

CE Marking Summary

What is CE Marking? Who Needs it? What is Involved?

- Never have any two letters been more meaningful to or more feared by manufacturers than the capitals "CE"
- One of the most important aspects of marketing products in the European Union (EU) today is proper use of the "CE" symbol.
- Compliance with European "Standards" is very important and is the key to meeting the essential requirements of the Directives.
- Placing the manufacturer's "CE" mark on the product and making a manufacturer's "Declaration of Conformity" is mandatory for all electrical, medical and machinery equipment NOW!
- The "CE" symbol is affixed onto the equipment by the supplier (e.g., manufacturer, distributor or importer) as its assertion that the products meet the requirement of all relevant EU Directives and therefore can be marketed and sold in the EU.
- The European Union (EU) is replacing national regulations by developing a series of legislative Directives. Currently, there are approximately 300 Directives; about 20 of these are designated as "New Approach" Directives.
- Directives are legislative instruments which Obligate Member States to introduce them into their existing national laws. The national governments of the European Union are obliged to implement the Directives into national legislation and regulations.
- Once the product is verified, tested and properly CE marked to all of the applicable Directives, that product can be legally placed on the market of any EU Member country.
- The EU Members are currently comprised of the countries of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, Iceland, Norway, Liechtenstein, Switzerland and the United Kingdom.

Demonstrating Compliance

- Compliance with the essential requirements of a Directive can be achieved through a variety of methods: Self-declaration, type testing (to be reviewed by a Notified Body in Europe), full quality assurance, etc.
- Each Directive contains requirements for the manufacturer to demonstrate compliance.
- Key elements for demonstrating compliance are:
 1. The "CE" symbol affixed on the product and the shipping container

2. The Manufacturer's Declaration of Conformity
 3. The Technical File (TF)
- The "CE" Mark: To indicate that the manufacturer claims that the requirements of all necessary Directives have been met, the "CE" symbol must be applied to each product when entering the EU.
 - Declaration of Conformity: This certificate must be submitted prior to the import and distribution of any product into the EU. It is the manufacturer's assertion that the product has met the requirements of the relevant EU Directive(s).
 - Technical File: This document must be prepared in support of the Declaration of Conformity and must contain drawings, schematics, construction sheets, test reports and the explanation of how the manufacturer has complied.
 - Some of the most common Directives are listed below:
 1. *Low Voltage Device*
 2. *Electromagnetic Compatibility*
 3. *Medical Devices*
 4. *Active Implantable Medical Device Directive*
 5. *Machinery*
 6. *Gas Appliances*
 7. *Telecom Terminal*
 8. *Toys*
 - **Low Voltage Device Directive - LVD (73/23/EEC)**
 1. Applies to electrical products with 50-1000 VAC or 75-1500 VDC.
 2. Must comply with EC recognized standards (EN, IEC..., etc.).
 3. No Notified or Competent Body is required for equipment falling under the LVD.
 4. The LVD is similar to UL testing in the U.S.
 5. The LVD mainly deals with the safety of
 - Electric Shock Hazards
 - Fire Hazards
 - Mechanical Hazards
 - **Electromagnetic Compatibility Directive - EMC (89/336/EEC)**
 - All electrical or electronic equipment falls under this Directive. This includes all products that make use of electrical energy, including battery supplied products.

- The ability of a product to operate properly in its intended electromagnetic environment without causing interference to other devices. In short, the product is compatible with its electromagnetic environment.
- EMC is comprised of two parts:
 1. Emissions: Electromagnetic noise emanating from your equipment that might interfere with other equipment. It quantifies the extent to which any given electrical or electronic system can properly function without generating electromagnetic disturbances at a level that would cause a malfunction of other equipment.
 2. Immunity: The ability of your equipment to withstand the expected environment. It quantifies the extent to which any given electrical or electronic system can properly function without the risk of malfunction within a defined electromagnetic environment.
- **Medical Device Directive - MDD (93/42/EEC)**
 - This Directive applies to many medical products. It applies to any instruments, apparatus, appliance, material or other article, whether used alone or in combination (including software necessary for its proper application intended by the manufacturer), to be used for human beings for the purpose of:
 - Diagnosis, prevention, monitoring, treatment or alleviation of disease;
 - Diagnosis, monitoring, treatment, alleviation of or compensation for any injury or handicap;
 - Investigation, replacement or modification of the anatomy or of a physiological process;
 - Control of conception;
 - All medical devices will be assigned to one of four classes; broadly, these are Class I for low-risk devices, Classes IIa and IIb for medium-risk devices, and Class III for high-risk devices.
 - Depending on the classification of the device(s), demonstrating compliance with the Medical Device Directive may require the services of a Notified Body.
 - Products must meet the essential requirements of the directives, which include product safety, EMC, biocompatibility and assessment of the manufacturer's Quality Management System (compliance with EN 46000 standards).
- **Active Implantable Medical Device Directive - AIMDD (90/385/EEC)**
 - This directive applies to active implantable medical devices. It means any active medical device, which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.