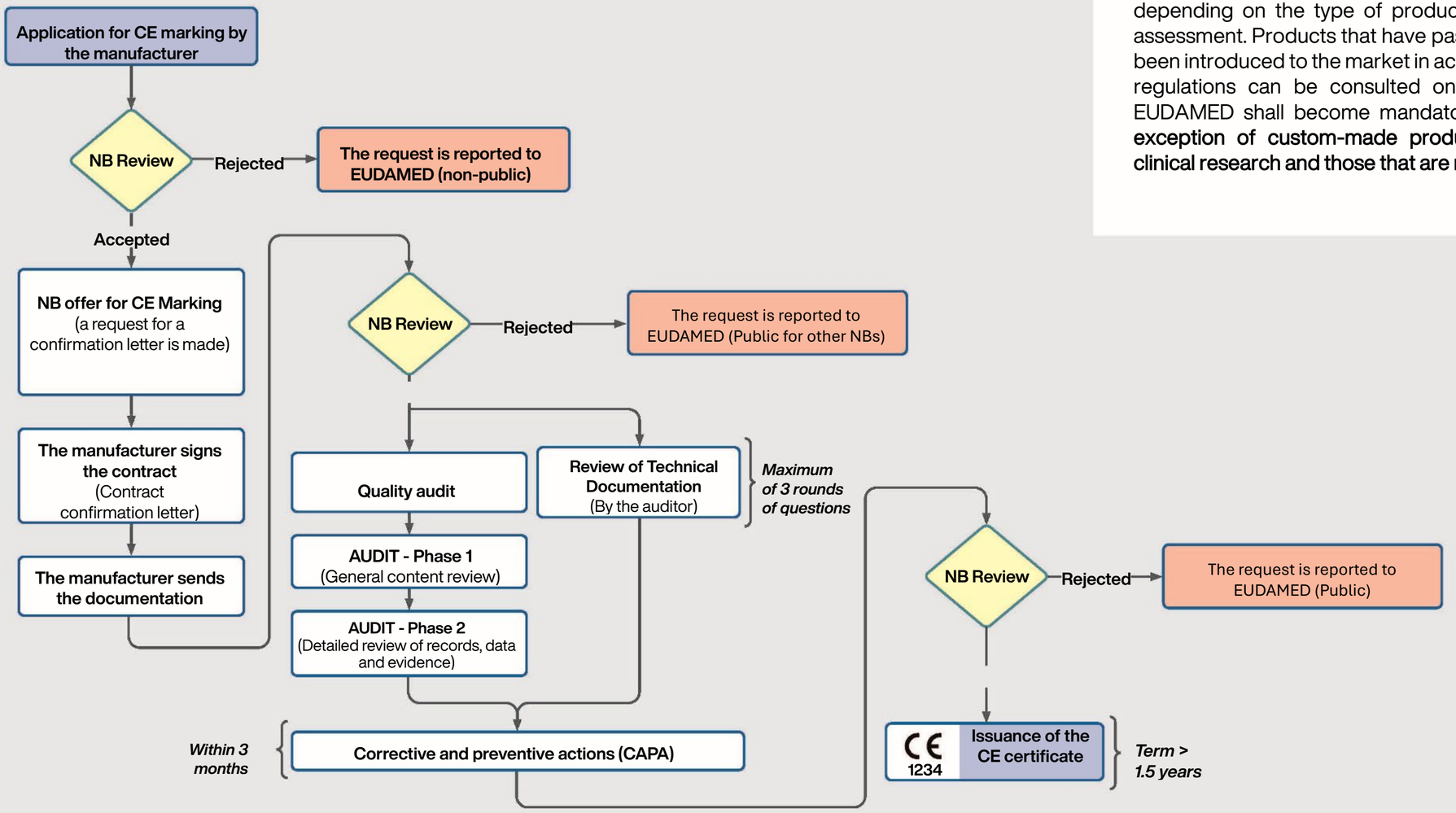
**Compliance requirements by risk class and regulation.**

| Product class | CE marking on label | Declaration of Conformity | Certification from the notified body as per annex | |
|---|---|---|---|---|
| | | | IX Chap. I | IX Chap. II |
| I (MDR), A (IVDR) | CE | X | - | - |
| Im (MDR)V | CE 1234* | X | X | - |
| IIa (MDR), B (IVDR) | CE 1234 | X | X/- | -/X |
| IIb (MDR), C (IVDR) | CE 1234 | X | X | X |
| III (MDR), D (IVDR) | CE 1234 | X | X | X |

*1234 is a notation commonly used to indicate the number of the specific notified body that evaluated the product.

The process conformity evaluation follows the following flow chart:

**Conformity assessment process as per Annex IX of the MDR/IVDR.**




The average time for assessment by a notified body is approximately one and a half years, although it may vary depending on the type of product and the complexity of the assessment. Products that have passed this evaluation and have been introduced to the market in accordance with the MDR/IVDR regulations can be consulted on EUDAMED. Registration in EUDAMED shall become mandatory for all products **with the exception of custom-made products, products intended for clinical research and those that are manufactured in-house**.

### 3.4.4 Evaluation as MDSW with AI as per MDR/IVDR

We have several types of MDSW, including AI algorithms. In accordance with the BSI/AAMI AI Machine Learning Guide in Medical Devices: Adaptation of regulatory frameworks and standards [19], which we can classify as:

- **Rule-based AI systems**
- **Data-driven AI/ML systems**
  - **Fixed ML Models**
  - **Adaptive/continuous learning models**

### AI/ML in MDSW: adapting regulatory frameworks and standards based on BSI-AAMI - Machine Learning AI in medical devices:

| Rule-based AI systems |
|---|
| Mimics human behaviour in decision-making by applying static rules to reach predictable decisions. |
| Usually visualised as a decision tree. |
| May be originally developed based on a set of rules provided by expert humans or it may be based on training data |
| The logic used for decision-making is clear and reproducible. |
| **Expert systems to support clinical decision-making:**<br>▪ Based on static rules.<br>▪ Treated as AI as their knowledge base has been generated ad hoc.<br>CE |

| Data-driven AI/ML systems | |
|---|---|
| Blocked ML models | Adaptive/continuous learning models |
| Neither the internal algorithms nor the system outputs change automatically. | Uses newly received data to test hypotheses that highlight its performance in real use. |
| More ML can be implemented through external approval or in a phased manner. CE | Programmed to automatically modify internal algorithms and update external outputs in response to identified improvements. CE |
| AI/ML systems for diagnosis/therapy:<br>▪ Not based on static programmed rules.<br>▪ Use statistical methods to establish relationships between data, learning and modifying their results. | |

**Rule-based systems are treated as conventional MDSW** and update the algorithm periodically as per scientific criteria, similar to releasing a new version of the MDSW.

**Data-driven AI/ML systems are the ones that present a significant change. Fixed ML models** are the most typical and their evaluation is done in accordance with the IG-NB guide, in which the manufacturer reviews the modifications to the algorithm or the output information and/or results supplied, and if these changes are relevant, validates and documents them, and presents them to the notified body for the evaluation thereof.

The other is the case of **continuous learning models,** which are data-driven AI/ML systems that include learning or retraining, continuously modifying the algorithm or the output information and/or results provided. These models **are not considered** "**certifiable**" unless the manufacturer takes measures to ensure the safe operation of the product within the scope of the validation described in the technical documentation. This can be addressed by establishing a DCCP or predetermined change control plan, where **the manufacturer anticipates its predictions of changes in the model's behaviour within certain conditions and limitations.**

The IG-NB guide establishes the following phases:

**Intended use and stakeholder requirements:** defines the medical purpose of the device, characterises users and environments of use, establishes quantitative requirements for safety and efficacy, and carries out a risk analysis and a clinical evaluation.

**Product and software requirements:** includes criteria for the functionality, performance and user interface of the software, ensures the management of internal errors and evaluates the risks related to data entry and security.

**Data management:** specifies quality criteria for data collection, annotation process and data pre-processing, as well as version control and traceability.

**Model development requirements:** justifies the feature selection, documents the model training and evaluation process, and includes a complete description of the architecture and limitations.

**Product development:** applies the IEC 62304 standard for software development, addresses software-specific risks, and includes accompanying materials for the user.

**Product validation:** executes usability testing and a clinical evaluation to ensure that the device meets the intended medical benefit.

**Product launch:** includes final model documentation, risk analysis, usability validation and post-marketing surveillance plans.

### 3.4.5 Assessment as an MDSW with AI as per the European AI regulation

In accordance with the new European AI regulation, MDSW with AI, which require the involvement of an ON, are considered high-risk products and, therefore, also require an ON for their conformity assessment and obtaining the CE marking.

To view the classification process and the necessary documentation for MDSW with AI, you can refer to the *Guide for the application of the European regulation on artificial intelligence in the field of health*.

## 3.5 Registration of products and operators in EUDAMED and AEMPS for access to the EU market.

### 3.5.1 Registrations and licence

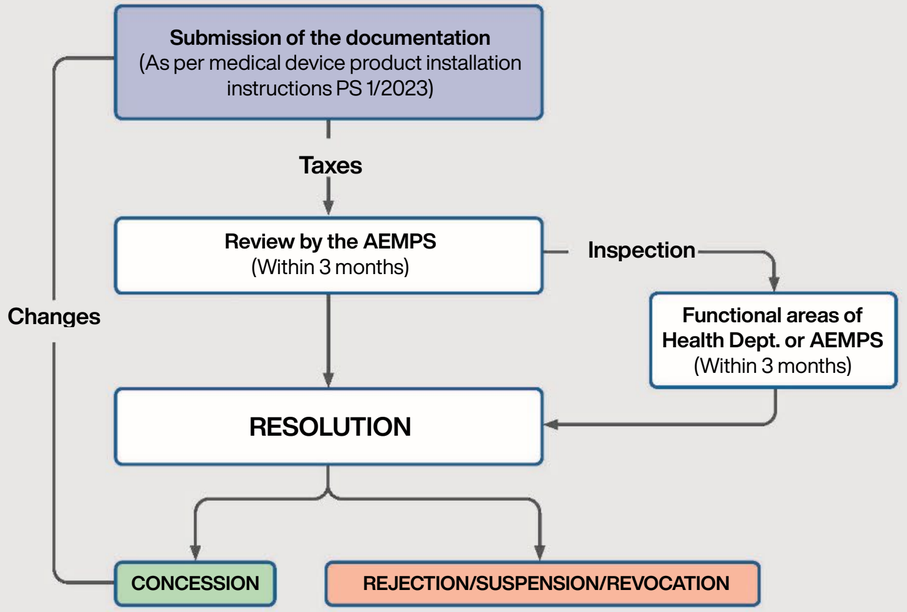
In accordance with national and European regulatory requirements, **organisations must register their activity with the competent authorities where they are established, communicating their data and that of the facilities where health products are manufactured.** Similarly, all product variants in the European databases (EUDAMED) and in the countries where they are introduced on the market need to be registered.

### 3.5.2 National requirements

In Spain, Royal Decree 192/2023 develops its own requirements related to organisations and economic operators that market health products. Among its requirements, it highlights that **Manufacturers of healthcare products established in Spain must have a prior operating licence for the activity** and must register in the Spanish database all variants of the products that are placed on the national market.

The following diagram illustrates the steps to follow to obtain the licence:

Licence obtaining process - AEMPS



In the case of a manufacturer of programs or applications for medical purposes (MDSW), the applicable requirements, which a general software developer would not generally have, include:

- Appoint and include in the staff:
  - Technical manager, person with appropriate qualifications depending on the products in charge.
  - Person responsible for compliance with ISO 13485 quality standards and applicable MDR/IVDR regulatory requirements (this may be the same technical manager).
  - Person responsible for the surveillance system.
- Implement a quality system as per ISO 13485.
- Draw up technical documentation for the product that guarantees that it meets the applicable safety and performance requirements, including the development and validation of software as per EN 62304, EN 82304-1 and other standards in specific cases such as AI.

### 3.5.3 European requirements. EUDAMED database

Within the EU, the necessary registrations must be completed in the EUDAMED database [20], which includes six modules:

- Actor Registration Module.
- Devices Module.
- Notified and certified bodies module.
- Surveillance Module.
- Market Control Module.
- Clinical Research Module/PE Performance Evaluation.

**Actor Registration Module**

The Actor Registration Module allows economic operators to submit, through an actor registration application, the information necessary to obtain **a unique actor identifier/registration number (actor ID/SRN).** Registry is mandatory for manufacturers, importers, authorised representatives and producers of systems or kits for procedures.

The ID/SRN actor ensures a unique identification across the EU for these economic operators.

Upon request, the information is sent to the competent national authority of the manufacturer's country (or the authorised representative in the case of manufacturers established outside the EU). After the assessment and approval of the application by the relevant national competent authority, EUDAMED generates the economic operator actor identifier/SRN and passes it on to the requesting economic operator. This system also makes it possible to search and list competent authorities, designating authorities, economic operators and clinical research sponsors, and shows contact details.

**Devices Module**

The MDR/IVDR Regulations introduce a **unique product identification system (UDI) that allows traceability**. This requires manufacturers to assign a UDI code to each product and at each packaging level and to send this information to EUDAMED. Manufacturers can now enter UDI/device information into the system on a voluntary basis and the use of the UDI/product registration module shall be required once EUDAMED is fully functional. However, additional national requirements on product registrations cannot be ruled out.

**Notified and certified bodies module**

The MDR/IVDR regulations also establish that NBs must register in EUDAMED any information relating to certificates issued (including amendments and supplements), suspended, reinstated, withdrawn or refused and other restrictions imposed on such certificates. This information shall be accessible to the public.

This module provides a list of NBs in the area of MDR/IVDR and their subsidiaries. It also enables a link to be set up to the NANDO database to obtain details on the designation/notification and its scope (conformity assessment activities and product types). It shall allow the public to search and view information on certificates and summaries of safety and clinical performance, as well as select and display, for an MS specifically, one of its summary reports on the on-site supervision and evaluation activities relating to the NBs and their subsidiaries.

**Surveillance Module**

It shall allow the public (including healthcare professionals) to search and view with the appropriate level of access the public part of the final reports of serious reportable incidents, as well as field safety notes (FSNs), PSUR, FSCA, FSN, MIR, Trend Reports and PSR.

**Market Control Module**

It shall make it possible to open/download a **summary of the results of reviews and assessments of surveillance activities** of the market of an EU member state. Confidential information related to market surveillance data from Member States shall not be included.

**Clinical research/performance evaluation module (CI/PS)**

This module shows the list of requests/notifications for clinical investigations (PS) and performance evaluation studies (IVDs), which shall be made available to the public regardless of the outcome. Allows filtering between the list of CI/PS requests/notifications based on a set of user-defined search criteria on the relevant metadata available in EUDAMED. It shall show the **details of the information in a CI/PS report and the summary made available to the public.** It shall provide links to related available information, such as adverse effects and product deficiencies, the CI/PS report and summary, and UDI/products. All information on CI/PS applications/notifications and related updates must be accessible to everyone, unless full or partial confidentiality of the information is justified (protection of personal data, confidential commercial information, effective supervision by Member States). The exchange of information on CI/PS between Member States and between them and the Commission shall not be accessible to the public.

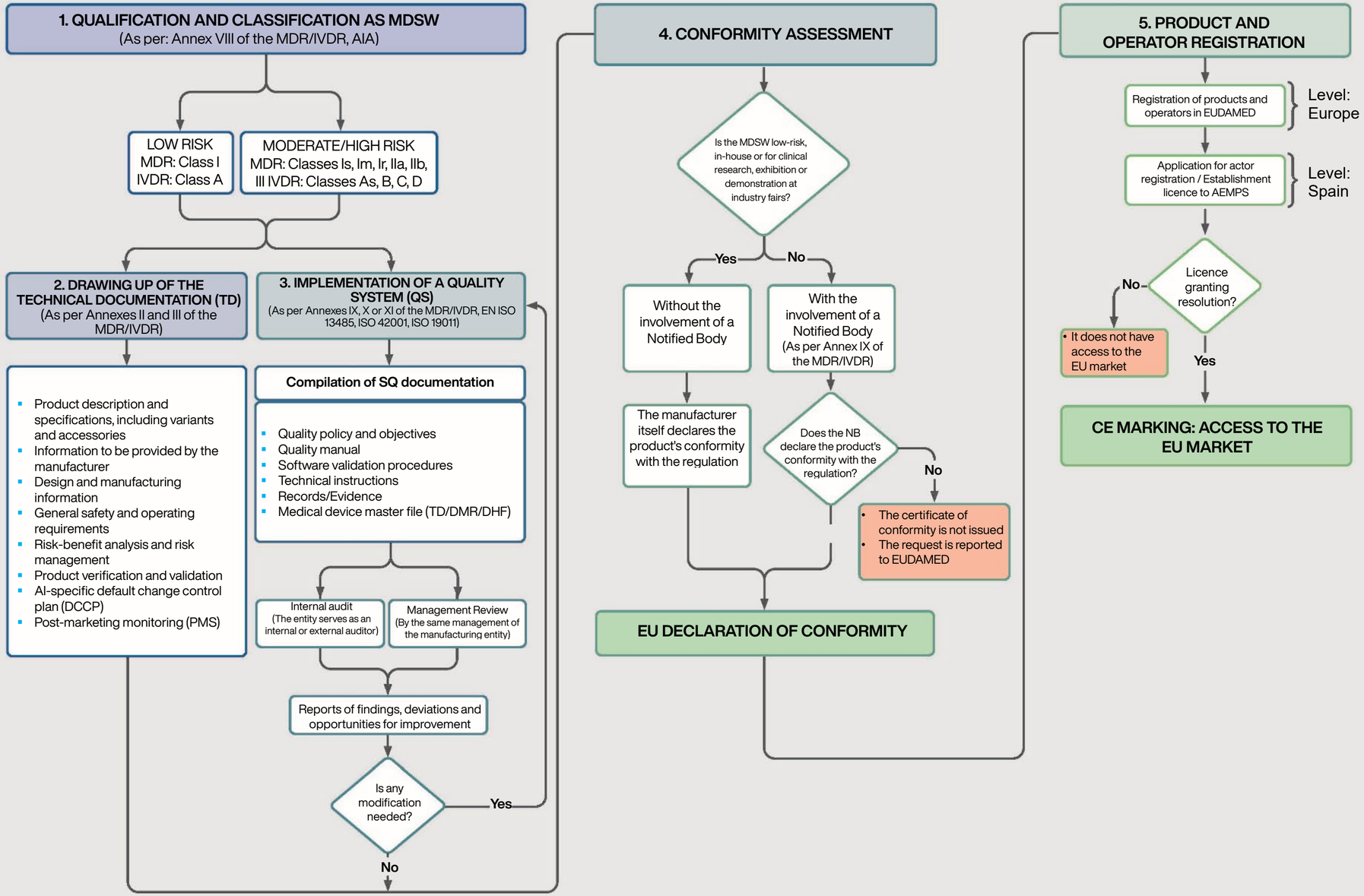
**The communication of information to this database shall be mandatory throughout Europe once its implementation is published in the OJEU, with a transitional period of two years.**

# 4

# Process for obtaining the CE marking of an MDSW: flowchart

Below is the expanded flowchart of the entire process of obtaining the CE marking:

## 4. PROCESS FOR OBTAINING THE CE MARKING OF AN MDSW: FLOWCHART



# 5

# References

# References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