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TECHNICAL STANDARDS AND REGULATIONS

GUIDE TO CE MARKING FOR THE EU MARKET

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INTRODUCTION

CE Marking (CE-Marking), also known unofficially as "CE mark" or "EC Mark", is a mandatory mark for many products sold in the European Union (EU) market and it is often referred as the "Trade Passport to Europe" for non-EU products. The letters, "CE" - French for "Conformité Européene," indicate that the manufacturer has satisfied all assessment procedures specified by law for its product to be sold on the European market.

The **CE marking** certifies that a product has met EU consumer safety, health or environmental requirements. If you manufacture or import a product which falls within the scope of one or more of the New Approach Directives (<http://www.newapproach.org>) and wish to place your product on the market in any of the members states of the European Economic Area (EEA), then you must apply CE marking to your product against the essential requirements of all these applicable directives (See Chapter 4). The CE marking addresses itself primarily to the national surveillance authorities of the member states, and its use simplifies their task. Just looking at the CE marking will not tell surveillance authorities to which directive a given product complies. Rather, it is the declaration of conformity that contains the details of the directive(s) to which the product complies and the standards that were relied upon in assuring compliance. The CE marking affixed to products is a declaration by the person responsible that:

- the product conforms to all applicable Community provisions, and
- the appropriate conformity assessment procedures have been completed.

Why would we consider the CE Marking important? Does the time, effort and cost associated with attempting to obtain the same, justify the benefits associated? These are questions that every individual producer should eventually take on his own, based on his markets and his priorities. It should be noted that the primary goal of obtaining this mark is to gain access to the wide EU Market (particularly Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxemburg, the Netherlands, Portugal, Spain, Sweden and United Kingdom, Iceland, Liechtenstein and Norway) which tends to pay more (more profits?) for better quality goods. Below is a table that represents the share of the import value of EU (27) for some of the products covered by the CE Marking:

Imported Value of Selected Goods to the 'European Union (EU 27)

Product		Imported value in 2004	Imported value in 2005	Imported value in 2006	Imported value in 2007
Product : 68 Stone, plaster, cement, asbestos, mica, etc articles	Imports into the EU(27)	10,591,475	11,758,673	13,493,949	16,481,149
	Share of World Imports	41.66%	40.43%	40.68%	42.60%
Product : 69 Ceramic products	Imports into the EU(27)	11,946,893	12,779,280	13,789,199	16,560,005
	Share of World Imports	42.28%	41.31%	40.35%	42.24%
Product : 84 Nuclear reactors, boilers, machinery, etc	Imports into the EU(27)	481,414,099	522,439,570	581,737,784	674,589,345
	Share of World Imports	38.09%	37.20%	37.21%	37.86%
Product : 85 Electrical, electronic equipment	Imports into the EU(27)	388,561,305	418,636,540	478,552,090	538,248,889
	Share of World Imports	29.60%	28.40%	28.28%	28.29%
Product : 90 Optical, photo, technical, medical, etc apparatus	Imports into the EU(27)	102,861,039	111,547,527	127,237,473	130,612,973
	Share of World Imports	34.23%	33.47%	33.45%	31.96%

Note: All values are in USD '000

PROS and CONS

The obvious benefit of the CE Marking is that you will gain access to the European Economic Area (EEA). If the European product directives apply to your products and you want to continue to export to the European market (or introduce new products), then CE Marking is **mandatory** and therefore crucial to your success.

There will be only one set of laws and regulations to comply with in designing and manufacturing your product for the entire European Union (EU) marketplace. The multiple and conflicting national restrictions on regulated products will be eliminated. Additional benefits may include your product being made safer for end-users and consumers as well as reduced damage claims and liability premiums.



However, it should be noted that the new product directives may exceed the current national laws and regulations. These increased or new essential requirements may require a manufacturer to change their design or production processes to continue or enter into this market. You will incur costs in obtaining the product certification and any required testing. Also, the new directives and their implementation is confusing, undergoing constant change and subject to interpretation.

OBLIGATIONS

The obligation to affix the CE marking extends to all products within the scope of directives providing for its affixing, and which are intended for the Community market.

Thus, the CE marking must be affixed:

- To all new products, whether manufactured in the EU Member States or in third countries;
- To used and second-hand products imported from third countries; and
- To substantially modified products that are subject to directives as new products.

EU legislation, e.g. EU directive concerning Liability for Defective Products, make EU importers liable for the products they import, including the machinery they provide to their employees for work. Many non-EU exporters are finding that no matter how interested a prospective EU importer may be in the product, the importer will NOT risk importing non-conforming products (i.e. the products without CE Marking) which, in case of accident, may generate legal action against them. CE Marking may be achieved through several modules (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993D0465:EN:HTML>):

Module A: internal production control	Module E: product quality assurance
Module Aa: intervention of a Notified Body	Module F: product verification
Module B: EC type-examination	Module G: unit verification
Module C: conformity to type	Module H: full quality assurance
Module D: production quality assurance	

One of the most practical ways, which is preferred by many EU importers who are neither specialized in the complicated CE Marking process nor willing to take risk, is that the manufacturer designates an Authorized Representative in the EU member states who will handle the CE Mark approval, CE testing issues and ensure to meet the CE mark requirements, meanwhile the importers and/or distributors focus on the marketing and sales of the products.

The manufacturer may need only ONE Authorized Representative in EU whereas may have many importers and/or distributors. The Authorized Representative may in some cases register the product(s) in the EU member states and thus obtain a **Certificate of Registration**. The Product Certificate of Registration for CE Marking obtained from one EU member state is valid for the entire European Free Trade Association, EFTA plus EU market, i.e. 30 countries for the following products: appliances burning gaseous fuels, cableway installations to carry persons, construction products, electrical equipment, equipment and protective systems for explosive atmospheres, explosives for civil uses, hot water boilers, household refrigerators & freezers, lift, machinery, marine equipment, measuring instruments, medical devices, active implantable medical devices, in vitro diagnostic medical devices, non-automatic weighing equipment, personal protective equipment, pressure equipment, simple pressure vessels, recreational craft, radio equipment & telecommunications terminal equipment, toys and trans-European conventional rail system.

ITEMS REQUIRING CE MARKING

1. Appliances Burning Gaseous Fuels (AppliGas)

The "appliances burning gaseous fuels" used for cooking, heating, hot water production, refrigeration, lighting or washing and having, where applicable, a normal water temperature not exceeding 105 gC. Forced draught burners and heating bodies to be equipped with such burners will also be considered as appliances. The "gaseous fuel" means any fuel which is in a gaseous state at a temperature of 15 gC under a pressure of 1 bar. (Directive 90/396/EEC: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0396:EN:NOT>)

2. Cableway Installations to Carry Persons

The "cableway installations designed to carry persons" shall mean installations made up of several components, designed, manufactured, assembled and put into service with the object of carrying persons. These on-site installations are used for the carriage of persons in vehicles or by towing devices, whereby the suspension and/or traction is provided by cables positioned along the line of travel. (Directive 2000/9/EC : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32000L0009:EN:NOT>)

3. Low Voltage Electrical Equipment

The "Electrical Equipment" means **any** equipment designed for use with a voltage rating of between **50 and 1000 V** for alternating current (**A.C.**) and between **75 and 1500 V** for direct current (**D.C.**). Therefore, it is called often "Low Voltage Electrical Equipment" which includes the vast majority of electrical equipment in everyday use. (Directive

2006/95/EC:

[http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006L0095:EN:NOT)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006L0095:EN:NOT](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006L0095:EN:NOT)

4. Construction Products

The "construction product" means any product which is produced for incorporation in a permanent manner in construction works, including both buildings and civil engineering works. (Directive 89/106/EEC :

[http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0106:EN:NOT)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0106:EN:NOT](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0106:EN:NOT))

5. Equipment and Protective Systems for Used in Potentially Explosive Atmospheres

Equipment means machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy for the processing of material and which are capable of causing an explosion through their own potential sources of ignition.

Protective systems means design units which are intended to halt incipient explosions immediately and/or to limit the effective range of explosion flames and explosion pressures. Protective systems may be integrated into equipment or separately placed on the market for use as autonomous systems.

Components means any item essential to the safe functioning of equipment and protective systems but with no autonomous function. Explosive atmospheres Mixture with air, under atmospheric conditions, of flammable substances in the form of gases, vapours, mists or dusts in which, after ignition has occurred, combustion spreads to the entire unburned mixture.

Potentially explosive atmosphere means an atmosphere which could become explosive due to local and operational conditions.

(Directive

94/9/EC

:

[http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994L0009:EN:NOT)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994L0009:EN:NOT](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994L0009:EN:NOT))

6. Explosives for Civil Uses

The "Explosives" here shall mean the materials and articles considered to be such in the **United Nations recommendations** on the transport of dangerous goods and falling within **Class 1** of those recommendations. Directive: 93/15/EEC : [http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0015:EN:NOT)

7. Hot Water Boilers

The "hot-water boilers" here means a boiler fired by liquid or gaseous fuels with a rated output of between **4 kW** and **400 kW** (including 4 kW and 400 kW).

Directive 92/42/EEC: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992L0042:EN:NOT>

8. **Lift**

The "lift" here means an appliance serving specific levels, having a car moving along guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal and intended for the transport of persons, persons and goods, goods alone if the car is accessible, that is to say, a person may enter it without difficulty, and fitted with controls situated inside the car or within reach of a person inside. (Directive 95/16/EC : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0016:EN:NOT>)

9. **Machinery**

the "machinery" means:

- an assembly of linked parts or components, at least one of which moves, with the appropriate actuators, control and power circuits, etc., joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material,
- an assembly of machines which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole,
- interchangeable equipment modifying the function of a machine, which is placed on the market for the purpose of being assembled with a machine or a series of different machines or with a tractor by the operator himself in so far as this equipment is not a spare part or a tool.

(Directive 98/37/EC : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0037:EN:NOT>)

10. **Measuring**

Instruments

the "measuring instrument" means: any device or system with a measurement function that is covered by Articles 1 and 3; (Directive 2004/22/EEC : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0022:EN:NOT>)

11. **Medical Devices**

A "Medical Device" is defined: any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including software necessary for proper application, intended by manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of a disease, an injury or a handicap.
- investigation, replacement or modification of the anatomy or of a physiological process.
- control of conception

- and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted by such means.

(Directive 93/42/EEC : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0042:EN:NOT>)

12. Active Implantable Medical Devices

The "active medical device" means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity. The "active implantable medical device" 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. (Directive 90/385/EEC : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0385:EN:NOT>)

13. In Vitro Diagnostic Medical Devices

The "in vitro diagnostic medical device" means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures..

(Directive 98/79/EC : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0079:EN:NOT>)

14. Non-automatic Weighing Instruments

A "Weighing Instrument" is defined as a measuring instrument serving to determine the mass of a body by using the action of gravity on that body. A weighing instrument may also serve to determine other mass-related magnitudes, quantities, parameters or characteristics. A "non-automatic weighing instrument" is defined as a weighing instrument requiring the intervention of an operator during weighing. (Directive 90/384/EEC : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0384:EN:NOT>)

15. Radio Equipment & Telecommunications Terminal Equipment (R&TTE)

A "radio equipment" means a product, or relevant component thereof, capable of communication by means of the emission and/or reception of radio waves utilising the

spectrum allocated to terrestrial/space radio communication. A "telecommunications terminal equipment" means a product enabling communication or a relevant component thereof which is intended to be connected directly or indirectly by any means whatsoever to interfaces of public telecommunications networks (that is to say, telecommunications networks used wholly or partly for the provision of publicly available telecommunications services). (Directive 1999/5/EC : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0005:EN:NOT>)

16. Personal Protective Equipment (PPE)

The "personal protective equipment" means any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards. (Directive 89/686/EEC : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0686:EN:NOT>)

17. Simple Pressure Vessels

The "simple pressure vessel" means any welded vessel subjected to an internal gauge pressure greater than **0,5 bar** which is intended to contain air or nitrogen and which is not intended to be fired. (Directive 87/404/EEC : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31987L0404:EN:NOT>)

18. Pressure Equipment

The "Pressure Equipment" means vessels, piping, safety accessories and pressure accessories. Where applicable, pressure equipment includes elements attached to pressurized parts, such as flanges, nozzles, couplings, supports, lifting lugs, etc. 'Vessel` means a housing designed and built to contain fluids under pressure including its direct attachments up to the coupling point connecting it to other equipment. A vessel may be composed of more than one chamber.

'Piping` means piping components intended for the transport of fluids, when connected together for integration into a pressure system. Piping includes in particular a pipe or system of pipes, tubing, fittings, expansion joints, hoses, or other pressure-bearing components as appropriate. Heat exchangers consisting of pipes for the purpose of cooling or heating air shall be considered as piping.

'Safety accessories` means devices designed to protect pressure equipment against the allowable limits being exceeded. Such devices include: devices for direct pressure limitation, such as safety valves, bursting disc safety devices, buckling rods, controlled safety pressure relief systems (CSPRS), and limiting devices, which either activate the means for correction or provide for shutdown or shutdown and lockout, such as pressure switches or temperature switches or fluid level switches and 'safety related measurement control and regulation (SRMCR) devices.

'Pressure accessories` means devices with an operational function and having pressure-bearing housings.

'Assemblies` means several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole.

(Directive 97/23/EC : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31997L0023:EN:NOT>)

19. **Recreational Craft**

The "Recreational craft" means any boat of any type, regardless of the means of propulsion, from 2.5 to 24 m hull length, measured according to the appropriate harmonized standards intended for sports and leisure purposes. (Directive 94/25/EC : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994L0025:EN:NOT>)

20. **Toys**

A "toy" shall mean any product or material designed or clearly intended for use in play by children of less than 14 years of age. (Directive 88/378/EEC : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31988L0378:EN:NOT>)

21. **Packaging and Packaging Waste**

This Directive aims to harmonize national measures concerning the management of packaging and packaging waste in order, on the one hand, to prevent any impact thereof on the environment of all Member States as well as of third countries or to reduce such impact, thus providing a high level of environmental protection, and, on the other hand, to ensure the functioning of the internal market and to avoid obstacles to trade and distortion and restriction of competition within the Community. To this end this Directive lays down measures aimed, as a first priority, at preventing the production of packaging waste and, as additional fundamental principles, at reusing packaging, at recycling and other forms of recovering packaging waste and, hence, at reducing the final disposal of such waste.

(Directive 94/62/EC : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994L0062:EN:NOT>)

22. **Electromagnetic compatibility**

This Directive regulates the electromagnetic compatibility of equipment. It aims to ensure the functioning of the internal market by requiring equipment to comply with an adequate level of electromagnetic compatibility. This Directive shall not apply to:

- (a) equipment covered by Directive 1999/5/EC;
- (b) aeronautical products, parts and appliances as referred to in Regulation (EC) No 1592/2002 of the European Parliament and of the Council of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency [7];
- (c) radio equipment used by radio amateurs within the meaning of the Radio Regulations adopted in the framework of the Constitution and Convention of the ITU [8], unless the

equipment is available commercially. Kits of components to be assembled by radio amateurs and commercial equipment modified by and for the use of radio amateurs are not regarded as commercially available equipment. (Directive [2004/108/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0108:EN:NOT) : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0108:EN:NOT>)

EXCLUSIONS

Directives may exclude the application of the CE marking on certain products, even if the directive otherwise applies to the product. As a general rule, such products are subject to free circulation, if:

- they are accompanied by a declaration of conformity (as is the case for safety components referred to in the Directive on machinery and partly completed boats referred to in the Directive on recreational craft);
- they are accompanied by a declaration of compliance (as is the case for products playing a minor part with respect to the health and safety listed in accordance with the Directive on construction products);
- they are accompanied by a statement (as is the case for custom-made medical devices and devices intended for clinical investigations referred to in the Directives on active implantable medical devices and medical devices, and devices intended for performance evaluation referred to in the Directive on *in vitro* diagnostic medical devices);
- they are accompanied by a certificate of conformity (as is the case for components referred to in the Directive relating to potentially explosives atmospheres which are intended to be incorporated into equipment or protective systems, and fittings referred to in the Directive relating to gas appliances);
- the product bears the manufacturer's name and an indication of maximum capacity (as is the case for instruments not subject to conformity assessment according to the Directive relating to non-automatic weighing instruments); or
- the product is manufactured in accordance with sound engineering practice (as is the case for certain vessels referred to in the Directives relating to simple pressure vessels and pressure equipment).

During the transitional period of a directive the manufacturer usually has the choice to either meet the requirements of the directive or the relevant national regulations. The option chosen and, hence, the extent of the conformity expression enshrined in the CE marking shall be clarified by the manufacturer in the EC declaration of conformity, and in the documents, notices or instructions accompanying the product.

HOW DO YOU ACQUIRE CE MARKING?

There are a series of steps outlined below. Depending upon your product and the nature of the risks it presents, there are several alternatives also noted that may apply to your situation.

- **Identify the Directive(s) that are applicable to your product:** Determine if any directives apply to your product. If more than one applies you will have to comply with all of them.
- **Determine existing Compliance:** Determine the extent to which your product complies with the essential requirements for design and manufacturing in the applicable directive(s).
- **Identify the conformity assessment procedure:** Choose the conformity assessment procedure from the options called out by the directive for your product. The directives often use a series of questions about the nature of your product to classify the level of risk and refer to a chart called "Conformity Assessment Procedures". The chart includes all of the acceptable options available to a manufacturer to certify their product and affix the CE Marking. Options for products with minimal risk include self certification where the manufacturer prepares a declaration of conformity and affixes the CE Marking to their own product. Options for products with greater risks can require tests, audits or additional certificates from a notified body.
- **Identify if there are any Harmonised European Standards applicable to your product:** Select the applicable product standards and test methods for your product and select an independent lab If the product testing is to be done externally.
- **Authorized Representative:** Establish an authorized representative for regulatory affairs in the European Union for your product. Some directives require that a manufacturer designate in Europe a representative to produce technical documentation in a timely fashion when called upon to do so. The directives require for many products that a technical file be prepared by the manufacturer. The technical file holds information that verifies that the testing was conducted properly and that the product complies with applicable standards.
- **Prepare the Declaration of Conformity and the required supporting evidence:** Prepare a declaration of conformity that includes a list of the directives and standards that your product conforms to; product identification, the manufacturer's name, address and signature. The declaration of conformity

contains information adequate for tracing the product back to the manufacturer or the authorized representative in the European Union.

- **Affix the CE Marking to your product:** There are specific rules to adhere to in CE Marking. These rules address the size and location of the marking, affixing the CE Marking to products, packaging and material or documents shipped with the product, and specific limitations on when and who is permitted to affix the CE Marking.

NOTIFIED BODIES

Many directives require products/systems with greater risks to be independently certified; this must be done by a "Notified Body". This is an organization that has been nominated by a Member Government and has been notified by the European Commission. Notified bodies serve as independent test labs and perform the steps called out by directives. They must have the necessary qualifications to meet the testing requirements set forth in the directives. Notified bodies may be a private sector organization or a government agency. Manufacturers may choose a notified body in any member state of the European Union. Lists of notified bodies are published by the European Commission in the Official Journal of the European Communities. A Notified Body is usually able to offer some of the services required:

- product testing
- type examination certificate issue
- Technical File and design dossier evaluation
- surveillance of product and quality system
- identification of standards

A notified body may be involved in the design phase, the production phase, or both, depending on the conformity assessment procedures applied. The CE marking and the identification number of the notified body do not necessarily have to be affixed within the Community. They may be affixed in a third country, for example if the product is manufactured there and the notified body carried out conformity assessment in accordance with the directive in that country. The CE marking and the identification number can also be affixed separately, as long as they remain combined. The CE marking consists exclusively of the letters 'CE' followed by the identification numbers of any notified body involved in the production phase.

What Can A Notified Body Do For You?

Most companies need a guide to take them through the CE Marking maze. There are many expert sources of information available to you (conferences, consultants, Department of Commerce, the Internet, hot lines, etc.) all of which are more than willing to sell or give you their best opinion as to whether you may self-certify or not.

In case of third party certification the only opinion that matters is that of the agencies that certify products for the European Union. These agencies, independent and 'for profit' are called "notified bodies", there are a couple hundred of them and they are all located in Europe (some have satellites outside the EU that perform tests and submit results back to Europe for final approval). Notified bodies are authorized by European countries to serve as independent test labs and perform the steps called out by product directives, only in cases where self-certification is not possible. They must have the necessary qualifications to meet the testing requirements set forth in the directives. Notified bodies may be a private sector organization or a government agency. Manufacturers may choose a notified body in any member state of the European Union. Lists of notified bodies are published by the European Commission in the Official Journal of the European Communities.

What To Look For In A Notified Body

Once it is determined that you manufacture a product that is not subject to the self-certification route, the best way to proceed is to contact a notified body whose qualifications match up with your product, and whose credentials/affiliations match with your and your target markets. After that there are a number of variables to consider.

- Price - Obtain quotes from at least a few notified bodies; pricing can vary dramatically.
- Service - Many notified bodies do not provide adequate service; usually due to peakload situations, lengthy European vacations and some simply disregard customer needs.
- Consulting - Some notified bodies will (and some will not) offer advice in addition to testing to accelerate the process and simplify the process for you (such as a desk audit of your technical documentation prior to actual submission).
- ISO 9000 and Product Certification - Very convenient and economical (when both are required) if a notified body can provide both services.
- Documentation - Find a notified body that will accept documents in English

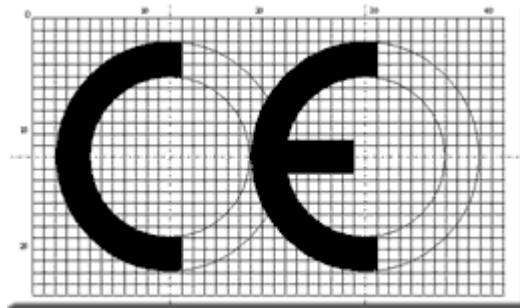
AFFIXING THE MARK AND RESPONSIBILITY

The manufacturer, whether is the person ultimately responsible for the conformity of the product with the provisions of the directive and for the affixing of the CE marking. The manufacturer may appoint an authorised representative established in the Community to act on his behalf. The person responsible for placing the product on the market may, exceptionally, be deemed to have assumed the responsibilities of the manufacturer. The CE marking may not, in principle, be affixed until the conformity assessment procedure has been completed to ensure that the product complies with all the provisions of the relevant directives. This will usually be at the end of the production phase. This poses no problem if, for example, the CE marking is on a data plate that is not affixed to the product until after the final inspection. However, if the CE marking forms an inseparable part of the product, or of a component, for example by stamping or casting, the marking can be affixed at any other stage of the production phase, provided that the conformity of the product is verified as appropriate throughout the production phase.

The CE marking shall, as a rule, be affixed to the product or to its data plate. In addition, it can be affixed, for instance, to the packaging or to the accompanying documents. However, it may exceptionally be moved from the product or its data plate if this rule cannot be followed. This would be justified where affixing it to the product was impossible (for example on certain types of explosives), or not possible under reasonable technical or economic conditions, or where the minimum dimensions could not be respected, or it could not be ensured that the CE marking was visibly, legibly and indelibly affixed. In such cases, the CE marking has to be affixed to the packaging, if it exists, and to the accompanying document, where the directive concerned provides for such documents. The CE marking on the product may neither be omitted nor be moved to the packaging or accompanying documents on purely aesthetic grounds. The CE marking symbolises conformity to essential public interests covered by the directives in question. Therefore, it is to be considered as essential information to Member States' authorities as well as other relevant parties (for example distributors, consumers and other users). Accordingly, the requirement for visibility means that the CE marking must be easily accessible for all parties. It could, for instance, be affixed on the back or underside of a product. A minimum height of 5 mm is required to ensure that it is legible. It shall also be indelible so that it cannot be removed under normal circumstances without leaving noticeable traces (for example some product standards use a rub test with water and petroleum spirits). However, this does not mean that the CE marking must form an integral part of the product.

The CE mark, covered by Council Decision 93/465/EC. Annex B(d) requires:

1. The CE conformity marking must consist of the initials 'CE' taking the form as below. If the CE conformity marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
2. Where the directive concerned does not impose specific dimensions, the CE marking must have a height of at least 5 mm.
3. The CE marking must be affixed to the product or to its data plate. However, where this is not possible or not warranted on account of the nature of the product, it must be affixed to the packaging, if any, and to the accompanying documents, where the directive concerned provides for such documents.
4. The CE marking must be affixed visibly, legibly and indelibly.



OTHER MARKS

CE marking is the only marking in the EU which symbolises conformity to all the obligations incumbent on manufacturers for the product as required by the applicable directives providing for its affixing. EU Member States shall refrain from introducing any reference to another conformity marking into their national regulations, which would signify conformity with objectives that relate to the CE marking. A product may bear additional markings and marks, provided that they:

- * fulfill a different function from that of the CE marking,
- * are not liable to cause confusion with it, and
- * do not reduce its legibility and visibility.

REFERENCES

- Guide to the implementation of directives based on the New Approach and the Global Approach (ISBN 92-828-7500-8) is available with EDC For further reading.
- <http://www.ce-marking.org/index.html>
- <http://www.bsi-global.com/en/ProductServices/About-CE-Marking/>
- <http://www.cemarking.net/>
- <http://eur-lex.europa.eu/en/index.htm>

DEFINITIONS

The European Commission

The government agency responsible for writing all product legislation, including medical devices, which are published as Directives

The Competent Authorities

Equivalent of the ESMA in the UAE, except every EU country has at least one. They supervise and often provide 'interpretations' to Notified Bodies.

Notified Bodies

These are European Certification Agencies. In order to become a Notified Body, these agencies must apply to the Competent Authority in the country where they originate to become accredited in accordance with the relevant Directive. They have to prove that they have expertise in certain areas before they become accredited in accordance with a certain 'scope' of accreditation. All EU countries accept certifications from all EU Notified Bodies. Notified Bodies close agreements with manufacturers to audit their quality management systems and technical files for the purpose of CE-marking of most devices. Notified Bodies are supervised and reviewed by the Competent Authorities. There have been cases of cancellation of Notified Bodies due to poor performance. Notified Bodies may not perform consulting work and cannot be authorized representatives, it is considered a conflict of interest.

Manufacturer and its Authorized Representative

Manufacturer is the party that places its name on the device label. There may be only 1 name and it must be identified by the 'manufacturers' symbol. If the manufacturer is domiciled outside the EU it must hire an Authorized Representative domiciled in the EU (Example: QNET B.V. in The Netherlands) for regulatory affairs and its name must appear on all labels and inserts identified by the 'Authorized Representative' Symbol, they must keep a copy of the confidential technical files. The Notified Body usually looks for an agreement that clearly outlines this relationship, The Competent Authorities contact the AR in case of problems. It is a unique way of bringing a non-EU manufacturer into their legal jurisdiction.

ANNEXURE - RELEVANT EU DIRECTIVES IN REGARD TO PRODUCT CERTIFICATION

Directive/ Guideline	Products or Title
Type A: Basic Directives (for all products)	
85/374/EEC	Liability for Defective Products
1999/34/EC	Liability for Defective Products (amending)
92/59/EEC	General Products Safety
2001/95/EC	(new) General Products Safety Directive
93/68/EEC	"CE Marking" Directive
93/465/EEC	Conformity Assessment Procedures & CE Marking Rules
Guideline	Guide to Implementation of directives based on new approach & global approach
Type B: Generic Directives (take precedence over Type A)	
73/23/EEC	Low Voltage Electrical Equipment (LVD)
Framework	2000&2001 Framework of implementation of LVD 73/23/eec (79pages)
Guideline	Guideline on Low Voltage Directive (LVD) 73/23/EEC & Annex I, II
89/336/EEC	Electromagnetic Compatibility (EMC)
Guideline	Guideline on Directive of Electromagnetic Compatibility (EMC) 89/336/eec
Tech-Aspects	Technical-Aspects relating Electromagnetic Compatibility EMC 89/336/eec (150pages)
Framework	framework of implementation of EMC Directive 89/336/EEC
2002/95/EC	RoHS- Restriction of use of Hazardous Substances in Electrical and Electronic Equipment
2002/96/EC	WEEE- Waste from Electrical and Electronic Equipment
Type C: Product-Specific Directives (take precedence over Type A & B)	
87/404/EEC	Simple Pressure Vessels
88/378/EEC	Toys
Guideline	Guidance to 88/378/eec Toys (for Scooter & FloatingSeats)
89/106/EEC	Construction Products
Guideline	Guidance to Directive 89/106/eec: Construction Products
89/686/EEC	Personal Protective Equipment (PPE)
UsefulFacts	Useful Facts relating to Directive 89/686/eec PPE (143pages)
Framework	Framework of implementation of (PPE) Directive 89/686/eec (13pages)
90/384/EEC	Non-automatic Weighing Instruments
90/396/EEC	Appliances Burning Gaseous Fuels (AppliGas)
Framework	Framework of implementation of (AppliGas) Directive 90/396/eec
92/42/EEC	Efficiency of (Liquid or Gaseous fueled) Hot Water Boilers
93/15/EEC	Explosives for Civil Uses
93/42/EEC	Medical Devices
Guidelines	Guidelines for Classification of Medical Devices
Guideline	Guideline relating to the demarcation between Directives 90/385/eec, 93/42/eec and 65/65/eec.
90/385/EEC	Active Implantable Medical Devices
98/79/EC	In Vitro Diagnostic Medical Devices
Guideline	Guideline on Medical Devices Vigilance System

Directive or Guideline	Products or Title
93/65/EEC	Air Traffic Management Equipment & Systems
94/9/EC	Equipment used in Potentially Explosive Atmospheres (Atex)
Framework	Framework of implementation of (Atex) Directive 94/9/ec, 7pages
Guideline	Guideline on directive 94/9/ec (Atex)
94/25/EC	Recreational Craft
Guid&Frame	Guidelines & Framework: directive 94/25/ec (RecCraft) (106pages)
95/16/EC	Lifts
96/48/EC	Trans-European High-speed Rail System
96/57/EC	Energy Efficiency: Household Refrigerators & Freezers
96/98/EC	Marine Equipment
97/23/EC	Pressure Equipment
Framework	2000&2001 Framework of implementation of Directive 97/23/ec
1998/37/EC	Machinery
Comments	Comments on Directive of Machinery 98/37/ec (269pages)
UsefulFacts	Useful Facts relating to Directive of Machinery 98/37/ec (266pages)
Proposal	2001 Proposal to amend Directive 98/37/ec Machinery (106pages)
1999/5/EC	Radio Equipment & Telecommunications Terminal Equipment (R&TTE)
Guidelines	Guidance to Directive 99/5/ec R&TTE, 38pages
Framework	2001 Framework of implementation of 99/5/ec R&TTE
1999/36/EC	Transportable Pressure Equipment Directive
2000/9/EC	Cableway Installations to Carry Persons