SCHEDULE 9

Regulation 10(3)(*b*)(i)(*bb*) (Annex VII to the ATEX Directive)

Module: Product quality assurance

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 ensures and declares that the equipment is in conformity with the type as described in the EC type-examination certificate. The manufacturer or his authorised representative established in the Community shall affix the CE marking to each product and draw up a written declaration of conformity. The CE marking shall be accompanied by the identification number of the notified body responsible for surveillance as specified in paragraph 4.

2. The manufacturer shall operate an approved quality system for the final inspection and testing of equipment as specified in paragraph 3 and shall be subject to surveillance as specified in paragraph 4.

Quality system

3

3.1 The manufacturer shall lodge an application for assessment of his quality system for the equipment and protective systems with a notified body of his choice.

The application shall include:

- all relevant information for the product category envisaged;
- documentation on the quality system;
- technical documentation on the approved type and a copy of the EC type-examination certificate.

3.2 Under the quality system, each piece of equipment shall be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 of the ATEX Directive or equivalent tests shall be carried out in order to ensure its conformity with the relevant requirements of the ATEX Directive. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instruments. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain, in particular, an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality;
- the examinations and tests which will be carried out after manufacture;
- the means to monitor the effective operation of the quality system;
- quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

3.3 The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2. It shall presume conformity with these requirements in respect of quality systems which implement the relevant harmonized standard.

The auditing team shall have at least one member experienced as an assessor in the product technology concerned. The assessment procedure shall include an assessment visit to the manufacturer’s premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.4 The manufacturer shall undertake to discharge the obligations arising from the quality system as approved and to maintain it in an appropriate and efficient manner.

The manufacturer or his authorised representative shall inform the notified body which has approved the quality system of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the notified body

4

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

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

— quality system documentation;

— technical documentation;

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

4.3 The notified body shall periodically carry out audits to ensure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4 Furthermore, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or arrange for tests to be carried out in order to check the proper functioning of the quality system, where necessary; it shall provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer shall, for a period ending at least 10 years after the last piece of equipment was manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the third indent of paragraph 3.1;

— the updating referred to in the second sub-paragraph of paragraph 3.4;

— the decisions and reports notified or provided to it from the notified body which are referred to in paragraphs 3.4, 4.3 and 4.4.

6. Each notified body shall forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.