Client Alert.

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CE Marking 101 –
Frequently Asked Questions About CE Marking (or Questions That Ought to be Asked More Frequently)

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Despite the fact that the CE mark has been around for more than 15 years, its meaning and importance are often not well understood by those who wish to market their products in Europe, as well as the consumers and end users of such products. In this article, we review the CE marking requirements that apply to many products sold in Europe, and we set the CE rules in the context of other European product labelling requirements.

Imagine this – your company has developed a new product using cutting-edge technology. You now wish to market the product in Europe. Production is running at full steam, marketing arrangements are made, and distributors and other business partners in Europe are engaged. At the eleventh hour before product launch, one of your distributors rings you and says: "*Your products aren't CE marked. Are you sure that they don't have to be CE marked?*"

If this scenario sounds familiar to you, you are not alone. All businesses wishing to sell products in the European market face the inevitable question regarding the CE mark, the passport many different types of products need to obtain before they can be marketed in Europe.

WHAT IS A CE MARK?

A "CE mark" is a mark that must be affixed to certain categories of products sold in the 27 member states of the EU and Iceland, Liechtenstein, and Norway (in other words, the European Economic Area, or "**EEA**"). This is how a "CE mark" looks:

CE

WHAT IS THE MEANING OF A CE MARK?

"CE" is the abbreviation of the French phrase "*Conformité Européenne*" (literally "European Conformity").

A CE mark is a declaration by the manufacturer that the product in question complies with all relevant EU legislation that mandates:

- compliance with specific standards and requirements concerning product safety, environmental impact, consumer protection, etc.; *and*
- the placing of a CE mark.

It is important to bear in mind that the mere fact that a product bears a CE mark does not mean (and must not be taken to mean) that the product complies with *all* EU legislation that applies to that product (including those EU laws that don't mandate CE marking – see below).

WHY SHOULD WE BOTHER WITH A CE MARK?

Most importantly, CE marking is a legal obligation derived from EU legislation that provides that certain types of products must comply with specific standards and requirements. If a business wishes to market its products in Europe and those products are covered by the relevant EU legislation that prescribes CE marking, then a CE mark must be placed on such products as part of compliance with the applicable legal requirements.

CE marking is also important because it acts as a "passport" which enables a product to enter the European market. More than 30% of industrial products can be sold on the EU market only if they bear the CE Mark. Within the EU and the broader EEA, the marketing and use of products which carry a CE mark cannot be restricted unless there is evidence of non-compliance with the underlying EU legislation justifying such restriction. A CE mark also serves as a sign of assurance for consumers and other end users of the products.

WHAT PRODUCTS ARE COVERED BY THE CE MARKING REQUIREMENT?

A wide range of products are covered by EU laws that mandate CE marking. Categories of products which are subject to the CE marking requirement and which are relevant to businesses in the technology sector include the following:

- **Medical Devices in General**
  If a product is intended to be used for medical purposes (either alone or in combination, and including accessories for it), then it's likely that the product has to comply with the requirements of Directive 93/42/EEC of 14 June 1993, and be CE marked[1].

- **Medical Devices – Implants**
  If a product is a medical implant powered by battery or any other artificial power source (including software and accessories for it), then it's likely that the product has to comply with the requirements of **Directive 90/385/EEC of 20 June 1990**, and be CE marked[2].

- **Medical Devices – In Vitro Diagnostic Devices**
  If a product is intended to be used for *in vitro* examination[3] of samples derived from the human body (including accessories for it), then it's likely that the product has to comply with the requirements of **Directive 98/79/EC of 27 October 1998**, and be CE marked.

- **Products that have an impact on energy consumption**
  If a product uses gas, petrol, electricity, or otherwise "has an impact on energy consumption during use", including parts intended for use in such product (but excluding trains, cars and other means of transport), then the product may need to comply with the requirements of **Directive 2009/125/EC of 21 October 2009** (the "**Ecodesign Directive**") and be CE marked.

[1] Note that this Directive has a very broad application and will cover simple products such as condoms, as well as complex products such as hearing aids.

[2] Care must be taken in determining whether a given medical device falls under the ambit of Directive 94/42/EEC, or Directive 90/385/EEC.

[3] A study is said to be carried out '*in vitro*' if a component of an organism (a human being in the context of Directive 98/79/EC) is isolated from the organism and then studied.

Whilst the Ecodesign Directive appears to have a rather broad application, unlike other Directives that mandate CE marking (which prescribe specific requirements and standards with which a given type of product must comply), the Ecodesign Directive only applies to those product types in respect of which an EU Regulation has been enacted under the Ecodesign Directive.

So far, 10 such EU Regulations have been published[4] and, of these, one arguably has a much broader application than the other nine; that is, **Regulation No 1275/2008 of 17 December 2008** which applies to a specific range of electrical and electronic equipments, including:

- Washing machines, tumble dryers, toasters, microwaves, hair dryers, electric toothbrush, and other household appliances used for cooking, clothing care, and personal care;
- personal computers, scanners, printers, and other IT equipments "*intended primarily for use in the domestic environment*";
- radios, video cameras, VCRs, hi-fi systems, musical instruments, and other AV equipment (but excluding televisions); and
- toys such as radio-controlled cars, handheld video games consoles, and other toys or sports/leisure equipment with electric/electronic components.

- **Products which are capable of causing EMI**
  If a product is capable of causing electromagnetic interference or radio frequency interference (*i.e.,* most electrical and electronic goods), then it's likely that it has to comply with the requirements of **Directive 2004/108/EC of 15 December 2004** and be CE marked.

- **Radio equipment and telecommunications terminal equipment**
  If the product is capable of communication by either emitting or receiving radio waves (in the 9kHz to 3000GHz band) or if the product enables communication through public telecommunications network – including any component parts – then it's likely that the product has to comply with the requirements of **Directive 95/5/EC of 9 March 1999**, and be CE marked[5].

- **Electrical goods which operate in low voltage range**
  If a product is "*electrical equipment*" that operates in the voltage range of 50-1000 V AC or 75-1500 V DC, then it is likely that the product must comply with the requirements of **Directive 2006/95/EC of 12 December 2006** (the Low Voltage Directive, or "**LVD**"), and be CE marked.

  The term "*electrical equipment*" is not precisely defined within the LVD but, for the purposes of the LVD, this term essentially means anything which generates, carries, or utilises electricity. Therefore, the LVD applies to a very broad range of products, including goods such as electrical wiring, couplers and cord sets, lightbulbs (including both traditional incandescent lamps, as well as fluorescent lamps), etc., which one might not immediately perceive as 'equipment'[6].

[4] These EU Regulations cover specific types of products such as refrigerators, televisions, electric motors, set-top boxes, and lamps (including fluorescent lamps). The European Commission will be regularly reviewing the product categories that fall under the ambit of the Ecodesign Directive and going forward, further EU Regulations governing other types of products are likely to be enacted. Thus, even if a given product is not caught by the Ecodesign Directive today, it may come under the ambit of the Ecodesign Directive in the future.

[5] Note, however, that conventional radios and televisions which only received broadcasting signals, cabling/wiring, amateur radios, marine equipment and equipment for civil aviations, etc., are excluded from the scope of this particular Directive.

[6] Note, however, that exclusions apply to some equipment, *e.g.*, electrical equipment for radiology and medical purposes, electricity meters, and plugs/socket outlets for domestic use.

- **Measuring Instruments**
  If a product is a device or a system with a measuring function, such as a water meter, gas meter, electricity meter, taxi meter, measuring tape, measuring cap, or exhaust gas analyser, then it's likely that it has to comply with the requirements of **Directive 2004/22/EC of 31 March 2004**, and be CE marked.

The above list of product categories is not exhaustive. Other product categories which are subject to CE marking requirements include:

- Appliances that burn gaseous fuels and gaseous fuel regulators/controllers;
- Personal protective equipment;
- Construction products;
- Explosives for civil uses, pyrotechnic articles, and equipment and protective systems intended for use in potentially explosive atmospheres;
- Hot-water boilers;
- Cableway installations for passengers and elevators;
- Machineries, as well as certain accessories and related equipment such as safety components to be fitted to machineries, interchangeable equipments to be used with machineries, etc.
- Brush cutters, lawnmowers, hedge trimmers, high pressure water jet machines, portable chain saws, compaction machines, compressors, construction machineries such as bulldozers, drill rigs, and hydraulic hammers, and other similar noisy equipments for outdoor use;
- Non-automatic weighing instruments;
- Pressurised vessels for containment of fluids, piping, and related accessories;
- Boats intended for sports and leisure purposes (including small motor-powered boats), and certain components intended for such boats; and
- Toys.

Last but not least, businesses in the technology sector should bear in mind the requirements of **Directive 2011/65/EC of 8 June 2011** (the so-called "**RoHS2 Directive**") which will eventually replace Directive 2002/95/EC of 27 January 2003 (the original "**RoHS Directive**"). Both the original RoHS Directive and RoHS2 Directive restrict the way in which certain hazardous substances such as lead, cadmium, and mercury can be used in electrical and electronic equipment but, unlike the original RoHS Directive, the RoHS2 Directive now mandates CE marking as evidence of compliance. Thus, even if electrical/electronic products are not subject to any CE marking requirement as of today, they may have to be CE marked in the near future[7], due to the RoHS2 Directive.

[7] The implementation deadline for the RoHS2 Directive is 2 January 2013.

IT LOOKS LIKE OUR PRODUCTS ARE CAUGHT BY EU LEGISLATION THAT MANDATES CE MARKING. WHAT DO WE HAVE TO DO TO COMPLY?

The exact details of what has to be done in order to comply with EU legislation that mandates CE marking will vary depending on which EU law applies. However, generally speaking, products will need to follow the following steps:

- **Step 1: Ascertain with what specific requirements your products have to comply under the relevant EU legislation.** EU legislation that prescribes CE marking tends to require products to comply with:
    - a set of fundamental, qualitative criteria (for example, under the aforementioned LVD, electrical equipment caught by the LVD must, amongst other things, "*be made in such a way as to ensure that it can be safely and properly assembled and connected*", and be marked with "*the essential characteristics, the recognition and observance of which will ensure that electrical equipment will be used safely and in applications for which it was made*"); and
    - specific technical specification, standards, or requirements (for example, the LVD provides that where an electrical equipment complies with the "*safety provisions of relevant harmonised standards*", the equipment should be deemed to have complied with the requirement of the LVD that electrical equipment may be placed on the market only if it meets the safety requirements set out in the LVD[8]).
- **Step 2: Test your products to make sure that your products comply with the specific requirements imposed under the relevant EU legislation.** In respect of many EU laws that prescribe CE marking, you can conduct your own assessment, but some EU legislation requires an assessment by an appropriately authorised third party to be involved in such assessment and, if this is the case, you will have to have your products examined by such authorised third party (for example, in Germany, organisations such as TÜV[9] and, in the UK, organisations such as BSI[10], are authorised to conduct such conformity assessments in respect of the LVD, as well as in respect of other EU legislation).
- **Step 3: Prepare technical documentation regarding your products.** This documentation must enable the conformity of the product with the relevant legal requirements to be assessed. The precise content will vary depending on the product in question and the EU legislation concerned but, generally speaking, it must, as a minimum:
    - contain a general description of the product;
    - contain drawings and diagrams depicting the scheme of assembly of the product and explanations of such drawings and diagrams as necessary for the understanding of them, as well as the operation of the product;
    - set out the list of harmonised European standards or other relevant technical standards/specifications with which the product complies; and
    - set out results of design calculations, examinations, etc., including test reports.

[8] Note that compliance with European Harmonised Standards (*e.g.*, EN-60335-X series of safety standards for household and similar electrical appliances for the purposes of LVD) is not always mandatory, but use of European Harmonised Standards is widely accepted and is likely to be the best way to ensure compliance under most circumstances, whether for the purposes of LVD or other EU legislation that mandate CE marking.

[9] See http://www.tuv.com/

[10] See http://www.bsigroup.com/

- **Step 4: Affix a CE mark to your product.** There are specific rules surrounding CE marking. So, for example, a CE mark must generally be:
    - affixed "visibly, legibly and indelibly to the product";
    - at least 5mm high, and the aspect ratio must be maintained;
    - affixed *before* the product is placed on the European market; and
    - followed by the official identification number of the authorised third party who conducted the conformity assessment of the product (where applicable).
- **Step 5: Prepare "EC Declaration of Conformity".** You must draw up and sign a written declaration that your product complies with the requirements of all relevant EU legislation which prescribes CE marking (the precise content of such declaration varies depending on the underlying EU legislation). This declaration must be kept together with the technical documentation referred to in Step 3 above, and be made available to the appropriate authorities upon request.

WE'RE JUST A MANUFACTURER AND WE DON'T SELL DIRECTLY IN EUROPE; WE JUST LEAVE IT TO THE IMPORTERS AND DISTRIBUTORS WHO BUY THE PRODUCTS FROM US. DO WE STILL HAVE TO WORRY ABOUT CE MARKING?

Yes. Where the CE marking requirement applies to your product, your product must be CE marked before it is made available in the EEA. Whilst you can have your authorised representative in the EEA carry out the actual exercise of CE marking, CE marking is your sole and ultimate responsibility as a manufacturer.

The only exception to this general rule is if you are an OEM producing 'white label goods', which will be marketed within the EEA by importers and distributors under their own name/brand. In that case, the onus of CE marking shifts to such importers and distributors (although such importers and distributors ought to require you, as the manufacturer, to CE mark your products).

DOES CE MARKING ADDRESS ALL REGULATORY REQUIREMENTS THAT APPLY TO OUR PRODUCTS?

No it doesn't. A CE mark only signifies compliance with a certain set of EU legislation that specifically mandates CE marking. There is other EU legislation that regulates products, but does not mandate CE marking. To give just two examples:

- **Directive 2001/95/EC of 3 December 2001** (the "**General Product Safety Directive**") stipulates that a product which is intended for consumers (or could be used by consumers even if not intended for them) must meet certain product safety requirements before it is placed on the market. However, the General Product Safety Directive does not require such product to be CE marked; and
- **Directive 2002/96/EC of 27 January 2003 on waste electrical and electronic equipment** (the "**WEEE Directive**"), amongst other things, stipulates the manner in which electrical and electronic equipment which constitutes waste should be collected and treated, and also provides that electrical and electronic equipment must not be designed or produced in a manner which prevents the reuse of their waste. However, the WEEE Directive does not require such products to be CE marked.

Thus, the mere fact that a product bears a CE mark does not necessarily mean that it complies with all other EU legislation that applies to that product, but which does not mandate CE marking. Conversely, the fact that no CE marking requirement applies to a given product does not mean that that product does not have to comply with other EU legislation that applies to that product, but does not mandate CE marking.

ASIDE FROM CE MARKING, WHAT OTHER MARKING OR LABELLING REQUIREMENTS DO WE HAVE TO WORRY ABOUT?

There is no simple answer to this question. Different products are subject to different labelling, marking, and information disclosure requirements (which are, as with the CE marking requirement, always in addition to other legal requirements as to consumer protection, product safety, environmental protection, etc.), and the applicable legal requirement must be carefully examined on a case-by-case basis depending on the type of product a business wishes to introduce to the EEA.

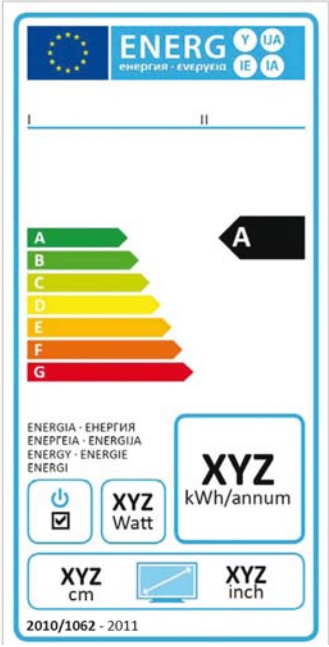
As a rule of thumb, the more specific and targeted the regulatory regime that applies to a particular product is, the more comprehensive and/or onerous the labelling, marking, and information disclosure requirements tend to become. Products such as food, pharmaceuticals, cosmetics, tobacco products, and chemicals are regulated under their specific regulatory regimes, and whilst such products are not subject to CE-marking requirements in their own right, the applicable regulatory regime imposes its own mandatory requirements, including (but not limited to) labelling, marking and information disclosure requirements.

Some nonexhaustive examples of labelling and marking requirements other than the CE marking requirement imposed under EU legislation that are relevant to technology products include the following:

- Under the aforementioned General Product Safety Directive, where a product could pose a risk, a requirement could be imposed that such product be "*marked with suitable, clearly worded and easily comprehensible warnings, in the official languages of the Member State in which the product is marketed, on the risks it may present*", and therefore different labelling requirements in connection with the General Product Safety Directive may apply in different EU member states.
- Under the aforementioned WEEE Directive, users must be informed about how electrical and electronic equipments should be disposed of, and almost all electrical and electronic equipment will need to be marked with a special mark to inform the end users that such equipment must not be discarded as general municipal waste:

- Under **Directive 2009/48/EC of 18 June 2009**, which concerns safety of toys, aside from CE mark, certain categories of toys must carry specific warnings, and toys not intended for babies must carry a special mark to inform consumers that the toys are not suitable for very young children:

- **Directive 2010/30/EU of 19 May 2010** (the "**Energy Labelling Directive**"), amongst other things, requires various household appliances to be labelled in a very specific way to show the energy efficiency of the product in question[11]. Shown below is one of the pro forma labels prescribed for televisions:



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Because of the generality of this update, the information provided herein may not be applicable in all situations and should not be acted upon without specific legal advice based on particular situations.

[11] At the moment, only televisions, air conditioners, washing machines, refrigerators, and dishwashers are caught by the labelling requirement under the Energy Labelling Directive, but other types of appliances are likely to come within the scope of the Energy Labelling Directive in the future. Also note that, in respect of certain product types, similar energy-efficiency labelling requirements are mandated under separate EU legislation, *e.g.* lightbulbs need to be labelled under Directive 98/11/EC of 27 January 1998.