ANNEX IV

EC DECLARATION OF CONFORMITY (FULL QUALITY ASSURANCE SYSTEM)

4. Examination of the design of the product

4.1. For devices covered by Annex II, List A, in addition to the obligations imposed by section 3, the manufacturer must lodge with the notified body an application for examination of the design dossier relating to the device which he plans to manufacture and which falls into the category referred to in section 3.1.

4.2. The application must describe the design, manufacture and performances of the device in question. It must include the documents needed to assess whether the device conforms to the requirements of this Directive, as referred to in section 3.2(c).

4.3. The notified body must examine the application and, if the device conforms to the relevant provisions of the Directive, issue the application with an EC design-examination certificate. The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the requirements of the Directive. The certificate must contain the conclusions of the examination, the conditions of validity, the data needed for the identification of the approved design and, where appropriate, a description of the intended purpose of the device.

4.4. Changes to the approved design must receive further approval from the notified body which issued the EC design-examination certificate wherever the changes could 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 design-examination certificate of any such changes made to the approved design. The additional approval must take the form of a supplement to the EC design-examination certificate.

4.5. 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* diagnostic medical device concerned.