CE marking

The Single Market

At the beginning of 1992, the European Single Market was created. The objective was to remove barriers to trade throughout the European Economic Area allowing companies free access to markets in all the different countries without having to meet particular local requirements such as safety testing regulations, customs tariffs or contract conditions. Potentially, manufacturers now have access to a market with a spending power even larger than North America.

The Directives

In the period up to 1992, and subsequently, the European Parliament has enacted a series of measures intended to put the Single Market into practice. Some of these Directives have been aimed at removing barriers of a purely customs/excise nature, others have concentrated on transport arrangements to ensure the free movement of goods, while a series of Directives (produced under the heading of `New Approach Directives) are intended to provide controls on product design, with the principal objective being to provide a `level playing field' for product safety requirements across the European Community.

The directives cover a very wide range of product areas. One of the first to be implemented concerned the safety of children's toys. Subsequent directives have included provisions for machinery, electromagnetic compatibility (EMC), personal protective equipment, medical devices, gas appliances and commercial explosives, among others. Also relevant is the Low Voltage Directive. Strictly speaking the LVD, which was first enacted in 1973, pre-dates the New Approach directives, but subsequent amendments have given it a very similar function and legal structure, and the amendment which introduced the requirement to CE mark products recognised that the LVD should broadly be treated as if it were a New Approach directive.

Product assessment and quality control

The primary function of the New Approach directives is to ensure that products are sufficiently well designed and built that they will be fit for the purpose for which they are sold and that reasonable precautions are taken to protect the user against injury while the product is being used. The Directives recognise that different product categories require different precautions; for instance the Low Voltage Directive generally only requires that products be designed to comply with the relevant international safety standards and while an independent check that the standards have been complied with is often advisable, it is not mandatory and manufacturers are free to declare their products safe without the need for independent testing. The Machinery Directive, on the other hand, requires that for certain categories of equipment a third party independent check be made by a test house notified for the purpose by the Government. The most stringent requirement, which applies to certain products covered by the Personal Protective Equipment Directive and to the Gas Appliances Directive, is that not only should the product undergo an independent type test, but that it also has to be manufactured using a quality management system which has been assessed to ISO9000.

Protection requirements, administration requirements.

Directives essentially contain two distinct sets of requirements. The first, the *protection requirements*, are the parts of the directive which lay down the safety requirements which must be met in order to comply with the directive. Different directives go into different levels of detail on these points, but the full requirements are never contained in the directive itself - this is left to product standards which are developed by multinational committees made up from the national standards organisations of all countries in the EU.

The *administrative requirements* are the part of the directive which lays down how the manufacturer (or their agent) must CE mark the product. The manufacturer must produce a declaration of conformity stating that the product meets the requirements of the directives which apply to it, and the standards or other references which were used to judge that it complies. Usually there is also a requirement to produce and maintain a file of design and manufacturing information, known as a technical file or technical construction file, which shows how the product was designed and built to meet the requirements of the directive. The Directive may lay down time limits during which the manufacturer must keep the technical file, even after the end of a product's market life.

It should be noted that, before the product can be CE marked, it must comply with all the directives which apply to it.

The CE Mark

The CE mark must be affixed to (in order of preference) the product, its instruction manual or to its packaging. Recent guidance from the European Commission indicates that the mark must appear on the product itself unless there are good technical reasons why it cannot. It must be at least 5 mm high. It is not intended to be a mark of quality - rather it is intended to indicate to the authorities responsible for enforcing the Directives that the product's manufacturer claims compliance with the directives which apply to the product.

The act of fixing the mark to the product, and signing the Declaration of Conformity, constitutes a declaration by the manufacturer that the product meets the requirements of all the Directives which apply to it. The onus is very much on the manufacturer to take responsibility for this actually being true. Marking a product which is not fully in accordance with the requirements of the applicable directives is an offence in its own right, and would also contravene related consumer safety and trades descriptions legislation.

Implications for manufacturers

The purpose of the directives is not to ban any products from the European Single Market, unless the product is very poorly made or is unsafe. For most reputable manufacturers, complying with the essential protection requirements of the directives is not particularly onerous and companies which have always taken a responsible attitude to the performance and design of their products will have few problems complying with the New Approach directives.

Where a manufacturer is based outside the EU, it is the person who is responsible for bringing the equipment across the first EU border who has legal responsibility for CE marking it. However, because of their intimate involvement in the safety of the product, manufacturers almost always have some responsibilities under the CE mark directives even if they are not directly responsible for importing the goods into the EU.

Where the manufacturer has a formally appointed distributor or subsidiary ('authorised representative') the situation is reasonably straightforward. Where a piece of equipment is imported for the use of the importer, things get more complex and each case must be considered on the basis of the individual circumstances.

Where there may be difficulties is in the administrative requirements since these will require a new way of working for some manufacturers and suppliers, particularly small businesses. Manufacturers may well find it

cost effective to seek outside help in the early stages of complying with the Directives in order to save time and prevent expensive mistakes. However, it is important to be aware that it is rarely necessary to commit to an expensive program of testing and modifications: **unless the Directives which apply to the product specifically require the involvement of a third party for product approval or quality system assessment, the manufacturer can affix the mark without having to involve a test house, consultant, the DTI or anyone else.**

Further advice

As with all CE marking directives, the actual requirements for any piece of equipment under the directive are complex and dependent on not only the design but also the type of user, the intended use and sometimes even what is claimed in the instructions or sales literature.

For further advice specific to your products, please contact us at Conformance and we will be pleased to discuss your needs. If you'd like us to prepare a no-obligation quote for assisting you with CE marking your products, please take a look at our page which gives details of the information required in order to be able to give you an accurate idea of the costs and procedures involved.

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Back to the Conformance CE marking contents page