CE marking

The **CE marking** as it has been legally called since 1993 (per directive 93/68/EEC)(Decision 93/465/EEC), or formerly **EC mark**, is a mandatory conformity marking for products placed on the market in the European Economic Area (EEA).
With the CE marking on a product, the manufacturer declares that the product conforms with the essential requirements of the applicable EC directives
Legally, the CE marking is not a quality mark. But, depending on the applicable directive, the CE marking can actually be considered to be a quality mark. Deviating from sectoral directives regulating other industrial goods, *medical devices* have to comply with "essential requirements" as described in Annex I of Directive 93/42/EEC. According to this, medical devices must not only be safe but also function in a medical-technical way as described in the manufacturer's "intended purpose". Compliance with these requirements is proved within a certified quality management system according to EN ISO 13485.

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 an EC declaration of conformity. 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 EC directives 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 directives 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 if the conformity assessment procedure has been carried out accordingly.
- The manufacturer draws up an EC declaration of conformity and affixes the CE marking on the product.

- If stipulated in the directive(s), an authorized third party (Notified Body) must be involved in the conformity assessment procedure.
- 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.

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 where manufacturers a Declaration of Conformity and affixes the CE marking to their own product. Manufacturer then must do several things:

1. Decide whether the product needs to have a CE marking and if the product applies to more than one directive it needs to comply with all of them.
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, Declarations of Conformity for the critical

components and materials used

- Details of any design calculations
- Test reports and/or assessments
- Instructions
- EC 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 EC Declaration of Conformity must be completed or, for partly completed machinery under the Machinery Directive, an EC 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 a 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.

Declaration of conformity

The DoC 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
- Appliances burning gaseous fuels
- Cableway installations designed to carry persons
- Eco-design of energy related products
- Electromagnetic compatibility
- Equipment and protective systems intended for use 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
- Safety of toys
- Simple pressure vessels

For a complete listing, see the New Approach website established by the European Commission and EFTA with the European Standardisation Organisations.

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

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
- 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 marking. This is done under the responsibility of the Notified Body.