



# A Brief Introduction to CE Marking



The CE Marking that appears on many different products (from teddy bears to 30-ton hydraulic presses) is an important feature of a product and indicates it complies with the detailed essential requirements for that type of products. CE marking a product is required if the product falls under one of the appropriate EU Directives. The converse is also true, if a product is not covered by an appropriate directive then it should not carry the CE marking.

**Not an Option:** CE marking a product is not an option; it is a legal requirement within the European Economic Area ("EEA", consisting of the 27 EU Member States, and the EFTA countries Iceland, Liechtenstein and Norway), if the product falls under one of the European Union (CE Marking) Directives. By adding the mark, the manufacturer, their authorized representative, or an importer is declaring that the products meet all the essential requirements of all applicable EU directives. Effectively CE marking indicates to all authorities that the product is in compliance with the essential health and safety requirements of all directives that apply to the product.

With the exception of some high-risk products, most products can be "self-assessed" by the manufacturer. The meaning of the CE Mark is widely misunderstood, it is not a quality mark or "certificate of approval", it is a declaration of the supplier's own responsibility and it allows only for the free movement of the item with the EEA it also enables the withdrawal of non-conforming products to be accomplished more easily.



## Some frequently asked questions

**Why have CE Marking?** CE marking was introduced throughout the EU for the following reasons,

- *To harmonise requirements in the EEA*
- *Create a single European market*
- *Protect the consumer/customer and the environment*
- *Simplify the lives of manufacturers and importers!*

The last point often comes as a surprise to people involved in the manufacture of products, however before the introduction of these harmonized requirements it was not uncommon for a manufacturer involved in export to have to "jump through a variety of compliance hoops" for each European country.

**What does CE Marking stand for?** There is some debate... but it is generally thought that CE stands for "Conformité Européen". It is intended to facilitate the free movement of products within the EU by signifying that essential health and safety requirements have been met. It is not a quality mark or a specific statement concerning the test methodology that has been employed.

**What is CE Marking?** The CE mark is the manufacturers (or distributors) claim that the product meets the essential requirements of all relevant EU directives are satisfied. If a product requires CE-marking, it cannot be legally "taken-into-use" in any of the EU countries. The term "taken-into-use" applies to a wide range of situations including,

- *Sold and delivered to a customer*
- *Hired out*
- *Given away!*
- *On loan \**
- *Demonstration equipment*
- *Your own in-house equipment*

CE marking a product is not an option; it is required by law if the product falls under one of the European Union New Approach Directives. The CE mark indicates to all

authorities that the product is in compliance with the essential health and safety requirements of all directives that apply to the product.

When considering any new product development or improvement it is essential to consider the regulatory requirements. It is always easier to design in compliance rather than to try and sort things out once the product has been made

**Why have CE Marks?** CE marking was introduced throughout the EU for the following reasons,

- *To harmonise standards through the EU*
- *Create a single European market*
- *Protect the consumer/customer*
- *Protect the environment*
- *Simplify the lives of manufacturers!*

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**What types of products need to be CE marked?** The official answer to this is anything that is covered by the regulations! These include,

- *Medical devices of all types*
- *Stand-alone electrical products*
- *"Working" sub-assemblies*
- *Installations*
- *Custom-designed units*
- *Second-hand equipment*
- *Upgraded installations or equipment*

CE marking only applies to products within the scope of these Directives and should not be applied to products if they are outside the scope. The problem is that there are a large (and growing) number of directives and interpretation of them is not straight forward. We've been doing this for a long time and so can help, often if a product is outside the scope we can tell you pretty quickly, and unless this take a vast amount of time (so borderline products take a lot of work), it will cost you nothing.

**Should all products be CE marked?** The simple answer is No! Only products within the scope of the "CE Marking" directives should bear the CE Mark. Increasingly manufacturers are being asked to CE marked "inappropriate" products

**Does my Product need CE marking?** A simple question which can take a while to answer! So give us a call or email us. We don't charge for initial discussions and a lot of people go away happy without ever paying for our services!

**I just sell/import, does CE marking affect me?** Any product offered for sale in the EU must be CE marked (if it is covered by the directives); if the product is not CE marked by the manufacturer then you will be responsible for the CE mark.

**Is third party testing/involvement required?** In most cases no, ... but some compliance requirements involve the mandatory use of approvals or certification bodies. In some cases the requirement for the involvement of a "Notified body" depends on the route chosen to demonstrate compliance.

**What is a notified body?** These are organizations appointed by each member State under the appropriate national regulations to conduct third-party conformity assessment procedures to the product in question or its production processes, as required by the Directives, in order that it may carry the CE Marking. The procedures vary according to the Directives and third-party involvement is not compulsory for all products. Manufacturers can use the services of Notified/Approved/Competent Bodies in any member State of the European Community. Normally Notified bodies are only involved

when considering higher risk products or for some directives when appropriate standards have not been applied or only partly applied. It should be noted that Notified bodies are not "permitted" to provide advice concerning solutions to any problems that are found, although a good one will provide off-the-record guidance

**Is PCL a notified body?** No, we are a CE Marking Consultancy, however we do work closely with Notified bodies as required. Being an independent organization we are able to provide detailed assistance concerning solutions to problems and even help to implement those remedial actions. When a project does require the involvement of a notified body, we can help to define the scope, identify a suitable body and act as liaison throughout the project.

**What does the CE mark signify?** CE marking is a declaration by the manufacturer (or distributor/ importer) that the product meets all the appropriate provisions of the relevant legislation implementing certain European Directives.

**What is the process?** The process that you need to go through to be able to apply the CE-marking to your products vary widely and depends on a number of things including,

- *The applicable Directives*
- *The product itself*
- *The target user/customer*
- *The market requirements*
- *The manufacturers choice (in most cases).*

In a majority of situations, the New Approach Directives allow self-declaration in place of third party (notified body) involvement; but the right to self-declare compliance with the law means that a manufacturer must be responsible for completing all the procedures required by the law and must be able to prove it. This is done by the production of a Technical File. The Technical File is the written justification that all aspects of a product are

safe and should be prepared before the product is placed on the market. The Technical File includes information that demonstrates the technical basis for conformity of the product to the applicable requirements of the directive. The manufacturer must keep the Technical File for ten years after the last unit is placed on the market, unless the directive provides for a different duration.

**Who enforces - and what would happen if I don't CE mark a product that should be marked?** In the UK, enforcement varies according to the Directives. Some are enforced by local Trading Standards Departments, others by HSE and yet others by the Medical and Healthcare Products Regulatory Agency and the Vehicle Certification Agency and OFCOM. Except where safety is at risk, the relevant enforcement authority will usually provide you with an opportunity to ensure that your product is correctly CE-marked. If you fail to comply then you will be obliged to take your product off the market, and you may also be liable to a fine and/or imprisonment.

**Who can help?** We can! , give us a call.

Tel: 01825 767188

Fax: 0844 5042948

Email: [contactus@petts-consulting.co.uk](mailto:contactus@petts-consulting.co.uk)

Web: [www.petts-consulting.co.uk](http://www.petts-consulting.co.uk)

**Important statement:** *Petts Consulting Limited will provide the Company with the knowledge of the Directives and an appropriate process which when applied correctly will demonstrate due-diligence. However, the CE-mark is the manufacturers claim that the product meets the essential requirements of all relevant European Directives. The process to be carried out is a self-certification process and the responsibility for any decisions lie with the management of the Company. During the course of the project Petts Consulting Limited will provide guidance and advice but ultimately it cannot be held responsible for such decisions.*

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