ANNEX IV

EC DECLARATION OF CONFORMITY (FULL QUALITY ASSURANCE SYSTEM)

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.