The CE marking: separating fact from fiction

DAVID LOHBECK, TUV RHEINLAND OF NA INC

As a designer and user of European electronic products, you should be aware that a product's CE marking does *not* imply a particular level of quality; it simply indicates that a product conforms to relevant European directives and standards.

The European Union's (EU) goal of single-market access has finally arrived and, for the most part, appears to be working. The EU's new approach reduces, or in many cases eliminates, the legal and technical differences among the member-state countries that existed under the old approach. The new approach is based on four principles: harmonized directives, harmonized standards, harmonized conformity-assessment procedures, and CE marking.

The CE (European Conformity) marking is a symbol that manufacturers affix to products or machines to indicate that a product conforms to all relevant European directives and standards (**Figure 1a**). The CE marking is generally based on compliance with European standards, some of which have been in place for decades. Various directives and standards contain the requirements for this marking, including the Low-Voltage Directive (73/23/EEC), the Machinery Directive (89/392/EEC), and the Electromagnetic Compatibility (EMC) Directive (89/336/EEC). These directives, along with the appropriate European standards, cover all safety, EMC, health, and environmental concerns. CE marking of machinery became effective in January 1995, EMC conformity has been a requirement since January 1, 1996, and electrical products must bear the CE marking as of January 1, 1997.

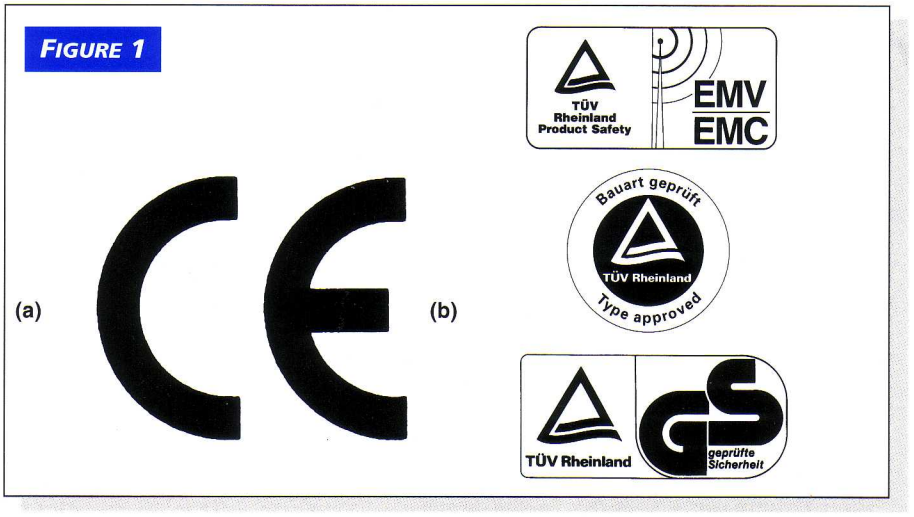
Clear up the confusion

Unfortunately, confusion still surrounds the CE marking in countries outside the EU, especially in the United States. Furthermore, the value of the CE marking for selling products has been overstated, and the associated risks of nonconformity are generally not well-understood.

The purpose of the CE marking is to allow manufacturers to place products on the market and ensure the free movement of goods. The CE marking is primarily for market control by customs inspectors and enforcement authorities. The EU did not intend the CE marking to be a sales or marketing tool.

The CE marking simply indicates that the product conforms to the relevant directives' safety and EMC requirements and that the manufacturer has performed all the necessary evaluation procedures. The "CE" symbol is not a registered trademark and is, in principle, the manufacturer's responsibility. Except for some high-risk products, most manufacturers can perform a self-assessment of their products to meet the essential requirements of the directives. In doing so, the manufacturer has a choice of meeting the minimum legal requirements or meeting the market expectations as well. In Europe, expectations vary considerably among countries.

FIGURE 1



The CE marking (a) is generally a manufacturer's self-declaration symbol indicating conformity with the essential requirements of all relevant directives; the symbol does not imply any level of quality. The highest level of conformity verification and acceptance in Europe are the voluntary product-safety and EMC-approval marks issued by European notified and competent bodies, such as TUV Rheinland (b).

You should not confuse CE marking with another mark, certificate, or approval issued by an accredited certification body, as listed in the Official Journal of the European Communities (OJEC). Regardless of the presence of a CE marking, and to achieve a higher level of quality and ensure safety/EMC compliance, customers can also demand an approval mark, certification, or test report from a European third party (a testing laboratory referred to as a "notified body" for safety or a "competent body" for EMC) (**Figure 1b**).

The following list clearly states what the CE marking is and is not:

- The CE marking is a declaration for customs inspectors and allows the product to be placed on the market;
- It is not for sales, marketing, or promotion, and it cannot guarantee sales;
- It is not a quality marking;
- It is not a mark of certification or approval;
- And it is not for components (with a few exceptions).

All products covered by the directives must by assessed for conformity by either the manufacturer or an accredited body and bear the CE marking before entry into the EU. Neither the quantity of products or machines nor the nature of the transfer relieves the manufacturer of performing the conformity assessment and affixing the CE marking. The marking applies to all products and machines (paid for or free) put into service in a public or private capacity for professional or nonprofessional use. In certain circumstances, such as at trade shows, you can bring products into the EU for a limited time with the proper warnings on the product. In this case, only the manufacturer may operate the product.

Follow steps to assess conformity

Figure 2 lists the steps necessary to affix the CE marking. An important step is "conformity assessment." The objective of the conformity-assessment procedures in the 93/465/EEC directive is to enable the authorities to ensure that products placed on the market conform to the directive's requirements and that products meet the high level of safety for a given product or product sector. There are seven procedures, or modules, in 93/465/EEC, but the applicable generic or product-specific directive sets the range of conformity choices as follows (**Figure 3**):

- Self-declaration: The self-declaration route is available for products or machines that don't require a mandatory examination, which is the case for most products and machines. The manufacturer takes complete responsibility for the assessment, testing, documentation, declaration of conformity, and application of the CE marking. A technical file must be available on demand for national enforcement authorities. Keep in mind that this process is an internal self-assessment that results in issuance of the manufacturer's own declaration of conformity and the CE marking. The buyer may demand proof of safety/EMC compliance from a European notified/competent body in the form of a mark, certificate, or test report.
- Voluntary certification: Manufacturers often have a European body, such as a notified/competent body, assess the product and apply a mark and certification for marketing purposes and as a defense of due diligence, in case there is a challenge to the product's conformity. This certification route provides confirmation of the testing accuracy and documentation to help support the manufacturer's declaration of conformity and CE marking.
- Mandatory certification: The EU does not require most products and machines to undergo mandatory certification. However, some high-risk machinery requires type examination by a European notified body. After successful testing, the EU body issues a "type-examination certificate" for machine safety or a "certificate of conformity" for EMC. The manufacturer then affixes the CE marking to the product and issues a declaration of conformity.

FIGURE 2

STEPS TO THE CE MARKING

1. IDENTIFY ALL THE APPLICABLE EU DIRECTIVES AND STANDARDS FOR THE PRODUCT IN QUESTION.
2. PERFORM THE CONFORMITY ASSESSMENT ACCORDING TO THE RELEVANT EU STANDARDS AND ESSENTIAL REQUIREMENTS OF THE DIRECTIVES.
3. MANUFACTURER CORRECTS ANY DEVIATIONS FOUND AND INCORPORATES THE NECESSARY CHANGES INTO THE PRODUCTS AND THE MANUFACTURING PROCESS.
4. ESTABLISH A TECHNICAL FILE (TEST REPORTS, DOCUMENTATION, CERTIFICATES, ETC).
5. PREPARE AND SIGN THE EU DECLARATION OF CONFORMITY.
6. AFFIX CE MARKING TO THE PRODUCT.

Six steps are necessary before affixing the CE marking to a product. A manufacturer can perform these steps by way of "self-declaration" or select a notified body for "voluntary certification."

Note that the low-voltage and machinery directives include no provisions for CE marking of components. The directives define components as any items used in the composition of the finished product. Manufacturers need to affix the CE marking only to finished products, such as electrical equipment, apparatus, systems, or machines, that are intended for the final user and placed on the market as one commercial unit. (One notable exception to this components rule under the EMC Directive are computer cards sold directly to the end user.) Components must comply with the relevant requirements but do not need CE marking because they have no autonomous use. To ensure safety compliance, product designers and manufacturers often demand third-party "type-approval marks" from notified bodies on components that the designers and manufacturers specify. These component marks help to ensure compliance with EU standards and reduce testing costs.

A product's technical file consists of the documentation necessary to demonstrate the product's conformity to the essential requirements of the directives. The file must cover the design, manufacture, and operation of the product. The file is for market-surveillance purposes and must be at the disposal of national enforcement authorities for inspection and control. The file must be readily available and can be in English or another EU language.

The necessary contents of the file depend on the applicable directive but in general consist of the following: declaration of conformity, name and address of the manufacturer, general description and identification of the product, list of the applied harmonized standards, solutions adopted to satisfy essential requirements and rationales, examination results and design calculations, test reports, designs and drawings, parts lists, operation manual, and measures adopted to ensure ongoing compliance.

The declaration of conformity is the procedure that the manufacturer or authorized representative uses to ensure and declare that the products satisfy the requirements of the applicable directives. The declaration of conformity contains the following: name and address of manufacturer or representative, description of the product, directives declared, list of applied harmonized standards, additional standards and specifications where appropriate, place and date of issue, and name and signature of authorized person.

When harmonized standards do not exist or are applied only in part, the EMC Directive sometimes mandates the use of a competent body for mandatory certification and a special file called the "technical construction file" (TCF). The TCF is common for large machines or for products that have numerous variations. The manufacturer generates the TCF in conjunction with a competent body. This process is commonly called the "TCF route" and is a certification process that requires the competent body to issue a certificate of conformity. Under the TCF route, the manufacturer may place the CE marking on the product only after satisfactory testing, completion of the TCF, and receipt of the certificate from the competent body.

Limiting liability

By signing the declaration of conformity, the manufacturer or authorized representative in Europe is responsible for all aspects of the assessment, testing, documentation, declaration, and CE marking. In all cases, the manufacturer or representative assumes the responsibility and liability even when using the services of a consultant or test lab. The liability is not transferable to the consultant, outside test lab, or notified body.

Notified bodies can subcontract certain testing activities to private laboratories. The rules concerning subcontracting of work by notified bodies to outside laboratories are strictly limited to specific tasks and stipulate that the notified body itself must perform the assessment, appraisal, and certification. Notified bodies can subcontract testing to audited laboratories, but the notified body must directly supervise the procedures and tests. Only the European body certificate and validated test report have the support of the notified or competent body. Some test labs improperly issue so-called EC "certificates." In Europe, this right is exclusively reserved for European accredited certification bodies.

Risks of nonconformity

The objective of the Product Liability Directive (85/374/EEC) is to protect consumers from defective products. This directive states that all producers involved in production are liable, insofar as the finished product, component, or any raw material they supply is defective. The liability extends to importers and persons who present themselves as producers by affixing their name. The directive does not set any financial ceiling on the producer's liability.

A VIEW FROM THE EUROPEAN COMMISSION

The European Parliament posed written questions concerning the CE marking to the European Commission. Martin Bangemann, vice president of the European Commission, published answers in the Official Journal of the European Communities (OJEC; 95/C 326/50). A summary of the first four questions and answers are as follows:

Question: Does the CE mark on a product guarantee free access to the whole internal market for the product concerned? Answer: Yes. The CE marking can be described as a "passport for industrial products," allowing them to circulate freely throughout the European Economic Area (EEA). It is a mandatory conformity marking that shows the compliance of products with all provisions of 16 directives that relate to safety, public health, consumer protection, or other essential requirements of Community interest.

Question: Is the CE verification mark recognized in all countries of the European Union? Answer: Yes. The CE marking addresses the market-surveillance authorities of the member states and aims to facilitate their surveillance tasks by visibly demonstrating conformity.

Question: Is the Commission aware that, in some countries in the Union, other seals of approval are still used in addition to the CE verification mark? Answer: Yes. Other product marks are prohibited only if they are likely to deceive third parties as to the meaning and form of the CE marking or if they are liable to cause confusion with the CE marking. Quality markings, as opposed to the CE marking, are voluntary...and thus have a different function from the CE marking. These other marks are therefore acceptable.

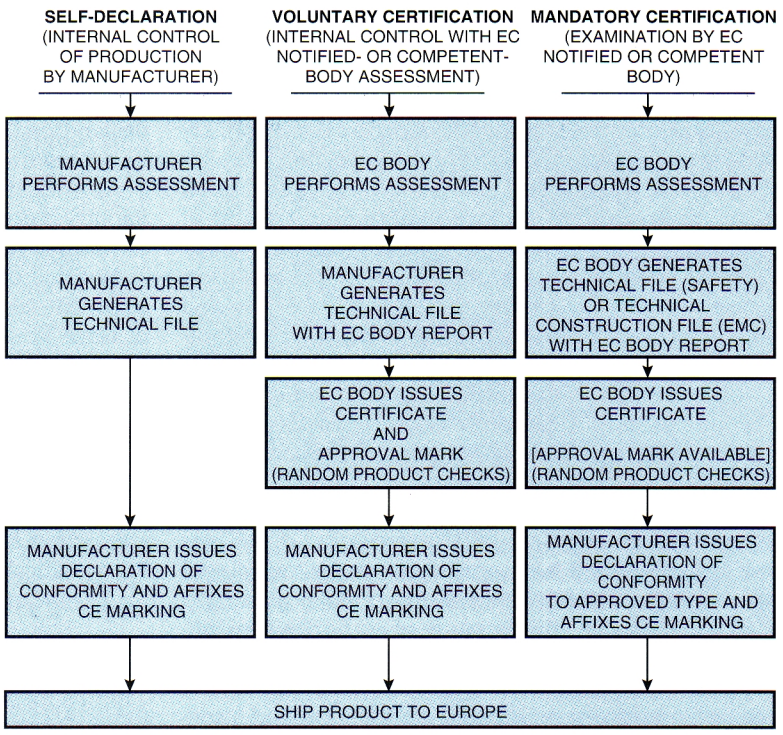
Question: Is the Commission aware that such national seals of approval are held in higher esteem? Answer: Yes. The CE marking is not a quality marking, although it is often wrongly perceived as such and then compared to other quality marks.

The primary directives clearly state that a member state can restrict a product's market access for any of the following reasons: The product fails to conform to standards, the manufacturer faultily applies the standards, the product fails to comply with good engineering practice, the product is likely to endanger a person's safety, the product does not comply with the protection requirements (EMC), or the manufacturer unduly affixed the CE marking.

The General Product Safety Directive (92/59/EEC) gives member states the authority to control nonconforming products and take appropriate measures. The severity of the action depends on the situation and the nonconformity of the product. When a member state ascertains that a product does not comply with the requirements, the manufacturer must do one or more of the following with the product: restrict or prohibit its sale, make it comply, withdraw it from the market, or destroy it. The member state must inform the commission, which in turn informs the other member states. These states can also take appropriate action and may impose financial penalties.

Under the old approach, a manufacturer was required to show only that it took reasonable measures to ensure a safe product. The new approach in directive 85/374/EEC changes the emphasis to strict liability: Consumers can initiate civil actions themselves and don't need to prove negligence. Also, the consumer can take simultaneous action against all parties involved in the supply chain.

FIGURE 3



These conformity assessment procedures show the three paths manufacturers can take to assure conformity with the relevant directives.

"Due diligence" reduces risk

Manufacturers can use certification and inspection bodies and testing laboratories to reduce the risks and hence the likelihood of damages. The EU and member states sanction notified and competent bodies to interpret directives and standards and issue test reports and certificates on conformity. Various member states, such as Germany, provide accreditation for their own bodies at the national level, which then are accredited at the European level.

Be clear on one thing: Such testing and reporting doesn't change or reduce the manufacturer's liability. However, a mark, certificate, or test report from a notified body can reduce the risk and ensure a defense of "due diligence" in the event of challenge. Due diligence means taking all reasonable steps to ensure conformity. Using testing and certification, the role of the notified body is to accurately interpret directives and standards and thereby ensure conformity. EDN

Author's biography

David Lohbeck is a manager at TUV Rheinland of NA Inc (Skokie, IL), where he has worked for 11 years. He conducts seminars and training sessions on European Union safety and EMC standards and is writing a book on European conformity. He holds a BS from Arizona State University (Tempe, AZ)

NATIONAL INSTRUMENTS™

David Lohbeck
Principal Safety Engineer

dave.lohbeck@ni.com

11500 N. Mopac Expwy.
Building C
Austin, TX 78759-3504
Tel: (512) 683-8474
Fax: (512) 683-8880
ni.com

Reprinted from **EDN** January 2,1997
©1997 CAHNERS PUBLISHING COMPANY