

## What is CE marking?

### Introduction

The CE mark has existed in its present form since 1993. Many European products bear this mark. CE stands for 'Conformité Européenne', meaning 'conforms to EC Directives'. This indicates that the product may be traded freely within the European Economic Area (EEA) because it meets the requirements of the EC directives. The EEA consists of the Member States of the EU and a number of members of the European Free Trade Association who have opted to join. They are Norway, Iceland and Liechtenstein.



It is the manufacturer who has to apply the marking and who is responsible for the correct implementation of the EC directives. However there are many others who are also involved with CE marking. Designers, dealers, buyers, employers and users are all accountable for the correct application of the requirements.

### Free trade is not possible without obligations

The primary aim of CE marking is to facilitate free trade of products within the EU by reducing the effect of the physical borders between the Member States. A secondary, though by no means less important, aim is the harmonisation across the EU of the legal requirements for safety, health and the environment. This relates to both safety at work and protection of the public interest.

The CE mark on a product indicates that the manufacturer or the importer for the EEA has respected the requirements for safety, health and the environment. These requirements are set out in EC-directives. The Member States have committed themselves to incorporating these exact requirements into their national legislation. This will result in the harmonisation of all legislation in this field throughout the EU.

CE marking usually involves the following obligations:

- Carrying out a risk analysis for the product. What hazards could be caused by the product? How great is the risk to people, animals, goods or the environment? What solutions can be applied to reduce risks in compliance with the appropriate EC directive?
- Writing a user's instruction manual. This should also set out the purpose for which the product is intended. The manual should be written in the language of the user.
- Drafting an EC declaration of conformity. The manufacturer (or the importer for the EEA) declares that the product complies with the specified EC directives and norms.
- Preparing a product dossier . This will include in all cases the documents mentioned above, as well as design data, drawings, calculations and test reports. In other words, it contains everything which makes it possible to demonstrate that the essential requirements relating to CE marking have been met.

## A bit of history

Back in the 'old days' every European country had its own trade regulations. This made life expensive as for each country you wanted to trade with your product had to be approved under the national legislation, frequently by an expert body. With the founding of the EC central directives were established with which products had to comply. This was the system used for product safety until about 1987. However the excessively severe regulation was a barrier to product development. Too many detailed technical requirements were imposed on products. Furthermore, the European Council had to approve any decision unanimously. There was no central policy for product liability. This route was abandoned in 1985 and the Old Approach disappeared.

## The New Approach

The change to less direct governmental involvement in the details of a product made it possible to introduce a whole new phenomenon in the area of legislation. Goods can now be traded freely within the European Economic Area (EEA). The basis for this was the idea that the greatest barriers to trade were linked to safety aspects which required too much detailed negotiation to achieve approval by all Member States.

Thus for various product groups general requirements were defined and set out (in clear and unambiguous language) in the New Approach directives which were approved by all Member States.

A CE mark on a product indicates that it complies with the requirements.

For as many products as possible the obligatory national approval procedures have been abolished throughout the EEA. Manufacturers (or importers) must now ensure that they meet the legal requirements and must be able to provide evidence of this should problems arise. To this end a system has been devised which brings together quality assurance and the assessment of conformity with the EC directives.

CE marking is self-certification, which is particularly good for small and medium companies. Only in exceptional cases, for example for specific dangerous machines or for large pressure valves, is it necessary to consult an external expert (a Notified Body) which will examine those aspects of the product and issue a declaration.

The national authorities ensure that random testing takes place to ascertain whether procedures are being followed correctly.

The EC directives form a legal obligation. This harmonisation means that for many product groups the same laws on safety, health, the environment and consumer protection apply throughout the EU.

## Harmonised standards

In order to assist the manufacturer (or importer) with the conformity assessment of a product, standards which apply across the EEA are being drafted at a relatively high rate. They are known as harmonised standards and can be recognised as such by the indication EN before the standard number.

Many of these standards make it possible to do without an extensive risk analysis. By adhering closely to the articles of the standard it can be assumed that there is a 'presumption of conformity' with the relevant EC directives.

In contrast to the EC-directives the standards are very technical. Standards can be much more easily adapted to take account of current technical developments. EN-standards are not mandatory but often serve as a very useful tool.

## Product liability

Since the introduction of CE marking product liability in a European framework has become much more strictly controlled in order to avoid an 'American situation'. There is a separate directive which only applies only to products which do not meet the essential requirements.

It is now up to the manufacturer, or his representative, to demonstrate that things are in order on delivery. In order to receive compensation the victim must be able to prove that the damage was caused by the product. However, he does not have to prove that the manufacturer has been negligent.

## Applying CE-marking

The CE marks are applied by the manufacturer or the importer for the EEA. The CE logo should be clearly visible on the product (or on the packaging if there is no space on the product). In conjunction with the EC declaration of conformity the manufacturer is stating here that the product meets the requirements of the EC directives for CE marking. These are usually New Approach directives, but there are also a few other directives that affect CE marking, such as some of the Global Approach directives.

## EC-directives for CE-marking, in accordance with the New Approach

<i>EC-directive</i>	<i>Subject</i>	<i>Compulsory with</i>	<i>Document no. (amendment)</i>
Low voltage directive	Products with a voltage rating of 50-1000 V AC or 75-1500 V DC Replaced by codified version	1997-01-01 2007-01-16	2006/95/EC
Simple pressure vessels	Welded vessels with a pressure greater than 0,5 bar intended to contain air or nitrogen Replaced by codified version	1992-07-01 2009-10-28	2009/105/EC
Toys	Products designed or intended for use in play by children of less than 14 years of age Replaced first phase Replaced complete	1990-01-01 2011-07-20 2013-07-20	88/378/EEC (93/68/EEC) 2009/48/EC
Construction products	Products for incorporation in a permanent manner in construction works (buildings and civil engineering works)	1991-06-27	89/106/EEC (93/68/EEC)
Electromagnetic Compatibility (EMC)	Apparatus liable to cause electromagnetic disturbance or which is liable to be affected by such disturbance Replaced by new version	1996-01-01 2007-07-20	2004/108/EC
Personal protective equipment	Appliances designed to be worn or held by an individual for protection against health and safety hazards.	1995-07-01	89/686/EEC (93/68/EEC) (93/95/EEC) (96/58/EC)
Non-automatic weighing instruments	Weighing instruments requiring the intervention of an operator Replaced by codified version	2003-01-01 2009-06-05	2009/23/EC
Active implantable medical devices	Electrically driven medical devices implanted in the human body	1995-01-01 2010-03-21	90/385/EEC (93/42/EEC) (93/68/EEC) (2007/47/EC)

## EC-directives for CE-marking, in accordance with the New Approach

<i>EC-directive</i>	<i>Subject</i>	<i>Compulsory with</i>	<i>Document no. (amendment)</i>
Appliances burning gaseous fuels	Appliances burning gaseous fuels used for cooking, heating, hot water production, refrigeration, lighting or washing Replaced by codified version	1996-01-01  2010-01-05	  2009/142/EG
Efficiency requirements for hot water boilers	Efficiency requirements applicable to new hot-water boilers fired by liquid or gaseous fuels	1998-01-01	92/42/EEC (93/68/EEC) (2004/8/EC) (2005/32/EC) (2008/28/EC)
Explosives	Explosives for civil uses	2003-01-01	93/15/EEC
Medical devices	Medical devices (general)	1998-06-14  2010-03-21	93/42/EEC (98/79/EC) (2000/70/EC) (2001/104/EC) (2007/47/EC)
Equipment in explosive atmospheres (ATEX)	Equipment and protective systems intended for use in potentially explosive atmospheres	2003-07-01	94/9/EC
Recreational craft	Craft intended for sport and leisure purposes	1998-06-16	94/25/EC (2003/44/EC)
Lifts	Lifts permanently installed in buildings and constructions	1999-06-30 2009-12-29	95/16/EC (2006/42/EC)
Pressure equipment	Pressure equipment and assemblies with a maximum allowable pressure greater than 0,5 bar	2002-05-29	97/23/EC
Machinery directive	Machinery Replaced Modification regarding machinery for pesticide application	1995-01-01 2009-12-29 2011-12-15	2006/42/EC  (2009/127/EC)
Medical devices for in-vitro diagnostics	Medical devices intended for in-vitro examination of specimens derived from the human body	2003-12-07	98/79/EC

### EC-directives for CE-marking, in accordance with the New Approach

<i>EC-directive</i>	<i>Subject</i>	<i>Compulsory with</i>	<i>Document no. (amendment)</i>
Radio and telecommunications terminal equipment	Equipment that is either radio equipment or telecommunications terminal equipment or both	2000-04-08	1999/5/EC
Cableway installations	Cableway installations designed to carry persons	2004-05-03	2000/9/EC
Measuring instruments	Devices or systems with a measurement function Modification	2006-10-30 2011-06-01	2004/22/EC (2006/96/EC) (2009/137/EC)
Pyrotechnic articles	Fireworks category 1, 2, 3: Fireworks category 4, other pyrotechnical articles, and those for theatrical use.	2010-07-04 2013-07-04	2007/23/EC

### EC-directives for CE-marking, in accordance with the New Approach and the Global Approach

<i>EC-directive</i>	<i>Subject</i>	<i>Compulsory with</i>	<i>Document no. (amendment)</i>
Refrigeration equipment	Energy efficiency requirements for household electric refrigerators, freezers and combinations thereof Replaced	1999-09-03 2010-07-01	1996/57/EC (2005/32/EC) (2008/28/EC) 2005/32/EC
Transportable pressure equipment	Safety within the EU of nationally approved portable pressure equipment (□ mark)	2001-07-01	1999/36/EC (2002/50/EC)
Noise emission	Noise emission in the environment by equipment for use outdoors	2002-01-03	2000/14/EC (2005/88/EC)
Ballasts	Energy efficiency requirements for ballasts for fluorescent lighting  Replaced	2002-04-08  2010-07-01	2000/55/EC (2005/32/EC) (2005/28/EC) 2005/32/EC