What is CE marking?

CE marking is a key indicator of a **product's compliance with EU legislation** and enables the free movement of products within the European market. By affixing the CE marking on a product, a manufacturer is declaring, **on his sole responsibility**, conformity with all of the legal requirements to achieve CE marking and therefore ensuring validity for that product to be sold throughout the **European Economic Area** (EEA, the 27 Member States of the EU and EFTA countries Iceland, Norway, Liechtenstein), as well as Turkey. This also applies to products made in third countries which are sold in the EEA and Turkey.

However, not all products must bear the CE marking. Only those product categories subject to specific directives that provide for the CE marking are required to be CE marked.

CE marking does not indicate that a product was made in the EEA, but merely states that the product is **assessed before being placed on the market** and thus satisfies the legislative requirements (e.g. a harmonised level of safety) to be sold there. It means that the manufacturer has verified that the product complies with all relevant **essential requirements** (e.g. health and safety requirements) of the applicable directive(s) – or, if stipulated in the directive(s), had it examined by a **notified conformity assessment body**.

It is the manufacturer's responsibility to carry out the conformity assessment, to set up the technical file, to issue the EC declaration of conformity and to affix CE marking on a product. Distributors must verify the presence of both the CE marking and the necessary supporting documentation. If the product is being imported from a third country, the importer has to verify that the manufacturer outside the EU has undertaken the necessary steps and that the documentation is available upon request.

This leaflet sets out the six necessary steps. Follow them to comply with the legal requirements and **make Europe's market yours!**

Further information

For further information on the regulatory policy and CE marking, please visit:
www.ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/index_en.htm

www.ec.europa.eu/CEmarking

NANDO database of notified conformity assessment bodies:
www.ec.europa.eu/enterprise/newapproach/nando

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CE

CE marking makes Europe's market yours!

European Commission
Enterprise and Industry

6 STEPS TO CE MARKING FOR YOUR PRODUCT

STEP 1 – Identify the directive(s) and harmonised standards applicable to the product

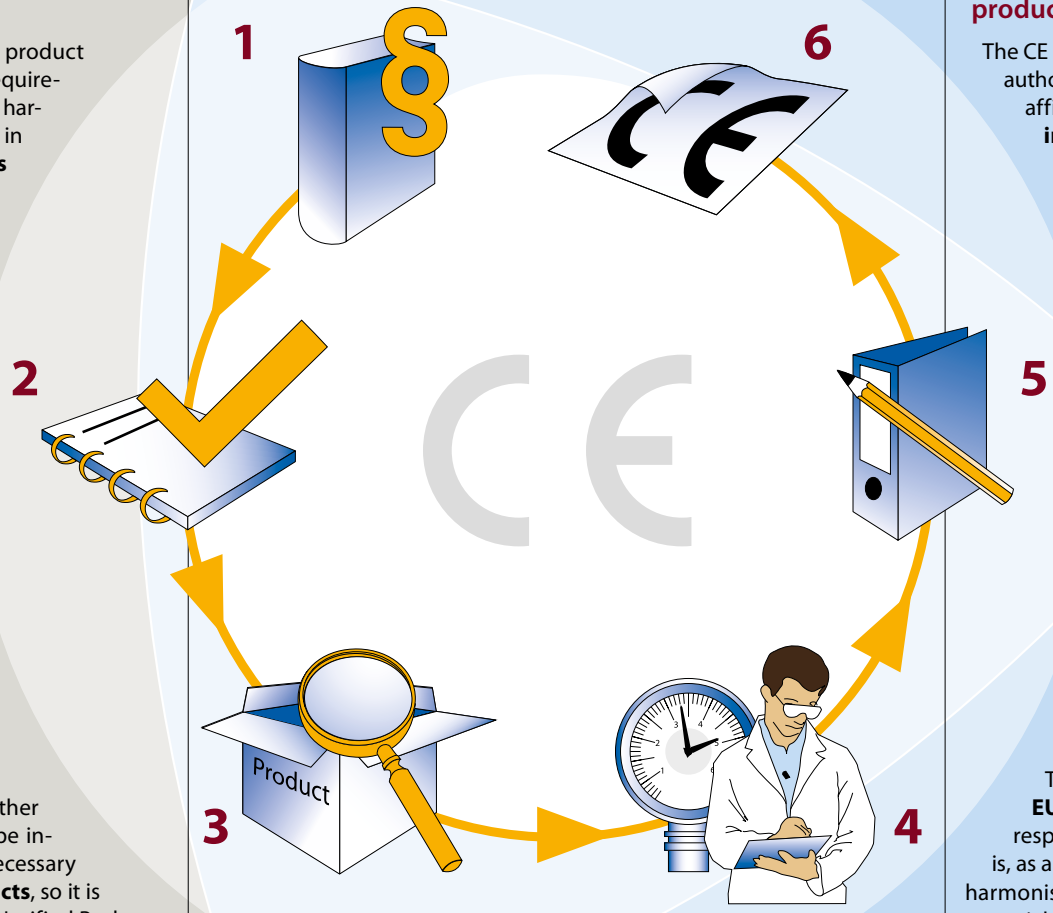
There are **more than 20 directives** setting out the product categories requiring CE marking. The essential requirements that products have to fulfil (e.g. safety) are harmonised at EU level and are set out in general terms in these directives. **Harmonised European standards** are issued with reference to the applied directives and express in detailed technical terms the essential requirements.

STEP 2 – Verify the product-specific requirements

It is up to you to ensure that your product complies with the essential requirements of the relevant EU legislation. **Full compliance** of a product to the harmonised standards gives a product the **"presumption of conformity"** with the relevant essential requirements. The use of harmonised standards remains voluntary. You may decide to choose other ways to fulfil these essential requirements.

STEP 3 – Identify whether an independent conformity assessment is required from a Notified body

Each directive covering your product specifies whether an **authorised third party** (Notified Body) must be involved in the conformity assessment procedure necessary for CE marking. This is **not obligatory for all products**, so it is important to check whether the involvement of a Notified Body is indeed required. These Bodies are authorised by national authorities and officially "notified" to the Commission and listed in the **NANDO** (New Approach Notified and Designated Organisations) database.



STEP 6 – Affixation of the CE marking to your product and EC Declaration of Conformity

The CE marking must be **affixed by the manufacturer**, or by his authorised representative within the EEA or Turkey. It must be affixed according to its legal format **visibly, legibly and indelibly** to the product or its data plate. If a Notified Body was involved in the production control phase, its identification number must also be displayed. It is the manufacturer's responsibility to draw up and sign an **"EC declaration of conformity"** proving that the product meets the requirements. **That's it! Your CE-marked product is ready for the market.**

STEP 5 – Draw up and keep available the required technical documentation

The manufacturer has to establish the **technical documentation** required by the directive(s) for the assessment of the product's conformity to the relevant requirements, and for the **risk assessment**. Together with the EC declaration of conformity, the technical documentation must be presented on request to the relevant national authorities.

STEP 4 – Test the product and check its conformity

Testing the product and checking its **conformity to the EU legislation** (Conformity Assessment Procedure) is the responsibility of the manufacturer. One part of the procedure is, as a general rule, a **risk assessment**. By applying the relevant harmonised European standards, you will be able to fulfil the essential legislative requirements of the directives.