



# CE

## Marking



*Business Support on Your Doorstep*

### Enterprise Europe Network London

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## Introduction

The aim of this factsheet is to help businesses, in particular manufacturers, to understand the complexities of CE marking by providing concise answers to key questions.

The CE mark proves to the buyer or user that the product has been subjected to a certain procedure that guarantees its compliance with safety and environmental requirements. By putting the CE mark on its products, the manufacturer or importer declares that the product meets the provisions of the relevant legislation implementing EU Directives. CE marking is not a mark of origin as it does not indicate where the product was manufactured.

### 1. What is CE marking?

The CE mark is the mandatory declaration by the manufacturer that the product meets the safety requirements set by the applicable EU legislation and that the appropriate conformity assessment procedures have been completed.

#### What does CE stand for?

It may be reasonable to think that CE stands for Communauté Européenne, meaning European Community in French, or Conformité Européenne (European conformity) but officially it is simply a logo.

#### What does the CE mark look like?

In general, the CE mark must appear on products but it may also appear on packaging, in manuals or other supporting literature. The CE mark must take the form below, which can be reduced or enlarged, but the proportions must be maintained. The height of the letters must not be less than 5mm. It should be noted that the C and the E are not perfect semi-circles.



#### What products need to be CE marked?

Products included:

- New products manufactured in the 27 member states, Iceland, Liechtenstein and Norway
- New, used and second-hand products imported from third countries
- Products that have been subject to important changes and therefore may be considered as new products

Products excluded:

- Products that have been repaired without changing the original performance, purpose or type
- Products specially or exclusively intended for military or police purposes

#### Who is responsible for placing CE marking on the products?

It is the responsibility of the manufacturer to verify whether or not a product falls within the scope of one or more of the directives listed on page 3 and 4, and to have those products marked. Where the products are imported from countries outside the European Economic Area (EEA), this responsibility falls on the importer within the community.

#### Which countries require products to be CE marked?

The CE marking must be placed on a product before it is launched within the European Economic Area (EEA), i.e. 27 EU member states plus Iceland, Liechtenstein and Norway. The CE marking is mandatory even if the product was manufactured outside these countries but it is not required for exporting a product to non-EEA countries. According to the free movement of goods principle within the EU, member states may not forbid, restrict or impede the placing on the market of products

bearing the CE mark, unless the provisions relating to CE marking are incorrectly applied, or there is a hazard that is not covered by the applicable directives.

### **Who carries out the conformity assessment of a product?**

The conformity assessment is carried out either by the manufacturer through self-declaration, or by notified bodies. Notified bodies are organisations appointed by each member state to carry out the conformity assessment procedures referred to in the applicable directive(s) when third party intervention is required. To be eligible as a notified body the organisation must:

- Be a legal entity established on the territory of the member states
- Have the necessary personnel and equipment available
- Be independent and impartial in relation to those directly or indirectly concerned with the product
- Have technical competence of personnel that is relevant to the products and conformity assessment procedure in question
- Maintain professional secrecy and integrity
- Subscribe to civil liability insurance, unless that liability is covered by the state under national law.

### **What would happen if a product was not CE marked?**

Enforcement varies according to the national administrative and penal laws. If there is no safety risk, the relevant enforcement authority may provide the manufacturer with another opportunity to ensure that the product is correctly CE marked before being obliged to take the product off the market. The manufacturer may also be liable to a fine and/or imprisonment.

## **2. Products that need CE marking**

Below is the list of European directives that provide for CE marking and the links to their texts. Each directive defines the products that are within its scope. Manufacturers should study the directive(s) in order to decide whether their products need CE marking. Products not covered by the scope of these directives may not bear the CE mark.

- [Directive 2006/95/EC](#) Low voltage equipment
- [Directive 87/404/EEC](#) Simple pressure vessels
- [Directive 88/378/EEC](#) Safety of toys
- [Directive 89/106/EEC](#) Construction products
- [Directive 2004/108/EC](#) Electromagnetic compatibility (EMC)
- [Directive 98/37/EC](#) Machinery
- [Directive 89/686/EEC](#) Personal protective equipment (PPE)
- [Directive 90/384/EEC](#) Non-automatic weighing instruments
- [Directive 90/385/EEC](#) Active implantable medical devices
- [Directive 90/396/EEC](#) Appliances burning gaseous fuels
- [Directive 92/42/EEC](#) Hot-water boilers fired with liquid or gaseous fuels
- [Directive 93/15/EEC](#) Explosives for civil uses
- [Directive 93/42/EEC](#) Medical devices
- [Directive 94/9/EC](#) Potentially explosive atmospheres (ATEX Directive)
- [Directive 94/25/EC](#) Recreational craft
- [Directive 95/16/EC](#) Lifts
- [Directive 97/23/EC](#) Pressure equipment
- [Directive 98/79/EC](#) In vitro diagnostic medical devices
- [Directive 99/5/EC](#) Radio equipment and telecommunications terminal equipment
- [Directive 2000/9/EC](#) Cableway installations designed to carry persons
- [Directive 2004/22/EC](#) Measuring instruments
- [Directive 96/57/EC](#) Household electric refrigerators, freezers and combinations thereof
- [Directive 2000/14/EC](#) Noise emission in the environment by equipment for use outdoors
- [Directive 2000/55/EC](#) Ballast for fluorescent lighting

The texts of these directives and their amendments can also be accessed at the following websites:  
<http://ec.europa.eu/enterprise/newapproach/legislation/directives/table3.htm>

N.B. Please note that Directive 99/36/EC on transportable pressure equipment does not provide for CE marking but for another conformity marking, which looks like the Greek symbol  $\pi$  (see Annex VII of the Directive).

### **3. Advantages of CE marking**

There are a significant number of advantages of CE marking for the manufacturer and for the consumer. In particular:

- CE marking provides manufacturers with market access to the whole European Economic Area, since countries within this area may not restrict the placing on the market of products bearing the CE marking.
- It guarantees that the product conforms to the regulations in the specific directive(s)
- It is a guarantee for the manufacturer that the product is safe for consumers
- It may significantly reduce damage claims and liability premiums.

### **4. Procedure to CE mark a product**

Once the European directive(s) that are applicable to a particular product have been identified, the product has to go through the following process:

#### **Conformity assessment procedure**

The essential objective of a conformity assessment procedure is to ensure that products placed on the market conform to the requirements as expressed in the provisions of the directives, in particular with regard to the health and safety of users and consumers. Conformity assessment is subdivided into modules which relate to the design phase of products, their production phase, or both. The eight basic modules (modules A to H) and their eight possible variants can be combined in a variety of ways to establish complete conformity assessment procedures.

The European directives that provide for CE marking establish different procedures, according to the categories of products covered. A list of the eight basic modules, their eight possible variants and the different conformity assessment procedures by directive can be found in annexes 7 and 8 of the European Commission's 'Blue Guide' on CE marking:

<http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm>

#### **Application of standards**

The manufacturer must ensure the product complies with all the essential requirements of the directive(s). It is therefore helpful to establish whether there are any harmonised European Standards applicable to the product. These are not mandatory standards for manufacturers, although there is a presumption that this will conform to the essential requirements of the Directive. Whenever possible or appropriate, manufacturers should follow harmonised standards. A list of harmonised standards by directive can be found at:

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

N.B. Please note that directive 94/62/EC on packaging and packaging waste does not provide for CE marking.

#### **Notified bodies**

The manufacturer must establish whether independent assessment of the conformity to the directive, or some aspects of it, is required from a notified body. This will be stated on the specific directive and will depend on the kind of product that needs CE marking. In case a notified body is required to carry out the conformity assessment procedure, the manufacturer must not affix the CE mark to the product until all necessary certifications have been obtained from the notified body.

## Documentation needed

- Technical documentation: this technical file (drawn up by the manufacturer) is intended to provide information on the design, manufacture and operation of the product, and to demonstrate the conformity of the product to the applicable requirements set by the specific directive(s).
- Declaration of conformity: it states the conformity of the product with the requirements of the directive. It also allows an enforcement authority to identify who is responsible for a product and what that person claims to have done to CE mark it. The declaration of conformity must contain all relevant information to identify the Directive(s) according to which it is issued, as well as the manufacturer, the authorised representative, the notified body if applicable, the product and, where appropriate, a reference to harmonised standards or other normative documents.
- Other documents: the manufacturer must check that no other national requirements exist in the countries where the product will be sold. These may include national standards, labelling or packaging requirements.

## 5. UK Notified Bodies

The links below contain details of UK notified bodies for each particular CE marking directive. Please note that for some of the directives, the contact details of the relevant UK notified bodies were not available through a hyperlink. In these cases, a reference to the European Commission's NANDO database has been made. The database contains lists of notified bodies for each EU country and directive and is easily accessible at <http://ec.europa.eu/enterprise/newapproach/nando> (choose country/UK and then the relevant directive from the drop-down menu).

### Low voltage equipment

[www.bis.gov.uk/policies/business-sectors/environmental-and-technical-regulations/technical-regulations/ec-product-directives/electrical-equipment-Safety-regulations-1994](http://www.bis.gov.uk/policies/business-sectors/environmental-and-technical-regulations/technical-regulations/ec-product-directives/electrical-equipment-Safety-regulations-1994)

### Simple pressure vessels

[www.bis.gov.uk/files/file41531.pdf](http://www.bis.gov.uk/files/file41531.pdf)

### Toys

[www.bis.gov.uk/files/file11286.pdf](http://www.bis.gov.uk/files/file11286.pdf)

### Construction products

See NANDO database

### Electromagnetic compatibility

[www.bis.gov.uk/files/file35641.pdf](http://www.bis.gov.uk/files/file35641.pdf)

### Personal protective equipment

[www.bis.gov.uk/policies/business-sectors/environmental-and-technical-regulations/technical-regulations/ec-product-directives/personal-protective-equipment-directive](http://www.bis.gov.uk/policies/business-sectors/environmental-and-technical-regulations/technical-regulations/ec-product-directives/personal-protective-equipment-directive)

### Non-automatic weighing instruments

See NANDO database

### Medical devices: directives 90/385/EEC, 93/42/EEC and 98/79/EC

<http://www.mhra.gov.uk/Howweregulate/Devices/NotifiedBodies/UKNotifiedBodiesundertheMedicalDevicesDirectives/index.htm>

### Appliances burning gaseous fuels

[www.bis.gov.uk/files/file38871.pdf](http://www.bis.gov.uk/files/file38871.pdf)

### Hot-water boilers fired with liquid or gaseous fuels

[www.bis.gov.uk/files/file11281.pdf](http://www.bis.gov.uk/files/file11281.pdf)

### Explosives for civil uses

<http://www.hsl.gov.uk/centres-of-excellence/explosives-notified-body.aspx>

**Potentially explosive atmospheres (ATEX Directive)**

[www.bis.gov.uk/files/file44775.pdf](http://www.bis.gov.uk/files/file44775.pdf)

**Recreational craft**

[www.bis.gov.uk/files/file11294.pdf](http://www.bis.gov.uk/files/file11294.pdf)

**Lifts**

[www.bis.gov.uk/assets/biscore/corporate/docs/l/10-680-lifts-guidance-notes-on-the-uk-regulations](http://www.bis.gov.uk/assets/biscore/corporate/docs/l/10-680-lifts-guidance-notes-on-the-uk-regulations)

**Pressure equipment**

[www.bis.gov.uk/files/file11284.pdf](http://www.bis.gov.uk/files/file11284.pdf)

**Machinery**

[www.bis.gov.uk/files/file52968.pdf](http://www.bis.gov.uk/files/file52968.pdf)

**Radio equipment and telecommunications terminal equipment**

[www.bis.gov.uk/files/file11993.pdf](http://www.bis.gov.uk/files/file11993.pdf)

**Cableway installations designed to carry persons**

[http://ec.europa.eu/enterprise/rail\\_guided\\_transport/cableways/nb\\_rfu.htm](http://ec.europa.eu/enterprise/rail_guided_transport/cableways/nb_rfu.htm)

N.B. Please note that there are no notified bodies in the UK for this Directive. Therefore, if needed, the manufacturer should contact the notified bodies mentioned in the link above.

**Noise emission in the environment by equipment for use outdoors**

[www.bis.gov.uk/files/file11897.pdf](http://www.bis.gov.uk/files/file11897.pdf)

**Measuring instruments**

See NANDO database

**Ballast for fluorescent lighting\*****Household electric refrigerators, freezers and combinations thereof\***

\*There are no notified bodies for Directive 2000/55/EC on ballast for fluorescent lighting and Directive 96/57/EC on household electric refrigerators, freezers and combinations thereof. These Directives do not provide for conformity assessment procedure involving a third party (i.e. the notified body). Both Directives require internal production control, according to which the manufacturer declares conformity of the product with the essential requirements.

## 6. Useful contacts and websites

### EU Sources on CE marking

#### General information on CE marking

European Commission DG Enterprise  
Unit G1 - Legal aspects of the Internal Market  
1049 Brussels  
E: [entr-regul-coord-mra@ec.europa.eu](mailto:entr-regul-coord-mra@ec.europa.eu)

#### European Commission Guide to CE marking

<http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm>

#### Useful information on the specific Directives requiring the CE mark for products

[http://ec.europa.eu/enterprise/newapproach/index\\_en.htm](http://ec.europa.eu/enterprise/newapproach/index_en.htm)

#### NANDO database

Contains lists of notified bodies designated by the Member States and the EFTA countries  
<http://ec.europa.eu/enterprise/newapproach/nando>

### UK sources on CE marking

#### The British Standards Institute (UK notified body for 17 of 24 Directives)

BSI Product Services  
Maylands Avenue, Hemel Hempstead  
Herts, HP2 4SQ  
T: +44 (0) 8450 765600 E: [product.services@bsigroup.com](mailto:product.services@bsigroup.com)  
W: <http://www.bsi-global.com/ProductServices/About-CE-Marking/>

#### Department for Business, Innovation and Skills – Technical Regulations

[www.bis.gov.uk/policies/business-sectors/environmental-and-technical-regulations/technical-regulations](http://www.bis.gov.uk/policies/business-sectors/environmental-and-technical-regulations/technical-regulations)

#### Contacts for specific technical regulations/Directives

[www.bis.gov.uk/policies/business-sectors/environmental-and-technical-regulations/technical-regulations/activities](http://www.bis.gov.uk/policies/business-sectors/environmental-and-technical-regulations/technical-regulations/activities)

#### Enterprise Europe Network desk at the London Chamber of Commerce

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[www.een-london.co.uk](http://www.een-london.co.uk)

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