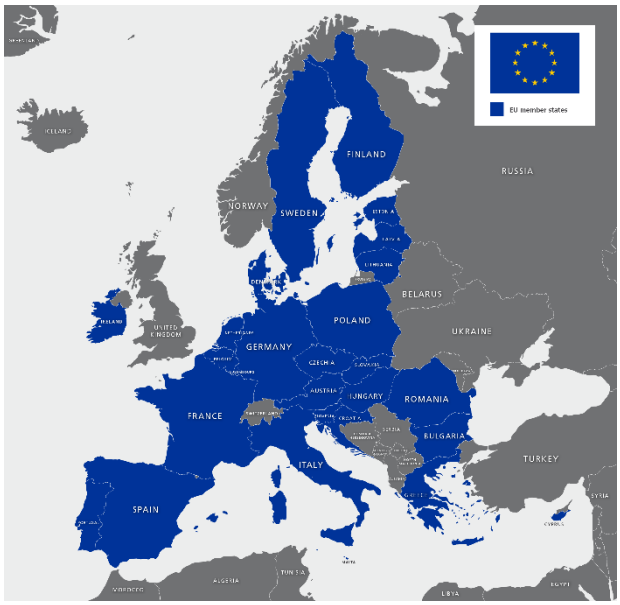
What is CE marking?

Introduction

Many products that are sold in the EU bear the CE mark. The two capital letters *CE* stand for ‘Conformité Européenne’, meaning ‘conforms to the European legislation’.
With the CE marking attached the product may be traded freely within the European Economic Area (EEA), because it meets the requirements of EU directives or EU regulations.

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

The map shows the 27 member countries of the European Union. The United Kingdom left the EU on January 31, 2020. (Source: https://maproom.net/shop/eu-map).



Seven countries are candidate for the membership: Albania, Moldova, Montenegro, North Macedonia, Serbia, Türkiye and Ukraine. The potential candidate countries are Bosnia and Herzegovina, Georgia, and Kosovo. The EEA consists of the member countries of the EU and three 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 countries belong to the EU but are not part of the area for free movements of goods.

A bit of history

Shortly after the Second World War international parties in Europe started to set up agreements for free trade of goods. Consequently, new partnerships between European countries established and new rules were agreed.

1958	EEC became a fact, Treaty of Rome
1959	EEC legislation for work, free movement of persons and goods, product safety
1985	New directives for product safety and free trade according to 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)
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
2020	United Kingdom leaves the EU

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 countries. A secondary aim is the harmonisation across the EU 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 countries have committed themselves to incorporating the requirements of the directives into their national legislation, whereas regulations directly apply. The result is harmonisation of all legislation for free trade.

CE marking usually involves the following obligations:

- Conducting 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 according to appropriate legislation?
- Providing 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 EEA importer declares that the product complies with all of the specified EU directives, EU regulations together with certain standards.
- Preparing the technical documentation. This will include the documents mentioned, as well as design data, drawings, calculations, and test reports, making it possible to demonstrate that the essential requirements have been met.

The New Approach

For various product groups general requirements were defined in 1985 under the New Approach. By means of this harmonisation the same legislation for safety, health, environment, and public interests applies for many product sectors in all of the countries in the EU. The CE mark on a product indicates that it complies with the requirements. Because of that goods can be traded freely within the European Economic Area.

Manufacturers or importers for the EU must ensure that the legal requirements are met and must be able to provide evidence. To this end a system has been devised which brings together quality assurance and conformity assessment with EU directives and regulations.

CE marking is a form of 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 certain product groups.

The New Legislative Framework

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

In July 2008, the EU member countries 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 will also lighten the burden for the small and medium companies in particular.

The methods 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. There are better safeguard mechanisms for non-compliant products, and the responsibilities of the economic operators and of the national authorities are revised. Furthermore, have all important concepts been redefined and the meaning of the CE marking was consolidated properly.

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 NLF puts the emphasis on ‘making available on the market’ of a product, i.e., the supply of a product on the EEA market in the course of a commercial activity. The NLF attaches in this way significant importance to what happens after a product is ‘first made available on the market’. That way the new framework is better anchored for market surveillance and the tracing back of a non-compliant product to the manufacturer. This led to equal attention for the compliance of products when placing on the market as for the whole life cycle of products.

All new EU directives and regulations for products are based upon the New Legislative Framework for product trading.

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.
- 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 (ACAA).

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, and which have connections with the EU directives and EU regulations. They are known as harmonised standards and can be recognised as such by the indication *EN* before the standard number.

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 for 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* (Rapid Alert System) 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 extended 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 applicable EU directives or EU 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 for example the case for a medical device that is produced for one particular patient only, or also for partly completed machinery.

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.

Directives and regulations for CE marking			
Product group or sector	*Subject*	*Compulsory: First date Amended*	*EU directive, or EU regulation [amendment]*
Cableway installations	Cableway installations designed to carry persons	2004-05-03 2018-04-21	**(EU) 2016/424**
Construction products (CPR)	Harmonised conditions for the marketing of construction products Replacing regulation CPR Amendment Annex V Amendment Annex III Market surveillance and conformity	1991-06-27 2011-04-24/ 2013-07-01 2021-07-16	 **(EU) 305/2011** [(EU) 568/2014] [(EU) 574/2014] [(EU) 2019/1020]
Hot water boilers	Efficiency requirements applicable to new hot-water boilers fired by liquid or gaseous fuels Partly amended/ partly repealed	1998-01-01 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 Latest amendment	1996-01-01 2016-04-20	**2014/30/EU** [(EU) 2018/1139]
Equipment in explosive atmospheres (ATEX)	Equipment and protective systems intended for use in potentially explosive atmospheres	2003-07-01 2016-04-20	 **2014/34/EU**

Directives and regulations for CE marking

Product group or sector	*Subject*	*Compulsory: First date Amended*	*EU directive, or EU regulation [amendment]*
Explosives	Making available on the market and supervision of explosives for civil uses	2003-01-01 2016-04-20	 **2014/28/EU**
Appliances burning gaseous fuels	Appliances (non-industrial) burning gaseous fuels used for cooking, heating, hot water production, refrigeration, lighting or washing	1996-01-01 2018-04-21	 **(EU) 2016/426**
Lifts	Lifts and safety components for lifts	1999-06-30 2016-04-20	 **2014/33/EU**
Electrical equipment (Low voltage equipment LVD)	Electrical equipment designed for use with a voltage rating between 50-1000 VAC or 75-1500 VDC	1997-01-01 2016-04-20	 **2014/35/EU**
Machinery	Machinery Safety components and potentially dangerous machinery Machinery for pesticide application Agricultural and forestry tractors Amendment regarding lifts Latest amendment	1995-01-01 2009-12-29 2011-12-15 2016-01-01 2016-04-20 2016-04-20 2019-07-26	 **2006/42/EC** [(EC) 596/2009] [2009/127/EC] [(EU) 167/2013] [2014/33/EU] [(EU) 2019/1243]
Measuring instruments	Devices or systems with a measurement function Water meters	2006-10-30 2016-04-20 2016-04-20	 **2014/32/EU** [2015/13/EU]
Medical devices (MDR)	Medical devices (general) Directive repealed by regulation [Change application date]	1998-06-14 2021-05-26 [2020-04-23]	93/42/EEC **(EU) 2017/745** [(EU) 2020/561]
Active implantable medical devices (MDR)	Electrically driven medical devices implanted in the human body Directive repealed by regulation [Change application date]	1995-01-01 2021-05-26 [2020-04-20]	90/385/EEC **(EU) 2017/745** [(EU) 2020/561]

Directives and regulations for CE marking

Product group or sector	*Subject*	*Compulsory: First date Amended*	*EU directive, or EU regulation [amendment]*
Medical devices for in-vitro diagnostics (IVDR)	Medical devices intended for in-vitro examination of specimens derived from the human body Transitional provisions and application date	2003-12-07 2022-05-26 [2022-01-28]	98/79/EC **(EU) 2017/746** [(EU) 2022/112]
Non-automatic weighing instruments (NAWI)	Weighing instruments requiring the intervention of an operator	2003-01-01 2016-04-20	**2014/31/EU**
Personal protective equipment (PPE)	Appliances designed to be worn or held by an individual for protection against health and safety hazards, interchangeable components, and connexion systems	1995-07-01 2018-04-21	**(EU) 2016/425**
Pressure equipment (PED)	Pressure equipment and assemblies with a maximum allowable pressure greater than 0,5 bar	2002-05-29 2016-07-19	**2014/68/EU**
Fireworks	Pyrotechnical articles	2010-07-04 2015-07-01	**2013/29/EU**
Radio equipment (RED)	electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radiodetermination Amendment aviation safety	2000-04-08 2016-06-12 2018-09-11	**2014/53/EU** [(EU) 2018/1139]
Recreational craft	Recreational craft and personal watercraft	1998-06-16 2016-01-18	**2013/53/EU**
RoHS	Restriction of the use of certain hazardous substances in electrical and electronic equipment 78 amendments, latest amendment	2004-08-13 2013-07-22 2022-03-16	**2011/65/EU** [(EU) 2022/287]

Directives and regulations for CE marking			
Product group or sector	*Subject*	*Compulsory: First date Amended*	*EU directive, or EU regulation [amendment]*
Simple pressure vessels (SPVD)	Welded vessels with a pressure greater than 0,5 bar intended to contain air or nitrogen	1992-07-01 2016-04-20	**2014/29/EU**
Toys	Products designed or intended for use in play by children of less than 14 years of age 16 amendments, latest amendment	1990-01-01 2011-07-20 2021-01-04	**2009/48/EC** [(EU) 2020/2089]
Noise emission	Noise emission in the environment by equipment for use outdoors Latest amendment	2002-01-03 2019-07-26	**2000/14/EC** (2005/88/EC) ((EC) 219/2009) [(EU) 2019/1243]