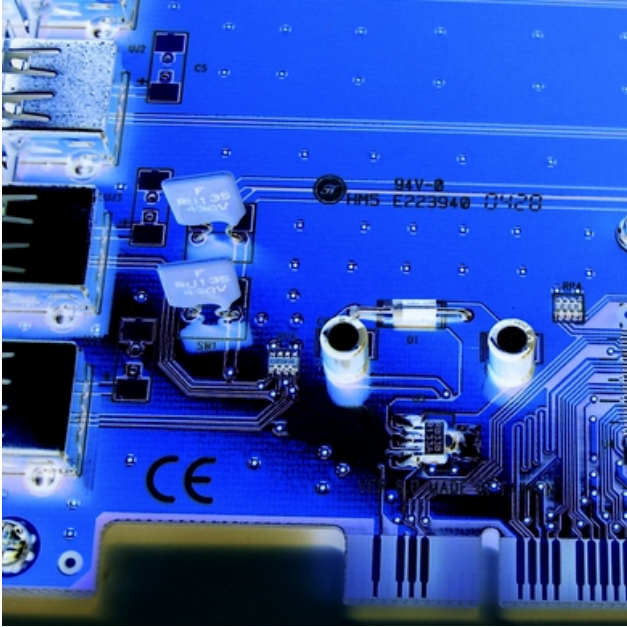


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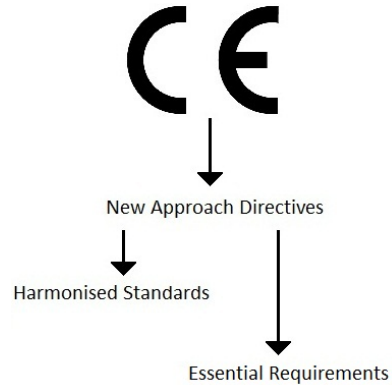


Introduction to the CE Marking Directive

CE stands for Conformitee Europeenne. It is a required mark for products falling within the scope of European Conformity. CE has been implemented by the European Commission to allow products to be freely distributed across the common European market, without the need for separate conformity declarations in each member state. Affixing the CE mark is a declaration by the producer that the product has been designed, tested and manufactured to meet the essential requirements of all applicable new approach directives. Not only does it declare that a product is safe, but it is also suitable for use in the function for which it was designed and that it will not have adverse effects on its surroundings. CE also requires that products be designed to be environmentally friendly, in their manufacture, operation and at end of life.

CE mark has, at its centre, a fundamental set of essential requirements which define obligatory product characteristics. These essential requirements depend on the function of the product and are separated into discrete directives which sit under the umbrella of the CE mark.

Within each new approach directive sit a set of harmonised standards which specifically outline criteria manufacturers can use to declare compliance for products of a similar type.



Requirements

CE marking is complicated and there are specific requirements depending on the applicable directive(s) - it is important to understand the requirements of the directive(s) being applied to the product. It is the responsibility of the manufacturer to ensure products are designed and manufactured to comply with the essential requirements of all applicable new approach directives. The manufacturer documents their effort to ensure conformity in the product's technical file. The technical file must be kept on record for a period of ten years after the last point the product was available on the European market. This file has to include details of design, testing, continuation of manufacture and QA process as well as a copy of the instructions for use and any safety information. The manufacturer must draw up a Declaration of Conformity (DoC) giving specific information about the product, the manufacture's EU contact details and the essential requirements or harmonised standards being declared against. The DoC must be signed by a person responsible for the manufacturing process. The content and format of the technical file and manufacturer obligations differs for each directive the various methods are outlined in Annex 2 decision number 768/2008/EC of the European Parliament.

The technical file must be made available to enforcement bodies upon request and the DoC made available to customers, in situations where products have to be designed to a certain environmental standard manufacturers are obliged to provide additional information. Some directives require certification by a notified body that the product being marked is in compliance; this must be kept up to date as the requirements of directives change.

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Once these measures are in place the manufacturer must affix the CE mark in accordance with the requirements of the directive.

RoHS Recast

In 2013 the recast of the RoHS Directive (2011/65/EU) will require all equipment falling within scope to carry CE marking obligations. The indicative list of Electric and Electronic Equipment (EEE) that appears in the directive is as follows:

1. Large household products
2. Small household products
3. IT and telecommunication equipment
4. Consumer equipment
5. Lighting equipment
6. Electric and electronic tools
7. Toys, leisure and sports equipment
8. Medical devices
9. Monitoring and control equipment
10. Automatic dispensers
11. Other EEE not covered

Products can only contain the maximum concentration values by weight in homogeneous materials of the following:

- Lead (0.1 %)
- Mercury (0.1 %)

- Cadmium (0.01 %)
- Hexavalent chromium (0.1 %)
- Polybrominated biphenyls (PBB) (0.1 %)
- Polybrominated diphenyl ethers (PBDE) (0.1 %)

Dev Kits

Under the RoHS Recast Directive, equipment that is used solely for research and development (R&D) will be out of scope. So whilst a PCB kit will be out of scope, a programmer in an enclosure for production quantities will be in scope.

Any R&D equipment that is within the RoHS Recast scope will also be required to be CE mark compliant.

Cables

An area of concern remains over whether cable will be subject to CE marking / a declaration will be required under the RoHS Recast Directive.

At this stage it is unclear and further guidance is needed from the European Commission.

Obligations

The responsibility to prove conformity will be as defined in the CE Mark Directive with manufacturers, importers and distributors having varying degrees of responsibility. The proof of this process must be provided in the technical file, along with the specifics given in Module A of Annex 2 768/2008/EC. This is the most basic of conformity assessment procedures and is achieved by internal production control process.

Below is a summary of obligations (full text can be found in the Official Journal)

	Category and obligations
A manufacturer	Article 7 (a)
	when placing EEE on the market, manufacturers ensure that it has been designed and manufactured in accordance with the requirements set out in Article 4;
	Article 7 (b)
	manufacturers draw up the required technical documentation and carry out the internal production control procedure in line with module A of Annex II to Decision No 768/2008/EC or have it carried out;
	Article 7 (c)
	where compliance of EEE with the applicable requirements has been demonstrated by the procedure referred to

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	<p>in point (b), manufacturers draw up an EU declaration of conformity and affix the CE marking on the finished product. Where other applicable Union legislation requires the application of a conformity assessment procedure which is at least as stringent, compliance with the requirements of Article 4(1) of this Directive may be demonstrated within the context of that procedure. A single technical documentation may be drawn up;</p>
	<p>Article 7 (d)</p> <p>manufacturers keep the technical documentation and the EU declaration of conformity for 10 years after the EEE has been placed on the market;</p>
	<p>Article 7 (e)</p> <p>manufacturers ensure that procedures are in place for series production to remain in conformity. Changes in product design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of EEE is declared shall be adequately taken into account;</p>
	<p>Articles 7 (f)</p> <p>manufacturers keep a register of non-conforming EEE and product recalls, and keep distributors informed thereof;</p>
	<p>Article 7 (g)</p> <p>manufacturers ensure that their EEE bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the EEE does not allow it, that the required information is provided on the packaging or in a document accompanying the EEE;</p>
	<p>Article 7 (h)</p> <p>manufacturers indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. The address must indicate a single point at which the manufacturer can be contacted. Where other applicable Union legislation contains provisions for the affixing of the manufacturer's name and address which are at least as stringent, those provisions shall apply;</p>
	<p>Article 7 (i)</p> <p>manufacturers who consider or have reason to believe that EEE which they have placed on the market is not in conformity with this Directive immediately take the necessary corrective measures to bring that EEE into conformity, to withdraw it or recall it, if appropriate, and immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;</p>
	<p>Article 7 (j)</p> <p>manufacturers, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the EEE with this Directive, in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with this Directive of EEE which they have placed on the market.</p>
An importer	<p>Article 9 (a)</p> <p>importers place only EEE that complies with this Directive on the Union market;</p>
	<p>Article 9 (b)</p> <p>importers, before placing an EEE on the market, ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer, and that they further ensure that the manufacturer has drawn up the technical documentation, that the EEE bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in points (f) and (g) of Article 7;</p>
	<p>Article 9 (c)</p>

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	<p>where an importer considers or has reason to believe that an EEE is not in conformity with Article 4, that importer does not place the EEE on the market until it has been brought into conformity, and that that importer informs the manufacturer and the market surveillance authorities to that effect;</p>
	<p>Article 9 (d)</p> <p>importers indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. Where other applicable Union legislation contains provisions for the affixing of the importer's name and address which are at least as stringent, those provisions shall apply;</p>
	<p>Article 9 (e)</p> <p>importers, in order to ensure compliance with this Directive, keep a register of non-compliant EEE and EEE recalls, and keep distributors informed thereof;</p>
	<p>Articles 9 (f)</p> <p>importers who consider or have reason to believe that an EEE which they have placed on the market is not in conformity with this Directive immediately take the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, as appropriate, and immediately inform the competent national authorities of EN 1.7.2011 Official Journal of the European Union L 174/95</p> <p>the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;</p>
	<p>Article 9 (g)</p> <p>importers keep, for 10 years following the placing on the market of the EEE, a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request;</p>
	<p>Article 9 (h)</p> <p>importers, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of an EEE with this Directive in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with this Directive of EEE which they have placed on the market.</p>
A distributor	<p>Article 10 (a)</p> <p>when making an EEE available on the market, distributors act with due care in relation to the requirements applicable in particular by verifying that the EEE bears the CE marking, that it is accompanied by the required documents in a language which can be easily understood by consumers and other end-users in the Member State in which the EEE is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in points (g) and (h) of Article 7 and in point (d) of Article 9;</p>
	<p>Article 10 (b)</p> <p>where a distributor considers or has reason to believe that an EEE is not in conformity with Article 4, that distributor does not make the EEE available on the market until it has been brought into conformity, and that that distributor informs the manufacturer or the importer as well as the market surveillance authorities to that effect;</p>
	<p>Article 10 (c)</p> <p>distributors who consider or have reason to believe that an EEE which they have made available on the market is not in conformity with this Directive make sure that the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, as appropriate, are taken and that they immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;</p>

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Article 10 (d)
distributors, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of EEE with this Directive, and that they cooperate with that authority, at its request, on any action taken to ensure the compliance with this Directive of the EEE which they have made available on the market.

More information:

- Dedicated legislation website - www.element14.com/legislation
- Questions answered – glegislation@premierfarnell.com

Please note:

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