

## SCHEDULE 9

Module: Product 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 inspection, testing and storage premises and shall provide it with all necessary information, in particular:

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