SCHEDULE 5 Regulation 5(2)

EC DECLARATION OF CONFORMITY PROCEDURE
(CORRESPONDING TO ANNEX 2 OF THE DIRECTIVE)

PART I

QUALITY SYSTEM

Application for evaluation of quality system

1. A manufacturer who wishes to have his quality system for design, manufacture and final inspection approved shall make an application in writing to a notified body for evaluation of his quality system.

2.—(1) The application shall include—

(a) a description of the type of devices manufacture of which is envisaged;

(b) details of any relevant national Standard or harmonised Standard with which the devices comply;

(c) the quality system documentation;

(d) an undertaking by the manufacturer to fulfil the obligations arising from the quality system as approved;

(e) an undertaking by the manufacturer to maintain the approved quality system in such a way that it remains adequate and efficacious;

(f) an undertaking by the manufacturer to institute and keep up-dated a post-marketing surveillance system.

(2) The undertaking referred to in sub-paragraph (1)(f) shall include an obligation for the manufacturer to notify the Secretary of State of the following incidents immediately on learning of them—

(a) any deterioration in the characteristics or performances of, and any inaccuracies in the instruction leaflet for, a device which might lead to or have led to the death of a patient or a deterioration in the state of his health;

(b) any technical or medical reason for withdrawal of a device from the market which results in such withdrawal by the manufacturer.

Approval and evaluation of quality system

3.—(1) Approval of a quality system shall not be given unless the conditions specified in subparagraphs (2) to (4) are fulfilled.

(2) The application of the quality system must ensure that the devices conform to the provisions of the Directive which apply to them at every stage, from design to final controls.

(3) All the elements, requirements and provisions adopted by the manufacturer for his quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures, and the documentation must make possible a uniform interpretation of the policies and procedures as to quality such as those programmes, plans, manuals and records which relate to quality.

(4) The documentation referred to in sub-paragraph (3) shall include in particular an adequate description of—

(a) the manufacturer's objectives as to quality;

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

(i) the organisational structure of the organisation and the responsibilities and degrees of authority of the managerial staff, where quality of design and manufacture of devices is concerned;

(ii) the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of the design and of the devices, including control of devices which do not conform to harmonised Standards;

(c) the procedures for monitoring and verifying the design of the products and in particular—

(i) the design specifications, including the standards which will be applied and a description of the solutions adopted to fulfil the relevant essential requirements when the relevant national Standards are not applied in full;

(ii) the techniques of control and verification of the design, and the processes and systematic actions which will be used when the devices are being designed;

(d) the techniques of control and of quality assurance at the manufacturing stage and in particular:

(i) the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,

(ii) 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 effected before, during and after production, the frequency with which they will take place, and the equipment used for testing.

4.—(1) The notified body shall effect an evaluation of the quality system to determine whether it fulfils the conditions specified in paragraph 3(2) to (4), and in doing so shall presume fulfilment of those conditions for a quality system which is in accordance with relevant harmonized Standards.

(2) The team of individuals entrusted with the evaluation shall include at least one person who has already had experience of evaluations of the technology concerned.

(3) The evaluation shall include an inspection at the manufacturer's premises.

(4) A decision as to whether or not approval is given shall be notified to the manufacturer after the final inspection and shall contain a reasoned evaluation and the conclusions of the notified body.

5.—(1) The manufacturer shall inform the relevant notified body of any plan to modify his approved quality system.

(2) The relevant notified body shall evaluate the proposed modifications and shall determine whether the quality system as proposed to be modified would fulfil the conditions specified in paragraph 3(2) to (4).

(3) A decision as to whether or not to approve the system as modified shall be notified to the manufacturer and shall contain a reasoned evaluation and the conclusions of the relevant notified body.

(4) In this paragraph "relevant notified body" in relation to a quality system means the notified body which approved it, except that where that body is no longer a notified body as respects tasks under this paragraph, it means such other notified body as the Secretary of State shall have designated as the notified body in relation to those tasks and that system.

Design dossier

6.—(1) A manufacturer who makes an application under paragraph 1 relating to a type of device shall also make an application for examination of the design dossier relating to that type of device which he plans to manufacture.

(2) The application shall describe the design, manufacture, and performances of the device in question and shall include the necessary particulars which make it possible to evaluate whether it complies with the requirements of the Directive.

(3) The particulars referred to in sub-paragraph (2) shall include the following:—

(a) the design specifications, including the Standards which have been applied;

(b) the necessary proof of their appropriateness, in particular where the relevant national Standards have not been applied in full, including the results of the appropriate tests carried out by the manufacturer or under his responsibility;

(c) a statement as to whether or not the device incorporates, as an integral part, a substance referred to in paragraph 10 of Schedule 2, whose action in combination with the device may result in its bioavailability, together with data on the relevant tests conducted;

(d) the clinical data referred to in Schedule 3;

(e) the draft instruction leaflet.

Design examination certificate

7.—(1) The notified body shall examine the application and, where the type of device complies with the relevant provisions of the Directive, shall signify approval by issuing the applicant with an EC design examination certificate.

(2) The notified body may require the application to be supplemented by further tests or proof so that compliance with the requirements of the Directive may be evaluated.

(3) The certificate shall contain the conclusions of the examination, the conditions of its validity, the data needed for identification of the approved design and, where appropriate, a description of the intended use of the type of device.

8.—(1) An applicant to whom an EC design examination certificate has been issued shall inform the relevant notified body of any modification made to the approved design.

(2) Any such modification must receive approval from the relevant notified body where it may affect conformity with the relevant essential requirements or the conditions prescribed for the use of the type of device.

(3) Any supplementary approval which is given shall be given in the form of an addendum to the EC design examination certificate.

(4) In this paragraph and paragraph 9 "relevant notified body" in relation to a design means the notified body which issued the EC design examination certificate in respect of it, except that where that body is no longer a notified body as respects tasks under this paragraph it means such other notified body as the Secretary of State shall have designated as the notified body in relation to those tasks and that design.

9. The relevant notified body—

(a) shall withdraw any EC design examination certificate or supplementary approval given by it if it considers that the device no longer conforms with the relevant essential requirements or the conditions prescribed for the use of the type of device; and

(b) may withdraw the EC design examination certificate or supplementary approval if it has been given on the basis of false or misleading information.

PART II

SURVEILLANCE

10.—(1) The manufacturer whose quality system for manufacture and inspection is approved shall authorise the notified body to carry out the inspections, and shall supply it with all the appropriate information, which the notified body needs to ensure that the manufacturer duly fulfils his obligations arising from the approved quality system, and that information shall include—

(a) the documentation relating to the quality system;

(b) the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests, etc.;

(c) the data stipulated in the part of the quality system relating to manufacture, such as reports concerning inspections, tests, standardisations, calibrations, the qualifications of the staff concerned, etc.

(2) The notified body shall periodically carry out appropriate evaluations, including inspections, in order to ascertain that the manufacturer is applying the approved quality system, and shall supply the manufacturer with a report about any such evaluation.

(3) In addition, the notified body may make inspections on unannounced visits to the manufacturer, and shall supply him with a report about any such inspection.

(4) Every notified body shall communicate to the other notified bodies the information necessary to establish in respect of which quality systems it has issued, refused or withdrawn approval.