

Maintaining your Technical Construction File

Your work is not over when the CE mark is applied

TCF Contents: Once you have verified CE compliance for your product, you must prepare a Technical Construction File (TCF) that includes both product design documentation and, proof that the product complies with the CE Directives. Each CE Directive specifies what must be included in the Technical Construction File (TCF). Your CE-TCF should therefore include the information required by all CE Directives that are listed on your Declaration of Conformity (DoC).

After the CE Mark is applied, you need to build and continue to maintain your Technical Construction File. This file should be treated as a “living document” that requires regular maintenance to keep it, and by extension your product, compliant with the CE requirements.

TCF Areas to Maintain: To accurately maintain your product CE and TCF compliance, we suggest that you include the TCF review as part of your product revision system and, we recommend that “compliance” be included as a sign-off for all product revisions.

- 1) Product Variations: Each product variation or revision does not require you to start the CE process over. You simply review the changes or differences for compliance, document how they comply, and add it to your existing TCF.
 - a) Product Family: If you test one product and apply the results to a product line, you should include a breakdown of the models, model features/differences, and a compliance review of the changes. If you are declaring compliance of one model based on similarity to another model, keep a written record of your engineering rationale and decisions.
 - b) New Models: If you create any future product variations, you should detail the variations in your TCF and include a compliance review of the changes.
 - c) Product Revisions: If you make future revisions to the product, you should detail the variations in your TCF.
- 2) Product Design Details: Your TCF should include all final product design documentation = Schematic Diagrams, Mechanical Diagrams, Component Details, PCB layout and trace diagrams, Spec Sheets, CE DoC’s for major components, etc. As part of the revision process to the product design or components, review the changes for compliance, document how they comply, and add the updated documentation to your existing TCF.
- 3) Manufacturing Details: Your TCF should include all final product manufacturing documentation, updated as revisions occur. Manufacturing documentation and process revisions will only require a compliance review if they result in a design change.



- 4) Instruction Manual: A current copy of your instruction manual and installation instructions should be in your TCF. You should also consider maintaining a record of all documents provided to the customer so you can clearly know what documents were included with each product sold.
- 5) Compliance Reports: Any new compliance reports generated as part of the review of product variations, product revisions, or model additions should be added to your TCF.

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