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ANNEX IV

Module D: Production quality assurance

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 2 ensures and declares that the appliances concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of this Directive. **[**[F1]The manufacturer or his authorized representative established within the Community shall affix the CE marking to each appliance and draw up a written declaration of conformity. The CE marking is accompanied by the identification number of the notified body responsible for the checks referred to in section 4.**]**

Textual Amendments

F1 Substituted by Council Directive 93/68/EEC of 22 July 1993 amending Directives 87/404/EEC (simple pressure vessels), 88/378/EEC (safety of toys), 89/106/EEC (construction products), 89/336/EEC (electromagnetic compatibility), 89/392/EEC (machinery), 89/686/EEC (personal protective equipment), 90/384/EEC (non-automatic weighing instruments), 90/385/EEC (active implantable medicinal devices), 90/396/EEC (appliances burning gaseous fuels), 91/263/EEC (telecommunications terminal equipment), 92/42/EEC (new hot-water boilers fired with liquid or gaseous fuels) and 73/23/EEC (electrical equipment designed for use within certain voltage limits).

2. The manufacturer must operate an approved quality system for production, final appliance inspection and testing as specified in section 3. He is subject to the checks referred to in section 4.

3. Quality system

3.1. The manufacturer lodges an application for assessment of his quality system with a notified body of his choice, for the appliances concerned.

The application must include:

— all relevant information for the appliance category envisaged,

— the documents concerning the quality system,

— the technical documents pertaining to the approved type and a copy of the EC type-examination certificate.

3.2. The quality system must ensure conformity of appliances with the type as described in the EC type-examination certificate and with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documents must permit a consistent interpretation of the quality programmes, plans, manuals and quality records.

It must contain in particular an adequate description of:

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

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

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— 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 quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,

— the means of monitoring the achievement of the required appliance quality and the effective operation of the quality system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in section 3.2. It must presume conformity with those requirements in respect of quality systems that implement the relevant harmonized standard. The auditing team must have at least one member with experience of assessing the relevant product technology. The assessment procedure includes an inspection visit to the manufacturer's premises.

The decision is notified to the manufacturer. The notification must contain the conclusions of the examination and the duly substantiated assessment decision.

3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and maintain it at an adequate and efficient level.

The manufacturer or his authorized representative must keep the notified body that has approved the quality system informed of any proposed change in the quality system.

The notified body must assess the changes proposed and decide whether the altered quality system will still satisfy the requirements referred to in 3.2 or whether reassessment is required.

It must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the substantiated assessment decision.

4. Monitoring under the responsibility of the notified body

4.1. The purpose of monitoring is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer must allow the notified body access for inspection purposes to the manufacturing, inspection, testing and storage premises and provide it with all necessary information, in particular:

— the quality system documents,

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc..

4.3. The notified body must periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and provides an audit report to the manufacturer.

4.4. Additionally the notified body may pay unannounced visits to the manufacturer. During such visits the notified body may carry out tests or have them carried out to verify that the quality system is functioning correctly; if necessary, the notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer must, for a period of at least 10 years after the last date of manufacture of the product, keep at the disposal of the national authorities:

— the document referred to in the second indent of 3.1,

— the updating referred to in the second paragraph of 3.4,

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— the decisions and reports from the notified body which are referred to in the final paragraph of 3.4, and in 4.3 and 4.4.

6. Each notified body must give the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.