

ANNEX III

Module B: EC type-examination

1. This module describes that part of the procedure by which a notified body ascertains and attests that an example, representative of the production envisaged, meets the relevant provisions of the Directive.
2. The application for EC type-examination is lodged by the manufacturer or his authorized representative established within the Community with a notified body of his choice.

The application must include:

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, the name and address in addition,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documents, as described in section 3.

The applicant must place at the disposal of the notified body an example representative of the production envisaged, hereinafter called 'type'. The notified body may request further examples if needed for carrying out the test programme.

3. The technical documents must enable the conformity of the appliance with the requirements of the Directive to be assessed. They must, as far as is relevant for such assessment, cover the design, manufacture and operation of the appliance and contain as far as is relevant for assessment:
 - a general type-description,
 - conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
 - descriptions and explanations necessary for the understanding of the drawings and diagrams and the operation of the product,
 - a list of the standards referred to in Article 5 (2), applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied,
 - results of design calculations made, examinations carried out, etc.,
 - test reports.
4. The notified body must:
 - 4.1. examine the technical documents, verify that the type has been manufactured in conformity with those documents and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in Article 5 (2) as well as the components which have been designed without applying the relevant provisions of those standards;
 - 4.2. perform or have performed the appropriate examinations and necessary tests to check whether, where the standards referred to in Article 5 (2) have not been applied, the solutions adopted by the manufacturer meet the essential requirements of the Directive;
 - 4.3. perform or have performed the appropriate examinations and necessary tests to check whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied;

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- 4.4. agree with the applicant the location where the examinations and necessary tests are to be carried out.
5. Where the type meets the relevant provisions of this Directive, the notified body issues an EC type-examination certificate to the applicant. The certificate contains the name and address of the manufacturer, the conclusion of the examination and necessary data for identification of the approved type.

A list of the relevant parts of the technical documents is annexed to the certificate and a copy kept by the notified body.

If the manufacturer or his authorized representative established in the Community is refused a type certificate, the notified body must provide detailed reasons for such refusal.

Provision must be made for an appeals procedure.

6. The applicant informs the notified body that holds the technical documents concerning the EC type-examination certificate of all modifications to the approved appliance which must receive additional approval where such changes may affect the conformity with the essential requirements or the prescribed conditions for use of the product. This additional approval is given in the form of an addition to the original EC type-examination certificate.
7. Each notified body must communicate to the other notified bodies the relevant information concerning the EC type-examination certificates and additions issued and withdrawn.
8. The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The Annexes to the certificates must be kept at the disposal of the other notified bodies.
9. The manufacturer or his authorized representative established within the Community must keep with the technical documents copies of EC type-examination certificates and their additions for a period of at least 10 years after the last date of manufacture of the product concerned.

Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documents available is the responsibility of the person who places the product on the Community market.