ANNEX III

PART A

Module B: EU-type examination

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an apparatus and verifies and attests that the technical design of the apparatus meets the essential requirements set out in point 1 of Annex I.

2. EU-type examination shall be carried out by assessment of the adequacy of the technical design of the apparatus through examination of the technical documentation referred to in point 3, without examination of a specimen (design type). It may be restricted to some aspects of the essential requirements as specified by the manufacturer or his authorised representative.

3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

   The application shall specify the aspects of the essential requirements for which examination is requested and shall include:

   (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

   (b) a written declaration that the same application has not been lodged with any other notified body;

   (c) the technical documentation. The technical documentation shall make it possible to assess the apparatus conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the apparatus. The technical documentation shall contain, wherever applicable, at least the following elements:

      (i) a general description of the apparatus;

      (ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

      (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus;

      (iv) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

      (v) results of design calculations made, examinations carried out, etc.;

      (vi) test reports.

4. The notified body shall examine the technical documentation to assess the adequacy of the technical design of the apparatus in relation to the aspects of the essential requirements for which examination is requested.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of this Directive that apply to the apparatus concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the aspects of the essential requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

   The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured apparatus with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the apparatus with the essential requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the apparatus has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

PART B

Module C: conformity to type based on internal production control

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the apparatus concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured apparatus with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3. **CE marking and EU declaration of conformity**

3.1. The manufacturer shall affix the CE marking to each individual apparatus that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

3.2. The manufacturer shall draw up a written EU declaration of conformity for each apparatus model and keep it at the disposal of the national authorities for 10 years after the apparatus has been placed on the market. The EU declaration of conformity shall identify the apparatus model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

4. **Authorised representative**

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.