

# Six steps to CE marking

## A Guide to CE Certification for Personal Protective Equipment (PPE)

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**STRIJDCORONA**

Samen kunnen we veilig terug naar werk

As manufacturers of personal protective equipment, you are obligated to ensure that your products meet all mandatory requirements and are certified. Personal protective equipment without the CE-marking may not be sold in the EU. This is to ensure the protection as well as health and safety of the users.

Personal protective equipment refers to products that are designed to protect against risks. These products need to meet regulations stated in the Regulation (EU) 2016/425. Therefore, to sell PPE in the EU, you need to comply with the requirements of these regulations to obtain the CE mark.

To obtain a CE certification for your PPE products, you will be required to go through a process of checks and verification to ensure that your product and its documentation meet all mandatory provisions.

Below are the steps you need to undertake

1

### Identify which EU guidelines and standards for the specific PPE product group

Product groups with CE marking must comply with [European Commission directives](#). The legislation differs per product group, the legislation for Personal Protective Equipment (PPEs) can be found [here](#). [European standards](#) provide essential requirements for each directive. Standard sheets can be requested from the [NEN institute](#).

2

### Check the product specific requirements against your product

Make sure your product meets the necessary [EU directives](#). If your product fully complies with the standards (according to the [NEN standard sheets](#)), a "presumption of conformity" applies, which you can use to demonstrate that you comply with the guidelines. You can also use [other methods](#) to meet the requirements. Pay close attention to guidelines in product descriptions and manuals, warnings, and manufacturer's contact information.

3

### Find out if you need independent conformity assessment

If necessary, you can engage an [independent conformity assessment](#) body to apply each guideline for your product. This is not always mandatory, but it may be necessary for high-risk products or if you are unsure about applying the guidelines. In the [NANDO information system](#) you will find the notified bodies per country and per directive.

4

### Test the product and check the conformity

You are responsible for testing your product. With the testing you check the conformity: whether the product meets the requirements and guidelines. A risk assessment is an important part of the procedure. By applying [the EU standards](#) you can easily meet the requirements.

5

### Prepare technical documentation and make it available if necessary

As a manufacturer, you must prepare technical documentation that states the conformity of your products. In the technical documentation you include drawings, specifications, test reports, inspection certificates, manuals, and the declaration of conformity. If you use goods from outside the [European Economic Area](#), the foreign manufacturer must confirm in writing that you have access to technical

documentation. Documentation must be available in the language or languages of the country in which the product is sold or used. The language and content of the documentation may differ per guideline.

6

### Mark your product with CE and draw up an EU declaration of conformity

As a manufacturer, you must ensure that the [CE marking](#) is visible, legible and indelible on the product. The identification number of all bodies that have been involved in the production phase must be indicated on the product. Finally, you must prepare and sign an [EU declaration of conformity](#). You take responsibility for the conformity of your products. The declaration of conformity must also be included in the technical documentation.

Please note that product requirements may vary by guideline.

More information about the certification of your products can be found on the web pages of the [European Commission](#), the [Netherlands Enterprise Agency](#), and [Your Europe](#).