MODULE 6

PRODUCT ENGINEERING

UNIT 1

RISK ANALYSIS AND RISK MANAGEMENT

Juan Carlos Bañón Guillén • María Sánchez Melero • Marta Martínez Navarro

DESIRE

DESIGN FOR ALL METHODS TO CREATE AGE-FRIENDLY HOUSING

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DESIRE will provide professionals in the building industry and home furnishings sector with the tools and skills to apply Design4All methods as an integral part of the design process, with the aim to create or adapt age friendly housing as a solution for the wellbeing, comfort and autonomy of the older adults or dependents at home.

The DESIRE training platform consists of six modules and 21 units.

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PRODUCT ENGINEERING

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UNIT 1 – RISK ANALYSIS AND RISK MANAGEMENT

The walls of home are always a synonymous of security and protection. However, the objects and accessories that we like the most can become dangerous if the sources, before being put on the market, an exhaustive analysis of the risks is not made. This unit will offer a global vision of the regulations and methodology for effective management and analysis of risks in product design process.

1.1 WHAT IS IT AND WHY IS IT IMPORTANT?

The term risk is defined by the Royal Spanish Academy of Language as “a contingency or proximity of harm”. Therefore, being aware of these risks gives us an important advantage over their consequences.

Risk in an activity that may have two components: the likelihood or probability of a negative outcome occurring and the size of that outcome. Therefore, the greater the probability and the potential loss, the greater the risk.

In a broad sense, **risk analysis** is the systematic use of available information to determine the frequency with which certain events may occur and the magnitude of their consequences. It is a document that describes the methodology followed during the analysis for product evaluation, considering the way in which failures can occur.

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The basic concepts to be considered for risk analysis are:

- **Risk:** Probability of occurrence of a hazardous situation causing damage and the degree of severity of such damage.
- **Hazard:** Potentially harmful effect on the user or the environment.
- **Harm:** Physical injury or damage to health or the environment.
- **Severity:** Qualitative measure of the possible consequences of a hazardous situation.
- **Residual risk:** Risk identified by the risk analysis that remains after all appropriate safety measures have been taken.

The importance of carrying out a risk analysis lies in the fact that thanks to it, decisions can be taken to implement preventive measures to avoid potential dangers or reduce their impact, since its prior evaluation allows us to anticipate the circumstances.

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TECHNICAL FILE:

Each risk analysis process shall be reflected in a written document which shall be part of the Technical File. This document shall contain at least:

1. Full description of the product.
2. Any assumptions adopted for the analysis.
3. Hazards identified.
4. Hazardous situations identified.
5. Information and data used for the evaluation.
6. Safety measures implemented to reduce and/or eliminate the hazards.
7. Residual risks after the implementation of the safety measures.
8. Final result of the product risk assessment.

More specifically, considering the ISO 14971 definition of the application of risk management in medical devices, then risk analysis is described as “the systematic use of available information to identify hazards or potential sources of harm and to estimate risk, understood as the combination of the probability of occurrence of harm and the severity of that harm”.

This concept has two components:

1. Probability of the harm occurring, i.e., the frequency with which it is likely to occur.
2. Consequences of the harm, i.e. how severe it may be.

The aim is to anticipate all risks that may arise during the design, manufacture, transport, storage and use of the product in order to provide solutions that guarantee the highest possible level of safety.

IN A NUTSHELL

SAFETY OF MACHINERY – GENERAL PRINCIPLES FOR DESIGN – RISK ASSESSMENT AND RISK REDUCTION STANDARD (ISO 12100):

A recent addition to the furniture industry, Safety of machinery – General principles for design – Risk assessment and risk reduction standard (ISO 12100) applies to many of them. It defines risk analysis as "the combination of machine boundary specification, hazard identification and risk estimation".

Risk analysis according to ISO 12100 comprises:

1. Determination of the limits of the machine
2. Identification of hazards
3. Risk estimation

By applying this standard, the manufacturer can anticipate possible risks, the designer is provided with tools to ensure that the machine (in this case, the piece of furniture) is safe and besides, a risk assessment is obtained throughout the life cycle of the furniture that allows us to anticipate the consequences. It is, therefore, the ideal way to ensure that the piece of furniture meets the expected safety requirements.

Moreover, risk management refers to the process of identifying and assessing risks, as well as creating a plan to reduce or control them in order to reduce the effect they could have on the company.

Through risk management, we can proactively identify, analyse and respond to risk factors throughout the life of a project or product and control potential future events.

IN A NUTSHELL

RISK MANAGEMENT:

ISO 14971 states that: "Risk management is a complex issue because each stakeholder may assign a different value of acceptability of risks in relation to the expected benefits". Even so, the manufacturer must estimate the risk of the device and act based on how that risk compares to the (previously defined) risk acceptability levels to comply with the standard, as well as define the necessary acceptance/rejection criteria, determine the test parameters, add safety features, etc. This risk management system should consider the entire life cycle of the device, not just the design stage.

As described in ISO 12100, risk assessment is defined as "the overall process comprising risk analysis and risk evaluation". Risk assessment is a series of logical steps to systematically analyse and assess the risks associated with machinery.

The objective of the application of risk assessment according to ISO 12100 is to reduce risk as much as possible, considering four factors. The process itself is iterative and several successive applications may be necessary to reduce the risk, making best use of available technology. When carrying out this process, these four factors are to be considered in the following order of preference:

- the safety of the machine during all phases of its life cycle
- the suitability of the machine to perform its function
- the operability of the machine
- the costs of construction, operation and decommissioning of the machine.

1.1.1 Example: Medical devices – Application of risk management to medical devices (ISO 14971:2020)

Within the furniture sector, a medical device is any product intended by the manufacturer to be used by humans for any of the medical purposes specified in ISO 14971 standard. A medical device may be:

- diagnosis, prevention, monitoring, treatment or alleviation of a disease,
- diagnosis, prevention, monitoring, treatment or alleviation of an injury,
- research, replacement, modification or support of the anatomy or a physiological process,
- the maintenance or prolongation of life,
- conception control,
- disinfection of a medical device,
- to provide information with in vitro examination of human body derivatives, and without exerting its main action in or on the human body by pharmacological, immunological or metabolic means, but to whose function such means may contribute.

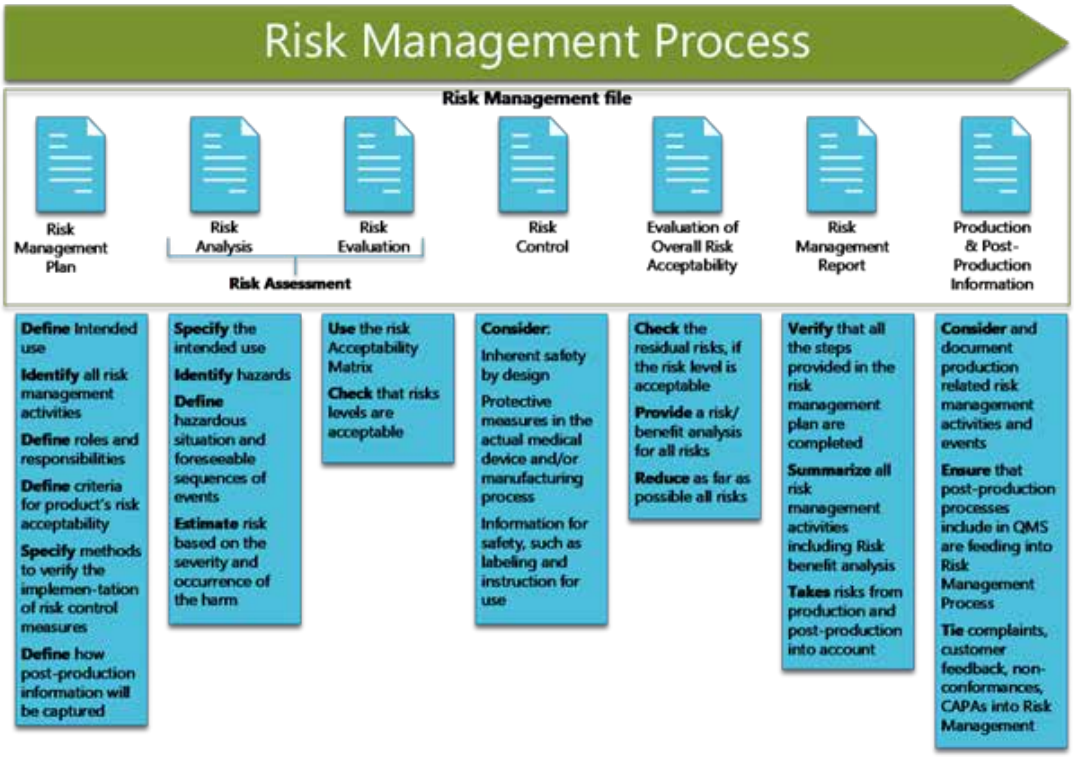

Figure 6.1.1 Steps of the Risk Management process.

Thus, chairs, beds, handles or any support product introduced in healthcare environments and used by people in any of the processes mentioned by this standard could be included in this definition.

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ISO 14971:2020

ISO 14971 standard specifies a process to be followed by the manufacturer to identify the hazards associated with medical devices, to estimate and evaluate the associated risks, to control such risks and to monitor the effectiveness of the controls.

The requirements of this standard are applicable to all stages of the medical device life cycle, from design to post-market and recall. These requirements also provide manufacturers with a framework within which experience, knowledge and judgement are systematically applied to manage the risks associated with the use of the medical device. This document addresses the processes for managing risks associated with medical devices. Risks may relate to injury, not only to the patient, but also to the user and others and may also relate to damage to property (e.g., objects, data, other equipment) or to the environment.

For a correct risk management according to this standard, the manufacturer is obliged to:

- Identify the risks and avoid the potential hazards,
- Document the process and update documents and procedures in case new ones appear or the existing one's change.

Regulation (UE) 2017/745 pays particular attention to managing these risks: anticipating them, combating them, documenting them, testing the absence before marketing and feeding the system with post-sale experience. In short, it closes the circle around risks, aims to control the known risks and to provide quick and effective responses to the unanticipated ones.

1.2 METHODOLOGY

Among other aspects, 14791 determines that there must be a risk management plan that includes the scope of planned risk management activities, identifying and describing the medical device and the life cycle phases for which each element of the plan applies; the assignment of responsibilities and authority; the requirements for review of risk management activities; or criteria for risk acceptability, among other aspects.

The risk management process includes the following actions:

Risk analysis: This phase involves an understanding of the risk, i.e. determining its consequences and probabilities, taking into account the presence and effectiveness of existing controls. The methods used for this risk analysis can be qualitative, semi-quantitative or quantitative.

- Qualitative assessment is often expressed with “high”, “medium” and “low” levels to define consequences, probabilities or level of risk.
- Semi-quantitative methods mainly use linear or logarithmic numerical rating scales.
- Quantitative analysis works with realistic numerical values and obtains the same type of results. The problem is that sometimes, in addition to these values, other factors that are difficult to quantify or simply missing data must be considered.

Risk assessment: Decisions are made about future actions based on the knowledge of risk that has been obtained during the analysis phase.
Risk control: The process of making decisions and implementing measures by which risks are reduced to or kept within specified levels.
Overall residual risk assessment: An overall process comprising a risk analysis and a risk assessment. This considers the contributions of all residual risks, in relation to the benefits of the intended use, using the overall residual risk acceptability method and criteria defined in risk management.
Risk management review: Verification of compliance with the implementation of the risk management plan. This review should at least ensure that:

- the risk management plant has been properly implemented
- the overall residual risk is acceptable,
- there are appropriate methods implemented for collecting and reviewing information in the production and post-production phases.

Production and post-production information: Active review of all documentation generated by the manufacturer in the production and post-production phases where considerations should be given to the appropriateness of the methods of data collection and processing.

Risk identification is the stage in management where uncertainty factors are identified. This stage is particularly important because failure to identify risks would make subsequent management ineffective.

This standard requires manufacturers to determine objective criteria for risk acceptability, but does not specify acceptable levels of risk, so it does not specify an exact methodology with which to perform risk management but leaves it to the manufacturer to decide which of all existing methodologies best suits his/her type of organisation and product, as long as the results obtained from such application comply with the instructions given therein.

Some methodologies used in risk management are:

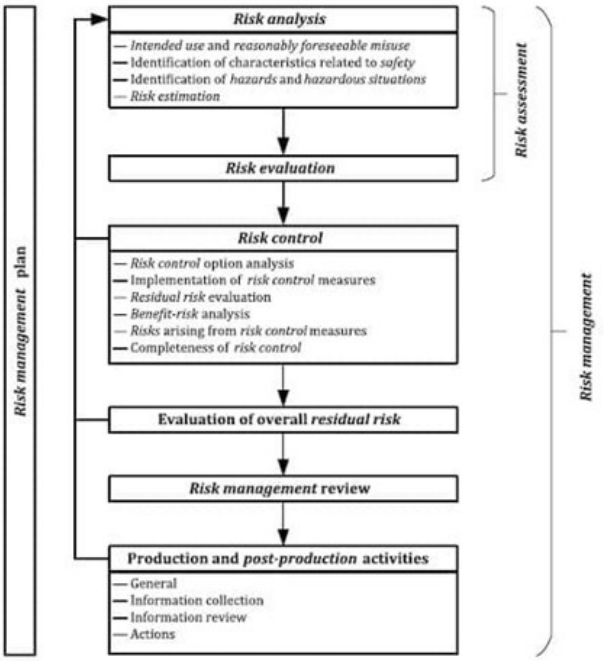

Figure 6.1.2 Schematic representation of the risk management process according to ISO 14791

6.2.1 Delphi method

DEFINITION:

This method consists of a group communication process to predict results based on the opinions of a group of experts. It is a strategic method to prevent risks or predict certain situations by repeatedly consulting experts in an area. In this way, information is obtained about certain events, their probability and possible consequences. Qualitative but precise information is obtained about future situations.

It is a method characterised by heterogeneity. These experts belong to different branches of activity making the study observed from different perspectives. It should also be noted that the experts do not know the identity of the other participants. In this way, they do not feel pressured or conditioned by the other participants.

APPLICATION:

The key to the method is consensus, the convergence of opinions. In this way, the experts will draw up a questionnaire which will then be analysed. If no consensus has been reached, another questionnaire is drawn up with the processed information. The process is repeated until there is consensus among the experts.

The aim of this method is to reduce as much as possible the different predictive possibilities or forecasts. Thus, one could say that it simplifies the outcome of a complex project thanks to the group opinion of several expert individuals, leading to a possible decision making.

Four of the main features of the Delphi method are:

- Experts remain anonymous
- Group heterogeneity.
- All responses are considered in a statistical way.
- It is an iterative process and controlled question feedback

PHASES:

1. Identify the reason for carrying out the process.
2. Define objectives.
3. Select the team of experts.
4. Prepare and hand out questionnaires.
5. Analysis of the results.
6. Redistribution of the questionnaire.

Each opinion is evaluated, and a difference or quantitative average of the group consensus is obtained. In addition, questionnaires can be carried out as many times as required until the objectives are met. Although it is a method included in qualitative research (experts make qualitative comments), quantitative techniques are also used.

Figure 6.1.3 The Delphi Method

The application of this predictive method has the following benefits: a greater degree of objectivity than purely qualitative research; credibility by reaching consensus; opinions are not categorical, as it encourages the exchange and mixing of different opinions; it avoids conflicts between experts and increases the possibility of being creative; it promotes freedom of expression and keeps all experts on equal footing, without favouring any one expert.

6.2.3 What if-analysis

DEFINITION:

This methodology is usually used in the first phase of management when risks are just being identified. Afterwards, this technique can be complemented by a more in-depth analysis of the risks and their causes through additional techniques. It is a qualitative risk identification technique that is usually applied to any unusual design condition of the facility or operations.

It is a very flexible and creative method that consists of scheduling meetings between collaborators who have in-depth knowledge of the process being analysed without any limitation as to the areas that can be covered by the questions. What-if analysis can be used in any area that is of interest for study. The kick-off meeting is scheduled for brainstorming, and questions that may help in making problems visible are developed. The name What-if comes from the type of questions generated.

In subsequent meetings the expert group will find answers to address the questions that were asked, seeking causes, consequences and recommendations.

This method basically consists of defining trends, formulating questions, developing answers and evaluating them appropriately, including the widest range of likely consequences, and does not require special quantitative methods or concrete planning to answer these questions.

APPLICATION:

Specific information on the process is used with the aim of creating enough questions to be asked at the best time and over the lifetime of the organisation's facilities. This method can be performed at any stage in the life of the process using the available information and process knowledge and can introduce appropriate changes during the lifetime of the industrial facility. Through its application, it questions the outcome of the presence of undesired events that may cause adverse consequences within a process or manufacturing plant.

PHASES:

This type of analysis encourages questions beginning with “What if...?”. Using them, an experienced group identifies possible accidents, their consequences and existing safety levels, later suggesting alternatives for risk reduction. Identified potential accidents are not ranked and are not given quantitative implications.

Its main objectives are:

- To identify events that can lead to major hazards
- To increase the operability of facilities.
- To identify more effectively all conditions and situations that are more likely to be hazardous, as they may be the result of applying inadequate controls.
- To provide different suggestions to start an operational process reducing the risk the installation may generate.

6.2.4 Failure Modes and Effects Analysis (FMEA)

DEFINITION:

It is a structured analytical methodology used to anticipate and identify failures that may arise in the process of creating a product or system, in order to avoid them. It is one of the most common tools to prevent potential failures during product development and is applied when designing new products, services or processes.

Thus, a modal analysis is aimed at discovering all the possible failures of a product during the industrial design process and at avoiding such failures or, where appropriate, limiting their effect.

There are different types:

1. Modal analysis of failures and functional effects.
2. Modal analysis of failures and design effects.
3. Modal analysis of failures and process effects.

APPLICATION:

This method is used to prevent situations that jeopardise the design and operations of a company's products or services so that detection procedures can be established to prevent these situations. Its purpose is to study possible failures ("failure modes") and then classify them according to their importance. From there, we will obtain a list that will help us to prioritise which are the most dangerous, most annoying for the user, most difficult to detect or most frequent, and which are the least relevant, which we should not worry about, either because they are infrequent, or because they have very little negative impact, or because they are easy for the company to detect before bringing the product to the market.

This tool is particularly useful to reduce risks and potential failures that may generate waste, defects or negative consequences for the final user.

PHASES:

Steps in the analysis:

1. List all the possible failure modes

The first thing to do is to create a working group of 4 or 5 people who have knowledge of the product being developed. They should be from different disciplines and include different profiles, such as designers, engineers, technicians and even final users. In this way, we will get a broader vision.

With the group assembled, we proceed to list the "failure modes" of the design: faults that the finished product could have, which can range from aesthetic, functional and safety defects to problems related to misuse. Here it is important to consider what the expected use of the product will be.

2. Set the priority index

Now we will have a long list of possible failure modes. All should be included in a table in which the following data should be encompassed:

AMFE							
Elemento / Función	Modo de fallo	Efecto	S	O	D	NPR = S*O*D	Acciones propuestas
			1 a 10	1 a 10	1 a 10	1 a 1000	

Failure modes must then be ranked according to their importance. For this purpose, each of them shall be assigned three values:

S: severity level (severity of the failure as perceived by the user).

O: occurrence level (probability of occurrence of the failure).

D: detection level (probability that we do not detect the failure before the product is used).

Each failure mode will be assigned S, O and D values, ranked on a scale from 1 to 10.

VALUE	DETECTION (D)	MEANING
1	ALMOST ALWAYS	The defect is obvious. It is highly unlikely to go undetected by existing controls.
2-4	**FREQUENTLY**	**The defect, although obvious and easily detectable, it may escape a first check, although it would certainly be detected later.**
5-7	SOMETIMES	The defect is of such nature that it is difficult to detect with standard procedures.
8-10	**HARDLY EVER**	**The defect cannot be detected. It will certainly be perceived by the customer.**

VALUE	OCCURRENCE (O)	MEANING
1-4	NOT EXPECTED	There is only a very remote possibility of danger occurring.
5-6	**UNUSUAL**	**It is unusual throughout the product lifecycle.**
7-8	OCCASIONAL	The hazard may occur at some point in the product lifecycle.
9-10	**FREQUENT**	**The hazard occurs repeatedly during the use of the product.**

VALUE	SEVERITY (S)	MEANING
1-2	MINOR	It does not cause injury.
3-4	**MODERATE**	**Damage curable with normal therapeutic measures within a short period of time.**
5-8	MAJOR	Damage requiring medical intervention. Healing usually takes considerable time.
9-10	**CATASTROPHIC**	**Damage requiring urgent surgical intervention. It may cause permanent injury or death.**

Once S, O and D have been estimated, we will multiply them to obtain the RPN (Risk Priority Number)

RPN = S × O × D

(Risk Priority Level = Severity × Occurrence x Detection)

This value will mean the importance of the analysed failure mode.

3. Prioritize failure modes and seek solutions

Once the RPN is calculated for all the failure modes, we will rank them from high to low. Failure modes with the highest RPN will be the ones that need to be addressed first. If a failure mode is unacceptable, severity can be reduced:

- Acting so that if it occurs, it will be less severe (S will decrease)
- Acting so that it happens less frequently (O will decrease)
- Acting so that if it occurs, it is detected before delivering the product to the customer (D will decrease).

This way your initial RPN can be compared to your final RPN.

6.3 ANALYSIS AND RISK MANAGEMENT IN THE DESIGN PROCESS

When a product comes to market (medical or otherwise), it will not be perfect, even after carrying out the appropriate tests. In an ideal situation, after the tests and trials, all the faults and deviations in the initial design would have been found and improvements would have been introduced in a new design so that it would reach the end customer as a perfect product, in terms of quality or usability.

Due to the complication of controlling all aspects related to the design and development of a product, some details may be left unattended and will be carried over into the product. Therefore, the manufacturer must make a great effort to avoid errors, since correcting any deficiencies will mean a great economic investment, time and loss of brand image. Carrying out a complete and exhaustive risk analysis during the first stages of the product creation process will increase its reliability, quality and safety.

6.3.1 Risks in the design of medical devices

ISO 14971 requires the manufacturer to establish a risk management process as part of the design and development of a medical device, although it should be emphasised that the risk management process does not end with design and production but continues into the post-production phase.

When designing a medical device, inherently safe design must be taken into account, i.e., the features that the product is provided with during design must meet all the safety requirements and must not be able to be modified during the whole process.

Risk analysis, therefore, becomes a mandatory phase in the design process of any medical device, as many of the problems that occur after the product has been manufactured and even with products already launched on the market can sometimes be avoided by careful risk assessment during the conceptualisation and design stage.

Successful risk management is essential to the design and development of safe and effective medical devices. Unfortunately, manufacturers too often consider it as an isolated activity that must be performed simply to comply with a regulatory requirement, unaware of the costs at all levels if not considered. Early exploration of potential risks allows risk to be used as a tool during concept selection.

6.3.2 Hazards in machine design

In the process of designing machinery or furniture considered as such, according to ISO 12100, inherently safe design measures are the first and most important step in the risk reduction process. These measures consist of avoiding hazards or reducing risks by appropriate selection of design features for the product itself and/or the interaction between exposed persons and the product.

Inherently safe design are preventive measures that eliminate hazards or reduce the risks associated with hazards by changing design or functional features without the use of guards or protective devices. As such, they become effective features that cannot be modified, as safeguards, even if well designed, can fail or be breached.

When designing any piece of furniture that can be included within the definition of a machine in the standard, different geometrical factors and physical aspects must be taken into consideration.

By **geometric factors** we mean the final shape of the product, which must be designed to acquire the appropriate characteristics to ensure that the user has a correct vision during handling, thus avoiding any risk derived from the movement of the product both for the user himself and for other people exposed in dangerous areas.

It is also intended to ensure that the product design does not contain sharp edges or angles, protruding parts and that the existing mechanical parts that can lead, among other things, to the shearing or crushing of some parts of the body, have the appropriate separation to ensure that they can enter easily or, on the contrary, cannot enter the product. In addition, the final design must ensure that it can be handled from an appropriate position that does not involve physical effort that could lead to injury.

On the **physical side**, the design shall include features to limit the driving force, mass and speed of moving parts and emissions of noise, vibration, substances or radiation.

In addition to these two factors, it is also advisable to consider the properties of the materials used in terms of fatigue, wear, toxicity, etc., the use of intrinsically safe power supplies and the application of ergonomic principles among others.

In both cases, it is essential to comply with these aspects when designing and developing products, otherwise we would be introducing into the market a dangerous product without enough quality that will have consequences not only at an economic level for the manufacturer but also for the customer's use and safety.

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MODULE 6

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UNIT 2

USABILITY ENGINEERING OF USE AND CE MARKING

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UNIT 2 – USABILITY ENGINEERING OF USE AND CE MARKING

The term usability acquires great importance when we refer to age-friendly products. We can define usability as the extent to which a product can be used by specific users to achieve specific objectives with effectiveness, efficiency, and satisfaction in a specified context of use. This is where engineering comes into play to find technical solutions that allow effective development and adaptation of product development. In addition, the participants will learn about different directives applicable to furniture and harmonized regulations such as the CE marking.

2.1 USABILITY AND SUITABILITY FOR USE

Many people find some consumer products and walk-up-and-use products, including consumer products provided for public use, difficult to install and use, particularly when using them for the first time or at infrequent intervals. This is clearly undesirable for the producers of such products, for organizations that use the products to provide a service, and for the people who use them. Information about the usability of a product would, therefore, be of great value to producers, as part of development and marketing, to service providers, and to potential purchasers making purchase decisions or comparing alternative products. This would provide an incentive for producing products that are easier to install and use and would enable potential purchasers to pay specific attention to usability when selecting a product to buy and use. It is difficult to judge usability in a purchase situation without available comparable usability test results.

The objective of designing and evaluating systems, products and services for usability is to enable users to achieve goals effectively, efficiently and with satisfaction, taking account of the context of use.

IN A NUTSHELL

Usability is relevant to:

- regular ongoing use, to enable users to achieve their goals effectively, efficiently and with satisfaction.
- learning, to enable new users to be become effective, efficient, and satisfied when starting to use a system, product, or service.
- infrequent use, to enable users to be effective, efficient, and satisfied, with the system on each reuse.
- use by people with the widest range of capabilities.
- minimizing the risk and the undesirable consequences of use errors.
- maintenance, in that it enables maintenance tasks to be completed effectively, efficiently and with satisfaction.

Usability is relevant when designing or evaluating interactions with a system, product, or service for the purposes of:

- development
- procurement
- review or comparison
- marketing and market research

Poor usability and/or accessibility can result in errors that can lead to several types of risks, for example, inconvenience resulting from not achieving a goal or achieving the wrong goal, incurring unexpected costs, or physical injury. In many countries, there are legal requirements to provide accessible products, services, and facilities.

Usability is defined as many standards as characteristic of the user interface that facilitates use and thereby establishes effectiveness, efficiency and user satisfaction, in the intended use environment.

Effectiveness is accuracy and completeness with which users achieve specified goals, and efficiency are the resources expended in relation to effectiveness.

In regards of suitability for use, or fitness for use, some standards define it as the feature that stablish effectivity, efficiency, and easy-to-learn and satisfaction of the operator. (Being the operator the person that uses the equipment).

Suitability or fitness for use engineering is the application of human knowledge, capacities, limitations, and other features for the design of tools, machines, equipment, devices, tasks, works, and environments for achieving a suitability or fitness of use appropriate.

There are international standards that specifies to manufacturers a process to analyse, specify, design, verify and validate the suitability for use, in regards of basic safety and essential operation of their products. This engineering process of suitability of use assess and mitigates the risks caused by the problems of suitability of use associated to a correct use and to use-errors, what means, in a normal use. It may be used for identifying but not to evaluate and minimize the risks associated to a not-normal use.

2.2 INTENDED USE, NORMAL USE, REASONABLY FORESEEABLE MISUSE, USE ERROR

Here in this chapter, the following terms regarding usability and suitability for use are explained:

- **Normal use:** operation, including routine inspection and adjustments by any user, and stand-by, according to the instructions for use or in accordance with generally accepted practice for those devices provided without instructions for use. Note: Normal use should not be confused with intended use. While both include the concept of use as intended by the manufacturer, intended use focuses on the purpose while normal use incorporates not only the purpose, but maintenance, transport, etc., as well. Also, use error can occur in normal use.
- **Correct use:** normal use without use error.
- **Use error:** user action of lack of user action while using the device that leads to a different result than that intended by the manufacturer or expected by the user. Note: use error includes the inability of the user to complete a task. Use errors can result from a mismatch between the characteristics of the user, user interface, task, or use environment.
- **Intended use:** It's the intended purpose of the device. Use of a product, process or service in accordance with specifications, instructions and provided information by the manufacturer.
- **Abnormal use:** conscious, intentional act or intentional omission of an act that is counter to or violates normal use and is also beyond any further reasonable means of user interface-related risk control by the manufacturer.
  - Example: Reckless use or sabotage or intentional disregard of information for safety are such acts.
  - Comments: An intended but erroneous action that is not abnormal use is considerer a type of use error. Abnormal use does not relieve the manufacturer from considering non-use interface-related means of risk control.

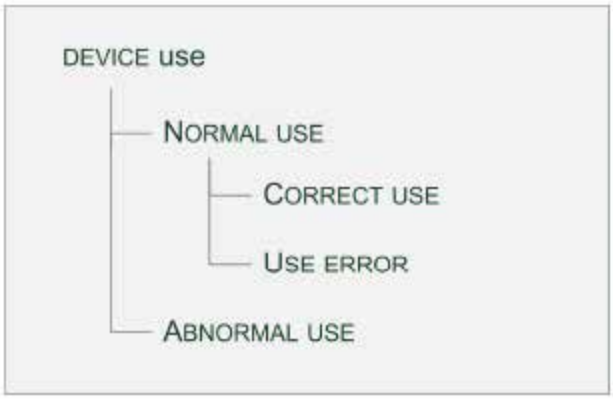


Figure 6.2.1 Relationship of the types of use

- **Use environment:** actual conditions and setting in which users interact with the device.
- **Use scenario:** specific sequence of task performed by a specific user in a specific use environment and any resulting response of the device.
- **User interface:** means by which the user and the device interact. It includes all the elements of the device with which the user interacts including the physical aspects of the device as well as visual, auditory, tactile displays and is not limited to a software interface.
- **Hazard-related use scenario:** use scenario that could lead to a hazardous situation or harm. A hazard-related use scenario can often be linked to a potential use error.

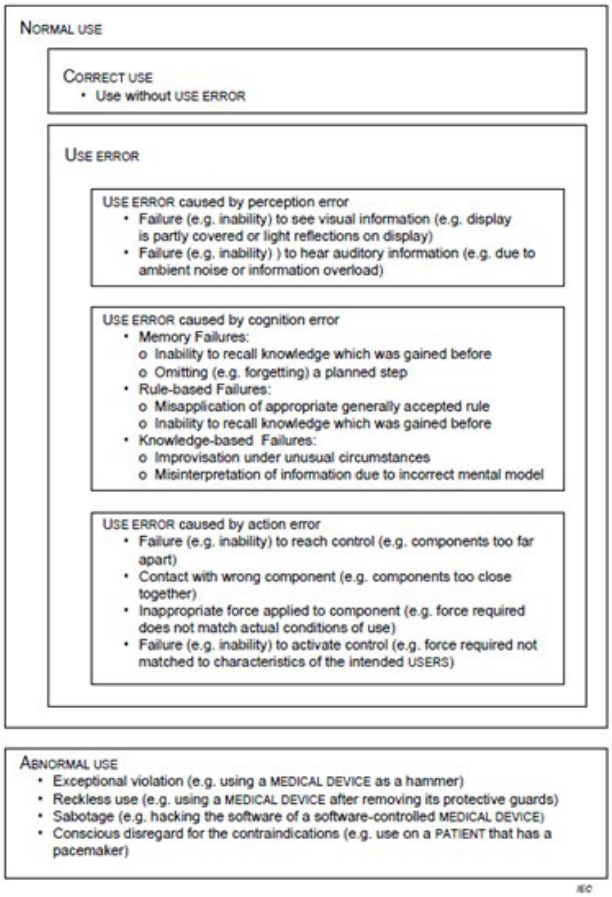


Figure 6.2.2 Example of interrelationships between the different types of a medical use

2.3 ISO 9241 – ERGONOMICS OF HUMAN-SYSTEM INTERACTION

Here in this chapter, ISO 9241 parts 11 and 210 are going to be introduced and commented. Part 11 is about terms and definitions and part 210 is about human-centred design for interactive systems.

As ISO 9241-210 specifies, human-centred design is an approach to interactive systems development that aims to make systems usable and useful by focusing on the users, their needs, and requirements, and by applying human factors/ergonomics, and usability knowledge and techniques. This approach enhances effectiveness and efficiency, improves human well-being, user satisfaction, accessibility, and sustainability; and counteracts possible adverse effects of use on human health, safety, and performance.

Using a human-centred approach to design and development has substantial economic and social benefits for users, employers, and suppliers. Highly usable systems and products tend to be more successful both technically and commercially. In some areas, such as consumer products, purchasers will pay a premium for well-designed products and systems. Support and help-desk costs are reduced when users can understand and use products without additional assistance. In most countries, employers and suppliers have legal obligations to protect users from risks to their health, and safety and human-centred methods can reduce these risks (e.g., musculoskeletal risks). Systems designed using human-centred methods improve overall quality, for example, by:

- Increasing the productivity of users and the operational efficiency of organizations.
- Being easier to understand and use, thus reducing training and support costs.
- Increasing usability (effectiveness, efficiency, and satisfaction).
- Increasing accessibility (for people from a population with the widest range of user needs, characteristics, and capabilities).
- Improving user experience.
- Reducing discomfort and stress.
- Providing a competitive advantage, for example by improving brand image.
- Contributing towards sustainability objectives.

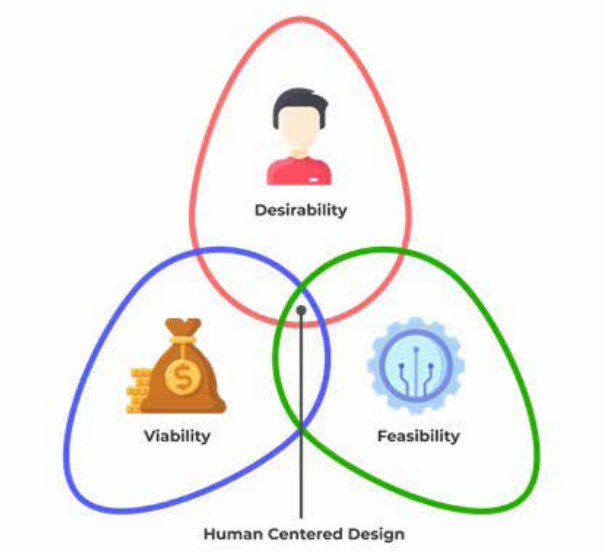


Figure 6.2.3 Human centered design scheme

The complete benefits of human-centred design can be determined by considering the total life cycle costs of the product, system, or service, including conception, design, implementation, support, use, maintenance and, finally, disposal. Taking a human-centred design approach contributes to other aspects system design, for example, by improving the identification and definition of functional requirements.

Here are illustrated some examples of outputs from human-centred design activities:

ACTIVITIES	OUTPUTS FROM HUMAN-CENTRED DESIGN	EXAMPLES OF INFORMATION CONTAINED IN OUTPUTS
understand and specify the context of use	context of use description	• user group profiles • as-is scenarios • personas
specify the user requirements	user needs description user requirements specification	• identified user needs • derived user requirements • required design guidance
produce design solutions to meet these requirements	user-system interaction specification user interface specification implemented user interface	• scenarios of use • low-fidelity prototypes • high-fidelity prototypes
evaluate the designs against requirements	evaluation results conformance test results long-term monitoring results	• usability-test report • field report • user survey report

Also, ISO 9241-210 specifies that, whatever the design process and allocation of responsibilities and roles adopted, a human-centred approach should follow the principles here listed:

a) **The design is based upon an explicit understanding of users, tasks, and environments.**
Products, systems, and services should be designed for considering people who will use them. Therefore, all relevant user and stakeholder groups should be identified.

b) **Users are involved throughout design and development.**
That provides a valuable source of knowledge about the context of use, the tasks, and how users are likely to work with the future product. User involvement should be active, acting as source relevant data or evaluating solutions, and these users should have capabilities, characteristics and experience that reflect the range of users for whom the product is being designed.

c) **The design is driven and refined by user-centred evaluation.**
Evaluating designs with users and improving them based on their feedback provides an effective means of minimizing the risk of a system not meeting user or organizational needs. Such evaluation allows preliminary design solution to be tested against “real world” scenarios.

d) **The process is iterative.**
Interaction should be used to progressively eliminate uncertainty during the development of interactive systems or products. Iteration implies that descriptions, specifications, and prototypes are revised and refined when new information is obtained to minimize the risk of the system under development failing to meet user requirements. Many of the needs and expectations of users that will impact on the design of the interaction only emerge during development.

e) **The design addresses the whole user experience.**
Designing for the user's experience involves considering, where appropriate, organizational impacts, user documentation, on-line help, support and maintenance, training, long-term use, and product packaging. Users' strengths, limitation, preferences and expectations should be taken into account when specifying which activities are carried out y the users, and which functions are carried out by the technology.

f) **The design team includes multidisciplinary skills and perspectives.**
Human-centred design teams should be sufficiently diverse to collaborate over design and implementation trade-off decisions art appropriate times.

Once the need for developing a system, product, or service has been identified, and the decision has been made to use human-centred development, four linked human-centred design activities shall take place during the design of any interactive system:

a) **Understanding and specifying the context of use.**
The context-of-use description shall include the users and other stakeholder groups, the characteristics of them, the goals and tasks of the users and the environment(s) of the system.

b) **Specifying the user requirements.**
This activity shall be extended to create an explicit statement of user requirements in relation to the intended context of use and the business objectives of the system. User and other stakeholder needs should be identified, taking account of the context of use. These should include that which users need to achieve, and any constraints imposed by the context of use. Specification of user requirements shall include the intended context of use, requirements derived from user needs and the context of use, requirements arising from relevant ergonomics and user interface knowledge, standards and guidelines,

usability requirements and objectives, and requirements derived from organizational requirements that directly affect the user. Also, potential conflicts between user requirements should be resolved.

c) **Producing design solutions.**
Potential design solutions are produced by drawing on the description of the context of use, the results of any baseline evaluations, the established state of the art in the application domain, design and usability guidelines and standards, etc. They should include the following: designing user tasks, user-system interaction, and user interface to meet user requirements, taking into consideration the whole user experience, making the deign solutions more concrete, altering the design solutions in response to user-centred evaluation and feedback and finally, communicating the design solutions to those responsible for their implementation.

d) **Evaluating the design.**
User-centred evaluation can be used to collect new information about user needs, provide feedback on strengths and weaknesses of the design solution from the user's perspective, assess whether user requirements have been achieved, and stablish baselines or make comparisons between designs. User-centred evaluation should involve allocating resources both to obtain early feedback in order to improve the product, planning the user-centred evaluation so that it fits the project schedule, carrying out sufficiently comprehensive testing to provide meaningful results for the system as a whole, analysing the results, prioritizing issues and proposing solutions, and communicating the solutions appropriately so that they can be used effectively by the design team.

2.4 USABILITY ENGINEERING IN THE DESIGN PROCESS

This chapter aims to explore the transferability of usability concepts and evaluation methods to processes in the field of engineering design. Implementing new Engineering Design processes involves a lot of effort, time, and costs, including trainings, software, and pilot projects. However, the results are not always satisfactory. Many issues can be traced back to factors that are subjective, and context dependent for example: high perceived complexity, non-intuitive information flow, and missing feedback from downstream activities.
In Engineering Design, consequences of “bad process usability” may include long process-related training for new employees, missing process compliance, or many non-value activities, such as looking for information. So far, Engineering Design Processes are generally optimized towards efficiency, quality, costs, risks, etc. However, an analysis that includes requirements from the process users' view is missing.

So, what is “process usability” in the context of engineering design processes? And how could the usability of engineering design processes be evaluated or measured? For answering this, some terms or usability attributes are described.

IN A NUTSHELL

Usability attributes:

- **Accessibility:** describes a product, service, environment, or facility that is usable by people with the widest range of capabilities. It is also to achieve the highest possible levels of effectiveness, efficiency, and satisfaction during usage.
- **Consistency:** is a general principle in the interaction between humans and systems. Within the context of processes, consistency is realized by a coherent representation of all relevant information in a formal structure, which avoids different words, situations or actions with the same meaning. Good design should consider both internal consistency – within the system itself – and external consistency – among a specific number of systems.
- **Compliance:** is ensuring that business processes, operations and practice are in accordance with a prescribed and/or agreed set of norms. These ensure that the considered system is capable to adhere to standards, conventions, regulations, or similar prescriptions.
- **Compatibility/Interoperability:** Compatibility describes a broader view, being the extent to which a system can exchange information with other systems to perform its required functions whilst being used in the same environment. Interoperability ensures that the exchange of information is possible, and that this information can be used at all.
- **Flexibility:** describes the extent to which a system can be usable in contexts that exceed those the system was initially specified for. Engineering Design processes demand for flexible process structures to react adequately and with relation to the situation.
- **Reliability/Maturity:** Reliability can be defined as a system's capability to maintain a predefined level of functional performance being exposed to a specified environment and being used under specified conditions for a specified period. In addition, maturity can be seen as sub-characteristic of reliability, it can be described as the property to avoid failure caused by system native faults.
- **Robustness:** In system design, activities and functions are considered robust if they can even be executed if invalid, incomplete, or conflicting inputs are present. In regard of process usability, robustness means that a process can deliver successful results even when for example human errors or incomplete information are present.
- **Transparency:** is a process's capability of being monitored, controlled, and managed by decision makers.
- **Understandability:** Usability is highly determined by whether the user experiences an interaction with the relevant system as understandable. This includes that the system must enable the user to understand whether itself and its components are suitable, which functions it delivers and how all this can be executed in a specified context of use.

2.5 WHAT IS CE MARKING? REGULATIONS AND DIRECTIVES

The European Union has as one of its main objectives the establishment of an internal market, or single European market, consisting of a territory without internal barriers or obstacles to the free movement of goods, services, workers or capital.

The internal market currently consists of the 27 Member States, Norway, Iceland and Liechtenstein (acceded through the Treaty on European Economic Union) and Switzerland (following the signature of various bilateral agreements with the European Union).

One of the main pillars of the internal market is the **free movement of goods** whereby any product manufactured and marketed in one Member State, and in accordance with the rules of that State, must be admitted into any other Member State, except for reasons of general interest recognised by Community law.

EU Regulation 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully placed on the market in another Member State aims to strengthen the functioning of the internal market by better implementing the principle of mutual recognition and removing unjustified barriers to trade.

Figure 6.2.4 CE marking example in a product

2.5.1 CE marking. Definition and functionsdirectives

The acronym CE stands for “Conformité Européenne, which translates to “European Compliance”

The CE marking or European Compliance Indicator is the passport for products guaranteeing their free movement within the European Economic Area (EEA).

Assigning a CE marking or label to a product is a declaration of compliance with relevant or applicable health, safety and environmental protection legislation for products sold within the EEA. The CE marking can also be found on products sold outside the EEA, which have been manufactured or created to be sold in the EEA.

The fact that a product is identified with the CE marking does not imply that it is manufactured in the European Union, but rather that it has been placed on the Community market in accordance with European safety regulations. The marking must be done before the product is placed or put into service for the first time on the EU market, regardless of its price or the way it is marketed.

The affixing of the CE marking on a product brings certain benefits to both the manufacturer and the consumer.

For the manufacturer:

- It allows unrestricted access to the European market, avoiding technical barriers, while being recognised in other markets globally.
- Equality in the European market, avoiding discrimination and ensuring legal competition.
- Simpler and more economical trade relations between EU countries.

For the consumer:

- Purchasing a CE marked product ensures that the product is safe as it guarantees common European levels of safety, functionality, durability, energy savings or environmental protection.

CE marking is only mandatory for certain products for which EU specifications exist and for which CE marking is required.

Once the CE Marking has been affixed to the product, its value increases directly.

DO YOU WANT TO KNOW MORE ABOUT...

The Official Journal of the European Union (C272) of 26 July 2016 details as definition and functions of CE marking the following:

- The CE marking indicates the conformity of the product with the EU legislation applicable to the product covered by the CE marking.
- The CE marking is affixed on products to be placed on the EEA (European Economic Area) and Turkish market, whether they are manufactured in the EEA, Turkey or elsewhere.

The CE marking is a key indicator (but not proof) of a product's conformity with EU legislation and allows the free movement of products within the European market whether they are manufactured in the EEA, Turkey or elsewhere.

EEA Member States (i.e. EU Member States and some EFTA countries (Iceland, Norway and Liechtenstein)) are not allowed to restrict the placing on the market of CE marked products, unless such measures are justified by evidence of non-compliance of a product. This also applies to products manufactured in third countries that are sold in the EEA.

The CE marking is the visible consequence of a whole process involving conformity assessment in a broad sense and indicates that a product is declared by its manufacturer to be in conformity with Union harmonisation legislation.

2.5.2 CE marking. Placement and responsibilities process

Products bearing the CE marking are those that are affected by a directive or regulation. It is not correct to incorporate this symbol if it is not required by the regulations, as it creates false legal certainty for customers who buy the product thinking that it complies with safety requirements that do not exist.

It is the responsibility of the manufacturer to check whether his product falls within the scope of one or more directives. Two or more directives may apply simultaneously or jointly to the same product.

It is just as illegal to sell a product without CE marking, if the standard indicates it, as it is to put a CE certificate on a product that the various harmonised standards exclude from obtaining this certification.
The manufacturer of a product bearing the CE marking must:

- Ensure the conformity of the product with all relevant requirements at EU level.
- Determine whether it can assess the product itself or must involve a **notified body**.
- Prepare a **technical file** documenting the conformity of the product.
- Draw up and sign an **EU declaration of conformity**.

DO YOU WANT TO KNOW MORE ABOUT...

The Official Journal of the European Union (C272) of 26 July 2016 states that:

- The CE marking is affixed by manufacturers (established inside or outside the Union) or by their authorised representative established within the Union.
- By affixing the CE marking, the manufacturer declares on his sole responsibility that the product is in conformity with all applicable EU legislative requirements, and that the relevant conformity assessment procedures have been carried out satisfactorily.

The manufacturer, whether based inside or outside the Union, is the entity ultimately responsible for the conformity of the product with the provisions of the Union harmonisation legislation and for affixing the CE marking. The manufacturer may assign an authorised representative to affix the CE marking on his behalf.

By affixing the CE marking on a product, a manufacturer declares, on his sole responsibility

- regardless of a third party being involved in the conformity assessment process or not
- conformity with all legal requirements for obtaining the CE marking.

If the importer or distributor or other agent places products on the market under his own name or trademark, or modifies them, he assumes the responsibilities of the manufacturer. This includes responsibility for product conformity and the affixing of the CE marking. In this case, he must have sufficient information on the design and manufacture of the product, as he will assume legal responsibility when affixing the CE marking.

CE marking applies to the following product groups:

- SAFETY OF TOYS. Directives 88/378/CEE and 2009/48/CE apply.
- CONSTRUCTION PRODUCTS. EU Regulation 305/2011 applies.
- PERSONAL PROTECTIVE EQUIPMENT. EU Regulation 2016/425 applies.
- MEDICAL DEVICES. EU Regulation 2017/745 applies
- HOT-WATER BOILERS. Directive 92/42/CEE applies.
- EXPLOSIVES FOR CIVIL USES. Directive 2014/28/UE applies
- ACTIVE IMPLANTABLE MEDICAL DEVICES. Directive 90/385/CEE applies
- RECREATIONAL CRAFT. Directive 2013/53/UE applies.
- LIFTS. Directive 2014/33/UE applies.
- PRESSURE EQUIPMENT. Directive 2014/68/UE applies.
- IN VITRO DIAGNOSTIC MEDICAL DEVICES. EU Regulation 2017/746 applies.
- RADIO EQUIPMENT AND TELECOMMUNICATIONS TERMINAL EQUIPMENT. Directive RED 2014/53/UE applies.
- CABLEWAY INSTALLATIONS DESIGNED TO CARRY PERSONS. Directive 2000/9/CE applies.
- MEASURING INSTRUMENTS. Directive 2014/32/UE applies.
- ELECTRICAL AND ELECTRONIC DEVICES. Directive 2014/30/UE applies.
- MACHINERY. Directive 2006/42/CE applies.
- LOW VOLTAGE. Directive 2014/35/UE applies.
- PYROTECHNICS. Directive 2007/23/CE and 2013/29/UE apply.
- SIMPLE PRESSURE VESSELS. Directive 2014/29/UE applies.
- APPLIANCES BURNING GASEOUS FUELS. UE regulation 2016/426 applies.

DO YOU WANT TO KNOW MORE ABOUT...

According to The Official Journal of the European Union C272) of 26 July 2016, not all products must be CE marked. CE marking is mandatory in all products falling withing the scope of legislative acts providing for its affixing, and which are intended for the European market. CE marking applies to:

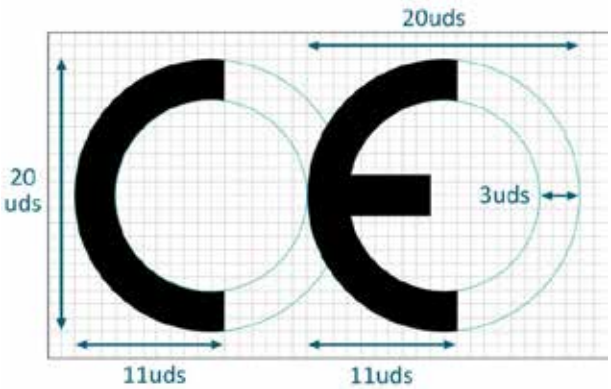
- on all newly manufactured products which are subject to legislation providing for CE marking, whether manufactured in Member States or in third countries.
- on used and second-hand products imported from third countries which are subject to the legislation covering the CE marking,
- on modified products which, like new products, are subject to the legislation covering the CE marking and which have been modified in a way that could affect the safety or the conformity of the product with the applicable harmonisation legislation.

In the case where a product bearing the CE marking is incorporated into another product which also requires CE marking, this will create a situation where a product may bear more than one CE marking.

2.5.3 CE marking. Logo

This symbol is formed by the outline of two letters CE forming two circles tangentially touching each other. The proportions of this grid pattern must be respected if the symbol is reduced or enlarged.

The different elements shall have substantially the same vertical dimension, which shall not be less than 5 mm. Exceptionally, smaller sizes may be used in the case of small products.



The CE marking shall be affixed visibly, legibly and indelibly to the products or to its data plate. However, where that is not possible or not warranted on account of the nature of the product, it must be affixed to the packaging, if any, and to the accompanying documents.

The requirement of visibility means that the CE marking must be easily accessible to all parties. This does not imply that it must be visible before opening the packaging of a product, as the CE marking only needs to be affixed on the packaging also in cases where this is explicitly required by the relevant Union acts.
The CE marking may take different forms (e.g., coloured, solid/hollow) provided that it is affixed in a visible, legible and proportionate manner.

Regulation (EC) No 765/2008 and Decision 768/2008/EC lay down the general principles relating to CE marking.

2.5.4 CE marking. Notified body

Public administrations need specialised instruments and entities to prevent and control industrial safety and minimise the risks to which users are exposed during the use of a product. To this end, they designate different control bodies to analyse whether, during its design, execution, production, commissioning and useful life, the product continues to provide the performance required to be safe during use.

When Control Bodies act in the European regulatory environment, they are called NOTIFIED BODIES. That is why the Notified Body will be mandatory to obtain the CE Marking for some products.

A Notified Body is a Control Body in charge of applying the Directives or Regulations (European Regulations) to control the placing on the market and the proper use of the CE Marking. A Notified Body is the entity designated by a Member State and approved by the European Commission to assess the conformity of certain products to which certain directives and regulations apply and on which the Notified Body is previously authorised to assess.

In Spain, in order to carry out their activity, Notified Bodies must have the prior approval of ENAC (National Accreditation Entity) to confirm that this institution has the necessary competences, tools and means to fulfil its function under a specific European Regulation. These bodies carry out tasks related to conformity assessment procedures when their intervention is required and have the technical ability to do so in an independent and impartial manner. It is up to the manufacturer to check in the regulations or to decide on a voluntary basis whether he wants to have the product assessed by a notified body.

Not all products are subject to assessment by a Notified Body. Notified Bodies act on products that can put the life of the user at risk or cause serious permanent injury. That is why, for example, for some Personal Protective Equipment or Medical Devices (Class I) the intervention of this figure is not necessary, but for others it is.
Where such assessment is required, the CE marking is accompanied by the identification number of the notified body. The CE marking and the identification number may be affixed separately, where they are clearly linked.

CE
0318

If verification by a notified body is not necessary, the manufacturer shall personally verify compliance with the technical requirements including estimation and documentation of possible risks arising from the use of the product.

IN A NUTSHELL

NOTIFIED BODY-CERTIFYING BODY-ACCREDITED LABORATORY

In addition to the Notified Bodies, there are other accredited entities that fulfil an independent function and close the safety circuit to be fulfilled by a product before being placed on the market.

- **Accredited laboratories**, for example, are responsible for carrying out tests and issuing reports on them with the results, whether satisfactory or not, in order to comply with the technical criteria, set out in the different standards for which they are accredited. These laboratories have been previously accredited by ENAC in order to be able to carry out product testing in accordance with a specific standard, regulation or directive.
- **Certifying Bodies** are entities accredited to issue a product evaluation report in accordance with the specific standards that affect the product. In addition to evaluating the test reports issued by the accredited laboratory, these entities normally carry out periodic factory audits to check that the production standard has not changed over time, and that, therefore, the product continues to comply with its certification.

DO YOU WANT TO KNOW MORE ABOUT...

For example, in Spain, the **Spanish Agency for Medicines and Health Products (AEMPS)** acts as:

- Notified Body 0318 for CE Marking of Medical Devices and Conformity Assessment of all medical devices.
- Certification Body approved by ENAC for the certification of quality management systems for medical devices in accordance with the standard UNE-EN-ISO 13485.

In addition to the AEMPS as a Notified Body, there are many Notified Bodies in Spain for the evaluation and certification of different products (around 68 bodies).

To search the Notified Bodies existing in a specific country, you should visit the European Commission website and check the NANDO list.

2.5.5 CE marking. Technical documentation

The technical documentation is necessary to prove that the product meets the essential requirements and, therefore, CE marking can be affixed. This includes the technical file and the information documents:

- **Technical file:** intended to provide information on design, tests, manufacture, operation of the product, inspections, etc. Each directive establishes the content of the documentation according to the nature of the product and what is deemed necessary from a technical point of view to demonstrate conformity with the essential requirements of the relevant directive.
- **Information documents:** sometimes they must accompany the product when it is placed on the market. For example, instruction manuals to be drawn up by the manufacturer or his authorised representative established in the Community and drafted in one of the Community languages.

The **technical documentation** must include at least:

- The name and address of the manufacturer or his authorised representative(s)
- A brief description of the product
- Identification of the product, e.g. its serial number
- The name and address of the facilities involved in the design and manufacture of the product
- The name and address of any Notified Body involved in the conformity assessment of the product (if necessary)
- A statement of the conformity assessment procedure followed by the declaration of conformity
- The label and instructions for use
- A statement of the relevant regulations with which the product complies
- Identification of the technical standards claimed to be complied with
- The parts list
- The test results

The technical documentation should be available when the product is placed on the market, regardless of its origin or location. This documentation must be kept by the manufacturer for 10 years from the date of placing the product on the market, unless the applicable Union harmonisation legislation expressly provides for a different duration.

Generally, the documentation shall include a description of the product and its intended use, and cover the design, manufacture and operation of the product. The information included shall depend on the nature of the product and on what is deemed necessary from a technical point of view to demonstrate the conformity of that product with the essential requirements of the relevant Union harmonisation legislation or, where harmonised standards have been applied, its conformity with those standards by specifying the essential requirements subject to those standards.

2.5.6 Penalties

The Administration, for control purposes, establishes annual inspection plans (Industry, Consumer Affairs...) that result in the establishment of fines, and the withdrawal from the market or prohibition of the circulation of products that endanger the safety or health of people, goods or the environment, both in Spain and in the rest of the EU member states.

DO YOU WANT TO KNOW MORE ABOUT...

The Official Journal of the European Union (C272) of 26 July 2016 states that:

- Member States shall ensure the correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of the marking.
- Member States shall also provide for appropriate penalties, which may include criminal sanctions for serious infringements.
- A Member State must notify the Commission and the other Member States when it has decided to restrict free movement due to incorrect affixing of the CE marking, or when it acts against those responsible for a non-compliant product bearing the CE marking.

2.6 DIRECTIVES APPLICABLE TO FURNITURE

CE marking is mandatory for most, but not all products. However, this does not mean that a product without CE Marking is exempt from complying with European Regulations.

2.6.1 Directive 2001/95/CE

When manufacturing and placing a product on the market, the General Product Safety Directive 2001/95/EC must be considered, whose transposition in Spain has been made by Royal Decree 1801/2003 of 26 December 2003.

When there are Directives applicable to different types of products, the safety requirements of the General Product Safety Directive are always included, in addition to those specific to each type of product. In other words, the General Product Safety Directive 2001/95/EEC will have a supplementary and complementary application for all products, whether they have a CE marking.

"The General Product Safety Directive 2001/95/EEC was created to enforce minimum safety and quality requirements for products to protect users. This directive applies to both CE-marked products and products that do not require certification."

When the European CE Marking Regulation does not define its application for a specific product class, the General Product Safety Directive must be complied with in order to require a minimum of product safety and quality for their use and consumer protection.

This Directive is mainly aimed at products which may be potentially dangerous, and which are intended for children and the elderly.

Products not subject to CE marking must submit their technical documentation in the same way as any product to which CE marking applies. In some cases, products must pass laboratory tests.

The application of this directive promotes the manufacture of safe products, understood as those products which, under normal or reasonably foreseeable conditions of use, present no risk, or present minimal risks compatible with the use of the product, considering:

- The characteristics of the product.
- Interaction with other products. Whether there is a risk from contact or co-use with another product that is unsafe.
- The information accompanying the product. Labelling, warnings and instructions for use and maintenance.
- The presentation and advertising of the product.

This Directive applies to manufacturers, importers and distributors of products. Each must ensure the safety of the product, provide information on the risks, indicate product and company information on the packaging, take appropriate measures to avoid risk in the case of products on the market, and notify the competent authorities of products presenting a risk and being placed on the market.

European regulations are clear in defining the products that require CE marking, such as medical devices, electronic devices, machinery and toys. However, many manufacturers are unaware that the European Union provides a horizontal legislative framework to ensure the safety of all products, including those to which CE marking does not apply. In this way, it ensures the protection of the health and safety of consumers within the European Economic Area (EEA).

This directive shall apply to:

- Products intended for the consumer.
- Products which, although not intended for the consumer, are reasonably foreseeable to be used by the consumer.
- Products which are supplied or made available to the consumer, irrespective of the selling technique (including distance or electronic selling).

- Within these products there are some exceptions such as:
- Antiques.
- Used products that are sold to be repaired or reconditioned before use, provided that the seller clearly informs the person to whom he supplies the product.
- Services. However, if the Directive applies to products offered or made available to the consumer in the context of the provision of services for use by the consumer.
- Means of transport on which consumers move or travel and which are driven by a professional.

Implementation of Directive 2001/95/EC on general product safety protects not only the end-customer, but also the manufacturer, who must become liable for accidents or problems arising from the use of his products, as well as face possible penalties and criminal responses. They must then also invest in cleaning up their image and thereby regain the trust of their customers.

In the specific case of the furniture sector, in addition to the General Product Directive, other directives and/or regulations apply. We will focus on two of them:

- **Directive 2006/42/EC** of the European Parliament and of the Council of 17 May 2006 on machinery.
- **Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices.

2.6.2 Directive 2006/42/EC

This Directive is a revised version of the first Machinery Directive, the first version of which was adopted in 1989, the latter version being applicable since 29 December 2009. It has the aim of harmonising the health and safety requirements, thereby achieving a high level of health and safety protection, while ensuring the free circulation of machinery on the EU market.

It sets out:
the “essential health and safety requirements”, meaning mandatory provisions relating to the design and construction of the products subject to this Directive to ensure a high level of protection of the health and safety of persons and, where appropriate, of domestic animals and property and, where applicable, of the environment.

It is therefore understood that any machine must be designed and constructed considering risks that it may generate during its use. Using the risk assessment results becomes essential here.

The free interpretation of the directives, largely due to abstract formulations and inconsistencies in explaining the text, promotes the creation of guides that facilitate understanding and help market surveillance authorities and manufacturers themselves in the correct application of their bases.

DO YOU WANT TO KNOW MORE ABOUT...

The latest published version is the **Guide to application of the Machinery Directive 2006/42/CE Edition 2.2 – Ocotber 2019** (update of 2nd Edition). Therein the mandatory application of the Machinery Directive in the furniture sector is clearly demonstrated.

The content of this Guide serves only as an interpretative aid to market surveillance authorities and is not legally binding.

The Guide to application of the Machinery Directive 2006/42/EC states that furniture incorporating a motor is subject to compliance with the Machinery Directive 2006/45/EC and therefore the product must be CE marked. This guide has been published to give guidance and clarify which products are machinery and therefore fall within its scope.

"Electrically operated furniture, such as beds, chairs, tables, storage furniture including kitchen furniture, remain subject to the Machinery Directive as they are not household appliances of the types indicated above.

This includes electrically operated furniture which "entertains", e.g., by responding to a sound or film track, events in a video game, "simulates" function such as machinery at shows or exhibitions, or provides a non-medical stimulus (e.g. for relaxation), unless the products are specifically intended for use in fairgrounds or amusement parks – see §49 comments on the exclusion of Article 1 (2) b. However, where provided for medical purposes such that they are within scope of the Regulation 2017/745 concerning medical devices, that Regulation applies instead of the Machinery Directive".

For manufacturers of household furniture incorporating mains-operated electric drive motors, this is an obligation that they must be aware of and comply with due to the important implications of the Directive.

It is therefore understood that the definitions given in this Directive apply to household furniture:

- "machinery" means an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application,
- an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion,
- an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure,
- assemblies of machinery referred to in the first, second and third indents or partly completed machinery referred to in the next point which, in order to achieve the same
- an assembly of linked parts or components, at least one of which moves, and which are joined together, intended for lifting loads and whose only power source is directly applied human effort.
- "partly completed machinery" means an assembly which is almost machinery, but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies.

According to Directive 2006/42/EC, examples of products that must be CE marked are:

- Height-adjustable desks and tables.
- Bases and elevating beds.
- Adjustable beds and seats.
- Beds with TV lifting devices.
- Air mattresses with integrated pumps.
- Adjustable storage units.
- Electrically operated doors and drawers and, in general, all movable elements operated in the same way.
- Electrically operated massage and relaxation chairs.

We are therefore talking about furniture that incorporates electrical components (such as cable, fluorescent tube, LED, switch, plug, anti-fogging system for mirrors, electric motor, etc.) to be connected to the mains. All of them must comply not only with Directive 2006/42/EC on machinery, but also with Directive **2004/108/EC** on electromagnetic compatibility of electrical and electronic equipment and Directive **2014/35/EU** on the marketing of low-voltage electrical equipment.

Directive 2004/108/EC applies to equipment (apparatus and fixed installations), and Directive 2014/35/EU applies to electrical equipment intended for use within certain voltage limits which is new to the EU market when it is placed on the market, either new electrical equipment produced by a manufacturer established in the EU or new or second-hand electrical equipment imported from a third country.

None of them cover all the hazards listed in Annex I to Directive 2006/42/EC and are therefore complementary to it and may not cease to apply.

Therefore, in order to be able to access the European market with this type of furniture, manufacturers must integrate all the requirements of the 2006/45/EC directive in the design and manufacturing phases, as well as when defining the installation and maintenance method.

The directive divides machinery into two typologies and describes the certification procedures according to the hazardous nature of each piece of equipment.

For machinery classified as hazardous (Annex IV), the conformity assessment process involves the intervention of a Notified Body. For less hazardous machinery, the manufacturer or his representative in the EU will be responsible for carrying out the necessary tests and making a declaration of conformity under his responsibility. This second case would apply to most of the furniture manufactured within the definition of machinery.

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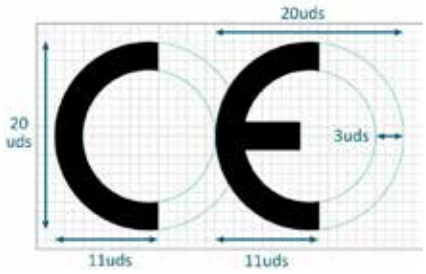
In the case of needing a notified body, in Spain there are:

- ECA (Collaborating Entity of the Administration) S.A.U **ON-0056**
- AENOR (Spanish Association for Standardisation and Certification) **ON-0099**
- LGAI Technological Center, S.A. / Applus **ON-0370**

The CE marking of conformity of machinery shall follow the same guidelines as any other CE marking, namely:

- It shall consist of the letters "CE" in the following format:



- In the case of reducing or increasing the size of the CE marking, proportions must be respected.
- The various elements must have substantially the same vertical dimension, which may not be less than 5 mm. Exceptions to the minimum dimension are permitted in the case of small machines.
- It must be placed next to the name of the manufacturer or his authorised representative.
- Where the intervention of a notified body has been required, the identification number of the Notified Body must be affixed after the CE marking.

According to the directive, a marking shall be considered as non-compliant when:

- A marking is affixed under the Machinery Directive on products outside this Directive.
- There is no CE marking and/or declaration of conformity under this Directive.
- Affixing of a marking other than the CE marking or not complying with the above indications.

Member States will be responsible for detecting such non-compliance. In such a case, manufacturers or their authorised representatives shall be obliged to bring the product into conformity by putting an end to the infringement. Failure to do so will result in the Member State taking the necessary measures to restrict or prohibit the placing on the market of the product or to ensure that it is withdrawn from the market.

Depending on the seriousness of the non-compliance, Member States shall determine the system of penalties applicable and shall take all the measures necessary to ensure that they are applied. The penalties provided for must be effective, proportionate and dissuasive.

2.6.3 Regulation (EU) 2017/745

Regulation (EU) 2017/745 of the European Parliament of 5 April 2017 on medical devices repeals Council Directives 93/42/EEC and 90/385/EEC on active implantable products.

This Regulation responds, on the one hand, to a widespread concern about the safety of medical devices and their regulatory framework based on the new approach, and on the other hand, to establish a regulation ensuring the availability of safe and effective medical devices on the market.

The main objective is to provide a legal framework for medical devices that ensures a high level of quality, safety and health protection, while also supporting innovation.

This Regulation affects the furniture sector as there is furniture whose features and functionality are included in the definition of medical devices and accessories for medical devices.

DO YOU WANT TO KNOW MORE ABOUT...

This Regulation defines:

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

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

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

- devices for the control or support of conception.
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

"accessory for a medical device" as an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s).

Under normal conditions, all medical devices marketed in the European Union must have the CE marking. It is up to the manufacturer to place the product on the market with this certification. In the case of other economic operators, it is up to them to ensure that the product has the CE marking.

Before applying Regulation (EU) 2017/745 we must classify the product as such, and once this Regulation applies, before starting certification, manufacturers must identify the class of the product in order to establish the applicable requirements. The class of the medical device can be determined using the classification rules set out in the Regulation itself. The classification is determined on the basis of the intended use of the device, its characteristics and its inherent risks. Identifying the medical device class will help to determine the conformity assessment route or procedure that the medical device manufacturer should follow for his certification project.

The implementing legislation defines a classification in relation to the duration of use of the product by the patient. Thus, it tries to influence the product risk classification by making a time of use – risks relationship.

Devices shall be classified in **Class I, IIa, IIb and III**, considering their intended purpose and inherent risks, in accordance with Annex VIII of the Regulation. In this Annex, different definitions are given which must be clear in order to make a correct classification of medical devices:

- Duration of use
- Invasive and active devices

“Invasive device”: Any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body. (Definition from (EU)2017/745).

“Active device”: any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any notable change, shall not be deemed to be active devices. (Definition from (EU)2017/745)

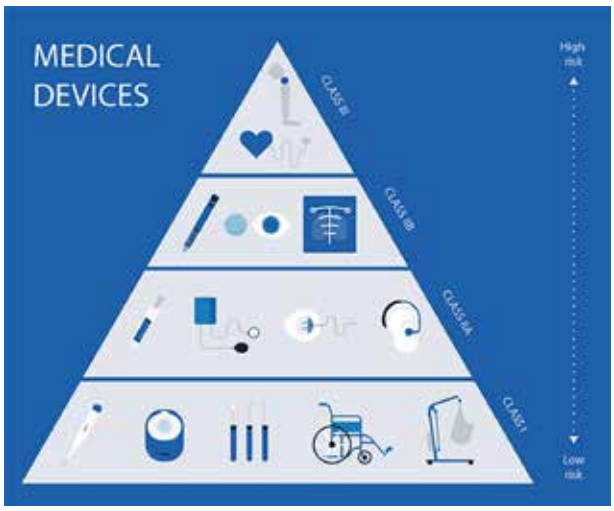


Figure 6.2.5 Different classes for medical devices

CLASS I DEVICES

Class I device means any device which only comes into contact with the patient's intact skin. They are also those devices that have a low or very low risk to the health of users. Examples include wheelchairs, extraction chairs, articulated beds, crutches, bandages, etc.

Thus, for Class I medical devices, no notified bodies are required to be involved in the conformity assessment process. Generally, all Class I devices require a conformity assessment procedure based on the sole responsibility of the manufacturer.

The manufacturer shall document and keep up to date the technical file associated with the product and to issue the corresponding declaration of conformity, stating the absence of foreseeable hazards.

Within Class I we may also find **Class I sterile and Class I with measuring function**.

CLASS IIA DEVICES

Class IIa devices are those listed as less hazardous than those that do require Notified Body control. At the beginning, the manufacturer submits an application for CE marking, describing the characteristics of the product and proposes a category, which will later be confirmed by a Notified Body and the Competent Authority (AEMPS, in the case of Spain).

These devices are found in the vicinity of wounds (without coming into direct contact with them), active drug delivery products, short-term invasive and others. Examples include blood bags, dressings intended to treat the vicinity of a wound or insulin pens.

CLASS IIB DEVICES

Class IIb devices are those which come into contact and enter the body of a patient and have significant effects on him. These devices require monitoring by a Notified Body, which are responsible for verifying the manufacturer's ability to control the risks that the use of the product poses to patients and users.

CLASS III DEVICES

Class III devices pose the greatest risk to users. These are devices capable of compromising the life of patients and therefore require full risk management. They come into contact with the nervous or circulatory systems; or have biological effects or are largely absorbed, such as coronary stents or IUDs.

They require examination of a Notified Body, which shall confirm that the use of the product has a risk management that is capable of combating many of the hazards that could pose to the patient.

The manufacturer, in accordance with the classification rules of Regulation 2017/745, proposes a classification for his product, which will have to be confirmed by the Notified Body and the competent authority in the country where the new medical device market is managed.

Depending on the use, the product will be classified as follows:

- **Transient use:** the device is intended for continuous use for less than 60 minutes. Examples are thermometers, tongue depressors or syringes.
- **Short term:** the device is intended for continuous use for more than 60 minutes and not more than 30 days. Examples are diagnostic medical imaging equipment.
- **Long term:** the device is intended for continuous use for more than 30 days. Examples are beds and accompanying chairs.

The Regulation details 22 classification rules within which the product will fit, selecting the most appropriate ones.
The complete analysis of the product classification will be documented in the Technical File, as well as the duration of use, which will be closely linked to the intended purpose.

Any lack of agreement concerning the classification of a medical device between the manufacturer and the Notified Body shall be resolved by the Competent Authority of the country where the manufacturer is located and in case the countries of the manufacturer and of the Notified Body are not the same, the Competent Authority of the manufacturer's country shall consult the Competent Authority of the country of the Notified Body.

In the case of needing a **Notified Body**, in Spain there is the Spanish Agency for Medicines and Health Products (AEMPS), **Notified Body 0318**. It is the only Notified Body in Spain designated by the Ministry of Health for the conformity assessment of medical devices and accredited by the National Accreditation Entity (ENAC) for certification in accordance with UNE-EN-ISO 13845.

DO YOU WANT TO KNOW MORE ABOUT...

In general, furniture that is eligible for CE marking under the requirements of Regulation (UE) 2017/745, as can be deduced from the above, will be classified as a **Class I medical device**, so it will be up to the manufacturers to self-certify that their product is safe.

However, for a manufacturer to be able to place a medical device on the market, it must comply not only with Regulation (EU)2017/745, but also with **Royal Decree 1591/2009**, that regulates medical devices in Spain, in particular:

a) The health guarantees for products and the essential requirements they must meet.
b) The procedures for the granting of prior licences for the operation of facilities.
c) Requirements for the conformity assessment of medical devices and for the affixing of the CE marking.
d) Requirements for the placing on the market and putting into service of medical devices for a special purpose
e) Requirements and actions of Notified Bodies.
f) The placing on the market and putting into service of medical devices.
g) Intra-Community and external trade in medical devices.
h) Clinical investigations involving medical devices.
i) The vigilance system for medical devices.
j) Inspection and health protection measures.
k) Advertising and displays

Scope of application and exclusions. This Royal Decree shall be applicable to:

a) medical devices and their accessories.
b) conditions for the use of devices in clinical investigations.
c) non-corrective contact lenses; devices and instruments used in permanent or semi-permanent make-up or tattooing of the skin by invasive techniques.

This Royal Decree shall not be applicable to:

a) in vitro diagnostic medical devices
b) implantable devices
c) medicines
d) cosmetic products.
e) human blood, blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market or put into service, such blood products, plasma or cells, except for devices referred to in paragraph 5.
f) transplants, tissues or cells of human origin, or products containing or consisting of them, except for devices referred to in paragraph 5.
g) transplants, tissues or cells of animal origin, except for devices manufactured utilising tissues or cells of animal origin or their derivatives, which are non-viable or are rendered non-viable.

In application of the Royal Decree 1591/2009 (Article 9. Chapter II), natural or legal persons engaged in the manufacture, importation, packaging or sterilisation of medical devices shall fulfil the obligation on requesting a **prior operating licence** for its facilities granted by the AEMP (Spanish Medicines and Health Products Agency).

Businesses/activities requiring a prior operating licence include:

- Serial manufacturers
- Tailor-made manufacturers in the autonomous cities of Ceuta and Melilla
- Groupers
- Third party sterilisers
- Distributors of medical devices and their accessories, active implantable medical devices, in vitro diagnostic medical devices and their accessories, non-corrective contact lenses, and devices and instruments for permanent, semi-permanent or invasive tattooing and permanent make-ups.

Businesses/activities not requiring a licence:

- Manufacturing companies for third parties that do not market in their own name.
- Medical device distribution companies.
- Medical device control laboratories.

This Royal Decree sets out specific guidelines with respect to concepts developed in Regulation (EU) 2017/745 and which, if necessary, we will have to treat as complementary to these, for example:

- Classification
- Conditions for affixing the CE marking.
- Notified Bodies
- Infringements
- Etc.

In most cases, companies engaged in the manufacture of furniture considered as a medical device do so in mass production, producing large quantities of product using standardised designs. Therefore, they shall obtain a prior operating licence.

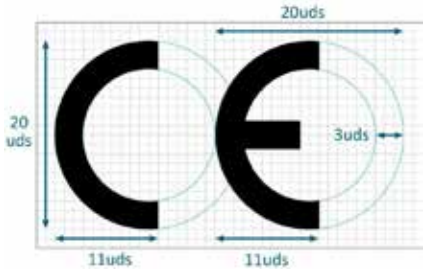
The authorisation procedure will require the AEMPS to verify that the applicant company and, where appropriate, the subcontracted companies have the appropriate facilities, means, procedures and personnel to carry out the activities in question, for which reason the interested parties must provide, together with the application, the documentation evidencing the availability of these. These verifications will involve the AEMPS requesting the Health Areas of the Government Delegations to visit the facilities of the applicant company and, where appropriate, those of the subcontractors, and to issue a report on the conditions in which the companies are going to carry out the activities.

To apply for this prior operating licence, the following is required:

- Having an organisational structure capable of guaranteeing quality.
- Availability of adequate facilities, procedures, equipment and personnel.
- Availability of a technical manager.
- Availability of a documentary archive (technical dossier and other documents).
- Availability of a person responsible for the vigilance system.
- Availability of a procedure for implementing restriction or monitoring measures.

The **CE marking of conformity of a medical device** shall follow the same guidelines as any CE marking, namely:

- It shall consist of the letters "CE" in the following format:



- In the case of reducing or increasing the size of the CE marking, proportions must be respected.
- The various elements must have substantially the same vertical dimension, which may not be less than 5 mm. Exceptions to the minimum dimension are permitted in the case of small machines.

As for the placement, the Regulation indicates that:

- shall be affixed visibly, legibly and indelibly to the device or to its sterile packaging. Where such affixing is not possible or not warranted on account of the nature of the product, the CE marking shall be affixed to the packaging. The CE marking shall also appear on all instructions for use and on any sales packaging.
- the CE marking shall be affixed before the product is placed on the market. It may be followed by a pictogram or other mark indicating a special risk or use.
- where appropriate, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedure referred to in Article 52. The identification number shall also appear in any advertising material mentioning that a device complies with the CE marking requirements.
- where products are subject to other Union legislation which also requires the affixing of the CE marking, the CE marking shall indicate that the products also fulfil the requirements of that other legislation.

As a rule, devices considered to be in conformity with the requirements of Regulation (EU)2017/745 shall bear the CE marking so that they can move freely within the European Union and be put into service in accordance with their intended purpose. Member States shall not create obstacles to the placing on the market or putting into service of devices which comply with the requirements laid down in this Regulation. However, Member States may decide whether they will restrict the use of a specific type of device in relation to aspects not covered by this Regulation.

As indicated above, if a piece of furniture is considered a medical device, it will be a Class I device. In this case, placing these products on the market will have to be done according to the following steps:

1. Integrating the Medical Devices Regulation into the quality management system (QMS). This will allow the correct assessment/decision to be made and appropriate documented evidence to be created to ensure that the following requirements are met.
2. Confirming that it is a medical device. Confirm that the product has the legal status of a medical device as defined in the Regulation in accordance with its intended purpose and its principal mode of action.
3. Confirming that it is a Class I medical device. Consult the Annex VIII of the Regulation to confirm that the product is correctly classified as Class I.

4. Procedures before placement on the market:
   - Comply with general safety and operational requirements. Particular attention shall be paid to products that are also machines. A risk management system shall be implemented at this stage to enable the identification and analysis of the risks associated with each product.
   - Conduct a clinical assessment. The manufacturer shall specify and justify the level of clinical evidence necessary to demonstrate conformity with the general safety and performance requirements. This level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.
   - Prepare technical documentation. The manufacturer shall establish and keep up to date the technical documentation demonstrating the conformity of his products with the technical requirements of the Regulation. It shall be prepared following the review of the general safety and performance requirements and the relevant technical provisions of the Regulation and, where applicable, the Machinery Directive.
   - Requesting the involvement of the notified body. The intervention of a notified body on Class I devices is only required for devices to which the procedures laid down in Annex IX, Chapters I and III or Annex XI, Part A of the Medical Devices Regulation apply.
   - Drafting instructions for use and labelling. All devices must be accompanied by the safety and operational information necessary to use them safely and which helps to identify both the device and the manufacturer, considering the training and knowledge of potential users. Instructions for use are not required for Class I products if they can be used properly without such instructions.
5. Reviewing compliance with the general obligations for manufacturers. Before placing a product on the market, the manufacturer shall ensure that the general obligations for manufacturers set out in Article 10 are met.
6. Drafting the EU declaration of conformity. The procedure whereby the manufacturer, having fulfilled the obligations imposed, declares that the products concerned satisfy the requirements of the Regulation that apply to them.
7. Affixing the CE marking. All Class I medical devices placed on the market shall bear the CE conformity marking, which shall be affixed visibly, legibly and indelibly to the device. The affixing of markings which are likely to mislead third parties as to the meaning of the marking is prohibited.
8. Registering products and manufacturers in EUDAMED. Prior to placing on the market, the manufacturer of a Class I medical device must register it in EUDAMED (European database on medical devices), which pursues safety in use and regulatory compliance applicable to the medical device.
9. Post-market surveillance (PMS). After having placed the Class I product on the market, the manufacturer shall follow the following steps of the PMS:
   - Evaluate experience gained during the post-market surveillance. This includes actively and regularly gathering user experience of products on the market, reviewing them and ensuring that any necessary measures are implemented.
   - Monitoring. The manufacturer is responsible for reporting all serious incidents and field safety corrective actions to the competent authorities.
   - Products that are not in conformity with the quality standards. If a manufacturer has reason to believe that a product which he has placed on the market is not in conformity with the Regulation, he shall immediately take the necessary corrective measures to bring the product into conformity, to cease its production or to withdraw it as appropriate.

2.6.4 EUDAMED

EUDAMED is intended to be a system for the exchange of legal information between the countries of the European Union (through the Health Authorities) and the European Business and Industry Commission.

It is aimed to assist the European Authorities in monitoring and controlling the European medical device market, by exchanging information.

It will contain high quality information in a database, being divided into different sub-systems and objectives:

- Registration of manufacturers
- Unique Product Identifier, UPI.
- Registration of clinical product evaluations.
- Post-market follow-up of the product.
- Vigilance, which will inform Member States about incidents and findings.

EUDAMED benefits citizens by allowing them to consult information on incidents immediately, increasing their safety, and also greatly benefits healthcare professionals by providing them with information and transparency.

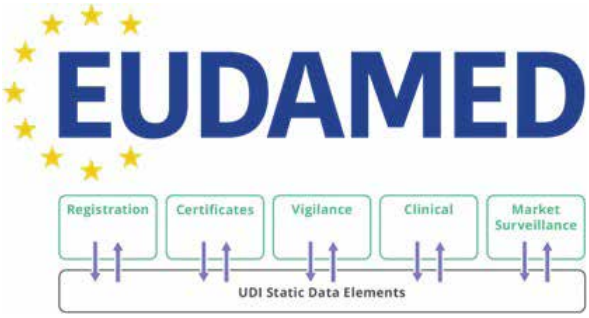


Figure 6.2.6 EUDAMED definition

2.7 REQUIREMENTS AND DOCUMENTATION

Having determined which Directives and/or Regulations apply to our product, the manufacturer shall ensure that the product complies with the essential requirements set out in these documents.

Essential requirements are specifications intended to provide and ensure a high level of protection, in particular the protection of the health and safety of users and cover other essential requirements (protection of property or the environment).

Compliance with these essential requirements ensures the main objective of protection and is derived from certain risks associated with the product (electrical properties, flammability, mechanical resistance, etc.).

Where several directives apply to the same product, the manufacturer must simultaneously fulfil the essential requirements of all the applicable directives.

Compliance with these essential requirements will be achieved using **harmonised standards**, which establish presumption of conformity with the essential requirements of the relevant directives. These standards, like the others, are not mandatory and the manufacturer is free to use other means to meet the essential requirements. However, in such a case, a level of safety at least equivalent to that laid down by these harmonised standards must be achieved.

IN A NUTSHELL

Harmonised European standards: technical specification of a non-mandatory nature setting out the essential safety requirements, conferring presumption of conformity with the essential requirements and laying down the level of safety achievable and required of the product at the time of manufacture.

In the absence of a harmonised standard for a particular product, other standards covering the essential requirements of the applicable directives may be applied. In such a case, the presumption of conformity established by a harmonised standard does not apply. The manufacturer must analyse the essential requirements and describe the solutions adopted to meet them. By referring to a standard, even if it is not applied, designers and manufacturers can get an idea of the level of safety required for their product.

Any product intended to be marketed in the European Union must present the following documentation:

2.7.1 Conformity assessment

The process carried out by the manufacturer to demonstrate product compliance with the essential requirements laid down in the product directives.

A conformity procedure is the different evaluation processes specified in the evaluation modules. They are procedures that refer to the checks to be carried out at the design stage and/or at the manufacturing stage of the product.

There are different conformity assessment procedures, called also “modules”, as set out below:

MODULE	BRIEF DESCRIPTION
Module A Internal production control	It covers the internal design and production control. This module does not require a notified body to take action.
Module B EC-type examination	It covers the design phase and should be followed by a module allowing for evaluation in the production phase. A notified body issues an EC-type examination certificate.
Module C Conformity to type based on internal production control	It covers the production phase and follows module B. It deals with conformity to type as described in the EC-type examination certificate issued in accordance with module B. This module does not require a notified body to take action.
Module D Conformity to type based on quality assurance of the production process	It covers the production phase and follows module B. It requires the intervention of a notified body which shall be responsible for the approval and control of the quality system established by the manufacturer. It derives from the quality assurance standard UNE-EN-ISO 9002.
Module E Conformity to type based on product quality assurance	It covers the production phase and follows module B. It requires the intervention of a notified body which shall be responsible for the approval and control of the quality system established by the manufacturer. It derives from the quality assurance standard UNE-EN-ISO 9001.
Module F Conformity to type based on product verification	It covers the production phase and follows module B. A notified body check conformity with the type described in the type-examination certificate issue under module B and issues a certificate of conformity.
Module G Conformity based on unit verification	It covers the design and production phases. A notified body examines each unit of the product, checks the unit verification of the design and production of each product and issues a certificate of conformity.
Module H Conformity based on full quality assurance	It covers the design and production phases. With the intervention of a notified body, which will be responsible for the approval and control of the quality system established by the manufacturer.

The module to use will be specified in the directive that applies to the device. Usually, most directives offer a choice between several modules, or even a combination of some of them.

2.7.2 Technical file

The technical construction file is the set of documents drawn up by the manufacturer himself to detail the entire manufacturing process and to demonstrate the conformity of the product with all the essential requirements of the applicable directives and which must be available to the competent authorities for surveillance and inspection activities.

This dossier must be built up before the product is placed on the market as it is an essential element for the conformity assessment procedures of a product. It also facilitates the inspection work of the competent authorities.

Essentially the file must contain the following elements:

- **Device description.** It shall include all the necessary information that helps to understand the type of product and its safe operation. Among the documents to be developed will be the instruction manual, technical specifications, bills of materials, etc.
- **Assessment of the essential requirements of the applicable directive(s).** They should all be listed and the measures taken to comply with them should be indicated.
- **Risk assessment.** The methodology followed should be described, considering the way in which failures can occur and then describe the solutions adopted to prevent the risks presented by the product.
- **List of standards applied** in whole or in part, and a description of the solutions adopted to comply with the safety aspects of the Directive, where the standards have not been applied.
- **Technical reports** with results of tests carried out or certificates obtained from a competent body or laboratory. All certificates of conformity of critical components incorporated in the product must be included.

All test reports may be carried out either by the manufacturer himself or by a competent body or laboratory. The test reports shall reflect all tests/tests to which the product in question has been subjected.

- **Design and manufacturing drawings**, and diagrams of components, sub-assemblies, circuits, etc. Explanations and descriptions necessary for the understanding of the said drawings and diagrams and the operation of the product.
- **Homogeneity in production.** All necessary measures taken by the manufacturer so that the manufacturing process ensures the conformity of the products manufactured.

In the case of mass production, the manufacturer must ensure the homogeneity of production, so that all products manufactured are "identical" to the one on which the tests were carried out in order to satisfy the essential health and safety requirements of the applicable directive. In order to satisfy this requirement, it is sufficient to implement a quality system.

These documents are not required for all directives; therefore, the indications of the specific parts of each directive should be followed to confirm the obligatory nature of each document.

All the documentation detailed above must be in one of the official languages of the European Community, except for the instruction manual for the product, which must be in the language of the country in which the equipment is sold.

The Technical File shall be available to the competent authorities for inspection and control purposes. Except as specifically provided for in a Directive, at least one Technical File must be available to the competent authorities in the territory of the European Union when placing a product on the market in the European Union.

Anyone responsible for placing a product on the Community market must have the Technical File or be guaranteed to be able to produce it as soon as possible in the event of a reasoned request. Failure to produce the documentation in response to a duly substantiated request by the competent national authorities may constitute sufficient grounds for doubting the presumption of conformity with the provisions of the CE marking.

Part of the Technical File may be in an electronic or other format, as it is not realistic for manufacturers to physically archive all technical documents relating to the product. Therefore, a manufacturer may not be required to provide the Technical File instantaneously in response to a request from a competent authority.

It must be maintained for a period of 10 years after the last date of manufacture of the product, unless otherwise specified in the Directive applied.

2.7.3 Declaration of conformity

In order to certify the conformity of a product, the manufacturer must draw up a Declaration of conformity for each of the devices.

IN A NUTSHELL

The **Declaration of Conformity** is the document whereby the manufacturer declares that his product complies with the applicable directives, being an essential document for the marketing of a product.

This document shall be drawn up in the language of the country of destination and it is the responsibility of the manufacturer or person introducing the product into that country to translate this document.

The following information must be included in every declaration of conformity:

1. Name and address of the manufacturer or his authorised representative established within the EC. In the case of products manufactured outside the EC, both the name of the manufacturer and the name of the authorised representative must be indicated. The full address of the head office or one of the factories or one of the establishments in the country of destination must be given.
2. Product description.
3. All relevant provisions with which the product complies. Reference to the implementing Directives. Although not mandatory, references to national transpositions, i.e. reference to the Royal Decrees transposing the implementing Directives, may also be included.
4. Reference to harmonised standards. Although harmonised standards are not mandatory, it is in the manufacturer's interest that such standards are indicated, as they provide a presumption of conformity with the essential requirements of the

Directive. If harmonised standards are not used, the alternative procedure used to satisfy the essential requirements must be specified.

5. Identification of the person signing the document and place and date of signature.
6. Name and address of the notified body and EC type-certification number, if applicable.
7. Name and address of the notified body to which the technical construction file has been notified or which has checked the technical construction file, if applicable.

EXAMPLE:

DECLARATION OF CONFORMITY

JMF S.L
Sol Street, 24
30510 Yecla (Murcia)
Spain

We, the manufacturer, hereby declare that:
Type of product: electric reclining chair
Model: PP-101
The medical device specified above meets the provision of the Directive 2006/42/CE on machinery complying with the technical specifications laid down in Standard 60601-1 on electromedical equipment
12182:2012 Supportive products for people with disabilities

Date and place: Yecla, 14 November 2021
Legal signature: José María Fernández

General Manager

2.7.4 CE marking on the product

Once the entire process has been completed, the manufacturer may affix the CE marking on the product.

This symbol must be affixed visibly, legibly and indelibly to the equipment or its nameplate. In certain cases, it is acceptable for the CE marking to be affixed to the product packaging. If the CE marking is reduced or increased in size, the proportions must always be maintained.

2.7.5 Market surveillance

Member States are obliged to take measures to review products placed on the market in order to verify their conformity. To this end, the competent authorities may:

- Require access upon request to the place of manufacture and/or storage of the products.
- Require upon request the documentation relating to compliance (technical file).
- Taking samples for tests and/or examinations relating to compliance.

To this end, the safeguard clause is envisaged, which specifies the measures to be taken by Member States when they detect that a product may compromise the safety and/or health of users and/or third parties. The measures adopted may be:

- Withdraw the product from the market.
- Prohibit it from being placed on the market.
- Restrict its marketing.

The measures taken should always be based on the principle of proportionality, i.e. they should be proportionate to the risk posed by the product in question.

The safeguard clause may be applied to those which, although bearing the CE marking, may compromise the safety and/or health of users due to:

- Non-compliance with essential requirements.
- Incorrect application of harmonised standards.
- Gaps in harmonised standards.

In the event of application of the safeguard clause, the Member State shall immediately inform the Commission and the person concerned.

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