

Exporting to Europe And CE Marking

CE Marking is currently required for many products sold in Europe, yet many U.S. exporters are still unsure or unaware of what affect this has on their business.



Welcome to our publication of Exporting to Europe and CE Marking.

This guide has been compiled to provide an easy to understand summary of the EU CE Marking process.

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Chapter 1

CE Marking – What's In It for You

The good news – The most obvious benefit is that a CE Mark on your product will gain you access to the European Economic Area (EEA), more commonly referred to as the EU.

If a European product safety directive(s) applies to your products and you want to continue to export to the EU market (or introduce new products), then CE Marking is legally **mandatory** and therefore crucial to your success.

Compliance with the same set of laws and 'essential requirements' outlined in the Directive(s), covering design and manufacturing of the product, is accepted by the entire European Union (EU) marketplace. The old multiple and conflicting national restrictions of 32 EU countries regulating products have been mostly eliminated.

The not so good news - The new product directive(s) may exceed the old national laws and regulations. These increased or new 'essential requirements' may lead to a manufacturer having to change its design or production processes in order to continue or enter into these markets.

You will incur costs in obtaining the product certification and any required testing referred to as 'ce-marking'. Also, the new directives and their implementation is confusing, undergoing constant change and subject to interpretation. In a recent move a few 'Directives' have been changed to 'Regulations'.

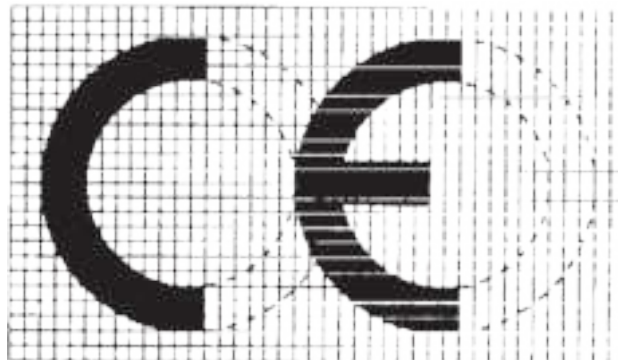
In recent years multiple environmental directives have been published that may also apply to your product.

Chapter 2

What is CE Marking

The European Commission refers to the CE Marking of products as a “passport” which can allow a manufacturer to freely circulate their products within the European marketplace. The marking applies to products regulated by the European Commission’s health, safety and environmental protection legislation (product directives and regulations) this is estimated to include more than 50% of the goods currently exported from the U.S to Europe. All other consumer products are subject to the requirements of the General Product Safety Directive 2001/95/EC, which does not require the CE mark symbol to be affixed to the products.

The actual CE Marking symbol is the letters “CE” which a manufacturer affixes to certain products for access to the European market (consisting of 32 EU countries and also referred to as the European Economic Area or EEA). The letters “CE” are an abbreviation of a French phrase “Conformité Européenne”. Applying the “CE” marking symbol indicates that the manufacturer has conformed with all the obligations required by the product and environmental directives applicable to their products. Initially, the phrase was “CE Mark”: however, “CE Marking” was legislated as its replacement in 1993.



Chapter 3

What Can a Notified Body Do For You?

Most companies need a guide to take them through the CE Marking maze. There are many expert sources of information available (conferences, consultants, Department of Commerce, the internet, etc.) all of which are more than willing to sell or give you their best opinion as to whether you may self-certify a product or if third party certification is required.

In the case of third party certification the only opinion that matters is that of the agencies that certify products for the European Union. These agencies, independent and 'for profit' are called "notified bodies", there are a few hundred of them and they are all located in Europe (some have satellites outside the EU that perform tests and submit the results back to Europe for final approval).

Notified bodies are accredited by European country government agencies to serve as independent certification companies that assess and perform the steps called out by product directives, only in cases where self-certification is not possible. They must have the necessary qualifications and personnel to meet the testing and assessment requirements set forth in the directives.

Notified bodies may be a private sector organization or a government agency. Manufacturers may choose a notified body in any member state of the European Union but can only apply to one agency for the same product.

Lists of notified bodies are published by the European Commission in the Official Journal of the European Communities.

<http://ec.europa.eu/enterprise/newapproach/nando/index.cfm>

Chapter 4

What To Look For In A Notified Body

Once it is determined that you manufacture a product that is not subject to the self-certification compliance route, the best way to proceed is to contact a notified body whose accreditation matches up with your product and whose credentials and affiliations match up with your target markets, and your suppliers and sub-contractors..

- Fees – Be aware that you may file only one application with one notified body. It is not possible to file with multiple agencies to compare fees.
- Service – A Notified Body, a for profit agency, does not provide ‘customer service’ in accordance with the American definition.
- Consulting- Notified bodies may not offer consulting or authorized representative services in addition to certification services. Many do offer seminars and publish ‘white papers’ and ‘guidance’ documents.
- ISO 9000/13485 and Product Certification – Both services must be provided by the same notified body.
- Find a notified body that will consider using qualified U.S. based auditors for audits to reduce travel related expenses.
- Unannounced audits- Notified Bodies may perform unannounced audits. For Medical and In-Vitro Diagnostic Devices unannounced audits are mandatory.

Chapter 5

Which EU Directive Applies To My Product

There are 25 product directives that require CE Marking compliance activities and the affixing of the symbol.

- Active Implantable Medical Devices - 90/385/EEC.
- Appliances Burning Gaseous Fuels – 2009/142/EC.
- Cableway Installations Designed to Carry Persons – 2000/9/EC.
- Construction Products – Regulation 305/2011.
- Eco-Design of Energy Related Products - 2009/125/EC.
- Electromagnetic Compatibility – 2004/108/EC. *
- Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres (ATEX) – 94/9/EC. *
- Explosives for Civil Uses – 93/15/EEC. *
- Hot-Water Boilers – 92/42/EEC.
- In Vitro Diagnostic Medical Devices – 98/79/EC.
- Lifts – 95/16/EC. *
- Low Voltage – 2006/95/EC. *
- Machinery – 2006/42/EC.
- Measuring Instruments – 2004/22/EC. *
- Medical Devices – 93/42/EEC.
- Noise Emission in the Environment – 2000/14/EC.
- Non-Automatic Weighing Instruments – 2009/23/EC. *
- Personal Protective Equipment – 89/686/EEC.
- Pressure Equipment – 97/23/EC.

- Pyrotechnics – 2007/23/EC.
- Radio and Telecommunications Terminal Equipment (RTTE) - 1999/5/EC. *
- Recreational Craft – 94/25/EC.
- Restriction of the use of certain hazardous substances (RoHS) - 2011/65/EU
- Safety of Toys – 2009/48/EC.
- Simple Pressure Vessels – 2009/105/EC. *

Europe's New Legislative Framework



“CE Marking” is based on the ‘New Legislative Framework’ adopted by the European Commission on 9 July 2008 and effective 1 January 2010 to implement Decision 768/2008/EC – Marketing of Products and reiterate the requirements of Regulation 765/2008/EC – Market Surveillance relating to the marketing of products.

Decision 768/2008/EC is binding upon the European Commission, the Member States and the European Parliament. It sets out a common framework for EU harmonized product legislation and when the Commission introduces proposals for alignment of specific Directives with the provisions of the Decision, Member States are then obligated to legislate the implementation of the revised Directives. Doing nothing is not an option.

On 29 March 2014 the following “Alignment Package” was published in the Official Journal of The European Union:

- Low Voltage Directive 2014/35/EU, formerly known as 2006/95/EC;
- Electromagnetic Compatibility Directive, formerly known as 2004/108/EC;
- ATEX Directive 2014/34/EU, formerly known as 94/9/EC;
- Lifts Directive 2014/33/EU, formerly known as 95/16/EC;
- Simple Pressure Vessels, formerly known as 2009/105/EC;
- Measuring Instruments Directive 2014/32/EU, formerly known as 2004/22/EC;
- Non-automatic Instruments Directive 2014/31/EU, formerly known as 2009/23/EC;
- Civil Explosive Directive 2014/28/EU, formerly known as 93/15/EEC;

Member States must adopt these Directives into national law to be applicable from 20 April 2016.

- Radio Equipment Directive 2014/53/EU, formerly known as RTTE Directive 199/5/EC. Member States must adopt this Directive before 13 June 2016.

Environmental Directives that do not require affixing of the CE Mark, but do require compliance are:

Waste Electrical and Electronic Equipment (WEEE) – 2012/19/EU

Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)-
Regulation No. 1907/2006.

Chapter 6

Which Directives Are Most Likely to Apply?

There are four directives which are quite inclusive. In addition, when more than one directive applies to a product, the product must comply with all applicable directives.

► **The Machinery Directive 2006/42/EC**

This directive applies to the following products:

- (a) machinery;
- (b) interchangeable equipment;
- (c) safety components;
- (d) lifting accessories;
- (e) chains, ropes and webbing;
- (f) removable mechanical transmission devices;
- (g) partly completed machinery.

► **The Medical Device Directive 93/42/EEC**

This directive applies to medical devices, their accessories and software.

► **The Low Voltage Directive 2006/95/EC**

This directive applies to electrical equipment designed for use with a voltage rating of between 50 and 1000V for alternating current and between 75 and 1500V for direct current, other than the equipment and phenomena listed in Annex II.

► **The Electromagnetic Compatibility Directive 2004/108/EC**

This directive requires equipment to comply with an adequate level of electromagnetic compatibility to function satisfactorily within that environment.

► **The Restriction of the Use of certain Hazardous Substances Directive 2011/65/EU**

This directive applies to 10 categories of products until 22 July 2019 at which time all electrical and electronic equipment must comply.

Restricts six hazardous substances and their maximum concentrated values:

- 1) Lead (Pb) (0.1%)
- 2) Mercury (Hg) (0.1%)
- 3) Cadmium (Cd) (0.01%)
- 4) Hexavalent Chromium (Cr6) (0.1%)
- 5) Polybrominated biphenyls (PBB) (0.1%)
- 6) Polybrominated diphenyl ethers (PBDE) (0.1%)

Chapter 7

CE Marking is required if your customers are located in certain countries

Countries comprising the European Economic Area (EEA) (28 EU countries and 4 EFTA countries) that require CE Marking:

- Austria
 - Belgium
 - Bulgaria
 - Croatia
 - Cyprus
 - Czech Republic
 - Denmark
 - Estonia
 - Finland
 - France
 - Germany
 - Greece
 - Hungary
 - Iceland (EFTA)
 - Ireland
 - Italy
 - Latvia
 - Liechtenstein (EFTA)
 - Lithuania
 - Luxembourg
 - Malta
 - Netherlands
 - Norway (EFTA)
 - Poland
 - Portugal
 - Romania
 - Slovakia
 - Slovenia
 - Spain
 - Sweden
 - Switzerland (EFTA)
 - United Kingdom
- Turkey- Although not a member of the EEA, a Customs Union agreement between Turkey and the EU requires Turkey to adopt CE Marking requirements.

Chapter 8

How Do You Acquire CE Marking?

There are a series of steps outlined below. Depending upon your product and the nature of the risks it presents, there are several alternatives, also noted, that may apply to your situation.

- Determine if any directives apply to your product. If more than one applies you will have to comply with all of them.
- Determine the extent to which your products complies with the essential requirements for design and manufacturing in the applicable directive(s).
- Choose the conformity assessment procedure from the options called out by the directive for your product.

The directives often use a series of definitions regarding intended use of your products to classify the level of risk and refer to a section called “Conformity Assessment Procedures”. The section includes all of the acceptable options available to a manufacturer to certify their product and affix the CE Marking.

Options for products with minimal risk include self-certification where the manufacturer, after compiling a technical file in accordance with the essential requirements, completes a declaration of conformity, appoints a European Authorized Representative for regulatory affairs and affixes the CE Marking to their own product.

Options for products with greater risks require Notified Body certification based on ongoing assessments of a Quality Management System, Technical file, testing reports etc., and appointing of a European Authorized Representative.

- Select the applicable product standards harmonized with the directive essential requirements outlining test methods etc. for your product and select an independent accredited lab if the product testing is to be done externally.
- Establish a European Authorized Representative for regulatory affairs in the European Economic Area (EEA) for your product. This is based on some directives that require that a manufacturer designate a European Authorized Representative to submit product technical documentation in a timely fashion when called upon to do so by the Competent Authorities.

The directives require for many products that a technical file be compiled by the manufacturer. The technical file holds information that verifies that the risks were assessed and the testing was conducted properly and that the product complies with the essential requirements using applicable harmonized standards in the process.

- Prepare a signed declaration of conformity, a legally binding document, that includes a list of the directives and standards that your product conforms to; product identification, the manufacturer's name, address and signature.

The declaration of conformity contains information adequate for tracing the product back to the manufacturer or the European Authorized Representative in the European Union.

- Affix the CE Marking to your product. There are specific requirements to adhere to in the Directives and Regulations. These rules address the size and location of the marking, affixing the CE Marking to products, packaging and material or documents shipped with the product, and specific limitations on when and who is permitted to affix the CE Marking.

- Translation of labels and instructions for use/manuals apply to low, medium and high risk products.

Chapter 9

Who's Going to Enforce the Requirements for CE Marking?

Each member state of the European Union is bound to adopt into their National Law, regulations and administrative provisions to ensure that products placed on the market are safe. Each country has its own way of handling enforcement through its Competent Authorities and customs officials.

Many have added staff specifically to conduct spot checks against implemented directives and respond to complaints. Countries have also set in place a combination of return-to-origin procedures, financial penalties, criminal prosecution, etc. European Union legislation makes European importers and distributors liable for the products they import.

Machinery manufacturers should be aware of the Use of Work Equipment directive 2009/104/EC which mandates employers provide safe (correctly ce-marked) products to their employees.

U.S. exporters are finding that no matter how interested a prospective European customer may be in their product, they will not risk importing non-conforming products when accidents will generate legal or criminal action against them.

Clearly defined responsibility of the manufacturer, importer, distributor and authorized representative can be found in Decision No. 768/2008/EC. <http://www.ce-mark.com/7682008EC.pdf>

Chapter 10

The Role of the European Authorized Representative

Several directives, the medical device directive 93/42/EEC and the machinery directive 2006/42/EC and In-Vitro Diagnostic Medical Devices 98/79/EC in particular, require the appointment of an authorized representative.

The term 'Authorized Representative' does not describe a sales and marketing function, it describes a CE Compliance/regulatory affairs function only.

Non-European manufacturers are required to identify a 'person' or 'entity' established in the European Union who is authorized to keep the manufacturers technical file or have quick access to it.

The Authorized Representative must have a written mandate (agreement) from the manufacturer before its name appears on the Declaration of Conformity along with the name and address of the manufacturer.

Conclusion:

CE-marking is complicated and takes time, but successful US exporters have adopted many of the strategies outlined in these directives and found them to be of common sense. Their sales increases reflect the CE compliance efforts to be worth it!