



Choose Scandinavian trust

The CE process

Step-by-step guide
for Manufacturers



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CE marking has existed in its present form since 1993. CE stands for “Conformité Européenne”, which in practice means that it “conforms to European directives”. CE marking of a product means that it complies with the legal requirements placed on the product within the EEA and therefore can be sold there. The manufacturer or their authorized representative gives the product its CE marking and is liable for ensuring that the product complies with the requirements of the directives.

This E-book will give Manufacturers a step-by-step guide to how they can CE mark their product, and ensure that it can be marketed and sold within the European market.



STEP 1

IDENTIFY THE EU DIRECTIVES APPLICABLE TO THE PRODUCT

The EU directives describe the requirements that the product must fulfil within the EU/EAA. The harmonised EN standards proceed from the directives and list the necessary requirements and the technical specifications. Identifying the EU directives that apply to the product is the most important step in the entire CE marking process.

In addition to directives for CE markings, there are other directives that manufacturers may have to deal with. These often involve environmental and recycling issues. Examples of these are WEEE, REACH, the Batteries Directive and the Packaging Directive and the Energy Labelling requirements, where relevant.



HOW TO DO IT?

1. Start by answering the following questions:
 - Who will be using the product?
 - In what environment (climate) will the product be installed/used?
 - Is the product intended for household, industrial or agricultural use?
2. Click the link to the [European Commission's website for the CE process](#).

Select the product group(s) in which your product is included. For each product group you will find out which directives apply, and other tips about how to proceed. Note that the product often comes under more than one directive. You are then guided forward in the six-step process, by clicking on the illustrations/ images showing the various steps.

3. If you are uncertain about which directives apply to your product, you may contact [Nemko](#). We offer a CE pre-compliance service where the output is a report that defines the directives and standards your product falls under. The report will also include an overview over the required documentation you need to put together in a technical construction file for your product and a meeting with one of our experts to answer questions you have in connection with CE marking of your product.



STEP 2. COMPILE THE SPECIFIC REQUIREMENTS AND HARMONISED EN STANDARDS THAT APPLY TO THE PRODUCT

When you have found out which EU directives your product comes under, it is up to you as manufacturer to prove that the product complies with the requirements in those directives. The easiest way is to follow the harmonised EN standards based on the directives and compile the necessary requirements and technical specifications. When the product meets the relevant harmonised EN standards, it receives its “presumption of conformity” in relation to the requirements in the directives. If you meet all the requirements in the EN standards, it is assumed that you automatically fulfil the requirements in the corresponding EU directive. This is called the “principle of presumption”.

Using the standards as a basis to ensure that the product meets the requirements in the directives is optional. The use of harmonised EN standards is, however, the easiest way to demonstrate compliance with the directives. The methods are already accepted by technical committees and the various European authorities.



HOW TO DO IT:

In step 2 you will find out which requirements and harmonised EN standards apply to the product.



STEP 3. FIND OUT IF A THIRD PARTY CERTIFICATION (NOTIFIED BODY) IS REQUIRED

It is explained in each EU directive if you need to use a Notified Body during the process in order to meet the requirements.

If you are using a Notified body, it is advisable to invite them into the process as early as possible. It provides you with access to expert help early in the development process, which simplifies further work and saves time.

Nemko is Notified body for the following directives:

- EMC (Electromagnetic compatibility)
- RED (Radio equipment)
- MED (Marine equipment)
- ATEX (Explosive atmospheres)
- CPR (Construction Products)



HOW TO DO IT:

1. In step 3 you will find out if third party certification is needed.
2. The European Commission has a database called “NANDO” (New Approach Notified and Designated Organisations). You can search the database for Notified Bodies. A link to NANDO is available [here](#).



STEP 4. TESTING THE PRODUCT

Now you need to test the product to verify that it meets the requirements of the EU directives. This often involves performing a risk assessment of the product.

Risk assessment:

- What dangers are associated with the product?
- Are there risks to humans, animals, goods or the environment?
- What solutions can be applied to minimise the risks in accordance with applicable EU directives?



HOW TO DO IT:

By using a harmonised standard you can avoid certain parts of the risk assessment, as many of the risks were already covered in drafting the standard. However, you must understand the standard(s) that the product comes under and verify that the product meets the testing requirements. If you find it difficult, you can engage Nemko to do this.



STEP 5. COMPILE TECHNICAL DOCUMENTATION

As a manufacturer, you shall compile the technical documentation, consisting of documentations as described in the EU-directive(s) and any risk assessments you have made, as well as your EU Declaration of Conformity. At the request of the authorities, this documentation and an EU Declaration of Conformity (EC Declaration of Conformity) must be rapidly made available.

Normally, a technical construction file should contain relevant information about the design, manufacture and use of the product. In other words, it contains everything to demonstrate that the essential requirements imposed on CE marked products have been fulfilled.

Some examples of this are:

- A general product description
- Design information (for example wiring diagrams, design drawings, mechanical drawings, parts list, manufacturing documentation, etc.)
- Descriptions and explanations necessary to understand the above-mentioned drawings
- Installation instructions and user manual/guide for the product. The installation instructions should clarify how to install and use the product. The user guide shall be written in the language of the country in which the product is to be sold.
- A list of the standards applied, either in full or in part, or own standards/methods used to demonstrate compliance with the directive
- Other data used or that may be of benefit (for example, calculations, simulations, etc.)
- Test reports

NOTE!

The manufacturer/manufacturer's representative/ importer shall maintain copies of the technical construction file for a time period that normally is set to 10 years after the last product was put on the market. This time period can vary depending on the directive.



HOW TO DO IT:

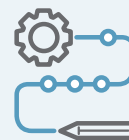
When you have tested your product, you create a technical construction file according to the requirements in the EU directives that the product comes under. Visit https://www.ec.europa.eu/growth/single-market/ce-marking/manufacturers_en and start by stating the product group. You are then guided forward in the six-step process, by clicking on the illustrations/ images showing the various steps. In step 5 you get tips and help with the exact documentation that is required for your specific directives.



STEP 6.

DRAW UP AND SIGN THE EU DECLARATION OF CONFORMITY AND CE MARK YOUR PRODUCT

CE marking is carried out by the manufacturer. The CE mark must be placed in a visible position on the product (or on the package if there is no space on the device itself). This labelling and the EU Declaration of Conformity demonstrate that the product meets the requirements in the directives.



HOW TO DO IT:

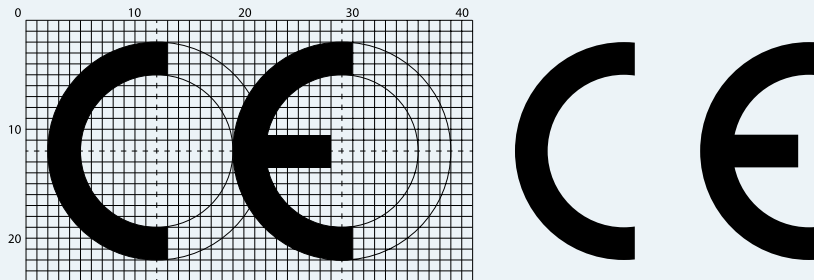
1. Once the technical construction file is complete, the manufacturer must ensure that the product meets the requirements specified in the EU directives and relevant standards. This is done by drawing up and signing an EU Declaration of Conformity.

These elements should be included in a Declaration of Conformity:

- Name and address of the manufacturer issuing the declaration
- Identification of the product (name, type or model number, and any additional relevant information (such as batch, lot or serial number and number of items).
- The directives under which you feel the product comes, defined in an accurate, complete and unambiguous manner. The standards/methods used to verify that the product conforms to the requirements in the directives. These must also be defined accurately, completely and clearly.
- The date of issue of the declaration, signature and title of the CEO or equivalent.
- Declaration that the certificate has been issued in accordance with sole manufacturer liability, and where relevant, its representative's liability.
- Name, address and identification number of any third party bodies that have been involved in assessing conformity.
- Name and address of the person in possession of the technical documentation.

2. The marking must adhere to these rules:

- The CE marking shall consist of the initials “CE” in accordance with the format in the below picture.



- If the CE marking is minimised or enlarged, the proportions given in the picture must be maintained.
- The CE marking must be affixed visibly and legibly on the product.
- Certain exceptions for products where it is not practically possible to CE mark the product due to the product’s size or design. The label can then be placed on the packaging and accompanying documentation instead.
- The label must be durable so that it cannot be easily worn down or rubbed off.
- Vertically, the various components of the CE marking must be approximately the same height and no lower than 5 mm.
- If there are requirements for the involvement of Notified Bodies in the CE marking process, their identification numbers must also appear on the label.

These are the basics, of course you can always contact us if you have any questions, are uncertain about which directives apply to your product or if you need more information. Our team of experts is ready to help!

Fill in this [form](#) and we will get back to you.

ABOUT NEMKO

The NEMKO foundation works for safety, sustainability and the environment through the Nemko Group. Companies around the world trust Nemko to assess their products, systems, installations and personnel for conformity with relevant standards and regulations. Since 1933, we have ensured that our customers comply with requirements anywhere in the world. Our services include international approvals, product and system certifications, cyber assurance services as well as product testing and pre-compliance. Through our offices, laboratories and extensive partner network in Asia, North America, Europe, Middle East and Africa we are able to serve our customers in a reliable, efficient and open manner. We provide access to our global knowledge through our local presence.

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