

Rules for the issue of Factory Production Control (FPC) certification according to Regulation (EU) no. 305/2011 relating to Construction Products (Annex V point 1.3 – System of assessment and verification of constancy of performance 2+)

Effective from 01.07.2013

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CHAPTER 1 - GENERAL

1.1 - Purpose and scope

These rules establish the procedures applied by RINA for issuing factory production control certification for the purpose of CE marking, pursuant to Regulation (EU) no. 305/2011 (hereinafter known as the CPR Regulation) concerning construction products.

The CPR Regulation applies to those construction products that are required to guarantee compliance with one or more basic requirements for construction works in which they are incorporated.

The certificate of conformity issued by RINA refers to factory production control of a single product defined by an applicable harmonised standard, production site, essential characteristics and intended use.

As well as the procedures for issuing certification, this document describes how to request, obtain, maintain and use said certification, as well as its duration and possible suspension or withdrawal.

For any issues not covered in this document, reference should be made to "GENERAL CONTRACT CONDITIONS GOVERNING SYSTEM, PRODUCT AND STAFF CERTIFICATION" which can be downloaded at www.rina.org.

Certification is open to all producers and does not depend on whether they belong to an association or group.

A producer may request certification of factory production control for more than one product provided that a factory production control system compliant with the specific contents of the harmonised standards concerning the manufactured product/s is adopted for each.

1.2 - Definitions

Construction product: any product or kit which is produced and placed on the market for incorporation in a permanent manner in construction works or parts thereof and the performance of which has an effect on the performance of the construction works with respect to the basic requirements for construction works.

Kit: a construction product placed on the market by a single manufacturer as a set of at least two separate components that need to be put together to be incorporated in the construction works.

Construction works: buildings and civil engineering works.

Factory Production Control (hereinafter known as "FPC"): permanent and documented internal control of factory production, in compliance with the pertinent harmonised technical specifications.

Manufacturer's declaration of performance: document which must be drawn up when such a product is placed on the market when a construction product is covered by a harmonised standard; the manufacturer shall assume responsibility for the conformity of the construction product with such declared performance.

Making available on the market: any supply of a construction product for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.

Placing on the market: the first making available of a construction product on the Union market.

Harmonised technical specifications: means harmonised standards and European Assessment Documents.

Harmonised standard: means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC, on the basis of a request issued by the Commission, in accordance with Article 6 of that Directive.

CE marking: the "CE mark" is the standardised marking by affixing which the manufacturers indicate that they take responsibility for the conformity of the construction product with the declared performance as well as the compliance with all applicable requirements laid down in CPR Regulation and in other relevant Union harmonisation legislation providing for its affixing. Article 9 of CPR Regulation and the applicable harmonised standard establish the methods of applying the marking, including the required accompanying information.

Manufacturer: any natural or legal person who manufactures a construction product or who has such a product designed or manufactured, and markets that product under his name or trademark.

Essential characteristics: those characteristics of the construction product which relate to the basic requirements for construction works.

Performance of a construction product: the performance related to the relevant essential characteristics, expressed by level or class, or in a description.

Product-type: the set of representative performance levels or classes of a construction product, in relation to its essential characteristics, produced using a given combination of raw materials or other elements in a specific production process.

Type Testing: tests performed to assessment and verification of constancy of performance of the product respect to the basic requirements for construction works of the CPR Regulation; the type testing are defined in the harmonised standards; for a determined product, the type testing to perform depend on the compulsory requirements concerning the product in question, on its intended use, on market requests, and on the design requirements of a determined product.

Basic requirements for construction works: the basic requirements for construction works applicable to the works and capable of affecting the technical characteristics of a product and described in detail in Annex 1 of the CPR Regulation, are:

- 1. mechanical resistance and stability,
- 2. safety in case of fire,
- 3. hygiene, health and the environment,
- 4. safety and accessibility in use,
- 5. protection against noise,
- 6. energy economy and heat retention,
- 7. sustainable use of natural resources.

System of assessment and verification of constancy of performance: this is the assessment and verification of constancy of performance procedure, pursuant to the CPR Regulation, applied for CE marking of a product identified in the relative harmonised standard.

For all other terminology used in these rules, reference is made to standards UNI CEI EN ISO/IEC 17000, UNI CEI EN ISO/IEC 17020, UNI CEI EN ISO/IEC 17021, UNI CEI EN ISO/IEC 17065.

CHAPTER 2 - REFERENCE STANDARDS / GENERAL REQUIREMENTS FOR THE CERTIFICATION OF THE FPC FOR THE PRODUCT SUBJECT TO CE MARKING

2.1 - Reference legislation

These rules have been drawn up bearing in mind the following reference provisions:

- Regulation (EU) No. 305/2011;
- Specific harmonised and supporting standards for the product subject to certification;
- Other sectorial documents (Legislative mandates, EU Commission Guidelines, etc.).

2.2 - General requirements for the issue of certification

For the products subject to certification, the Producer must implement an FPC that is capable of satisfying and maintaining the requirements of the reference legislation.

Additionally, an FPC is considered compliant and completely operative when:

- the objectives and processes for obtaining results compliant with specific requirements for each product have been defined, also as regards its origin and intended use;
- processes and products suitable for guaranteeing conformity of the declared essential product characteristics/requirements have been monitored, measured/tested and recorded;
- it has been fully implemented and its effectiveness can be demonstrated;

- the records of the checks/tests/controls performed on the product during the production process phases (even if outsourced) are available;
- integrations have been specified or exclusions have been justified in the sphere of application (with respect to the contents of the reference standards), and the reasons why such exclusions do not affect product quality have been illustrated.

CHAPTER 3 - ISSUE OF CERTIFICATION

3.1 - Informative questionnaire

Producers wishing to obtain factory production control certification must provide RINA with the essential information for each specific product subject to certification by filling in all the sections of the relative "Informative Questionnaire" and sending it to RINA which will then draw up an offer.

In particular, the following information is required:

- producer information;
- product typology (description, trade name, etc.);
- intended use;
- reference provisions (reference harmonised standard, national legislation, etc.) and system of assessment and verification of constancy of performance required;
- number of production sites and the relative activities performed there, as well as the site/s from which the raw materials are picked, if applicable;
- possession of any certificates relative to the producer's quality management system (e.g.: ISO 9001).

This information is required in order to verify the application of certain requirements of the applicable standards in advance.

On the basis of this information, RINA formulates a specific offer.

3.2 - Certification request

If the applicant producer (hereinafter also known as the "organisation") accepts RINA's offer, it formalises the certification request by sending RINA the relative form "Certification request".

Upon receipt of the certification request, RINA sends the organisation written acceptance of the request and communicates the name of the reference person for the certification procedure and that of the technician appointed to perform the documents review.

The organisation may object to the appointment of the above persons, justifying its reasons.

The organisation's request, which makes specific mention of these rules, and its acceptance by RINA, contractually formalise the relationship between RINA and the organisation, and the applicability of these rules.

The agreement signed by RINA and the organisation comprises:

- the documents review as per Section 3.4;
- the certification audit and, possibly, issue of certification;
- the subsequent periodic surveillance activities as per Chapter 4.
- any additional services specified in the offer.

The contract may be changed, on agreement by the parties, if the conditions according to which RINA drew up its initial offer were to significantly change over time.

3.3 - Technical documentation provided by the producer

Together with the certification request, or at a later stage, the organisation must send RINA the following documents:

- (a) FPC manual adopted with detailed description of the products involved in the certification process, list of essential product characteristics/ requirements applicable to the product, list of technical and supporting applicable specifications;
- (b) list of procedures/instructions concerning the FPC system adopted;
- (c) available test reports, records and certificates concerning the product;
- (d) inspection plan with minimum test frequencies;
- technical documentation concerning procured materials (e.g.: documentation pertaining to raw materials, their origin and, if necessary, maps showing the quarrying site and plan, storage location, etc., if applicable);
- (f) technical documentation relative to the test equipment used;
- (g) additional documentation required by the reference standards;
- (h) Chamber of Commerce registration certificate or equivalent document. certifying the existence of the organisation and describing the activity it performs.

In particular, information must be provided about:

- any requirements of the reference standards that it deems and sufficiently justifies as being inapplicable or requiring interpretation or adaptation;
- any outsourced processes (required to manufacture a certain product that is determining

as regards the capacity of the product to satisfy applicable requirements);

RINA may, at its sole discretion, also ask to examine other documents which it deems necessary for the purposes of FPC certification of the product/s in question.

3.4 - Documents review

RINA assesses the documentation referred to in Section 3.3 according to the requirements indicated in the applicable reference standards and in these rules.

The outcome of this review will be notified to the organisation; any discrepancies found in the documentation are to be eliminated by the organisation before the certification procedure can continue.

The documentation referred to in section 3.3 will normally be kept by RINA for its files.

If specific agreements are made with the organisation, some of the above documents may be directly reviewed at the organisation's facilities.

On agreement with the organisation, a preliminary audit of the FPC may be made to check its general state of application.

3.5 - Audit at the producer's facilities

If the above documents review is successful, RINA conducts an audit at the organisation's facilities, communicating in advance the names of the members of auditing team appointed to verify the correct application of all the factory production control procedures examined during the documents review phase.

The organisation may object to the appointment of the above persons, justifying its reasons.

The audit comprises:

- an initial meeting with the organisation to agree on the audit methods;
- verification that the corrective action relative to the findings identified during documents review have been effectively implemented;
- an inspection of the offices, the production site/s and, where necessary, the raw materials picking/storage site/s, as well as the laboratory/ies in order to check the conformity of the factory production control system with the applicable reference standards;
- a final meeting to illustrate the outcome of the audit.

The RINA auditing team will verify the suitability of any exclusions from the requirements of the reference standards. In the event of any shortcomings or differences from the declaration in the FPC system documentation, it may notify the organisation of one or more non-conformities.

During the audit, the organisation must demonstrate, for each product, that the applicable reference standard is applied and that the FPC system has been fully operative for at least three months and that the system and the relative documented procedures are effectively implemented.

For this purpose, also during the surveillance audits (specified below), the RINA auditors must be allowed free access to the production areas, to staff and to documentation and be given all necessary assistance by the staff appointed to supervise the audit.

3.6 - Audit report

At the end of the visit, the organisation is given an audit report containing any non-conformities found as well as any recommendations.

The organisation may indicate any reservations or observations concerning the findings by the RINA surveyors in the relative space in the audit report.

The contents of this report are subsequently confirmed by RINA in writing.

If no written communication is received from RINA, the report is deemed to be confirmed three working days after it was given to the organisation.

After analysing the causes of any non-conformities (the various typologies of which are defined in section 3.7) contained in the above report, the organisation must, within the date indicated on the report, propose the necessary corrective action to RINA as well as the expected deadline required for their implementation.

Acceptance of the proposals and of the relative implementation deadlines will be notified in writing to the organisation by RINA.

In the event of A-type findings (see next section) the certification process is suspended; in the event of other findings, the number of which, in the audit team's judgement, may compromise the efficiency of the system, the certification process is also suspended.

In these cases, RINA may perform a supplementary audit within three months in order to ascertain whether the proposed corrective action has been taken; if this audit is successful the certification process is resumed.

The auditing team may decide to perform the supplementary audit on site or on the documents, depending on the type of corrective action involved.

If the above deadline is exceeded, the FPC adopted by the organisation is fully reviewed within six months from the date of the finding.

After the six month period has elapsed and the situation still remains negative, RINA reserves the right

to definitively close the certification file and charge the organisation for the time spent and expenses incurred up to that moment.

In such a case, if the organisation wishes to proceed with RINA certification, it must submit a new application and repeat the certification procedure.

In special cases, the above time limits may be modified at the request of the organisation, if considered justified by RINA.

3.7 - Typology of findings

The findings relative to the object of the certification are divided into the following types:

- (a) A-type findings (major non-conformities):
 - the total non-consideration of one or more requirements of the reference standards;
 - a situation that could lead to the delivery of nonconforming products or products which do not comply with the legislation in force on the product emission SM;
- the non-observance of one or more requirements of these rules;
- a situation that is likely to cause a failure in the FPC system or reduce its ability to assure the control of the product subject to marking.
- (b) B-type findings (secondary failures or minor nonconformities):
 - a condition that, in the RINA auditing team's opinion and experience, is likely to not cause a failure in the FPC system or not reduce its ability to assure product control
- (c) C-type findings (recommendations, observations):
- suggestions made with a view to improving the system that do not directly pertain to the prescriptions of the reference standard applicable to the product.

3.8 - Issue of certification

Following the successful completion of the findings and validation by the relative Technical Committee, a special certificate with relevant annex is issued for the factory production control of each type product and production site, as required by the reference harmonised standard.

RINA issues a specific certificate for each product typology in relation to the production facility where it is manufactured.

The certificate contains the name and address of the organisation, the address of the production site, the identification of the product object of FPC, the applicable harmonised standard, the date of initial issue and the current date of issue.

The Annex to the certificate contains a detailed description of the product/s object of the FPC.

From the moment of issue of the certificate by RINA, this and the relative surveillance audit plan will made available to the organisation in the "Member Area" of the RINA website (www.rina.org).

The organisation may therefore enter and download the above documents directly from this area of the RINA website.

If it is impossible to access the Internet, the organisation may request a hardcopy from the pertinent RINA Office.

The validity of the certificate is subject to the success of the subsequent surveillance audits defined in Chapter 4.

The frequency and scope of these audits will be established by RINA on a case-by-case basis according to a periodic audit plan that will be sent to the organisation together with the certificate.

The Manufacturer's Declaration of Performance must then be drawn up in accordance with the reference harmonised standard and the contents of RINA certification.

CHAPTER 4 - MAINTAINING CERTIFICATION

4.1 - General conditions for maintaining certification

The organisation must ensure its factory production control system remains compliant with the applicable reference standards.

The organisation undertakes to inform RINA of any significant change that may affect the requirements that determined FPC certification.

The organisation must keep records of any claims relative to the certified product and the relative corrective action taken to address the non conformities made during the surveillance audits and must make then available to RINA.

RINA reserves the right to conduct supplementary audits at the organisation in the event of particularly significant claims or reports concerning non-conformity of the FPC with the requirements of the reference standard and of these rules.

If the organisation refuses without a justified reason, RINA may decide to suspend certification.

If RINA considers the claims and reports to be justified, the cost of the supplementary audit will be charged to the organisation.

The validity of the certificate is confirmed following the successful outcome of the surveillance audit.

4.2 - Maintenance of certification for products subject to system of assessment and verification of constancy of performance 2+

For products subject to system of assessment and verification of constancy of performance 2+, the validity of the certificate is subject to the successful outcome of the periodic surveillance audits performed by RINA on the factory production control system.

Unless otherwise indicated in the reference standards, surveillance audits are performed at least once a year, within the date established in the periodic audit plan communicated to the organisation.

This plan may be modified by RINA on the basis of the results of each audit.

Any differences with respect to the above audit plan, due to justified reasons, must be agreed in advance with RINA

The surveillance audit dates are agreed with the organisation in good time and confirmed in writing together with names of the members of the RINA auditing team.

The organisation may object to the appointment of the above persons, justifying its reasons.

The outcome of the audits is notified as described in section 3.6.

The validity of the certificate is confirmed following the successful outcome of the surveillance audits.

In the event of major non-conformities or other findings whose number, in the auditing team's opinion, is such as to impair the correct functioning of the FPC, the organisation will be subject to a supplementary audit within the time limits established by RINA in relation to the type of the non-conformities and, in any case, not more than three months after the surveillance audit, in order to check the effectiveness of corrections and of the proposed corrective action.

If the non-conformities are not eliminated within the established times or if they prevent the supplied product from satisfying applicable standards, RINA may suspend certification until these non-conformities have been eliminated (see section 6.1).

All expenses deriving from any additional audits, as described above, will be charged to the organisation.

CHAPTER 5 - MODIFICATION OF CERTIFICATION

5.1 - Modifications made by the organisation

During the validity of the certification, the organisation must promptly inform RINA of any significant changes concerning the certified factory production control system.

Depending on the type of modifications proposed, RINA informs the organisation of its valuations within 30 working days from receipt of notification of the proposed modifications, reserving the right to perform a supplementary audit to assess the influence of the variants on the factory production control system.

If the modifications proposed by the organisation involve an extension of auditing activities, RINA may ask the organisation to review the contractual conditions for future auditing activities. If the organisation refuses to do so, RINA may withdraw from the agreement with thirty day's notice.

In case of a change of company name, the organisation must inform RINA accordingly and send the following documentation:

- a copy of the organisation's new Chamber of Commerce registration certificate or equivalent document.
- a copy of the notarial act certifying the change.

After making appropriate investigations, RINA issues a new certificate, which cancels and replaces the previous one.

A copy of each revision of the relevant documentation for the purposes of the FPC system in question (manual, procedures, etc.) must be kept at RINA's disposal for examination at the organisation's facilities.

During audits, RINA may request, for filing purposes, an extract from the above documentation in order to have evidence of the documental structure of the organisation's FPC System in force at the moment such audits took place.

5.2 - Modifications to the Technical Specifications and rules

Each modification made by RINA to its rules for obtaining and maintaining certification, for example, following the issue of new legislation, will be notified to all the Organisations certified by RINA and which must adapt to the new provisions.

When informing the above organisations of any modifications made to its rules, RINA:

- considers any comments they may wish to make;
- specifies and notifies to the organisations the date the modifications come into force, the deadlines of the transitory period and any modifications required;
- checks, where necessary, the conformity and suitability of the measures taken by organisations to comply with the new requirements, also by conducting supplementary audits at the latter's expense.

Organisations must keep the documents sent by RINA updated and eliminate all obsolete versions.

The failure of the organisation to adapt to the new requirements within the agreed deadlines may cause certification to be suspended or withdrawn.

Organisations that do not accept the new requirements withdraw from certification as indicated in chapter 7.

5.3 - Transfer of certificates

If an organisation possessing factory production control certification issued by a notified body other than RINA, presents an application for certification as indicated in section 3.1, RINA, after verifying that the certificate is valid, performs an audit which includes:

- a documents review as indicated in section 3.4 of these rules:
- a review of the audit reports drawn up by the notified body issuing the previous certification;
- an examination of the evidence of the corrective action taken related to the non-conformities issued during the previous audit, or the evidence of the review, acceptance and verification of the effectiveness by the previous notified body;
- possible audit at the organisation, the scope of which depends on the conformity and validity of the previously issued certification

The contract between RINA and the organisation is managed as indicated in chapter 3, depending on the scope of auditing activities.

After the satisfactory completion of the above activities and validation by the relative RINA Technical Committee, certification of the FPC system in question is issued, as indicated in these rules.

Generally speaking, surveillance audits are performed according to the plan established by the organisation that issued the previous certification.

CHAPTER 6 - SUSPENSION, REINSTATEMENT AND REVOCATION OF CERTIFICATION

6.1 - Suspension of certification

The validity of the certification may be suspended as indicated in "GENERAL CONTRACT CONDITIONS GOVERNING SYSTEM, PRODUCT AND STAFF CERTIFICATION" and in the following specific cases:

- if the Organisation refuses to allow the scheduled surveillance audits to be performed at the required frequencies;
- if serious non-conformities are found in the factory production control system which have not been corrected within the time limits established by RINA;

- if the organisation does not observe the deadlines established for the communication of corrective actions, following non-conformities indicated on the audit report;
- if the organisation has made modifications to its factory production control system that have not been accepted by RINA;
- if the organisation has undergone important restructuring and this has not been reported to RINA.
- if the organisation refuses or obstructs the participation of observers from the competent Supervisory Authority in audits;
- if the organisation fails to pay RINA for its services;
- if any justified and serious claims received by RINA are confirmed;
- if the organisation has incorrectly used the RINA identification information to apply to the producer's declaration of performance for the purposes of CE marking on the product and/or the certification issued by RINA and has not applied the measures requested by RINA;
- if there is evidence to show that the factory production control system does not ensure observance of the law and compulsory regulations applicable to the characteristics of the supplied product;
- any other circumstances that RINA considers have a negative affect on the factory production control system.

The organisation may also make a justified request to suspend certification, normally for not more than six months.

This suspension will be notified to the organisation by registered letter, stating the conditions for re-instating certification and the date by which the new conditions are to be complied with.

Suspension of the validity of certification may be made public by RINA.

During suspension, the organisation may not make use of RINA certification (number of the Certificate, RINA identification, etc.) both on the producer's declaration of performance for the purposes of CE marking of the product in question, and on any other document.

6.2 - Reinstatement

Reinstatement of certification is subject to verification that the shortcomings which led to the suspension itself have been eliminated. This is achieved by means of an analytical audit checking the compliance of the factory production control system with all the requirements of the reference standards.

This is notified by registered letter to the organisation and made public by RINA if the notice of suspension was also made public.

6.3 - Revocation

Failure to fulfil the conditions as per 6.2 above by the established date will lead to revocation of certification.

Revocation of the certificate may be decided as indicated in "GENERAL CONTRACT CONDITIONS GOVERNING SYSTEM, PRODUCT AND STAFF CERTIFICATION" and in the following specific cases:

- when there are reasons such as those indicated in 6.1 for suspension, which are held to be particularly serious;
- upon formal request if the organisation does not want to or cannot comply with the new instructions issued by RINA (see chapter 5);
- if the organisation stops supplying the product covered by the certified factory production control for a period lasting not more than six months as a rule;
- if the organisation regularly fails to pay RINA for its services;
- if the organisation does not accept the new economic conditions established by RINA due to a modification in the contract;
- for any other reason that RINA deems to be serious.

Revocation of certification is notified to the organisation by registered letter. Revocation is made public by RINA.

The organisation whose certification has been revoked must return the relative certificate to RINA and may not make use of RINA certification (number of the Certificate, RINA identification, etc.) both on the producer's declaration of performance for the purposes of CE marking of the product in question, and on any other document.

Any organisation which, following revocation of its Certificate, wishes to be re-certified, must submit a new application and follow the entire procedure all over again.

CHAPTER 7 – WITHDRAWAL FROM CERTIFICATION

7.1 - Withdrawal by the producer

The organisation may present a request to withdraw certification of some or all of the products for which it had obtained certification due to termination of production or other reasons.

In this case the organisation must return the relative certificate.

On receipt of a withdrawal request, RINA updates the

lists indicated in chapter 8 and informs the competent authorities that the certification is no longer valid, and informs the organisation, where necessary, of any actions it must take on products that have already been manufactured.

From the date of the withdrawal request, the organisation may not make use of RINA certification (number of the Certificate, RINA identification, etc.) both on the producer's declaration of conformity for the purposes of CE marking of the product in question, and on any other document.

CHAPTER 8 - PUBLICATION BY RINA

8.1 - Drawing up and keeping lists

RINA issues and updates on its Internet site a list of organisations that have obtained factory production control certification, making reference to the product typology and the relative reference harmonised standard.

Information on the validity of the certificate is shown in the above list.

This list generally contains:

- name and address of the organisation or of its designated authorised representative in the European Union and the production site;
- description of the product (commercial name and type, identification, use, etc.);
- regulations with which the product complies (in particular the reference harmonised standards);
- identification number and status of the Certificate (valid, relinquished, suspended, withdrawn);
- date of initial certification;
- date of last update of the certificate.

CHAPTER 9 - ADVERTISING - USE FOR THE PURPOSES OF CE MARKING

9.1 - Advertising

The organisation may advertise the fact that it has obtained RINA certification using the methods it considers most suitable.

The organisation must clearly indicate any limitations and conditions imposed by RINA at the time of issue of the certification.

The organisation may reproduce the certificate in full, enlarge or reduce it, provided that it remains legible and is not modified in any way.

9.2 - Use for the purpose of CE product marking

When in possession of valid RINA certification, the organisation must indicate the information required by the reference provisions on the producer's declaration of performance for the purposes of CE marking of the product in question.

When using the certificate, the organisation must make sure it cannot be interpreted as being extended to other products or production sites not covered by the certification issued by RINA.

CHAPTER 10 - CONTRACT CONDITIONS

For contract conditions, the contents of the current edition of RINA rules "General contract conditions governing system, product and personnel certification" apply.