# ANNEX VIII

## STATEMENT AND PROCEDURES CONCERNING DEVICES FOR PERFORMANCE EVALUATION

1. For devices for performance evaluation the manufacturer or his authorised representative shall draw up the statement containing the information stipulated in section 2 and ensure that the relevant provisions of this Directive are met.

2. The statement shall contain the following information:

— data allowing identification of the device in question,

— an evaluation plan stating in particular the purpose, scientific, technical or medical grounds, scope of the evaluation and number of devices concerned,

— the list of laboratories or other institutions taking part in the evaluation study,

— the starting date and scheduled duration for the evaluations and, in the case of devices for self-testing, the location and number of lay persons involved,

— a statement that the device in question conforms to the requirements of the Directive, apart from the aspects covered by the evaluation and apart from those specifically itemised in the statement, and that every precaution has been taken to protect the health and safety of the patient, user and other persons.

3. The manufacturer shall also undertake to keep available for the competent national authorities the documentation allowing an understanding of the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of this Directive. This documentation must be kept for a period ending at least five years after the end of the performance evaluation.

The manufacturer shall take all the measures necessary for the manufacturing process to ensure that the products manufactured conform to the documentation mentioned in the first paragraph.

4. The provisions of Article 10(1), (3) and (5) shall apply to devices intended for performance evaluation.