



A GUIDE TO THE **MACHINERY REGULATION (EU)**

2023/1230

Key changes and challenges

The Machinery Regulation (EU) 2023/1230¹

As the “go to” document for machine builders, the European machinery directive lays out the minimum safety requirements for machinery. The last change to the directive was on 29 December 2009, when 2006/42/EC was introduced.

In 2020, as part of the commission work program ‘A Europe fit for the Digital Age’, the Machinery Directive underwent an impact assessment, and it was concluded that a number of gaps required addressing – namely (i) tackling new risks originating from emerging technologies; (ii) legal uncertainty on scope definitions; (iii) insufficient provisions for high-risk machines; (iv) adoption of digital documentation; and (vi) divergences in transposition interpretation.

As the implementation date draws closer, it is important for OEM/ machine builders to understand the key changes and challenges.

What is the impact on OEMs?

For OEMs exporting or selling equipment in the EU this will replace the Machinery Directive 2006/42/EC. It highlights:

- A new compliance route
- A revised structure to the annexes to improve the flow
- Additional requirements added into the essential health and safety requirements
- Digital documentation
- Cybersecurity requirements

¹<https://eur-lex.europa.eu/eli/reg/2023/1230/oj> 

Key dates

The new Machinery Regulation (EU) 2023/1230 was published in the official journal on 29 June 2023, and entered into force on 19 July 2023, with a 42-month transition to the application date of 20 January 2027. This date is the same for all EU and EFTA countries; and being a regulation and not a directive means it will be adopted at the same time with no modification. After 20 January 2027, all machinery and related products will need to meet the requirements of the new regulation before being placed on the market.

The key changes to the new machinery regulation include a reordering of the annexes from the current machinery directive 2006/42/EC, a focus on changing technologies, and the threat from cybersecurity breaches.

MACHINERY REGULATION (EU) 2023/1230 TIMELINE

2023

2024

2025

2026

2027

JUNE 2023

Publication of Regulation (EU) 2023/1230 in the Official Journal.

JULY 2023

Regulation (EU) 2023/1230 enters into force.

JULY 2025

Member States must provide data and information related to machinery and related products, including whether specific events have occurred.

JULY 2026

First report by the member states that assesses the effectiveness of Articles 6(4) and (5)

OCTOBER 2026

Member States must notify the European Commission of their penalty rules and measures.

20 JANUARY 2027

Application of Regulation (EU) 2023/1230 for private companies

BEFORE 20TH JANUARY 2027

Machines must comply with the requirements of Directive 2006/42/EC; it will not be possible to issue declarations of conformity to Regulation (EU) 2023/1230.

AFTER 20TH JANUARY 2027

Machines must comply with the requirements of Regulation (EU) 2023/1230 and be accompanied by an EU Declaration of Conformity under that regulation.

It is the first regulation to tie together **machinery safety** and **cybersecurity**.

Re-ordering of the annexes

The annexes have been re-ordered to provide a better flow, with the **essential health and safety regulations (EHSRs) moving to Annex III**, and the requirements for categories of machines and products, and the **indicative list of safety components moving to Annex I & II**.

Annex IV details the requirements for any technical documentation needed to support compliance with the regulations, with Annex V providing the details for either a declaration of conformity or declaration of incorporation.

Annex VI to Annex IX provide support for the compliance route to follow for the machinery or related product being manufactured.



Annex I

Categories of machinery or related products

As mentioned previously, the annexes have been reordered to provide better flow.

Annex I now covers - **Categories of machines or related products** and has been split into Part A and Part B.

- **PART A** includes the addition of safety components and embedded safety systems with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions, a nod towards future solutions that may use AI technology.
- **PART B** covers the majority of the current Annex IV machines in 2006/42/EC of the current machinery directive, with the exception of removable mechanical transmission devices, including their guards, guards for removable mechanical transmission devices, vehicle servicing lifts, and portable cartridge-operated fixing and other impact machinery, which are included in PART A.

(see bibliography for Annex I categories of machinery or related products)

Annex II

Indicative list of safety components

It also includes and covers the aspects for components and embedded safety systems using fully or partially self-evolving behavior using machine learning approaches ensuring safety functions.

The other addition in Annex II is filtration systems intended for integration into machinery cabins, in order to protect operators or other persons against hazardous materials and substances, including pesticides. It also covers filters for such filtration systems.

(see bibliography for Annex I categories of machinery or related products)

Annex III

Essential health and safety requirements (EHSRs)

This Annex has seen a number of significant additions including:

Ergonomics (Clause 1.1.6) gives consideration to how operators interact with machinery or related products that have either fully or partially self-evolving behavior.

Autonomous mobile machinery (Clause 3.6.3.3) gains extra requirements, which are included in annex III and the supplementary essential health and safety requirements to offset risks due to the mobility of machinery or related products.

Protection against corruption (Clause 1.1.9) introduces cyber security requirements related to OT (Operational Technology) and has been added to cover the increase in industrial networks for safety systems, and also the generation of data to support the growth of connected enterprise solutions. It covers both hardware and software requirements.

Machinery needs to ensure that the connection of another device – either locally or remotely – **doesn't lead to a hazardous situation**. In addition, any hardware component that transmits signals or data and has access to software that is critical for the machinery's compliance to relevant health and safety requirements, needs to be protected against both accidental or intentional corruption, and **will collect evidence of both legitimate or illegitimate interventions**.

Finally, for protection against corruption, **software and data that are critical for the compliance of the machinery or related products with the relevant health and safety requirements, shall be identified as such and shall be adequately protected against accidental or intentional corruption. The machinery or related product shall identify the software installed on it that is necessary for it to operate safely; and shall be able to provide that information at all times in an easily accessible form. The machinery or related product shall collect evidence of a legitimate or illegitimate intervention in the software or a modification of the software installed on the machinery or related product or its configuration.**



Additional requirements have been included for control systems.

Safety and reliability of control systems (Clause 1.2.1)

Control systems shall be designed and constructed in such a way as to prevent hazardous situations from occurring. They also should withstand where appropriate to the circumstances and risks, the intended operating stresses and intended and unintended external influences, including reasonably foreseeable malicious attempts from third parties leading to a hazardous situation.

It's here that the link between safety and cybersecurity is evident. There is also the need for a tracing log containing **the data generated in relation to an intervention, and of the versions of the safety software uploaded after the machinery or related product has been placed on the market or put into service. This needs to be enabled for five years after such an upload.**

The requirement here is **exclusively to demonstrate the conformity of the machinery or the related product with this EHSRs should a reasonable request from a competent national authority be made.**

For OEMs developing control systems or logic with fully or partially self-evolving behavior, that are designed to operate with varying levels of autonomy, additional requirements have been added into the EHSRs in Annex III.

They shall not cause the machinery or related product to perform actions beyond their defined task and movement space.

Recording of data on the safety related decision-making process for software-based safety systems ensuring safety functions must be enabled and **retained for one year after** the machinery or related product is placed on the market or put into service. At all times it must be possible to correct the machinery or related product in order to **maintain its inherent safety.**

Substantial modifications – explanation of Article 3 (16)

After being placed on the market or put into service, should machinery be modified, by physical or digital means (meaning hardware or software), in a way that is not foreseen by the manufacturer, and which affects the safety of such products **by creating a new hazard or increasing an existing risk, the modification should be considered as substantial when significant new protective measures are required.** The person that carries out the substantial modification should be required to perform a new conformity assessment before placing the modified product on the market or putting it into service. This conformity assessment can be restricted to the part of the production line that has been modified, and so does not have to be completed for the whole assembly.



Compliance Route

There is more emphasis in the regulation for third-party certification. However, self-certification is still possible as long as the machinery is in Annex I Part B and is built preferably using harmonized standards or a common specification. If the machinery is not in Annex I, the preferred route is to follow harmonized standards. The compliance route for this type of equipment is in Annex VI module A.

For all other equipment, third-party certification through a notified body is required.

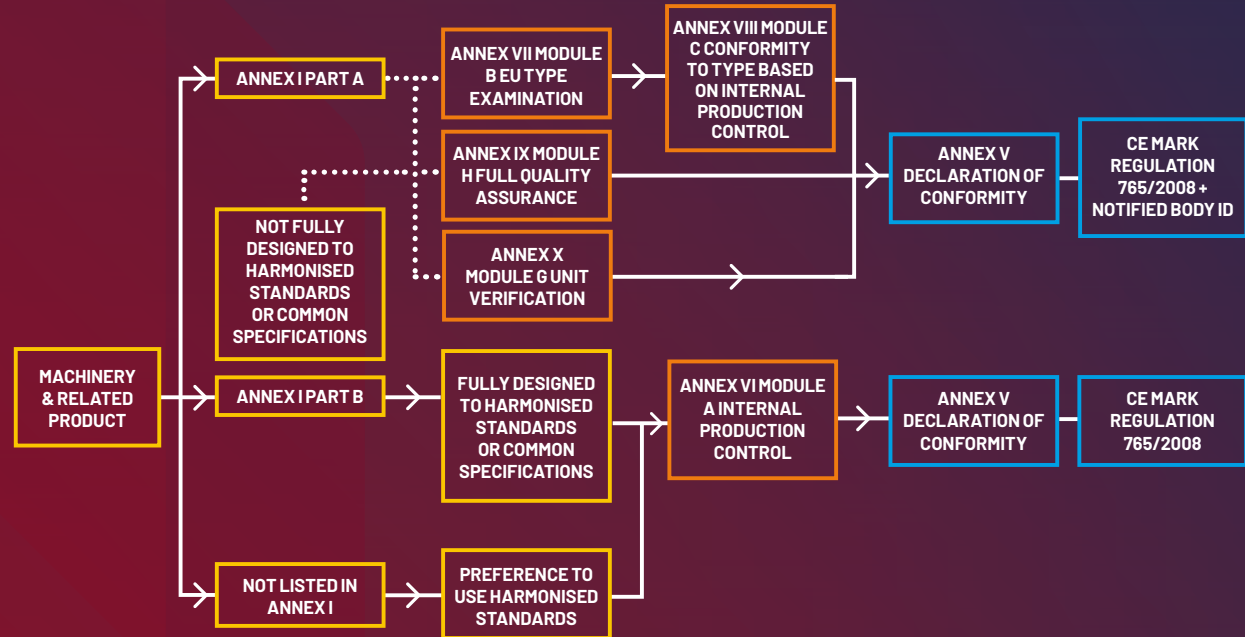
The route to compliance is covered in Annexes VII VIII & IX of the Machinery Regulation (EU) 2023/1230².

² <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32023R1230>

Fines & Penalties

Article 50 empowers member states to define the exact size of the fines and penalties against the Machinery Regulations (EU) 2023/1230. Although not yet confirmed it is expected that these will aligned with other recent directives, such as the Network & Information Security Directive (NIS2) which can impose fines of up to €10,000,000 or 2% of global annual revenue.

COMPLIANCE ROUTE



OEM – Call to Action

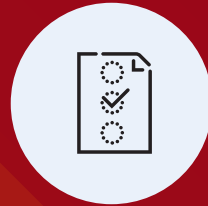


As an OEM, **download a copy** of the Machinery Regulation 2023/1230 and review the document. The Machinery Regulation can be found [here](#). ↗



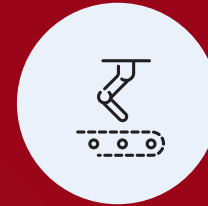
Identify the changes that affect you and your machinery. With the additional requirements for protection against corruption, Rockwell Automation recommends you conduct a cyber risk assessment.

Learn more [here](#) ↗



If you have any form of network, **conduct a vulnerability assessment** to allow the development of relevant cybersecurity requirements, and then implement the necessary mitigation / technology.

Learn more [here](#) ↗



Review, update, or generate cybersecurity policy documents.

This may need the organization to partner with a third-party consultancy.

Learn more [here](#) ↗



Finally, **keep yourself updated.**

Learn more [here](#) ↗

Further Information

The Rockwell Automation website will provide further details on the Machinery Regulation (EU) 2023/1230 and also provide updates as the standards covering the new requirements highlighted in this guide are released.

If you're looking to enhance the performance, safety, and productivity of your business, you might want to learn more about the services, tools, and technology available. You can check out [this webpage](#) to explore the best-in-class options available for your business needs and outcomes.

If you're interested in learning more about industrial cybersecurity and how to protect your operational technology (OT) environment, check out our latest cybersecurity resources [here](#).



BIBLIOGRAPHY • ANNEX I • CATEGORIES OF MACHINERY OR RELATED PRODUCTS

PART A

Categories of machinery or related products to which a procedure referred to in Article 25(2) shall be applied:

1. Removable mechanical transmission devices including their guards.
2. Guards for removable mechanical transmission devices.
3. Vehicle servicing lifts.
4. Portable cartridge-operated fixing and other impact machinery.
5. Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions.
6. Machinery that has embedded systems with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions that have not been placed independently on the market, in respect only of those systems.

PART B

Categories of machinery or related products to which one of the procedures referred to in Article 25(3) shall be applied:

1. Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics, or for working with meat and material with similar physical characteristics, of the following types:

- 1.1. sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the workpiece or with a demountable power feed;
 - 1.2. sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;
 - 1.3. sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading;
 - 1.4. sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.
2. Hand-fed surface planing machinery for woodworking.
 3. Thicknesses for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.

4. Bandsaws with manual loading and/or unloading for working with wood and material with similar physical characteristics, or for working with meat and material with similar physical characteristics, of the following types:

- 4.1. sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;
- 4.2. sawing machinery with blade(s) assembled on a carriage with reciprocating motion.
5. Combined machinery of the types referred to in points 1 to 4 and in point 7 for working with wood and material with similar physical characteristics.
6. Hand-fed tenoning machinery with several tool holders for woodworking.
7. Hand-fed vertical spindle molding machinery for working with wood and material with similar physical characteristics.
8. Portable chainsaws for woodworking.
9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.
10. Injection or compression plastics-molding machinery with manual loading or unloading.
11. Injection or compression rubber-molding machinery with manual loading or unloading.

12. Machinery for underground working of the following types:


- 12.1. locomotives and brake-vans;
- 12.2. hydraulic-powered roof supports.
13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.
14. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than 3 m.
15. Protective devices designed to detect the presence of persons.
16. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11 of this Part.
17. Logic units to ensure safety functions.
18. Roll-over protective structures (ROPS).
19. Falling-object protective structures (FOPS).

BIBLIOGRAPHY • ANNEX II • INDICATIVE LIST OF SAFETY COMPONENTS

1. Guards for removable mechanical transmission devices.
2. Protective devices designed to detect the presence of persons.
3. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11 of Annex I, Part B.
4. Logic units to ensure safety functions.
5. Valves with additional means for failure detection intended for the control of dangerous movements of machinery.
6. Extraction systems for machinery emissions.
7. Guards and protective devices designed to protect persons against moving parts involved in the process of the machinery.
8. Monitoring devices for loading and movement control in lifting machinery.
9. Restraint systems to keep persons in their seats.
10. Emergency stop devices.
11. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges.
12. Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Annex III.
13. Systems and devices to reduce the emission of noise and vibrations.
14. Roll-over protective structures (ROPS).
15. Falling-object protective structures (FOPS).
16. Two-hand control devices.
- 17. The following components for machinery designed for lifting and/or lowering persons between different landings:**
 - (a) devices for locking landing doors;
 - (b) devices to prevent the load-carrying unit from falling or unchecked upwards movement;
 - (c) overspeed limitation devices;
 - (d) energy-accumulating shock absorbers, non-linear or with damping of the return movement;
 - (e) energy-dissipating shock absorbers;
 - (f) safety devices fitted to jacks of hydraulic power circuits and used to prevent falls;
 - (g) safety switches containing electronic components.
18. Software ensuring safety functions.
19. Safety components with fully or partially self-evolving behavior using machine learning approaches ensuring safety functions.
20. Filtration systems intended to be integrated into machinery cabins in order to protect operators or other persons against hazardous materials and substances, including plant protection products, and filters for such filtration systems.

DISCLAIMER

This ebook presents the Rockwell Automation perspective on the latest EU Machinery Regulation. It offers insights based on our current understanding and interpretation, in line with the current regulation status. Any actions taken based on this content are at your own risk. We recommend seeking and conducting further research to validate and supplement the information provided herein.

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rockwellautomation.com

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AMERICAS: Rockwell Automation, 1201 South Second Street, Milwaukee, WI 53204-2496 USA, Tel: (1) 414.382.2000

EUROPE/MIDDLE EAST/AFRICA: Rockwell Automation NV, Pegasus Park, De Kleetlaan 12a, 1831 Diegem, Belgium, Tel: (32) 2663 0600

ASIA PACIFIC: Rockwell Automation SEA Pte Ltd, 2 Corporation Road, #04-05, Main Lobby, Corporation Place, Singapore 618494, Tel: (65) 6510 6608

UNITED KINGDOM: Rockwell Automation Ltd., Pitfield, Kiln Farm, Milton Keynes, MK11 3DR, United Kingdom, Tel: (44)(1908) 838-800

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