	CONFORMITY ASSESSMENT PROCEDURE	*EXPLOSIVES*
	Module D **Conformity to type based on quality assurance of the production process**	

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 requested to carry out the module and the documentation concerning the quality system (quality manual). In case that module B on these products was performed by another NB, applicant will also send a copy of all final documents issued by this NB (certificates including all amendments, final reports, certificate attachments...) from which it is possible to find out what parameters the individual products had on EU-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. Documentation must be in Slovak, Czech or English language. Documentation in other language can be submitted only after mutual agreement. Applicant shall 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 case of approval of the price proposal, the applicant shall send filled form “Žiadosť na posudzovanie zhody“ KOTA D-414 in Slovak language, or “Application Form for Conformity Assessment“ KOTA D-523 in English language to the Notified Body. The form must be completed fully and legibly. The veracity of the information provided shall be confirmed by the applicant´s signature and if appropriate with a company stamp.

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, however the primary focus is on verification of:

— 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 etc.,

— 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 Certificate on assessment of the quality management system and Assessment Report. NB shall state the validity period in the Certificate. These documents together with the invoice are sent to the applicant's address. At the same time NB shall authorize the manufacturer to affix the CE marking to the relevant products, to which the number 1395 is attached. Using of CE marking on the products is checked during the audit.

Notified Body performs the audit in one-year or two-year intervals in the manufacturer´s premises.

The length of interval is defined on the base of the following criteria:

- audit is performed after one year from the first audit;
- in case that there were not found any deficiencies requiring corrective actions interfering with the quality control system, the next audit will be performed within two years from the last audit; otherwise the next audit will be performed within one year.

In case of identifying serious deficiencies in the system under assessment during the audit, the Notified Body shall reject to certify the system in question and send the Assessment report to the applicant in which NB justifies such decision. At the same time, NB will inform applicant about the possibilities and method of appeal.

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

Notified Body shall evaluate the proposed changes and decide whether the modified quality system will meet the requirements or whether a reassessment is necessary.

NB will announce to manufacturer his decision. The announcement shall include the conclusions of the review and the reasoned assessment decision.

In case that it is not possible to perform the follow-up audit within the period of validity of the Certificate on assessment of the quality management system due to “force majeure”, Notified Body will prolong the validity of the Certificate on assessment of the quality management system administratively for the necessary time period (however, the maximum limit is of 6 months).

After passing the abovementioned circumstances, Notified Body shall perform the audit and issue new Certificate on assessment of the quality management system and Assessment Report. NB shall state the period of Certificate validity defined in accordance with the rules for determination of the validity period shortened by the time of administrative prolongation.

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