CE marking

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CE marking is a mandatory conformity marking for certain products sold within the European Economic Area (EEA) since 1985.[1] The CE marking is also found on products sold outside the EEA that are manufactured in, or designed to be sold in, the EEA. This makes the CE marking recognizable worldwide even to people who are not familiar with the European Economic Area. It is in that sense similar to the FCC Declaration of Conformity used on certain electronic devices sold in the United States.

The CE marking is the manufacturer's declaration that the product meets the requirements of the applicable EC directives.[2]

The mark consists of the CE logo and, if applicable, the four digit identification number of the Notified Body involved in the conformity assessment procedure.

"CE" originated as an abbreviation of ***Conformité Européenne***, meaning **European Conformity**,[3] but is not defined as such in the relevant legislation. The CE marking is a symbol of free marketability in the European Economic Area (Internal Market).

CE marking

Expansion	Conformité Européenne
Effective region	European Economic Area
Product category	Various
Legal status	Mandatory
Website	CE Marking homepage (http://ec.europa.eu/growth/single-market/ce-marking/)

Contents

Meaning

Existing in its present form since 1985, the CE marking indicates that the manufacturer or importer claims compliance with the relevant EU legislation applicable to a product, regardless of where manufactured. By affixing the CE marking on a product, a manufacturer is declaring, at its sole responsibility, conformity with all of the legal requirements to achieve CE marking which allows free movement and sale of the product throughout the European Economic Area.

For example, most electrical products must comply with the Low Voltage Directive and the EMC Directive; toys must comply with the Toy Safety Directive. The marking does not indicate EEA manufacture or that a product has been approved as safe by the EU or by another authority.[4] The EU requirements may include safety, health, and environmental protection, and, if stipulated in any EU product legislation, assessment by a Notified Body or manufacture according to a certified production quality system. The CE marking also indicates that the product complies with directives in relation to 'Electro Magnetic Compatibility'[5] - meaning the device will work as intended, without interfering with the use or function of any other device.

Not all products need CE marking to be traded in the EEA; only product categories subject to relevant directives or regulations are required (and allowed) to bear CE marking. Most CE-marked products can be placed on the market subject only to an internal production control by the manufacturer (Module A; see Self-certification, below), with no independent check of the conformity of the product with EU legislation; ANEC has cautioned that, amongst other things, CE marking cannot be considered a "safety mark" for consumers.[6]

CE marking is a self-certification scheme. Retailers sometimes refer to products as "CE approved", but the mark does not actually signify approval. Certain categories of products require type-testing by an independent body to ensure conformity with relevant technical standards, but CE marking in itself does not certify that this has been done.

Countries requiring the CE marking

CE marking is mandatory for certain product groups within the European Economic Area (EEA; the 28 member states of the EU plus EFTA countries Iceland, Norway and Liechtenstein) plus Switzerland and Turkey. The manufacturer of products made within the EEA and the importer of goods made in other countries must ensure that CE-marked goods conform to standards.

As of 2013, CE marking was not required by countries of the Central European Free Trade Agreement (CEFTA), but members Republic of Macedonia, Serbia, and Montenegro had applied for membership of the European Union, and were adopting many of its standards within their legislation (as did most Central European former member countries of CEFTA that joined the EU, before joining).

Rules underlying CE marking

Responsibility for CE marking lies with whoever puts the product on the market in the EU, i.e. an EU-based manufacturer, the importer or distributor of a product made outside the EU, or an EU-based office of a non-EU manufacturer.

The manufacturer of a product affixes the CE marking to it but has to take certain obligatory steps before the product can bear CE marking. The manufacturer must carry out a conformity assessment, set up a technical file and sign a Declaration stipulated by the leading legislation for the product. The documentation has to be made available to authorities on request.

Importers of products have to verify that the manufacturer outside the EU has undertaken the necessary steps and that the documentation is available upon request. Importers should also make sure that contact with the manufacturer can always be established.

Distributors must be able to demonstrate to national authorities that they have acted with due care and they must have affirmation from the manufacturer or importer that the necessary measures have been taken.

If importers or distributors market the products under their own name, they take over the manufacturer's responsibilities. In this case they must have sufficient information on the design and production of the product, as they will be assuming the legal responsibility when they affix the CE marking.

There are certain rules underlying the procedure to affix the marking:

- Products subject to certain EU directives or EU regulations providing for CE marking have to be affixed with the CE marking before they can be placed on the market.
- Manufacturers have to check, on their sole responsibility, which EU legislation they need to apply for their products.
- The product may be placed on the market only if it complies with the provisions of all applicable directives and regulations and if the conformity assessment procedure has been carried out accordingly.
- The manufacturer draws up an EU declaration of conformity or a declaration of performance (for Construction Products) and affixes the CE marking on the product.
- If stipulated in the directive(s) or regulation(s), an authorized third party (Notified Body) must be involved in the conformity assessment procedure or in setting up a production quality system.
- If the CE marking is affixed on a product, it can bear additional markings only if they are of different significance, do not overlap with the CE marking and are not confusing and do not impair the legibility and visibility of the CE marking.

Since achieving compliance can be very complex, CE-marking conformity assessment, provided by a notified body, is of great importance throughout the entire CE-marking process, from design verification, and set up of the technical file to the EU declaration of conformity.

Self-certification

Depending on the level of risk of the product, the CE marking is affixed to a product by the manufacturer or authorized representative who decides whether the product meets all the CE marking requirements. If a product has minimal risk, it can be self-certified by a manufacturer making a declaration of conformity and affixing the CE marking to their own product. In order to self-certify, the Manufacturer must do several things:

1. Decide whether the product needs to have a CE marking. The product must conform to all Directives that apply to the product.
2. Choose the conformity assessment procedure from the modules called out by the directive for the product. There are several modules available for the Conformity Assessment Procedures as listed below:

    - **Module A** – Internal production control.
    - **Module B** – EC type-examination.
    - **Module C** – Conformity to type.
    - **Module D** – Production quality assurance.
    - **Module E** – Product quality assurance.
    - **Module F** – Product verification.
    - **Module G** – Unit verification.
    - **Module H** – Full quality assurance.

These will often ask questions about the product to classify the level of risk and then refer to the "Conformity Assessment Procedures" chart. This shows all the acceptable options available to a manufacturer to certify the product and affix the CE marking.

Products considered to have a greater risk have to be independently certified by a notified body. This is an organization that has been nominated by a Member State and has been notified by the European Commission. These notified bodies act as test labs and carry out the steps as listed in the directives mentioned above and then decided whether the product has passed. A manufacturer can choose its own notified body in any Member State of the European Union but should be independent of the manufacturer and a private sector organization or a government agency.

In reality the self-certification process consists of the following stages:

Stage 1: Identify the applicable Directive(s)

The first step is to identify whether the product needs to bear CE marking or not. Not all products are required to bear CE marking, only the products that fall within the scope of at least one of the sectoral directives requiring CE marking. There are more than 20 sectoral product directives requiring CE marking covering, but not limited to, products such as electrical equipment, machines, medical devices, toys, pressure equipment, PPE, wireless devices and construction products.

Identifying which directive(s) may be applicable, as there may be more than one, involves a simple exercise of reading the scope of each directive to establish which apply to the product (An example of the scope of the Low Voltage Directive below). If the product does not fall within the scope of any of the sectoral directives, then the product does not need to bear CE marking (and, indeed, must not bear CE marking).

Low Voltage Directive (2006/95/EC)

Article 1 states the Directive covers "*any equipment designed for use with a voltage rating of between 50 and 1000 V for A.C. and between 75 and 1500 V for D.C, other than the equipment and phenomena listed in Annex II.*"

Stage 2: Identify the applicable requirements of the Directive(s)

Each Directive has slightly different methods of demonstrating conformity depending on the classification of the product and its intended use. Every Directive has a number of ‘essential requirements’ that the product has to meet before being placed on the market.

The best way to demonstrate that these essential requirements have been met is by meeting the requirements of an applicable ‘harmonised standard,’ which offer a presumption of conformity to the essential requirements, although the use of standards usually remains voluntary. Harmonised standards can be identified by searching the ‘Official Journal’ on the European Commission’s website, or by visiting the New Approach website established by the European Commission and EFTA with the European Standardisation Organisations.

Stage 3: Identify an appropriate route to conformity

Although the process is always a self-declaration process,there are various ‘attestation routes’ to conformity depending on the Directive and classification of the product. Some products (such as invasive medical devices, or fire alarm and extinguisher systems) may, to some extent, have a mandatory requirement for the involvement of an authorised third party or "notified body".

There are various attestation routes which include:

- An assessment of the product by the manufacturer.

- An assessment of the product by the manufacturer, with additional requirement for mandatory factory production control audits to be carried out by a third party.
- An assessment by a third party (e.g. EC type test), with the requirement for mandatory factory production control audits to be carried out by a third party.

Stage 4: Assessment of the product's conformity

When all of the requirements have been established, the conformity of the product to the essential requirements of the Directive(s) needs to be assessed. This usually involves assessment and/or testing, and may include an evaluation of the conformity of the product to the harmonised standard(s) identified in step 2.

Stage 5: Compile the technical documentation

Technical documentation, usually referred to as the technical file, relating to the product or range of products needs to be compiled. This information should cover every aspect relating to conformity and is likely to include details of the design, development and manufacture of the product.

Technical documentation will usually include:

- Technical description
- Drawings, circuit diagrams and photos
- Bill of materials
- Specification and, where applicable, EU declaration of conformity for the critical components and materials used
- Details of any design calculations
- Test reports and/or assessments
- Instructions
- EU declaration of conformity
- Technical documentation can be made available in any format (i.e. paper or electronic) and must be held for a period of up to 10 years after the manufacture of the last unit, and in most cases reside in the European Economic Area (EEA).

Stage 6: Make a declaration and affix the CE marking

When the manufacturer, importer or authorised representative is satisfied that their product conforms to the applicable Directives, an EU declaration of conformity must be completed or, for partly completed machinery under the Machinery Directive, an ECU declaration of incorporation.

The requirements for the declaration vary slightly, but will at least include:

- Name and address of the manufacturer
- Details of the product (model, description and the serial number where applicable)
- List of applicable sectoral Directives and standards that have been applied
- A statement declaring that the product complies with all of the relevant requirements
- Signature, name and position of the responsible person
- The date that the declaration was signed
- Details of the authorised representative within the EEA (where applicable)
- Additional Directive/standard specific requirements
- In all cases, except for the PPE Directive, all of the Directives can be declared on one declaration.
- Once an EU declaration of conformity has been completed, the final step is to affix the CE marking to the product. When this has been done, the CE marking requirements have been met for the product to be placed legally on the EEA market.

Purpose for safety issues.

EU declaration of conformity

The EU declaration of conformity must include: manufacturer's details (name and address, etc.); essential characteristics the product complies; any European standards and performance data; if relevant the identification number of the notified body; and a legally binding signature on behalf of the organization.

Product groups

The directives requiring CE marking affect the following product groups:

- Active implantable medical devices (excludes surgical instruments)
- Appliances burning gaseous fuels
- Cableway installations designed to carry persons
- Construction products according to Regulation (EU) No. 305/2011 under specific rules
- 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
- 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
- Restriction of the use of certain hazardous substances in electrical and electronic equipment RoHS 2
- Safety of toys
- Simple pressure vessels

Mutual recognition of conformity assessment

There are numerous 'Agreements on Mutual Recognition of Conformity Assessment' between the European Union and other countries such as the USA, Japan, Canada, Australia, New Zealand and Israel. Consequently, CE marking is now found on many products from these countries. Japan has its own marking known as the Technical Conformity Mark.[7]

Switzerland and Turkey (which are not members of the EEA) also require products to bear CE marking as an affirmation of conformity.[8][9]

Characteristics of CE marking

- The CE marking has to be affixed by the manufacturer or its authorized representative in the European Union according to its legal format visibly, legibly and indelibly to the product

- When a manufacturer puts the CE marking on a product it implies that it complies with all the Essential Health and safety requirements from all the directives that applies to its product.
    - For example, for a machine, the Machinery directive applies, but often also:
        - Low voltage directive
        - EMC directive
        - sometimes other directives or regulations, e.g. ATEX directive
        - and sometimes other legal requirements.

When the manufacturer of a machine puts the CE marking, it engages itself and guarantees, that it makes all the tests, assessments and evaluation on the product to conform to all the requirements of **ALL** the directives that apply to its product.

- CE marking has been introduced by the COUNCIL DIRECTIVE 93/68/EEC of 22 July 1993 amending Directives 87/404/EEC (simple pressure vessels), 88/378/EEC (safety of toys), 89/106/EEC (construction products), 89/336/EEC (electromagnetic compatibility), 89/392/EEC (machinery), 89/686/EEC (personal protective equipment), 90/384/EEC (non-automatic weighing instruments), 90/385/EEC (active implantable medicinal devices), 90/396/EEC (appliances burning gaseous fuels), 91/263/EEC (telecommunications terminal equipment), 92/42/EEC (new hot-water boilers fired with liquid or gaseous fuels) and 73/23/EEC (electrical equipment designed for use within certain voltage limits)
- The size of the CE marking must be at least 5 mm, if enlarged its proportions have to be kept
- If the appearance and workmanship of a product do not allow for the CE marking to be affixed on the product itself, the marking has to be affixed to its packaging or accompanying documents
- If a directive requires the involvement of a Notified Body in the conformity assessment procedure, its identification number has to be put behind the CE logo. This is done under the responsibility of the Notified Body.[1]

E mark

On motor vehicles and related parts, the UNECE "**e** mark" or "**E** mark", rather than the CE logo, has to be used.[10] Contrary to the CE logo, the UNECE marks are not self-certified.[11] They are not to be confused with the estimated sign on food labels.[12]

Misuse

The European Commission is aware that CE marking, like other certifications marks, is misused. CE marking is sometimes affixed to products that do not fulfill the legal requirements and conditions, or it is affixed to products for which it is not required. In one case it was reported that "Chinese manufacturers were submitting well-engineered electrical products to obtain conformity testing reports, but then removing non-essential components in production to reduce costs".[13] A test of 27 electrical chargers found that all the eight legitimately branded ones with a reputable name met safety standards, but none of those unbranded or with minor names did, despite bearing the CE mark;[13] non-compliant devices were actually potentially unreliable and dangerous, presenting electrical and fire hazards.

There are also cases in which the product complies with the applicable requirements, but the form, dimensions, or proportions of the mark itself are not as specified in the legislation.[14]

Domestic plugs and sockets

Directive 2006/95/EC, the “Low Voltage” Directive, specifically excludes (amongst other things) *plugs and socket outlets for domestic use* which are not covered by any Union directive and therefore must not be CE marked.[15] Throughout the EU, as in other jurisdictions, the control of *plugs and socket outlets for domestic use* is subject to national regulations. Despite this, the illegal use of CE marking can be found on domestic plugs and sockets, particularly so-called "universal sockets".[16]

China Export

A logo very similar to CE marking has been alleged to stand for *China Export* because some Chinese manufacturers apply it to their products.[17] However, the European Commission says that this is a misconception. The matter was raised at the European Parliament in 2008.[18] The Commission responded that it was unaware of the existence of any "Chinese Export" mark and that, in its view, the incorrect application of the CE marking on products was unrelated to incorrect depictions of the symbol, although both practices took place. It had initiated the procedure to register CE marking as a Community collective trademark, and was in discussion with Chinese authorities to ensure compliance with European legislation.[19]

Legal implications

There are mechanisms in place to ensure that the CE marking is put on products correctly. Controlling products bearing CE marking is the responsibility of public authorities in member states, in cooperation with the European Commission. Citizens may contact national market surveillance authorities if the misuse of the CE marking is suspected or if a product's safety is questioned.

The procedures, measures and sanctions applying to counterfeiting of the CE marking vary according to the respective member state's national administrative and penal legislation. Depending on the seriousness of the crime, economic operators may be liable to a fine and, in some circumstances, imprisonment. However, if the product is not regarded as an imminent safety risk, the manufacturer may be given an opportunity to ensure that the product is in conformity with the applicable legislation before being forced to take the product off the market.

See also

- Country of origin
- FCC Declaration of Conformity
- Kite mark

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External links

Wikimedia Commons has media related to ***CE logo***.

- European Commission (http://ec.europa.eu/growth/single-market/ce-marking/index_en.htm): Blue Guide (http://ec.europa.eu/DocsRoom/documents/11502/attachments/1/translations/en/renditions/native)
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