

The Steps to CE

Many CE Mark Directives permit a manufacture to self-declare compliance. “Self declaration” means that YOU decide when you are authorized to apply the CE mark. If you have the knowledge, standards, report templates, and test equipment, you can conduct the CE process yourself. However, in most cases, it will be less expensive and the process will be completed much faster if you hire a CE expert to perform some or all the work for you.

Steps to Apply the CE Mark:

- 1) Directives: Identify the EU Directives applicable to your product.
 - Be sure that all applicable directives are eligible for “self-declaration” – otherwise, you will be required to have a European “Notified Body” sign off on the compliance work and in some cases even perform a Quality audit.
- 2) Standards: Identify the EN Standards applicable under each of the Directives identified in step 1.
- 3) Verify Compliance - Prepare Compliance Report(s): Verify compliance to each of the required Directives & Standards per steps 1 & 2. This process should involve a clause by clause review of each applicable Standard while documenting how the product complies with each clause. Requirements specified in the Directive must also be reviewed for compliance. In addition, all applicable tests identified during the review should be performed with suitably calibrated test equipment while recording the test data in the compliance report.
- 4) Create your Technical Construction File (TCF): By EU law, you may be asked at anytime by EU authorities to prove your CE compliance by providing your TCF. You are expected to be able to present your TCF in a reasonable time frame (i.e. 48 hours). Each TCF should contain a copy of the materials generated during the CE compliance process = your DoC, Risk Assessments where required by the standard, Directive Compliance Reports, Compliance Report for each standard, and copies of Design & Production documentation critical to compliance with the standard. The TCF should also contain a section for logging all future product changes and the compliance review/report to show that, with each change, the product continues to comply with the applicable standards.
- 5) Create your Declaration of Conformity (DoC): Create this one page document per the required content specified in the applicable Directives, and have it signed by an Officer of the Corporation.
- 6) Apply the CE Mark:
 - a) Once you have a complete TCF and the signed DoC, you can begin applying the CE mark to your product.
 - b) The CE mark has specific dimension/shape requirements. You can include the CE mark with your product rating label or you can apply a separate CE label. CE labels can be purchased at www.productsafet.com.
 - c) Cheating the CE system is relatively easy BUT it comes with big penalties = corporations found guilty of fraud within the CE system are blacklisted throughout all EU countries (banned from selling products throughout the EU). And the corporate officer who signed the DoC can be criminally charged and jailed in Europe. You should note that many of the EU ports of entry have test equipment to spot check compliance. If your product is found to be out of compliance, it will be impounded and it is unlikely that you will ever see it again. Remember, you may be asked at any time to provide the TCF = what do you do if you get asked and you don't have one? (It is also common for purchasers to request copies of documentation to insure you comply so they have confidence the product complies. Some Directives also require the distributor to verify.)

CertifiGroup works with ALL CE Directives.
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