

Machinery Directive 98/37/EC

CE-MARKING

What Manufacturers Need to Know & Do

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Conformity with the Machinery Directive became **mandatory on January 1, 1995** and covers new and used machinery being placed on the market for the first time.

Definitions of machinery and safety components within the scope

Machinery:

-An assembly of linked parts or components, at least one of which moves, with the appropriate actuators, control and power circuits, etc., joined together for specific application, in particular for the processing, treatment, moving or packaging of material.

OR

-An assembly of machines which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole.

OR

Interchangeable equipment modifying the function of a machine, which is placed on the market for the purpose of being assembled with a machine or a series of different machines or with a tractor by the operator himself in so far as this equipment is not a spare part or a tool.

Compliance in Eleven Logical Steps:

STEP 1: Before CE-marking machinery the “**manufacturer**” i.e. the **one party** who takes responsibility for the design and manufacture of a machine and puts its name on the name plate, must conform to all applicable European Directives.

STEP II: Determine if your machine falls within the scope of Annex IV of the Machinery Directive and requires the certification of a **Notified Body**. Check list here: www.ce-mark.com/iv.html .

STEP III: Determine if your machine falls outside the scope of Annex IV of the Machinery Directive and can be **self-certified**. 93% of all machinery may be self-certified. Details at www.ce-mark.com/self.html .

STEP IV: Prepare a Technical File **describing and documenting** how the machine(s) comply with the (48) Essential requirements of Annex I of the Machinery Directive. **European standards can be used** as a guideline when meeting specific requirements but their use is voluntary and international or national standards can also be used.

Building a Technical File is not only mandatory, but also good insurance, and relies heavily on the completion of a thorough Hazard and Risk Analysis. Satisfying the requirements of Annex I may require the implementation of engineering changes. More at: www.ce-mark.com/mach.html and www.ce-mark.com/atf.htm .

STEP V: Upon completion of the Technical File, manufacturers whose machinery is subject to **self-certification** may:

- 1) Issue a Declaration of Conformity and
- 2) Affix the CE-mark to the machine
- 3) Hold the Technical File contents available for the European Competent Authorities “on request”.

Building of a **non-complex** machine Technical File requires an estimated **80-140 hours** by an experienced design engineer who is familiar with the Machinery Directive requirements and European Standards.

STEP VI: Manufacturers whose equipment is subject to an **EC-Type examination by a Notified Body** must:

- 1) Hire a Notified Body to perform an EC-Type examination. This usually means submittance of the completed Technical File for evaluation by the Notified Body and an ON-SITE visit to check machine performance against the Technical File content.
- 2) Issue a Declaration of Conformity once an EC-Type examination Certificate has been issued by the Notified Body.
- 3) Affixing of the **CE-mark + the 4 digit** Notified Body number to the machine.
- 4) Keeping the Technical File available for up to 10 years following production of the last machine ever made so that it can always be made available to a European Competent Authority if requested.

STEP VII: A manufacturer’s **Declaration of Conformity** signed by the Competent Person must be shipped with each machine. The person signing this declaration holds personal as well as a corporate liability for the validity of the declaration being made. The credibility of the Technical File determines whether such a declaration can be made.

STEP VIII: Be aware of, or designate, who may act as your company’s European **Authorized Representative**, this may be your distributor, agent, importer, end-user or independent party in the EU.

STEP IX: Comply with all **other Directives** that apply to your machinery, most often these are:

Electromagnetic Compatibility (EMC)

All appliances, equipment, machinery and installations containing electrical and electronic components that are liable to generate or be susceptible to electromagnetic interference.

www.ce-mark.com/emcdir.html

Low Voltage Directive (LVD)

Electrical equipment designed for use with a Voltage rating between 50V and 1000V for alternating current and between 75V and 1500V for direct current. www.ce-mark.com/LVD.html

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