Machinery Directive 2006/42/EEC
CE-Marking
What Manufacturers Need to Know & Do

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Conformity with Machinery Directive 2006/42/EEC became mandatory on December 29, 2009 and covers new, used and partly completed machinery.

The Parties Responsible for the CE-Marking Are the Economic Operators

consisting of:

1) The manufacturer

The directive clearly states: Manufacturers should retain the full responsibility for certifying the conformity of their machinery to the provisions of this Directive. ('Shall' or 'should' to be read as 'must').

2) Importers, Distributors, End-users

Importers, distributors and end-users shall place only compliant products on the EU market. They shall ensure that the appropriate conformity assessment procedure outlined in the Directive have been carried out by the manufacturer and that they have drawn up the technical documentation (technical file); the machine bears the required conformity marking and is accompanied by the required documents.

When an importer, distributor or end-user has reason to believe that the machine is not in conformity, they may not place it on the market until it is in conformity. If they decide that the machine presents a risk they must notify the National Competent Authorities. (Enforcement Agency)

They must also make sure that the instructions for installation, operation and maintenance are in the local language of the end-user.

Compliance in Eight Logical Steps

Step I: Before CE-Marking machinery make sure that you are the 'manufacturer' i.e. the party that places its name or trademark on the plate or label, thereby taking responsibility for the design and production of a machine, and ensure that it conforms with all applicable directives.

Step II: Determine if the machinery or equipment (including partly completed machinery or used equipment) falls under the definition of a machine in accordance with Article 2 of the Machinery Directive 2006/42/EEC.

Step III: Self- certification or Third Party (Notified Body) Certification?
All machinery listed in Annex IV of the Machinery Directive may require Notified Body certification. See step V.

All machinery not listed in Annex IV may use the self-certification compliance route.

Step IV: Self-certification compliance route.
Machines that fall outside the scope of Annex IV of this directive may follow the self-certification compliance route which consists of:

a) Compilation of a technical file in accordance with Annex VII. This includes describing and documenting how the machine complies

with the Essential Health and Safety Requirements (EHSR) in Annex I. Compiling a technical file is not only mandatory, but is also good insurance, and relies heavily on the completion of a thorough Hazard and Risk Assessment in accordance with EU Standards as a first step in the process. EU standards are to be used as a more specific guideline when meeting specific requirements, their use is 'voluntary' and they are not free. International or US Standards may be used only in the absence of EU Standards. Satisfying the requirements of Annex I may require the implementation of engineering changes.

b) Designate an EU Authorized Representative for regulatory affairs, who holds available for the EU Competent Authorities the manufacturer's completed technical file. The Authorized Representative must be domiciled in one of the EU countries. It may be the distributor, agent, importer, end-user or independent party (such as QNET BV).

   This is an important decision to make. The completed technical file contains a manufacturer's proprietary design information which should be kept confidential. Only the Competent Authorities are entitled to ask and review this file. Entities with commercial interest (agents, distributors, end-users) are not entitled to ask for this file. Most companies select an independent Authorized Representative (QNET BV) for reasons of confidentiality and compliance knowledge.

Upon completion of the Technical File, manufacturers of <u>complete machinery</u>, subject to self-certification shall:

1) Issue a Declaration of Conformity in accordance with Annex II, 1.A
2) Affix the CE-Mark to the machine in accordance with the labeling instructions.
3) Make sure that the Authorized Representative holds the technical file content available to the EU Competent Authority.

Upon completion of the Technical File, manufacturers of <u>partly completed machinery</u>, subject to self-certification shall:

1) Issue a Declaration of Incorporation in accordance with Annex II, 1.B
2) Affix the CE-Mark to the partly completed machinery in accordance with the machinery directive labeling instructions.
3) Make sure that the Authorized Representative holds the technical file content available to the EU Competent Authority.

Step V: Annex IV machinery – 2 Compliance Routes

Important Note: All EU Product Directives are supported by a group of standards that have been harmonized in accordance with the essential health and safety requirements of the Directive. There are type A, B, and C standards. The Type 'C' standards are the most product specific.

If a machine is <u>designed</u> in accordance with a Type 'C' standard it qualifies for compliance route 1 described below.

If a Type 'C' standard does not exist for the machinery manufactured it must follow compliance route 2 described below.

Annex IV Compliance Route 1: Compliance in accordance with a Type C Standard.
For Annex IV machinery designed according to a type 'C' harmonised standard, covering all the relevant essential requirements, the manufacturer will be able to certify the conformity of the machinery himself. (Self-certification).

Compliance route 1 consists of:

a) Compilation of a Technical Assessment File in accordance with each requirement of the harmonized Type 'C' standard.
b) Designating of an EU Authorized Representative
c) Affixing of the CE-Mark.
d) Issuing a Declaration of Conformity for a complete machine or a Declaration of Incorporation for a partly complete machine.

Annex IV Compliance Route 2: Compliance including Notified Body Certification.

For all other Annex IV machinery (Not covered by a type 'C' standard), the manufacturer must choose between 1) EC type-examination by a Notified Body or 2) approval by a Notified Body of his full quality assurance system.

Compliance route 2 consists of:

a) Full quality assurance system in accordance with Annex X
b) Compilation of a technical file in accordance with Annex VII and Essential Health and Safety Requirements.
c) Selecting and hiring an EU third party certification agency, referred to as a Notified Body. The completed technical file must be submitted for evaluation to the Notified Body, who will make an on-site visit to assess the machine design, performance etc. against the technical file content and the Essential Health and Safety requirements of the directive. As well as the full quality assurance system.
d) Designating of an EU Authorized Representative
e) Affixing of the CE-mark + the 4 digit Notified Body number.
f) Issuing a Declaration of Conformity after an EC Type certificate has been issued by the Notified Body.

Important note:
Notified Bodies are commercial for profit agencies, accredited by their governments to perform the assessment and certification of machinery.

Step VI. Production Control/Quality Management Systems
Machinery Directive 2006/42/EC require a certified quality management system for Annex IV machinery certified by a Notified Body.

For non-annex IV machinery the manufacturer must take all measures necessary in order that the manufacturing process insures compliance of the manufactured machinery with the technical file. In other words, if you make changes to the manufacturing process or the machine the technical file must be updated accordingly.

Step VII. Complying with all additional CE Marking Directives that apply to machinery.

Most often these are:

Electro Magnetic Compatibility (EMC) Directive 2014/30/EU in effect April 20, 2016

Electromagnetic Compatibility means the ability of equipment to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to other equipment in the environment.

The equipment covered by this directive should include both apparatus and fixed installations. However, separate provision should be made for each. This is so because whereas apparatus as such may move freely within the EU, fixed installations on the other hand are installed for permanent use at a predefined location, as assemblies of various types of apparatus and, where appropriate, other devices. The composition and function as such installations correspond in most cases to the particular needs of their operators.

Whereas this Directive regulates apparatus it should apply to finished apparatus placed on the market. Certain components or sub-assemblies should under certain conditions, be considered to be apparatus if they are made available to the end-user.

Low Voltage Directive (LVD) 2014/35/EU in effect April 20, 2016
This directive shall apply to electrical equipment designed for use with a voltage rating of between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current other than equipment and phenomena listed in Annex II.

ATEX Directive 2014/34/EU in effect April 20, 2016
This Directive shall apply to the following:

(a) Equipment and protective systems intended for use in potentially explosive atmospheres.
(b) Safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres but required for or contributing to the safe functioning of equipment and protective

systems with respect to the risks of explosion

(c) Components intended to be incorporated into equipment and protective systems referred to in point (a)

Pressure Equipment Directive 2014/68/EU in effect 1 June 2015.

This Directive shall apply to the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure PS greater than 0,5 bar.

'Pressure equipment' means vessels, piping, safety accessories and pressure accessories.
Where applicable, pressure equipment includes elements attached to pressurized parts, such as flanges, nozzles, couplings, supports, lifting lugs, etc.

ROHS Directive 2011/65/EU Restriction of the use of hazardous substances in electrical and electronic equipment. Staged effective dates but applies to all electrical and electronic equipment effective 2019 with listed exemptions.

This Directive shall apply to 'Electrical and electronic equipment' or 'EEE' meaning equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1000 volts for alternating current and 1 500 volts for direct current;

Important Notes:
These directives cover products which are new to the EU market when they are placed on the market. That is to say they are either new products made by a manufacturer in the EU, or products whether new or second hand, imported from a third country.

These directives should apply to all forms of supply, including distance selling (on-line or over the phone).

Step VIII: Preparing for Market surveillance or enforcement
Compiling a non-complex machinery directive technical file requires an estimated 80 to 250+ hours by an experienced design/compliance engineer. During market surveillance activities an EU Competent Authority (National Enforcement Agency in each EU State) requires a technical file to be submitted, manufacturers are given 7 to 21 days for delivery. There is no process to request an extension.

Non-submittance results in recalls, fines (50,000 Euro) and notification of non-compliance to all EU countries. Importers, distributors, end-users may be held criminally liable for purchasing non-compliant machinery/equipment.

CE-marking of machinery is an EU legal requirement.

Do's and Don'ts that save CE marking $$$$$$$

- **Do not** prepare a technical file for each machine
- **Do** prepare a master file to cover a line or family of machines.

- **Do not** create duplicate files to support your technical files.
- **Do** use your document control system to index your technical file's existing support documents.

- **Do not** provide parts of or entire technical files to your clients or potential clients
- **Do** protect your design and DO use your risk analysis as a sales tool.

- **Do not** assume that building a machine with CE-marked components automatically results in a ce-marked machine eliminating the need for compliance steps.
- **Do** lower your EMC & Low Voltage testing costs via tests performed by your component suppliers.

- **Do not** get the notion that tests or technical files for non-annex IV equipment reviewed by Notified Bodies provide a more credible CE-mark – they only increase the cost.
- **Do** make sure that your machine is not listed in Annex IV of the Directive so you may pursue self-certification.

- **Do not** accept clients claims that “you don’t need to worry about the CE-Mark”.
- **Do** learn to ask clients: where does it say that?

QNET LLC is a quality assurance and CE compliance consulting firm specializing in cost effective CE marking in accordance with Machinery, ATEX and Pressure Equipment directives since 1996.

QNET BV – Netherlands - delivers EU Authorized Representative services in accordance with the Machinery, PPE, RoHS, Low Voltage, EMC, PED, ATEX, Medical and IVD directives since 1997.

Link to Directives:

http://www.ce-mark.com/EUdirectives.htm

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