ANNEX II

TECHNICAL DOCUMENTATION

3. DESIGN AND MANUFACTURING INFORMATION

3.1. Design information

Information to allow the design stages applied to the device to be understood shall include:

(a) a description of the critical ingredients of the device such as antibodies, antigens, enzymes and nucleic acid primers provided or recommended for use with the device;

(b) for instruments, a description of major subsystems, analytical technology such as operating principles and control mechanisms, dedicated computer hardware and software;

(c) for instruments and software, an overview of the entire system;

(d) for software, a description of the data interpretation methodology, namely the algorithm;

(e) for devices intended for self-testing or near-patient testing, a description of the design aspects that make them suitable for self-testing or near-patient testing.

3.2. Manufacturing information

(a) information to allow the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device to be understood. More detailed information shall be provided for the audit of the quality management system or other applicable conformity assessment procedures;

(b) identification of all sites, including suppliers and sub-contractors, where manufacturing activities are performed.