SCHEDULE 7

Regulation 5(4)

EC VERIFICATION PROCEDURE (CORRESPONDING TO ANNEX 4 OF THE DIRECTIVE)

1. The manufacturer shall, before the start of manufacture, prepare and submit to the notified body documentation defining the manufacturing process, in particular as regards sterilisation, and all the routine, pre-established procedures to be implemented to ensure homogeneity of production and conformity of the devices with—

(a) the type described in the EC type-examination certificate; and

(b) the relevant requirements of the Directive.

2.—(1) The manufacturer shall undertake to the notified body to institute and keep up-dated a system of post-marketing surveillance.

(2) The undertaking shall include an obligation for the manufacturer to notify the Secretary of State of the following events 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 his state of health;

(b) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

3.—(1) The notified body shall carry out EC verification by controls and tests on the products on a statistical basis in accordance with paragraph 4.

(2) The manufacturer shall authorise the notified body to evaluate the efficiency of the measures taken pursuant to paragraph 1, by audit where appropriate.

4.—(1) The manufacturer shall present the manufactured products to the notified body in the form of homogeneous batches.

(2) A random sample shall be taken by the notified body from each batch.

(3) The devices which make up the sample shall be examined individually and appropriate tests, defined in the relevant national Standards or equivalent tests, shall be carried out to verify the conformity of the devices with the type described in the EC type-examination certificate, in order to determine whether the batch is to be accepted or rejected.

(4) Statistical control of products will be based on attributes, entailing a sampling system with the following characteristics:

(a) a level of quality corresponding to a probability of acceptance of 95%, with a non-conformity percentage of between 0.29 and 1%;

(b) a limit quality corresponding to a probability of acceptance of 5%, with a non-conformity percentage of between 3 and 7%.

(5) If a batch is accepted, the notified body shall draw up a written certificate of conformity, and all the devices in the batch may, subject to regulation 3(1), be placed on the market, with the exception of those devices in the sample which were found not to conform.

(6) If a batch is rejected, the notified body shall take the appropriate measures to prevent the batch from being placed on the market.

(7) If justified on practical grounds, the manufacturer may affix the EC mark during manufacture, under the responsibility of the notified body, in accordance with regulation 4(1), accompanied by the identifying logo of the notified body responsible for statistical verification.