

2.3.1. CE MARKING DOCUMENTATION

In European law, the so-call “New Approach” separates essential requirements from the detailed technical specifications. The directives themselves identify the essential requirements and the technical specifications and tests are detailed in harmonised standards, which are incorporated into national standards. The essential requirements identified in the directives must be satisfied and compliance with the harmonised standards is sufficient to prove that. However, a manufacturer (or other body having to satisfy such a directive) may choose another method to prove that the essential requirements are met.

Each directive will identify the possible routes to compliance and some of those routes require the involvement of a notified body for examination and/or verification. The directives will require the following:

- The manufacturer or representative to affix the **CE** mark to each product. Specific directives may allow the mark to be displayed on the packaging and/or documentation as an alternative. Depending on the directive and the route to compliance, the identification number of the notified body may also be required.
- A Declaration of Conformity to be at the disposal of the national authorities with some directives requiring a copy supplied with each unit (or a batch of units delivered to a single user).
- A technical documentation file including information such as; a technical description, tests and standards applied, any other steps taken to ensure compliance.

Depending on the route to compliance, additional information such as procedures, reports & records relating to the quality system may also be required.

Some of the directives and compliance methods require the Declaration of Conformity, the technical file, and other documentation to be available for 10 years after the last product has been manufactured.

National legislation will implement the directives and the following is a non-exhaustive list of directives that may have to be considered for weighing equipment:

2009/23/EC	Non-automatic weighing instruments
2004/22/EC	Measuring instruments (automatic weighing instruments)
2004/108/EC	Electromagnetic compatibility (EMC)
2006/95/EC	Electrical equipment designed for use within certain voltage limits (low voltage directive)
2006/42	Machinery
94/9/EC	Equipment and protective systems for use in potentially explosive atmospheres
93/42/EC	Medical Devices

Some of the above directives will have been amended by directive 93/68/EEC to bring them in to line with the general requirements for CE marking and Decision 768/2008 which details those requirements with modules for the various phases of conformity assessment procedures.

The exact format of the Declaration of Conformity is not specified, but an example layout is given in an annex to this article for an item of equipment relating to the EMC Directive.

See also sections on specific Directives and the general section on the notes for guidance on New Approach Directives.

References

Specific Directives mentioned directly in this article.

“Guide to the implementation of directives based on the New Approach and the Global Approach”, available from the EU website.



Example layout for a Declaration of Conformity

DECLARATION of CONFORMITY

MANUFACTURERS NAME

MANUFACTURERS ADDRESS

TYPE of EQUIPMENT

MODEL NUMBER

I hereby declare that the equipment specified above conforms with the protection requirements of the **EC DIRECTIVE 2004/108/EC** on Electromagnetic Compatibility (EMC), having applied the following standards;

BS EN 61000-6-1:2007
EMC GENERIC IMMUNITY STANDARD
(RESIDENTIAL, COMMERCIAL and LIGHT INDUSTRY)

BS EN 61000-6-3:2007
EMC GENERIC EMISSION STANDARD
(RESIDENTIAL, COMMERCIAL and LIGHT INDUSTRY)

SIGNED

FULL NAME

POSITION

DATE