ANNEX IV

EC DECLARATION OF CONFORMITY (FULL QUALITY ASSURANCE SYSTEM)

5. Surveillance

5.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

5.2. The manufacturer must authorise the notified body to carry out all the necessary inspections and supply it with all relevant information, in particular:

— the documentation on the quality system,

— the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculation, tests, etc.,

— the data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

5.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and must supply the manufacturer with an assessment report.

5.4. In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.