Modul E

Conformity to type based on product quality assurance

Conformity to type based on manufacturing process quality assurance is that part of the conformity assessment procedure which the manufacturer or his authorized representative established within the association guarantees and declares that the products concerned under his responsibility are in conformity with the type described in the EC type-examination certificate and satisfy the requirements Directive 93/15 / EEC.

Applicant shall send a list of the products for which it is requested to carry out the module in question and the documentation concerning the quality system (quality manual). In case that module B was performed another NB on these products, applicant will also send a copy of all final documents issued by this NB (certificates including all amendments, final reports, final protocols, certificate attachments ...) from which it is possible to find out what parameters the individual products had an EC type examination when they were assessed. At the same time, applicant will also send a complete technical documentation of the products if it is not part of the documents concerned. It shall also propose the place and date of the audit.

Notified body shall send applicant a price proposal for the assessment, including an audit program.

In case of of the price proposals approval, the applicant shall send to the Notified Body the completed form “Application for conformity assessment” KOTA D-414. The form shall be completed in full and legible. The applicant shall confirm the truthfulness of the data by his signature and if possible imprint of company stamp.

The notified body shall carry out an audit at the manufacturer's registered office. The aim of the audit is a comprehensive review of the established quality assurance system of the production process, but the emphasis is on verifying:

— the quality objectives and the organizational structure, responsibilities and powers of the management with reguard to product quality,

— the examinations and tests that will be carried out after manufacture,

— the quality records, such as inspection reports and test data, calibration data, reports of the qualifications of the staff concerned, etc.,

— means of monitoring the effective operation of the quality system.

The audit shall also include an assessment of real performance of the test methods in order to physically verify the knowledge of the test procedures, test equipment and gauges, as well as an assessment of the correctness of the measurement values.

Upon completion of the assessment, the Notified Body shall draw up the Quality System Assessment Certificate and the Final Report. The certificate indicates the validity period of the certificate. These documents, together with the invoice, are sent to the applicant's address. It shall also authorize the manufacturer to affix the CE marking to the relevant products, to which the number 1395 is attached.

In the case that significant deficiencies have been identified in the system under assessment during the audit, the Notified Body shall refuse to certify the system concerned and shall send the Applicant a Final Report explaining its decision. At the same time, he will instruct him about the possibility and method of appeal.

Manufacturer shall inform the Notified Body of any intended change to the quality system.

Notified body shall evaluate the modifications proposed and decide whether the modified quality system will continue to satisfy the requirements or whether a reassessment is required.

Notified body shall notify the manufacturer of its decision. The notification shall include the conclusions of the examination and the reasoned assessment decision..