Conformity assessment of construction products under systems "1+" and "1" according to the Regulation for the Essential Requirements to Constructions and Conformity Assessment of Construction Products (RERCCACP)

CONTENTS

Developed by:	Endorced by:	
Stoyanova– Head of Department /family, position/	Tsvetkova - Manager / family, position /	Edition № 14
2016 /Date, signature/	2016 / Date, signature /	Valid from: 2016

1 Aim and scope of the procedure

1.1 This procedure has been prepared in compliance with REGULATION (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (CPR), which requirements are introduced in Chapter I and II of the Regulation for the Essential Requirements to Constructions and Conformity Assessment of Construction Products (RERCCACP) and Annex 1 to Article 1, p.2.

1.2 The procedure specifies a sequence and rules on the conformity assessment of construction products intended for permanent use in constructions subject to conformity attestation systems „1^+" and „1" in accordance with the CPR, mandates of the European Commission (EC) and Chapter II of the Regulation for the Essential Requirements to Constructions and Conformity Assessment of Construction Products (RERCCACP) and Annex 1 to Article 1, p.2.

1.3 This procedure also specifies a sequence and rules on Product Certification in accordance with Chapter III, Article 55 (2) of the Regulation for the Essential Requirements to Constructions and Conformity Assessment of Construction Products (RERCCACP).

1.4 For the purpose of attesting the conformity of each separate construction product with the requirements of the technical specifications, working procedures have been prepared and approved, according to Guidance from the Group of Notified Bodies (GNB) and guidelines on implementing CPD. This procedure shall be applied as integral part of the working procedure for the relevant construction product or group of construction products.

2 Responsibilities

2.1 The Conformity Assessment Body (CAB) is responsible for all conformity assessment actions and the conformity certificate issue in accordance with rules laid out in this procedure.

2.2 The participants in the assessment process, including those who work on service contract, shall be responsible for keeping professional secrecy regarding the information they obtain in the course of performing their activities.

3 Terms, definitions and acronyms

3.1 **CPR** – REGULATION (EU) No 305/2011

3.2 **RERCCACP** - Regulation for the Essential Requirements to Constructions and Conformity Assessment of Construction Products

3.3 **Conformity Assessment Body (CAB)** – a legal entity granted authorization to construction products conformity assessment with harmonized European technical specification and/or Bulgarian technical specification under the provisions of RERCCACP.

Note: Where conformity assessment is performed under harmonized European specifications in accordance with Chapter II of RERCCACP, the term CAB means NB (Notified Body) throughout the procedure.

3.4 **NB** – Notified Body. CAB in the context of 3.3 that has been granted authorization to carry out construction products conformity assessment with harmonized European technical specifications and announced to the European Commission.

3.5 **GNB** – Group of Notified Bodies

3.6 **Manufacturer** – legal or physical entity applying directly or through its authorized agent for attestation of conformity of construction products manufactured by it.

3.7 **Mandate** – document drawn up by EC, representing assignment for preparation of harmonized standard or European Technical Approval

3.8 **Technical specifications** – Technical documents according to Article 4 of RERCCACP.

3.9 **Initial type testing of product** – complete set of tests or other procedures (e.g. calculations) determining the performance of representative product samples, having influence on satisfying of at least one of the essential requirements to the construction works

3.10 **Initial type test report** – document presenting the results from the initial type testing of the product and any other information related to the test

3.11 **Factory production control** – permanent internal production control exercised by the manufacturer so as to ensure conformity of the product with the technical specification.

3.12 **FPC** – factory production control system

3.13 **Production control system documentation** – documents providing information about the factory production control exercised by the manufacturer in order to ensure conformity of the construction product with the requirements of the relevant technical specification

3.14 **Conformity assessment** – system of procedures attesting that the defined requirements with respect to the product and/or the system are fulfilled

3.15 **Conformity** – fulfillment of certain requirements for a product or a process

3.16 **Non-conformity** – non-fulfillment of a requirement

3.17 **Observation** – non-compliance that does not affect the effective functioning of the factory production control system or the product technical characteristics and could be correct in a short time period.

3.18 **Significant non-conformity** – non-compliance that affects the effectiveness and the functioning of the factory production control system or the product performance characteristics and requires repeated audit of all the factory production control system or parts thereof.

3.19 **Certificate of Conformity** – attestation document issued by a conformity assessment body certifying the conformity of the manufactured product or group of products with the requirements of the technical specification,

4 Description of the procedure

CAB authorized to assess conformity of construction products under system **"1^{+}"** and **"1"** and "product certification" procedure of RERCCACP has to certify construction product following:

- **initial type testing of the products;**
- **initial inspection of the factory production control;**

- **continuous surveillance, assessment and approval of factory production control**
- **control testing (audit) of test samples taken at the factory, on the market or on the construction site** (only for products specified under assessment system "1" and "product certification")

Conformity assessment stages

Stage 1 – Application and concluding an agreement

- Acceptance and registration an application form of conformity assessment
- Review of provided documents
- Concluding an agreement

Stage 2 – Initial type testing of the product

- Sampling
- Initial type testing

Stage 3 – Initial inspection (audit) of the factory production control

- Assessment of the factory production control system documentation
- Agreement of the team and the date for carrying out initial inspection of the factory production control with the Applicant
- Initial inspection (audit) of the factory and the factory production control
- Report on the Initial inspection

Stage 4 – Issue of certificate

- Report on conformity assessment
- Issue of Certificate of conformity or application canceling

Stage 5 – Continuous surveillance, assessment and approval of factory production control

- Regular inspection of the factory and the factory production control
- Report on the results of the inspection

Stage 6 – Control testing (audit) of test samples taken at the factory, on the open market or on the construction site

- Sampling of audit testing samples
- Testing of the samples

Етап 7 – Decision on confirmation or termination of the certificate validity

- Report containing proposal for confirmation of the certificate validity

4.1 Application for conformity assessment

In order to start conformity assessment procedure the Applicant completes an application form provided by the CAB. The application form should contain at least the following information:

- name and address of the manufacturer and his authorized agent (if any) as well as the location of the factory;

- identification of the product or group of products subject of the application for conformity assessment;
- declaration attesting that no application for the conformity assessment the same product or group of product to another CAB has been made.

The following have to be enclosed to the application form:

- document of company registration;
- certificate of current state;
- technical documentation for the construction product(s);
- the factory production control system documentation.

Following the review of the documents enclosed to the application and, if the documents meet the requirements of the RERCCACP and/or the product technical specification, CAB sends proposal for agreement (draft contract) to the applicant not later than 10 days after their receipt.

In the event that the documentation accompanying the application is incomplete, the applicant shell be informed in writing to complete or correct the factory production control documentation within 10 days. The agreement will be signed after presentation of all necessary documents.

Concluding of an conformity certification agreement may be refused in one of the following cases:

- absence of a documented factory production control system;
- essential deviations of submitted documentation from the requirements of the RERCCACP and/or the technical specification for the product.

4.2 Initial type testing

The Initial type-testing is carried out to determine the performance characteristics of the product as follows:

- according to Annex ZA, where a harmonized standard for the product exists;
- according to the European Technical Approval (ETA), where an ETA for the product has been issued;
- according to a Bulgarian State Standard (BDS) or equivalent standard or Bulgarian Technical Approval (BTA) for products whose conformity is assessed under the provisions of Part Three of RERCCACP.

Where a product is manufactured under ETA or BTA, the CAB takes the testing of performance characteristics for approval of the fitness of the product (the test results based on which the relevant ETA or BTA is issued) as initial type-testing of the product.

CAB is responsible for sampling of initial type-testing.

Sampling is performed by a representative of the CAB in the presence of the manufacturer or his authorized agent and it is recorded in a proper way. The test sample selection and the testing itself are based on the requirements stated in the relevant technical specification. Samples are marked by the CAB representative in order to ensure the tested samples originality.

Three samples or one combined sample which is divided into three parts are taken unless the technical specification states other. The first one is tested at the manufacturer's laboratory, the second one is tested by the CAB and the third one is kept under suitable conditions as control sample by the manufacturer for the purpose of further testing in case of dispute arising between the two parties, or accidental damages, loss or contamination of any of the other two samples, until the certificate is issued.

Samples are tested in a laboratory owned by the CAB or other laboratory contracted by the CAB as sub-contractor.

As an exception, samples for initial type-testing may be tested at the manufacturer's laboratory under the surveillance of CAB representatives and according to the provisions of Guidance NB-CPD/AG/03/005r2 of 05.08.2008.

Samples are tested in accordance with the requirements of the relevant technical specifications.

Upon completing the test, the respective laboratory issues a test report in three originals. One original is given to the conformity assessment expert, who attaches it to the product file with the relevant identification number. The second original is sent to the manufacturer for information and the third one is kept in the records of the testing laboratory.

In case of disagreement, the manufacturer submits his objections in writing. The objection is reviewed by the CAB. In case the argument is found to be reasonable, the third sample is tested in the presence of a representative of the manufacturer, but only the characteristics subject to dispute are tested. The results of this test are deemed final.

In case of negative initial type-testing results the manufacturer is informed in writing. If the manufacturer can show evidence of meeting the technical specifications of the product within 6 months, the certification body will repeat the initial type-testing of the product.

If the second initial type-testing of the product all the requirements of the technical specification are not being met, the certification body (CAB) sends to the manufacturer its motivated decision for cancellation of the procedure.

4.3. Initial inspection (audit) of the factory production control system

The CAB prepares an audit plan and appoints the team of auditors, experts and subcontractors (if any) prior to performing the initial inspection of the factory production control. The least ones are agreed with the manufacturer in order to avoid any conflict of interest.

The initial inspection (audit) of the factory production control verifies whether the documented factory production control system is correctly established and implemented in accordance with the requirements of the technical specification and the RERCCACP.

Where the manufacturer maintains an operating Quality Management System (QMS) in accordance with the requirements of standard BDS EN ISO 9001, (EN ISO 9001), for which he has been given a valid certificate, the auditing team inspects the part of QMS relating to the factory production control. In that case the factory production control system has to be integrated in the Quality Management System.

The factory production control audit includes inspection of the following:

- incoming control of materials;
- management of manufacturing processes and interim control;
- control of finished products;
- results of control;
- checking and calibration of processing equipment;
- in-factory transport, storage, identification and marking of raw materials and finished products;
- methods of checking used by the manufacturer;
- frequency of sampling and testing of production samples;

- laboratory performing tests of the product during production and of the final product;
- control of nonconforming products;
- complaints and research on the client satisfaction;
- corrective and preventive actions;
- document control;
- training and qualification of the personnel;
- internal audits and management review.

During the initial inspection of the factory and the factory production control the auditor uses a checklist reflecting the specific nature of production and the requirements of the relevant technical specification. The checklist must be in agreement with the provisions of the GNB-CPR Guidance, if any.

The auditor verifies the extent within which the manufacturer follows the procedures concerning the requirements of the relevant technical specification when exercising factory production control, and whether the manufacturer applies the methods of testing prescribed in the relevant technical specifications (standards). Alternative methods may only be used if they are validated and if allowed by the technical specification. In case of doubt the method prescribed in the technical specification is applied.

The results of the initial inspection of the factory production control system are summarized in a report addressing all matters covered during the audit, and containing all findings, observations and non-conformities, if any. The report is prepared in 2 originals. One original is sent to the manufacturer not later than 4 weeks from the inspection, if no other period is fixed in the GNB Guidance for the specific product.

In case of non-conformities, the CAB agrees with the manufacturer a period for taking corrective measures proposed by the manufacturer. Within three months from the receipt of the initial inspection report, the manufacturer must inform the CAB about the corrective actions taken by him.

In case of significant non-conformities, the auditor may require additional audit, the results of which are presented in an additional report.

Where the manufacturer has not observed the time agreed for taking corrective actions, or the auditor has found them ineffective, the latter proposes a temporary suspension of the certification process.

The head of CAB makes the final decision for continuation or cancellation of the certification process.

4.4. Certificate issue

Based on the results of the initial type-testing of the product, the audit report and the technical documentation of the product, the conformity assessment expert prepares a report on the assessment of conformity, together with a proposal for issue or refusal of certificate of conformity.

If the issue of certificate is refused, the applicant will be informed in writing within 10 days after making such decision. The applicant has the right to submit motivated objection in written within 14 days after the refusal information receipt.

The head of CAB decides on the issue of certificate(s) of conformity based on the proposal made by the conformity assessment expert.

Certificate of conformity is issued for a single product or group of products with respect to the technical specification(s) and for one production site/factory.

EC Certificate of conformity has a unique identification number according to Guidance NB-CPD/AG/03/001r2 of 03.04.2013 of GNB. The certificate complies with Guidance NB-CPD/AG/03/003r7 of 27.03.2013 of GNB and includes the following information:

- name, full address and identification of the CAB;
- number and date of issue;
- name and full address of the manufacturer and his authorized representative (if any);
- name and full address of production site/factory;
- description of the product (type, identification, use, etc.);
- technical specifications to which the product conforms;
- particular conditions applicable to the use of the product in the design, installation and operation;
- conditions and period of validity.

The certificate is valid until the requirements of the technical specification are met and the conditions of production and of the factory production control remain unchanged.

CAB maintains a current register of issued certificates of conformity and makes it available to the Ministry of Regional Development and Public Works (MRRB), Association of conformity assessment bodies of construction products (ACABCP) and any other parties concerned.

Based on the obtained certificate, the manufacturer has the right to issue declaration of conformity for the product manufactured by him, and to place EC marking on it or its accompanying documents together with the CAB identification number, in case of attesting conformity according to the provisions of Part Two of RERCCACP (EC Declaration of conformity) or declaration of conformity with the registration number of CAB, when attesting conformity according to the provisions of Part Three of RERCCACP.

Manufacturer, wishing to obtain extension of the certificate of conformity for other products manufactured in compliance with the same technical specification or another technical specification but at the same factory and under the same factory production control system, can apply to the CAB, using a new application form. In that case the CAB can decide whether to conduct full or partial inspection of the factory and of the factory production control, but it is obliged to carry out initial type-testing of the product.

4.5 Surveillance, assessment and approval of the factory production control

CAB exercises surveillance to ensure that the manufacturer continuously fulfills all of the obligations he has undertaken, as specified in the approved FPC documentation, as well as to identify any possible changes in the manufacturing process or the FPC.

Surveillance of the factory production control includes:

- check of the factory production control documentation and records made in order to document the conformity of the manufactured product performance characteristics with the requirements of the technical specification;
- records of performed incoming control of materials;
- records of conducted internal audits and taken corrective actions;
- check of the implementation of the plan for calibration of machinery and equipment;
- filed complaints, claims and actions taken;

- recording of any changes made (in the technical documentation, FPC documentation, raw materials and constituents, modifications to the production technology, interruption of production, etc.);
- comparison of data obtained during the initial inspection or previous surveillance;
- sampling and testing samples for continuous control according to the approved plan of the manufacturer.

Surveillance is carried out not less than once a year if the surveillance frequency is not defined in the technical specifications of the products.

Surveillance is carried out by a team of auditors using a checklist prepared in advance. Where non-compliance is identified or an observation made, the CAB can require further investigations. In such cases the manufacturer is informed in writing.

The auditor assembles a report on the surveillance results in 2 originals, one of which is sent to the manufacturer not later than 4 weeks from the date of completing the surveillance. The manufacturer informs the CAB about any corrective actions taken by him (if any) within three months after receipt of the report.

The manufacturer has to maintain the factory production control system up-to-date and to monitor its efficiency, also notify CAB about any intended modification of the system, which is likely to affect the stated properties of the product. In such cases it is up to the CAB to determine whether the announced changes require it to take actions (additional type-testing of the product and/or other further investigation of the factory production control). The manufacturer is not allowed to place CE-making on products manufactured under the changed conditions until the CAB informs him about its decision in writing.

4.6. Control-testing (audit) of samples taken at the factory, on the open market or on a construction site

During surveillance visits or any other time, a representative of CAB, at his discretion, takes selectively samples for testing at the factory, on the open market or construction site. The sampling is documented and each sample is appropriately marked by the CAB.

Samples for audit-testing are taken at intervals laid down in the relevant technical specification. If the frequency of sampling is not defined by the technical specifications of the respective products, samples are taken at least once a year.

The method of sampling, transportation and storage are in compliance with the relevant technical specification.

The samples are tested at the CAB own laboratory or other laboratory with which the CAB has signed subcontractor agreement. The characteristics and test methods conform to the requirements of the relevant technical specifications.

As an exception, samples may be tested at the manufacturer’s laboratory under the surveillance of CAB representatives and according to the provisions of Guidance NB-CPD/AG/03/005r2 of 05.08.2008.

Following the completion of testing the samples, an audit-test result report is issued in three originals. One original is given to the conformity assessment expert to prepare a report which is put in the manufacturer’s file, the second original is sent to the manufacturer for information, and the third one is kept in the laboratory, performing the test.

In case of unsatisfactory results from the audit-testing, the CAB requires the manufacturer to take corrective actions. For a specified (statistically representative) period of time the CEB requires increase of the frequency of taking samples for self-control. After expiration of the period specified by the CAB, an audit of the factory production control system is performed. In case the self-control test results prove conformity with the requirements of the relevant technical specifications, the manufacturer brings the frequency of audit-testing in line with the test plan.

4.7. Decision concerning the issued certificate validity

Based on surveillance report and the results of the audit-testing of the samples, the conformity assessment expert prepares a report to confirm the Certificate of conformity validity. The head of CAB decides on the maintaining, termination (suspension) or withdrawal of the Certificate of conformity.

In case of affirmative decision, the manufacturer is notified in writing about the confirmation of the issued certificate of conformity validity.

In case of negative decision, the manufacturer is informed about the suspension of his certificate of conformity until the non-conformity is corrected.

An issued Certificate of conformity will be withdrawn in any of the following cases:

- failure to take corrective actions within the agreed time period regarding non-conformities established during surveillance of FPC leading to non-conformity of the product with the technical specification;
- non-conformities repeatedly established during the audit-testing of samples (under system 1^+ and product specification);
- absence of production activities for longer than one year, without having informed the CAB thereof;
- obstructing the performance of scheduled surveillance of FPC and/or the taking of test samples;
- upon proven illegal use of the certificate and the identification (registration) number of the CAB;
- non-observance of the certification agreement provisions.

If the certificate of conformity is suspended or withdrawn the CAB informs MRRB, DNSK, ACABCP and the market surveillance authorities. In cases where EC certificate for production located in another EC Member-State has to be suspended or withdrawn, the market surveillance authorities in the respective country should also be informed.

5. Documentation and archiving

The documentation collected during the conformity assessment procedure must be kept in a file of the company-applicant, identified in appropriate manner.

All documents relating to the conformity assessment activity and certification of the product on paper or electronic media are kept in accordance with the Documents and Records Management procedure of the CAB Quality Management System.

6. Normative references

- REGULATION (EU) No 305/2011
- Regulation for the Essential Requirements to Constructions and Conformity Assessment of Construction Products (RERCCACP), adopted by Council of Ministers Decree No. 325 of 06.12.2006 and published, the State Gazette Issue 106/2006.
- Guidance from GNB on the implementation of REGULATION (EU) No 305/2011
- Guidance on the issue of European Technical Approvals

7. Annexes

Annex No. 1 - Application form for conformity assessment

Annex No. 2 - Agreement for conformity assessment

Annex No. 3 - Checklist for initial inspection (audit) of factory and factory production control

Annex No. 4 – Audit Report

Annex No. 5 – Report on conformity assessment with proposal for issue of certificate of conformity or refusal (report on confirmation of the certificate validity)

Annex No. 6 – EC – Certificate of Conformity under system "1+"

Annex No. 7 – EC – Certificate of Conformity under system "1"

Annex No. 8 - Certificate of Conformity according to Article 55, para. 2 of the RERCCACP

Annex No. 9 - Surveillance checklist