Technical file

Changes due to Brexit

Your health and safety responsibilities will not change when the UK leaves the EU. This guidance is under review.

Find the latest information on our Brexit pages

Manufacturers of new products subject to European product safety Directives must collect and be able to assemble comprehensive information covering the design, construction, conformity assessment and use of the product to demonstrate how their product complies with all applicable Directives. This is known as a technical file. It should be in one or more of the official Community languages and kept available for at least the time specified in the relevant Directive (eg for machinery this means for at least 10 years since last production of the product range).

Why do I need to compile a technical file?

As manufacturer you, or if from outside the EU your appointed authorised representative, must compile a technical file for each product you place on the market (or one for a series of identical products) as required by the relevant European product safety Directive. This is required so that as manufacturer you can demonstrate with appropriately detailed documentation, calculations and drawings, how your product complies with all relevant Directives, and so is safe during all phases of its life. Systematically assembling the technical file may also help you when undertaking the conformity assessment process for a particular product. If you have to submit your product for EC Type-examination, a copy of the technical file must be provided to the Notified Body at the same time.

Who is entitled to examine a technical file?

The Responsible Person (manufacturer or the manufacturer's authorised representative) must be able to provide the technical file to any European market surveillance authority (MSA) on request and within a reasonable time scale. A failure to do so may give sufficient grounds for the MSA to doubt the conformity of the product in question with essential requirements and so prevent its placing on the market. HSE will normally only request relevant extracts of a technical file, but like any other MSA has the right to require production of the full technical file.

Purchasers are not entitled to see a products' technical file, but they should be provided with User Instructions, including information on noise and vibration levels (if relevant), and for safe installation.

What needs to be in a technical file?

The depends on the relevant product safety Directives applicable to the product, but generally:

- information concerning the products design assessment and construction, including information showing how relevant essential requirements have been met (which may include references to technical standards applied)
- the conformity assessment procedure applied to the product
- a copy of the Declaration of Conformity (and any other Declarations of conformity or Incorporation relevant to the product or its subassemblies)

- a copy of the User Instructions,
- details of relevant research and test reports,
- and where a series of products are made, details of the quality systems to assure the safety of those products.

Normally the technical file does not have to be permanently available in material form, nor located within the territory of the Community, provided it is capable of being assembled and made available in a reasonable period of time. For the Machinery Directive if the manufacturer is based outside the EU/EEA a legal entity (ie a company or person) established in the EU must be appointed by the manufacturer to provide the technical file to a market surveillance authority (MSA) - note that this legal entity does not have to compile the technical file, just to liaise with the MSA and the manufacturer and ensure the relevant information is provided.