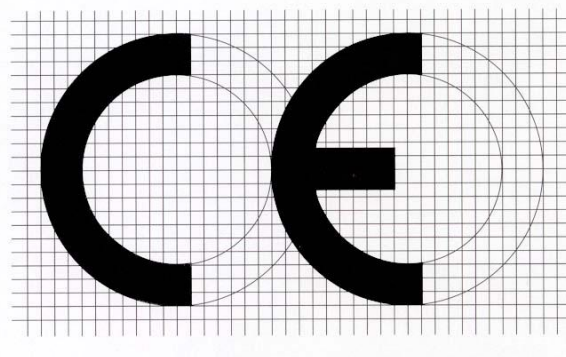


# CE Marking

*An Overview of the Nuts & Bolts of CE Marking*



**What are the purpose and scope of the CE marking system?**

The CE marking is a symbol that indicates that a particular product complies with European product safety, health and environmental requirements. This system covers approximately half of all U.S. products exported to Europe.

The CE marking system promotes free trade with Europe by providing a single set of safety and environmental requirements a product must meet. Before the CE marking system was developed, US exporters to Europe had to comply with multiple, and often inconsistent, sets of national regulatory requirements.

Products complying with CE marking are currently accepted in 30 European countries. This is a market of 360 million people with a GNP over \$8 trillion. CE marking is accelerating as the “globally accepted system” for ensuring product safety and environmental requirements. Possible extensions to other areas of the world are being negotiated at this time.

**CE marking participating countries:**

<u>European Union Countries:</u>			
Austria	Ireland	Cyprus	Slovenia
Belgium	Italy	Czech Republic	
Denmark	Luxembourg	Hungary	
Finland	Netherlands	Latvia	
France	Portugal	Lithuania	
Germany	Spain	Estonia	
Greece	Sweden	Malta	
U.K.	Poland	Slovakia	
<u>EFTA Participating Members:</u>		<u>Planning to Participate:</u>	
Iceland		Bulgaria	
Liechtenstein		Romania	
Norway			
Switzerland			
Turkey			

**The safety and environmental requirements that products must meet under the CE marking system are set forth in 23 New Approach Directives (laws).**

**“New Approach” Directives**

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|--|--|
| 1. Machinery Safety                                    | (98/37/EC)<br>(2006/42/EC starting 12/29/09) |
| 2. Low voltage   | (2006/95/EC)                                 |
| 3. Electromagnetic Compatibility                       | (2004/108/EC)                                |
| 4. Pressure Equipment                                  | (97/23/EEC)                                  |
| 5. Simple Pressure Vessels                             | (87/404/EEC)                                 |
| 6. Construction Products                               | (89/106/EEC)                                 |
| 7. Radio & Telecommunications Terminal Equipment       | (99/5/EC)                                    |
| 8. Personal Protective Equipment                       | (89/686/EEC)                                 |
| 9. Non-automatic Weighing Instruments                  | (90/384/EEC)                                 |
| 10. Active Implantable Medical Devices                 | (90/385/EEC)                                 |
| 11. Medical Devices                                    | (93/42/EEC)                                  |
| 12. In Vitro Diagnostic Medical Devices                | (98/79/EC)                                   |
| 13. Explosives for Civilian Use                        | (93/15/EEC)                                  |
| 14. Potentially Explosive Atmospheres                  | (94/9/EC)                                    |
| 15. Gas Appliances                                     | (90/396/EEC)                                 |
| 16. Recreational Craft                                 | (94/25/EEC)                                  |
| 17. Lift Safety  | (95/16 EEC)                                  |
| 18. Refrigeration Appliances                           | (96/57/EC)                                   |
| 19. Hot Water Boilers                                  | (92/42/EEC)                                  |
| 20. Noise Emission                                     | (2000/14/EC)                                 |
| 21. Cableway Installation Designed to Carry Passengers | (00/9/EC)                                    |
| 22. Ballasts for Fluorescent Lighting Efficiency       | (2000/55/EC)                                 |
| 23. Safety of Toys                                     | (87/378/EEC)                                 |

**Directives based on the “New Approach” or “Global Approach,” but do not require the CE marking symbol**

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|--|--------------|
| 1. Packaging & Packaging waste                                     | (94/62EEC)   |
| 2. Waste Electrical and Electronic Directive (WEEE)                | (2002/95/EC) |
| 3. Removal of Hazardous Substances Directive (ROHS)                | (2002/96/EC) |
| 4. High Speed Rail System  | (96/48/EC)   |
| 5. Interoperability of the Trans-European Conventional Rail System | (2001/16/EC) |
| 6. Marine Equipment  | (96/98/EC)   |
| 7. Transportable Pressure Equipment Directive                      | (1999/36/EC) |

**Directive Proposals**

- |                                    |              |
|------------------------------------|--------------|
| 1. Articles of Precious Metal      | (COM/93/322) |
| 2. Marking of Packaging            | (COM/96/191) |
| 3. EUP – Energy Utilizing Products |              |

## **New Approach Directives contain:**

- A definition of the products covered by the directive.
- A set of essential requirements that the products must meet.
- The procedures needed to establish compliance.

## **How is the CE marking system organized?**

The safety and environmental concerns listed in the New Approach directives are far too general to be useful. A manufacturer must rely on product standards to show that a product meets the underlying essential requirements of the directive. Use of European harmonized standards (HS standards), although voluntary, provide for a “presumption of conformity,” which shifts the burden of proof of conformity from the manufacturer to the surveillance authority.

For most products, a manufacturer may self-declare compliance with the appropriate directive(s). However, this may require the services of an outside testing laboratory to document product performance.

For some classes of products, as defined in the directives, the manufacturer must have the product design, performance or production quality assurance system approved by a European “Notified Body”. A “Notified Body” is a private agency that has been appointed by a national government as the review expert in that country for a particular type of product or directive.

The different requirements for an outside review have been codified into a system of “compliance assessment modules”. There are eight basic procedures, labeled as Modules A through H.

Enforcement of the CE marking system is delegated to each European member state. Different state government and private offices have been given different enforcement responsibilities in each European country. Collectively, these agencies are known as the “surveillance authorities”.

## **How can I have my products covered by the CE marking system?**

1. You will have to review the directives to determine which apply to your product, as well as, determine which compliance assessment module may or will apply to your product<sup>1</sup>.
2. You will have to find applicable standards that apply to your product. In some cases, you will find that harmonized standards have not been developed for your product. If so, you will have to identify other standards to use that effectively address the same concerns.

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<sup>1</sup> Depending on the directive and the risk classification of a product, a manufacturer will have a choice on what compliance assessment module to use.

3. You may need to ask a third party to test your product for compliance with the standards.
4. You may need to hire a Notified Body to review the design, performance and/or manufacturing quality assurance system for your product. The conformity assessment procedure that covers your product will be specified in the directive(s).
5. You will have to develop a “Technical File” that documents product design, application of relevant directives, applied standards and other relevant documentation proving “due diligence” regarding safety and environmental hazards.
6. You will have to draft and sign a “Declaration of Conformity” that identifies the product, the manufacturer and the “authorized representative” for the manufacturer. By signing the “Declaration of Conformity,” you are legally attesting that you have met all CE marking requirements.
7. If required, you will have to appoint an “Authorized Representative” in the E.U. The Authorized Representative is your agent who holds your “Technical File” and “Declaration of Conformity” in the E.U. for at least 10 years after production of the product has ended. The surveillance authorities will contact your authorized representative if any questions arise about CE marking compliance and your product.
8. Put the CE mark logo on your products and ship them to Europe!

**Penalties for failing to meet these requirements can include the removal of your products from service, a ban on the importation of the product into the EU in the future, and/or civil and criminal punishment.**

### **Sounds simple? Where are the pitfalls?**

1. You will have to make a number of judgment calls while working through the CE mark requirements. For example, a number of key standards require the manufacturer to assess the relative seriousness of different types of risk that could be posed by a product. The results of these judgments form the basis for selecting the risk areas that will have to be addressed.
2. If there are no European harmonized standards available for your type of product, then you will have to find other standards that can be used to reduce these risks to acceptable levels. You will then have to justify your choice of standards in the technical file. There is no “presumption of conformity” given to products that do not use HS or EN standards, even if they have not been developed yet.
4. You may have to hire a third party to review your product design, performance and/or manufacturing quality assurance program. The affiliates that are in the

U.S. vary widely in their scope of authority, in their charges and in what they expect from their client companies. What can a firm do to develop a cost effective working relationship with a notified body? Shop around. Discuss what the notified body's capabilities are, what they expect from you and their fees.

### **How Does This Affect Your Product?**

The following are a few common examples of the modifications manufacturers have made to their products and production procedures to comply with CE marking:

- Provide a "Declaration of Conformity." Certain products for sale in the EU require a "Declaration of Conformity," a document that attests that the manufacturer has complied with the CE marking requirements, to accompany every product.
- Include new safety measures. The machinery directive set forth additional requirements for "positive failsafe interlocks" on certain equipment, not required in the same instances in the U.S.
- Elimination of more electrical risks. The electromagnetic compatibility directive calls for the addition of an extra filter to be placed between the motor and the source of current in electric handheld power tools.
- European approvals for materials. U.S. manufacturers of pressure vessels must utilize European approved materials, and meet certain specifications and verifications for welds.
- Required quality assurance systems. For certain products, manufacturers have been required to implement an ISO 9000 quality assurance system before they could place their products on the European market.
- European countries have different electrical systems. Producers of electrical equipment have been required to make significant changes to their products' voltage, cycle, amperage, and cable polarity and ground requirements.
- Obtaining certifications from European testing organizations. High-risk medical equipment and machines are required to be tested and certified by European testing and certification organizations.

### **What can I do to make sure my product and product technical file will be accepted?**

- Do a sound job identifying all of your product's risks and applicable standards. Justify your choices in your product technical file.

- If required, work with an authorized representative in Europe that understands CE marking and your industry.

### **Closing thoughts**

New directives and standards are always being developed to address different product safety and environmental issues. Take a systematic approach to finding and qualifying new directives and standards that may apply to your product.

Products that are not covered by the CE marking system may be subject to other “old approach” directives and/or national product requirements. The “old approach” system is still in force for many products in the areas of transportation equipment, pharmaceuticals, cosmetics, and agricultural and industrial commodities.

Your products will be subject to the E.U. directives on product safety and liability. Fortunately, the product liability system in the E.U. is more predictable, and less onerous than it is in the U.S. Compliance with CE marking requirements will not shield you from liability. However, a failure to meet CE marking requirements will increase your civil and criminal liability substantially.

CE marked products may also be subject to EU performance and environmental standards. This is particularly true for medical products and noisy machines.

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*For further information or assistance please contact us.*

## **CITRA<sup>SM</sup> CE Marking Products & Services:**

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