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Role of CE marking in the placing on the market of electronic components

Within the European internal market, the placing of products on the market is governed in many areas by so called “New Approach” directives and regulations. These legislative provisions require manufacturers to affix CE marking to products that fall under the scope of such a provision. At the same time, these regulations in conjunction with Regulation (EC) No 765/2008 [8] prohibit the affixing of CE marking to products that are not subject to an applicable CE directive.

CE marking symbolizes that a product is covered by a harmonised EU directive or regulation, that it complies with the statutory requirements contained within it and therefore, that national authorities cannot impede the free circulation of such products within the European Economic Area. However, CE marking is not intended to be a mark of safety or quality.

Since components are frequently incorporated into products which themselves fall under the scope of a statutory provision that requires CE marking, the question of whether or not CE marking is required for individual electronic components is fraught with uncertainty.

Legal background

There are currently around 30 directives for specific product groups or aspects which overlap in some areas. The CE marking requirement and associated requirements for the manufacturer to perform a conformity assessment and to provide a declaration of conformity always relates to the product defined within the scope of the applicable directive. In most cases, directives govern only ready-to-use end products. It is up to the manufacturer of the end product to determine which bought-in components are needed to satisfy the requirements of the directives applying to his end product.

Generally, the requirements of a directive, including the CE marking requirement, apply to components only if they themselves are *directly* covered by the applicable directive.

The following directives are continually cited as relevant to electronic components:

- Low Voltage Directive 2006/95/EC [1]
- EMC Directive 2004/108/EC [2]
- Machinery Directive 2006/42/EC [3]
- Toy Safety Directive 2009/48/EC [4]
- Medical Devices Directive 93/42/EC [5]
- R&TTE Directive 99/5/EC [6]
- RoHS Directive 2011/65/EC [7]

These directives are addressed individually below.

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Low Voltage Directive 2006/95/EC

The Low Voltage Directive (LVD) governs the safety of 'electrical equipment' with a voltage between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current, according to its Article 1. The operational voltage of many electronic components lies outside this range. Therefore, such components do not fall under the scope of the Low Voltage Directive. However, if the operational voltage lies within the limits of the Low Voltage Directive, manufacturers must decide whether the components themselves are considered electrical equipment in the sense of the Directive. Components may be intended for incorporation into end products. This includes, for example, electronic ballast and bulb holders in lamps, mains switches, mains transformers and mains plug-and-socket outlets. The definition in the Directive is not clear in this respect, however, the Commission's guidelines on the LVD [9] make clear in Section 9 that certain "basic components", unlike these examples, do not constitute electrical equipment and are therefore not covered by the Directive, if *"the safety of which can only, to a very large extent, be assessed taking into account how they are incorporated and for which a risk assessment cannot be undertaken"*. Footnote 13 of the guidelines lists examples of basic components which are excluded from the scope of the Directive:

> *"This includes, for example, active components such as integrated circuits, transistors, diodes, rectifiers, triacs, GTO's, IGTB's, opto-semi-conductors; passive components such as capacitors, inductance, resistors, filters[1]; electromechanical components such as connectors, devices for mechanical protection which are part of equipment, relays with terminals for printed circuit boards, micro switches"*

In light of this information, electronic components cannot bear the CE marking in accordance with the Low Voltage Directive. When considering plug-in connectors in this context, please refer to the separate position paper published by ZVEI (German Electrical and Electronic Manufacturers' Association) [10].

EMC Directive 2004/108/EC

The EMC Directive governs the electromagnetic compatibility of "equipment", according to its Article 1. Article 2 states that equipment refers to "apparatus" or "fixed installations".

Section (1) defines "apparatus" as follows:

> *"... any finished appliance or combination thereof made commercially available as a single functional unit, intended for the end user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance;"*

According to Section (2), apart from complete finished products, this also includes:

> *"a) 'components' or 'sub-assemblies' intended for incorporation into an apparatus by the end user, which are liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance;".*[2]

Normally electronic components are not placed on the market independently; instead they are incorporated into an apparatus by a converter (manufacturer of a complete unit or finished product). As such, electronic components themselves are not covered by the Directive. On the other hand, if they are sold separately for incorporation into equipment by the end user, the manufacturer must assess whether the components themselves are liable to generate electromagnetic disturbance, or can be affected by such disturbance.

[1] This means different types of filter such as ZF filters, EMC filters etc.

[2] Typical examples are retrofit and conversion sub-assemblies for computers, such as hard drives and graphics cards, which are fitted by the end users themselves.

Although this is not the case for individual electronic components, an assessment is necessary for functional units such as computer graphics cards.

A conformity assessment and CE marking is therefore not required for individual electronic components in accordance with the EMC Directive.

Machinery Directive 2006/42/EC

The Machinery Directive governs the safety of complete machinery. In two exceptions, it contains requirements for machinery components: "partially completed machinery" and "safety components".

Article 2 (g) defines partially completed machinery as “an assembly which is almost machinery". This clearly does not apply to an electronic component.

In principle, safety components can also be electronic components. However, according to the corresponding definition, to fall within the scope of the Machinery Directive, the manufacturer must assign to the component a specific purpose which serves to fulfil a safety function in accordance with the Machinery Directive. Only in this particular case does the Machinery Directive require a conformity assessment with CE marking for electronic components. This applies, for instance, to special sensors or logic units intended by the component manufacturer to fulfil specific safety functions within the machinery.

Toy Safety Directive 2009/48/EC

The Toy Safety Directive applies exclusively to end products which are designed or intended, whether or not exclusively, for use in play by children under 14 years of age. Even when electronic components are incorporated into toys, they themselves are not toys and are therefore not covered by the Directive. For this reason there is no requirement for CE marking.

Medical Devices Directive 93/42/EEC

The Medical Devices Directive (MDD) applies exclusively to complete end-products (and their ready-to-use accessories) intended to be used for the diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap. The Directive does not apply to components which are incorporated into these products. Accordingly, CE marking and a declaration of conformity are not required in accordance with the Medical Devices Directive.

R&TTE Directive 99/5/EC

The R&TTE Directive governs the placing on the market of radio equipment and telecommunications terminal equipment. Components are covered only if they can be defined as a “relevant component” of telecommunications terminal equipment in the sense of Article 2 (b). Whether standard electronic components are to be included within this definition is determined by whether conformity of the component to the “essential requirements" of Article 3 can be fully assessed. This requires the “relevant component” to embody assessable essential telecommunications, safety or EMC functions within the meaning of the Directive, intended for the complete end-device. This may be assumed for more complex sub-assemblies, but not for traditional electronic components such as individual capacitors, inductors, filters, transistors or ICs.

Electronic components therefore do not fall within the scope of the R&TTE Directive and do not require CE marking.

RoHS Directive 2011/65/EC

The RoHS Directive restricts the use of certain substances in “electrical and electronic equipment”. Unlike the previous version 2002/95/EC, the new directive, which came into force on the 13 January 2013, also prescribes the CE marking of products within its scope. The scope of this directive is initially restricted to “devices”, but does not include their components directly. The latter are only indirectly covered by it, in that device manufacturers are obliged to procure those components that will enable them to satisfy the RoHS requirements in the final product. This they can arrange by private legal agreement with their suppliers. In this case there is no provision for CE marking under public law.

Irrespective of this, in addition to end devices, the RoHS Directive also directly governs their “accessories” and “spare parts”. Under certain circumstances, electronic components could fall into one of these categories. However, the RoHS Directive does not stipulate CE marking for accessories and spare parts, but simply requires them to comply with the substance restrictions.

Electronic components therefore cannot be provided with CE marking in accordance with the RoHS Directive.

Summary

None of the directives referred to above cover electronic components directly. The provision of CE marking or a declaration of conformity in accordance with these directives is neither intended nor permitted. (The national implementations of these guidelines usually make provision for fines for the unauthorised use of CE marking.)

Sources

[1] DIRECTIVE 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits. (The Low Voltage Directive, identical to previous Directive 73/23/EC in conjunction with 93/68/EEC).

[2] DIRECTIVE 2004/108/EC of the European Parliament and of the Council of 15 of December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and to repealing Directive 89/336/EEC.

[3] DIRECTIVE 2006/42/EC of the European Parliament and of the Council of the 17 May 2006 on machinery, and amending Directive /16/EC (recast)

[4] DIRECTIVE 2009/48/EC of the European Parliament and of the Council of the 18 June 2009 on the safety of toys

[5] DIRECTIVE 93/42/EEC of the European Parliament and of the Council of 14 June 1993 concerning medical devices (consolidated version)

[6] DIRECTIVE 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity

[7] DIRECTIVE 2011/65/EC of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)

[8] REGULATION (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EC) No 339/93

[9] European Commission (eds.): "Guidelines on the Application of Directive 2006/95/EC (Electrical equipment designed for use within certain voltage limits), English edition of August 2007

[10] ZVEI (ed.): “Treatment of industrial plug-in connectors in accordance with the Low Voltage Directive 2006/95/EC". Date: 6 February 2009.