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## **General Introduction on Directives**

The Council of the European Union has issued a series of Directives intended to ensure the harmonization of requirements for the health and safety of individuals working with machinery. They cover all aspects of safety, including provisions covering how machinery should be designed and constructed, installed and maintained. They set out a common framework, for Member States to implement at national level, of laws, regulations and administrative procedures necessary to comply with the requirements of the Directives.

### **What is a directive?**

Directives are the best means of harmonizing the legislation between Member States. A European directive is legally binding for every Member State of the European Union and is superior to the legislation of the individual Member States. The Member State is free to decide how the directive must be implemented into national legislation. However, authority is given to national bodies to select the form and means for realising the aim of the directive.

### **What is the EU's New Approach to product certification?**

The European Union (EU) developed ["New Approach" Directives](#) to streamline product approvals for a broad range of goods in order to facilitate trade within the EU single internal market. The "Old Approach" Directives contained a high degree of technical detail. EU member states introduced national standards or regulations at a faster pace than the European Commission could finalize these "Old Approach" Directives. These national specifications often proved to be trade barriers.

New Approach Directives are limited to essential health and safety requirements for sectors such as machinery, electrical products, or medical devices. They do not cover specific products such as motor vehicles, cosmetics, or chemicals, which are still covered under the Old Approach Directives. The main difference between the New and Old Approach Directives is that under the New Approach, the technical details outlining the minimum requirements a product must meet are usually not found in the directive itself. The New Approach Directives are more general.

Technical details on how to meet these minimum health and safety requirements are left to the following three groups: 1) Manufacturers who self-certify products by meeting the requirements of the applicable directives, in some cases by using appropriate European standards; 2) the three regional European standards organizations (CEN, CENELEC and ETSI), which now develop Europe-wide standards covering product sectors falling under the New Approach Directives; and, 3) government-appointed product certification bodies (called notified bodies), which provide testing and product approvals.

Under the New Approach, the European Commission gives mandates to the European standards organizations to develop technical standards that meet the essential health and safety requirements of CE Marking directives. The New Approach Directives are designed to facilitate product certification, to maintain a high level of consumer and workplace safety, and to expand intra-European trade.

## **What is a CE marking?**

The CE Marking indicates that a product complies with the requirements of the applicable directive. These directives for products, which are called “New Approach” directives, set out essential requirements which must be met before products may be marketed or traded within the European Economic Area. Thus, to indicate that a product complies with the applicable directive, it must bear the CE Marking.

## **What does CE stand for?**

CE stands for *Conformité Européenne*, which, translated literally, means “European Conformity”. A product bearing the CE Marking accompanied with the right formalities can be traded in every country of the European Economic Area.

## **What does the CE marking mean?**

The CE marking is, in effect, a "passport" for manufacturers to market their products throughout the EEA. However, products declared characteristics will still need to satisfy the level of performance set by the Member State where it is intended to be used.

The CE marking must be affixed according to a number of rules. The marking must be no less than 5mm high, and must respect the dimensions of the graduated diagram shown in Figure 1.



**Figure 1: The CE marking**

The marking may be affixed to the product itself, to a label attached to it, on its packaging or on any accompanying documentation (e.g. a bill of lading or delivery note). Harmonised technical specifications will include details of how the marking should be affixed.

The marking must also be accompanied by details of:

- The identification of the supplier
- Indications of the relevant technical specification, along with details of classes of performance
- The last two digits of the year of manufacture
- Where appropriate, identification of any approved testing and/or certification body, and
- Where appropriate, the number of the EC Certificate of Conformity.

## **What are the advantages of the CE Marking?**

The advantages of CE Marking are that with a CE Marking on your product you have unrestricted trade within the European Economic Area because there are no more different national trade barriers for products.

Besides with the CE Marking, claims for damages will also be limited, because a safe product must be put on the market with good instructions for the user and with safety regulations. This also means that the product is safer for the consumer.

## **How do I go about getting a CE marking?**

It is necessary first to establish which Directives apply to the product. It is impossible to draw up hard-and-fast rules, and it is important to seek independent and impartial advice if you are in any doubt.

It is important also to understand that not all EC Directives relating to products, e.g. the General Product Safety Directive, require CE marking, nor that a particular Directive applies to all products that could be described by its title e.g. the Machinery Directive does not apply to every conceivable product that might be termed a machine. Most of the Directives set out 'scopes' i.e. the range of products to which they apply.

## **Must the CE marking appear on any packaging, in manuals or other supporting literature?**

In general CE marking must appear on the product but see the individual guidance for exceptions. It may also appear on the packaging, in manuals or other supporting literature, but again it is best to study the guidance.

## **Is ISO 9000 required in order to get the CE marking?**

ISO 9000 registration (or EN 29000 certification) is used widely in Europe on a voluntary basis as a condition of acceptance of a manufacturer's product or as a way of recognizing the manufacturer's credibility. While a quality system such as ISO 9000 indicates that a company has an efficient organization structure and has low failure costs, it does not always certify conformity with the CE marking directives. However,

some directives require use of a quality management system as part of the conformity assessment.

For example, the Machine Directive requires manufacturers to set up a quality control system to make sure that future products coming off an assembly line meet CE marking requirements. However, the quality control system does not have to be ISO 9000, although ISO 9000 is a good choice, since it is widely recognized. The Medical Device Directive does require ISO 9000 (EN 13485) as part of the conformity assessment process.

## **Can a product fall under the scope of more than one New Approach Directives?**

Yes.

There are undoubtedly a number of products, particularly in the mechanical and electrical services field, that will simultaneously be under the scope of a number of EC Directives (e.g. the Low Voltage Directive, the Electromagnetic Compatibility Directive, the Machinery Directive, the Construction Products Directive).

## **What is the importance of standards?**

A Standard is a published specification that establishes a common language, and contains a technical specification or other precise criteria and is designed to be used consistently, as a rule, a guideline, or a definition. Standards are applied to many materials, products, methods and services. They help to make life simpler, and increase the reliability and the effectiveness of many goods and services we use.

Standards are designed for voluntary use and do not impose any regulations. However, laws and regulations may refer to certain Standards making compliance with them compulsory. For example, the format of credit cards, Standard number MSA EN ISO/IEC 7810:1996 defines their dimensions. Adhering to this Standard means that the cards can be used worldwide.

## **What is a European Standard?**

European Standards are a key component of the Single European Market. Though rather technical and unknown to the general public and media, they represent one of the most important issues for business. Although often perceived as boring and not particularly relevant to some organizations, managers or users, they are actually crucial in facilitating trade and hence have high visibility among manufacturers inside and outside the European territory. A standard represents a model specification, a technical solution against which a market can trade. It codifies best practice and is usually state of the art.

In essence, standards relate to products, services or systems. Now, however, standards are no longer created solely for technical reasons but have also become platforms to enable greater social inclusiveness and engagement with technology, as well as convergence and interoperability within a growing market across industries.

But the European Standard is something much more relevant than this. The **Internal Regulations**, Part 2, states that the EN (European Standard) “carries with it the obligation, to be implemented at national level, by being given the status of a national standard and by withdrawal of any conflicting national standards”.

The fact that European Standards must be transposed into a national standard in all member countries guarantees that a manufacturer has easier access to the market of all these European countries when applying European Standards.

## **What is a harmonised European standard?**

It is a European standard prepared by CEN/CENELEC under a mandate from the Commission, with a view to the fulfillment the essential requirements of a New Approach Directive. So the term harmonised standard shows a direct connection to the compliance with New Approach Directives. Infact products meeting these harmonised European standards will automatically be *presumed to conform* with the European directive.

Note that the European standards referred to in the Public Procurement Directive are not necessarily harmonised standards.

## **Where do European Standards come from?**

European Standards (EN) are documents that have been ratified by one of the three European Standards Organizations, CEN, CENELEC or ETSI. They are designed and created by all interested parties through a transparent, consensual process.

Standards are written by CEN, the European standards organisation, on the basis of a mandate (a contracted instruction) from the Commission. For products with an electric or electronic dimension, standards will be written by CENELEC.

## **Are standards mandatory?**

No. Only the application of the EU directives is mandatory. Application of the standards is voluntary. It is therefore not illegal to depart from the standards and conformity with the standards does not necessarily provide protection against liability.

## **What are Notified / Approved / Competent Bodies? How can I find one?**

These are bodies appointed by each Member State under the appropriate national regulations to conduct third-party conformity assessment procedures to the product in question or its production processes, as required by the Directives, in order that it may be CE-marked. The procedures vary according to the Directives and third-party involvement is not compulsory for all products. Manufacturers can use the services of Notified/Approved/Competent Bodies in any member State of the European Community.

A list of these Bodies can be obtained from the [European Commission's website](#).

## **What are the conformity assessment procedures?**

Conformity assessment is defined as: "any activity concerned with determining directly or indirectly that relevant requirements are fulfilled." Conformity assessment procedures provide a means of ensuring that the products, services, or systems produced or operated have the required characteristics and that these characteristics are consistent from product to product, service to service, or system to system.

Conformity assessment includes: sampling and testing; inspection; certification; management system assessment and registration; accreditation of the competence of those activities and recognition of an accreditation program's capability. A specific conformity assessment process may include one or more of these conformity assessment activities. While each of these activities is a distinct operation, they are closely interrelated. In addition, standards are interwoven into all aspects of these activities and can have a major impact on the outcome of a conformity assessment process.

Conformity assessment activities form a vital link between standards (which define necessary characteristics or requirements for products) and the products themselves. Together standards and conformity assessment activities impact almost every aspect of life in Europe.