

MASKINFÖRORDNINGEN 2023/1230 FRÅN JANUARI 2027

Kompletterar riskerna med viss ny teknik som inte finns i maskindirektivet

Förordningen omfattar bland annat risker med ny teknik. Det kan till exempel vara artificiell intelligens, det vill säga maskiner som har ett helt eller delvis självutvecklande beteende och som använder metoder för maskininläring.

Maskinförordningen ersätter maskindirektivet

Den 19 juli 2023 trädde EU:s maskinförordning i kraft och den 20 januari 2027 ska den börja tillämpas, vilket betyder att tillverkningen av maskiner ska ha anpassats till den nya förordningen.

Förordningen riktar sig mot tillverkare, importörer och distributörer i EU:s medlemsländer.

Bland nyheterna kan nämnas att:

- Det blir tillåtet med digitala bruksanvisningar (pappersdokumentation för icke-professionella användare)
- En tredje part måste göra en bedömning av ett antal produkter om de uppfyller kraven
- Det ska finnas ett skydd mot förvanskning eller korruption av programvara.
- Uppkopplade maskiner måste ha ett säkerhetsskydd mot förvanskning av programvara, så att kommunikationen mellan maskiner inte förvanskas.
- Spårningslogg. Det ska finnas en spårningslogg över de uppgifter som genereras i samband med ett ingrepp och de versioner av säkerhetsprogramvara som laddats upp efter det att maskinen har släppts ut på marknaden.
- Maskiner som byggs om med väsentliga ändringar omfattas av förordningen
- Det ställs krav på importörer och distributörer

Förövrigt

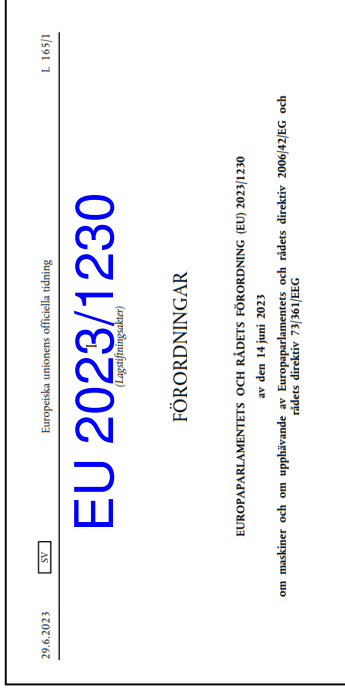
Är kraven likvärdiga med dagens regler i maskindirektivet

även om Bilagorna kastats om mot tidigare och lite anpassning till ny teknik och den digitala utvecklingen.

Förordningen innebär att det blir samma lagtext i hela EU.

Den gäller ordagrant och är en bindande rättsakt som alla EU-länder ska tillämpa i dess helhet.

Den kommer inte att finnas tillgänglig i form av en föreskrift från Arbetsmiljöverket.

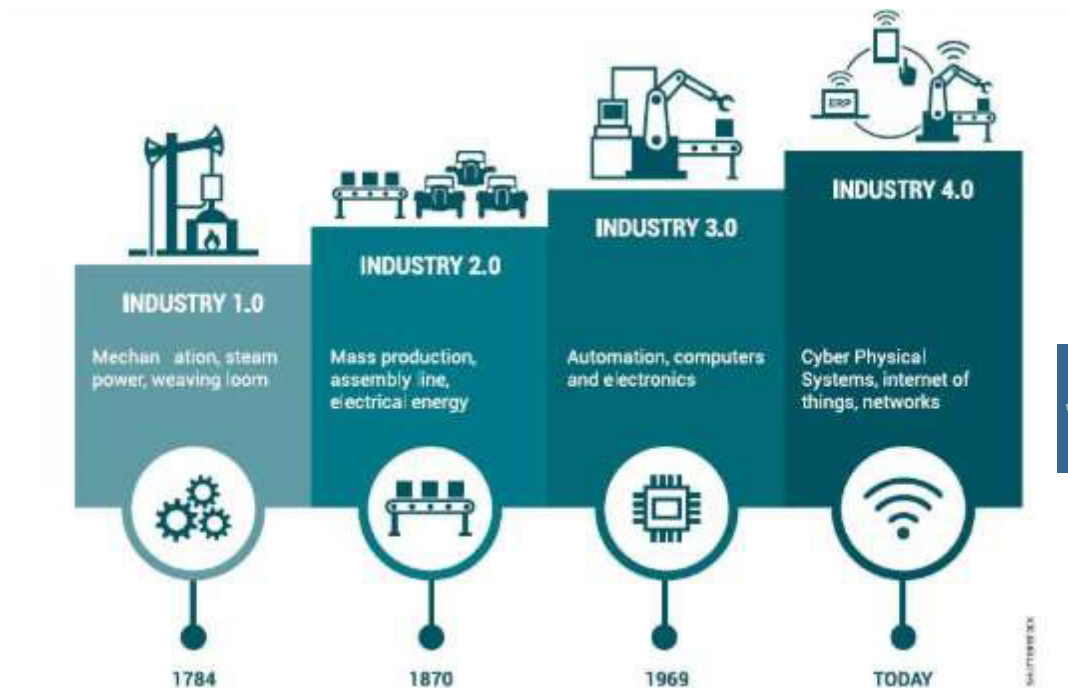


DE ÄNDRADE BILAGORNA I MASKINFÖRORDNINGEN

BILAGA I KATEGORIER AV MASKINER ELLER RELATERADE PRODUKTER PÅ VILKA NÅGOT AV FÖRFARANDENA I ARTIKLARNA 25.2 OCH 25.3 SKA TILLÄMPAS (Följa C std eller inblandning av anmält organ)	FÖRFARANDET FÖR BEDÖMNING AV ÖVERENSSTÄMMELSE
BILAGA II (F.d Bilaga 5) VÄGLEDANDE FÖRTECKNING ÖVER SÄKERHETSKOMPONENTER	SÄKERHETSKOMPONENTER
BILAGA III (F.d Bilaga 1) GRUNDLÄGGANDE HÄLSO- OCH SÄKERHETSKRAV PÅ KONSTRUKTION OCH TILLVERKNING AV MASKINER ELLER RELATERADE PRODUKTER 1.1.9 Skydd mot förvanskning 1.2 f) spårningsloggen över de uppgifter som genereras i samband med ett ingrepp Registrering	RISKBEDÖMNINGSKRAVEN
BILAGA IV (F.d Bilaga 7) Teknisk dokumentation	UPPRÄTTA TEKNISKA FILER
BILAGA V (F.d Bilaga 2) EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE OCH EU-FÖRSÄKRAN OM INBYGGNAD EU-försäkran om inbyggd av en delvis fullbordad maskin	SKRIVA CE CERTIFIKAT
BILAGA VI INTERN TILLVERKNINGSKONTROLL (Modul A)	EGENCERTIFIERING
BILAGA VII EU-TYPKONTROLL (Modul B)	TYPKONTROLL
BILAGA VIII ÖVERENSSTÄMMELSE MED TYP SOM GRUNDAR SIG PÅ INTERN TILLVERKNINGSKONTROLL (Modul C)	TYPNING
BILAGA IX ÖVERENSSTÄMMELSE SOM GRUNDAR SIG PÅ FULLSTÄNDIG KVALITETSSÄKRING (Modul H)	KVALITESSÄKRING
BILAGA X ÖVERENSSTÄMMELSE SOM GRUNDAR SIG PÅ KONTROLL AV ENSKILDA EXEMPLAR (Modul G)	ENSTYCKSVRIFIERING
BILAGA XI (F.d Bilaga 6) MONTERINGSANVISNINGAR FÖR DELVIS FULLBORDADE MASKINER	MONTERINGANVISNINGAR
BILAGA XII JÄMFÖRELSETABELL MED 2006/42/EG	JÄMFÖRELSE MED MD

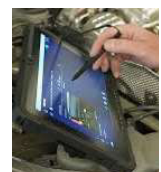
Key Changes

- **Scope Expansion:** The Machinery Regulation EU 2023/1230 expands the scope to cover a wider range of products, including certain partially completed machinery and safety components. This broader scope ensures that all relevant products are subject to uniform safety standards.
- **Risk Assessment and Mitigation:** The new regulation emphasizes a risk-based approach to safety, requiring manufacturers to conduct comprehensive risk assessments throughout the machinery's lifecycle. This proactive approach aims to identify and mitigate potential hazards more effectively.
- **Digitalization and Connectivity:** With the rise of Industry 4.0, the Machinery Regulation EU 2023/1230 addresses the integration of digital technologies and connectivity in machinery. It sets out requirements for cybersecurity, data protection, and interoperability to ensure the safe and secure operation of digitally enabled machinery.



Source: lotsens

- **Market Surveillance and Enforcement:** Enhanced market surveillance measures and stricter enforcement mechanisms are integral parts of the new regulation. Authorities are empowered to monitor compliance more closely and take swift action against non-compliant products, safeguarding the safety of end-users.
- **Implications and Considerations:** The transition from the Machinery Directive 2006/42/EC to the Machinery Regulation EU 2023/1230 presents both challenges and opportunities for stakeholders. Manufacturers need to adapt their processes and products to meet the updated requirements, investing in research, development, and compliance measures. Regulatory bodies must ensure smooth implementation and provide guidance to facilitate the transition for businesses.
- **Digital manuals allowed.** If the end user accept digital manuals there is no need of paper manuals (instructions for use)



Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC. Mandatory from Jan 20 2027 www.mpsa.se

The new Machinery Regulation applies to the following areas:

- Machines
- Related products (interchangeable equipment, safety components, lifting accessories, chains, ropes and webbing, removable mechanical transmission devices)
- Partly completed machinery

The new regulation does not apply to:

- Aeronautical products, motor vehicles, two- or three-wheel vehicles and quadricycles, agricultural and forestry tractors; however, scooters and pedelecs (elcyklar) remain within the scope of the regulation
- Electrical and electronic products such as household appliances for domestic use (except electrically operated furniture) or ordinary office machines (except machines for additive printing)

What is Partly Completed Machinery?

The term “partly completed machinery” is defined in the new Machinery Regulation EU 2023/1230 as follows: “‘Partly completed machinery’ means an assembly which is not yet machinery as it cannot in itself perform a specific application and which is only intended to be incorporated into or assembled with machinery or other partly completed machinery or equipment, thereby forming machinery”.

Incomplete machines are, for example, robots or combustion engines.

Only in the final installation can a meaningful task be carried out with them.

Incomplete machines cannot fulfill all “Essential Health and Safety Requirements” and are therefore not CE marked. The final assessment according to Machinery Regulation takes place during installation.

In addition, the new Machinery Regulation also contains slightly modified definitions of some other terms.

Conformity Assessments for the Various Machine Categories

The conformity assessment is a procedure used to determine whether the machinery and associated products meet the applicable health and safety requirements.

Annex I of the new regulation lists the machinery for which a special conformity assessment procedure with the support of a Notified Body is required.

The list is divided into Part A (mandatory involvement of a Notified Body)

and Part B (procedure as in 2006/42/EC, Annex IV Machinery)

One innovation is the module for type conformity with internal production control.

The manufacturer is responsible for carrying out this procedure based on the EC type examination.

Another new feature is the “unit verification” module, in which a Notified Body tests and certifies individual, particularly complex machines.

Possible conformity assessment procedures for the different categories of machinery

All other machinery and related products	Machinery or related products listed in Annex I		
	Category Annex I, part B (e.g. Presses, Woodworking, Injection Molding, ...)		Category Annex I, part A (6 Categories including e.g. Vehicle lifts, Safety-Systems containing self-evolving behavior, ...)
	Full compliance to harmonized standards	No only partly compliance to harmonized standards	
	a) Module B (Annex VII) EC Type Examination AND Module C (Annex VIII) Conformity to Type Based on Internal Production Control b) Module H (Annex IX) Full Quality Assurance c) Module G (Annex X) Unit Verification		
Module A (Annex VII) Internal Production Control Voluntary testing by TÜV Rheinland and Certificate of Conformity possible		Involvement of a Notified Body mandatory (e.g. TÜV Rheinland LGA Products GmbH) CE with Number of Notified Body (e.g. CE 0197 TÜV Rheinland LGA Products GmbH or CE 1008 TÜV Rheinland InterCert (Hungary))	

Chapter I General provisions

Article 1 Subject matter

Article 2 Scope

Article 3 Definitions

Article 4 Free movement

Article 5 Protection of persons during installation
or use of machinery or related products

Article 6 Categories of machinery and related products listed in
Annex I subject to relevant conformity assessment procedures

Article 7 Safety components

Article 8 Essential health and safety requirements for products within the scope of this Regulation

Article 9 Specific Union harmonisation legislation



Chapter II Obligations of economic operators

Article 10 Obligations of manufacturers of machinery and related products

Article 11 Obligations of manufacturers of partly completed machinery

Article 12 Authorised representatives

Article 13 Obligations of importers of machinery and related products

Article 14 Obligations of importers of partly completed machinery

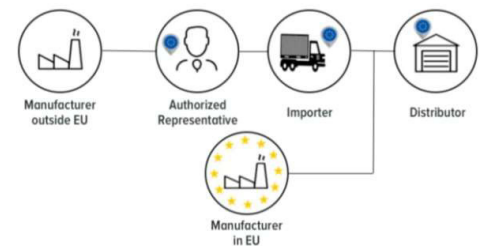
Article 15 Obligations of distributors of machinery and related products

Article 16 Obligations of distributors of partly completed machinery

Article 17 Cases in which obligations of manufacturers apply to importers and distributors

Article 18 Other cases in which obligations of manufacturers apply

Article 19 Identification of economic operators



CHAPTER III Conformity of products within the scope of this Regulation

Article 20 Presumption of conformity of products within the scope of this Regulation

Article 21 EU declaration of conformity of machinery and related products

Article 22 EU declaration of incorporation of partly completed machinery

Article 23 General principles of the CE marking

Article 24 Rules for affixing the CE marking to machinery and related products

CHAPTER IV Conformity assessment

Article 25 Conformity assessment procedures for machinery and related products

CHAPTER V Notification of conformity assessment bodies

Article 26 Notification

Article 27 Notifying authorities

Article 28 Requirements relating to notifying authorities

Article 29 Information obligation of notifying authorities

Article 30 Requirements relating to notified bodies

Article 31 Presumption of conformity of notified bodies

Article 32 Use of subcontractors and subsidiaries by notified bodies

Article 33 Application for notification

Article 34 Notification procedure

Article 35 Identification numbers and lists of notified bodies

Article 36 Changes to notifications

Article 37 Challenge of the competence of notified bodies

Article 38 Operational obligations of notified bodies

Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC. Mandatory from jan 20 2027 www.mpsa.se

Article 39 Appeals against decisions of notified bodies

Article 40 Information obligation of notified bodies

Article 41 Exchange of experience

Article 42 Coordination of notified bodies

CHAPTER VI Union market surveillance and union safeguard procedures

Article 43 Procedure at national level for dealing with products within the scope of this Regulation presenting a risk

Article 44 Union safeguard procedure

Article 45 Compliant products within the scope of this Regulation which present a risk

Article 46 Formal non-compliance



CHAPTER VII Delegated powers and committee procedure

Article 47 Exercise of the delegation

Article 48 Committee procedure



CHAPTER VIII Confidentiality and penalties

Article 49 Confidentiality

Article 50 Penalties



CHAPTER IX

Article 51 Repeals

Article 52 Transitional provisions

Article 53 Evaluation and review

Article 54 Entry into force and application



ANNEX I Categories of machinery or related products to which one of the procedures referred to in Article 25(2) and (3) shall be applied

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

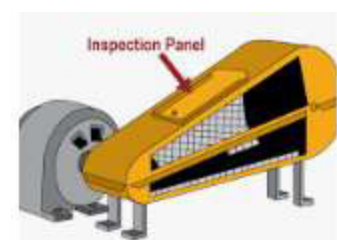
1. Removable mechanical transmission devices including their guards.
2. Guards for removable mechanical transmission devices.
3. Vehicle servicing lifts.
4. Portable cartridge-operated fixing and other impact machinery.
5. Safety components with fully or partially self-evolving behaviour using machine 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:

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 behaviour using machine learning approaches ensuring safety functions.



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.

ANNEX III (Former Annex 1 in MD) Essential health and safety requirements relating to the design and construction of machinery or related products

PART A Definitions

PART B

General principles

1. Essential health and safety requirements
 - 1.1. General remarks
 - 1.2. Control systems
 - 1.3. Protection against mechanical risks
 - 1.4. Required characteristics of guards and protective devices
 - 1.5. Risks due to other causes
 - 1.6. Maintenance
 - 1.7. Information



2. Supplementary essential health and safety requirements for certain categories of machinery and related products

- 2.1. Machinery and related products for foodstuffs and machinery and related products for cosmetics or pharmaceutical products
- 2.2. Portable hand-held or hand-guided machinery or related products
- 2.3. Machinery or related products for working wood and material with similar physical characteristics
- 2.4. Machinery or related products for plant protection products application



3. Supplementary essential health and safety requirements to offset risks due to the mobility of machinery or related products

- 3.1. General
- 3.2. Work positions
- 3.3. Control systems
- 3.4. Protection against mechanical risks
- 3.5. Protection against other risks
- 3.6. Information and indications



4. Supplementary essential health and safety requirements to offset risks due to lifting operations

- 4.1. General
- 4.2. Requirements for machinery or related products whose power source is other than manual effort
- 4.3. Information and markings
- 4.4. Instructions for use



5. Supplementary essential health and safety requirements for machinery or related products intended for underground work.

- 5.1. Risks due to lack of stability
- 5.2. Movement
- 5.3. Control devices
- 5.4. Stopping
- 5.5. Fire
- 5.6. Exhaust emissions



6. Supplementary essential health and safety requirements for machinery or related products presenting particular risks due to the lifting of persons

- 6.1. General
- 6.2. Control devices
- 6.3. Risks to persons in or on the carrier
- 6.4. Machinery or related products serving fixed landings
- 6.5. Markings



Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on **machinery** and repealing **Directive 2006/42/EC**. Mandatory from jan 20 2027 www.mpsa.se

ANNEX IV Technical documentation

PART A Technical documentation for machinery and related products

PART B Technical documentation for partly completed machinery



ANNEX V EU declaration of conformity and EU declaration of incorporation

PART A EU declaration of conformity of machinery and related products

PART B EU declaration of incorporation of partly completed machinery



ANNEX VI Internal production control

(Module A)

ANNEX VII

(Module B)

ANNEX VIII Conformity to type based on internal production control

(Module C)

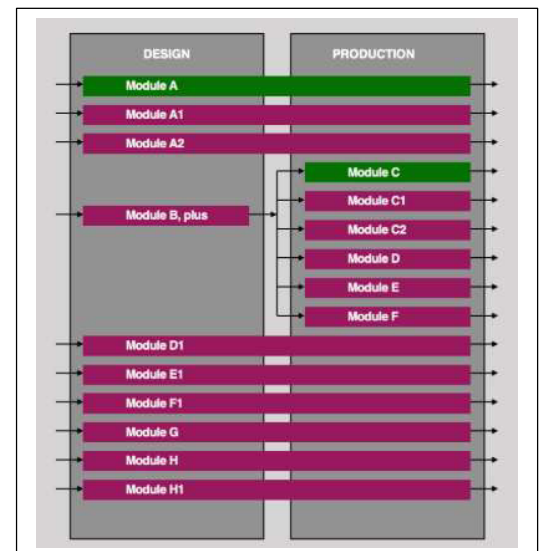
ANNEX IX Conformity based on full quality assurance

(Module H)

ANNEX X Conformity based on unit verification

(Module G)

ANNEX XI Assembly instructions for partly completed machinery



ANNEX XII Correlation table