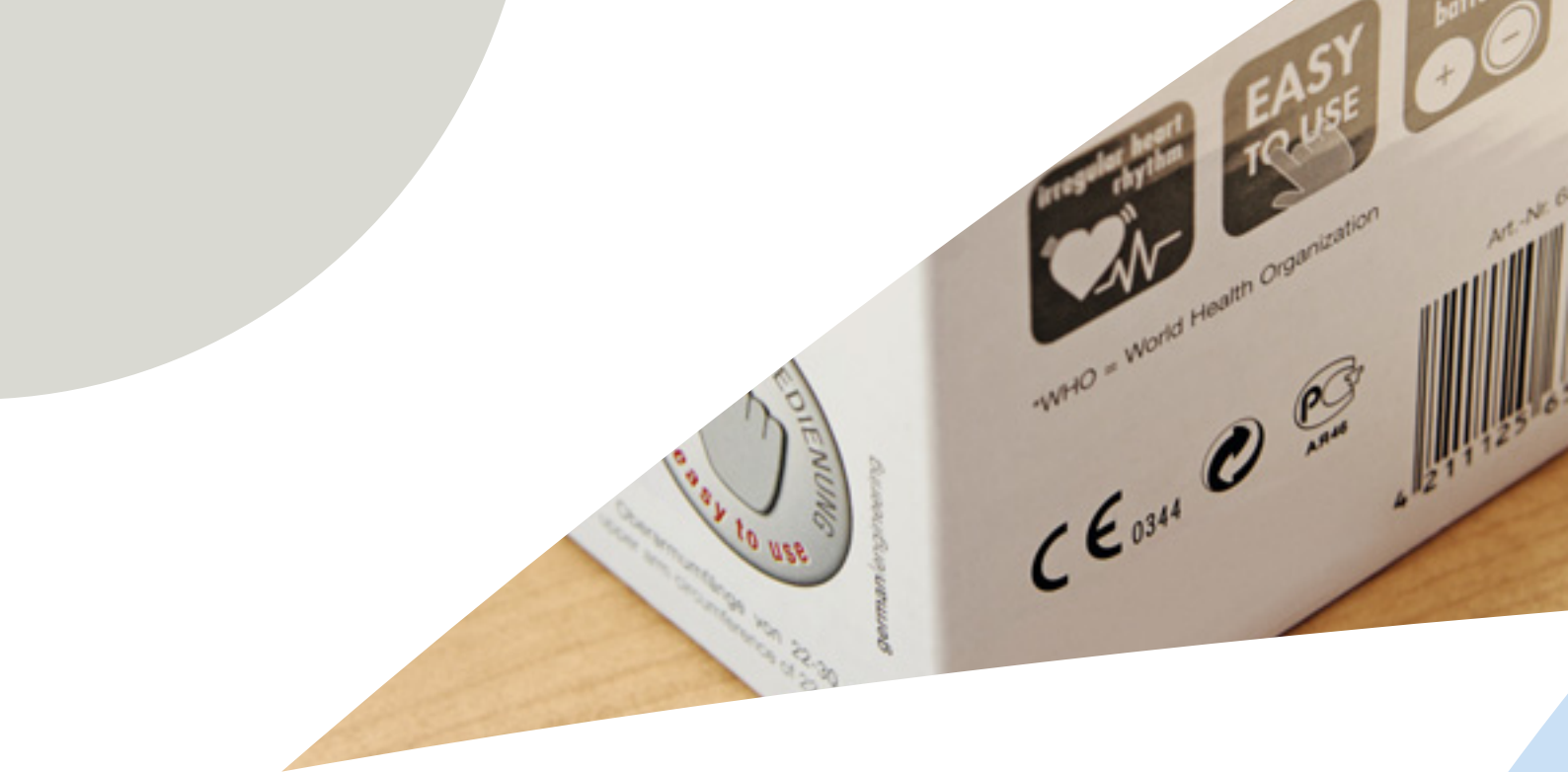


CE

CE marking makes Europe's market yours!

European Commission
Enterprise and Industry

Table of contents

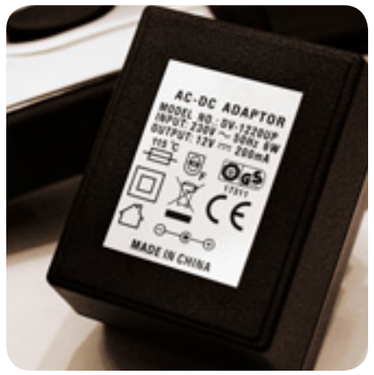
What is CE marking?

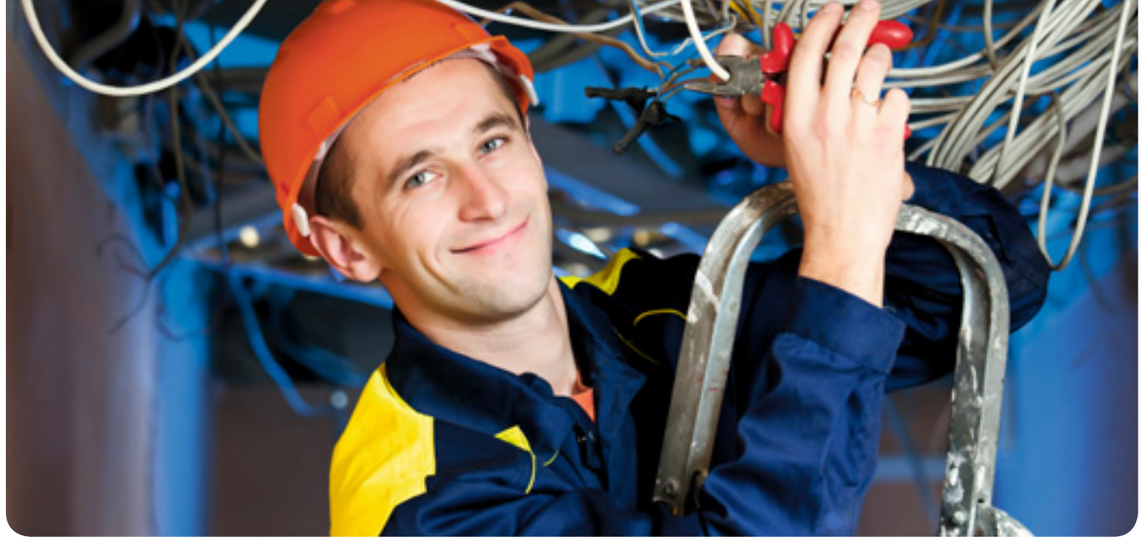
By introducing the CE marking into its legislation, the EU has developed an innovative instrument to remove barriers from the circulation of goods and to protect public interest.

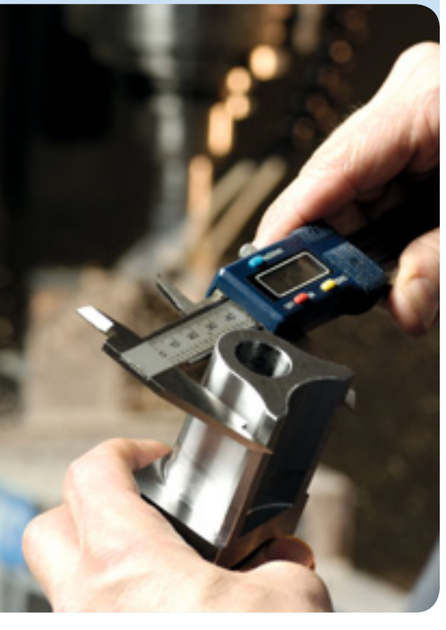
Existing in its present form since 1993, the CE marking is a key indicator of a **product's compliance with EU legislation** and enables the free movement of products within the European market. By affixing the CE marking on a product, a manufacturer is declaring, **on his sole responsibility**, conformity with all of the legal requirements to achieve CE marking, and is 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). This also applies to products made in third countries which are sold in the EEA.

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. safety, health, environmental protection requirements) of the applicable directive(s) – or, if stipulated in the directive(s), has had it examined by a notified conformity assessment body.

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 marked products are bought not only by professionals (e.g. medical devices, lifts, machinery and measuring equipment) but also by consumers (toys, PCs, mobile phones and light bulbs).







Legal obligations
of manufacturers

The affixing of the CE marking takes place before the product is placed on the market and is **the result of a successful conformity assessment procedure** completed **by the manufacturer** as laid down in Community legislation applying to the product in question.

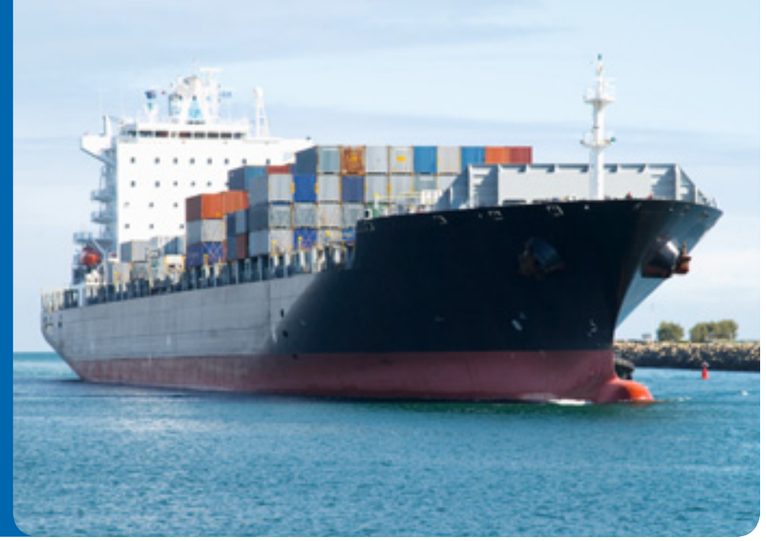
A manufacturer is defined as "any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark"[1]. A person or company must also assume the responsibilities of a manufacturer if they use ready-made products that will be traded on the EEA market under his or her own name or brand. Therefore, they must also have the required information about the design, production and conformity assessment of the product that they intend to sell, as specified by the legislation applying to it.

The manufacturer must go through a series of checks to assess and ensure that its products conform to the relevant EU directives. By affixing the CE marking, drafting the technical documentation and the EC declaration of conformity, **the manufacturer declares on his sole responsibility, the compliance of the product to the relevant legislative requirements and confirms that the necessary assessments have been completed.** Technical documentation provides information on the assessment of the product's conformity to the relevant requirements, as well as for the **risk assessment.**

National authorities inspect the products, thus it is very important that a manufacturer keeps documentation – including technical documentation and an EC Declaration of Conformity – to provide as evidence should problems arise.

Whether a manufacturer is based in the EEA or elsewhere, it can choose to appoint an authorised representative (who must be based in the EEA) to carry out certain administrative tasks on its behalf. This could include the affixing of the CE marking. However, **the checks/tests required to ensure the conformity of the product are carried out only by the manufacturer**. In order to ensure clarity, the manufacturer must clearly state in writing the tasks being delegated to the representative.

[1] Regulation (EC) No 765/2008



Legal obligations
of importers and distributors

Products from third countries that fall within the scope of directives providing for CE marking and which will be sold within the EEA must also bear the CE marking.

While manufacturers are responsible for ensuring product compliance and affixing the CE marking, importers and distributors also play an important role in making sure that only products which comply with the legislation and bear the CE marking are placed on the market. Not only does this help to reinforce the EU's health, safety and environmental protection requirements, it also supports fair competition with all players being held accountable to the same rules.

When goods are produced in third countries and the manufacturer is not represented in the EEA, **importers must make sure that the products they place on the market comply with the applicable requirements** and do not present a risk to the European public. The importer has to verify that the manufacturer outside the EU has taken the necessary steps and that the documentation is available upon request.

Thus, they must have an overall knowledge of the respective directives and are obliged to support national authorities should problems arise. Importers should have a written assurance from the manufacturer that they will have access to the necessary documentation – such as the EC Declaration of Conformity and the technical documentation – and be able to provide it to national authorities, if requested. Importers should also make sure that contact with the manufacturer can always be established.

Further along in the supply chain, **distributors play an important role in ensuring that only compliant products are on the market and must act with due care** to ensure that their handling of the product does not adversely affect its compliance. The distributor must also have a basic knowledge of the legal requirements – including which products must bear the CE marking and the accompanying documentation – and should be able to identify products that are clearly not in compliance.

Distributors must be able to demonstrate to national authorities that they have acted with due care and have affirmation from the manufacturer or the importer that the necessary measures have been taken. Furthermore, a distributor must be able to assist the national authority in its efforts to receive the required documentation.

If the importer or distributor markets the products under his or her own name, he then takes over the manufacturer's responsibilities. In this case he/she must have sufficient information on the design and production of the product, as he/she will be assuming the legal responsibility when affixing the CE marking.

6 STEPS TO CE MARKING FOR YOUR PRODUCT

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

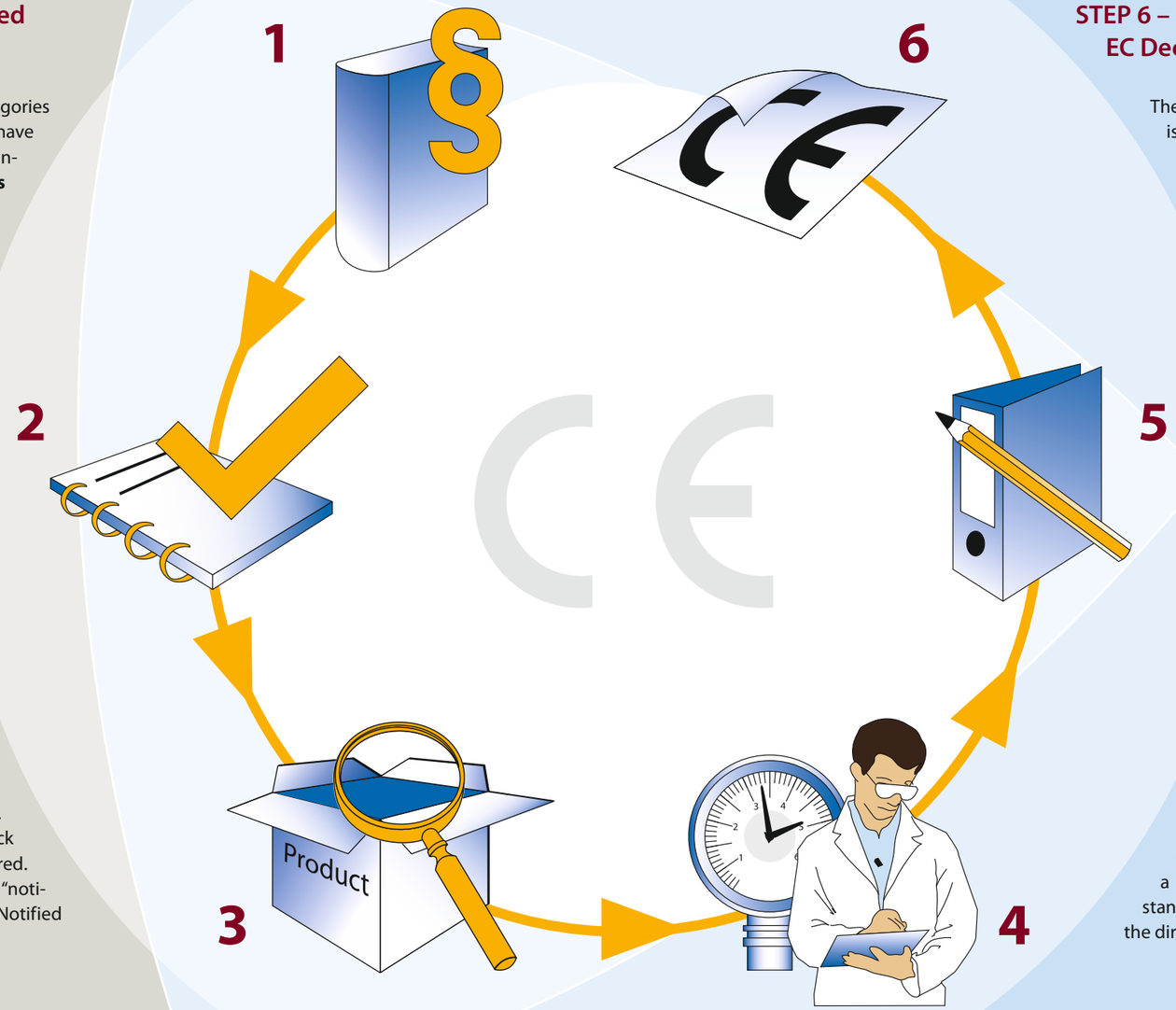
There are **more than 20 directives** setting out the product categories requiring CE marking. The essential requirements that products have to fulfil (e.g. safety) are harmonised at EU level and are set out in general terms in these directives. **Harmonised European standards** are issued with reference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

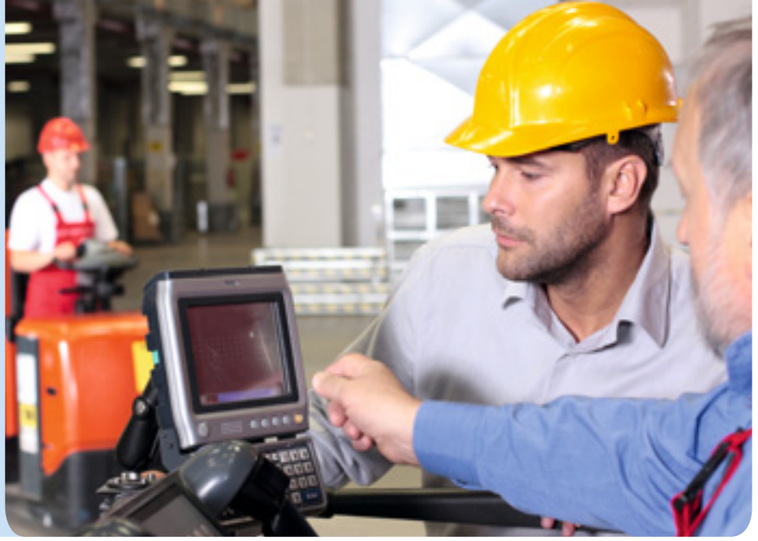
The CE marking must be **affixed by the manufacturer**, or by his authorised representative within the EEA or Turkey. It must be affixed according to its legal format visibly, legibly and indelibly to the product or its data plate. If a Notified Body was involved in the production control phase, its 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 appropriate 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.



Notified Body

There is a common misunderstanding that products with the CE marking have been inspected and approved by some kind of authority. In reality, many products can be assessed by the manufacturer itself. The ability to carry out this process is particularly useful for small and medium-sized enterprises that may not have the resources for checks by external bodies.

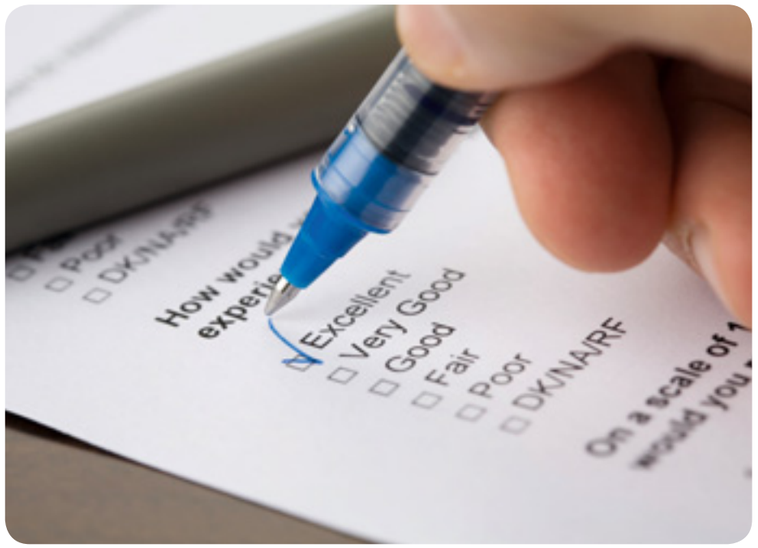
However for certain product groups presenting a higher potential impact on the public interest, such as dangerous machines or large pressure valves, it is necessary to involve a "Conformity Assessment Body", which will check the product and decide whether it fulfils the legislative requirements that apply to it and whether an EC Declaration of Conformity can be issued. **EU directives clearly indicate for which product types a Conformity Assessment Body must be involved in the conformity assessment process**.

Each country is responsible for designating the Conformity Assessment Bodies which will carry out conformity assessment for each directive within their territory, and for notifying them to the European Commission. These bodies are listed in the NANDO (New Approach Notified and Designated Organisations) database.

The "Notified" Bodies must meet certain requirements, including technical competence, impartiality and confidentiality. The Notified Body assessments include the inspection and examination of a product, its design and how it is manufactured. Once the Notified Body has confirmed the product's compliance, the manufacturer can issue the EC Declaration of Conformity and affix the CE marking on the inspected product.

Whether or not a Notified body has been involved, it is always the manufacturer who affixes the CE marking, issues the EC Declaration of Conformity, and who is responsible for the compliance of a product.

National authorities carry out checks to ensure that the Notified Bodies accomplish their duties.



Harmonised standards – A reliable way to ensure compliance

In removing the complicated mix of national laws, the guiding principle of the EU is to minimise harmonised legislation to the essential requirements for protecting the public interest. This includes health and safety issues, as well as the protection of the environment. Across the market, harmonisation legislation is removing administrative burdens to free up the movement of goods.

The legislation embodied in the EC directives covers the hazards to be addressed and the final goals to be attained. Alongside these directives, standards which apply across the EEA are being drafted by the European Standards Organisations (CEN, CENELEC, ETSI)[2] with reference to these directives. These are called harmonised standards and are far more technical than the EC directives. They can be recognised by the letters "EN" placed before the standard number. **While these standards are not mandatory, they adhere closely to the directives, express in detailed technical terms the essential requirements and are a reliable way for the manufacturer to achieve conformity**.

[2] www.cen.eu, www.cenelec.eu, www.etsi.org

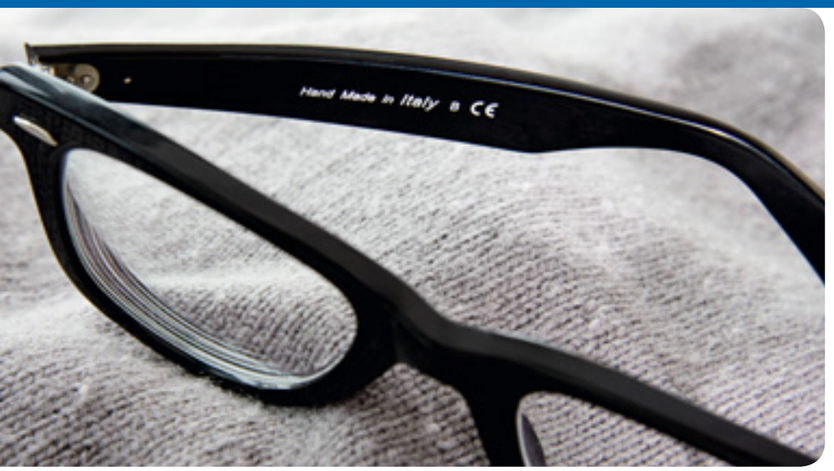
They are updated by the European Standards Organisations to keep up with new developments and technologies.

If manufacturers implement the harmonised standards, there is a "presumption of conformity" for the products in question with relevant EU directives.

Standardisation is a voluntary process where technical specifications are developed by independent standards bodies. The standards are based on a consensus among a variety of interested parties, including small and medium-sized enterprises, consumers, trade unions, environmental non-governmental organisations, public authorities and others.

Since the mid-1980s, the European Union has increasingly made use of harmonised standards to support better regulation and to help bolster the competitiveness of European industry. Harmonised standards can be considered a useful tool for implementing the EU directives in an efficient manner.

How is public interest protected?



The CE marking provides the first indication that the necessary assessments have been carried out, before the product in question is placed on the market, in order to ensure its compliance with the legislative requirements. Nothing prevents authorities from making additional checks for the sake of protecting public interest.

After being placed on the market, CE-marked products are subject to inspection by market surveillance authorities. Furthermore, national authorities ensure proper enforcement of CE marking provisions and pursue violations and abuse.

Indeed, European legislation provides for a complete market surveillance framework for products covered by Community harmonisation legislation. **Sanctions are laid down in the relevant national legislation of the Member States**.

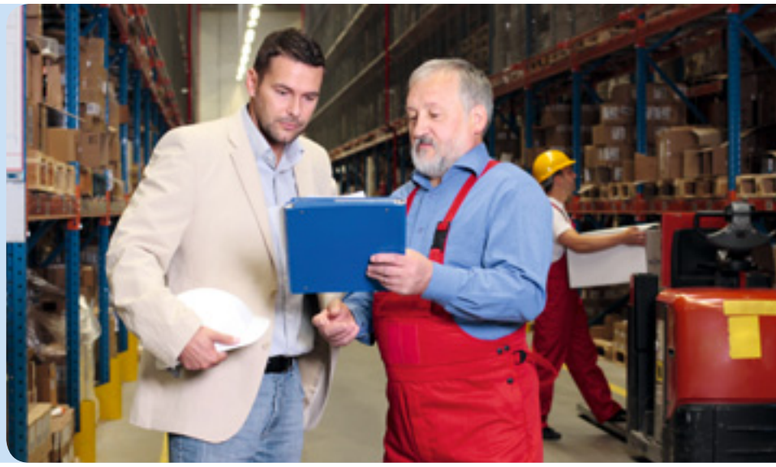
The objectives of the market surveillance framework are three-fold: (a) ensuring that products placed on the market (including products imported from third countries) are safe and compliant with the related legislation, (b) ensuring the CE marking is lawfully affixed, and (c) ensuring a consistent and equivalent enforcement of the Community legislation (level playing field for economic operators and reduction of fraud).

The Commission, in co-operation with the Member States, is responsible for the enforcement of this framework. In particular, this includes: coordination of the national programmes; organisation of market surveillance (monitoring of complaints, accidents, resources, powers, etc.); national measures for market surveillance (ensure adequate checks by national authorities and coordinate rules for entering the manufacturer's premises or destroying unsafe products, if necessary, informing the public, cooperating with the relevant stakeholders, etc.); coordination of the organisation of applying restrictive measures; cooperation and exchange of information (for serious and non-serious risks); sharing of resources, etc.

In order to avoid any confusion, affixing markings, signs or inscriptions to a product, which are likely to mislead third parties regarding the meaning or form of the CE marking, are prohibited. Any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking are not thereby impaired.

The CE marking must be affixed visibly and legibly to the product or to its data plate. Where that is not possible because of the nature of the product, it must be affixed to the packaging and to the accompanying documents. If a Notified Body was involved in the production control phase, its identification number must also be displayed.

Who should be involved and what documentation is necessary?



When beginning the conformity assessment procedures, you should make sure that the right people in your company are involved. Employees with expertise in the following fields should be informed about the CE marking procedure and have a clearly defined role in the process.

- **Legal:** This person should have a clear understanding of the EC directives and harmonised standards that apply to the product, as well as the legal responsibility the company assumes by affixing the CE marking.
- **Design and manufacturing:** Representatives from the teams responsible for these phases of production will provide information necessary for the assessment process, as well as the technical documentation.
- **Compliance:** At least one person should oversee the entire CE marking process. He or she should be knowledgeable in the legal, design and manufacturing aspects relevant to the conformity process and should make sure that the technical documentation and EC Declaration of Conformity are correctly drafted. He or she should be available as the contact person if national authorities request the documentation or additional information.

Manufacturers are obliged to write up technical documentation that demonstrates that a product complies with the applicable requirements. The manufacturer or authorised representative is responsible for keeping the technical documentation for at least ten years from the last date that the product was manufactured, unless the directive specifies a different timeframe.

Each directive specifies the content of the technical documentation for each product type. If more than one directive applies to that product, all required information must be included. As a rule, the documentation should cover the design, manufacture and operation of the product. The details included in the documentation depend on the nature of the product and the technical aspects that are necessary to demonstrate the conformity of the product in meeting the essential requirements of the directives or the specifications of the harmonised standards.

The language of the technical documentation is also important and several directives require that it is written in an official language of the Member State where the compliance procedures are carried out. If a directive requires the involvement of a Notified Body, the documentation must be in a language that is understood by the body, even if this was not explicitly mentioned in the Directives.

The manufacturer or its authorised representative must also draw up an EC Declaration of Conformity once the product is ready to go on the market. The declaration should contain all relevant information to identify the directives that apply to the product, the contact information of the manufacturer or authorised representative, and, where appropriate, the Notified Body and references to the harmonised standards or other normative documents.

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

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

European Commission
Directorate-General for Enterprise and Industry
B-1049 Brussels, Belgium
Fax: +32 2 299 08 31
E-mail: entr-reg-approach-for-free-circ @ec.europa.eu

Enterprise Europe Network
http://www.enterprise-europe-network.ec.europa.eu/

ec.europa.eu/CEmarking

ISBN 978-92-79-15674-8
9 789279 156748
NB-80-10-346-EN-C
doi:10.2769/59895