

Conformity assessment

Changes due to Brexit

Your health and safety responsibilities will not change when the UK leaves the EU. This guidance is under review.

[Find the latest information on our Brexit pages](#)

Within the context of the European New Approach Directives this is the process by which persons can legally place safe and compliant products onto the European market (or bring them into use) for the first time. Conformity assessment is a common feature of the New Approach Directives concerned with product safety, and includes various checks on the:

- design and construction of products to meet essential requirements which normally are for health and safety
- and being able to demonstrate this through a technical file

before declaring and certifying a products' conformity with all relevant Directives, and affixing CE marking to the product. Some products can be self-certified through this process, but others must undergo one of a number of specific conformity assessment procedures involving third parties known as Notified or Conformity Assessment Bodies, before the manufacture can declare conformity.

When do I have to undertake conformity assessment?

Before placing new products on the market, or bringing them into service, for the first time, the Responsible Person (the manufacturer or his authorised representative) must undertake the one of the conformity assessment procedures that apply to the product. This may include [second-hand products](#) "new" to the market such as imports from outside Europe of non-CE marked products, or products so substantially [refurbished](#) as to be considered new.

How do I undertake conformity assessment?

Depending on the Directive and the nature of the product and risk conformity assessment ranges from self-assessment of the product to third party type-examination and /or full quality assurance. Full details of the procedures (also referred to as modules) are given, normally within the Annexes, of each [European product safety Directive](#). Manufacturers and their authorised representatives need to find out what these procedures are for any of their products destined for the European market. Information generated and obtained during the conformity assessment procedure must be retained by the Responsible Person as part of the product's [technical file](#).

Where a third party is required for conformity assessment the Responsible Person must select an appropriate competent organisation known as a Conformity Assessment or [Notified Body](#) to assist. However, whilst the Notified Body will undertake an assessment of the product and the manufacturer's quality system, and may issue an EC Type-Examination Certificate, the duty to meet the relevant conformity assessment procedure always remains with the Responsible Person. It is the Responsible Person who must declare the product's conformity with all relevant Directives and apply the CE mark before placing the product on the market.

If a Notified Body issues an EC Type-Examination Certificate for a product submitted to them for conformity assessment this must be retained by the Responsible Person and included in the

technical file. There is sometimes confusion as to what the EC Type-examination certificate means. It is a document indicating that in the Notified Bodies' judgement the product meets the requirements of one or more Directives. It is not a Declaration of Conformity, although details of any Notified Body issuing such a certificate should be included on the Declaration of Conformity.

Where the use of a Notified Body is not required for conformity assessment, this is referred to as the self-certification route. This applies to many products that are not considered of high or special risk. There is nothing to stop the Responsible Person approaching a Notified Body, or another organisation, to assist with his product assessment but if a Notified Body is used it only as a consultant and no EC Type-Examination Certificate must be issued and the number of the Notified Body must not be quoted on the Declaration of Conformity. This option is at the Responsible Person's own election and cost, and does not relieve the Responsible Person of his fundamental duty to declare conformity of, and take full responsibility for, the product.