IKEA Industry

# CE-MARKING OF MACHINERY

## WHAT

A description of how to CE-mark machinery within a factory.

## WHY

All machinery that are used in production requires to have a CE-marking

## HOW

Follow the steps in the process

## Revision Log

| Edition | Revision | Published | Comment |
|---|---|---|---|
| 2 | 1 | 2025-05-20 | Changed author |
| 2 | | 2024-06-18 | Update of Chapter 9, due to conversion issues to pdf. |
| 1 | 1 | 2023-04-17 | Updated Properties of File. |

# 1 General

The scope of this document is to describe how to perform a CE-marking of a machinery or a line within the factory.

Each machine included in the machine line may be risk assessed and CE-marked by itself, but it is not enough. New risks are added when the individual machines are connected to a machine line and therefore a total assessment of safety also needs to be made.

# 2 References

2006/42/EC - Machinery Directive (MD)
2009/104/EC - Use of work equipment by workers at work
2014/35/EU - Low Voltage Directive (LVD)
2014/34/EU - ATEX-Directive
2014/68/EU - Pressurized Equipment Directive (PED)

ISO 12100:2010 Safety of machinery – General principles for design – Risk assessment and risk reduction

ISO TR 14121-2:2012 Safety of machinery – Risk assessment –
Part 2: Practical guidance and examples of methods

ISO 11161:2007 Safety of machinery – Integrated Manufacturing Systems

# 3 Definitions

**CE-marking** – It is final step when applying a sticker or a metal plate when all the documentation are completed and the Declaration of Conformity is signed.

**Declaration of Conformity** - (2A) - A signed document by authorized person that tells that all technical documentation have been compiled into a Technical File.

**Declaration of Incorporation** – (2B) - A signed document by authorized person that tells that all technical documentation have been compiled into a Technical File for an incomplete machinery, and needs further documentation when installed and safety investigation.

**Technical File** – A collection of documentation that demonstrate the products fulfill the requirements of the Directive, the requirements to sign a Declaration of Conformity.

# 4 Different Scenarios

Here we go through different concepts and give examples of how different types of machine lines can look like.

## 4.1 New machine line with CE-marked machines

You will build a machine line with new machines, all machines are CE-marked. A risk assessment of the boundary cuts between the machines shall be carried out and documented. The instructions for use need to be compiled and even complemented. Emergency stops for the machine line shall be assessed for risk. The entire machine line shall be CE-marked if it has a common control system.

## 4.2 New machine line with two CE-marked machines and one partially completed machine

You will build a machine line with two CE-marked machines and a partially completed machine, for example a Robot. Risk assessment of the interfaces between the machines shall be carried out and documented. The partially completed machine shall be supplemented according to the installation instructions. The instructions for use need to be compiled and supplemented, if necessary. Emergency stops for the machine line shall be assessed for risk. The entire machine line shall be CE-marked if it has a common control system.

## 4.3 New machine line with both CE-marked machines and older machines

You will build a new machine line with two CE-marked machines and an older machine (before 1993). Risk assessment of the interfaces between the machines shall be carried out and documented. A new machine line shall always comply with the requirements of Machinery Directive and CE-marked when placed on the market or put into service. If one or more old machines are included in the machine line, these do not need to be CE-marked, but all the machines included must be upgraded if necessary, so that the machine line meets the requirements. The instructions for use need to be compiled and even complemented. Emergency stops for the machine line shall be assessed for risk. The entire machine line shall be CE-marked if it has a common control system.

## 4.4 Rebuilding an existing machine line

If you are rebuilding an existing machine line, each machine in it must meet the requirements of it, whether it is an old or new machine. In addition, the machine line as a whole shall be safe and meet the requirements of User Directive. Risk assessment of the interfaces between the machines shall be carried out and documented. The machine line shall not be CE-marked again unless it is considered to be a new machine line. See 4.3. The instructions for use need to be compiled and supplemented, if necessary. Emergency stops for the machine line shall be assessed for risk.

## 4.5 Procurement

It is important that the person who buys a machine line has the necessary knowledge. Find out what requirements apply and decide who takes responsibility for the whole. If you or your company do not have that competence, use help of an expert, such as a consultant. Overall assessment of safety risks are added when different machines are connected together and a risk assessment of the whole must be carried out.

### 4.6 What does "put into operation" mean?

When the machine line is put into operation, i.e. used for the first time in production, it must meet all requirements and be CE-marked. An exception is a machine line as shown in example 4.4. A machine line is considered to be operational when its own personnel start using it or when it can manufacture what it is intended for. Commissioning does not depend on whether the line has reached full capacity.

### 4.7 Rebuilding may need new CE marking

A rebuilding shall always be risk assessed and documented. A machine or machine line shall be safe. If you are not the manufacturer yourself, contact the manufacturer before starting rebuilding. A new CE marking may need to be made in the event of significant rebuilding. For example, in:

• major capacity increases,

• change in use, such as manufacture of other products,

• changes related to strength or stability.

Assessment of whether a new CE marking needs to be made is determined in a documented risk assessment, on a case-by-case basis.

## 4.8 Manufacturer

The manufacturer is responsible for ensuring that the machine meets all requirements. The person who assembles a machine line must decide early on who is responsible for the safety of the entire machine line. For example, a user (factory) might be the end manufacturer, or integrator.

# 5 Preparation

The objective and scope for CE-marking should be defined in the beginning.

### 5.1 Team

A Technical File compilation will be more thorough and effective when performed by a team. The team should consist of people that:

- Can answer technical questions about the design and function of the machinery
- Have experience of how the machinery is operated, set-up, maintained, etc
- Have knowledge of the accident history
- Have a good understanding of relevant regulations, standards, etc

To be effective the team should not be too big, 3-5 people is normally enough, and when specific question that is outside of the teams' knowledge, then other people can be involved, during these questions.

### 5.2 Source of information

The information required to compile a Technical File may include:

- Technical drawings
- Diagrams
- Photos

- Manuals
- Standard Operating Procedures (SOP)
- Maintenance information

It will also require that the relevant regulations, standards are considered.

Other things to consider is related to experience of use:
- Any accidents, incidents history for actual or similar machinery
- History of damage to health, e.g. noise, dust, vibration, etc
- Experience of users of similar machines
- Relevant ergonomic principles

# 6 Define Scope

It is important to define the scope for the CE-marking so everyone understands the limits and content. What shall be included and what shall not?

There are also several directives to consider

- 2006/42/EC - Machinery Directive (MD)
- 2014/35/EU - Low Voltage Directive (LVD)
- 2014/34/EU - ATEX-Directive
- 2014/68/EU - Pressurized Equipment Directive (PED)

Under what directive should the machinery be CE-marked?

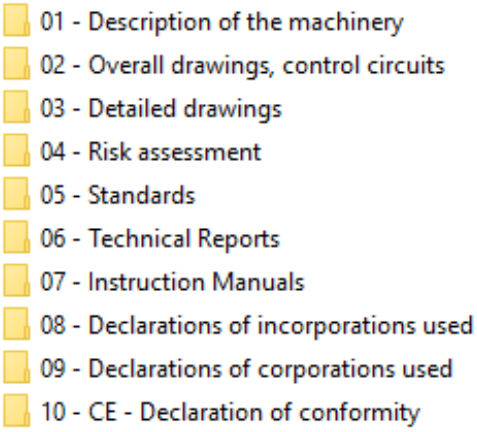
# 7 Integrated Manufacturing System

A machine can stand independently or be part of larger system of machines that are connected. An integrated manufacturing system (IMS):
- incorporates two or more industrial machines which:
  - can operate independent of each other, and
  - are intended for the purpose of manufacturing, treatment, movement or packaging of discrete parts or assemblies;
- is linked by a material handling system; and
- is interconnected by a control system(s) for coordinated operation

There is a harmonized standard EN-ISO 11161:2007 that support this.

# 8 Structure of a Technical File

A Technical File a compilation of documents and files that are stored in relevant folder.




A Technical File consists of documentation that are “frozen”/released. No changes/updates are allowed. If changes are made, then an updated of the Technical File is needed and a new Declaration of Conformity need to be signed.

## 8.1 Description of the Machinery

It is important to define the scope of the machinery/Line, what is included in this CE-marking.

- A Layout is good to explain the different machinery
- A list of machines, including name machine numbers and serial numbers
- What CE-markings are there before?
- Span of control (can be shown in a layout)
- What is this functionality of this machinery/line?
- Are there any previous Risk Assessments done that are available?

## 8.2 Overall Drawings – Control Circuits

This folder will summarize the content this Technical File

- Layout drawing of what this Technical File will include
- Control Circuits of the safety
    - Location of Emergency Stops, other safety protections
    - Layout of passages for walk ways, and forklift driveways
    - Other critical danger zones

## 8.3 Detail drawings

Here you place the detail drawings that are included, or a reference where to find the information.

- Mechanical drawings
- Electrical drawings
- Pneumatic diagrams
- PLC-programs
- It is important to note what versions of programs, drawings that this Technical File was done on. Changes will lead to a new Technical File.

## 8.4 Risk Assessment

- A Risk Assessment contains the following steps:
  - Define scope (including documentation collection)
  - Risk Analysis
  - Risk Evaluation
  - Risk Reduction
- A Risk Assessment are usually done three times
  - A pre-risk assessment (before installation)
  - A Risk Assessment (when installation is done before startup)
  - A follow up risk assessment (to check that the risks are reduced to ok level)

## 8.5 Standards

- What Standards are relevant for this Technical File?

## 8.6 Reports

- Reports that confirms validation to fulfill requirements
- Test of emergency stops, safety barriers

## 8.7 Manuals

Copy of Instruction Manuals, e.g.

- Operator Manual
- Maintenance Manual
- Installation Manual
- Spare parts catalog

## 8.8 Declarations used

- A copy of the declarations used in this installation

## 8.9 Declaration of Conformity

- A copy of the signed Declaration of Conformity

# 9 Working process