Modul D

Type conformity based on quality process assurance

Conformity to type based on quality assurance of the production process is that part of the conformity assessment procedure by which the manufacturer or his authorized representative operating in the community guarantees and declares on his responsibility that relevant products are in compliance with the type described in the EU type-examination certificate and meet requirements of Directive 2014/28/EU.

The applicant shall send a list of the products for which it is required to carry out the module and the documentation concerning the quality system (quality manual). In the event that Module B on these products was performed by other NB , applicant will also send a list of all final documents issued by that NB (certificates including all additions, final reports, final reports, certificate appendices ...) from which it is possible to determine which parameters individual products had when assessed by the ES type examination. At the same time, he will also send the complete product technical documentation if it is not part of the documents in question. Applicant will also propose the place and date of the audit.

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

In the event of price proposal being approved, the applicant submits to the Notified Body the completed form "Application for Conformity Assessment" of KOTA D-414. The form must be completed in full and legibly. The truthfulness of the given data will be confirmed by the applicant by his signature or by his / her signature. stamp.

The notified body shall carry out an audit at the manufacturer's premises. The objective of the audit is to comprehensively review the established quality management system of the production process, with focus is on :

— quality objectives and the organizational structure, responsibilities and competence of the management with regard to product quality

— the corresponding methods, procedures and systematic actions used in production, quality control and quality assurance

— examinations and tests that will be carried out before, during and after manufacture, including the intervals at which they will be carried out

— quality records, such as inspection reports and test data, calibration data, qualification reports of relevant staff and so on...

— means of monitoring the desired product quality achievements and the effective operation of the quality system.

Upon completion of the assessment, the Notified Body draws up the Assessment report. At the same time, the report will also contain the interval of the following surveillance. He sends the Assessment report together with the invoice to the address of the applicant. At the same time, it entrusts the manufacturer with the CE marking of the relevant products with the number 1395 attached.

In the event that serious deficiencies in the system under assessment were identified during the audit, the Notified Body refuses to certify the system in question and sends the Assessment report to the applicant in which he justifies his decision. At the same time, he will inform applicant about the possibilities and method of appeal.

The manufacturer must inform the Notified Body of any intended change to the quality system.

The notified body shall evaluate the proposed changes and decide whether the modified quality system will continue to meet the requirements or whether a reassessment is necessary..

NB will notify manufacturer about his decision. The notification shall include the conclusions of the review and the reasoned assessment decision.