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# The CE Mark

The British American Chamber receives numerous telephone calls from manufacturers and exporters who have had their product seized by customs officials in the European Union at the worst or returned to them because they did not have the CE mark affixed to them. To assist manufacturers/exporters considering exporting their product to Europe, the following explanation of the CE mark is given.

***The CE (Conformité Europeenne) mark*** appears on products that meet safety standards that apply to all countries of the European Union (EU). It was created under the Single European Act and introduced to facilitate the free movement of goods (and services) within the European Union.

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.

Products, which do not carry the CE Mark and are not in compliance with the directives, may be restricted, prohibited from sale or forced to withdraw from the European market.

Manufacturers and authorized representatives or anyone responsible for placing products on the European market can be held personally liable for damages or injury.

Each country is responsible for enforcing the law and inspecting the product to ensure it meets the required specifications. Companies and its employees can be prosecuted where discrepancies are found.

Products bearing the CE mark indicating that the manufacturer has conformed to all the requirements under the legislation can be traded freely throughout the EU without further modification or testing.

## The EU members as at January 2001 were:

| | |
|---|---|
| Austria | Belgium |
| Denmark | Finland |
| France | Germany |
| Greece | Ireland |
| Italy | Luxembourg |
| Netherlands | Portugal |
| Spain | Sweden |
| United Kingdom | |

*Note: In addition to the 15 EU member states, the provisions of European product legislation also apply to signatory states of the European Economic Area (EEA), Iceland, Liechtenstein and Norway. Switzerland declined to participate.*

## New Approach Directives:

The problem of creating uniformity in the European Union was addressed by the creation of "New Approach Directives".
Each of these directives covers a range of products and sets out the essential safety requirements that products -- including imports – must satisfy before they may be sold anywhere in the EU. Products covered by one or more directives (see list) must meet the requirements set out in the directive(s). They bear the CE mark, which is affixed by the manufacturer or exporter as proof of their compliance.

## The following directives have been issued as at 1st January 2001:

- Low voltage (73/23/EEC)
- Industrial Trucks (74/150 EEC)
- Motor Vehicles trailers (70/50/56 EEC)
- Products labeling directive (83/374 EEC)
- Simple Pressure Vessels (87/404/EEC)
- Safety of Toys (87/378/EEC)
- Construction Products (89/106/EEC)
- Electromagnetic Compatibility (89/336/EEC)
- Machinery Safety (89/392/EC)
- Personal Protective Equipment (89/686/EEC)
- Non-automatic Weighing Instruments (90/384/EEC)
- Active Implantable Medical Devices (90/385/EEC)

- Gas Appliances (90/396/EEC)
- Telecommunications Terminal Equipment (91/263/EEC)
- Mobile Machinery (91/368 EEC)
- Hot Water Boilers (92/42/EEC)
- Medical Devices (93/42/EEC)
- Lift Machinery (93/44 EEC)
- Explosive for Civil Uses Directive (93/5)
- Satellite Earth Station Equipment (94/9/EEC)
- Recreational Craft (94/25/EEC)
- Packaging & packaging waste (94/62EEC)
- Lift Safety (95/16 EEC)
- Energy Labeling (97/75 EEC)
- Pressure Equipment (97/23/EEC)

## The directives that we receive the greatest number of enquiries about are:

- Low voltage directive (73/23/EEC)
- Electromagnetic compatibility directive (89/336/EEC)
- Machinery Safety Directive (89/336/EEC)
- Active implantable medical devices directive (90/385/EEC)
- Medical devices directive (93/42/EEC)

## Procedure for affixing the CE mark to a product – manufacturing:

The procedures to be followed can be no more complicated than the specification requirements that a manufacturer has to meet laid down by purchasers of their product.

THERE IS NO REASON FOR MANUFACTURERS TO INCUR THE EXPENSE OF CONSULTANTS EXCEPT in the case of a complicated piece of machinery, which has to conform to more than one directive and numerous standards or in cases where a notified*body has to be employed.

**Notified bodies* are independent testing houses or laboratories authorized by the EU member states and located in them to perform the conformity assessment tasks specified in directives, these have to be employed in the case of active implantable medical devices and one or two other products of which woodworking machinery is one of the main ones.
Manufacturers and exporters may choose a notified body located in any EU member state.

## Procedure for affixing the CE mark to a product – administrative:

An important part of the procedure is the compilation of a ***Technical Construction File (TCF)***, which must be compiled before the CE mark can be affixed, and the product is sold in the EU.
The TCF must be produced in one of the official languages of the European Union and be made available to the responsible authorities in any EU country.

## The technical construction file's main elements are:

- Declaration of Conformity
- A general description of the product
- Design and production drawing and diagrams
- Detailed technical data for essential aspects of the product
- List of standards and/or solutions applied
- Report of calculations and tests that have been carried out
- Certificate and inspection reports
- In the case of series production, the internal conditions that have been observed to safeguard compliance with the directive
- CE user manual

***The declaration of conformity*** must be produced in the language of each country in which the product is sold with a copy of the declaration at the disposal of the national authorities. They may also request a copy for their files. It should contain the following:

- Name and address of the manufacturer or his authorized representative established within the Community
- A description of the product
- Reference to the harmonized standards
- Where appropriate, reference to the specifications on which conformity is declared
- Identification of the signatory who has been empowered to enter into commitments on behalf of the manufacturer or his authorized representative established within the community
- The last two digits of the year in which the CE marking was affixed (for the first time)
- The declaration of Conformity must be drawn up at least in one of the official languages of the community.

### The CE user manual:

The EEC directive usually lists very specifically what the operating manual must contain, amongst items will be the following:

- Putting into service and use
- Assembly, dismantling and adjusting
- Maintaining service and repair
- Where necessary training instruction

British Standards have issued an excellent series of handbooks written by their experts who are employed to help manufacturers to comply with the CE Mark rules.

Apart from setting out how one can conform to the requirements of the directive applicable to them, they include a copy of the directive and a list of all standards issued in terms of it to date of publication.

We recommend these handbooks to manufacturers contemplating exporting to Europe as they can save them many hours in researching how to prepare their product for the European market, as

well as saving the costs of consultants.

They may also after studying the requirements for the CE mark come to the conclusion that their potential sales do not justify the cost of their meeting the required standards laid down.

The following are the handbooks issued to date covering the directives in force, which we can supply as an authorized distributor of British Standards:

| **Technical Handbook #** | **Directives #** |
|---|---|
| TH 42056: Electromagnetic Compatibility Europe | *Electromagnetic Compatibility (89/336 EEC)* |
| TH 42072: Personal Protective Equipment | *Directive 89/686/EEC* |
| TH 42073: CE Marking for Machinery | *Machinery Safety (89/686/EEC)* |
| TH 42075: CE Marking for Electrical Equipment | *Directive for Safety of Electrical Equipment designed for certain Voltage limits (73/23/EEC)* |
| TH 42076: CE Marking of Medical | *Medical Devices Directive Medical* Devices *(93/42/EEC)* |
| TH 42087: Packaging and packaging Waste – Europe | *Packaging and packaging waste (94/62 EEC)* |
| TH 42091: CE Marking for pressure equipment | *The pressure equipment Directive (97/23 EEC)* |
| TH 42097: CE Marking of the Construction Products Directive | *Construction products (89/106 EEC)* |
| TH 42098: Radio and Telecommunications Terminal | *Telecommunication Terminal Equipment (91/263/EEC)* |

Equipment (R&TTE) Guide. On CD Rom

All of these handbooks can be supplied by the British American Chamber at a price of $200 each except for TH 42098, which is $375.

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