**Established:**

**Manager:........................................**

**/Asen Hristov/**

**10.01.2019г.**

**SC.PR.CPR[SYS 2+]**

COMMON PROCEDURE

For certification of factory production control of construction products according system for evaluation and inspection of constancy of performance – 2+

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“SZUTEST” Ltd.

The current procedure is developed and accepted by the members of the ALOSSP and it is valid till revision of the applicable stadards and requirements for the certification scheme.

1. Purpose and scope of the procedure

1.1. This procedure is developed in conformance with Regalement (EU) № 305/2011 of the European Parliament of the Council from 9th March 2011 for defining the harmonized conditions for placing on the market construction products in Republic of Bulgaria.

1.2. This procedure defines the order and the rules of certification of the production control of the construction products, intended for incorporation in buildings which take place in system of evaluation and inspection of performance’ constancy acc. System 2+, acc. The Regalement 305/2011, the mandates of the European Commission and Annex # 1 and its applicable technical specifications.

1.3. For certification of the production control of each item of the construction product according the requirements of the technical specification are developed and established working procedures, according the Guides of the group of Notified Bodies (GNB) and the Guides for application of CPR. The current procedure shall be applied not separately from the relevant working procedure for the relevant construction product or group construction product or products’.

2. Responsibilities

2.1. The certification body of production control (EFPC) has the responsibility of all activities for evaluation and issuance of certificate for factory production control, regarding the rules, defined in the current procedure.

2.2. The participants in the evaluation process, including these in civil contracts, are responsible for keeping the professional secret regarding the information which they have received during conduction of their activity.

3. Terms, definitions and abbreviations

3.1. OCOICPCRB – ORDINANCE No OD-02-20-1 of 5 February 2015 on the conditions and the order of introducing construction products in the constructions of the Republic of Bulgaria;

3.2.Body on product certification (BPC)- governmental or nongovernmental notified body of the necessary competency and responsibility for the conduct of product certification according to given rules for procedure and management;

3.3.NB – Notified Body . –BPC within the meaning of i.3.2, that has got permission for the certification of construction products and production control with harmonized European technical specifications and announced before the European Commission;

3.4.GNB – Group of Notified Bodies;

3.5.Economic operator – manufacturer, importer, distributor or authorized representative;

3.6.Manufacturer – every physical or legal entity producing a construction product or who assigns the design or the production of such a product and offers this product on the market with its name or trade mark;

3.7.Importer – every physical or legal entity, instituted in the Union, who releases on the market of the Union a construction product from a third country;

3.8.Mandate – a document, developed by the EC which represents an assignment for working out of a harmonized standard or European technical approval;

3.9.Provision to the market – means every supply of a construction product for distribution or use on the market of the Union in the process of a commercial activity against payment or free of charge;

3.10.Placing on the market – means providing a construction product to the market of the Union for the first time;

3.11.Technical specifications – technical documents according to Art.8 (1) of the Ordinance;

3.12.Specifying the type of the product – a system of activities to define the performances of representative for the type of the product samples on the basis of the testing of the type (including selection of a sample), calculation of the type, tabular values or descriptive documentation of the product;

3.13.Production control in the enterprise – means the documented constant internal control of the production in the production enterprise according to the corresponding harmonized technical specifications;

3.14.SPC – system for production control;

3.15.Documentation of the system for production control – documents which provide information for the control of the production process in the factory, performed by the manufacturer in order to ensure the conformity of the construction product with the requirements of the respective technical; specification;

3.16.Conformity – performing certain requirements to a product or a process;

3.17.Non-conformity – non-performance of a requirement;

3.18.Insignificant non-conformity – non- conformity which does not affect the efficient functioning of the system for production control or the technical characteristics of the product and can be eliminated for a short term;

3.19.Essential non-conformity – non-conformity which affects the efficient functioning of the system for production control or the technical characteristics of the product and requires a repeated audit of the whole system for production control or parts of it;

3.20.Certificate for consistency of the performances – a document for assessment, issued by a body for product certification, which certifies the consistency of the performances of the manufactured product or group of products with the requirements of the technical specification;

3.21. Efficiency – a level to which the planned activities are fulfilled and the planned results are achieved;

3.22. Efficiency – correlation between received results and used resources;

3.23. Rebranding Manufacturer – A manufacturer (see CPR Article 2(19)) who does not himself physically produce the rebranded construction products he places on the market under his own name or trademark. - NB-CPR/17-743r4, Issued 29 November 2017.;

3.24. Physical Producer – according NB-CPR/17-743r4, Issued 29 November 2017 – Any natural or legal person who manufactures a product intended to be placed on the market as a rebranded construction product under the name or trademark of a rebranding manufacturer. In case of rebranding, the physical producer is not the manufacturer as defined by CPR.

3.25. Significant manufacturing process – Process of which the controlling is likely to have a significant influence on the conformity of the construction product with the declared performance.

**4. Description of the procedure**

А Body, received the permission for Body for certification of production control of construction products acc. System “2+” shall implement the following activities:

* The initial inspection of the production control;
* Surveillance, evaluation and approval of the production control;

**Activities for evaluation of conformity**

**During contractual activities with economic operators (rebranding producers), which do not physically produce the product, but place such products on the market by own name or trade mark, and are considered as manufacturers acc. CPR, SZUTEST applies and the following guidelines for such cases - NB-CPR/17-743r4, Issued 29 November 2017 [14].**

**In such cases SZUTEST:**

* **Check concluded contracts between the rebranding producer and physical manufacturer.**
* **Evaluates the conformity acc. (systems 1 and 1+ for products under harmonized standards)**
* **Conducts initial inspection (system 1, 1+ and 2+);**
* **Conducts surveillances (system 1, 1+ and 2+);**
* **Audit testings (system 1+ );**

**4.1. Application form**

* Receiving of application form/review;
* Confirmation of receiving the application form / rejection of the application form;
* Conclusion of a contract for certification;

**4.2. Initial inspection (audit) of the manufacturing and production control**

* Evaluation of the documentation of FPC- stage I;
* Initial inspection of the manufacturing and production control - stage II;
* Review of the results from identification of the type product from manufacturer;
* Report with the results of initial inspection;

**4.3. Certification of the system for factory production control**

* Evaluation of the results for identification products‘ type and initial inspection of the manufacturing and production control;
* The Lead Assessor takes decision for certification, fills in a Report SC.FR.-03-03 with stated decision for certification;
* Making decision and issuing/rejection certificate for conformity evaluation of production control;

**4.4. Permanent control (surveillance), evaluation and approval of the production control**

* Surveillance of the manufacturing and production control;
* Report of the results from surveillance;
* Management of nonconformitiy/corrective actions;
* Evaliation of the results from the surveillance;

**4.5. Making decision for the validity of the certificate of conformity of the production control;**

**4.1. Application form for certification and production control**

To open a procedure for certification of production control, the Manufacturer or Authorized by it Person, named as “Applicant”, submit to “SZUTEST” Ltd. (named also as OSPK( filled in application form according (SC.FR.CPR[SYS1/2+]-01), provided by SZUTEST Ltd. The application form shall content at least the following information:

* Name and address of the manufacturer and its authorized representative (if there is such) and the place of manufacturing of the product;
* Identification of the concrete product or groups of products, for which it has been submit evaluation of conformity (scope of certification);
* Declaration, that it is not prepared and submit application form for conformity evaluation for the same product or groups of products to other Body.

The following documents shall be enclosed to the application form:

* Document for registration of the firm;
* Document for the current state of the firm;
* Technical documentation of the construction product;
* FPC documentation;

After the review of the enclosed documents, not later than 10 days after receiving the application, the Manager of “SZUTEST” Ltd. shall confirm, through email and/or scanned and signed copy of the Application to the Manufacturer, that accepts the application. If the application is accepted, SZUTEST Ltd. send to the client Proposal for Contract Conclusion (SC.FR.07-01). With Order from the Manager of SZUTEST Ltd. shall be defined the working team, including Lead Assessor and Lead Auditor.

In case, that the documentation which shall be enclosed to the application form is not full package, the Applicant shall be notified in written matter within 10-days to add and/or correct the documentation for factory production control. In this case proposal for contract conclusion shall be made after the Applicant presents the needed documents.

**Denial for contract conclusion for FPC evaluation shall be made in the following case:**

* Lack of documented production control system;
* Essential deviations of the presented documentation with the required technical specification of the product.

In case when the Manufacturer requests to wide up its certification scope for additional products’ types which have been manufactured according the requirements of the related product’ standard, and in the conditions of the same FPC and the same production site, the Manufacturer shall fill in again Application Form (SC.FR.CPR[SYS1/2+]-01) to request the widening.

**4.2. Initial inspection (audit) of the manufacturing and the production control**

Before conduction of the initial inspection of the production inspection control, the Lead Auditor shall make plan-schedule for an audit (SC.FR.03-01), he/she shall divide the tasks, to define auditors, experts, subcontractors (if any) and the duration of the audit. [4,5]

In order to avoid conflict of interests, all of the above shall be coordinated with the manufacturer. Each member of the team shall sign a Declaration for lack of relations (participation in preparation of FPC, internal audits or other contacts) with the manufacturer through the previous two years. (SC.FR.CPR[SYS1/2+]-06).

The initial inspection of the manufacturing and production control shall be done in two stages regarding the regalement of BDS EN ISO/IEC 17021-1, p. 9.3[6], which covers:

**I stage**

* Review and evaluation of the FPC’s documentation and manufacturing;
* Collection of information regarding the intended product’s usage, the management and technological processes, and applied normative documents;
* The content of the FPC’s Manual;
* The coverage of applicable clauses for the relevant production standard;
* Review and evaluation of conducted internal audits and management reviews;
* Coordination of dates, plan for conduction, resources for conduction of II stage of the inspection;

If the team consider, that the documentation does not response to the requirements, the team shall inform the Manufacturer for the documented nonconformities, the team shall require from the manufacturer to define and conduct corrective actions and to update the version of the documents.

If the documents are accepted without notes, the team shall propose and coordinate with the Manufacturer, a date and plan-schedule (SC.FR.03-01) for conduction of initial inspection of the manufacturing and production control on site – stage II.

During the initial inspection (audit) of the production control shall be checked if the documented production control system is implemented and is applied in conformity with the requirements of the technical documentation.

When the manufacturer maintains the Quality Management System (QMS) in accordance with the requirements of the standard BDS EN ISO 9001 [7], for which it poses а valid certificate, the auditing team shall check the part with QMS, regarding the production control. In this case the system for production control shall be integrated in the Quality Management System.

**II Stage**

The purpose of the audit in stage II is to be evaluated on site the level of implementation and the efficiency of the management system of the manufacturing and production control.

The inspection of the production control system includes at least the following documents:

* Input control of materials;
* Management of the production processes and intermediate control;
* Control of the ready product;
* Results from the control;
* Metrological assurance of the technical measurements;
* Internal transport, storage, identification and marking of the materials and end products;
* Frequency of taking and testing of samples from the manufacturing;
* The laboratory, where the testing of the product has been done -SC.FR.CPR[SYS1/2+]-07;
* Management of nonconformity product;
* Reclamations and research the client satisfaction;
* Corrective and preventive actions;
* Management of documents;
* Training and qualification of the personnel;
* Internal audits and management review;

During the initial inspection of the manufacturing and the production control, the auditor use Report/Checklist for inspection (SC.FR.CPR[XX]) according to specific technical specifications, which shall reflect the specification of the manufacturing and the requirements of the relevant technical specifications. The Checklist shall be in compliance with GNB-CPD-NB-CPD/AG/03/004r2. [8]

The auditor checks the implementation of the procedures regarding the requirements of the relevant technical specification and used methods for testing, which are in relation of relevant standards.

Definition of the product’s type (initial testing, type calculation, table values or describing documentation) is obligation of the Manufacturer and shall be conducted in compliance with the methods, required by the standard. The Audit Team shall be acknowledged with the evidences of the results of definition of the product type, to be compared with the requirements of the technical specification.

In conditions, that are defined in the applicable harmonized standard or documents as GNB-CPR Sector Group, (which used a procedure for taking a sample and if the product which has been test Is similar as the evaluated one, the laboratory, which conducts the testing is qualified for its conduction) could use as well as existing, and shared data, referenced in NB-CPD/AG/03/006r1; NB-CPD/AG/06/007 [9,10]

The inspection covers the conduction of product’s type definition, as well as the results, related with all characteristics, covered by FPC, related standard and declared by the manufacturer performance tab;. ZA 1.1.

The initial inspection of the manufacturing and production control includes also the laboratory for testing of products-methods for testing. They shall response to the prescribed requirements by the relevant standard. The competency of the laboratory shall be demonstrated with:

* Direct inspection, of the personnel, the measures and methods for testing within the scope of the production control in the laboratory, by the auditing team;
* Evaluation of , the external laboratory, by the auditing team;
* Checking the validity of the certificate for accreditation, when the laboratory (own or external) is accredited.

In case of nonconformities, the manufacturer shall be informed at the end of the inspection. -SC.FR.CPR[SYS1/2+]-03). The manufacturer shall notify the Notified body (SZUTEST Ltd.) , regarding the taken corrective actions within 3 months after receiving of the initial inspection’s report.

The records from the initial inspection of FPC shall be resumed in a Report, which covers all questions during the audit, contents all findings, notes and nonconformities, if any. The Checklist/Report (SC.FR.CPR[XX]) shall be prepared in 2 copies, one of which shall be send to the Lead Assessor, the other copy shall be send to the manufacturer not later than 4 weeks after conduction of the inspection, if other is not prescribed in the Guide of GNB for specific product.

The lead assessor could require conduction of additional audit, for which shall be prepared plan-schedule (SC.FR.03-01) and a checklist/report (SC.FR.CPR[XX]) is being drafted.

When the manufacturer has not complete the discussed deadlines for taking corrective action or / if the auditor evaluates the CA as not effective, the auditor shall make proposal for temporary suspension of the certification process.

**4.3. Certification of the FPC**

Based on the results from the product type definition, the audit report and technical documentation, the Lead Assessor prepares report-decision with proposal for issuance of a certificate for conformity of the FPC in the Manufacturer or with argued denial for issuance. The prepared by the Lead Assessor report shall be provided to the Manager for approval and signature.

If the results of the conducted FPC inspection are positive and when the results from the definition of the product type meet the requirements of the standard, shall be issued Certificate for conformity of production control acc. System 2+ **(**SC.FR.CPR.13-02), and the Applicant will be informed about it.

The issued certificate shall be related only for types of products required from the manufacturer and defined in the clauses of the applied standard. For each manufacturing site, clearly defined, shall be issued one certificate. The certificate shall be issued in Bulgarian language, and if it is discussed with manufacturer – in English. The Certificate for FPC conformance has unique identification number. The shape and content of the certificate are according the Guide NB-CPR 14-612r7 GNB. [11]

The widening of the certificate’s scope shall be conducted in the order of the current procedure, as the auditor, conducted the initial inspection shall define the necessity of follow up audit and its scope.

When refusal of issuance of certificate, the Applicant shall be notified in written matter within 10 days after the decision is taken. The Applicant has the right to prepare written appeal within 14 days of the receiving the notification for certificate’s denial.

In case that FPC’ certificate is refused to be issued (or it is canceled), the Manager informs about the issue the other announced persons and the Ministry of Development and Public Works. The Certification Body presents the above mentioned interested parties with the necessary data about the denial.

“SZUTEST” Ltd. Maintains up to date register for the issued certificates for production control and provide it to Ministry of the Development and Public Works, and to interested parties if any.

Based on the received certificate for conformity of production control, the Manufacturer has the right to issue a declaration of performance for produced by its products and to fix CE mark on the products or on its accompanying documents – together with the identification number of the Notified Body.

A manufacturer, who wants to wide its certificate for conformity of FPC for other products, produced in accordance with the same technical specification, or other technical specification, but in the same production site covered of the same FPC system, shall apply to the Notified body with new application form. In this case the Notified body has to decide if it is necessary to be conducted full or part audit of the manufacturing and the production control, but it is an obligation of the notified body to check the protocols from definition of the product’s type.

**4.4. Continuous control (surveillance), evaluation and approval of the production control**

The purpose of the surveillance is for the Notified body to assure, that the manufacturer shall confirm all requirements defined in the established documentation in FPC, the applicable technical specification, to declare the constancy of performance and to identify eventual changes in the manufacturing processes of FPC. If the frequency of the surveillances is not showed in the technical specification of the relevant products, the surveillance shall be conducted at least once per year in previously assigned plan-schedule (SC.FR.03-01) and checklist/report (SC.FR.CPR[XX]), as the Lead Assessor notifies beforehand the manufacturer for the time of the audit.

The FPC surveillance includes:

* Inspection of the documentation of the production control and created records, with which is documented the conformity of the technical characteristics of the manufactured product with the requirements of the technical specification.
* Records of the conducted input control of the materials;
* Records of the conducted internal audits and taken corrective actions;
* Records of management of the technical measures;
* Submitted appeals, complaints, and the taken actions;
* Revision of the made changes (in the technical documentation, in the FPC documentation, in the output materials and in the technology of the manufacturing, stopping the manufacturing and etc.);
* Comparing the data, received during the initial inspection or from the previously surveillances;
* Taking and testing of samples for current control, according the established plan of the manufacturer.
* All changes in FPC and/or manufacturing (its obligation of the manufacturer to inform beforehand the Lead Auditor. If this obligation is not fulfilled, this shall be defined as nonconformity);
* The frequency, keeping the current testing and the results;
* Methods and testing measurements;

For established nonconformities in surveillance of FPC, the Manufacturer shall be informed in the end of the surveillance (SC.FR.CPR[SYS1/2+]-03).

The auditor shall prepare a checklist/report (SC.FR.CPR[XX]) acc. relevant technical specification for the results of the surveillance in two copies, one of which shall be send to the Lead Assessor, the other copy shall be send to the Manufacturer within 4 weeks at latest from the conduction of the audit. Within 3 months after receiving the Report, the Manufacturer notifies the Lead Assessor for the taken corrective actions and the deadline for their implementation. When the Manufacturer does not meet the agreed deadlines for the taking of the corrective actions or the auditor considers them as not effective, the Lead Auditor makes proposal for cancellation or temporary withdrawal the activity of the issued certificate.

The Lead Assessor could require the conduction of follow up audit, for which shall be prepared plan –schedule (SC.FR.03-01) and shall be prepared an audit checklist/report (SC.FR.CPR[XX]).

The manufacturer shall inform the Notified body for every change in the FPC system which could lead to change in the products’ characteristics. In this case the Notified body takes decision if the made changes require taking of activities as additional testing of the product or/and unplanned inspection of the FPC.

The Manufacturer does not have right to fixes CE mark on products which have been manufactured in new conditions till the Notified body notifies him written for its decision.

**4.5. Decision regarding the validity of the issued certificate**

Based on the report from the conducted surveillance audit, the Lead Assessor shall prepare decision-statement for maintenance, suspension (temporary suspension) or withdrawal of the certificate for conformity of the manufacturing control, which shall be provided to the Manager for approval and signature.

If the decision of the Notified body is positive, the manufacturer shall be notified written for confirmation of the validity of the issued certificate.

If the decision is negative, the manufacturer shall be informed in written matter for temporary cancelation or withdrawal of the certificate for conformity till the nonconformities are removed. Till the nonconformities removal, the Manufacturer cannot refer to certification. In the above mentioned cases the Manufacturer is obliged to give back the original copies of the issued certificates within 3 days after the date of withdrawal.

If the Applicant has appeals according the made evaluations and actions of the current procedure, could submit written appeal to the Committee of appeals, after that shall be proceed in accordance with procedure SC.PR.04 [12] from Management System of “SZUTEST” Ltd.

Issued certificate for FPC conformity shall be withdrawn in one of the following cases:

* Not fulfillment of the agreed deadline for corrective actions for the established during FPC surveillanceessential nonconformities which lead to nonconformance of the product with the technical specification.
* If there are raised nonconformities in the constancy of the performance characteristics;
* lack of manufacturing activity more than a year;
* if the company obstructs conduction of planned surveillance of FPC;
* if it is proved improper use of the certificate;
* non following the conditions of the certification contract;

If any temporary canceled or withdrawal of the issued FPC certificate, the Notified Body – SZUTEST Ltd., informs MDPW, the announced parties and the bodies for market surveillance. In cases when it is issued a certificate to a manufacturer in other Member State of EU, the Notified Body shall inform the Bodies for market surveillance in the relevant Member State.

**5. Documenting and archiving**

The documentation, collected during the procedure for conformity evaluation, shall be stored in file of the firm – applicant, and identified in appropriate way.

All documents related with the activity of the conformity and certification of the FPC system on hard or electronic copy shall be stored regarding procedure “Procedure for management of records” - (SC.PR.02) [13] from the Quality Management System of the notified body.

**Reference**

[1] REGULATION (ЕС) № 305/2011 OF THE EUROPEAN PARLLIAMENT AND THE COUNCIL from 9 March 2011 year;

[2] ORDINANCE № РД-02-20-1 from 5 февруари 2015 г. For the conditions and order of incorporation of construction products in the buildings in Republic of Bulgaria;

[3] Order № РД-02-14-1329/03.12.2015 г, of the Minister of MDPW;

[4] SC.PR.03 Management of audits on site;

[5] IAF MD 5:2015-issue3 IAF Mandatory Document for Duration of QMS and EMS Audits;

[6] БДС EN ISO/IEC 17021-1:2015 Conformity evaluation. Requirements to the bodies, conductiong audits for certification of management systems. (ISO/IEC 17021:2006);

[7] БДС EN ISO 9001:2008 Quality Management Systems. Requirements (ISO 9001:2008);

[8] NB-CPD/AG/03/004r2 Checklists for initial inspection of factory and factory production control and continuous surveillance of factory production control;

[9] NB-CPD/AG/03/006r1 The use of historic data by NBs for CE marking purposes against hENs;

[10] NB-CPD/AG/06/007 Shared and cascading ITT;

[11] NB-CPR 14-612r7 - Issuance of certificates under CPR;

[12] SC.PR.04 Management of appeals and complaints;

[13] SC.PR.02 Management of Records;

**6. Related documents - Annexes**

**Annex №1** - SC.FR.CPR.[SYS1/2+]-01- Application form for conformity evaluation of construction products;

**Annex №2 -** (SC.FR.CPR[XX]) - Checklist/ Report from inspection / surveillance of the manufacturing according to specific technical specification;

**Annex №3 -** SC.FR.CPR[SYS1/2+]-03-Report for nonconformity;

**Annex №4 -** SC.FR.CPR[SYS1/2+]-06- Declaration for lack of relations with the manufacturer;

**Annex №5 -** SC.FR.CPR[SYS1/2+]-07- Checklist for audit of laboratories;

**Annex №6 -** SC.FR.07-01 – Project of contract for certification;

**Annex №7 -** SC.FR.03-01 – Plan – schedule for conduction of inspection / surveillance of site;

**Annex №8 -** SC.FR.CPR.13-02-Certificate for conformity of production control;

**Annex №9** – SC.FR.-03-03 – Report from Lead Assessor;

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