

# Five Minutes On... CE Marking

The European Union single market offers access to more than 500 million consumers and 21 million small and medium-sized enterprises (SMEs) spread over 28 jurisdictions. Once a product is placed on the market of a Member State, it can move freely within the EU, without the need for additional registration or border checks.

This attractive access to the EU market is often conditioned on one step: CE marking.

Where this is properly carried out, the placing of a CE mark on a product:

- Shows that the manufacturer has checked that these products meet EU safety, health or environmental requirements
- Is a key indicator of a product's compliance with applicable EU legislation
- Allows the free movement of products within the European market

As well as acting as a trade passport, the CE mark serves as a sign of assurance as it allows consumers and end-users to identify standards in compliance with certain sets of rules and obligations.

### What is a CE Mark and Why is it Important?

"CE" is an abbreviation of the French phrase "Conformité Européenne" (which translates as "European Conformity").

It is a declaration made by the manufacturer, and a legal obligation derived from EU legislation, that the product in question complies with the standards and requirements applicable for that product. As a general rule, before placing a product on the EU single market, the EU mandates:

- Compliance with specific standards and requirements relating to product safety, health, environmental impact, consumer protection
- The placing of a CE mark

For example, if a business wishes to market its products in Europe and those products are covered by the relevant EU legislation that prescribes CE marking, then a CE mark must be placed on such products as part of compliance with the applicable legal requirements.

By placing the CE mark on a product the manufacturer is declaring, with sole responsibility, conformity with all of the legal requirements to achieve CE marking for that particular merchandise.



### How Must a CE Mark Be Affixed Onto a Product?

A "CE mark" is a mark that must be affixed to particular categories of products sold in the 28 EU Member States, as well as Iceland, Liechtenstein, Norway (as signatories of the Agreement on the EEA) and Turkey in certain cases. This is what a CE mark looks like:



The CE marking must be affixed visibly, legibly and indelibly to the product or its data plate. In instances where this is not possible, or not warranted on account of the nature of the product, it must be affixed to the packaging or to the accompanying documents.

The requirement for visibility means that the CE marking must be easily accessible for all parties, affixed on the back or underside of a product, with a minimum height of 5mm unless waived for small devices or components. CE marking can take different forms (e.g. colour, solid/hollow) as long as it remains visible, legible and respects its proportions.



**CAUTION:** The fact that a product bears a CE mark does not mean that it has been approved as safe by the EU or by another authority. Nor does It indicate the origin of a product.

Also, it is forbidden to affix CE marking when the product is not subject to this requirement.

### What Are My Obligations?

The CE marking may not, in principle, be affixed until the conformity assessment procedure has been completed to ensure that the product complies with all the provisions of the relevant EU harmonisation acts.

Where applicable, CE regulations impose on the manufacturer, importers and distributors responsibilities to:

### **Manufacturers**

- Carry out the conformity assessment
- Set up the technical file
- Issue the EC Declaration of Conformity (DoC)
- Place CE marking on a product

### **Importers/Distributors**

- Check presence of CE marking and the necessary supporting documentation when selling regulated merchandise
- Check that the manufacturer outside the EU has taken necessary steps to comply with the applicable certification requirements
- If marketing products under own name, they take over the manufacturer's responsibilities (ensure sufficient information on the design and production of the product, as assuming the legal responsibility when affixing the CE marking)

### What Are the Penalties for Incorrectly CE Marking a Product?

Each Member State provides in its national legislation for appropriate measures both to prevent the abuse and misuse of CE marking, and to redress the situation if such abuse or misuse takes place. The measures may include withdrawal, recall of products, penalties and criminal sanctions wherever necessary.

In the UK for instance, the penalties for incorrectly CE marking a product, falsely CE marking a product or failing to CE mark a product for which it is required, are generally fines but can include prison sentences.

If done properly, the CE marking is the passport for many different products to circulate freely in the 350 million-person market that is the EU.

If you have any question relating to CE marking, please contact one of the lawyers listed below.

## What Products Are Covered by the CE Marking Requirement?

A wide range of products are covered by EU laws that mandate CE marking. The following is a list of products that require CE marking when placed in the EU market:

- Active implantable medical devices
- Appliances burning gaseous fuels
- Cableway installations designed to carry persons
- Construction products
- Eco-design of energy related products
- Electromagnetic compatibility
- Equipment and protective systems intended for use in potentially explosive atmospheres
- Explosives for civil uses
- Hot-water boilers
- Household refrigerators and freezers
- In vitro diagnostic medical devices

- Lifts
- Low voltage
- Machinery
- Measuring instruments
- Medical devices
- Noise emission in the environment
- Non-automatic weighing instruments
- Personal protective equipment
- Pressure equipment
- Pyrotechnics
- Radio and telecommunications terminal equipment
- Recreational craft
- Safety of toys
- Simple pressure vessels

#### **Contacts**

#### **Aline Doussin**

Partner, London T +44 207 655 1146 E aline.doussin@squirepb.com

#### **Robert MacLean**

Partner, Brussels T +32 2 6277 619

E robert.maclean@squirepb.com

The contents of this update are not intended to serve as legal advice related to individual situations or as legal opinions concerning such situations nor should they be considered a substitute for taking legal advice.