1.11 CE MARKING

Ironically, the main objectives of CE marking are to remove barriers to free trade within the EU, though the process is seen by many manufacturers as a burden. The underlying intention is that products bearing the CE mark may be traded freely within the EU. The guide to the New Approach Directives (introduction) states:

> *"Member States must presume that products bearing the CE marking comply with all the provisions of the applicable directives providing for its affixing. Accordingly, Member States may not prohibit, restrict or impede the placing on the market and putting into service in their territory of products bearing the CE marking, unless the provisions relating to CE marking are incorrectly applied.!*

Manufacturers of any products to be placed on the market must ensure that those products comply with all relevant directives and the CE marking indicates compliance with those directives. The definition of CE mark in the Decision 768/2008/EC reads:

> *"a mark by which a manufacturer indicates that the product is in conformity with the applicable; requirements set out in the Community harmonisation legislation provided for its affixing:"*

The source legislation requiring CE marking is rather fragmented with; Council Decision 768/2008/EC providing overall requirements for conformity assessment and affixing the mark, Directive 93/68/EEC amending the relevant sections of the specific technical directives, and the individual technical directives themselves. The specific technical directives that typically would have to be considered for weighing equipment include:

2004/108/EC	Electromagnetic compatibility (EMC) directive	General electrical equipment
2006/95/EC	Low voltage directive	Equipment designed for use with a voltage rating between 50 and 1000V a.c. and/or 75 and 1500V d.c.
2009/23/EC	Non-automatic weighing instruments directive	Weighing instruments used for controlled applications
2006/42/EC	Machinery directive	Equipment with powered moving parts and machinery accessories
93/42/EC	Medical Devices	Instruments used for the purposes outlined in the Directive

It is the responsibility of the manufacturer to determine which directives are applicable. The guide to the New Approach directives gives a full list of directives that require CE marking. In addition to the CE marking, a declaration or certificate of conformity must be produced, identifying the directive(s) concerned and any technical standards used.

Conformity assessment

Council Decision 2008/768 EC describes 8 different methods (modules) of conformity assessment, which may be combined, resulting in quite a complex scheme. However, it is the individual specific technical directives that determine the method(s) of conformity assessment(s) to be used for each. To identify these methods, the original directives must be combined with the amendments listed in Directive 93/68/EEC.

In practice, there are two different general principles: either the manufacturer makes a declaration of conformity based on the equipment design, examination and testing (where testing may be carried out by a third party and a test report produced), or in addition to the manufacturer's declaration, a notified body issues a type-approval certificate for the product and each unit is then tested, affixed with the identification number of the notified body performing the tests, and issued with a certificate of conformity (unit verification).

References

Guide to the implementation of directives based on the New Approach and the Global Approach.
Council decision 2008/768
Directives 93/68/EEC, 90/384/EEC, 98/37/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC