

SCHEDULE 2

ANNEXES TO THE DIRECTIVE

Regulations 7(2)(b) and 8(1)(a)

PART 7

Annex VII: Technical files

A. Technical file for machinery

This part describes the procedure for compiling a technical file. The technical file must demonstrate that the machinery complies with the provisions of the Directive. It must cover the design, manufacture and operation of the machinery to the extent necessary for this assessment. The technical file must be compiled in one or more official Community languages, except for the instructions for the machinery, for which the special provisions of Annex I (Part 1 of this Schedule), section 1.7.4.1 apply.

1. The technical file shall comprise the following:
 - (a) a construction file including:
 - a general description of the machinery,
 - the overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery,
 - full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the machinery with the essential health and safety requirements,
 - the documentation on risk assessment demonstrating the procedure followed, including:
 - (i) a list of the essential health and safety requirements which apply to the machinery,
 - (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery,
 - the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,
 - any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the responsible person,
 - a copy of the instructions for the machinery,
 - where appropriate, the declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery,
 - where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery,
 - a copy of the EC declaration of conformity;
 - (b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of the Directive.

The manufacturer must carry out necessary research and tests on components, fittings or the completed machinery to determine whether

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by its design or construction it is capable of being assembled and put into service safely. The relevant reports and results shall be included in the technical file.

2. The technical file referred to in point 1 of this Annex must be made available to the enforcement authorities and the competent authorities of any other EEA state for at least 10 years following the date of manufacture of the machinery or, in the case of series manufacture, of the last unit produced.

The technical file does not have to be located in the territory of an EEA state, nor does it have to be permanently available in material form. However, it must be capable of being assembled and made available within a period of time commensurate with its complexity by the person designated in the EC declaration of conformity.

The technical file does not have to include detailed plans or any other specific information as regards the sub-assemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the essential health and safety requirements.

3. Failure to present the technical file in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the machinery in question with the essential health and safety requirements.

B. Relevant technical documentation for partly completed machinery

This part describes the procedure for compiling relevant technical documentation. The documentation must show which provisions of the Directive are applied and fulfilled. It must cover the design, manufacture and operation of the partly completed machinery to the extent necessary for the assessment of conformity with the essential health and safety requirements applied. The documentation must be compiled in one or more official Community languages.

Relevant technical documentation shall comprise the following:

- (a) a construction file including:
 - the overall drawing of the partly completed machinery and drawings of the control circuits,
 - full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the partly completed machinery with the applied essential health and safety requirements,
 - the risk assessment documentation showing the procedure followed, including:
 - (i) a list of the essential health and safety requirements applied and fulfilled,
 - (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks,
 - (iii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,
 - (iv) any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the responsible person,
 - (v) a copy of the assembly instructions for the partly completed machinery;

- (b) for series manufacture, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied.

The manufacturer must carry out necessary research and tests on components, fittings or the partly completed machinery to determine whether by its design or construction it is capable of being assembled and used safely. The relevant reports and results shall be included in the technical file.

The relevant technical documentation must be available for at least 10 years following the date of manufacture of the partly completed machinery or, in the case of series manufacture, of the last unit produced, and on request presented to an enforcement authority or a competent authority of any other EEA state. It does not have to be located in the territory of an EEA state, nor does it have to be permanently available in material form. It must be capable of being assembled and presented to the relevant authority by the person designated in the declaration for incorporation.

Failure to present the relevant technical documentation in response to a duly reasoned request by an enforcement authority or a competent authority of any other EEA state may constitute sufficient grounds for doubting the conformity of the partly completed machinery with the essential health and safety requirements applied and attested.
