

7. CE marking ⁽¹²⁰⁾

7.1. Principles of CE marking

- The CE marking symbolises the conformity of the product with the applicable Community requirements imposed on the manufacturer.
- The CE marking affixed to products is a declaration by the person responsible that:
 - ➔ the product conforms to all applicable Community provisions, and
 - ➔ the appropriate conformity assessment procedures have been completed.

CE marking symbolises conformity to all the obligations incumbent on manufacturers for the product by virtue of the Community directives providing for its affixing. When affixed to products it is a declaration by the natural or legal person having affixed or been responsible for the affixing of CE marking that the product conforms to all applicable provisions, and that it has been subject to the appropriate conformity assessment procedures. Hence, Member States are not allowed to restrict the placing on the market and putting into service of CE marked products, unless such measures can be justified on the basis of evidence of the non-compliance of the product ⁽¹²¹⁾.

7.2. Products to be CE marked

- The CE marking is mandatory and must be affixed before any product subject to it is placed on the market and put into service, save where specific directives require otherwise.
- Where products are subject to several directives, which all provide for the affixing of the CE marking, the marking indicates that the products are presumed to conform to the provisions of all these directives.
- A product may not be CE marked, unless it is covered by a directive providing for its affixing.

The obligation to affix the CE marking extends to all products within the scope of directives providing for its affixing, and which are intended for the Community market ⁽¹²⁴⁾. Thus, the CE marking must be affixed:

- to all new products, whether manufactured in the Member States or in third countries;
- to used and second-hand products imported from third countries; and

The directives providing for the affixing of the CE marking mostly follow the principles of the New Approach and the Global Approach, but this is in itself irrelevant for the application of the CE marking. In fact, CE marking can be introduced in Community legislation as legal conformity marking if:

- the method of total harmonisation is used, which means that diverging national regulations that cover the same public interests as the directive are prohibited; and

- the directive contains conformity assessment procedures according to Decision 93/465/EEC ⁽¹²²⁾.

As a general rule, all New Approach directives provide for the affixing of the CE marking. In duly justified cases a total harmonisation directive that follows Decision 93/465/EEC may provide for a different marking instead of the CE marking ⁽¹²³⁾.

Since all products covered by New Approach directives bear CE marking, this marking is not intended to serve commercial purposes. Neither is the CE marking a mark of origin, as it does not indicate that the product was manufactured in the Community.

- to substantially modified products that are subject to directives as new products.

Directives may exclude the application of the CE marking on certain products, even if the directive otherwise applies to the product. As a general rule, such products are subject to free circulation ⁽¹²⁵⁾, if:

- they are accompanied by a declaration of conformity (as is the case for safety components referred to in the Directive on machinery and partly completed boats referred to in the Directive on recreational craft);

- they are accompanied by a declaration of compliance (as is the case for products play-

ing a minor part with respect to the health and safety listed in accordance with the Directive on construction products);

- they are accompanied by a statement (as is the case for custom-made medical devices and devices intended for clinical investigations referred to in the Directives on active implantable medical devices and medical devices, and devices intended for performance evaluation referred to in the Directive on *in vitro* diagnostic medical devices);

⁽¹²⁰⁾ This Chapter does not apply to the Directive on the high-speed rail system.

⁽¹²¹⁾ For market surveillance, see Chapter 8.

⁽¹²²⁾ Conformity assessment according to the Directive relating to construction products does not follow Decision 93/465/EEC. However, this Directive provides for the CE marking.

⁽¹²³⁾ The Directive on marine equipment does not provide for a CE marking, but instead for a special conformity mark to which the guidelines of this chapter generally apply.

⁽¹²⁴⁾ For products submitted to directives, see Section 2.1.

⁽¹²⁵⁾ In addition, the Directive on pressure equipment entitles Member States to authorise, on their territory, the placing on the market and the putting into service by users, of pressure equipment or assemblies not bearing the CE marking, but that have been subject to a conformity assessment carried out by a user inspectorate instead of a notified body.

- they are accompanied by a certificate of conformity (as is the case for components referred to in the Directive relating to potentially explosive atmospheres which are intended to be incorporated into equipment or protective systems, and fittings referred to in the Directive relating to gas appliances);
- the product bears the manufacturer's name and an indication of maximum capacity (as is the case for instruments not subject to conformity assessment according to the Directive relating to non-automatic weighing instruments); or
- the product is manufactured in accordance with sound

The manufacturer, whether established inside or outside the Community, is the person ultimately responsible for the conformity of the product with the provisions of the directive and for the affixing of the CE marking. The manufacturer may appoint an authorised representative established in the Community to act on his behalf. The person responsible for placing the product on the market may, exceptionally, be deemed to have assumed the responsibilities of the manufacturer ⁽¹²⁷⁾.

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 directives. This will usually be at the end of the production phase. This poses no problem if, for example, the CE marking is on a data plate that is not affixed to the product until after the final inspection. However, if the CE marking forms an inseparable part of the product, or of a component, for example by stamping or casting, the marking can be affixed at any other stage of the production phase, provided that the conformity of the product is verified as appropriate throughout the production phase.

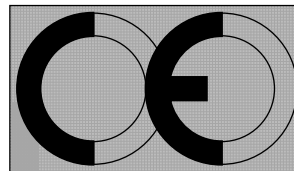
The CE marking shall, as a rule, be affixed to the product or to its data plate. In addition, it can be affixed, for instance, to the packaging or to the accompanying documents. However, it may exceptionally be moved from the product or its data plate if this rule cannot be followed. This would be justified where affixing it to the product was impossible (for example on certain types of explosives), or not possible under reasonable technical or economic conditions, or where the minimum dimensions could not be respected, or it could not be ensured that the CE marking was visibly, legibly and indelibly affixed. In such cases, the CE marking has to be affixed to the packaging, if it exists, and to the accompanying document, where the directive concerned provides for such docu-

engineering practice (as is the case for certain vessels referred to in the Directives relating to simple pressure vessels and pressure equipment).

During the transitional period of a directive the manufacturer usually has the choice to either meet the requirements of the directive or the relevant national regulations. The option chosen and, hence, the extent of the conformity expression enshrined in the CE marking shall be clarified by the manufacturer in the EC declaration of conformity, and in the documents, notices or instructions accompanying the product ⁽¹²⁶⁾.

7.3. Affixing of the CE marking

- **The CE marking must be affixed by the manufacturer, or by the authorised representative established within the Community.**
- **The CE marking must take the form below. If the CE marking is reduced or enlarged the proportions must be respected.**



- **The CE marking must be affixed visibly, legibly and indelibly to the product or to its data plate. However, where this is not possible or not warranted on account of the nature of the product, it must be affixed to the packaging, if any, and to the accompanying documents, where the directive concerned provides for such documents.**
- **Where a notified body is involved in the production control phase according to the applicable directives, its identification number must follow the CE marking. The manufacturer or the authorised representative established in the Community affixes the identification number, under the responsibility of the notified body.**

ments. The CE marking on the product may neither be omitted nor be moved to the packaging or accompanying documents on purely aesthetic grounds ⁽¹²⁸⁾.

The CE marking symbolises conformity to essential public interests covered by the directives in question. Therefore, it is to be considered as essential information to Member States' authorities as well as other relevant parties (for example distributors, consumers and other users). Accordingly, the requirement for visibility means that the CE marking must be easily accessible for all parties. It could, for instance, be affixed on the back or underside of a product. A minimum height of 5 mm is required to ensure that it is legible ⁽¹²⁹⁾. It shall also

⁽¹²⁶⁾ For the transitional period, see Section 2.4.
⁽¹²⁷⁾ See Sections 3.1 – 3.3.

⁽¹²⁸⁾ The provisions regarding the affixing of the CE marking vary between directives; in some sectors they are more stringent (see for instance Directives relating to simple pressure vessels, machinery, non-automatic weighing instruments, active implantable medical devices, gas appliances, medical devices, telecommunications terminal equipment, hot-water boilers, recreational craft (as regards boats), lifts, potentially explosive atmospheres, refrigeration appliances, pressure equipment, in vitro diagnostic medical devices, and radio and telecommunications terminal equipment), and in other sectors more flexible (see for instance Directives relating to low voltage equipment, toys, construction products and electromagnetic compatibility).
⁽¹²⁹⁾ According to the Directives relating to machinery, personal protective equipment, active implantable medical devices, medical devices, potentially explosives atmospheres, lifts (as regards safety components), in vitro diagnostic medical devices, and radio and telecommunications terminal equipment the minimum dimension of the CE marking may be waived for small devices. The same applies to the conformity mark provided for in the Directive on marine equipment.

be indelible so that it cannot be removed under normal circumstances without leaving noticeable traces (for example some product standards use a rub test with water and petroleum spirits). However, this does not mean that the CE marking must form an integral part of the product.

A notified body may be involved in the design phase, the production phase, or both, depending on the conformity assessment procedures applied ⁽¹³⁰⁾. The CE marking shall only be followed by the identification number of the notified body if it is involved in the production phase. Thus, the identification number of a notified body involved in conformity assessment according to module B does not follow the CE marking. Sometimes several notified bodies are involved in the production phase, which is possible where more than one directive is applicable. In these situations several identification numbers follow the CE marking.

Thus, the CE marking may appear on products either:

- *without* an identification number, which means that a notified body did not intervene in the production phase (module A, modules Aa1 and Cbis1 where the notified body only intervened during the design phase, and the combination of modules B and C); or
- *with* an identification number, which means that the notified body assumes the responsibility:

- for the tests on specific aspects of the product (modules Aa1 and Cbis1 where the notified body intervened during the production phase);
- for product checks (modules Aa2 and Cbis2);
- for the examinations and tests carried out to assess the conformity of the product during the production control phase (modules F, Fbis and G); or
- for the assessment of production, product quality assurance or full quality assurance (modules D, E, H and their variants).

The CE marking and the identification number of the notified body do not necessarily have to be affixed within the Community. They may be affixed in a third country, for example if the product is manufactured there and the notified body carried out conformity assessment in accordance with the directive in that country. The CE marking and the identification number can also be affixed separately, as long as they remain combined.

The CE marking consists exclusively of the letters ‘CE’ followed by the identification numbers of any notified body involved in the production phase. Pictograms or other marks indicating, for instance, the category of use are, according to some New Approach directives, complementary to the CE marking but do not form part of it ⁽¹³¹⁾.

7.4. CE marking and other marks

● **CE marking is the only marking which symbolises conformity to all the obligations incumbent on manufacturers for the product as required by the applicable directives providing for its affixing. Member States shall refrain from introducing any reference to another conformity marking into their national regulations, which would signify conformity with objectives that relate to the CE marking.**

● **A product may bear additional markings and marks, provided that they:**

- ➔ **fulfil a different function from that of the CE marking,**
- ➔ **are not liable to cause confusion with it, and**
- ➔ **do not reduce its legibility and visibility.**

The CE marking replaces all mandatory conformity markings having the same meaning, which existed before harmonisation took place. Such national conformity markings are incompatible with CE marking and would constitute an infringement of the applicable New Approach directives. When transposing the directives, Member States shall incorporate the CE marking in their national regulations and administrative procedures. They shall also refrain from introducing any other conformity marking into their national legislation that has the same meaning as the CE marking.

Owners of trademarks similar to the CE marking, that were acquired before the introduction of the CE marking, will be protected against expropriation since such marks will, as a rule, not be liable to deceive market surveillance authorities, distributors, users, consumers or other third parties.

In view of the objectives of technical harmonisation, markings and marks additional to the CE marking need to fulfil a different function from that of the CE marking. Thus, they should provide an added value in signifying conformity with objectives that are different from those to which the CE marking relates (for example environmental aspects not covered by applicable directives).

The affixing of legal marking (such as a protected trademark of a manufacturer), or of acceptable certification and other marks additional to the CE marking, is allowed to the extent that such markings or marks do not create confusion with the CE marking, and that they do not reduce the legibility and visibility of the CE marking. This confusion may either refer to the meaning or form of the CE marking ⁽¹³²⁾. Whether or not a marking or mark is confusing should be decided from the point of view of all relevant parties likely to come into contact with it.

⁽¹³⁰⁾ See Section 5.1 and Annex 7.

⁽¹³¹⁾ For instance, the symbol to indicate that telecommunications terminal equipment is suitable for connection to the public telecommunications network, the energy performance label required for hot-water boilers, the explosion protection symbol required for equipment and protective systems intended for use in potentially explosive atmospheres, or the equipment class identifier required for radio equipment. Some directives also require that the last digits of the year in which the CE marking was affixed is indicated.

⁽¹³²⁾ The wording used in various New Approach directives varies slightly, but any other interpretation would prevent achieving the purpose of the applicable provisions.