Nine steps to CE marking

A guide for manufacturers and importers of electrical and electronic products

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Content

Preface

Many products require CE marking before they can be sold in the European Union. These include, in particular, almost all electrical and electronic products. The affixing of the CE mark to a product certifies that the product complies with all applicable harmonized standards in the EU and that this has been proven in a conformity assessment procedure. The sole responsibility for CE marking lies with the manufacturer.

This guide describes in nine steps which tasks the manufacturer has in the context of CE conformity of his products, namely before the start of sales, during the distribution and from the end of distribution. In addition, general information on the CE marking as well as the tasks of other economic operators (authorised representatives, importers, distributors, fulfilment centres) are summarised in an introductory part I.

The guide is intended to give those who are responsible for the CE conformity of a product, place a product on the market in the EU, sell it under their own brand or, as an importer who wants to check the manufacturer's data, a compact overview of their tasks and obligations. The guide refers to products that fall under the sector-specific directives listed in Figure 1.

Anja Olsok
CEO Bitkom Servicegesellschaft mbH

I. The CE marking

What does CE marking represent?

Here is an excerpt from the Blue Guide, 2016: Commission Notice, Guidance for the Implementation of EU Product Regulations 2016 (»Blue Guide«) 2016/C 272/01, p. 57:

- *The CE marking indicates the conformity of the product with the Union legislation applying to the product and providing for CE marking.*
- *CE marking is the visible consequence of a whole process comprising conformity assessment in a broad sense and indicates that a product is declared by the manufacturer as in conformity with Union harmonisation legislation.*
- *CE marking does not indicate that a product was made in the European Union. The CE marking indicates conformity with the requirements laid down by the Union harmonisation text(s) in question. [...] CE marking does not serve commercial purposes, i. e. it is not a marketing tool.*

What does »CE« stand for?

The abbreviation CE originally stood for »Communautés Européennes« (= »European Communities«), but is now also used by the European standardisation institutes and is translated as Conformité Européenne (= »European Conformity«).

CE

Who is responsible for CE marking?

The manufacturer has sole responsibility for the CE marking. They must check whether their product falls under one of the EU harmonisation legislation. If this is the case, they must demonstrate the conformity of their product with all applicable EU legislation, declare its conformity (EU Declaration of Conformity) and affix the CE marking to the product.

A manufacturer is defined as any natural or legal person who manufactures a product or has a product designed or manufactured, and places it on the market under his own name or trademark. (Manufacturer definition from the Blue Guide, p. 29)

This means that anyone who merely marks a product with their name and trademark is also considered as manufacturer.

Which actors are in the supply chain and what are their obligations?

In order to ensure basic safety requirements for products in the EU, the obligations have been extended to all economic operators. In addition to the manufacturer, these include the manufacturer's potential authorised representatives, the importer, as well as distributors and fulfilment service providers. The end user is not an economic operator.

Details can be found in Section 3 of the Blue Guide.

a) Manufacturer

The manufacturer shall ...

- carry out a conformity assessment for the product to determine which guidelines, regulations and standards to be applied for and complied with the product;
- declare the CE conformity of the respective product with the applicable CE directives (EU Declaration of Conformity);
- be able to prove compliance with the legal requirements (prepare technical documentation and keep it available for 10 years after they have supplied the product);
- label the products accordingly (CE marking), including the name of the manufacturer, trade name or trademark and the company's address;
- also subsequently ensure conformity throughout the entire period of sale for each product, both with regard to changes in regulatory requirements and product design.

b) Authorised representative

Definition from Blue Guide, 2016, page 32:

Irrespectively of whether he is established in the EU or not, the manufacturer may appoint an authorised representative in the Union to act on his behalf in carrying out certain tasks.

Tasks also from the Blue Guide, 2016, pages 32/33:

Where the manufacturer appoints an authorised representative, the mandate shall at least allow the authorised representative to perform the following tasks:

- *keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authorities and cooperate with them at their request,*
- *upon a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a product,*
- *cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by products covered by their mandate.*

Depending on the conformity assessment procedure and the Union harmonisation act in question, the authorised representative can also, for instance, be appointed to perform tasks such as:

- *affix the CE marking (and where relevant other markings) and the notified body's number to the product,*
- *draw up and sign the EU declaration of conformity.*

c) Importer

The importer shall ...

- ensure that a conformity assessment has been carried out by the manufacturer; and
- ensure that the manufacturer has drawn up the technical documentation and affixed the CE marking;
- label the product with his name, trade name or mark and his company address;
- keep the EU Declaration of Conformity for ten years after placing on the market; and
- ensure that the technical documentation can be presented to the competent national authority on request.

d) Distributor

The distributor shall verify that ...

- the product bears the required conformity marking; and
- the product is accompanied by the required documentation (e. g., the EU Declaration of Conformity) as well as instructions for use and safety information; and
- the manufacturer and importer have provided their name, registered trade names or trademarks and their contact address.

e) Fulfilment Service Provider

Definition from EU Regulation 2019/1020 on Market Surveillance and Product Conformity:

»Fulfilment service provider« means any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching.

Note

The term »Fulfilment service provider« was first introduced by Regulation 2019/1020 and will be included in the next version of the Blue Guide (mid-2021).

According to EU Regulation 2019/1020, a fulfilment service provider can become an economic operator and, in that case, shall ...

- keep the EU Declaration of Conformity and performance declaration, and make these, as well as the technical documents, available to the authorities on request;
- inform the authorities if they believe that a product presents a risk;
- cooperate with the authorities, upon request, by taking prompt corrective action (from rectification of the defect to recall or destruction of the product) when a product is deemed to be non-compliant and helps to eliminate or mitigate risks;
- provide the product, packaging or accompanying documentation with their name and contact details.

Which products require a CE marking?

All products that fall within the scope of the following directives and regulations require a CE marking.

Product group resp. criterion	Link to the corresponding EUR-Lex page with the Directives/ Regulations in all EU languages
Active implantable medical devices	↗ Directive 90/385/EEC on active implantable medical devices
Lifts	↗ Directive 2014/33/EU on Lifts
Construction products	↗ Regulation (EU) No 305/2011
Restriction of Hazardous Substances in Electrical and Electronic Equipment	↗ RoHS Directive
Pressure equipment	↗ Directive 2014/68/EU on Pressure equipment
Simple pressure vessels	↗ Directive 2014/29/EU on simple pressure vessels
Electromagnetic compatibility	↗ Directive 2014/30/EU on electromagnetic compatibility
Explosives for civil uses	↗ Directive 2014/28/EU on explosives for civil use
Radio equipment	↗ Directive 2014/53/EU on Radio Equipment
Equipment and protective systems inten-ded for use potentially explosive atmospheres	↗ Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast)
Appliances burning gaseous fuels	↗ Gas Appliances Regulation (EU) 2016/426 (GAR)
In-vitro diagnostic medical devices	↗ Regulation (EU) 2017/746 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU ↗ Directive 98/79/EC on in vitro diagnostic medical devices
Machinery	↗ Directive 2006/42/EC on Machinery
Medical devices	↗ Regulation (EU) 2017/745 on medical devices (MDR)
Measuring instruments	↗ Directive 2014/32/EU on measuring instruments
Non-automatic weighing instruments	↗ Directive 2014/31/EU on Non-automatic weighing instruments
Low voltage	↗ Directive 2014/35/EU on Low Voltage
Ecodesign of energy related products	↗ Directive 2009/125/EC on the ecodesign of energy related products
Personal protective equipment	↗ Regulation (EU) 2016/425 on personal protective equipment (PPE)
Pyrotechnics	↗ Directive 2013/29/EU on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (recast)
Cableway installations designed to carry persons	↗ Regulation (EU) 2016/424 on cableway installations and repealing Directive 2000/9/EC
Safety of toys	↗ Directive (2009/48/EC) on the safety of toys
Recreational craft and personal watercraft	↗ Directive 2013/53/EU on recreational craft and personal watercraft

Product group resp. criterion	Link to the corresponding EUR-Lex page with the Directives/ Regulations in all EU languages
Noise emission in the environment by equipment for use outdoors	↗ Directive 2000/14/EC on Noise emission in the environment
Hot water boilers	↗ Directive 92/42/EEC on hot water boilers

Chart 1: Overview of EU directives and regulations that require CE marking[1]

Who controls compliance with the CE requirements?

To ensure that only safe products are placed on the EU market, the European Union has set up a comprehensive monitoring and information system. There are corresponding market surveillance authorities in all EU member states for monitoring products. In Germany, these include the Federal Institute for Occupational Safety and Health (for the Low Voltage Directive) and the Federal Network Agency (for the specifications of the EMC and Radio Equipment Directives). In addition, the control of imports of all goods is the responsibility of the customs authorities, and of course the trade supervisory offices and/or corresponding departments of the departments of the regional councils are responsible in the federal states of Germany.

In order to ensure a rapid exchange of information for both the authorities and consumers, the EU Commission has set up the Rapid Exchange of Information System (RAPEX) for dangerous non-food products.

The RAPEX system provides information about measures taken to prevent or reduce the use of dangerous products. Such measures include, for example, withdrawal or recall actions. RAPEX covers not only measures taken by the national market surveillance authorities but also voluntary measures taken by manufacturers and distributors.[2]

1 ↗ https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en

2 ↗ https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

Which general legal provisions apply to the CE marking?

The basis for product safety and CE marking is laid down in the following legislation (see also Fig. 1):

- **GPSD:** ↗ General Product Safety Directive, Directive 2001/95/EC of the European Parliament and Council of 3 December 2001 – on general product safety
- **NLF:** New legislative framework,
  - ↗ Regulation 765/2008/EC, Regulation (EC) No 765/2008 of the European Parliament and Council of 9 July 2008 – on the requirements for accreditation and market surveillance relating to the marketing of products
  - ↗ Decision 768/2008/EC, Decision No 768/2008/EC of the European Parliament and Council of 9 July 2008 – on a common legal framework for the marketing of products
- **NEW: EU Regulation** ↗ EU 2019/1020 on market surveillance and the conformity of products of 20 June 2019, comes into force on 16 July 2021, replaces/deletes § 15-29 of EU Regulation 765/2008.

  According to this regulation, almost all products covered by a CE directive may only be offered for sale from 16 July 2021 if there is a responsible 'economic operator' in the Union for these products (Article 4 (1)).

  Economic operator within the meaning of the Market Surveillance Regulation are according to Article 4 (2):

  - a manufacturer established in the Union;
  - an importer, where the manufacturer is not established in the Union;
  - an authorised representative who has a written mandate from the manufacturer designating the authorised representative to perform tasks on the manufacturer's behalf;

  or

  - a fulfilment service provider established in the Union with respect to the products it handles, where no other economic operator is established in the Union.

Which sector-specific guidelines does this guide focus on?

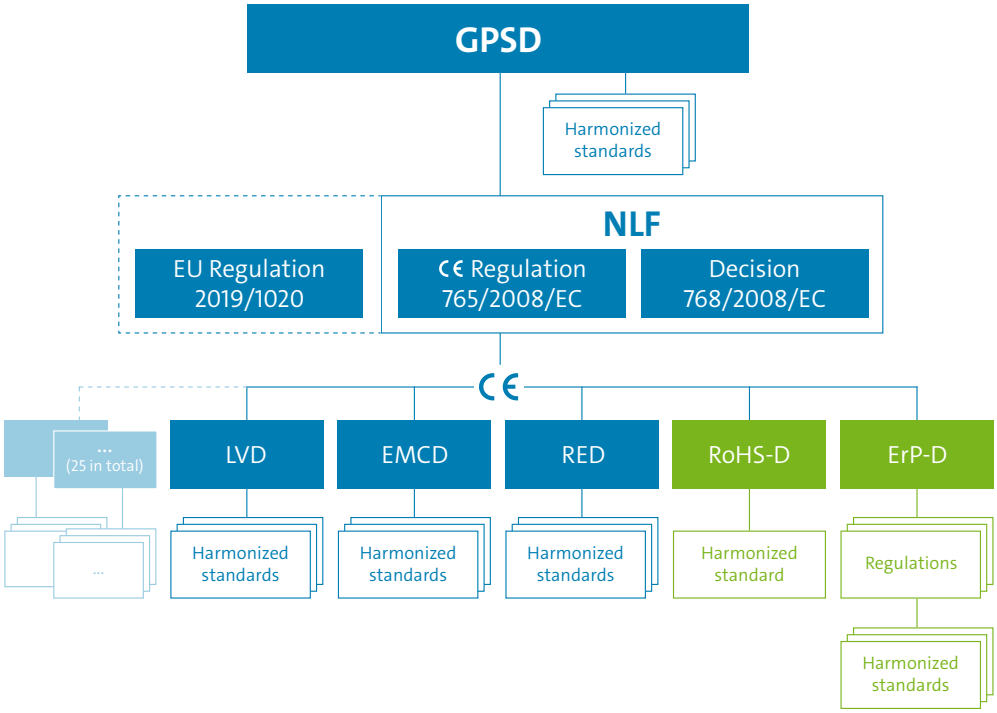


Figure 1: Legal Framework for CE marking and selection of sector-specific guidelines

Figure 1 lists the sector-specific guidelines on which this guide essentially focuses:

- **LVD**: ↗ **Low Voltage Directive**, 2014/35/EU
- **EMCD**: ↗ **Electromagnetic Compatibility Directive**, 2014/30/EU
- **RED**: ↗ **Radio equipment Directive**, 2014/53/EU
- **RoHS-D**: ↗ **RoHS-Directive**, 2011/65/EU
- **ErP-D**: ↗ **ErP-Directive**, 2009/125/EG

In which countries is the CE marking valid?

The CE marking is primarily in effect throughout the entire EU, but also in all EFTA countries (Norway, Iceland, Liechtenstein and Switzerland) and in other countries that have a corresponding agreement with the EU (e. g. Turkey). It guarantees the free movement of goods in all these countries, making it the »passport« for affected products in over 30 European countries.

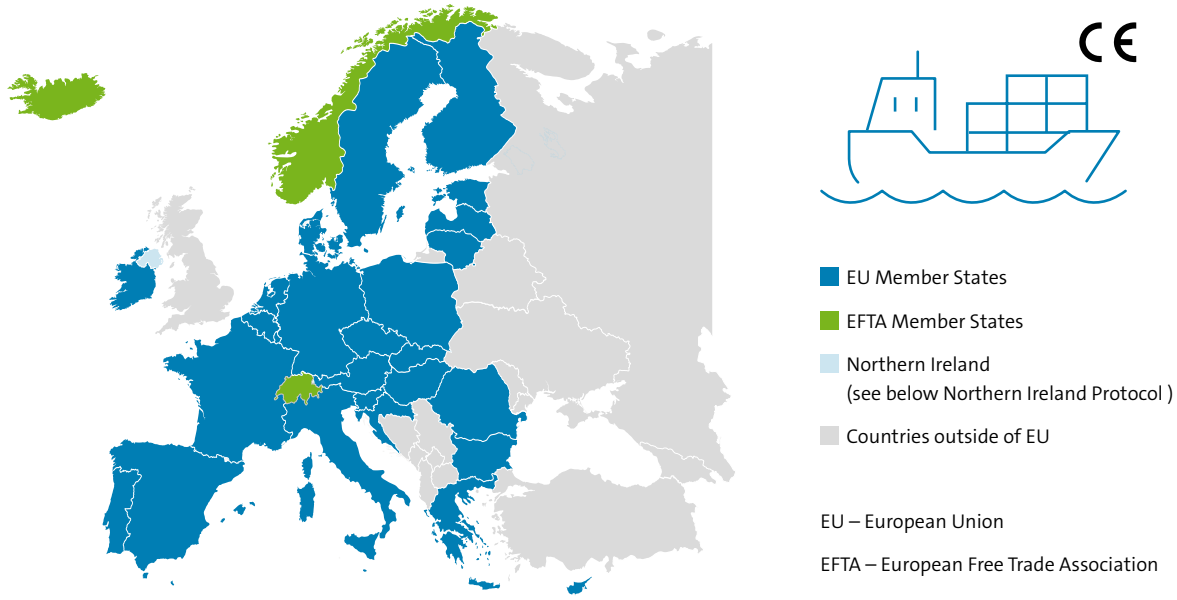


Figure 2: Overview of countries where the CE marking applies

The United Kingdom (UK: England, Scotland, Wales and Northern Ireland) left the EU on January 31, 2020 (Brexit) and replaced the prevailing EU rules, which were in effect until December 31, 2020, with their own rules (the so-called Statutory Instruments). It should be noted that these new regulatory requirements are in effect for Great Britain (GB: England, Scotland, Wales), but not for Northern Ireland. The »Northern Ireland Protocol« established that products intended for Northern Ireland will continue to require the CE marking, despite the fact that politically, Northern Ireland remains part of the UK. As of January 2021, it is now possible to use the UKCA marking instead of the CE marking in the United Kingdom (England, Scotland and Wales) and this marking will become mandatory on January 1, 2022. In Northern Ireland, however, the CE marking and/or the UKNI marking is still in effect. All essential information on this topic can be found on the corresponding websites of the »UK Governments«, including here: **↗ https://www.gov.uk/guidance/using-the-ukca-marking**

Please note: Although the regulatory requirements in the EU and UK are very similar, these guidelines only cover the EU requirements.

II. Nine steps to CE marking – the manufacturer's responsibilities

A. Before the sales launch

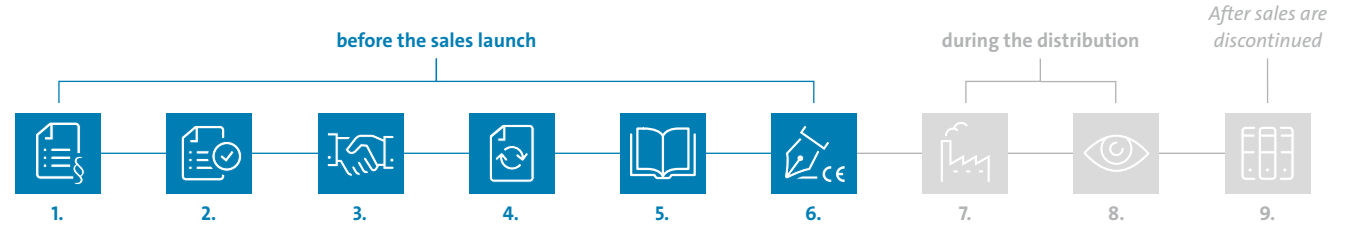


Figure 3: CE marking – Before the sales launch

1. Identify applicable directives and regulations and thus essential requirements for the product

The first and fundamental step on the way to a CE-compliant product is to identify the directives and regulations applicable to the respective product. This is the basis for all further steps and represents the following:

- define the specifications of the product;
- carry out a risk analysis to define which hazards could be posed by the product or lead to non-conformity;
- determine which directives apply to the product.

In the applicable directives, the »essential requirements« that a product must fulfil are defined. These include, e. g.:

- the product itself; for example, product safety, electromagnetic compatibility;

or

- the performance of the product; for example, its energy efficiency and radio characteristics.

This analysis is to be documented and represents part of the technical documentation. (see also step 5.).

2. Clarify product-related requirements, apply harmonized standards and define the conformity assessment module

Based on the applicable guidelines, the defined risks of a product result in the specific requirements for a product to avoid respectively minimize these risks.

For a number of product groups, these product-specific requirements are laid down in harmonised standards which are applicable throughout the EU. The application of the standards is not mandatory. Manufacturers may also demonstrate the conformity of their products by other suitable means. However, if a product is designed and manufactured in compliance with the standards listed in the Official Journal of the EU, this will ensure that the product complies with the applicable EU regulations (i.e. the »essential requirements«). This establishes the so-called presumption of conformity.

Harmonised standards are developed by the European standardisation organisations: the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI).

In order to help manufacturers identify the applicable product requirements, the EU has set up the following websites:

- **↗ https://europa.eu/youreurope/business/product-requirements/compliance/identifying-product-requirements/index_en.htm**
- Access2Markets: **↗ https://trade.ec.europa.eu/access-to-markets/en/content/welcome-access2markets-trade-helpdesk-users**

Determining the conformity assessment module

Which module the manufacturer would like to use for the conformity assessment will also be determined here, in step 2. For this purpose, the first step is to check which modules of conformity assessment are designated for the respective product in the applicable EU directives.

Conformity assessment procedures may consist of one or two modules:

- one module = includes the design and production phases
- two modules = one module for the design phase and one for the production phase.

The different modules of the conformity assessment are described in greater detail in section 5 of the Blue Guide.

3. Determine the necessity of involving a »notified body«

In many cases, manufacturers can carry out the conformity assessment of their product themselves, whereas in other cases, they need to consult a conformity assessment body, also called a »notified body«. The latter applies, for example, to products covered by the Personal Protection Equipment Directive.

The obligatory involvement of a notified body is determined in the corresponding EU legislation.

The notified bodies are designated by the EU member states and are listed in the European Commission's NANDO (Information System »New Approach Notified and Designated Organisations«) database.

If a notified body is involved, the four-digit identification number of the notified body must normally be placed typically after the CE marking.

4. Carry out conformity assessment procedures (Part 1: Design phase)

Conformity assessment is a process to be carried out by the manufacturer. In this process the manufacturer must prove that all requirements for the respective product are fulfilled.

In part 1 (design phase), the procedure will be carried out according to the module defined in step 2. (above). This includes, in particular, all necessary tests to ensure the conformity of the product with the requirements which are also specified in step 2., and, as the case may be, the involvement of a notified body. Part 2 (production phase) of the conformity assessment procedure is described in step 7. (below).

5. Prepare technical documentation

After completion of part 1 of the assessment procedure, the technical documentation is to be prepared. It contains all the documents proving that the product meets the technical requirements. The technical documentation should contain at least the following elements:

- the name and address of the manufacturer and/or the names and addresses of an authorised representatives;
- a brief description of the product;
- the product identification, e. g. serial number;

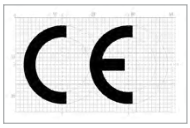
- the names and addresses of the operating sites involved in the design and manufacture of the product.
- the names and addresses of any notified bodies that were involved in the assessment of conformity of the product;
- the name of the conformity assessment procedure used;
- the EU Declaration of Conformity;
- the identification plate and operating instructions;
- a list of the relevant regulations with which the product complies;
- a list of the technical standards to which compliance is claimed;
- a list of the parts/components;
- test and measurement results. Source: ↗ **https://europa.eu/youreurope/business/product-requirements/compliance/technical-documentation-conformity/index_en.htm**

6. Issue the Declaration of Conformity and label the product

In the EU Declaration of Conformity (EU DoC), the manufacturer confirms the conformity of the product with the relevant EU directives. The basis for the declaration of conformity is the technical documentation. The EU DoC may only be issued by the manufacturer or their authorised representative. This also applies to the affixing of the CE marking on the product itself.

The CE marking

The shape and proportions of the two letters – CE – are exactly specified. The CE marking must be at least five millimetres high.



You can find the official image files here:
↗ **https://ec.europa.eu/growth/single-market/ce-marking_en**

Link to the corresponding EU page: ↗ **https://europa.eu/youreurope/business/product-requirements/labels-markings/ce-marking/index_en.htm**

The CE marking must be affixed to the product before the product is first made available for sale. A product may only be provided with a CE marking if the product is actually subject to a corresponding EU directive or regulation requiring CE marking.

For traceability of the product, the name and address, as well as the trade name/brand of the manufacturer, must be indicated on the product. If this address is not within the EU, the address of the importer must also be indicated. Clarifications can be found in section 4.2.2.2 of the Blue Guide.

Generally, the content of an EU Declaration of Conformity is determined in EU Decision 768/2008/EG:

EU DECLARATION OF CONFORMITY

No ... (unique identification of the product): _____

Name and address of the manufacturer or his authorised representative: _____

This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer): _____

Object of the declaration (identification of product allowing traceability. It may include a photograph, where appropriate): _____

The object of the declaration described above is in conformity with the relevant Community harmonisation legislation: _____

References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared: _____

Where applicable, the notified body ... *(name, number) ... performed ... (description of intervention) ... and issued the certificate: ...*

Additional information: _____

Signed for and on behalf of:

(place and date of issue)

(name, function) (signature)

Figure 4: Template for an EU Declaration of Conformity, based on Annex III of EU Decision 768/2008/EC

B. During the distribution

Figure 5: CE marking – During the distribution

7. Conduct continuous control of production (Conformity assessment procedure, part 2: production phase)

For each product, it must be ensured that it complies with the requirements identified in the design phase and which are certified in the declaration of conformity, throughout the entire production process.

This is achieved in part 2 of the conformity procedure (production phase) by means of continuous control of production. Whenever changes are made to the product (e. g. construction method, components or materials), it is necessary to check whether a reassessment is required.

8. Keep track of the market and legislation

Regular checks must be made to determine whether new/changed standards or directives apply to the product. If changes take place during ongoing production, the products must comply with the amended or new standards before the end of the transition period. This often means a new assessment procedure and new tests.

The market must also be continuously monitored to see whether there are any complaints or even damage cases which require corrective measures. Such measures are to be taken by the manufacturer or by the market surveillance authority.

C. After sales are discontinued

Figure 6: CE marking – After sales are discountinued

9. Ten year retention obligation for technical documentation

Most EU regulations specify a retention period for technical documentation of 10 years after sales are discontinued. This means that until 10 years after sales are discontinued, the manufacturer must be able to provide appropriate documentation for a product when requested by a market surveillance authority.

The nine steps to CE marking at a glance

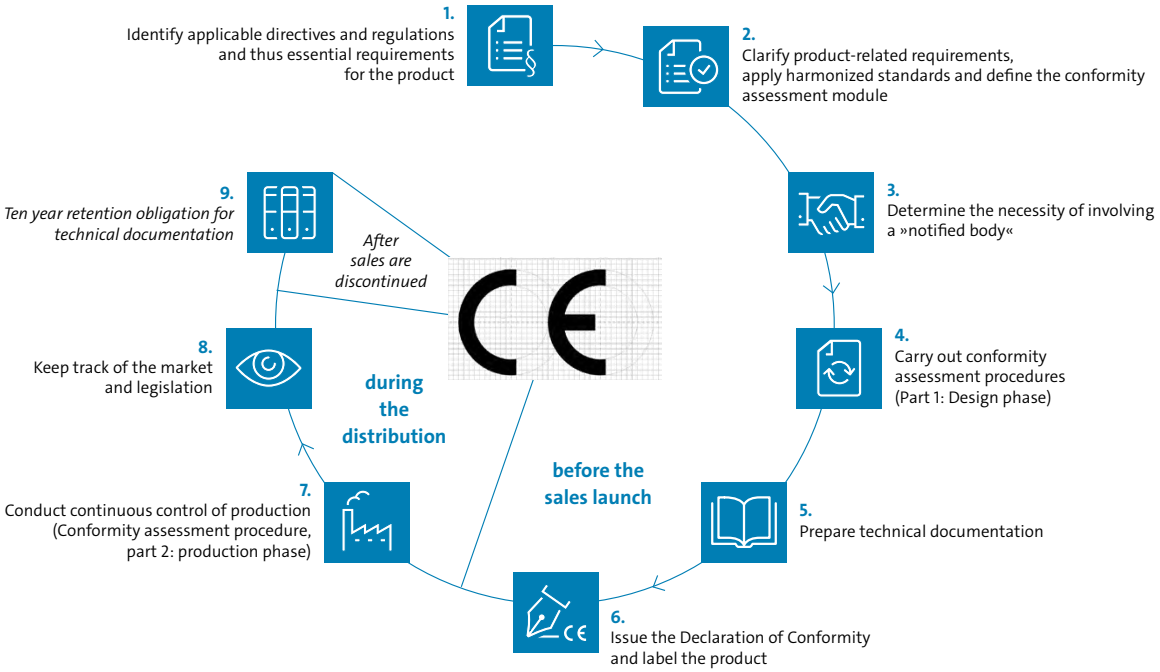


Figure 7: The nine steps to CE marking at a glance

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Sources:

Blue Guide: ↗ **Commission Notice, The »Blue Guide« on the implementation of EU products rules 2016**

EU Website: ↗ **https://europa.eu/youreurope/business/product-requirements/index_en.htm**

Bitkom represents more than 2,700 companies of the digital economy, including 2,000 direct members. Through IT- and communication services alone, our members generate a domestic annual turnover of 190 billion Euros, including 50 billion Euros in exports. The members of Bitkom employ more than 2 million people in Germany. Among these members are 1,000 small and medium-sized businesses, over 500 startups and almost all global players. They offer a wide range of software technologies, IT-services, and telecommunications or internet services, produce hardware and consumer electronics, operate in the digital media sector or are in other ways affiliated with the digital economy. 80 percent of the members' headquarters are located in Germany with an additional 8 percent both in the EU and the USA, as well as 4 percent in other regions of the world. Bitkom promotes the digital transformation of the German economy, as well as of German society at large, enabling citizens to benefit from digitalisation. A strong European digital policy and a fully integrated digital single market are at the heart of Bitkom's concerns, as well as establishing Germany as a key driver of digital change in Europe and globally.

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