ANNEX VI

EC VERIFICATION

1. EC verification is the procedure whereby the manufacturer or his authorised representative ensures and declares that the products which have been subject to the procedure set out in section 4 conform to the type described in the EC type-examination certificate and meet the requirements of this Directive which apply to them.

2.1. The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which conform to the type described in the EC type-examination certificate and the requirements of the Directive which apply to them. Before the start of manufacture, the manufacturer must prepare documents defining the manufacturing process, in particular as regards sterilisation and the suitability of starting materials, where necessary, and define the necessary testing procedures according to the state of the art. All the routine, pre-established provisions must be implemented to ensure homogeneous production and conformity of the products with the type described in the EC type-examination certificate and with the requirements of this Directive which apply to them.

2.2. To the extent that for certain aspects the final testing according to section 6.3 is not appropriate, adequate process testing, monitoring and control methods shall be established by the manufacturer with the approval of the notified body. The provisions of Annex IV, section 5, shall apply accordingly in relation to the abovementioned approved procedures.

3. The manufacturer must undertake 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 and notification action as referred to in Annex III, section 5.

4. The notified body must carry out the appropriate examinations and tests taking account of section 2.2 in order to verify the conformity of the product with the requirements of the Directive either by examining and testing every product as specified in section 5 or by examining and testing products on a statistical basis as specified in section 6, as the manufacturer decides. When carrying out statistical verification according to section 6, the notified body has to decide when statistical procedures for lot-by-lot inspection or isolated lot inspection have to be applied. Such decision must be taken in consultation with the manufacturer.

In as far as the conduct of examinations and tests on a statistical basis is not appropriate, examinations and tests may be carried out on a random basis provided that such procedure in conjunction with the measures taken in accordance with section 2.2 ensures an equivalent level of conformity.

5. Verification by examination and testing of every product

5.1. Every product is examined individually and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests must be carried out in order to verify the conformity of the products with the EC type described in the type-examination certificate and with the requirements of the Directive which apply to them.

5.2. The notified body must affix, or have affixed, its identification number to each approved product and must draw up a written certificate of conformity relating to the tests carried out.

6. Statistical verification

6.1. The manufacturer must present the manufactured products in the form of homogeneous batches.

6.2. One or more random samples, as necessary, are taken from each batch. The products which make up the sample are examined and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests must be carried out to verify, where appropriate, the conformity of the products with the type described in the EC type-examination certificate and with the requirements of the Directive which apply to them in order to determine whether to accept or reject the batch.

6.3. Statistical control of products will be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling scheme will be established by the harmonised standards referred to in Article 5, taking account of the specific nature of the product categories in question.

6.4. If the batch is accepted, the notified body affixes, or has affixed its identification number to each product and draws up a written certificate of conformity relating to the tests carried out. All products in the batch may be put on the market except any in the sample which failed to conform.

If the batch is rejected the competent notified body must take appropriate measures to prevent the batch from being placed on the market. In the event of frequent rejection of batches, the notified body may suspend the statistical verification.

The manufacturer may, on the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.