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# ANNEX II

## PROCEDURE FOR CERTIFICATION OF CONFORMITY

3. EC DECLARATION OF CONFORMITY TO TYPE (guarantee of production quality)

3.1. The EC declaration of conformity to type (guarantee of production quality) is the procedure whereby a manufacturer who fulfils the obligations in point 3.2 declares that the appliances concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the essential requirements of this Directive which applies to them. The manufacturer or his authorised representative established within the Community must affix the CE marking to each appliance and draw up a written declaration of conformity. This declaration may cover one or more appliances and must be kept by the manufacturer. The CE marking must be followed by the identification number of the notified body responsible for EC surveillance.

3.2. The manufacturer shall apply a quality system that ensures conformity of the appliances with the type as described in the EC type-examination certificate and with the essential requirements of this Directive which apply to them. The manufacturer is subject to EC surveillance as specified in point 3.4.

3.3. Quality system

3.3.1. The manufacturer must lodge an application for approval of his quality system with a notified body of his choice for the appliances in question.

The application must include:

— the quality system documentation,

— an undertaking to carry out the obligations arising from the quality system as approved,

— an undertaking to maintain the approved quality system to ensure its continuing suitability and effectiveness,

— documentation relating to the approved type and a copy of the EC type-examination certificate.

3.3.2. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and logical manner in the form of measures, procedures and written instructions. This quality system documentation must permit a uniform interpretation of the quality programmes, plans, manuals and records. It shall contain, in particular, an adequate description of:

— the quality objectives, the organisational structure and responsibilities of management and of their powers with regard to appliance quality,

— the manufacturing processes, quality control and quality assurance techniques and systematic actions that will be used,

— the examinations and tests that will be carried out before, during and after manufacture and the frequency with which they will be carried out,

— the method of monitoring attainment of the required appliance quality and the effective operation of the quality system.

3.3.3. The notified body shall examine and evaluate the quality system to determine whether it satisfies the requirements referred to in point 3.3.2. It will presume conformity with these requirements in respect of quality systems that implement the corresponding harmonised standard.

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It must notify its decision to the manufacturer and inform the other notified bodies thereof. The notification to the manufacturer must contain the conclusions of the examination, the name and address of the notified body and the reasoned assessment decision in respect of the appliances concerned.

3.3.4. The manufacturer must keep the notified body that has approved the quality system informed of any updating of the quality system in relation to changes brought about by, for example, new technologies and quality concepts.

The notified body must examine the proposed modifications and decide whether the modified quality system complies with the relevant provisions or whether reappraisal is necessary. It must notify the manufacturer of its decision. The notification must include the conclusions of the inspection and the reasoned assessment decision.

3.3.5. A notified body that withdraws approval of a quality system must so inform the other notified bodies, giving the reasons for the decision.

3.4. EC surveillance

3.4.1. The purpose of EC surveillance is to ensure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

3.4.2. The manufacturer must allow the notified body access for inspection purposes to the place of manufacture, inspection, testing and storage and must provide it with all necessary information, in particular:

— the quality system documentation,

— the quality records, such as inspection reports and test data, calibration data, reports on qualifications of the staff concerned.

3.4.3. The notified body must carry out a check at least once every two years to ensure that the manufacturer is maintaining and applying the approved quality system and must supply a report of the check to the manufacturer.

3.4.4. Furthermore, the notified body may make unannounced visits to the manufacturer. During these visits, the notified body may carry out tests on appliances or have them carried out. It must supply the manufacturer with an inspection report and, if appropriate, a test report.

3.4.5. The manufacturer may supply the notified body's report on request.