EU - Type Examination

(Directive 2014/30/EU EMC)

1. STEPS FOR ACTION

1.1 Application for "EU type examination"

The manufacturer or his authorized representative shall submit to the NB/ CAB (Notified Body / Conformity Assessment Body) an application for the EU type-examination accompanied by the technical documentation of the equipment. The application and the technical documentation may be provided on spot at the Technical Products Conformity Assessment Department, by courier / special delivery / or by e-mail.

The technical documentation accompanying the application shall allow the conformity of the device with the applicable requirements to be assessed and shall include appropriate risk analysis and assessment. The technical documentation shall specify the applicable requirements and cover as far as is necessary for the assessment, the design, manufacturing and operation of the device. The technical documentation shall contain, where appropriate, at least the following elements:

(A) a general description of the device;

(B) design and manufacturing drawings and schemes of components, assembled units, circuits, etc.;

(C) descriptions and explanations necessary for the understanding of these drawings and schemes and the operation of the device;

(D) a list of the harmonized standards applied in full or in part, the data for which have been published in the Official Journal of the European Union, and where these standards have not been applied- descriptions of the decisions adopted to meet the essential requirements, incl. a list of other relevant technical specifications attached. In the case of partly applied harmonized standards, the technical documentation shall indicate the parts which have been applied;

(E) results of design calculations made, examinations carried out, etc.;

(F) test reports.

The technical documentation shall be presented as follows:

- **On hard copy**
- arranged in folders according to the practice of the applicant (the assignor);
- all folders must be collected in a suitable envelope, ensuring their impeccable storage;
- each document (document sheet) from the technical file must be signed by the responsible representative of the applicant (the assignor).
- **On CD**
- the CD contains the technical documentation of only one facility (one model);
- the CD cover contains the name, the surname and the appropriate personal identification of the responsible representative of the applicant (the assignor). The fact is certified by his signature;
- the CD contents is prepared according to the template "Technical documentation contents presented on CD"
- **By e-mail**
  - arranged in folders according to the practice of the applicant (the assignor);
  - folders and files must have an ID that reflects their contents;
  - a scanned copy of an inventory of all folders and files certified by signature and stamp of the applicant (manufacturer) or his authorized representative

1.2 Acceptance of the technical documentation for expertise and evaluation

If the manufacturer or his authorized representative agrees (does not object to) the technical documentation to be assessed in its type and content found during the inspection, then the assessor, the department manager or the inspection body accepting the application and the accompanying documentation shall reflect the findings of the verification in the "Report for verification of the technical documentation composition" signed by both parties.

If new documents are required to be submitted in the course of the evaluation, they are added to the existing ones, according to the general procedure described here, where the old ones are not subtracted. A new verification report is filled in.

1.3 Conclusion of conformity assessment contract

Upon acceptance of the agreed and submitted application in the form of a NB / CAB, a "Conformity Assessment Contract under the EU Type Examination Procedure" shall be

signed.

The CTEC Manager or the Head of the Technical Products Conformity Assessment Department shall provide the applicant with the necessary clarifications on the conformity assessment procedure.

1.4 Assessment of the technical documentation for compliance with these essential requirements of the Ordinance which should be assessed

Within the scope of the technical documentation expertise, the assessors and experts must give their opinion on the suitability of the device's technical design with respect to the aspects of the essential requirements for which the study is requested. They examine the possible configurations and the different operating conditions /modes so that the evidence in the technical documentation refers to the most critical states regarding the Electromagnetic Compatibility (EMC).

When the type meets the requirements of the Directive /Regulation applicable to the respective device, the NB /CAB issues to the manufacturer an EU type examination certificate.

Where the team has found discrepancies and /or lack of sufficient evidence in the technical documentation, a decision to refuse to issue an EU type examination certificate shall be taken but at the same time it shall require that the manufacturer takes appropriate corrective actions.

NB /CAB publishes to third parties, in whole or in part, the content of the report, only with the consent of the manufacturer.

1.5 Decision to issue or refuse to issue an EU type examination certificate When issuing a certificate:

At the request of the applicant (assignor), reflected in the conformity assessment contract, the certificate may be issued in English.

After a final payment has been made, the NB /CAB sends the registered mail with 1 certificate to the applicant or the manager /head of department hands in the certificate personally against signature of an authorized person in the NB /CAB office.

In the case of a decision to refuse to issue a certificate:

NB /CAB creates a motivated written refusal / notification and sends it to the applicant (the assignor) by registered mail within one week.

In the event that the applicant (s) makes a written objection, the "Complaints and Appeals" procedure is applied.

NB /CAB informs the State Agency for Metrological and Technical Surveillance (SAMTS).

1.6 Maintenance of the EU type examination certificate

The applicant should inform the NB /CAB responsible for keeping the technical file on which the EU type examination certificate was issued for all modifications of the approved type which may affect the conformity of the device with the essential requirements or with the conditions of validity of the issued certificate.

The NB /CAB monitors any changes in the generally accepted level of technical knowledge that indicate that the approved type may no longer meet the applicable requirements of the Ordinance and assess whether such changes require further investigation. If so, the NB/CAB informs the manufacturer or his authorized representative.

The changes require additional approval in the form of a supplement to the original EU type examination certificate.

In these cases the applicant shall provide the NB /CAB with the necessary information for the amendments.

After evaluating the new documents submitted, the NB /CAB:

- confirms the validity of the EU type examination certificate issued when compliance has been established;

- requires the manufacturer to take appropriate corrective actions and suspend or revoke the certificate when the notified body finds that a device does not meet the requirements or the corrective actions taken does not produce the required result in the post-authorization compliance follow-up.

2. Obligations of NB/CAB

2.1 The NB/CAB shall inform the SAMTS of EU type-examination certificates and /or supplements issued or withdrawn and, once a year or upon request, provide a list of certificates and /or supplements which it has refused to issue or has stopped their action.

2.2 The NB /CAB shall inform the other notified bodies of the EU type-examination certificates and / or supplements issued, withdrawn, suspended and, on request, of such certificates and /or supplements thereto, which it has issued.

2.3 The NB /CAB shall provide the other notified bodies that carry out similar conformity assessment activities and which subject are the same devices with information on negative and, if required, positive conformity assessment results.

2.4 The NB /CAB shall provide the European Commission, the Member States and the other notified bodies, upon request, with a copy of the EU type-examination certificates and/or the supplements thereto. Upon request, the European Commission and the Member States can obtain a copy of the technical documentation and the results of the NB /CAB CTEC surveys.