VINÇOTTE

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Machinery regulation

The new European rules for smart, connected, and safe machinery

Machinery Regulation (EU) 2023/1230 | Applicable from 20 January 2027

NEW MACHINERY LEGISLATION. A NEW REALITY.

Machinery is becoming smarter. It communicates with corporate networks, receives remote software updates, and increasingly relies on artificial intelligence. European regulations are evolving accordingly.

As of 20 January 2027, the Machinery Regulation (EU) 2023/1230 will replace the current Machinery Directive 2006/42/EC. There is no transition or coexistence period: before this date, the Directive applies; from this date onwards, the Regulation applies. The fundamental principles of CE marking remain the same, but new technologies and clarified responsibilities demand timely preparation.

The question is not whether the rules are changing.
The question is: are you ready?

This guide helps you focus on the right questions:

- Which new requirements apply to your machinery and processes?
- When can a modification trigger a new CE assessment?
- Who assumes which responsibility in the supply chain?
- What measures can you take today?



TOMORROW'S MACHINERY IS BEING BUILT TODAY

2027 may still seem far away. However, machinery that will be placed on the market or put into service for the first time on or after 20 January 2027 is often already in the design, engineering, or tendering phase today. Machinery intended for in-house use and second-hand machinery originating from outside the EU entering the European market for the first time may also be subject to this Regulation.

Those who only examine the new requirements at the end of a project run the risk of additional testing, modifications to control systems, documentation gaps, or delivery delays. Starting early makes compliance manageable and avoids having to address safety retrospectively.

Evaluate early. Design smarter. Document more rigorously

What changes in practice?

- Cybersecurity now occupies an explicit place in machinery safety.
- AI and self-learning features require demonstrable controllability.
- Software modifications can influence the safety assessment.
- Importers and distributors are assigned clearly defined obligations.
- Digital information and documentation become the standard



WHAT EVERY MACHINERY MANUFACTURER NEEDS TO KNOW



Cybersecurity is now an integral part of machinery safety

A safe machine must not only be protected against physical hazards, but also against any manipulation via connections, software, and system control access.



AI becomes part of the regulatory framework

Machinery equipped with self-learning capabilities must remain predictable and controllable. Safety functions utilizing AI must operate reliably and verifiably, and require approval from a Notified Body.



Software matters

A change to software or firmware can introduce new hazards or increase existing risks. Change management therefore becomes an important element of CE compliance.



The entire supply chain is held accountable

Manufacturers, authorized representatives, importers, and distributors are each assigned a specific set of duties. Verification, traceability, and cooperation gain importance.



The regulatory framework becomes more uniform

A Regulation applies directly in all EU Member States. This promotes more consistent enforcement within the European internal market.

SAFETY DOES NOT STOP AT THE PHYSICAL BOUNDARIES OF THE MACHINE

A machine can be perfectly safe thanks to physical guards, light curtains, and emergency stops. But what happens if someone manages to manipulate parameters via a network connection? Or if an uncontrolled update alters a safety function?

The Machinery Regulation requires that safety-related functions remain protected against inadvertent or malicious influence. Cyber risks must therefore be taken into account in the risk assessment and technical documentation. Furthermore, any relevant intervention on hardware, software, and safety-critical data must be demonstrable and traceable.

Key measures include:

- Access management and user permissions.
- Secure and authenticated software updates.
- Protection of parameters and safety functions.
- Detection and logging of relevant modifications.
- A controlled approach to remote connections.

> “Can you demonstrate who is authorized to modify safety-critical software, how this is carried out **and what checks are performed afterwards?**”

SMART MACHINES MUST REMAIN PREDICTABLE

Artificial intelligence opens up new opportunities for quality control, autonomous movement, and human-machine collaboration. At the same time, it raises new questions regarding predictability, control, and intervention.

For AI systems that affect safety, this means avoiding any dangerous behavior: the machine must remain predictable, controllable, and correctable. A rigorous safety analysis considers hardware, data, software logic, and modifications throughout the entire lifecycle. Safety-related decisions and software versions must, where applicable, be logged and remain available for statutory periods.

Software also alters how modifications are evaluated:

- Identify the software version corresponding to the evaluated machine.
- Evaluate the impact on safety before deploying an update on the machine.
- Document modifications, validation, and release.
- Integrate machinery safety, automation, and OT security into a unified approach.



New reality:

A MACHINE CAN REMAIN PHYSICALLY UNCHANGED WHILE REQUIRING A COMPLETELY DIFFERENT SAFETY ASSESSMENT.

BEYOND CONVENTIONAL MACHINERY

The Machinery Regulation applies to machinery, related products, and partly completed machinery.

If a product features moving parts driven by a power source to perform a specific task, it generally falls under the definition of 'machinery'. This can range from a compact machine designed for a specific application to a fully automated production line where different machines operate together as an assembly.
Not all products constitute complete machinery from the outset. When an assembly of moving parts is intended to be incorporated into machinery later and does not yet perform a standalone function on its own, it is referred to as partly completed machinery.

A successful CE marking procedure begins with a correct determination of the scope and applicable product legislation. For further clarification, do not hesitate to consult our experts

Related products comprise the following product categories:

- Interchangeable equipment.
- Safety components, including digital components and software that perform a safety function.
- Lifting and handling accessories.
- Chains, ropes, and webbing intended for lifting remove and handling applications.
- Removable mechanical transmission devices, including their guards.



ATTENTION

Other European product regulations may apply in addition to, or for certain specific risks, in place of certain requirements of the Machinery Regulation. A correct legislative analysis therefore remains the essential first step in any CE marking process.

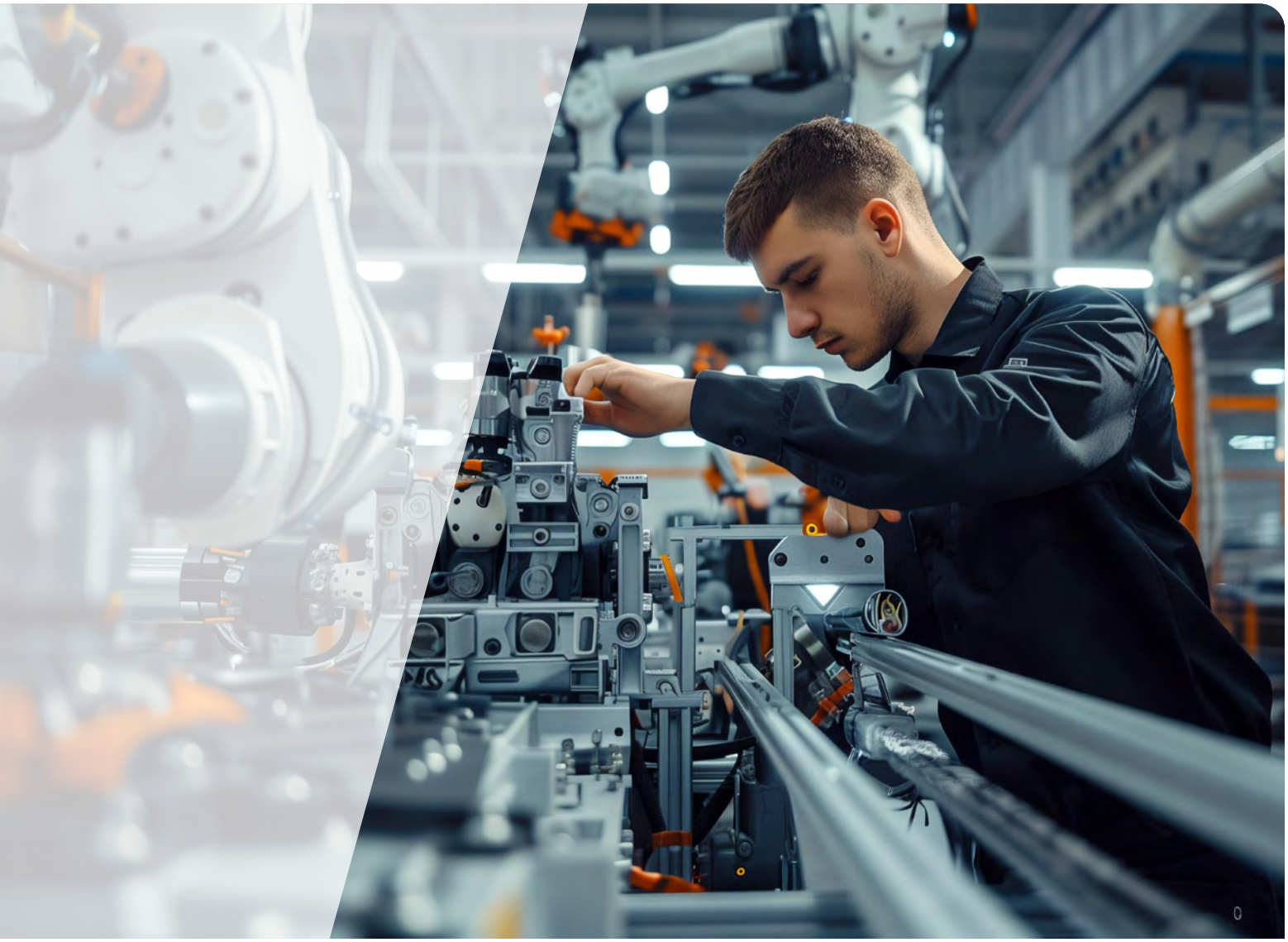
WHEN IS A MODIFICATION CONSIDERED SUBSTANTIAL?

A new sensor, a modified speed, a new gripper, or a software update: machinery evolves constantly. Not all modifications require a new CE marking procedure, but certain modifications can result in the person carrying them out being considered the manufacturer.

A modification requires special attention when it was not foreseen by the original manufacturer and introduces new hazards or increases existing risks. It may be substantial if additional measures are required in the safety control system, or if measures are needed to ensure mechanical strength or stability. The person responsible for such a substantial modification becomes the manufacturer of the modified machine.

Before making a modification, ask yourself at least the following questions:

- Was the modification foreseen by the original manufacturer?
- Do new hazards appear or do existing risks worsen?
- Are existing or additional protective measures sufficient?
- Do safety-critical controls need to be adapted?
- Are additional measures required to ensure strength and stability?
- Who assumes responsibility for design, assessment, and documentation?



EXISTING MACHINES

When is a modification considered substantial?

A modification to an existing machine may, in some cases, be so significant that the party carrying out the modification is regarded as the manufacturer. The decision tree below will help you quickly determine whether the modification is considered substantial under the legislation.

Important
Record your assessment in a risk assessment and document the reasoning in your technical file.



DECISION TREE: IS THE MODIFICATION SUBSTANTIAL?

1 Does it involve a physical or digital modification after the machine or related product has been placed on the market or put into service?

- NO → No 'substantial modification' within the meaning of Article 3(16). However, do assess the normal design and conformity obligations.

2 Was this modification envisaged or planned by the original manufacturer?

- YES → No 'substantial modification' according to this definition. Carry out the modification and comply with the manufacturer's conditions in a verifiable manner.
- NO ↓

3 Does the modification affect safety by creating a new hazard or increasing an existing risk?

- NO → No 'substantial modification' within the meaning of Article 3(16). Document the assessment and the modifications made, and implement them in accordance with the code of good practice.
- YES ↓

4 **4A** Are additional guards or safety devices required, and does their installation necessitate a modification to the existing safety control system?

- YES → The modification is substantial.
- NO ↓

4B Are additional protective measures required to ensure stability or mechanical strength?

- YES → The modification is substantial.
- NO → On the basis of Article 3(16), the statutory definition has not been met. Document the risk assessment.

Who is carrying out the substantial modification?

→ **The natural or legal person carrying out the modification is regarded as the manufacturer of the modified machine or related product in question and must comply with the applicable manufacturer's obligations and conformity procedures (Article 18).**
Exception: a non-professional user who carries out the modification for their own use is not regarded as a manufacturer in this context.

Is it an assembly of machines?

→ If, according to the risk assessment, the substantial modification affects only the safety of a single machine or related product within the assembly, the manufacturer's obligations apply to that affected component (Article 18).

LEGAL BASIS
Article 3(16) (definition of 'substantial modification') and Article 18 (consequences and exceptions) of Regulation (EU) 2023/1230.

This decision tree is intended to assist with the initial assessment. It is not a substitute for a full technical or legal analysis. Please take into account other applicable EU and national obligations.

CE MARKING IS A SUPPLY CHAIN-WIDE RESPONSIBILITY

ROLE	CORE RESPONSIBILITY
Manufacturer	Designs or has machinery designed and markets it or puts it into service under its own name.
Authorized Representative	Executes delegated tasks on behalf of the manufacturer in accordance with a written mandate. The manufacturer remains responsible for tasks that cannot legally be delegated, such as design and manufacturing according to essential requirements, as well as compiling technical documentation.
Importer	Places a product from outside the EU on the EU market and verifies compliance with requirements prior to making it available.
Distributor	Offers the product in the distribution chain and verifies the presence of the required markings, documentation and information information.
Employer / User	Primarily subject to work equipment legislation, but can become a manufacturer or importer for example, through in-house manufacture, import from a non-EU country, or a substantial modification.

SIX STEPS TO CONTROLLED CE MARKING

1

Define the scope

Identify the product and all applicable European legislation.

2

Perform the risk assessment

Determine boundaries, hazards, risks, and necessary risk reduction measures.

3

Design the product in accordance with essential requirements

Translate applicable requirements from Annex III into specific design measures.

4

Prepare the technical documentation

Gather supporting evidence, drawings, calculations, test results, software-related information, and instructions.

5

Choose the conformity procedure

Verify whether internal production control is sufficient. For machinery referred to in Annex I, Part A, involvement of a Notified Body is always mandatory; for Part B, this depends notably on the full application of a harmonised standard.

6

CE Declare and affix marking

Draft the EU Declaration of Conformity and properly affix the CE marking.

The basic process remains familiar.
Supporting evidence becomes more important.

WHAT CAN YOU DO TODAY?

Good preparation does not start with more paperwork, but by setting the right priorities.

1. Review your machinery portfolio

- Which machines will be placed on the market or put into service from 20 January 2027 onwards?
- Which projects incorporate AI, connected features, or remote updates?

2. Review your processes

- Is change management linked to machinery safety?
- Are the roles of manufacturer, importer, and integrator clearly defined?

3. Strengthen your technical documentation

- Are risk assessments, test results, and software versions traceable?
- Is cybersecurity integrated into design and the technical file?

4. Develop your knowledge

- Train designers, project managers, automation engineers, and procurement teams.
- Establish clear criteria for when to seek CE expertise.

Start with a specific project and use the lessons learned to improve your standard process.



FROM PRACTICAL QUESTIONS TO DEMONSTRABLE COMPLIANCE

The transition to the Machinery Regulation raises practical questions. Which requirements apply? Does an update affect CE compliance? When should a Notified Body be involved? And how do you translate new requirements into design, documentation, and procedures?

Vinçotte supports organizations with services including:

- Advice on applicable legislation and standards.
- Risk assessments in accordance with EN ISO 12100.
- Evaluation and structuring of technical documentation.
- Assesment and technical advice on safety functions and performance levels (PL).
- Support throughout CE marking procedures and in the event of substantial modifications.
- Training on the Machinery Regulation.

The best preparation for 2027 starts today

Contact your Vinçotte expert and make compliance a design choice, not just a final check.



DEEPEN YOUR KNOWLEDGE OF THE MACHINERY REGULATION

This practical guide provides an accessible introduction. Applicable obligations depend on the product, the economic operator's role, chosen technology, and other relevant European legislation.

To explore technical aspects further, consult Vinçotte's detailed white paper on CE marking of machinery in accordance with Machinery Regulation (EU) 2023/1230.

Official references:

- Machinery Regulation (EU) 2023/1230
- Machinery Directive 2006/42/EC, applicable until 20 January 2027
- NANDO database of Notified Bodies
- Cyber Resilience Act (EU) 2024/2847
- AI Act (EU) 2024/1689 and 'Digital Omnibus' on AI (EU) 2026/1744



This publication contains general information and does not replace product-specific technical or legal advice. Prior to any implementation, always verify the current status of product legislation and harmonised standards, designation of Notified Bodies, as well as complementary legislation such as the AI Act, Cyber Resilience Act, and additional European guidance.

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