

ANNEX VII

EC DECLARATION OF CONFORMITY (PRODUCTION QUALITY ASSURANCE)

3. Quality system
 - 3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.
 - The application must include:
 - the technical documentation on the types approved and a copy of the EC type-examination certificates.
 - 3.2. Application of the quality system must ensure that the devices conform to the type described in the EC type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policy statements and procedures. This quality system documentation must permit uniform interpretation of the quality policy and procedures such as quality programmes, plans, manuals and records.

It must include in particular an adequate description of:

- (a) the manufacturer's quality objectives;
 - (b) the organisation of the business and in particular:
 - the organisational structures, the responsibilities of the managerial staff and their organisational authority where quality of manufacture of the devices is concerned,
 - the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of product, including control of devices which fail to conform;
 - (c) the inspection and quality assurance techniques at the manufacturing stage and in particular:
 - the processes and procedures which will be used, particularly as regards sterilisation,
 - the procedures in relation to purchasing,
 - the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;
 - (d) the appropriate tests and trials to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible to trace back the calibration.
- 3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in section 3.2. It must presume that quality systems which implement the relevant harmonised standards conform to these requirements.

The assessment team must have past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

The decision must be notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.

3.4. The manufacturer shall inform the notified body which approved the quality system of any plan for substantial changes to the quality system.

The notified body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in section 3.2. It must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.