TECHNICAL FILE REVIEW

How do you prove your product meets the conformity requirements for the CE mark for self declaration?

An essential requirements of the CE marking process is to prepare and maintain a Technical File for the product , this is to provide evidence of conformity.
If the Technical File is prepared correctly it will detail how the product was developed, decisions made and how it has progressed from concept to final design.
The essential requirements of a Technical File is detailed in the relevant annex of the product Directive

WHAT GOES INTO A TECHNICAL FILE?

As a general guideline the following shall be incorporated in such a file

•An overview of the product and general description of its application
•Circuit diagrams , BOM's and constructional drawings, with any calculations, test results, that were performed in developing the product
•Any risk assessments that have been performed, and the identification of the risks corrective actions mitigate the risks and hazards, and justifications of the hazards can not be reduced
•A list of standards and directives that have been applied as part of the conformity assessment process.
•Copies of technical reports such as EMC and product safety.
•A copy of user and installation instructions and other information supplied to the user or installer for the safe use of the product.
•A signed copy of the manufacturer's Declaration of conformity.

WHO VIEWS THE TECHNICAL FILE?

The Technical File must be made available to the relevant authorities of the member states for at least ten years after the date that the product was last manufactured.
We have assisted many manufacturers, importers and distributors (both within and outside of Europe) with the Technical File requirements and we have a range of services to meet your needs.
Our services cover:
•Preparation of a Technical File
•Technical File reviews
•Preparation of a Declaration of Conformity for the manufacturer to sign

FREQUENTLY ASKED QUESTIONS:

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Why do I need a Technical File?

As an EU manufacturer you or an appointed authorised representative must compile a Technical File for each product that is placed on the European Market , this is a legal requirement determined by the relevant European Product Directive.
You must demonstrate how your product complies with all relevant Directives, this can be with documentation, calculations, risk assessments, drawings and test reports, not just as a new product, it must be compliant and safe throughout its operational life within all specified environmental conditions – our experience reviewing such documents for the manufacturer has highlighted this is normally a short fall when compiling a Technical File.

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Who can see my Technical File?

The EU manufacturer (or appointed authorised representative) must be able upon request and within a reasonable timeframe, provide the Technical File to any European Market Surveillance Authority.
A refusal or failure to do so may give authority to the MSA to remove your product from the Market until you prove compliance with the required Directives.

CRANAGE Veritas

ISO 17065
IVNAB
ACCREDITED
PRODUCT CERTIFICATION
DETAILED IN SCOPE REG NO.64

Cranage Veritas has been accredited by INAB against ISO/IEC 17065:2012,
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