CE Marking

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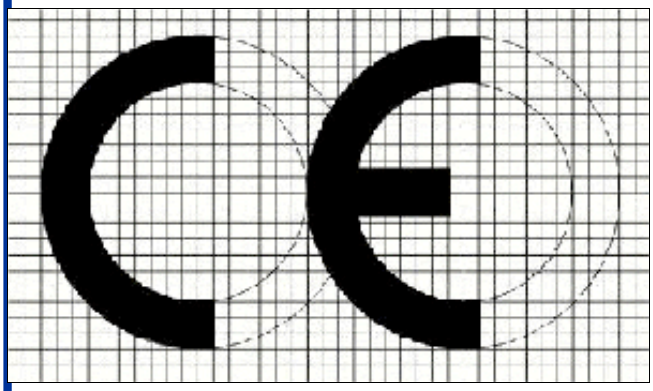

What is CE Marking?

The CE marking is a **conformity marking** consisting of the letters "CE", and taking the form as shown here. CE is an abbreviation for 'Conformité Européenne', French for 'European Conformity'. Initially the term used was “EC Mark” but this was officially replaced by “CE Marking” in 1993 and is now used in all EU official documents.

CE Marking on a product is a **manufacturer’s declaration that the product complies with the essential requirements** of the European technical regulations ("Directives"), related to European health, safety and environmental protection legislation, and that the product compliance has been established using the appropriate conformity assessment procedure(s).

CE marking is **obligatory** for any product covered by one or more of the European technical regulations requiring the affixing of the CE marking. Without the CE marking, these products are not allowed to be placed or to be put into service in Europe. In this regard, the CE marking sometimes is called a ‘**trade passport’**: like carrying a passport when entering a country, the CE Marking is **required for market access.**

Where is CE Marking required?

CE Marking Is only required in the **European Economic Area** (EEA) which includes all 27 member states of the **European Union** (Austria, Belgium, Bulgaria, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland,, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom) and **three EFTA members**, namely Iceland, Liechtenstein and Norway. Although Switzerland is a member of EFTA it is not a member of the EEA.

On the other hand, Turkey is neither a member of the EU nor the EFTA or EEA however, Turkey has implemented many of the European CE marking directives and therefore requires CE Marking for many products.

Benefits of CE Marking:

With the CE Marking being like a passport for the EEA (European Economic Area) it allows manufacturers to **freely circulate** their products throughout the EEA. Instead of adapting the products for each national market according to the regulations, there now is **only one set of requirements and procedures** in designing and manufacturing a product within the EEA.

For consumers CE Marking has the benefit that products will be safer and therefore damage and liability claims will be reduced.

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Which products require CE Marking?

-Active implantable medical devices
-Cableways
-Construction products
-Electrical equipment
-Electronic equipment
-Equipment and protective systems for use in explosive atmospheres
-Explosives for civil use
-Gas appliances
-In vitro diagnostic medical devices
-Lifts
-Machinery
-Medical devices
-Measuring Equipment
-New hot water boilers
-Non-automatic weighing instruments
-Personal protective equipment
-Pressure equipment
-Radio and Telecommunications terminal equipment
-Recreational craft
-Simple pressure vessels
-Toys

The following products do **NOT** require CE Marking:

-Chemicals
-Cosmetics
-Foodstuffs
-Pharmaceuticals

Main resources/helpful links:

www.ce-marking.org
www.cemarking.net
Summaries of EU legislations> Consumers> packaging and labelling:
http://europa.eu/legislation_summaries/consumers/product_labelling_and_packaging/l21013_en.htm
Department for Business Innovation and Skills:
http://www.berr.gov.uk/whatwedo/sectors/sustainability/regulations/cemark/page11646.html
To find out which directive applies:
http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/
To find the Irish Notified body for a specific directive, see NANDO website:
http://ec.europa.eu/enterprise/newapproach/nando/index.cfm

How is CE Marking obtained?

1: **Identify the Directives** that are applicable to your product. If more than one applies, you have to conform with all of them. The directives can be downloaded from the EU website for free (see *Main Resources* at the bottom of this page).

2: **Identify the conformity assessment procedure** that must be taken. This could either be self-declaration, involve testing inspection or quality system assessment from a Notifies Body or a combination of these. (There are 8 different modules A-H) Whether or not a product needs to be assessed by an independent party, depends on the level of risk. Directives often use a series of questions about the nature of the product to **classify the level of risk** and refer to a chart called “Conformity Assessment Procedures” The chart includes all of the acceptable options available to a manufacturer to certify their product and affix the CE Marking.

3: **Determine the date** by which action must be taken/ the relevant directive comes into force. Most directives are **already in force** and therefore it is an offence to place products on the market without CE Marking.

4: Identify if there are any **Harmonized European Standards** applicable to your product. Although some of them are not mandatory for manufacturers, there is a presumption that conformity to these standards will give conformity with the relevant part of the directive,

5: Ensure your product complies with all the **essential requirements of the Directives**.

6: **Maintain technical documentation** required by the directives. This should support your compliance with the directives.

7: **Prepare the Declaration of Conformity** and the supporting evidence. Along with the technical documentation it should be available to Competent Authorities (EU members) upon request.

8:Check that no **other purely national requirements** exist in the countries the products are to be sold. (national standards, packaging/labelling requirements, etc.)

9: **Affix the CE Marking** to your product and supply user operating instructions.

10: Ensure any **changes to the product** do not compromise your certification and review for amended or new directives that could affect your product regularly.

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