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# White paper

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# CE marking in a nutshell

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SUMMARY:

This white paper provides an overview of European CE marking standards and procedures for electronic devices and in partical wireless products.

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# 1 Introduction

This white paper aims to present regulations and standards. It avoids long lists of legal-oriented details and stay as engineer-oriented as possible. It presents European CE marking. Lots of misunderstandings, exaggerated fears or unconscious optimism exist around that subject...

**Warning : this white paper is just an introduction, and doesn't pretend to be either exhaustive, detailed enough or even up to date. Always refer to official documents for any compliance works. Its goal is to provide a high level view on the CE compliance process and spirit.**

Nota : The material presented in this white paper was also published in Circuit Cellar magazine (December 2011, #257, "The Darker Side : CE Marking – A process to ensure product conformity").

# 2 CE marking ?

What is CE marking ? Physically it is a CE logo, at least 5mm tall, that must be visible on nearly all products sold in Europe (figure 1). In fact, only some classes of products are in the scope of this regulation, but this is the case for all electrical and electronic equipments, radio devices and machines. CE means “Conformité Européenne”, which is the French for “European Conformity”.

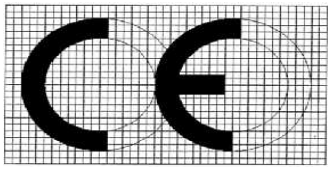

Figure 1

As the CE marking is mandatory it is absolutely not a kind of “quality mark” : all electronic devices must have it, even if they are poorly designed. It is neither a certificate of origin : Products sold in Europe must be CE marked, even if they were designed in the US and manufactured somewhere else. The CE marking is also not a proof of independent assessment : a manufacturer is usually not obliged to ask a third party to do the tests.

CE marking is a **conformity marking** : It states that the manufacturer of the product insures that the product is compliant with the Essential Requirements of the relevant European directives, meaning to the directives applicable to that product. Just read that sentence again : The CE marking is a **declaration of the manufacturer**. It engages its responsibility. Dot. So this is very different from UL or CSA approvals, which imply the verification of the product's characteristics by an independent test house. Here the manufacturer declares that he has done the required conformity assessment, possibly on his own, and that the product is compliant.

CE marking is required for all electronic products **sold in Europe**. More exactly the legislation says “placed on the market or put into service” rather than “sold”. This means that it is not applicable to an experimental prototype staying on a lab bench as it is not yet on the market, but it is theoretically required even if someone sends some products for free to early adopters or rent them for example.

The term “manufacturer” also needs some explanations : An importer or a distributor can also be considered as a manufacturer. This is in particular the case when the products are distributed under the distributor's name or when the product is not CE marked by the manufacturer. **The importer or distributor will them assume the legal responsibility of the CE marking process.**

# 3 Essential requirements ?

What are the essential requirements that the CE marking attest conformity to ? Basically these are quite **generic requirements** that the product must comply with. They are defined in so called **European directives**, which could be considered as European laws. In addition to generic paperwork-oriented directives, three of them are applicable to all electrical devices. They deal respectively with electrical **safety**, **electromagnetic compatibility** (EMC for short), and r**adio performances** (R&TTE). Moreover there are directives on hazardous substances restrictions, waste management and energy efficiency. However there are also plenty of European directives each applicable to certain classes of products : machineries, toys, medical devices, lifts, etc. Figure 2 (hereunder) gives you an overview.

| | |
|---|---|
| CE directives applicable to a large number of electronic products | |
| 2006/95/EC | Low Voltage Electrical Equipment (safety) |
| 2004/108/EC | Electromagnetic Compatibility (EMC) |
| 1999/5/EC | Radio Equipment & Telecommunications Terminal Equipment (R&TTE) |
| CE directives specific to some product classes | |
| 2009/48/EC | Toys |
| **2006/42/EC** | Machinery |
| 93/42/EEC | Medical devices |
| 204/22/EC | Measuring instruments |
| 94/9/EC | Equipment used in Potentially Explosive Atmospheres (Atex) |
| 95/16/EC | Lifts |
| Etc | |
| Other directives applicables to nearly all products, not directly linked to CE-mark | |
| 2002/95/EC | RoHS - Restriction of use of Hazardous Substances in Electrical and Electronic Equipment |
| 2002/96/EC | WEEE - Waste from Electrical and Electronic Equipment |
| 2009/125/EC | EuP - Ecodesign of energy-related products |

Figure 2 : There are now only twenty or so European directives linked to CE marking, each applicable to certain product classes. This table also lists the three directives linked to environment protection.
Source : http://www.ce-marking.org/how-many-directives.html

Hereunder an example of an essential requirement : the directive 2004/108/EC on EMC says that :

*"An equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:*
*(a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;*
*(b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use."*

Similarly the so-called "low voltage" 2006/95/EC safety directive says that :

*"The Member States shall take all appropriate measures to ensure that electrical equipment may be placed on the market only if, having been constructed in accordance with good engineering practice in safety matters in force in the Community, it does not endanger the safety of persons, domestic animals or property when properly installed and maintained and used in applications for which it was made.."*

However theses directives don't say at all HOW to achieve compliance with these requirements. This is the responsibility of the manufacturer ! So usually, at its roots, the CE marking in fact doesn't imply compliance with any precise measurement values or performances. Once again it says that the manufacturer commit that the product is compliant with these generic requirements, that's all. By the way all CE European Directives are quite short and down loadable for free. If you are interested feels free to read them but you will usually be disappointed by the level of details provided...

# 4 Harmonized standards ?

Fortunately the manufacturer has usually not to deal directly with the European Directives : There are European Harmonized Standards. These documents, developed by technical organisms like CEN, CENELEC or ETSI, are actual detailed engineering-oriented standards with gives thinks that a designer is looking for : test plans, thresholds, etc. The rule is the following : **if there are Harmonized Standards applicable to a product, say for EMC, and if the product is compliant to these standards then the product is presumed to comply with the associated Essential Requirements**.

You can probably read the sentence again. Between the lines you will understand that there is no formal obligation to comply with any standard for CE marking. However if you don't use standards then your life will be far more difficult : you will have to prove that you comply with very generic assumptions. For example for EMC you will need to prove that your product as no risk to interfere with any other product.

**It is the manufacturer's responsibility to find out which standards are applicable**, and there are plenty of them. The European Commission keeps a database of all harmonized standards associated with each directive, but the lists are longs. They are all listed on http://www.newapproach.org/. For example there are around three hundred harmonized standards associated with the generic “low voltage” safety directive, see figure 3 for some examples. Selecting which standards are applicable to your product is really a job for an expert. Our advice, even if it is not mandatory, is to consult an experienced test house, or if possible an official notified body (which are test houses accredited to do conformity assessments for a given list of standards) even just to list the applicable standards. This should be done as early as possible in the development cycle, and will make your life far more comfortable.

| | |
|---|---|
| EN 41003:1998 | Particular safety requirements for equipment to be connected to telecommunication networks |
| EN 60065:2002 | Audio, video and similar electronic apparatus - Safety requirements |
| EN 60204-1:2006 | Safety of machinery - Electrical equipment of machines -- Part 1: General requirements |
| EN 60215:1989 | Safety requirements for radio transmitting equipment |
| EN 60335-2-5:2003 | Household and similar electrical appliances - Safety -- Part 2-5: Particular requirements for dishwashers |
| EN 60335-2-59:2003 | Household and similar electrical appliances - Safety -- Part 2-59: Particular requirements for insect killers |
| EN 60598-2-7:1989 | Luminaries -- Part 2: Particular requirements -- Section 7: Portable luminaries for garden use |
| EN 60730-2-14:1997 | Automatic electrical controls for household and similar use -- Part 2-14: Particular requirements for electric actuators |
| EN 60825-1:2007 | Safety of laser products -- Part 1: Equipment classification and requirements |
| EN 60950-1:2006 | Information technology equipment - Safety -- Part 1: General requirements |
| EN 60950-21:2003 | Information technology equipment - Safety -- Part 21: Remote power feeding |
| EN 61010-1:2001 | Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 1: General requirements |
| EN 61558-1:2005 | Safety of power transformers, power supplies, reactors and similar products -- Part 1: General requirements and tests |
| Etc etc... | |

Figure 3 : This table shows you only some examples of the harmonized standards that could be used for the low voltage directive 2006/95/EC, from the hundreds of them (source : http://www.newapproach.org/ ). The difficulty is to find out which standards are applicable to your specific product.

What are the directives and standards actually about ? We will not be able to present here specific directives dealing with lifts or medical devices, but will try to give an overview of their spirit. As listed on figure 2, the three directives that are applicable to nearly all electronic devices deals with safety (low voltage directive), electromagnetic compatibility (EMC directive) and radio & telecommunications (R&TTE directive).

# 5 Low voltage directive

The so-called low voltage directive (2006/95/EC) covers all electrical equipment with input or output voltage between 50 and 1000 V AC or between 75 and 1500 V DC. Therefore it is applicable in particular to all 110/230V line powered equipments, but not to small battery-operated systems. Be careful as there is a **specific case** : it is also applicable to all radio transmitters. So a Zigbee—enabled sensor is concerned, even if its power source is a 1,5V AAA battery.

Let's take the example of a computer peripheral, say a printer. If you look at the list of the harmonized standards associated to the low voltage directive (previous page), you will find that the **EN60950-1 standard** is applicable to “information technology equipments”. Seems a good match... You will then have to buy a copy of this EN60950-1 standard (directives are free of charge, standards usually aren't...) and to read it carefully. You will find in this standard plenty of precise requirements on electrical insulation and safety (insulation distances, safety earth, double vs single insulation, surge suppressors, etc). The safety isn't restricted to the electrical side : for example you will also have to insure that the product is mechanically safe (stability, no harmful parts, etc) as well as thermally safe (no accessible hot spots, resistant to flame hazard, etc).

If you have a worldwide market you will be lucky : this standard is in fact aligned with the international IEC60950-1 standard as well as the UL60950-1 so you will have to do the job once. This is fortunately often the case, mutual recognition between standard agencies are better and better. Anyway you will have to check in details.

# 6 EMC directive

The other big part of the CE marking is the EMC directive (2004/108/EC). As for safety there are hundreds of applicable standards, depending on the product. Keeping the same example of a computer peripheral the usual best match is the **EN55022** standard (“Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement”), associated with the more generic **EN61000-X-X** EMC immunity standards. The EMC standards cover in fact five different topics :

- **Radiated emissions** : The product is switched on in an anechoic chamber, in front of a receiving RF antenna. It shouldn't radiate anything above the standard-defined thresholds from tens of MHz up to GHz's.
- **Conducted emissions** : Similarly if the product has any external wiring (power cord, I/O cables, etc), it shouldn't conduct any noise or spurious signals above given limits through these cables. Usually the performances to this test are linked to the radiated test : if there is conducted spurious then the cable will probably act as an antenna and radiate them too...
- **Radiated immunity** : This test is the opposite of the radiated emissions. Still in the anechoic chamber the product is exposed to high levels of electromagnetic fields (simulating for example a nearby mobile phone), of course with specified levels, frequencies and modulations. The device must not fail during the test. More exactly it should behave as stated in its documentation.
- **Conducted immunity** : The same kind of tests is also done on external cables, injecting RF noise and spikes on them and checking the behaviour of the product.
- **Electrostatic discharge immunity** : Lastly the product must not be destroyed and/or put in a non-recoverable state (depending on its classification) when exposed to ESD spikes of some kilo-volts. This is usually the last test done on the prototype, especially if it is unique... Be sure that something will fail if some metallic accessible part is not properly grounded.

Part of these tests are similar to some FCC standards, but the levels are unfortunately not identical. A conscious test house can do the tests once and deduct compatibility to both standards but this should be anticipated.

# 7 R&TTE directive

The last generic directive applicable to several classes of electronic products is the R&TTE directive (1999/5/EC). This stands for Radio Equipment & Telecommunications Terminal Equipment. This directive is applicable to **all radio transmitters**, but also to **radio receivers** and **wired telecommunication devices**. As in the safety or EMC case there are plenty of related harmonized standards, like the **EN300328** standard applicable to wide-band 2,4GHz devices (Wifi, etc) or **EN300220** for sub-GHZ ISM transceivers. These standards force you to design “good” RF devices, for an optimal use of the radio bandwidth. A transmitter must transmit at the good frequency and power even if the battery is low, must not pollute the adjacent channels, must not transmit spurious signals elsewhere in the RF spectrum, must usually check if the channel is free before transmitting, etc.

Similarly, and even if it is less obvious, a too bad receiver is also not allowed : this will force to use to higher power transmitter, so reducing the efficient use of the RF spectrum.

Lastly devices with a significant transmit power (above some tens of mW) will also have a comply with recent **EMF** limits, related to potential harmless of RF signals on human tissues. You will usually have to prove that there can't be more than 20mW of power dissipated in any sample of 10g of human tissues. These tests, called Specific Absorption Rate (SAR) tests, are unfortunately quite long so quite expensive.

# 8 What about ROHS, WEEE and EuP ?

Lastly, you have certainly heard of environmental oriented regulations that have emerged in Europe in these last years. Even if these directives are not actually linked to the CE marking they are mandatory so let's briefly go through the main ones. Firstly there are **RoHS** (2002/95/EC, Restriction of hazardous substances like lead, mercury, cadmium, etc). In a nutshell only RoHS-compliant products could be sold in Europe except for quite specific product types (to date medical devices, spares parts for older systems, etc), so there isn't any associated mandatory marking. Just buy only lead-free solder and RoHS-compliant parts...

The second mandatory environmentally-linked directive is **WEEE** (2002/96/EC, Waste from Electrical and Electronic Equipment)n also called **DEEE** in France. It is associated with a specific marking (a barred garbage bin), and basically states that the manufacturer will manage and/or pay for the recycling of the product at its end of life through defined procedures.

Last but not least there is the **EuP** directive (2009/125/EC, EuP - Ecodesign of energy-related products). Its target is to improve the energy efficiency of power-hungry devices as well as to push the suppliers to analyse the full life cycle of their products. For the moment it is applicable only to selected products types (domestic lightning, TV sets, electric motors, etc). The list is growing quickly so stay tuned ! For example all new TV sets introduced on the European market mid 2012 will have to use less than 1W in standby mode and, when in use, less than 16 W + A x 3,4579 W/dm2, with A the screen size in square decimetres. Do the maths on your TV and measure if you are close to that limit, this will show you that there is still some work for electronic engineers !

# 9 Responsibility and paperwork...


Figure 4 (Source : http://ec.europa.eu/enterprise/policies/single-market-goods/cemarking/downloads/further_information_en.pdf )

Let's briefly talk on the administrative side of the CE marking. As explained, the manufacturer of a product affixes himself the CE mark on its product, under its responsibility. However the CE mark states that he has taken some mandatory steps before (figure 4). Firstly, as discussed, he must determine which directives and then usually which standards are applicable to the product. Then he need to carry out a **conformity assessment** of the product. Practically speaking this means that you have to select the applicable standards, and execute the corresponding test plans. In rare case a notified body must be involved. This is stated in the directives, and concerns only “risky” product classes (pressure-related devices, explosive environments, medical devices, etc). In the other cases nothing prevent to do the tests in house. However usually it is more efficient to subcontract them to a dedicated test house just because you may not have all the required equipment and experience. Also nothing prevent to execute only part of the required tests, or even not to rely on any applicable standard. But in that case you will need to explain (and to document) how you can insure that your product is still 100% compliant to the applicable essential requirements. And you can be sure that it will be a far more complex task than to simply apply a predefined and standardized test plan...

After the conformity assessment, the manufacturer also need to set up a **technical file**. It must include all details on the product design : schematics, PCB layout, bill of materials, mechanical design, user manuals, test reports, etc. This document, which is the bible of the product, must be written in an European official language and must be kept by the manufacturer at least 10 years after the end of the commercialization of the product... This document must be available to authorities in case of controls, and moreover must be physically available somewhere in Europe. For non-European manufacturers this is usually done through an authorized representative, which could be a distributor or even an attorney if the manufacturer has not a 100% trust in its distributor (as the technical file can allow to duplicate the product...).

Lastly the manufacturer must write an **EC declaration of conformity**, which is a one-page document stating that the product is CE compliant, describing the applicable essential requirements and standards, and providing the manufacturer's name and address. This document must be signed and made available to each customer. Then you can apply the CE mark on the products and ship them.

It isn't finished : products are always alive. Your design will evolve, some components will be obsolete and will require small redesigns, etc. Through all these incremental changes, the manufacturer must insure that the CE marking is not impacted. At the minimum you will need to document the changes in the technical file and document why you can insure that the changes have no impact on the CE conformance. This may not be trivial, in particular when EMC is concerned, so you may need to conduct new full or partial conformance assessment in order to still be able to commit on the product's conformance. You also need to prove that the shipped products are always in line with the technical file, which will require either manufacturing testing or quality insurance procedures.

# 10 Wrapping up

CE marking is, as all regulations, a complex subject. There are two ways to see it : you can either focus only on the bad sides (more constraints, more costs, more delays, more paperwork, etc), or on the positive sides : Thanks to such frameworks the products we are using are by far safer and more environmental friendly than the ones we got twenty years ago.

# 11 Who is ALCIOM ?

ALCIOM is a consultancy and design house company specialized in mixed signal devices, from radiofrequencies and microwaves to high speed electronic systems, digital signal processing and ultra-low power embedded systems. Based in France, near Paris, we served more than 100 customers worldwide since 2003. We are Microchip certified wireless design center and gold partners, Cypress gold partners, Texas Instruments low power RF specialists and accredited Analog Devices experts.

You can join us at contact@alciom.com , or visit our web site for more information : www.alciom.com

# 12 Sources

European Council Directives, downloadable from http://eur-lex.europa.eu

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