

Medical Devices and Machinery Regulation: The Challenge of Functional Safety

The new **Regulation (EU) 2023/1230 on machinery** represents an important evolution of the European regulatory framework on machinery safety and replaces the previous **Directive 2006/42/EC**. It entered into force on 19 July 2023 and will become fully applicable on 20 January 2027, when the Machinery Directive will be repealed.

For the purposes of the Regulation, a machine is a set of components connected to each other, equipped with at least one moving element and a drive system other than direct human or animal power, designed for a specific application.

The aim of the new Regulation is to update European legislation according to the technological evolution of recent years, characterised by the increasing integration of electronic systems, software, advanced automation and artificial intelligence. Innovative aspects include greater attention to the safety of control systems, cybersecurity, safety-related software and machines with autonomous capabilities or based on new digital technologies. [1]

At the same time, Regulation (EU) 2017/745 on medical devices (MDR) is the main European regulatory reference for the safety and performance of medical devices, regulating their placing on the market and making available in the European Union.

But what happens when a medical device incorporates a motor, an actuator, a robotic system, or software that controls its movement? Is it still sufficient to assess conformity based solely on the MDR?

The answer is not to apply two standards separately, but to integrate the requirements of the MDR and the Machinery Regulation into a single design and risk management process. In this context, functional safety is one of the technical approaches through which demonstrate that safety-related control functions meet the applicable requirements.

Integration between MDR and Machinery Regulation

The integration of mechanical and electronic technologies means that medical devices increasingly incorporate features typically associated with machinery. It therefore becomes essential to understand how the requirements of the machinery legislation are integrated with those provided for by Regulation (EU) 2017/745 on medical devices (MDR).

Regulation (EU) 2017/745 on medical devices (MDR) explicitly addresses this situation by establishing that medical devices that are also machines must also comply, in the presence of relevant risks, with the essential safety and health protection requirements provided for by the

machinery legislation, if these requirements are more specific than the general safety and performance requirements of the MDR. [2]

This principle highlights how the conformity assessment cannot be limited only to the clinical use of the device, but must also consider the risks deriving from the mechanical functions, the drive and control systems that control the movement.

This implies that the manufacturer does not have to develop two distinct design processes, but a single risk management strategy capable of considering both clinical and typical machine functions.

If you consider a medical device equipped with an automatic handling system, the clinical function may be to support the patient's treatment, but the presence of moving parts introduces additional risks, such as crushing, unexpected movement, or loss of position control. In these cases, in addition to the specific requirements of the medical device, the safety aspects of the machine must also be considered.

Furthermore, risk management in accordance with ISO 14971, Medical devices — Application of risk management to medical devices, helps identify and evaluate hazards, while machinery safety standards provide technical principles and methods for designing safety functions to reduce the identified risks.

With the application of **Regulation (EU) 2023/1230 on machinery**, this approach takes on further relevance. Although the MDR reference was defined with the previously applicable machinery legislation (**Directive 2006/42/EC**), the principles underlying safe design, risk assessment and functional safety remain valid even in the new regulatory framework and represent fundamental elements for medical devices that integrate typical machine functions.

In this context, harmonised standards are an essential tool to support manufacturers in identifying the most appropriate technical solutions and demonstrating compliance with the applicable safety requirements.

Harmonised standards to support safe design

One of the key elements of the regulatory approach to machinery safety is the classification of standards into three categories: **type A, B and C standards**.

This classification allows for the use of established technical principles and solutions, creating a common reference framework for the safe design of machinery and for demonstrating compliance with essential health and safety requirements. Based on these considerations, a question arises: which standards can support the manufacturer in demonstrating compliance?

Type A standards define the fundamental concepts, terminology and general design principles applicable to all machinery, such as the methodology for risk assessment and risk reduction.

Type B standards deal with specific aspects of machinery safety or particular protective devices applicable to a wide range of machinery.

Type C standards, by contrast, are dedicated to specific categories of machinery and define detailed technical requirements for that application. When available, a type C standard represents the priority reference for the specific aspects it regulates, prevailing over the more general indications contained in type A and B standards.

The application of harmonised standards may provide a presumption of conformity with the safety requirements covered by the standard, but it does not replace risk assessment, which remains the starting point for identifying the applicable requirements and the most appropriate technical solutions. [3]

Among the type B standards, those dedicated to safety-related control systems are of particular importance, as they allow the design and validation of the safety functions necessary to reduce the risks identified during the risk assessment. It is precisely in this context that the concept of functional safety fits in.

Functional safety: the bridge between machine safety and medical devices

In the context of medical devices that also fall within the scope of the Machinery Regulation, functional safety represents the meeting point between the risk management required by ISO 14971 and the design of control systems according to the standards of the machinery sector. Safety functions are in fact a possible risk control measure when risk reduction depends on the correct functioning of electrical, electronic or programmable systems.

As defined in the **IEC 61508** series, dedicated to the safety of safety-related electrical, electronic, and programmable electronic systems, *functional safety* represents the portion of the overall safety related to the controlled equipment and its control system, which depends on the proper functioning of the systems and other risk reduction measures. [4]

In the context of modern machines, characterized by an increasing use of electronic systems, software and programmable devices, this concept plays a fundamental role in ensuring that safety functions are maintained even in the presence of failures or abnormal conditions.

An application example is medical devices with automatic movement, such as robotic systems for surgical applications or motorized rehabilitation equipment. In these systems, a failure of the sensor, software or control electronics could lead to dangerous movement. *Functional safety* allows you to

design and validate safety functions aimed at preventing such situations and bringing the system into the safe state defined in the design process.

A particularly significant case for embedded electronics and firmware developers is represented by devices for extracorporeal blood treatment, in which a safety function can be implemented by means of a dedicated embedded system. *Bare-metal* firmware, for example developed in C language and executed on a microcontroller, can acquire and process signals in real time from sensors monitoring the blood circuit, such as pressure sensors, to identify potentially hazardous conditions. When an abnormal condition occurs, such as exceeding a pressure threshold or detecting a signal that is inconsistent with the expected operating conditions, the control system can trigger an appropriate response depending on the risk scenario and the safety strategy adopted. This response may include stopping the centrifugal pump, if this measure is appropriate for bringing the system to the intended safe state.

In this scenario, the effectiveness of the safety function depends on the correct interaction between transduction, signal acquisition, firmware processing, and actuator control electronics. The design and validation must therefore consider not only the nominal behavior of the software, but also the possible failures of individual components, response times, and the ability of the system to achieve the safe condition expected for the specific scenario.

In the field of machinery, standards such as **ISO 13849-1** "Safety of machinery — Safety-related parts of control systems - Part 1: General principles for design", and **IEC 62061** "Safety of machinery - Functional safety of safety-related control systems", provide methodologies for the design and validation of safety-related parts of control systems. While pursuing similar objectives, they adopt different approaches to specify and evaluate the required safety performance.

ISO 13849-1 introduces the concept of **Performance Level (PL)**, a discrete level used to specify the ability of safety-related parts of control systems to perform a safety function under predictable conditions [5].

IEC 62061 introduces the **Safety Integrity Level (SIL)**, a discrete level used to specify the safety integrity requirements of safety functions to be assigned to safety-related systems [6].

In the context of medical devices that integrate programmable handling and control systems, these principles take on particular relevance. A medical device that also falls under the definition of a machine pursuant to Regulation (EU) 2023/1230 must in fact ensure not only the correct clinical performance, but also that any failures of the control system do not generate dangerous situations for the patient or operator.

Functional safety therefore represents the point where machine safety and the safety of medical devices converge. Integrated into the risk management process, based on **ISO 12100** for machines

and **ISO 14971** for medical devices, it contributes to the design and validation of safety functions throughout the product life cycle, in line with the applicable requirements.

Conclusion

The real challenge is not to determine whether a medical device is also a machine, but to design a system in which clinical safety and functional safety are considered from the early stages of development as complementary aspects of the same process.

In this context, functional safety serves as a technical tool for designing and validating the safety functions of control systems, contributing to the mitigation of risks identified during the risk management process. Its integration with the principles of the Medical Device Regulation (MDR) and the requirements of the Machinery Regulation makes it possible to address, in a consistent manner, the challenges posed by medical devices that are becoming increasingly complex, automated, and connected.

Sources:

1. [Regulation \(EU\) 2023/1230](#)
2. [Regulation \(EU\) 2017/745](#)
3. [Guide to the application of the Machinery Directive 2006/42/EC](#)
4. [IEC 61508-4:2010 - Functional safety of electrical/electronic/programmable electronic safety-related systems - Part 4: Definitions and abbreviations](#)
5. [ISO 13849-1:2023 – Safety of machinery — Safety-related parts of control systems – Part 1: General principles for design](#)
6. [IEC 62061:2021 - Safety of machinery - Functional safety of safety-related control systems](#)

Keywords:

Machinery Regulation (EU) 2023/1230, MDR, Medical Devices, Functional Safety, IEC 61508, ISO 12100, ISO 14971, ISO 13849-1, IEC 62061

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