

SCHEDULE 6

Module: Production quality assurance

Surveillance under the responsibility of the notified body

4.2 The manufacturer shall, for inspection purposes, allow the notified body access to the manufacture, inspection, testing and storage premises and shall provide it with all necessary information, in particular:

- the quality system documentation;
- the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.