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TECHNOLOGICAL
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CE guide

a brief guide to CE marking in accordance with
the Machinery Regulation (EU) 2023/1230

What is CE marking

CE marking is mandatory for all products covered by one or more of the EU's product-specific directives or regulations. By affixing the CE mark to a product, the manufacturer declares on their sole responsibility that the product meets all the legal requirements for CE marking, and that it can be freely sold throughout the European Economic Area (EEA).

From Machinery Directive to Machinery Regulation

The Machinery Regulation (EU) 2023/1230 (abbreviated MR) entered into force on 19 July 2023 and becomes applicable (mandatory) on 20 January 2027, thereby replacing the old Machinery Directive 2006/42/EC.

- **What is the difference between a directive and a regulation?**
A regulation applies simultaneously in all EU member states and does not need to be transposed into national law. This is intended to ensure uniform implementation and interpretation across the EU.

For machinery, the Machinery Regulation is the primary legislation, but other directives/regulations may still be fully or partially relevant, including:

- **ATEX** (Explosive atmospheres) - 2014/34/EU
- **PED** (Pressure equipment) - 2014/68/EU
- **EMC** (Electromagnetic compatibility) - 2014/30/EU
- **LVD** (Low voltage) - 2014/35/EU (though with specific limits/exclusions)
- **CRA** (Cyber Resilience Act) - (EU) 2024/2847



Scope of the Machinery Regulation (EU) 2023/1230

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

Machinery is defined as an assembly of linked parts or components, at least one of which moves, and which are joined together for a specific application, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort.

The definition now also covers machinery that lacks only the uploading of software intended for its specific application. Software ensuring a safety function and placed on the market independently is now also considered a safety component and therefore falls under the Machinery Regulation.

Assemblies of machinery, partly completed machinery, and linked parts or components are also defined as machinery – see the exhaustive list in the regulation.

Products covered by the regulation are the following:

- Machinery (and assemblies of machinery/machinery installations)
- Interchangeable equipment
- Safety components (both physical and digital/software)
- Lifting accessories
- Chains, ropes, and webbing
- Removable mechanical transmission devices
- Partly completed machinery

Exclusions from the scope of the Machinery Regulation

The following products are excluded from the scope of the regulation:

- Safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery
- Specific equipment for use in fairgrounds and amusement parks
- Machinery specially designed for nuclear purposes which, in the event of failure, may result in an emission of radioactivity Weapons, including firearms
- Means of transport:
 - Agricultural and forestry tractors (covered by Regulation (EU) No 167/2013)
 - Motor vehicles and their trailers (covered by Regulation (EU) 2018/858)
 - Means of transport by air, on water, and on rail networks are excluded (machinery mounted on these means of transport is, however, included)
 - E-bikes, electric scooters, and other personal mobility devices not covered by EU vehicle type-approval rules are covered by the Machinery Regulation
- Seagoing vessels and mobile offshore units and machinery installed on board such vessels or units
- Machinery specially designed and constructed for military or police purposes
- Machinery specially designed and constructed for research purposes for temporary use in laboratories

The following electrical and electronic products are excluded from the Machinery Regulation, insofar as they fall within the scope of the Low Voltage Directive or the Radio Equipment Directive:

- Household appliances intended for domestic use (which are not electrically operated furniture)
- Audio and video equipment Information technology equipment (IT equipment)
- Ordinary office machinery (except 3D printers)
- Low-voltage switchgear and controlgear
- Electric motors

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High-voltage electrical equipment that is excluded:

- Switchgear and controlgear
- Transformers

Important grey areas and interaction with other regulations

1. Radio equipment and Wi-Fi in machinery (Radio Equipment Directive – RED 2014/53/EU):

If a machine is equipped with wireless communication (e.g., Wi-Fi, Bluetooth, mobile networks, or remote control via radio waves), the radio component must comply with the RED. The Machinery Regulation establishes that even if the machinery features radio control, the mechanical and general safety requirements of the Machinery Regulation must still be fully complied with.

2. The boundary with the Lifts Directive (2014/33/EU):

Lifting appliances serving fixed landings in buildings generally fall under the Lifts Directive. However, there are important exceptions:

- The Machinery Regulation applies to lifting appliances whose speed does not exceed 0.15 m/s (e.g., slow-moving accessibility lifts or platform lifts).
- Construction hoists for persons or persons and goods are likewise covered by the Machinery Regulation, as they are not permanent installations in the building.

3. Machinery for research purposes:

The exclusion for "temporary use in laboratories for research purposes" is interpreted very strictly by the authorities. It applies only to entirely unique prototypes developed specifically for a concrete research project and operated exclusively by the researchers themselves under controlled conditions. As soon as a machine is put into use in actual production, or if it is made accessible to regular employees, the exclusion ceases to apply, and the machine must be fully CE marked in accordance with the Machinery Regulation.

Essential Health and Safety Requirements (EHSR)

Annex III sets out the essential health and safety requirements for the design and construction of machinery.

Principles of safety integration

The principle of integrated safety (the three-step method) continues to apply:

1. Eliminating or minimizing risks (inherently safe design)
2. Taking necessary protective measures against risks that cannot be eliminated
3. Informing users of residual risks (warnings and instructions)

What is new in the essential safety requirements?

- Cybersecurity: Requirements have been introduced for protection against malicious third parties and hacking that could affect the safety of the machinery (protection of the control system against external influence)
- Artificial Intelligence (AI) and self-evolving software: The risk assessment must take into account the ability of software and systems to modify their behavior after being placed into service
- Autonomous machinery: Requirement that driverless/autonomous machinery must have a supervisory control function

Structure of annex III (EHSR)

Annex III is divided into six sections, covering general as well as product-specific risks:

1. **GENERAL REQUIREMENTS** applicable to all machinery, including control systems, ergonomics, mechanical hazards, lighting, maintenance, instructions for use, etc.
2. **REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY**, e.g., food machinery, cosmetic or pharmaceutical products, as well as portable hand-held machinery
3. **REQUIREMENTS TO OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY**, including vehicles, operating positions, control systems, autonomous functions
4. **REQUIREMENTS TO OFFSET RISKS DUE TO LIFTING OPERATIONS**, including stability, mechanical strength, fall protection, control
5. **REQUIREMENTS FOR MACHINERY INTENDED FOR UNDERGROUND WORK**
6. **REQUIREMENTS FOR MACHINERY INTENDED FOR LIFTING PERSONS**, including specific risks associated with lifting persons, fall protection, emergency stop

Frequently used standards

Harmonised Standards for machinery safety

Harmonised standards (Type A, B, and C) confer upon the manufacturer a presumption of conformity with the essential health and safety requirements of Annex III covered by the standard.

Standard (type A & B)	Number
General principles for design – Risk assessment and risk reduction	EN ISO 12100
Electrical equipment of machines – Part 1: General requirements	EN 60204-1
Safety-related parts of control systems – Part 1: General principles for design	EN ISO 13849-1
Safety-related parts of control systems – Part 2: Validation	EN ISO 13849-2
Emergency stop function – Principles for design	EN ISO 13850
Safety distances to prevent hazard zones being reached by upper and lower limbs	EN ISO 13857
Prevention of unexpected start-up	EN ISO 14118
Interlocking devices associated with guards – Principles for design and selection	EN ISO 14119
Guards – General requirements for the design and construction of fixed and movable guards	EN ISO 14120
Permanent means of access to machinery – Part 1: Choice of fixed means and general requirements of access	EN ISO 14122-1
Permanent means of access to machinery – Part 2: Working platforms and walkways	EN ISO 14122-2
Permanent means of access to machinery – Part 3: Stairs, stepladders and guard-rails	EN ISO 14122-3
Explosive atmospheres – Explosion prevention and protection – Part 1: Basic concepts and methodology	EN ISO 1127-1

Standard (type C)	Number
Continuous handling equipment and systems – Safety and EMC requirements for the equipment for the storage of bulk materials in silos, bunkers, bins and hoppers	EN 617
Continuous handling equipment and systems – Safety and EMC requirements for equipment for mechanical handling of bulk materials except fixed belt conveyors	EN 618
Continuous handling equipment and systems – Safety and EMC requirements for equipment for mechanical handling of unit loads	EN 619
Continuous handling equipment and systems – Safety requirements for fixed belt conveyors for bulk materials	EN 620
Mobile elevating work platforms – Design calculations – Stability criteria – Construction – Safety – Examinations and tests	EN 280
Safety requirements for suspended access equipment – Design calculations, stability criteria, construction – Examinations and tests	EN 1808
Equipment for the lifting of persons – Part 1: Suspended baskets	EN 14502
Safety of woodworking machines – Circular sawing machines	EN 1870 PART 1 - 5
Loader cranes	EN 12999
Offshore cranes - General-purpose offshore cranes	EN 13852-1

Note: Following the transition to the Machinery Regulation in 2027, the standards will be updated to refer to the new regulation instead of the old Machinery Directive. As standards are continuously revised to meet the requirements of the new Machinery Regulation, you can find the most recent lists of harmonised standards here:

Danish Standard



European Commission



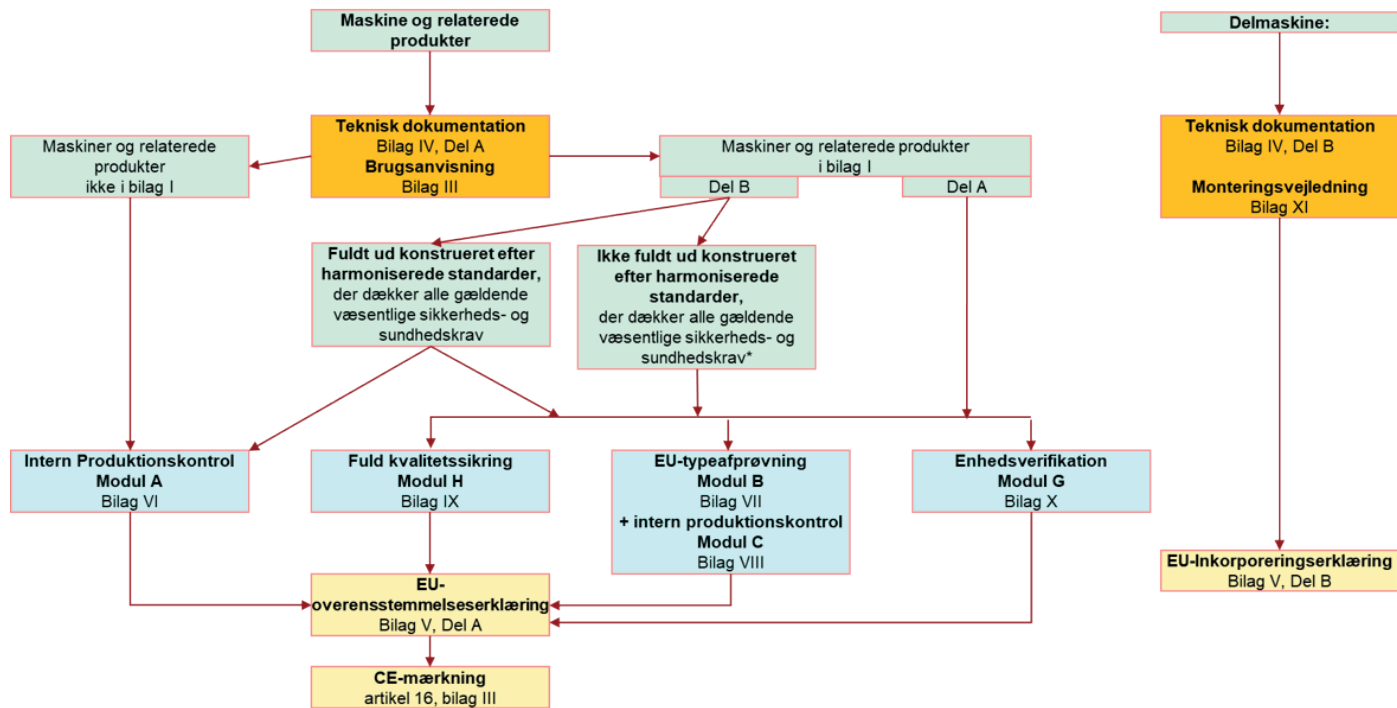
Conformity assessment procedures

Conformity assessment (Article 25)

The procedure depends on whether the machinery is considered a particularly hazardous machine (now listed in Annex I – previously Annex IV under the Machinery Directive).

1. For machinery that is NOT listed in Annex I, the manufacturer may carry out internal production control (Module A), which entails:
 - Preparation of technical documentation (Annex IV)
 - Performance of a risk assessment
 - The manufacturer signs the EU declaration of conformity (Annex V) and affixes the CE marking
2. Machinery listed in Annex I (High-risk machinery) is divided into two parts (Part A and Part B):
 - **Part A** applies to machinery or related products that involve particularly hazardous machinery, machinery and safety components with self-evolving behavior, etc. This always requires the involvement of a notified body (e.g., EU type-examination – Module B followed by Module C, or full quality assurance – Module H)
 - **Part B** applies to machinery or related products with significant risk, e.g., saws, presses, lifts. If the manufacturer applies applicable harmonised standards in full, they may use Module A (internal control). If harmonised standards do not exist, or if the manufacturer deviates from them, a notified body must always be involved

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Assemblies of machinery and process plants

Several machines or partly completed machinery that are arranged and controlled so that they function as an integral whole in order to achieve a common goal are considered an assembly of machinery. This installation must be CE marked as a complete unit.

Criteria for a machinery installation

For a series of machines to be considered an assembly of machinery, the following three criteria must be met:

1. **Common function:** The individual units are arranged to perform a common task (e.g., a production line).
2. **Functional interconnection:** The machines are linked so that the operation of one machine directly affects the function or safety of the others. This requires a risk assessment for the entire installation.
3. **Common control system:** The installation is controlled by a common or supervisory control system (e.g., a shared emergency stop or PLC control).

If the machines are merely placed side by side without functional and safety-related interdependence, they are not considered an assembly of machinery.

A classic example of an assembly of machinery is an industrial silo and conveyor installation, e.g., consisting of intake, bucket elevators, conveyor belts, silos, and discharge units — all controlled from a common control panel.

Even though the conveyor, the elevator, and the dampers are individually CE marked, or delivered as partly completed machinery with declarations of incorporation, the entity assembling and linking the equipment must carry out an overall risk assessment, draw up a comprehensive EU declaration of conformity, and affix an overall CE marking to the installation.



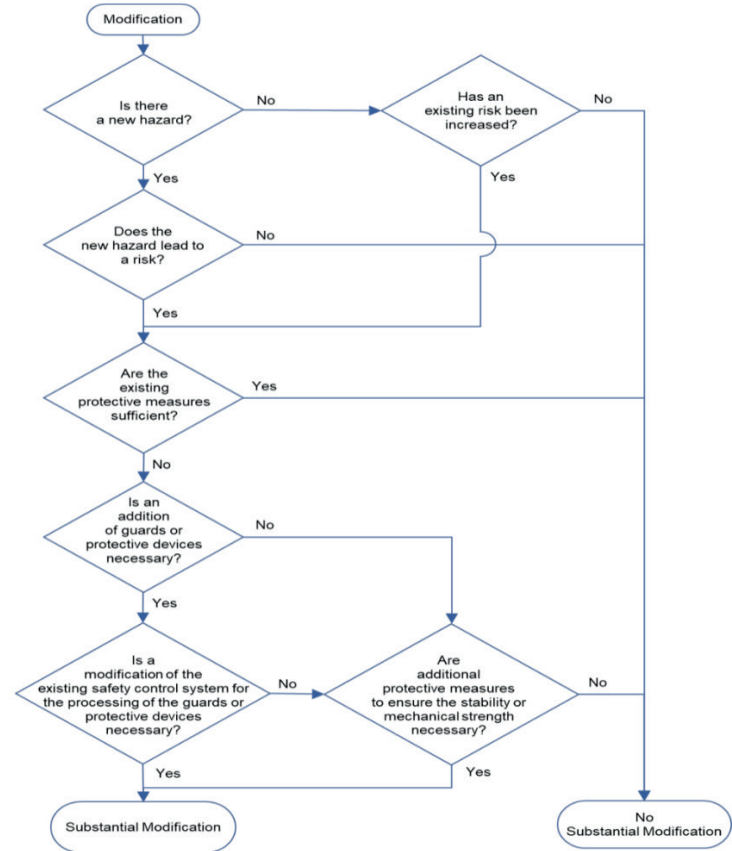
Substantial modifications

A modification of a machine (physical or digital) that is not foreseen by the manufacturer, which affects safety by creating a new hazard or increasing an existing risk, and which requires new significant protective measures.

What happens if a substantial modification is carried out?

The person or entity making the modification assumes all obligations of the manufacturer. This means that:

- A full conformity assessment must be carried out (Article 25)
- New technical documentation must be prepared
- A new EU declaration of conformity must be issued and a new CE marking affixed



Machinery and steel structures (EN 1090)

Steel structures that serve as construction products in buildings, bridges, etc., must be CE marked in accordance with standard EN 1090-1 under the Construction Products Regulation (CPR).

However, specific rules apply to machinery structures:

- **Machinery foundations and means of access:** If stairs, platforms, ladders, and supports form an integral part of the machine, they are covered by the machinery's CE marking (in accordance with the Machinery Regulation and EN ISO 14122). In this case, EN 1090 does not apply.
- **Building parts:** If a platform or staircase is attached to the building itself and is not part of the machinery, it must be CE marked in accordance with EN 1090.

However, many end users today require welding work and steel components to be executed in accordance with EN 1090 (e.g., EXC2) as a quality assurance requirement, even though it is formally covered by the Machinery Regulation.

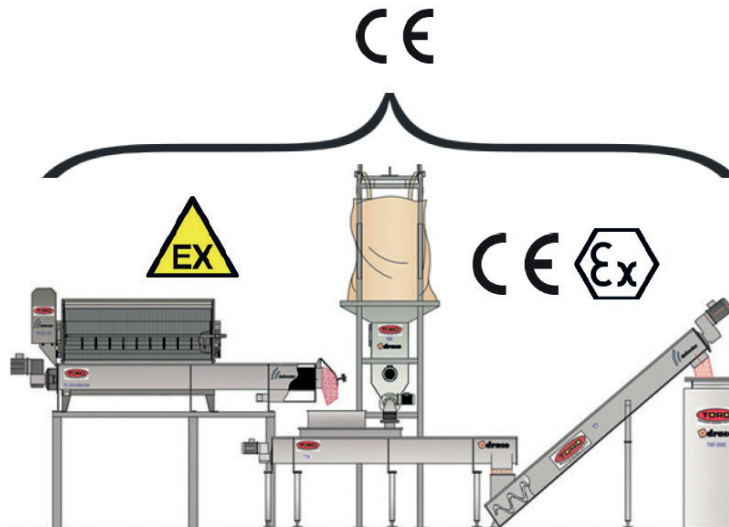


Machinery and the ATEX Directive

Requirements for explosion risks on machinery are laid down in Annex III, point 1.5.7 (Explosion). In practice, the standard EN ISO 1127-1 is applied for risk assessment and explosion prevention.

When machinery or installations are to be installed in or handle potentially explosive atmospheres:

- The entire installation must be risk-assessed for ignition sources (static sparks, hot surfaces, etc.)
- The sub-components used (motors, sensors, valves) that are placed in the ATEX zone must be CE and Ex marked in accordance with the ATEX Directive 2014/34/EU
- The overall machinery is CE marked in accordance with the Machinery Regulation



EU Declaration of Conformity (Annex V)

Annex V, Part A of the Machinery Regulation specifies the requirements for the declaration of conformity.

The requirements for the content are the following:

1. **Identification:** Model, designation, type, batch, or serial number of the machinery
2. **Manufacturer:** Name, registered trade name, postal address, email address/website
3. **Declaration:** An express statement that the machinery fulfills all relevant provisions of this Regulation and any other relevant directives (e.g., ATEX, EMC)
4. **Notified Body:** Where applicable, the name and ID number of the notified body that carried out the type-examination (Module B/H)
5. **Standards:** Reference to the harmonised standards applied. In the case of partial application of harmonised standards, the declaration must state which parts have been applied
6. **Date and signature:** Place and date of issue, as well as the signature of the person authorized to sign on behalf of the manufacturer

The Machinery Regulation allows for the full digitalization of documentation:

- **Digital declaration:** It is now permitted to provide the EU declaration of conformity digitally
- **Access via link:** The manufacturer may choose to provide an internet address or a machine-readable code (e.g., a QR code) in the machinery's instructions for use, leading directly to the declaration
- **Retention requirement:** The digital declaration must remain accessible online for the lifetime of the machinery, and for at least 10 years after the machinery has been placed on the market or put into service

CE marking and machinery marking

Each machine must be provided with visible, legible, and indelible marking containing at least the following information:

- The manufacturer's name, registered trade name, or trademark
- The manufacturer's postal address and website, email address, or other digital contact information
- Designation of the machinery (name/function)
- The CE marking
- Designation of series or type
- Serial or batch number (if applicable)
- Year of construction (the year in which the manufacturing process was completed)
- Applicable ATEX Ex marking for explosive atmospheres
- Additional technical data (current, voltage, pressure, maximum load, tare weight, etc.)

20V Max Lithium Ion
Max. guide bar length / Die maximale
Führungsschienenlänge. / longueur
maximale du guide-chaîne: 120mm

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User manual

One of the most significant and long-awaited changes in the Machinery Regulation is the permission to provide instructions for use digitally

Conditions for digital provision

When the instructions for use are provided digitally, the manufacturer must fulfill the following requirements:

1. **Access:** Clearly indicate on the machinery (or on the packaging) how the digital instructions for use can be accessed (e.g., via a QR code or URL link)
2. **Format:** It must be provided in a format that makes it possible for the customer to download, save, and print it (e.g., PDF)
3. **Availability:** It must remain accessible online for the lifetime of the machinery and for at least 10 years after the machinery has been placed on the market

When must paper format still be provided?

- **Upon request:** If the customer requests it at the time of purchase, the manufacturer must provide printed instructions for use in paper format free of charge within one month
- **Non-professional users:** If the machinery is intended for non-professional users, all essential safety information must be provided in paper format

A user manual under the Machinery Regulation must provide the operator with a clear, practical, and comprehensive basis for using the machinery safely throughout its entire lifecycle. The manual must support correct installation, daily operation, and maintenance, while conveying all relevant risks and protective measures. The objective is to ensure that the user can make safe decisions, understand the machinery's limitations, and react correctly in both normal and abnormal situations. The manual must be clear, targeted, and tailored to the intended user group.

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Overall, a user manual must contain all relevant points set out in Annex III of the Machinery Regulation – Content of the instructions for use, and can be briefly summarized as follows:

- The manual must describe the safe use of the machinery, including all operating modes It must specify installation, assembly, connection, and commissioning
- It must explain operation, start/stop, adjustment, and process control
- It must describe maintenance, inspection, cleaning, and service intervals
- It must indicate residual risks, warnings, and required personal protective equipment (PPE)
- It must contain technical data, capacities, limits, and environmental requirements
- It must describe protective devices, their function, and correct use
- It must state emergency procedures, emergency stop, fault responses, and troubleshooting
- It must specify requirements for training, qualifications, and user profiles
- The manual must be clear, comprehensible, and provided in a relevant EU language

A user manual is not merely an informational document, but a central safety component supporting both operator behavior and the safe function of the machinery. Following the requirements of Annex III to the Machinery Regulation ensures that all essential aspects – from installation to emergency procedures – are properly covered and communicated. The manual must be updated continuously whenever the machinery is modified or experience indicates a need for clarification. Thus, it remains an active and reliable tool within the overall safety strategy.

Danish Technological Institute

Danish Technological Institute is an independent, non-profit institution. We develop, apply, and disseminate research- and technology-based knowledge to Danish and international business sectors. As such, we participate in development projects that benefit society, in close collaboration with leading research and educational institutions both in Denmark and abroad.

Machinery certification

Danish Technological Institute's certification body, Dancert, is a notified body (Notified Body No. 1073) and performs EU type-examinations of machinery. We help you get safely through the process, from the initial assessment of documentation to the issuance of a certificate. Dancert can issue EU type-examination certificates in accordance with the Machinery Regulation (EU) 2023/1230 for the following products listed in Annex I:

- A.02. Guards for removable mechanical transmission shafts
- A.03. Vehicle servicing lifts
- A.05. Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions
- A.06. Machinery embedding systems with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions
- B.01. Circular saws (single- or multi-blade)
- B.02. Hand-fed surface planing machines
- B.03. Thicknessers for one-side dressing, having a built-in mechanical feed device, with manual loading and/or unloading
- B.04. Band-saws with manual loading and/or unloading
- B.05. Combined machines of the types referred to in points 1 to 4 and point 7
- B.07. Hand-fed vertical spindle moulding machines
- B.09. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading
- B.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 metres
- B.17. Logic control units to ensure safety functions



Technology for a better future



Danish Technological Institute (DTI) is a self-owned and not-for-profit institution, approved as a Research and Technology Organisation by the Danish Minister for Higher Education and Science.



Read more about Danish Technological Institute's expertise in CE marking of machinery by scanning the QR code on the left. Do you need competent advice on CE marking – or assistance with the CE marking itself? Contact our specialists.

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