

CE GUIDE

A SHORT GUIDE TO CE MARKING
ACCORDING TO THE MACHINERY
DIRECTIVE

MACHINERY AND ASSEMBLIES
OF MACHINERY - DIRECTIVE 2006/42/EC



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WHAT IS CE MARKING

CE marking is relevant for all products under one or more of the 24 New Approach Directives.

By affixing the CE mark to a product, a manufacturer declares that the product meets all the legal requirements for CE marking and can be sold throughout the EEA.

CE marking brings two main benefits to businesses and consumers within the EEA:

- Businesses know that products bearing the CE mark can be traded in the EEA without restrictions
- Consumers enjoy the same level of health, safety, and environmental protection throughout the entire EEA

For Machinery, the relevant Directives are MD 2006/42/EC but other directives can also be fully, partially, or indirectly relevant:

- ATEX 2014/34/EU
- PED 2014/68/EU
- EMC 2014/30/EU
- LVD 2014/35/EU



SCOPE OF MACHINERY DIRECTIVE 2006/42/EC

One of more definitions of 'machinery'

A machine is consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application powered by a drive system other than human effort.

Assemblies of machinery, partly completed machinery, linked parts or components are also defined as machines - see exhaustive list in the directive.

The Machinery Directives applies to the following products:

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

EXCLUSIONS FROM THE MACHINERY DIRECTIVE SCOPE

- 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/or amusement parks
- Machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity
- Weapons, including firearms
- The following means of transport, except machinery mounted on these:
 - Agricultural and forestry tractors for the risks covered by Regulation (EU) No 167/2013
 - Motor vehicles and their trailers covered by Council Regulation (EU) 2018/858
 - Means of transport by air, on water and on rail networks
- Seagoing vessels and mobile offshore units and machinery installed on board such vessels and/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
- Mine winding gear
- Machinery intended to move performers during artistic performances

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- Electrical and electronic products falling within the following areas, insofar as they are covered by Council Directive 2014/35/EU harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits:
 - Household appliances intended for domestic use
 - Audio and video equipment
 - Information technology equipment
 - Ordinary office machinery
 - Low-voltage switchgear and control gear
 - Electric motors

- The following types of high-voltage electrical equipment:
 - Switch gear and control gear
 - Transformers

ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

Annex I of Directive 2006/42/EC contains the Essential Health and Safety Requirements (EHSR) relating to the design and construction of machinery like:

- Principles of safety integration
 1. priority - Inherently safe design measures
 2. priority - Technical protective measures
 3. priority - Information for users

- Intended use and working environments
- Choice of materials
- Specific safety requirements to design, guards, mechanical strength and control system and software
- Ergonomics
- Marking
- Instructions for use

Annex I contains one section for general requirements and five sections for product specific requirements.

Annex I consist of six sections:

1. GENERAL REQUIREMENTS and SUPPLEMENTARY REQUIREMENTS for the
2. SUPPLEMENTARY EHSR FOR CERTAIN CATEGORIES OF MACHINERY
3. SUPPLEMENTARY EHSR TO OFFSET HAZARDS DUE TO THE MOBILITY OF MACHINERY
4. SUPPLEMENTARY EHSR TO OFFSET HAZARDS DUE TO LIFTING OPERATIONS
5. SUPPLEMENTARY EHSR FOR MACHINERY INTENDED FOR UNDERGROUND WORK
6. SUPPLEMENTARY EHSR FOR MACHINERY PRESENTING PARTICULAR HAZARDS DUE TO THE LIFTING OF PERSONS

FREQUENTLY USED STANDARDS

Harmonised Standards for Safety of machinery

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	14502
Safety of woodworking machines – Circular sawing machines	EN 1870 PART 1 - 5
Loader cranes	12999
Offshore cranes - General-purpose offshore cranes	13852-1

Harmonised standards are essential tools for applying the Machinery Directive and provide a good indication of the state-of-the-art that must be taken into account when applying the Essential Health and Safety Requirements.

Places to find information / current Harmonized Standards:

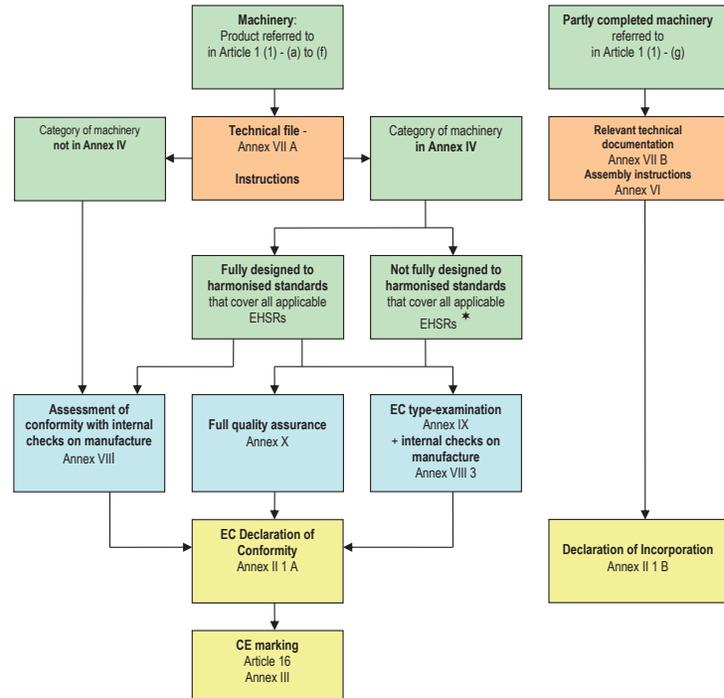
<https://www.teknologisk.dk/31633>

<https://www.teknologisk.dk/31633,2>

https://ec.europa.eu/growth/sectors/mechanical-engineering/machinery_en

CONFORMITY ASSESSMENT PROCEDURE

The following diagram summarises the procedures set out in Machinery Directive Article 12 and 13, for placement of machinery and partly completed machinery on the market.



* Harmonised standards are not available, the harmonised standards do not cover all the applicable EHSRs or the harmonised standards are not applied or are only partially applied.

Colour code: ■ Product category ■ Documents ■ Procedure ■ Declaration – marking

ASSEMBLIES OF MACHINERY AND PROCESS PLANT

Assemblies of machinery and partly completed machinery arranged and controlled so that they function as an integral whole in order to achieve the same end, is also covered by the CE marking requirements - even if the machine is for your own use!

For a group of units of machinery or partly completed machinery to be considered as an assembly of machinery, the following criteria must be fulfilled:

- The constituent units are assembled together in order to carry out a common function, e.g. the production of a given product
- The constituent units are functionally linked in such a way that the operation of each unit directly affects the operation of other units or of the assembly as a whole, so that a risk assessment is necessary for the whole assembly
- The constituent units have a common control system

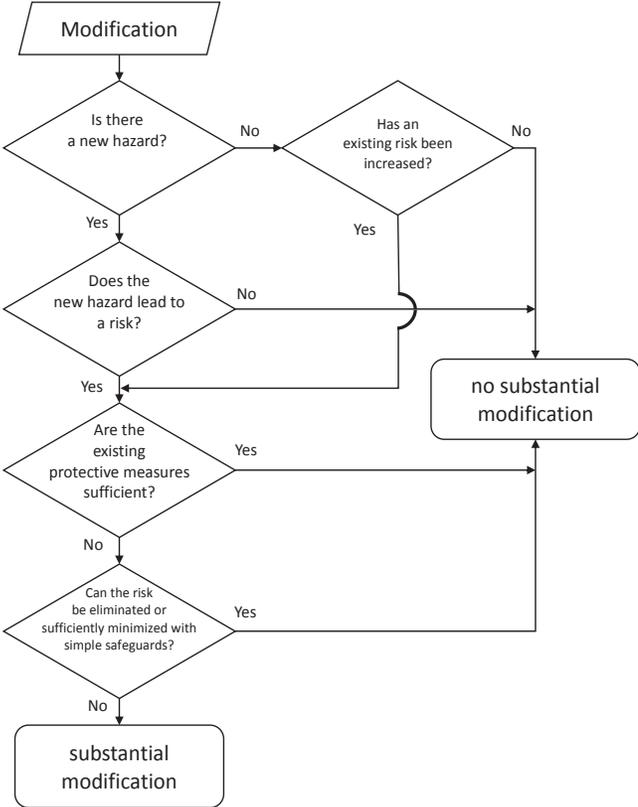
A group of machines that are connected to each other but where each machine functions independently of the others is not considered as an assembly of machinery in the above sense.

An example could be the silo plant seen on the following page.



MODIFICATIONS OF MACHINERY

If a modification of a machine/assembly of machinery causes substantial impact on the operation or the safety of the assembly (a substantial modification), a new CE marking may be required.



MACHINERY AND STEEL CONSTRUCTION (EN 1090)

Steel structures in construction products in buildings, bridges etc. must be CE marked in accordance with the European standard for the execution of steel and aluminum structures EN 1090-1.

Examples of CE marking of construction products (buildings etc.) relevant for machinery:

- Machinery supports, if integral part of the load bearing structure of the construction works
- Pipeline and pipe supporting structures
- Ladders, stairs and access platform IF it's a part of the building and NOT integrated in the machine



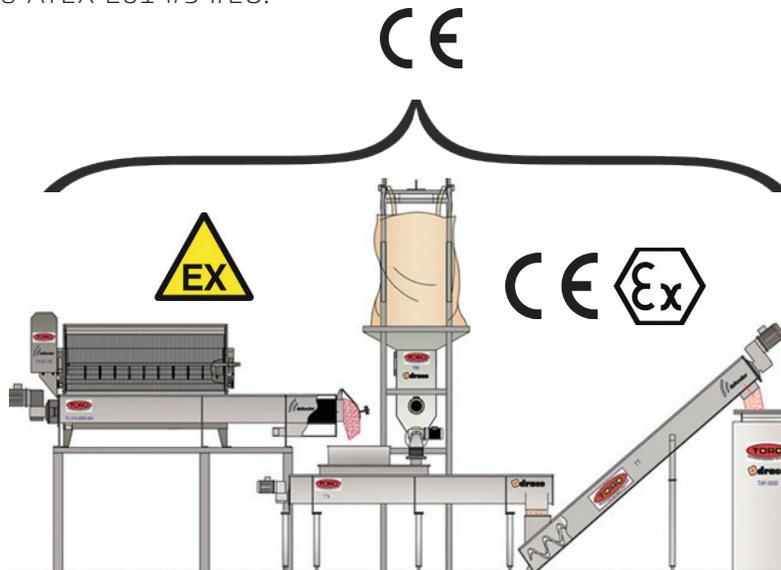
The requirement for CE marking of steel structures does NOT apply to steel structures that are part of machines - they are covered by the CE marking in accordance with the Machinery Directive - but for e.g. supports and foundations for the machines.

However, several end users require the use of steel that is CE marked in accordance with EN 1090 also in machine constructions.

MACHINERY AND THE ATEX DIRECTIVE

Requirements regarding risks of Explosion on machinery/assemblies of machinery are raised in ESHR 1.5.7 Explosion – in practice EN 1127 Explosion prevention and protection are used for risk assessment and documentation.

The assembly must be CE marked according to the Machinery directive – individual machinery in or with interface to explosive atmosphere and protective systems also according to ATEX 2014/34/EU.



DECLARATION OF CONFORMITY TO 2006/42/EC

The EC declaration of conformity must contain the following information (MD Annex II):

1. Business name and full address of the manufacturer and, where appropriate, his authorised representative
2. Name and address of the person authorised to compile the technical file, who must be established in the Community
3. Description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name
4. A sentence expressly declaring that the machinery fulfils all the relevant provisions of this Directive and where appropriate, a similar sentence declaring the conformity with other Directives and/or relevant provisions with which the machinery complies. These references must be those of the texts published in the Official Journal of the European Union
5. Where appropriate, the name, address and identification number of the notified body which carried out the EC type-examination
6. Where appropriate, the name, address and identification number of the notified body which approved the full quality assurance system
7. Where appropriate, a reference to the harmonised standards used

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8. Where appropriate, the reference to other technical standards and specifications used
9. The place and date of the declaration
10. The identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.

EC Declaration of Conformity or document setting out the contents of the EC Declaration is to be included in the instruction handbook.

CE MARKING OF MACHINERY TO 2006/42/EC

In addition to the required CE marking, all machinery must be marked visibly, legibly and indelibly with the following minimum particulars:

- The business name and full address of the manufacturer and, where applicable, his authorised representative
- Designation of the machinery
- The CE Marking (see Annex III)
- Designation of series or type
- Serial number, if any
- The year of construction, that is the year in which the manufacturing process is completed.

It is prohibited to pre-date or post-date the machinery when affixing the CE marking.

Furthermore, machinery designed and constructed for use in a potentially explosive atmosphere must be marked accordingly.

Machinery must also bear full information relevant to its type and essential for safe use.

Where a machine part must be handled during use with lifting equipment, its mass must be indicated.

INSTRUCTION MANUAL

The instruction manual must contain, where applicable, at least the following information:

- (a) the business name and full address of the manufacturer and of his authorised representative
- (b) the designation of the machinery as marked on the machinery itself, except for the serial number
- (c) the EC declaration of conformity, or a document setting out the contents of the EC declaration of conformity
- (d) a general description of the machinery
- (e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery and for checking its correct functioning
- (f) a description of the workstation(s) likely to be occupied by operators
- (g) a description of the intended use of the machinery
- (h) warnings concerning ways in which the machinery must not be used that experience has shown might occur
- (i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery is to be mounted
- (j) instructions relating to installation and assembly for reducing noise or vibration
- (k) instructions for the putting into service and use of the machinery and, if necessary, instructions for the training of operators

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INSTRUCTION MANUAL

- (l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted
- (m) instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided;
- (n) the essential characteristics of tools which may be fitted to the machinery
- (o) the conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns
- (p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery and of its various parts where these are regularly to be transported separately
- (q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked
- (r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed
- (s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations
- (t) the specifications of the spare parts to be used, when these affect the health and safety of operators
- (u) information on airborne noise emissions
- (v) information concerning the radiation emitted for the operator and exposed persons.

DANISH TECHNOLOGICAL INSTITUTE

The Danish Technological Institute is a self-owned and not-for-profit institution. We develop, apply and disseminate research and technologically based knowledge for the Danish and International business sectors.

As such, we participate in development projects, which are of use to society in close collaboration with leading research and educational institutions both in Denmark and abroad.

Machinery Certification

Danish Technological Institute's department "Certification & Inspection" is an independent accredited Notified Body for machinery.

Within the scope of our Notified Body no. "0396" we can issue the Type EC type examination certificate in accordance with Directive 2006/42/EC for following items listet in Annex IV:

- 1.1 – 1.4** Circular saws (single- or multi-blade) - sawing machinery
- 2.** Hand-fed surface planing machinery for woodworking

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- 3. Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking
- 4.1. – 4.2 Band-saws with manual loading and/or unloading - sawing machinery
- 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
- 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
- 13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism
- 14. Removable mechanical transmission devices including their guards
- 15. Guards for removable mechanical transmission devices
- 16. Vehicle servicing lifts
- 17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres



Danish Technological Institute

Taastrup & Aarhus

Denmark

+45 72 20 20 00

www.dti.dk

Direct contact:

Frits Fynbo: +45 7220 3564 - ffy@dti.dk

Max Schjeldal: +45 7220 1481 - msch@dti.dk

Alla Kongstad: +45 7220 2130 - alk@dti.dk

Read more at:

www.dti.dk - Machinery Directive