

CE marking machinery

Rinus Simonis
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Illustration
Trudy Simonis

© 2012, Rinus Simonis
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(info@simonisweb.nl)

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Preface:

This book is written to help machine designers to comply with the applicable directives published by the EU.

The common mistake that standards are the “law” and the directives “could be used” is explained. In this book you don’t find copies of the directives (Law) or the standards (Technical documents) to which references are made.

The directives can be downloaded free of charge from the EU site, because they are the law, the law is free accessible for everyone. (See chapter Links)

The standards are copyright protected and have to be bought from the local standardization institutes.

Where text fragments from the standards or directives are used for explanation purpose, they are placed in *Italic*.

To make sure you have the presumption of conformity with the **Essential Health and Safety Requirements** from the directives using the harmonised standards you have to buy the standards and make sure you know the content of the directives and standards.

The author.

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1 Introduction to CE marking

What is the meaning of the CE marking of machinery?

The meaning of the CE marking can be divided into two parts.

For the user it means that the machinery which bears the CE mark complies with the relevant directives and can be used in a safe way.

The other part of the CE marking makes it possible to move/sell this machinery in the EU without extra requirements from the countries in which this machinery is imported.

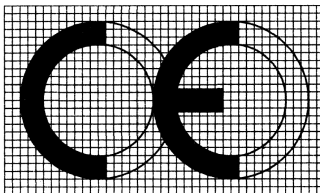
http://europa.eu/index_en.htm

Site with basic information about the European Union.

In principle we are talking about machineries which bear the CE mark and are accompanied by a declaration of conformity and a manual. Or partly completed machinery which may not bear the CE mark, but are accompanied by a copy of the fulfilled Essential Health and Safety Requirements from the Machinery directive, a declaration of incorporation and a manual.

Graphical representation of the CE mark.

See for details directive 93/68/EC



2 Designer / Manufacturer

Definition of the manufacturer from the machinery directive.

*(i) ‘manufacturer’ means any natural or legal person who **designs and/or manufactures** machinery or partly completed machinery covered by this Directive and is responsible for the conformity of the machinery or the partly completed machinery with this Directive with a view to its being placed on the market, under his own name or trademark or for his own use. In the absence of a manufacturer as defined above, any natural or legal person who places on the market or puts into service machinery or partly completed machinery covered by this Directive shall be considered a manufacturer;*

The designer is the responsible person in respect with the machinery directive.

The designer could also be the manufacturer who is really manufacturing the machinery based on the information / drawings he gets from the designer.

The designer knows all the ins and outs of the design he/she has created. That’s the reason the designer is the responsible person to for fill the legal requirements of the applicable directives.

The situation could occur that the designer and the manufacturer are different persons. In this case contract will be issued in which is agreed who is responsible for the legal requirements and puts the CE mark on the machinery.

In the directive the designer is called the manufacturer. For the sake of compatibility the same is done in this book. So we call the “**designer**”, “**manufacturer**”.

The manufacturer has to decide which directives are applicable for the designed machinery. The applicable harmonized standards are also chosen by the manufacturer.

3 Directives

We mostly talk about the machinery directive. At the moment this book was written there are 27 directives.

<u>90/385/EEC</u>	Active implantable medical devices
<u>94/9/EC</u>	Equipment and protective systems in potentially explosive atmospheres
<u>89/106/EEC</u>	Construction products
<u>97/23/EC</u>	Pressure equipment
<u>87/404/EEC</u>	Simple pressure vessels
<u>2004/108/EC</u>	Electromagnetic compatibility
<u>93/15/EEC</u>	Explosives for civil uses
<u>90/396/EEC</u>	Gas appliances
<u>00/14/EC</u>	noise emission in the environment by equipment for use outdoors
<u>96/57/EC</u>	household electric refrigerators, freezers and combinations thereof
<u>2000/9/EC</u>	Cableway installations designed to carry persons
<u>2006/95/EC</u>	Low Voltage Equipment
<u>2006/42/EC</u>	Machinery safety
<u>93/42/EEC</u>	Medical devices
<u>98/79/EC</u>	In vitro diagnostic medical devices
<u>95/16/EC</u>	Lifts
<u>89/686/EEC</u>	Personal protective equipment
<u>94/25/EC</u>	Recreational craft
<u>1999/5/EC</u>	Radio and telecommunications terminal equipment
<u>92/42/EEC</u>	New hot-water boilers fired with liquid or gaseous fluids (efficiency requirements)
<u>88/378/EEC</u>	Toys safety
<u>2009/48/EC</u>	Safety of toys
<u>90/384/EEC</u>	Non-automatic weighing instruments
<u>2004/22/EC</u>	Measuring instruments
<u>94/62/EC</u>	Packaging and packaging waste
<u>2007/23/EC</u>	Pyrotechnic articles

2000/55/EC Energy efficiency requirements for ballasts for
fluorescent lighting

93/68/EC CE mark

<http://www.newapproach.org/Directives/>

On this site you can find all the directives mentioned here.
Under the arrows (on Internet) behind the directives you find
a lot of additional info.

4 Definition of machinery

The definition of machinery from the machinery directive.

The following definitions shall apply:

(a) 'machinery' means:

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

— an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion,

— an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure,

— assemblies of machinery referred to in the first, second and third indents or partly completed machinery referred to in point (g) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole,

— an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;

(b) 'interchangeable equipment' means a device which, after the putting into service of machinery or of a tractor, is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool;

(c) 'safety component' means a component:

— which serves to fulfill a safety function,

— which is independently placed on the market,

- the failure and/or malfunction of which endangers the safety of persons, and*
- which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.*

An indicative list of safety components is set out in Annex V, which may be updated in accordance with Article 8(1)(a);

(d) ‘lifting accessory’ means a component or equipment not attached to the lifting machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself, or which is intended to constitute an integral part of the load and which is independently placed on the market; slings and their components are also regarded as lifting accessories;

(e) ‘chains, ropes and webbing’ means chains, ropes and webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;

(f) ‘removable mechanical transmission device’ means a removable component for transmitting power between self-propelled machinery or a tractor and another machine by joining them at the first fixed bearing. When it is placed on the market with the guard it shall be regarded as one product;

(g) ‘partly completed machinery’ means an assembly which is almost machinery but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies;

For a complete overview of the definitions see the machinery directive 2006/42/EC.

As you can read, the meaning of the word “machinery” covers a wide range of products.

In essence it doesn't make any difference when you design a machine or partly completed machinery.

The things you have to do are more or less the same:

Design with safety in mind

Create a technical file, in which you put all the relevant info of your designed machinery.

Determine the limits of the machinery

- Point out the potential hazards
- Risk assessment.
- Risk reduction by design.
- Risk evaluation.
- Residual risks. (can it be reduced with a technical measure?)

- Risk reduction by a technical measure (safety system(s)).
- Risk evaluation
- Residual risks. (mark en describe into manual)

- Determine the PL_r (Performance Level required) of the safety system.
- Choose the Category (B, 1, 2, 3 or 4) you need to achieve the required PL
- Design your category architecture
- Choose the components for your chosen architecture

- Calculate the $MTTF_d$ (**M**ean **T**ime **T**o **F**ailure **d**angerous) of your safety system (based on the B_{10} value).
- Evaluate your safety system design (fig 5 from the standard EN ISO 13849-1)

When an emergency stop can contribute to reducing the last part of the risk, create an emergency stop.

- Determine the PL_r (**P**erformance **L**evel required) of the safety system.
- Choose the Category (B, 1, 2, 3 or 4) you need to achieve the required PL
- Design your category architecture
- Choose the components for your chosen architecture
- Calculate the $MTTF_d$ (**M**ean **T**ime **T**o **F**ailure **d**angerous) of your safety system. (based on the B_{10} value).
- Evaluate your safety system design (fig 5 from the standard EN ISO 13849-1)
- Validate your designed machinery using the EN ISO 13849-2
- Create an overview of the Essential Health and safety requirements you have fulfilled.
- Create a manual with the appropriate info.

The “completed” machinery is delivered with a declaration of conformity and a manual.

The “partly completed” machinery is delivered with a declaration of incorporation, a copy of the fulfilled EHSR’s and a manual.

5 Harmonised standards

Harmonised standards are listed in the publication of the Official Journal of the EU.

When you use harmonised standards to comply with directives, you have the presumption of conformity.

It is not mandatory to use harmonised standards. When you use harmonised standards the burden of proof lays at the authorities. When you don't use the harmonised standards but instead a technical document in which you stated the way you have created safety in the machinery, you have to prove that your creation is "safe", the burden of proof lays with you.

Depending on which directive(s) is/are applicable to your machinery, you should reference the Official Journal of the EU to determine which harmonised standards are available and applicable to your machinery.

There are three types of standards.

Type A, B and C.

Type-A standards (basic standards) give basic concepts, principles for design and general aspects that can be applied to machinery.

Type-B standards (generic safety standards) deal with one or more safety aspect(s), or one or more type(s) of safeguards that can be used across a wide range of machinery:

- type-B1 standards on particular safety aspects (e.g. safety distances, surface temperature, noise);

- type-B2 standards on safeguards (e.g. two-hand controls, interlocking devices, pressure sensitive devices, guards).

Type-C standards (machinery safety standards) deal with detailed safety requirements for a particular machine or group of machines.

In this book we are using the following commonly used harmonised standards:

EN ISO 12100:2010 (type A)

Safety of machinery - General principles for design - Risk assessment and risk reduction.

EN ISO 13849-1:2009 (type B1)

Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design.

EN ISO 13849-2:2008. (type B1)

Safety of machinery - Safety-related parts of control systems - Part 2: Validation.

EN ISO 11161:2010 (type B1)

Safety of machinery - Integrated manufacturing systems - Basic requirements.

EN IEC 60204-1:2006 (type B)

Safety of machinery – Electrical equipment of machines Part 1: General requirements.

NPR-IEC/TR 61000-5-2

Electromagnetic compatibility (EMC) - Part 5: Installation and mitigation guidelines - Section 2: Earthing and cabling.

EN IEC 60529:2001 (type A)

Degrees of protection provided by enclosures (IP code).

6 Machinery directive 2006/42/EC

In the Machinery directive is stated that you should design machinery with safety in mind. In order to reduce the amount of accidents using machinery. To comply with the machinery directive you have to fulfill the EHSR (**E**ssential **H**ealth and **S**afety **R**equirements) stated in annex I of the Machinery directive.

When the machinery complies with the machinery directive it may be distributed in the EU without additional requirements.

The machinery directive is asking the following things from the manufacturer:

- Design with safety in mind.
- Comply with the relevant EHSR for your machinery
- Use harmonized Standards to prove your compliance
- Write a declaration of conformity for a complete machine and a declaration of incorporation for partly completed machinery.
- Create an manual with sufficient information so the machinery can be transported, commissioned, used, maintained, serviced, adjusted, dismantled and scrapped in a safe way.

Design with safety in mind means that in the concept phase, safety should be evaluated. This can only be done when the limits of the machinery are known.

The limits of the machinery are defined in the EN ISO 12100:2010