SCHEDULE 8

EC DECLARATION OF CONFORMITY TO TYPE PROCEDURE
(CORRESPONDING TO ANNEX 5 OF THE DIRECTIVE)

PART II

SURVEILLANCE

3. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations which arise from the approved quality system.

4. The manufacturer shall authorise the notified body to carry out all necessary inspections and shall supply it with all appropriate information, in particular:

(a) the documentation relating to the quality system documentation;

(b) 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.

5.—(1) The notified body shall periodically carry out appropriate inspections and evaluations in order to ascertain that the manufacturer is applying the approved quality system, and shall supply the manufacturer with an evaluation report.

(2) In addition, the notified body may make unannounced visits to the manufacturer, and shall supply him with an inspection report.

(3) The notified body shall communicate to the other notified bodies all relevant information concerning approvals of quality systems issued, refused or withdrawn.