SCHEDULE 5

(Annex V of Directive 99/5/EC)

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 10

Full quality assurance

4.2. The manufacturer must allow the notified body access for inspection purposes to the locations of design, manufacture, inspection and testing, and storage and must provide it with all necessary information, in particular:

- the quality system documentation,
- the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc.,
- the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.