ANNEX IV

EC DECLARATION OF CONFORMITY (FULL QUALITY ASSURANCE SYSTEM)

1. The manufacturer must ensure application of the quality system approved for the design, manufacture and final inspection of the devices concerned, as specified in section 3, and is subject to audit as laid down in section 3.3 and to the surveillance as specified in section 5. In addition, the manufacturer must follow, for devices covered by Annex II, List A, the procedures laid down in sections 4 and 6.

2. The declaration of conformity is the procedure whereby the manufacturer who fulfils the obligations imposed by section 1 ensures and declares that the devices concerned meet the provisions of this Directive which apply to them.

The manufacturer shall affix the CE marking in accordance with Article 16 and shall draw up a declaration of conformity covering the devices concerned.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.

The application must include:

— the name and address of the manufacturer and any additional manufacturing site covered by the quality system,

— adequate information on the device or device category covered by the procedure,

— a written declaration that no such application has been lodged with any other notified body for the same device-related quality system,

— the documentation on the quality system,

— an undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved,

— an undertaking by the manufacturer to keep the approved quality system adequate and efficacious,

— an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action and notification as referred to in Annex III, section 5.

3.2. Application of the quality system must ensure that the devices conform to the provisions of this Directive which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policies and procedures, such as quality programmes, quality plans, quality manuals and quality records.

It shall include in particular an adequate description of:

(a) the manufacturer's quality objectives;

(b) the organisation of the business and in particular:

— the organisational structures, the responsibilities of the managerial staff and their organisational authority where quality of design and manufacture of the devices is concerned,

— the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and of product, including control of devices which fail to conform;

(c) the procedures for monitoring and verifying the design of the devices and in particular:
— a general description of the device, 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,
— the techniques used to control and verify the design and the processes and systematic measures which will be used when the devices are being designed;

(d) the inspection and quality assurance techniques at the manufacturing stage and in particular:
— the processes and procedures which will be used, particularly as regards sterilisation,
— the procedures in relation to purchasing,
— the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

(e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible to trace back the calibration.

The manufacturer shall carry out the required controls and tests according to the latest state of the art. The controls and tests shall cover the manufacturing process including the characterisation of the raw material and the individual devices or each batch of devices manufactured.

In testing the devices covered by Annex II, List A, the manufacturer shall take into account the most recent available information, in particular as regards the biological complexity and variability of the specimens to be tested with the *in vitro* device concerned.

3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in section 3.2. It must presume that quality systems which implement the relevant harmonised standards conform to the requirements.

The assessment team must have experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.

The decision shall be notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.

3.4. The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system or the product-range covered.

The notified body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in section 3.2. It must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.

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.

5. Surveillance

5.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

5.2. The manufacturer must authorise the notified body to carry out all the necessary inspections and supply it with all relevant information, in particular:

— the documentation on the quality system,

— the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculation, tests, etc.,

— the data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

5.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and must supply the manufacturer with an assessment report.

5.4. In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

6. Verification of manufactured products covered by Annex II, List A

6.1. In the case of devices covered by Annex II, List A, the manufacturer shall forward to the notified body without delay after the conclusion of the controls and tests the relevant reports on the tests carried out on the manufactured devices or each batch of devices. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities.

6.2. The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed time-frame, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.