

I'm not a robot   
reCAPTCHA

**Continue**

## Declaration of conformity template ce

On this page Last checked: 14/08/2020 The technical documentation contains information on the design, manufacture and operation of a product and must contain all the information necessary to demonstrate that the product meets the applicable requirements. If you are a manufacturer, there are certain rules that must be followed when you market a product: you must: prepare the technical documentation before placing a product on the market; ensure that the technical documentation is made available to the market surveillance authorities (if they request to see it) as soon as the product is placed on the market; keep the technical documentation for 10 years from the date on which the product is placed on the market (unless otherwise explicitly stated). The technical documentation is necessary to prove that the product meets the essential requirements and therefore justify and support an EU declaration of conformity. You will need this documentation to affix the CE marking to the product. How do you prepare the technical documentation? The technical documentation shall include at least: your name and your name and address, or address, a brief description of the identification of the product by the product, e.g. the serial number and address of the installations involved in the design and manufacture of the product; the name and address of any notified body involved in the assessment of conformity of the product; a declaration of conformity assessment procedure followed in the EU Declaration of Conformity Label and instructions for use a declaration of relevant requirements with which the product complies with the identification of technical standards required, list of test results of parts As a manufacturer, you should be able to demonstrate where and how the different parts of the document and maintenance are stored. You can usually choose which language you want to prepare the technical documentation for. However, market surveillance authorities may ask you to translate the technical documentation depending on the EU country where the product has been placed on the market. If desired, you can also give it in electronic format. Risk assessment As a manufacturer, you are responsible for identifying all the possible risks that your product may pose and establishing the applicable essential requirements. This analysis shall be included in the technical documentation. In addition, you need to explain how you have handled the identified risks to ensure that your product complies with the applicable requirements, such as the EU Declaration of Conformity An EU Declaration of Conformity is a mandatory document that you, as a manufacturer or your representative, must sign to declare that your products meet EU requirements. By signing the doc, you take full responsibility for your product's compliance with applicable EU law. How prepare a declaration of conformity As a manufacturer, it is your responsibility to prepare the EU Declaration of Conformity (DoC). It shall contain the following information: your name and your authorised representative's serial number, model or type identification, a declaration in which you assume full responsibility for the identification of a product that enables traceability – this may include a picture of information about the notified body, having carried out the conformity assessment procedure (if applicable) the relevant legislation to which the product complies, as well as any harmonised standards or other means used to prove compliance with your name, and signature the date on which the declaration was issued, additional information (if applicable) For imported products, the importer shall ensure that the product is accompanied by the doc and keep a copy of it for 10 years after the product has been placed on the market. You must translate the EU Declaration of Conformity into the language or languages required by the EU country where your product is sold. Let's split it into actionable steps. Only 4 steps brings you to a compatible declaration of conformity! There are only four steps that make up the declaration of conformity template method. Go to the EU website. Select your product group(s). Find all information about the declaration of conformity in the Directive, you need Download the correct templates, and prepare your statement of conformity Check if you have met all the requirements Caution! This method in no way replaces the process of CE marking. It only supports at the last stage of this process, namely the drafting of the declaration of conformity. Always contact our CE expert for full guidance. There are 25 product groups that require CE marking and thus a declaration of conformity\*. If you have a product that fits into one of these product groups, then you need to prepare a declaration of conformity. Many products must comply with more than one directive. If this is the case for your product, all steps described below must be performed for each relevant directive. The requirements for the content of the declaration of conformity can mostly also be found in the current Directive. Most directives have their own specifications for the declaration of conformity, and very few directives have exactly the same requirements. Sometimes you will find no requirements in a directive (e.g. Directive 90/385/EEC on active implantable medical devices does not require). For these Directives, the harmonised standard EN-ISO/IEC 17050-1:2014 Supplier Declaration – Part 1: General requirements may be applied. Because compliance with harmonised standards above all gives rise to a presumption of conformity with the Directive. However, if a directive has its own specific requirements, such as the Machinery Directive or the Radio Equipment Directive, EN-ISO/IEC 17050-1:2014 may be used as but it should be improved or amended in accordance with the additional requirements laid down in the Directive. Another thing to be aware of is that the directives are being amended every now and then. And if they change, there is a great chance that the requirements of the declaration of conformity will also change. Don't be afraid! I've done all the hard work for you. But because it's your product you're dealing with (and legally you're responsible for it), I'd like you to also have a closer look yourself. This will be done in step 2 To find the directives that apply to your product: Go to the European Commission's website. From the drop-down menu, select the product group that applies to your product. – Information about the product group is shown below. Click the link to open the directive. – A page with links to the different languages and formats of the Directive opens. Choose your language and format (e.g. English and PDF). – The Directive opens To find all requirements and other relevant information: Press ctrl+f and type declaration of conformity - &gt; the number of hits is displayed. Note: For construction products, write a statement of performance. For submachines, write the incorporation declaration. Create a table with two columns in a document or worksheet. Copy/paste in the left column the article number and in the right column the text that contains the declaration of conformity. Read the text carefully. Copy/paste all other hits in the table. Example: DIRECTIVE 2014/28/EU – explosives for civil use Article No. Text24 In order to ensure effective access to market surveillance information, the information necessary to identify all applicable EU acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, this joint EU declaration of conformity may be a dossier consisting of relevant individual declarations of conformity. Article 5.2 If compliance with the applicable requirements is established by this procedure, manufacturers draw up an EU declaration of conformity and affix the CE marking. They have now prepared a summary of all relevant information on the declaration of conformity. In addition to the specific content requirements, this may also include information on the requirements as to whether or not to translate the declaration of conformity, to make the declaration of conformity with the product or to draw up a single declaration of conformity for all applicable directives. Now you are aware of the requirements, it is time to prepare the declaration of conformity for your to do so: Now you have created your declaration of conformity that meets all content requirements, it is time to check the other requirements. For this, the document you created in #2 can be used as a checklist. Check the document for other important information about the translation of the declaration of conformity, the medium to be et cetera. That's all! If you got some value from my post, I would appreciate a comment or social media share! Ferry G.A. Vermeulen Founder and Director Business Development at INSTRKTIV GmbH, Berlin, Germany INSTRKTIV helps companies and brands produce their technical documentation. INSTRKTIV stands for content quality, both in ease of use and responsibility: the manual as a legal document that not only serves as the cornerstone of responsibility, but also promotes safe and correct use, is at the heart of this. Since 2006 Ferry has been involved in techcomm. Over the years he gained knowledge through training and training on European and American legislation on instructions, ease of use, UX, Simplified Technical English, single sourcing, content management, MadCap Software and SCHEMA software, Information Mapping and minimalism in techcomm. By combining usability with responsibility, customers such as Electrolux, AEG, Lidl, Fischer, Leitz, Ströer, AkzoNobel, Schneider-Electric, Skil and Grundig are part of his portfolio. Ferry regularly gives presentations at conferences. You can read more of Ferry's thoughts on ease of use in techcomm on his blog: The Man-Machine Specialties: Information design, UX design, industrial design, user assistance, consulting Twitter LinkedIn consulting Twitter LinkedIn