Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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.