



CE Marking:

The goal of the European Union's standardization program under the "**New Approach**" is to streamline technical harmonization and the development of standards for certain product groups, including, but not limited to pressure equipment, machinery, toys, construction products, electromagnetic compatibility, personal protection equipment, non-automatic weighing machines, medical devices, gas appliances, hot water boilers, and telecommunication terminal equipment. Under the new approach, directives cover essential safety or other performance requirements in the general public interest. The three regional European standards organizations, CEN, CENELEC and ETSI are mandated by the Commission to develop technical standards that are consistent with the essential health and safety requirements of EU directives.

Products that meet the essential technical standards outlined by CEN, CENELEC and ETSI would be presumed to conform to the requirements of EU directives and be allowed to circulate freely within the European Union. A manufacturer can choose not to comply with the CEN/CENELEC/ETSI standards, but then must demonstrate the product meets the essential safety and performance requirements. A product manufactured in conformity with EU legislation in one Member State will be guaranteed automatic access to the markets of all the other Member States. U.S. manufacturers who obtain the CE mark also will be guaranteed access to all of the markets in the Member States of the European Union.

It is important to note that the new approach deals with large families of products--machinery, gas appliances, pressure equipment, toys, and construction products--or horizontal risks such as those addressed in the EU's Electromagnetic Compatibility Directive, as opposed to being product-based as under the old approach. It is possible that some products may be governed by more than one directive because different risks may be dealt with under separate directives.

EU directives are addressed to the Member States who have to transpose them into national law. The directives define a schedule for adoption, publication and implementation of national provisions. New approach directives also recognize a transitional period during which existing national provisions and new legislation will co-exist. In such cases, the manufacturer has a choice of following either of these series of conditions.

The European Commission describes the CE mark as a "passport" that allows manufacturers to circulate industrial products freely within the internal market of the EU. In cases where more than one directive may apply, the CE mark can only be affixed if the product complies with all of the appropriate provisions in all of the directives applicable to the product.

The CE mark addresses itself primarily to the national control authorities of the Member States and its use simplifies the task of essential market surveillance of regulated products. Although CE marking is intended primarily for inspection purposes by EU member state inspectors, the consumer may well perceive it as a quality mark.

The CE mark must be affixed to the product, to its data plate or, where this is not possible or not warranted on account of the nature of the product, to its packaging, if any, and to the accompanying documents by the manufacturer, the authorized representative in the community or in exceptional cases by those responsible for placing the product on the market. The CE mark must be affixed visibly, legibly and indelibly. Where special provisions do not impose specific dimensions, the CE mark must have a height of at least 5 millimeters.

The CE mark is not intended to include detailed technical information on the product, but there must be enough information to enable the inspector to trace the product back to the manufacturer or the authorized agent established in the EU. This detailed information should appear not next to the CE mark, but rather on the **declaration of conformity**, the **certificate of conformity** (which the manufacturer or authorized agent must be able to provide at any time together with the product's technical file) or the documents accompanying the product. New approach legislation provides for the issue of a declaration of conformity by the manufacturer or sometimes it requires a certificate of conformity by an independent certification body.