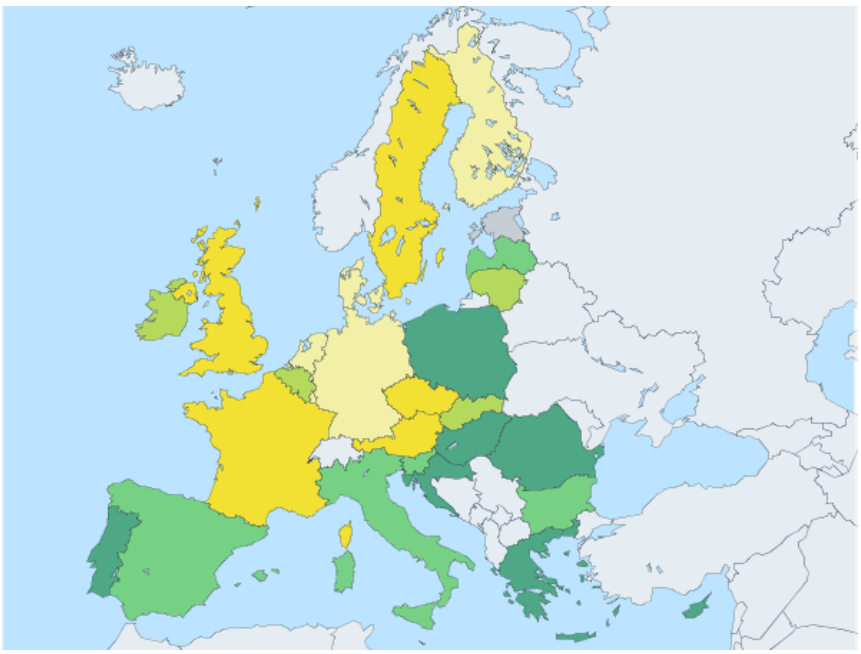
What is CE marking?

Introduction

Many products that are sold in the EU bear the CE mark. This indication became first mandatory in 1990 but it took no less than 3 years before the CE mark obtained its present graphic form. The two capital letters stand for 'Conformité Européenne', meaning 'conforms to the European legislation'. This indicates that the product meets the requirements of EU directives or EU regulations and it therefore may be traded freely within the European Economic Area (EEA).

It is the manufacturer of new products who has to apply the marking and who is responsible for the correct implementation of the EU directives and regulations. The same requirements apply for the importer placing a product on the EEA-market. However there are many others who are also involved with CE marking. Designers, distributors, retailers, suppliers or employers and users are all at least partly accountable for the correct application of the requirements.

Since 1 July 2013 the EU consists of 28 member countries, shown in the map in yellow and green (Source: http://epp.eurostat.ec.europa.eu/guip/countryAction.do). Six countries are candidate for the membership: Albania, Iceland, Montenegro, Serbia, Turkey and The Former Yugoslav Republic of Macedonia.



The EEA consists of the Member States of the EU and a number of members of the European Free Trade Association (EFTA), Norway, Iceland and Liechtenstein, who have opted to join. The 'Outermost Regions' and the 'Overseas Countries and Territories' of the member states belong to the EU, but are generally no part of the area for free movements of goods.

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Free trade is not possible without obligations

The primary aim of CE marking is to facilitate free trade of products within the EU by reducing the effect of the physical borders between the Member States. A secondary, though by no means less important, aim is the harmonisation across the EEA of the legal requirements for safety, health and the environment. This relates to both safety at work and protection of the public interest.

The requirements for CE marking are set out in Directives and Regulations. The Member States have committed themselves to incorporating the requirements of the Directives into their national legislation, whereas Regulations directly apply. This will result in the harmonisation of all legislation for free trade throughout the EEA.

CE marking usually involves the following obligations:

- Carrying out a risk analysis for the product. What hazards could be caused by the product? How great is the risk to people, animals, goods or the environment? What solutions can the manufacturer apply to reduce risks in compliance with the appropriate legislation?
- Delivery of an instruction manual in the language of the user, which sets out the intended purpose of the product. It contains furthermore the prohibitions and warnings, together with the instructions for assembly, controlling and maintenance.
- Drafting and signing the EU declaration of conformity. The manufacturer (or the importer for the EEA) declares that the product complies with the specified Directives or Regulations and standards.
- Preparing the technical documentation. This will include the documents mentioned above, as well as design data, drawings, calculations and test reports, making it possible to demonstrate that the essential requirements have been met.

A bit of history

The differences in trade regulations between the European countries that existed back in the ‘old days’ made life expensive for the traders. For each country of export the products frequently had to be approved by an expert body.
Shortly after the Second World War international parties in Europe started to set up agreements for free trade of goods. Consequently new partnerships between countries and regulations were established.

1958	EEC became a fact, Treaty of Rome
1959	EEC legislation for work, free movement of persons and goods, product safety
1985	Introduction of the New Approach
1987	First mentioning of the CE mark for products
1992	The European Economic Area (EEA) is designated
1993	Founding of the EU, EEC becomes EC (Treaty of Maastricht)
1995	The Machine directive mandatory for new machines
1997	Directive for the safe use of work equipment
2008	The New Legislative Framework for the marketing of products
2009	Radical reformation both on policy and decision-making by the EU

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The New Approach

The change to less direct governmental involvement in the details of a product made it possible to introduce a whole new phenomenon in the area of legislation. The basis for this was the idea that the greatest barriers to trade were linked to safety aspects which required too much detailed negotiation to achieve approval by all Member States. Thus for various product groups only general requirements were defined and set out under the New Approach which were approved by all Member States. By means of this harmonisation the same legislation for safety, health, environment and public interests apply for many product sectors in all of the countries in the EEA. The CE mark on a product indicates that it complies with the requirements. Goods can now be traded freely within the European Economic Area (EEA).

For as many products as possible the obligatory national approval procedures have been abolished throughout the EEA. Manufacturers (or importers) must now ensure that they meet the legal requirements and must be able to provide evidence of this should problems arise. To this end a system has been devised which brings together quality assurance and the assessment of conformity with the EU directives and regulations.

CE marking is self-certification, which is particularly good for small and medium companies. Only in exceptional cases, for example for specific dangerous medical devices, large pressure vessels or construction products, is it necessary to consult a Notified Body which will examine those aspects of the product and or the quality system and issue a certificate. Such institutes are appointed by the national authorities for a certain sector of a EU directive or regulation.

The New Legislative Framework

Throughout the years the many changes in the EU legislation lead to a large amount of differences in form and presentation of the requirements for the various product sectors. The need for a uniform and improved policy for market surveillance was obvious and not least because of the increased import of products from outside the EEA and unclear local certification rules.

In July 2008 the EU member states adopted the New Legislative Framework (NLF), which built on the achievements under the New Approach. This overall legislative framework contains all the elements required for an effective regulation for safety and compliance of industrial products, based on requirements adopted to protect the various public interests and for the proper functioning of the single market. This should also lighten the burden for the small and medium companies in particular.

The instruments for effective conformity assessment procedures are given in modules and the criteria for the designation and notification of conformity assessment bodies were renewed. Also market surveillance together with control of products from third countries is covered quite comprehensively and the safeguard mechanisms for non-compliant products, together with the responsibilities of the economic operators and of the national authorities are taken account for. Furthermore have all important concepts been redefined and the meaning of the CE marking was consolidated properly.

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The NLF takes account of all the economic operators in the supply chain, manufacturers, authorised representatives, distributors and importers. The importer now has a clear role in relation to the compliance of a product. And he, who modifies a product or markets it under his own name or trademark, must take on the responsibilities as if he were the manufacturer.

The former EU harmonisation legislation had the focus on the requirements for products when 'placing on the market', meaning the moment of *first making available* on the EU market. The NLF puts the emphasis on 'making available on the market' of a product, i.e. the supply of a product on the EU market in the course of a commercial activity. The NLF attaches in this way great importance to what happens *after* a product is first made available on the market. Hereby the legislative framework is better anchored for market surveillance and the tracing back of a non-compliant product to the manufacturer. It is important to note that the product must be compliant with the requirements applicable at the time of the first making available.

The most important *change* brought about by the NLF to the EU legislation was the introduction of a comprehensive policy on market surveillance. This has lead to equal attention for the compliance of products when placing on the market as for the whole life-cycle of products.

As from July 2008 all new EU directives and regulations are based upon the New Legislative Framework.

International trade

International trade in regulated products between the EU and third countries is promoted by mutual agreements, cooperation and programs for technical assistance.

- Three of the EFTA Countries, Iceland, Norway and Liechtenstein are fully integrated in the internal EU market by virtue of the EEA agreement.
- The inter-governmental Mutual Recognition Agreements (MRAs) for conformity assessment, certificates and marking make it possible for free trade in designated product sectors between the European Union and third countries, such as Australia, Canada, Japan, New Zealand, Switzerland and the United States, holding their national requirements in force.
- For certain product sectors it is possible to conclude agreements with Candidate countries to make a start with the alignment of the legislative system and infrastructure, before they enter the EEA.
- EU may agree to similar legislative alignments with the Neighbouring countries, such as Algeria, Israel, Jordan, Lebanon, Morocco, Palestinian Authority, by the so called Agreements on Conformity Assessment and Acceptance of industrial products (ACAAs).

Harmonised standards

In order to assist the manufacturer (or importer) with the conformity assessment of a product standards are being drafted at a relatively high rate, which are issued in connection with the Directives and Regulations for the product sectors. They are known as harmonised standards and can be recognised as such by the indication *EN* before the standard number.

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Many of these standards make it possible to do without an extensive risk analysis. By adhering closely to the articles of the standard it can be assumed that there is a ‘presumption of conformity’ with the essential requirements for the product.

In contrast to the Directives and Regulations the harmonised standards are very technical. Standards can be much more easily adapted to take account of current technical developments. EN-standards are not mandatory but often serve as a very useful tool.

General Product safety

In order to reach a high level of product safety throughout the EU a separate directive was drawn up for consumer products that are not covered by specific EU harmonisation legislation, but also complements the product directives and regulations in some aspects. Products may only be placed on the market by the manufacturers if these are safe for consumers.

Under this directive the rapid alert system *RAPEX* was set up, with which the authorities are able to be informed of dangerous products. In certain cases enables the Directive for general product safety to take emergency measures for the EEA. The RAPEX system has been gradually extend to apply to all industrial non-food products, thus not only for consumer products.

Product liability

For regulating the product liability in the European trade association there is a separate directive which applies to products which appear to be unsafe.

It is now up to the manufacturer, or his representative, to demonstrate that things are in order on delivery. In order to receive compensation the victim must be able to prove that the damage was caused by the product. However, he does not have to prove that the manufacturer has been negligent.

Applying CE marking

The CE mark is applied by the manufacturer or his importer for the EEA. The CE logo should be clearly visible on the product or on the packaging if there is no space on the product. In conjunction with the EU declaration of conformity the manufacturer is stating that the product meets the requirements of the Directives or Regulations for CE marking.

Apart from that do the Directives and Regulations for new products also contain provisions which do not lead to the actual CE marking, but the product must nevertheless comply with certain parts of the requirements. This is by example the case for a medical device that is produced for one particular patient only, or also for partly completed machinery.

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EU directives and EU regulations for CE marking

The following tables inform about the directives and regulations that may lead to the CE marking of products.

The Directives and Regulations for CE marking			
Product sector	*Subject*	*Compulsory with*	*EU directive, or EU regulation (amendment)*
Cableway installations	Cableway installations designed to carry persons	2004-05-03	2000/9/EC
Construction products	Harmonised conditions for the marketing of construction products Replacing CPR Amendment Annex V Amendment Annex III	1991-06-27 2011-04-25/ 2013-07-01 2014-06-16 2014-06-17	 (EU) 305/2011 ((EU) 568/2014) ((EU) 574/2014)
Efficiency requirements for hot water boilers	Efficiency requirements applicable to new hot-water boilers fired by liquid or gaseous fuels Partly amended/repealed Transitional provisions until	1998-01-01 2015-09-26/ 2018-09-26	92/42/EEC (93/68/EEC) (2004/8/EC) (2005/32/EC) (2008/28/EC) (EU) 813/2013
Ecodesign	Framework directive for the setting of ecodesign requirements for energy-related products Latest amendment	2010-11-20 2014-06-05	2009/125/EC (2012/27/EU)
Electromagnetic Compatibility (EMC)	Equipment liable to generate electromagnetic disturbance, or which is liable to be affected by such disturbance Replaced by new version Next replacing version	1996-01-01 2007-07-20 2016-04-20	 2004/108/EC 2014/30/EU
Equipment in explosive atmospheres (ATEX)	Equipment and protective systems intended for use in potentially explosive atmospheres Latest amendment Replacing version	2003-07-01 2013-01-01 2016-04-20	94/9/EC ((EC) 1882/2003) ((EU) 1025/2012) 2014/34/EU

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The Directives and Regulations for CE marking

Product sector	*Subject*	*Compulsory with*	*EU directive, or EU regulation (amendment)*
Explosives	Making available on the market and supervision of explosives for civil uses Latest amendment Replacing version	2003-01-01 2013-01-01 2016-04-20	93/15/EEC ((EC) 1882/2003) ((EC) 219/2009) ((EU) 1025/2012) 2014/28/EU
Appliances burning gaseous fuels	Appliances (non-industrial) burning gaseous fuels used for cooking, heating, hot water production, refrigeration, lighting or washing Replaced by codified version	1996-01-01 2010-01-05	 2009/142/EG
Lifts	Lifts permanently installed in buildings and constructions Latest amendment Replacing version	1999-06-30 2009-12-29 2013-01-01 2016-04-20	95/16/EC ((EC) 1882/2003) (2006/42/EC) (EU) 1025/2012 2014/33/EU
Low voltage equipment	Electrical equipment designed for use with a voltage rating between 50-1000 VAC or 75-1500 VDC Replaced by codified version Replacing version	1997-01-01 2007-01-16 2016-04-20	 2006/95/EC 2014/35/EU
Machinery	Machinery Replaced Amendment regarding machinery for pesticide application	1995-01-01 2009-12-29 2011-12-15	 2006/42/EC ((EC) 596/2009) (2009/127/EC)
Measuring instruments	Devices or systems with a measurement function Latest amendment Replacing version	2006-10-30 2013-01-01 2016-04-20	2004/22/EC (2006/96/EC) ((EC) 1137/2008) (2009/137/EC) ((EU) 1025/2012) 2014/32/EU
Medical devices	Medical devices (general) Latest amendment	1998-06-14 2010-03-21	93/42/EEC (98/79/EC) (2000/70/EC) (2001/104/EC) ((EC) 1882/2003) (2007/47/EC)

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The Directives and Regulations for CE marking

Product sector	*Subject*	*Compulsory with*	*EU directive, or EU regulation (amendment)*
Active implantable medical devices	Electrically driven medical devices implanted in the human body Latest amendment	1995-01-01 2010-03-21	90/385/EEC (93/42/EEC) (93/68/EEC) ((EC) 1882/2003) (2007/47/EC)
Medical devices for in-vitro diagnostics	Medical devices intended for in-vitro examination of specimens derived from the human body Latest amendment	2003-12-07 2012-01-11	98/79/EC ((EC) 1882/2003) ((EC) 596/2009) ((EU) 100/2011)
Non-automatic weighing instruments	Weighing instruments requiring the intervention of an operator Replaced by codified version Latest amendment Replacing version	2003-01-01 2009-06-05 2013-01-01 2016-04-20	 2009/23/EC ((EU) 1025/2012) 2014/31/EU
Personal protective equipment	Appliances designed to be worn or held by an individual for protection against health and safety hazards Latest amendment	1995-07-01 2013-01-01	89/686/EEC (93/68/EEC) (93/95/EEC) (96/58/EC) ((EC) 1882/2003) ((EU) 1025/2012)
Pressure equipment	Pressure equipment and assemblies with a maximum allowable pressure greater than 0,5 bar Latest amendment Amendment art. 9 Replacing version	2002-05-29 2013-01-01 2015-06-01 2016-07-19	97/23/EC ((EC) 1882/2003) ((EU) 1025/2012) 2014/68/EU art.13 2014/68/EU
Pyrotechnic articles	Fireworks category 1, 2, 3 Fireworks category 4, other pyrotechnical articles, and those for theatrical use Replacing version	2010-07-04 2013-07-04 2013-06-29/ 2015-07-01	2007/23/EC ((EU) 1025/2012) 2013/29/EU
Radio equipment	Equipment that is either radio equipment or telecommunications terminal equipment or both Latest amendment Replacing version	2000-04-08 2009-08-07 2016-06-12	1999/5/EC ((EC) 1882/2003) ((EC) 596/2009) 2014/53/EU

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The Directives and Regulations for CE marking

Product sector	*Subject*	*Compulsory with*	*EU directive, or EU regulation (amendment)*
Recreational craft	Recreational craft and personal watercraft Latest amendment Replacing version	1998-06-16 2013-01-01 2016-01-18	94/25/EC (2003/44/EC) ((EC) 1882/2003) ((EC) 1137/2008) ((EU) 1025/2012) 2013/53/EU
RoHS	Restriction of the use of certain hazardous substances in electrical and electronic equipment Replacing version Latest amendment	2004-08-13 2013-07-22 2014-01-29	 2011/65/EU (2012/50/EU) (2012/51/EU) (2014/2/EU)
Simple pressure vessels	Welded vessels with a pressure greater than 0,5 bar intended to contain air or nitrogen Replaced by codified version Latest amendment Replacing version	1992-07-01 2009-10-28 2013-01-01 2016-04-20	 2009/105/EC ((EU) 1025/2012) 2014/29/EU
Toys	Products designed or intended for use in play by children of less than 14 years of age Replaced first phase Complete replacement Latest amendment	1990-01-01 2011-07-20 2013-07-20 2013-07-20	 2009/48/EC (2012/7/EU) ((EU) 681/2013)
Noise emission	Noise emission in the environment by equipment for use outdoors	2002-01-03 2009-04-20	2000/14/EC (2005/88/EC) ((EC) 219/2009)

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