ANNEX V

EC TYPE-EXAMINATION

1. EC type-examination is the part of the procedure whereby a notified body ascertains and certifies that a representative sample of the production envisaged fulfils the relevant provisions of this Directive.

2. The application for EC type-examination shall be lodged by the manufacturer or by his authorised representative with a notified body.

The application shall include:

— the name and the address of the manufacturer and the name and address of the authorised representative if the application is lodged by the representative,

— the documentation described in section 3 needed to assess the conformity of the representative sample of the production in question, hereinafter referred to as the 'type', with the requirements of this Directive. The applicant shall make a 'type' available to the notified body. The notified body may request other samples as necessary,

— a written declaration that no application has been lodged with any other notified body for the same type.

3. The documentation must allow an understanding of the design, the manufacture and the performances of the device. The documentation shall contain the following items in particular:

— a general description of the type, including any variants planned,

— all documentation referred to in Annex III, section 3, indents 3 to 13,

— in the case of devices for self testing, the information referred to in Annex III, section 6.1.

4. The notified body shall:

4.1. examine and assess the documentation and verify that the type has been manufactured in conformity with that documentation; it shall also record the items designed in conformity with the applicable provisions of the standards referred to in Article 5, as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;

4.2. perform or have performed appropriate examinations and the tests necessary to verify whether the solutions adopted by the manufacturer meet the essential requirements of this Directive if the standards referred to in Article 5 have not been applied; if the device is to be combined with other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when combined with any such device(s) having the characteristics specified by the manufacturer;

4.3. carry out or ask for the appropriate examinations and the tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied;

4.4. agree with the applicant on the place where the necessary examinations and tests will be carried out.

5. If the type conforms to the provisions of this Directive, the notified body shall issue the applicant with an EC type-examination certificate. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the

conditions of validity and the data needed for identification of the type approved. The relevant parts of the documentation shall be annexed to the certificate and a copy shall be kept by the notified body.

6. The manufacturer shall inform the notified body without delay if it has obtained information about changes to the pathogen and markers of infections to be tested, in particular as a consequence of biological complexity and variability. In this connection, the manufacturer shall inform the notified body whether any such change is likely to affect the performance of the *in vitro* device concerned.

6.1. Changes to the approved device must receive further approval from the notified body which issued the EC type-examination certificate wherever the changes may affect conformity with the essential requirements of the Directive or with the conditions prescribed for use of the device. The applicant shall inform the notified body which issued the EC type-examination certificate of any such change made to the approved device. This new approval shall take the form of a supplement to the initial EC type-examination certificate.

7. Administrative provisions

Other notified bodies may obtain a copy of the EC type-examination certificates and/or the supplements thereto. The annexes to the certificates must be available to the other notified bodies on reasoned application, after the manufacturer has been informed.