

Background information

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New, globally relevant regulation covers Safety, digital requirements and Industrial Security for machinery

Machinery Regulation: The countdown has started!

Ostfildern, July 2026 – **As the successor to the Machinery Directive, the Machinery Regulation (EU) 2023/1230 (MR) will in future be the most important piece of legislation governing the safety of machinery used within the European Union. From the key date of 20 January 2027, it will be binding in all EU Member States – with no transition period. For companies worldwide, this means that anyone who places machinery on the market within the EU and operates it or substantially modifies it must comply fully with the new requirements. The MR is thus establishing a globally relevant regulation covering Safety, digital requirements and Industrial Security.**

The regulation takes a holistic approach to Safety: no longer must machinery be designed to merely be mechanically and functionally safe. Now it must also meet the requirements of an increasingly digital and networked industry – and therefore the requirements of modern production environments where machinery is becoming ever more interconnected and manipulation, cyberattacks and insecure remote access present real risks. Industrial Security, digital documentation and secure software update processes will in future be mandatory requirements, without which the conformity assessment procedure and subsequent CE marking will no longer be possible.

New obligations for manufacturers: Documentation and Security by Design

For manufacturers, the MR means far-reaching organisational and technical adjustments. A key element is the future provision of operating manuals and declarations of conformity in digital form – for a period of at least ten years. Companies must therefore restructure their documentation processes and develop long-term availability concepts. Even more important, however, is the integration of Security by Design: protective mechanisms against corruption, the defeat of safety devices or unauthorised software modifications must be considered even in the development stage. The processes for secure software updates, patch cycles and remote access must also be clearly defined and documented.

In addition, the MR introduces new requirements regarding the ability to verify safety functions. In future, machinery must be designed in such a way that users can test safety-related functions themselves if necessary. In addition, manufacturers are required to provide appropriate descriptions for inspection, setup, maintenance and procedural instructions. For the first time, these guidelines provide a clear framework for operators to check safety-related functions in accordance with the manufacturer's specifications. While the obligation to carry out inspections already existed in principle, operators had to define the practical implementation independently. The new requirements therefore lead to greater clarity and standardisation, while noticeably reducing the burden on operators at the same time.

Operators have greater responsibility: Focus on substantial modification

In addition to the stricter requirements imposed on manufacturers, greater attention is also paid to the role of operators. The demands placed on Industrial Security are increasing, particularly during operation: operators must demonstrate that they have implemented appropriate measures to protect against attacks and ensure that systems are permanently safeguarded against unauthorised access and manipulation. At the same time, it is necessary to guarantee the long-term availability of technical documentation. Combined with the manufacturer's specified inspection and testing procedures for safety functions, operational responsibility is increased significantly. Staff training and awareness-raising are becoming a key component in ensuring long-term compliance with the required safety standards.

What's more, the MR defines the term "substantial modification" specifically, thereby providing greater clarity for conversions and retrofits. If machinery is modified in a way that substantially affects its safety, a new conformity assessment is required. In this case, the operator legally becomes the manufacturer – with all the associated obligations, such as those relating to risk assessment, technical documentation and CE marking.

Interlinked machinery: New challenges for operators and integrators in Europe

One key aspect of the Machinery Regulation concerns interlinked machinery, which is widespread in Europe – particularly in sectors with modular or highly flexible production environments, such as pharmaceutical, automotive or electrical engineering. As soon as

several machines or modules are functionally interconnected and form a common process logic, they are regarded as an “assembly of machinery” within the terms of the MR. This means that a separate CE assessment and marking process is required for this interconnected plant, regardless of whether the individual modules were already fully CE-compliant when supplied.

Responsibility for this overall assessment usually lies with the person who interlinked the machinery – often the operators themselves or an integrator. So they assume the role of the manufacturer of the entire plant and must not only produce a new risk assessment, but also evaluate safety-related interfaces, shared emergency stop concepts, communication links and potential digital threats.

The definition of “substantial modification” as set out in the MR is often particularly relevant in interlinked plants. Even the expansion, retrofitting or rearrangement of individual modules can necessitate a new conformity assessment – a factor that presents new organisational challenges for flexible manufacturing concepts.

Global impact: the Machinery Regulation as a passport to Europe

However, the impact of the Machinery Regulation does not stop at the EU’s borders. Manufacturers outside Europe who import machinery into the EU must also adapt their products to the new requirements – even if corresponding specifications do not apply in their home market. This is particularly relevant for digital documentation, cybersecurity, update processes, as well as the expectation that machine modules in Europe are frequently interlinked or flexibly reconfigured.

The challenge for OEMs outside Europe: to bring their technical documentation, safety concepts and software processes up to a standard that enables European operators to integrate machinery safely and, if necessary, to combine it in new ways within interconnected plants. The MR therefore operates on a global scale and sets a new international standard for Safety and Security in mechanical engineering.

Case study: Japanese OEM supplies machinery to the European pharmaceutical industry

A specific example from one of Pilz's customers illustrates just how significantly the Machinery Regulation affects international supply chains:

A Japanese OEM supplies modular machinery to an operator in the European pharmaceutical industry. The modules can be operated individually or linked together later to form a production line – a classic example of modern, modular production.

The European operator wishes to ensure that the machinery already meets the requirements of the MR. Background: Some modules are to be deployed immediately, while others will be deployed at a later date or in new production lines. In future, the operator will assume CE responsibility for certain modules – particularly if they are placed on the market as part of a plant network or are functionally combined in a new way.

To ensure that this process is legally compliant, it is essential that the Japanese manufacturer CE marks each individual machine correctly. This forms the basis for all further conformity assessments and is crucial for ensuring that Functional Safety and Security are properly represented at machine level.

At the same time, correct CE marking does not relieve operators of their obligations: during commissioning – and throughout the entire lifecycle in the context of safe operation – they must carry out their own safety assessment. This takes into account the specific way in which the machine is integrated, how it is actually used in the production environment and its interactions within the plant network, as well as organisational and operational protective measures.

This example illustrates how closely manufacturers and operators must cooperate across national borders in order to bring technical documentation, digital security mechanisms, update processes and risk assessments up to a level that is MR compliant. Pilz helps both parties set up these processes to be MR compliant, ensuring that Safety and Security requirements are properly integrated from the start.

Support from Pilz: training and consultancy for MR compliance

Pilz offers targeted support to help companies implement the new requirements efficiently and in compliance with the law: the “Safety meets Security” training course covers the regulatory fundamentals as well as the interaction between Functional Safety and Industrial Security. “Fundamentals of Industrial Security” covers terminology, requirements, vulnerabilities and threats in industrial automation. “CESA – Certified Expert for Security in Automation” provides in-depth knowledge of security standards and measures with the aim of reducing risks arising from manipulation and cyber attacks.

Our Consulting Services also provide support throughout the entire machinery safety lifecycle – from safety design through to acceptance, including international conformity assessment procedures. One of our key areas of focus is CE marking: we provide

support in every stage of the CE process for new and modified machinery within the EU, including risk assessment, safety concept and design, implementation, validation and technical documentation. If necessary, Pilz will assume the role of authorised representative.

What happens next? Five practical tips

The Machinery Regulation is not a paper tiger. It is a wake-up call for the whole industry. Companies that act now can adapt their processes in good time, reduce risks and turn the new requirements into a competitive advantage. Those who wait, on the other hand, run the risk of getting stuck in a bottleneck under time pressure and overlooking compliance risks. The clock is ticking – and the foundations for future-proof machine concepts are being laid right now.

So it's worth taking a systematic approach to the next steps. The following five recommendations show how companies can not only meet the requirements of the MR, but actively use them to promote safety, efficiency and sustainability:

1. Build systematic digital documentation

Fully convert all operating manuals, declarations of conformity and technical documentation to digital formats. At the same time, define processes for long-term, audit-proof storage (for at least ten years).

2. Integrate Security at an early stage

Take Security requirements into account right from the development phase – from secure software design and clearly regulated update processes through to protection against corruption. Security by Design is one of the MR's key success factors.

3. Identify high-risk products

Check whether machinery falls into a high-risk category in accordance with the MR. If so: plan assessments and inspections by notified bodies at an early stage to avoid delays in placing the product on the market.

4. Structure operational processes clearly

Establish procedures that ensure that technical documentation is available at all times. Changes and interventions on machinery must be properly assessed – particularly with regard to what may be “Substantial modifications” and the new obligations for manufacturers this entails.

5. Targeted training for teams

Train employees from development, service and operations in how to deal with cyber risks, security-related updates and the key requirements of the Machinery Regulation. Expertise is crucial to ensuring Safety and Security in the long term.

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Pilz – The Spirit of Safety

Pilz is a global supplier of products, systems and services for automation technology. As a pioneer of safe automation, Pilz creates safety for human, machine and environment. Founded in 1948, today the family business with its head office in Ostfildern is represented worldwide with 2500 employees in 42 subsidiaries and branches.

The technology leader offers complete automation solutions for Safety and Industrial Security on the machine. These include sensor, control and drive technology – as well as systems for industrial communication, diagnostics and visualisation. An international range of services with consulting, engineering and training completes the portfolio. Pilz solutions are used in many industries beyond mechanical engineering, such as intralogistics, packaging, railway technology, or the robotics sector for example.

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Pilz on social networks:

On our social media channels we provide background information about the company as well as the people at Pilz and report on the latest news from automation technology.

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