# Rules for the issuance of the Certification of Fabrication Control Plan of Materials in accordance with Annex I Par. 4.3 of "PED" Directive 2014/68/EU

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Technical Rules

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## Chapter 1. GENERAL

### *1.1 PURPOSE AND SCOPE*

These Rules establish the procedures applied by RINA Services (hereinafter RINA) for the issuance of the certification of the Fabrication control plan of materials in accordance with Directive 2014/68/EU PED (hereinafter referred to as the 'PED Directive' or 'Directive') - Annex 1, Par. 4.3 and the pertinent Essential Safety Requirements of Annex 1 of the Directive, as applicable.

The certification covered by this Regulation is voluntary in nature and applies exclusively to manufacturers of materials as defined in the PED F-19 Guideline, i.e. manufacturers of:

- sheet metal
- Forgings (including forged flanges)
- mergers
- seamless pipes
- Welded pipes with a fully automated process
- Fittings

Therefore, material dealers are excluded from the certification covered by this regulation.

Manufacturers of components (bottoms, welded pipes with a NON-automated process, manholes, etc.) do not fall under the requirements of p.to 4.3 Annex 1 PED Directive and therefore cannot be subject to this approval.

In addition to the procedures for issuing the certification, this document describes the procedures for requesting, obtaining, maintaining and using, any suspension and revocation, as well as the duration of this certification.

A necessary requirement to access the certification is the possession of a valid Quality System Certificate according to ISO 9001 standards, with explicit reference to the materials subject to certification issued by a body established in the European Community and accredited in the EA 17 sector.

A manufacturer may also request the certification of Fabrication control plan in relation to several products, provided that for each of them a Fabrication control plan system is adopted in compliance with the contents of par. 4.3 and the remaining Essential Safety Requirements of Annex 1 of Directive 2014/68/EU PED, which may be applicable.

**1.2**

Access to certification is open to all Organizations and is not conditioned by their membership or not in any Association or Group. For certification activities, RINA will apply its current tariffs, ensuring their fairness and uniformity of application.

**1.3**

The certification issued by RINA refers to the materials indicated in the certificate produced by the applicant Organization, where Organization means a company, enterprise, firm, body or association, legally recognized or not, public or private, which has its own functions and its own administration or natural person. For Organizations with multiple business units, a single business unit can be defined as an Organization.

**1.4**

The information acquired during the certification activity is considered and treated as confidential.

**1.5**

The terminology used in these Rules is that set out in the PED Directive.

**1.6 Definitions**

Fabrication Control Plan (hereinafter "FPC"): means the permanent internal control of production applied by the manufacturer.

Manufacturer: the manufacturer of the product established in the European Community and any other person who presents himself as a manufacturer by affixing his or her name, trademark or other distinctive sign to the product, or the person who refurbishes the product; the manufacturer's representative if the manufacturer is not established in the Community or, if there is no representative

established in the Community, the importer of the product; other professional operators in the marketing chain to the extent that their activity may affect the safety characteristics of the products marketed.

### 1.7 General requirements for certification FPC

The Manufacturer must prepare and activate, for the product subject to the certification activity, an FPC capable of satisfying and guaranteeing over time the maintenance of the requirements of the reference regulatory provisions.

In addition, the FPC is considered compliant and fully operational when:

- the objectives and processes have been defined to obtain results that comply with the specific requirements for each product, also with reference to the origin and intended use;
- monitoring, measurements/tests of processes and products capable of guaranteeing compliance with the declared essential characteristics/requirements of the product have been carried out and recorded;
- is fully implemented and can be demonstrated as effective;
- records of the checks/tests/controls carried out on the product during the phases of the production process are available (even if entrusted to third parties);
- any additions or any exclusions in the scope of application (with respect to what is contained in the reference standards) are specified, illustrating the reasons why any exclusions do not affect the quality of the product.

## Chapter 2. REFERENCE LEGISLATION

The applicable legislation for the purposes of the pressure equipment conformity assessment is Legislative Decree no. 26 of 15/02/2016, implementing European Directive 2014/68/EU.

Any prescription of the above stated reference legislation is considered applicable even if not explicitly stated in this document.

For the application and standardized interpretation of the Pressure Equipment Directive, RINA uses the guidelines issues by the European Community Working Group for the Pressure Equipment Directive and the Agreed Interpretations issued by the Italian Notified Bodies Forum.

## Chapter 3. ISSUE OF CERTIFICATION

### *3.1 - INFORMATION QUESTIONNAIRE*

The Manufacturer who wishes to obtain the certification of the control of factory production must provide RINA with the essential data for the products subject to certification, by sending the appropriate "Information Questionnaire" form completed in all its parts, on the basis of which an economic offer is formulated by RINA.

In particular, the following information is required:

- manufacturer data;
- type of product(s) (description, trade name, etc.);
- intended use/use;
- number of production sites and the related activities carried out in them;
- valid certification relating to its ISO 9001 (or equivalent standard) quality assurance system certified by a competent body (refers to PED Guideline G-16 for further information).

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

### *3.2 - REQUEST FOR CERTIFICATION*

The applicant Manufacturer (hereinafter also referred to as the "Organization"), in the event of acceptance of the economic offer sent by RINA, formalizes the certification request by sending RINA the appropriate form.

Upon receipt of the certification request, RINA sends the Organization, in writing, the

confirmation of acceptance of the request itself and communicates the name of the contact person for the certification file.

The Organization may object to the appointment of such a technician, justifying the reasons.

The request of the Organization, in which these Rules are expressly referred to, and its acceptance by RINA contractually formalize the relationship between RINA and the Organization and the applicability of these Rules.

The contract stipulated between RINA and the Organization includes:

- the certification visit and the possible issuance of the certification;
- the subsequent periodic surveillance activities referred to in Chapter 4;
- any additional services specified in the offer.

The contract may be varied, subject to agreement between the parties, if the conditions on the basis of which the initial offer was drawn up by RINA are significantly changed over time.

### *3.3 - TECHNICAL DOCUMENTATION PROVIDED BY THE MANUFACTURER*

Together with the certification request, or subsequent to it, the Organization must send to RINA (in controlled copy):

(a) Valid quality system certificate according to ISO 9001 standards issued by a body with registered office in the European community and accredited in the EA 17 sector (see also PED Guideline G-02, G-07, G-16, G-25, G-30 for further information);
(b) detailed description of the material(s) subject to the certification activity.

In particular, information must be provided regarding:

- any requirements of the reference standards which, adequately justified, are deemed not to be applicable or which require interpretation or adaptation;
- any outsourced processes (necessary for the production of a given product, decisive for the ability of the product itself to meet the applicable requirements).

RINA may also request, at its discretion, for examination, other documents deemed important for the certification of the FPC in relation to the product(s) in question.

### *3.4 - EXAMINATION OF THE DOCUMENTATION*

The documentation referred to in 3.3 is evaluated by RINA on the basis of the requirements contained in the applicable reference standards and in these Rules.

The outcome of this examination shall be communicated to the Organization; any findings found in the documentation must be resolved by the Organization itself before the certification process continues.

The documentation referred to in 3.3 is, in general, retained for archival use by RINA.

In the case of specific agreements with the Organization, part of the aforementioned documentation can be verified directly at the Organization itself.

A preliminary examination of the FPC may be carried out by agreement with the Organization to verify the general state of application of the system itself.

### *3.5 - EVALUATION VISIT TO THE MANUFACTURER*

Upon successful examination of the documentation, RINA carries out an assessment visit to the Organization, communicating in advance the names of the assessment team responsible for verifying the correct application of all Fabrication control plan procedures.

The Organization may object to the appointment of such technicians, justifying the reasons.

The visit consists of:

- an initial meeting with the Organization to agree on the modalities of the visit itself;

- an inspection of the offices and production site(s), as well as the laboratory(s) (if in-house), to verify that the manufacturing processes and technologies used comply with the requirements of the standards relating to the materials produced
- a final meeting to illustrate the outcome of the visit.

During the visit, the Organization must demonstrate that the system of FPC has been fully operational for at least three months and that it effectively implements this system and its documented procedures.

To this end, even during the surveillance checks (specified below), RINA technicians must be guaranteed free access to the production sites, personnel and documentation and the necessary assistance from the responsible personnel in charge of the verification.

### *3.6 - AUDIT REPORT*

At the end of the assessment visit, an inspection report is delivered to the Organization, which contains any non-conformities, observations and recommendations found.

The Organization may note any reservations or observations regarding the findings expressed by RINA technicians in a special space in the inspection report.

The content of this report is subsequently confirmed by RINA through a written communication.

In the absence of written communication from RINA, the relationship is considered confirmed three working days after its delivery to the Organization.

The Organization, after analysing the causes of any non-conformities and observations (the types of which are defined in paragraph 3.7) reported in the aforementioned report, must propose to RINA, by the date indicated in the report itself, the necessary corrective actions and the timescales envisaged for their implementation.

The acceptance of these proposals and the timeframe envisaged for their implementation shall be communicated in writing by RINA to the Organization.

In the presence of type A findings (see next paragraph) the certification process is suspended; in the case of other findings, the number of which, in the opinion of the evaluation team, is such as to jeopardise the correct functioning of the system, the certification process is also suspended.

In such cases, within three months, RINA may carry out an additional verification aimed at ascertaining the correct application of the proposed corrective actions; upon successful completion of this verification, the certification process resumes.

If this deadline is exceeded, the FPC adopted by the Organization shall be subject to a full review within six months of the date of the survey.

If the aforementioned six-month period has elapsed without a positive conclusion of the assessment, RINA may consider the certification file closed, charging the Organization for the time and expenses incurred up to that moment. In such cases, the Organization wishing to continue with the RINA certification must submit a new request and repeat the certification process.

The aforementioned time limits may in particular cases be varied upon a reasoned request by the Organization, in the opinion of RINA.

### *3.7 - TYPES OF SURVEYS*

The findings relating to the subject of the certification are divided according to the following types:

(a) Type A (non-conformity) surveys:

- the total absence of consideration of one or more essential safety requirements;
- a situation that could result in the delivery of a product that does not comply with or does not comply with current Rules;

- failure to comply with one or more requirements of these Rules;
- a situation that would result in a serious deficiency of the FPC system or reduce its ability to ensure product control.

(b) Type B surveys (observations):

- condition that, in the opinion of the RINA Evaluation Team, on the basis of its experience, is such as not to cause a serious deficiency of the FPC system and does not reduce its ability to ensure the control of the product.

(c) Type C surveys (recommendations):

- suggestions for the purpose of improving the system, which are not directly related to the requirements of the reference standards applicable to the product.

### *3.8 - CERTIFICATION ISSUE*

Upon completion, with a favourable outcome, of the investigations and subject to validation by a specific Technical Committee, a special Certificate is issued for the control of the factory production of each product and production site, with an expiry date coinciding with that of the ISO 9001 (or equivalent) certificate, in any case with a maximum 3 years validity period.

The validity of the Certificate is subject to the successful completion of the subsequent surveillance audits defined in Chapter 4 and to the validity/maintenance of the ISO 9001 certificate and the contractual terms.

The periodicity and extent of the subsequent checks are established by RINA on a case-by-case basis by means of a plan of periodic checks that is sent to the Organization together with the Certificate.

## Chapter 4. VALIDITY PERIOD OF CERTIFICATION

### *4.1 - GENERAL CONDITIONS FOR MAINTAINING CERTIFICATION*

The Organization must maintain the compliance of its Fabrication Control Plan with the applicable reference standards.

The Organization undertakes to notify RINA of any significant changes that may affect the requirements that led to the certification of the FPC.

The Organization must keep records of any complaints relating to the product subject to the certification activity and the related corrective actions taken and must keep them available to RINA.

RINA reserves the right to carry out additional inspections at the Organization in the event of any complaints or reports, deemed particularly significant, relating to the non-compliance of the adopted FPC with the requirements of the reference standards and with these Rules.

In the event of refusal, without valid reasons, by the Organization, RINA may initiate the process of suspension of certification.

In the event that complaints and reports are deemed justified by RINA, the cost of carrying out the additional inspection is borne by the Organization.

### *4.2 -MAINTAINING CERTIFICATION*

Surveillance visits, unless otherwise indicated by the reference Rules, are carried out at least once a year and must be carried out by the date established on the periodic verification plan communicated to the Organization. This plan can be modified by RINA on the basis of the results of each visit.

In the case of Organizations in possession of a valid Quality System Certificate according to ISO 9001 standards issued by RINA, surveillance audits may be carried out in conjunction with ISO 9001 audits.

Any deviations from the aforementioned verification plan, due to justified reasons, must be agreed in advance with RINA.

The dates of the surveillance visits are agreed with the Organization well in advance and confirmed by a written communication containing the names of the RINA evaluation team. The Organization may object to the appointment of such technicians within 5 working days, justifying the reasons.

For the methods of communicating the result of the audit, please refer to point 3.6 above.

The validity of the Certificate is confirmed following the satisfactory outcome of the audit.

In the presence of non-conformities or other findings, the number of which, in the opinion of the assessment group, is such as to jeopardise the correct functioning of the FPC, the Organization shall be subjected to an additional verification within the time limits established by RINA, in relation to the type of non-conformities themselves and, in any case, no later than three months after the end of the surveillance visit.

If the non-conformities are not resolved within the established time frame or if the non-conformities detected are such as not to ensure the compliance of the product supplied with the applicable standards, RINA may suspend the certification until the non-conformities themselves have been corrected (see paragraph 6.1).

All expenses relating to any additional checks as described above are to be considered the responsibility of the Organization.

## Chapter 5. EXTENSION, MODIFICATION OF CERTIFICATION.

### *5.1 - CHANGES MADE BY THE ORGANIZATION*

During the period of validity of the certification, the Organization must promptly notify RINA of any significant change concerning the certified Fabrication control plan system.

In relation to the type of proposed changes, RINA shall communicate its assessments to the Organization within 30 working days of receipt of the notification of the proposed changes and reserves the right to carry out an additional verification to assess the influence of the variants on the Fabrication control plan system.

When the changes proposed by the Organization involve an extension of the verification activity, RINA may ask the Organization to review the contractual conditions for future inspection activities. In the event of refusal by the Organization, RINA may withdraw from the contract with thirty days' notice.

In the event of a change of company name, the Organization must notify RINA of the changes that have taken place, sending the following documentation:

- copy of the new certificate of registration with the Chamber of Commerce, or equivalent document,
- copy of the notary deed certifying the change.

RINA, having carried out the necessary investigations, issues a new Certificate, which cancels and replaces the previous one.

### *5.2 - CHANGES TO THE TECHNICAL SPECIFICATIONS AND THE RULES*

Any changes made by RINA to its provisions for obtaining and maintaining certification, for example following the issuance of new regulatory provisions, are notified to all Organizations certified by RINA, which must comply with the new provisions.

RINA, in informing the aforementioned Organizations of the changes made to its provisions, shall:

- take into account any comments they may have on the matter;
- specify and notify the Organizations themselves of the date of entry into force of the changes, the terms of the transitional period and any adjustments requested;
- verify, where necessary, the compliance and adequacy of the measures adopted by the Organizations to comply with the new requirements, including through additional assessments at their expense.

It is the responsibility of the Organization to keep the documentation sent by RINA up to date, eliminating outdated documents.

Failure of the Organization to comply with the new requirements within the agreed time frame may lead to the application of measures suspending or revoking certification.

The Organization that does not accept the new requirements renounces the certification as indicated in chapter 6.

## Chapter 6. SUSPENSION, REINSTATEMENT AND REVOCATION OF CERTIFICATION

### *6.1 - SUSPENSION OF CERTIFICATION*

The validity of the issued certification may be suspended in the following cases:

- if non-conformities are found in the Fabrication control plan that have not been resolved within the timeframe established by RINA;
- if the Organization has not complied with the deadlines set for the communication of corrective actions, following non-conformities reported on the audit report;
- if the Organization has made changes to the Fabrication control plan system that have not been accepted by RINA;
- in the presence of major corporate restructuring, which has not been communicated to RINA;
- for refusal or obstruction of surveillance visits;
- for payments in arrears for RINA services;
- acknowledgment of any justified and serious complaints received by RINA;
- for the evidence that the Fabrication control plan system does not ensure compliance with the mandatory laws and Rules applicable to the characteristics of the product supplied;
- in any other circumstance that RINA, in its opinion, considers to have a negative influence on the control of factory production.

The Organization may also request RINA, justifying the reasons, to suspend the certification for a period generally not exceeding six months.

The suspension shall be notified in writing by registered letter to the Organization, specifying the conditions for the reinstatement of the certification and the deadline within which they must be implemented.

The suspension of the validity of the certification may be publicly announced by RINA.

During the suspension, the Organization may not use the RINA certification (Certificate number, RINA identifier, etc.).

### *6.2 - REINSTATEMENT*

The reinstatement of the certification is subject to the verification of the elimination of the deficiencies that had caused the suspension itself through an in-depth visit that verifies the compliance of the Fabrication control plan system with all the requirements of the reference standards

It shall be notified in writing by registered letter to the Organization and made publicly known by RINA if the notice of the suspension had been made public at the time.

### *6.3 - REVOCATION*

Failure to meet the conditions set out in 6.2 within the prescribed period will result in the revocation of the certification.

The revocation of the Certificate can also be decided in the following cases:

- when circumstances arise, such as those mentioned in 6.1 for suspension, which are judged to be particularly serious;
- at the formal request of the Organization, including in the event that the Organization itself is unwilling or unable to comply with the new provisions issued by RINA (See Chapter 6);
- if the Organization suspends the supply of the product covered by the certified Fabrication control plan system for a period generally exceeding six months;

- for persistent payments in arrears for RINA services;
- if the Organization does not accept the new economic conditions established by RINA for any modification of the contract;
- for any other serious reason, in the opinion of RINA.

The revocation of the certification shall be notified in writing by registered letter to the Organization. The revocation is publicly announced by RINA.

The Organization whose certification is revoked must return the relevant Certificate to RINA and may not use the RINA certification (Certificate number, RINA identifier, etc.).

The Organization that intends to access the certification again after revocation must submit a new application following the entire process.

## Chapter 7. WAIVER OF CERTIFICATION

### *7.1 - MANUFACTURER'S WAIVER*

The Organization may submit to RINA a request for waiver of certification for some or all of the products for which it had obtained certification, due for example to the cessation of their production.

In this case, the Organization will return the relevant Certificate.

Upon receipt of the waiver request, RINA shall also prescribe to the Organization, if applicable , any actions that it must take for the products already manufactured.

The Organization, from the date of request for withdrawal, may not use the RINA certification (Certificate number, RINA identifier, etc.).

## Chapter 8. PUBLICATION BY RINA

### *8.1 - PREPARATION AND KEEPING OF LISTS*

RINA issues and keeps updated the list of Organizations that have obtained the certification of factory production control.

Information on the validity of the Certificate is given in the aforementioned list.

This list normally contains:

- name and address of the Organization or its designated authorized representative in the European Union and place of production;
- description of the product (type, identification, use, etc.);
- standards with which the product complies;
- identification number and status of the Certificate (valid, waived, suspended, revoked);
- date of first certification.
- Certificate expiration date

## Chapter 9. TRANSFER OF THE CERTIFICATE

If an Organization with certification currently in force issued by another PED competent body requests for transfer of certificate, RINA carries out a check that includes:
• document analysis as reported in Chapter 1;
•review of the reports of previous audits (including test reports on the product subject to certification, where applicable) conducted by the competent body that issued the previous certification;
•assessment audit at the Organization, whose extent of extension depends on the status of conformity and validity of the certification previously issued.

The Organization must also communicate to RINA:
•the reasons for the request for transfer of the certification;
•any claim, comments or remarks received from the national authorities in charge;
•any complaints received and related actions taken,
•on site audit for specific schemes (i.e. ISO 9001).

The contract between RINA and the applicant is managed in the same way as described in these Chapters.
Upon completion with a favorable outcome of the above mentioned activity, a "CERTIFICATE

OF QUALITY SYSTEM ASSESSMENT FOR MATERIAL PRODUCTION" is issued for the Product in question which, as general rule, maintains the deadline already established by the competent body that issued the previous certification (unless otherwise indicated in the Contract and/or applicable technical specification).

## Chapter 10. APPEALS AND COMPLAINTS

The Organization can appeal against RINA's decisions by explaining the reasons for dissent, within 30 days from the date of notification of the decision. The procedures to be followed for submitting appeals and complaints are described at www.rina.org by following the link found on the page dedicated to the PED Directive.

## Chapter 11. ADVERTISING

### *11.1 - CERTIFICATION PUBLICITY.*

The Organization may disclose in the most appropriate ways that it has obtained certification from RINA.

The Organization must in any case clearly indicate any limitations and conditions imposed by RINA at the time of issuing the aforementioned certification.

The Organization may reproduce the Certificate in its entirety, enlarging or reducing it, provided that it remains legible and is not altered in any way.it, provided that it remains legible and is not altered in any way.

## Chapter 12. CONTRACTUAL CONDITIONS

The provisions contained in the RINA Regulation "General Terms and Conditions for Conformity Assessment Activities", in the current edition, apply to the contractual conditions.

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