SCHEDULE 4

Modules for conformity assessment

PART 5

Module D (production quality assurance)

1. The manufacturer must operate an approved quality system in respect of—

(a) the production of the product; and

(b) the final product inspection and testing.

2. A quality system is approved if it is approved by a notified body and it meets the following criteria—

(a) it must ensure compliance of a listed product with the type as described in the EC type-examination certificate and that it conforms to the product requirements;

(b) 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; and

(c) the quality system documentation must—

(i) permit a consistent interpretation of the quality programmes, plan, manual and records; and

(ii) include the matters contained in paragraph 3.

3. The matters referred to in paragraph 2(c)(ii) are that the quality system documentation contain an adequate description of—

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

(b) the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(c) the examinations and tests that will be carried out before, during and after manufacture and the frequency with which they will be carried out;

(d) the quality records, including inspection reports and test data, calibration data and qualification reports of the personnel concerned; and

(e) the means to monitor the achievement of the required product quality and the effective operation of the quality system.

4. A manufacturer must apply for approval of his quality system to a notified body and must include in that application—

(a) all relevant information for the product category envisaged;

(b) the documentation concerning the quality system; and

(c) if applicable—

(i) the general technical documentation of the approved type; and

(ii) a copy of the EC type-examination certificate.

5. Where a notified body receives an application in accordance with paragraph 4, the it must—

(a) determine the application; and

(b) if it is satisfied that the quality system meets the criteria contained or referred to in paragraph 2, the notified body must provide its approval to the manufacturer.

6. An approval under paragraph 5 must be in writing and include—

(a) the reasons for the decision; and

(b) the conclusions of the examinations and tests.

7. If a manufacturer intends to modify the approved quality system—

(a) he must inform in writing the notified body that approved the quality system; and

(b) the notified body must determine whether or not the proposed modification requires a re-assessment of the quality system.

8. If the notified body determines that a re-assessment is required, the procedures in paragraphs 4 to 6 apply in respect of an application for assessment of the quality system as proposed to be modified.

9. A notified body must carry out—

(a) periodic audits of the quality system of the manufacturer; and

(b) periodic unannounced visits to the premises of the manufacturer,

whose quality system it has approved in order to determine that the manufacturer is maintaining and applying the quality system.

10. A notified body must inform the manufacturer of the results of the audit and visit by providing written audit and visit reports.

11. In relation to paragraph 9, a manufacturer must—

(a) allow the notified body access to the locations of manufacture, inspection and testing, and storage;

(b) provide all necessary documentation to the notified body, including—

(i) the documentation concerning the quality system; and

(ii) the quality records, including inspection reports and test data, calibration data and qualification reports of the personnel concerned;

and

(c) in respect of visits by the notified body, carry out or allow the notified body to carry out tests necessary to determine that the quality system is functioning correctly.

12. Relevant documentation under regulation 10 includes—

(a) the documentation concerning the quality system submitted with an application for approval;

(b) approvals in relation to the quality system;

(c) details of the modifications to the quality system; and

(d) audit and visit reports.