ANNEX B

Modules for conformity assessment

PRODUCTION-QUALITY ASSURANCE (MODULE D)

1. A manufacturer who satisfies the obligations of point 2 must ensure and declare that the products concerned conform to type as described in the EC type-examination certificate. The manufacturer or his authorized representative established within the Community must affix the mark to each product and draw up a written declaration of conformity. The mark must be accompanied by the identification symbol of the notified body responsible for surveillance as specified in point 4.

2. The manufacturer must operate an approved quality system for production, final-product inspection and testing as specified in point 3 and must be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body of his choice for the products concerned.

The application must include:

— all relevant information for the product category envisaged,

— the documentation concerning the quality system,

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

3.2. The quality system must ensure that the products conform to type as described in the EC type-examination certificate.

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 documentation must permit a consistent interpretation of the quality programmes, plan, manuals and records.

It must, in particular, include an adequate description of:

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

— the manufacturing, quality-control and quality-assurance techniques, processes 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 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 product 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 laid down in point 3.2. It must presume compliance 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 assessment in the product technology concerned. The assessment procedure must include a visit to the manufacturer's premises.

The manufacturer must be notified of the decision. The notification must include the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufacturer or his authorized representative established within the Community must keep the notified body that has approved the quality system informed of any intended updating of that quality system.

The notified body must assess the modifications proposed and decide whether the modified quality system will still satisfy the requirements laid down in point 3.2 or whether a reassessment is required.

The manufacturer must be notified of its decision. The notification must include the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance 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 locations of manufacture, inspection and 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, 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 must provide the manufacturer with audit reports.

4.4. In addition, the notified body may pay unannounced visits to the manufacturer. During such visits the notified body may carry out tests or cause tests to be carried out to check 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 at least 10 years after the last product has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second indent of the second paragraph of point 3.1,

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

— the decision and reports from the notified body referred to in the final paragraph of point 3.4, point 4.3 and point 4.4.

6. Each notified body must, on request, provide flag Member State administrations and the other notified bodies with the relevant information concerning the quality-system approvals issued and withdrawn.