



Rules for conformity assessment of pressure equipment in compliance with the Pressure Equipment Directive 2014/68/EU

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Technical regulations

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CHAPTER 1. GENERAL

1.1

These Rules describe the procedures that RINA applies for conformity assessment of pressure equipment according to the provisions of European Directive 2014/68/EU concerning pressure equipment (hereinafter "Pressure Equipment Directive" or "Directive" or "PED") and what Organisations need to do to apply for, obtain and maintain that certification.

1.2

Certification is open to all Organisations and does not depend on whether they belong to an association or group. RINA will apply its current certification rates and guarantees that it will be applied fairly and consistently.

1.3

Certification issued by RINA refers to the pressure equipment indicated in the certificate and manufactured by the applicant Organisation, where Organisation means a public or private company, enterprise, business, body or association, whether legally recognised or not, with its own functions and administration, or a natural person. For Organisations with more than one operating unit, a single operating unit can be defined as an Organisation.

1.4

Any information acquired during certification activities shall be considered confidential and handled as such.

1.5

The terms used in these Regulations are the same as the definitions given in the Pressure Equipment Directive.

1.6

The RINA identification number to include on the data plates of the pressure equipment covered by RINA certification is **0474**.

This number shall be given in accordance with the Pressure Equipment Directive provisions.

CHAPTER 2. REFERENCE LEGISLATION

2.1

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 are considered applicable even if not explicitly stated in this document.

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

CHAPTER 3. ISSUE OF CERTIFICATION

3.1

Organisations wishing to obtain the aforesaid certification for pressure equipment they intend to market shall send a specific application through fax, ordinary mail or email, containing the necessary information according to the applicable requirements of the Directive to formulate the proposal of services, such as:

- a. name and address of the Organisation;
- b. Description of pressure equipment, including sketches, drawings, maximum allowable pressure (PS), maximum and minimum allowable temperature (TS_{max}, TS_{min}), Volume (V) or DN, fluids contained and relevant group and physical state as specified in article 13 of the Directive;
- c. Assessment Module for conformity selected and category of pressure equipment;
- d. In the case of quality Modules (D, D1, E, E1, H, H1), indication of the presence of an ISO9001 certified quality management system (QMS), qualified processes and number of operators (employee, externals, outsourced);
- e. Number of items to be manufactured and for mass production, estimated number of pressure equipment manufactured per year;
- f. Standards used for the design, construction and inspection of the pressure equipment;
- g. Any eventual consulting company or self-employed professional that any technical activity has been outsourced to (drafting of technical file, design, manufacturing, inspection).

RINA performs a preliminary examination to verify that all needed information are provided to

formulate a proposal for services; RINA reserves the right to request further details, also if necessary with reference to the contents of the annexes to these Rules.

RINA formulates an economical proposal of services based on these information; said proposal will then be sent together with these Rules and with the 'Application for conformity assessment of pressure equipment' form.

3.2

Upon receipt of the filled 'Application for conformity assessment of pressure equipment' form with acceptance of the proposal for service issued, RINA will have five working days to produce comments on the application, or to reject it; if no communication is received within that time, the application is considered accepted and the activities carried out by RINA according to these Rules shall be considered as contractually formalised.

The 'Application for conformity assessment of pressure equipment' form, completed by the Organisation and its acceptance by RINA contractually formalise the activities performed by RINA according to these regulations.

RINA requires - for examination - the documents listed in the annexes to these Rules and applicable according to the module or combination of modules selected.

The organization shall identify (e.g. document and revision number) any document of the technical file.

RINA will notify the Organisation the name of person in charge of the job, and that person will then notify the Organisation of the name(s) of the technician(s) who will be visiting the workshop and/or worksite; the Organisation may object to the appointment of said technician(s) explaining its reasons for this.

3.3

In case of QMS conformity assessments (Modules D, D1, E, E1, H, H1), RINA will visit the Organisation to make an assessment, after notifying it the names of the audit team in charge for carrying out the assessment, to verify correct application of all applicable procedures relating to the design, construction and control of the pressure equipment that is the object of the application for assessment.

The Organisation may object to the appointment of the above persons, explaining its reasons for this.

QMS certified to ISO 9001 by an accredited Certification Body is deemed essential for Organizations applying to PED certification according to modules D, D1, E, E1, H, H1. If not, this will be evaluated on a case by case basis.

The audit consists of:

- an initial meeting with the Organisation to agree to the modalities of the actual audit;
- examination of the quality management documents relevant for PED purposes (alternatively, this examination can be made beforehand);
- an inspection of the offices, production site(s) and, where necessary of the site(s) where raw materials are collected/stored, along with the lab(s) to assess conformity of the factory production control system with the applicable reference standards;
- a closing meeting to share the outcome of the audit.

The RINA audit team makes sure the Organisation's QMS is adequate for the purposes of compliance with all the applicable essential safety requirements set forth in annex I of the Pressure Equipment Directive and, in the event of shortcomings or differences from the statements made in the system documents, will notify the Organisation of one or more findings.

During the audit, apart from demonstrating that they possess the relevant reference standards, the Organisation shall also demonstrate that the QMS has been fully operational for at least three months and that they effectively applies the system and corresponding documented procedures.

For this purpose, also during the surveillance audits (specified below), RINA technicians are to be guaranteed free access to the manufacturing sites, to personnel and to the documents, in addition to the necessary assistance by the responsible people assigned to the audit.

3.4

At the end of the visit, the Organisation is given an audit report containing any finding identified as well as any proposed recommendation.

The Organisation may indicate any reservations or observations concerning the findings of the

RINA technician(s) in the relevant field of the audit report.

The content of the report is 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 nonconformities contained in the above report, the Organisation shall propose the necessary corrective action to RINA by the date indicated in the report, as well as the expected deadline required for their implementation.

RINA will send written acceptance of the proposals and of the relative implementation deadlines to the Organisation.

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.

If the above period is exceeded, the QMS will be completely re-examined 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 time spent and expenses incurred up to that moment. In that case, if the Organisation wishes to proceed with RINA certification, it shall submit a new application and repeat the certification procedure.

In any case, if A-type findings are not closed within twelve months from the assessment audit, the Notified Body shall definitely refuse the certification request.

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

3.5

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-respect of one or more of the Directive essential safety requirements or requirements of the reference standards;
- a situation that may determine the delivery of a non-conforming product or one that does not comply with current law in the Member State where the product is placed on the market.
- non-compliance with one or more requirements of these regulations;
- a situation that is likely to cause a failure in the QMS or reduce its ability to assure control of marked products.

(b) B-type findings (secondary shortcomings or minor non-conformities):

- a condition that, in the RINA auditing team's opinion and experience, is not likely to cause a failure in the operation of the QMS and does not reduce its ability to guarantee product control.

(c) C-type findings (recommendations, observations):

- suggestions made with a view to improving the system that do not directly pertain to the requirements of the reference standards applicable to the product.

3.6

The inspection of the products provided for the pressure equipment shall be carried out in the presence of RINA inspectors, based on the requirements of the applicable assessment procedures (modules) described in the Annexes to this Rules.

The instruments needed to perform the tests (eg. dimensional measurements, nondestructive testing, hydrostatic test) are made available by the applicant Organizations.

The instruments shall be adequate to the test required and calibrated in accordance with the internal procedures of Organizations, based on the criticality of the measurement to be taken.

Instruments used for the hydrostatic test (pressure gauges) calibration is always required and shall be made in one of the following ways:

- a. calibration within the Organization, or

- b. by a laboratory accredited by a body signatory to the ILAC or EA Mutual Recognition Agreement, or
- c. by calibration centers qualified by the manufacturer, that possess the necessary expertise based on the requirements of UNI EN ISO / IEC 17025: 2005; in this case, it shall be guaranteed the metrological traceability to primary instruments with valid calibration certificates issued by laboratories accredited by a body signatory to the ILAC or EA Mutual Recognition

The instruments shall meet the following acceptability criteria:

- min. full scale 1.5 times and max. full scale 4 times the value to be measured;
- accuracy class ≤ 2.5 on the measured value (specified in the instrument calibration report);
- the last calibration of the instrument has to be done within 12 months.

In the case of calibration carried out within the Organization (case a.), It shall be used as the reference sample, an instrument subject to calibration as shown in b. or c.

RINA inspectors verify the identification of the instruments and their calibration certificates with metrological traceability.

In case necessary instruments are not made available or not ensured their adequacy and calibration, the relevant tests are not considered valid for certification.

3.7

Normally, the hydrostatic test is performed after the completion of the design appraisal by RINA (where applicable). Where, upon preliminary agreement with RINA, the hydrostatic test should be carried out before the design appraisal is completed, such test would not be considered valid for the purposes of the certification process if, as a result of design appraisal, any comment would be identified by RINA about the need to change (increase) the test pressure or, in any case, if subsequent significant modifications to the equipment would be carried out. In all these cases, the hydrostatic test shall be repeated.

However the Organization shall provide necessarily the documentation in the last document revision in order to carry out the final inspection. In case such documentation has not

been delivered to the notified body in advance, upon agreement with notified body itself, this shall be handed over to the inspector who will send it to the competent RINA office.

3.8

Following the successful outcome of all examinations and tests set forth in the annexes to these regulations, applicable according to the module selected and specified in the proposal of services sent to, and accepted by the Organisation, RINA will issue the certificate/authorisation/approval according to the assessment module selected.

If the result of the assessment is negative (for instance, in case the safety essential requirements of the Directive and or requirements of the relevant standards are not met), RINA will notify the Organisation of the outcome and will agree to a possible reassessment under the same terms and conditions.

3.9

Rina provides evidences of the approval of welding personnel and procedures in accordance with Annex I para.3.1.2 of Directive 2014/68/EU (Rules RC/C.52), and of the approval of NDT personnel, as per para. 3.1.3 of Annex I to Directive 2014/68/EU (Rules RC/C.14), by issuing a specific certificate containing the identification number N.B. 0474.

CHAPTER 4. OF CERTIFICATION

4.1

The validity of the RINA certificate/authorisation/approval is established by the Directive or, where provision is not made in the Directive, authorisations or approvals relative to modules A2, C2, D, D1, E, E1, H, H1 when referring to mass productions are valid for three years. There is no limit to the validity of certificates or authorisations relative to modules A1, C1, F, G issued for individual items of pressure equipment. EU type-examination certificates (Module B) are valid for ten years and are renewable when they expire, such as EC design-examination certificates issued in accordance with Module H1 following the validity of the system certificate.

CHAPTER 5. EXTENSION OF CERTIFICATION

5.1

Authorisation or approval corresponding to modules A2, C2, D, D1, E, E1, H, H1 may be extended for a further three years, as long as the procedures set forth in these regulations are repeated.

CHAPTER 6. SUSPENSION, RESTORATION AND WITHDRAWAL OF CERTIFICATION

6.1

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

- tali da comportare il non soddisfacimento dei requisiti della direttiva e delle altre norme di riferimento;
- if, during the monitoring activity following the issue of the certificate, RINA finds that the pressure equipment or the assembly is no longer in compliance with the requirements of the Directive and other standards;
- if the organization has made major changes to the equipment or to the assembly certified without informing RINA or such that the relevant products fail to meet the requirements of the Directive and other standards;
- if the Organisation does not allow scheduled audits to be performed at the requested date;
- if non-conformities are found in the Quality Management 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/observations indicated on the audit report;
- if the Organisation has made significant modifications to its Quality Management System which have not been accepted by RINA;
- if the Organization refuses or hampers participation of accreditation body observers in audits;
- for evidence that the Quality Management System does not guarantee respect of the laws and regulations applicable to the activity and/or the site(s);

- if any justified and serious claims received by RINA are confirmed.

The Organisation may also make a justified request to RINA to suspend certification, normally for not more than six months and in no case after the certification expiry date.

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

RINA informs the Italian Administration about any suspension of validity of the certificates.

6.2

Restoration of the 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 product and of the Organization with all the requirements of the reference standard.

This is notified in writing to the Organisation and to the Italian Administration.

6.3

Failure to fulfil the conditions as per point 6.2 above by the established date shall lead to withdrawal of the Certificate of Conformity.

Withdrawal of the Certificate of Conformity may be decided as indicated in "GENERAL CONTRACT CONDITIONS GOVERNING SYSTEM, PRODUCT AND PERSONNEL CERTIFICATION" and in the following specific cases:

- when there are reasons such as those indicated in point 6.1 for suspension, which are considered to be particularly serious;
- if the Organisation stops the activities or services covered by the certified Quality Management System and/or of the pressure equipment conformity assessment for over six months as a rule;
- if the Organisation does not accept the new economic conditions established by RINA through an amendment to the contract;
- for any other reason that RINA deems to be serious, including but not limited to the proven failure of the system to pursue its objectives in compliance with legislative or contractual provisions or with product safety.

If the Certificate of Conformity is withdrawn, RINA takes the following measures:

- a. gives the Organisation written, detailed reasons explaining its decision to withdraw the certificate and indicates the possibility to appeal against that decision;
- b. if the appeal is unsuccessful, it directly informs the Italian Administration, providing the details of the withdrawn certificates;
- c. informs the technical secretariat of the forum of European notified bodies of pressure equipment of the data relevant to the withdrawn certificate.

Any Organisation which, following withdrawal of its Certificate, wishes to be re-certified, shall lodge a new application and follow the entire procedure set forth in these Rules all over again.

In case of revocation or suspension of the Certificate of Conformity, starting from the date of the intervention of the same, the organization will have to suspend the marketing of the products marked according to the same, including any stock.

CHAPTER 7. LIST OF CERTIFICATIONS ISSUED

7.1

RINA make available to the Italian Administration the list of the issued, suspended, withdrawn certificates.

Said list contains:

- the name and address of the Organisation;
- the certificate/authorisation/approval number;
- a description of the certified pressure equipment
- the date of issue of the certificate/authorisation/approval;
- the expiry date of the certificate/authorisation/approval;

RINA may also provide the above data to:

- The Italian accreditation body;
- Federations of Certification Bodies that RINA is a member of;
- other Notified Bodies.

CHAPTER 8. TRANSFERRING THE CERTIFICATE

8.1

If the company name changes, the Organisation shall 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 check of the above documents, RINA issues a new Certificate of Conformity, which cancels and replaces the previous one.

CHAPTER 9. APPEALS

9.1

The Organisation may appeal against decisions made by RINA by expressing the reasons for its dissent within 30 days from the date of notification of the decision. Appeals will be notified to RINA as per procedure described at www.rina.org.

9.2

RINA will examine the appeal within two months from the time it is submitted, possibly consulting the Organisation's representatives.

9.3

The Organisation shall bear the cost of all expenses incurred by the appeal, unless it is found to be legitimate.

CHAPTER 10. WAIVER OF CERTIFICATION

A certified Organisation may send formal communication of waiver of certification to RINA, before the expiry of the certificate, including for cases whereby the Organisation does not wish to – or cannot – conform to new provisions established by RINA.

Upon receipt of this communication, RINA initiates the procedure to invalidate the certificate.

Generally, RINA updates the validity status of the certificate within one month from the date of the communication.

CHAPTER 11. CONTRACT CONDITIONS

11.1



For contract conditions, the contents of the current edition of RINA "GENERAL CONTRACT CONDITIONS GOVERNING SYSTEM, PRODUCT AND PERSONNEL CERTIFICATION" apply.

ANNEX 1 MODULE A2 (INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRESSURE EQUIPMENT CHECKS AT RANDOM INTERVALS INTERNAL MANUFACTURING CHECKS WITH MONITORING OF THE FINAL ASSESSMENT)

This module may be used for category II pressure equipment or, if the manufacturer decides, for pressure equipment falling within risk category I.

The manufacturer shall send a CE marking authorisation application, following the procedures described in module A2 of the Pressure Equipment Directive and for each individual item of pressure equipment intended for CE marking, the manufacturer shall include the following documents:

- a) a general description of the pressure equipment;
- b) conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment;
- c) risk assessment
- d) a list of the standards applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the Directive where the harmonised standards have not been applied;
- e) copy of the specifications and the reports qualifying the permanent joints (e.g. as regards WPS and WPQR) issued by Notified Body or Third Party Body
- f) certificates qualifying personnel/operators undertaking the permanent joining of parts, issued by Notified Body or by Third Party Body.

RINA examines the documents produced and may make a preliminary visit to the manufacturer to verify the methods used to execute the final assessment. If the outcome of this visit is positive, RINA issues authorisation for CE marking.

RINA approves the permanent joint operating procedures and personnel, in accordance with the provisions set forth in point 3.1.2 of annex I of the Pressure Equipment Directive.

The manufacturer carries out the final assessment of the pressure equipment under RINA's control, through unexpected inspections.

During the scheduled and the unexpected visits, the manufacturer shall provide RINA with the following documents:

- results of design calculations made, examinations carried out, etc. for experimental designs;
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment;
- list of materials used, with name of harmonised standard reference, or Particular Material Approval (PMA) issued by manufacturer or European Material Approval (EMA);
- certificates of the base and of the filler materials;
- traceability procedures;
- copy of the specifications and the reports qualifying the permanent joints (e.g. WPS and WPAR) issued by Notified Body or Third Party Body;
- heat treatment procedures;
- heat treatment diagrams;
- reports of non-destructive tests;
- reports of any destructive tests carried out (e.g. face bend and root bend welding tests);
- copy of certificates qualifying personnel undertaking non-destructive tests;
- certificates qualifying personnel/operators undertaking the permanent joining of parts, issued by Notified Body or by Third Party Body and relevant RINA approval;
- non-conformity reports issued in production and relevant corrective actions;
- operating instructions (installing and putting into service, use and maintenance, limits of use, residual risks connected to use, identification of replaceable parts, documents necessary for a full understanding of these instructions)
- declaration of conformity (ref. Article 17 of directive 2014/68/EU).

During these inspections, RINA ascertains that the manufacturer actually performs the final assessment required by the Directive (Annex I, par. 3.2) and shall take a sample of pressure equipment from the manufacturing or storage premises in order to perform, or have performed, all or part of the final assessment of the pressure equipment samples.

RINA also verifies that the CE marking is correctly affixed.

The frequency of the visits made by RINA shall be defined according to the average annual number of pressure equipment items manufactured, to the number of equipment types to certify and to the group of fluids contained.

Since these are unexpected visits, the manufacturer will communicate the intended schedule of production to RINA, so that visits can be made during final product assessment or in any case when product items are available for RINA

inspections, such as hydrostatic pressure tests, visual inspections and dimensional checks, non-destructive tests on permanent joints, examination of test reports.

If shortcomings to the final assessment system should emerge during these unexpected visits, RINA reserves the right to make other unexpected visits to verify whether the Organisation has remedied these non-conformities.

Under the responsibility of RINA, the manufacturer shall affix the CE marking on each item of pressure equipment, indicating the identification number of RINA.

ANNEX 2 MODULE B (EU TYPE-EXAMINATION)

EU-Type examination – production type

EU-type examination — production type is the part of a conformity assessment procedure in which RINA examines the technical design of the pressure equipment and verifies and attests that the technical design of the pressure equipment meets the requirements of the Directive.

EU-type examination — production type shall consist of an assessment of the adequacy of the technical design of the pressure equipment through examination of the technical documentation and supporting evidence referred to below, plus examination of a specimen, representative of the production envisaged, of the complete pressure equipment.

The manufacturer shall lodge an application for EU type-examination, following the procedures described in module B of the Pressure Equipment Directive and for each “type”, the manufacturer shall include the following documents:

- a) a general description of the pressure equipment;
- b) conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment;
- c) risk assessment;
- d) a list of the standards applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the Directive where the harmonised standards have not been applied;
- e) results of design calculations made, and plan of tests required in any experimental design procedures, describing the relevant acceptability limits for those tests;
- f) list of materials used, with name of harmonised standard reference, or European Material Approval (EMA);
- g) copy of the specifications and the reports qualifying the permanent joints (e.g. WPS and WPAR) issued by Notified Body or Third Party Body;
- h) certificates qualifying personnel/operators undertaking the permanent joining of parts, issued by Notified Body or by Third Party Body;
- i) copy of certificates qualifying personnel undertaking non-destructive tests;
- j) manufacturing quality control plan (inspection plan);
- k) non-destructive test procedures;
- l) heat treatment procedures;
- m) drawing of the plate;
- n) operating instructions (installing and putting into service, use and maintenance, limits of use, remaining risks connected to use, identification of replaceable parts, documents necessary for a full understanding of these instructions).

The manufacturer shall provide one or more representative examples of the production, hereinafter called “type”. One type may cover several variations of an item of pressure equipment under the condition that the differences between the variations have no effect on the level of safety.

Following this, RINA shall:

- examine and approve the documentation, send any comments, perform any assessments required;
- assess the materials used in relation to the function for which they are intended and to the compatibility with adjoining materials; where these are not in conformity with the relevant harmonized standards or with a European approval for pressure equipment materials, it shall issue a Particular Material Approval (PMA-PED form); it shall also check the certificates issued by the material manufacturer in accordance with section 4.3 of Annex I of the Directive,
- check that the type has been manufactured according to the documents submitted, establishing which elements are designed in conformity with the harmonised standards and which elements are designed in conformity with other standards of reference;
- approve the procedures for the permanent joining of pressure equipment parts, or check that they have been previously approved by a Notified Body or recognised third party, in accordance with section 3.1.2 of Annex I of the Directive;
- verify that the personnel undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved by a Notified Body or recognised third party, in accordance with sections 3.1.2 and 3.1.3 of Annex I of the Directive;
- perform the appropriate examinations and necessary tests to establish whether the solutions adopted by the manufacturer meet the essential safety requirements listed in Annex I of the Directive and issue a test performance report.

RINA will agree with the manufacturer the location where the examinations and tests are to be carried out.

Where the type meets the provisions of the Directive, RINA will issue an EU type-examination certificate to the manufacturer. The certificate will contain the name and address of the manufacturer, the conclusions of the examination and the necessary data for identification of the approved type. A list of the relevant parts of the technical documentation is annexed to the certificate and a copy kept by the RINA.

The manufacturer to which RINA issued the EU type-examination certificate shall inform RINA of all modifications to the approved pressure equipment; these are subject to additional approval where they may affect conformity with the essential requirements or the prescribed conditions for use of the pressure equipment. This additional approval shall be given in the form of a revision or an addition to the original EU type-examination certificate.

RINA shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, RINA shall inform the manufacturer accordingly.

EU-Type examination – design type

EU-type examination – design type is the part of a conformity assessment procedure in which RINA examines the technical design of the pressure equipment and verifies and attests that the technical design of the pressure equipment meets the requirements of this Directive.

The EU-type examination – design type shall consist of an assessment of the adequacy of the technical design of the pressure equipment through examination of the technical documentation and supporting evidence referred to below, without examination of a specimen.

The experimental design method provided for in point 2.2.4 of Annex I shall not be used in the context of this module.

The manufacturer shall lodge an application for EC design-examination of pressure equipment, following the procedures described in module B of the Pressure Equipment Directive and shall include the following documents:

- a) a general description of the pressure equipment;
- b) conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment;
- c) risk assessment;
- d) a list of the standards applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the Directive where the harmonised standards have not been applied;
- e) results of design calculations made and examinations carried out;
- f) list of materials used, with name of harmonised standard reference, or European Material Approval (EMA);
- g) copy of the specifications and the reports qualifying the permanent joints (e.g. WPS and WPAR) issued by Notified Body or Third Party Body;
- h) certificates qualifying personnel/operators undertaking the permanent joining of parts, issued by Notified Body or by Third Party Body;
- i) non-destructive test procedures;
- j) heat treatment procedures;
- k) copy of certificates qualifying personnel undertaking non-destructive tests approved by Third Party Body;
- l) drawing of plate
- m) operating instructions (installing and putting into service, use and maintenance, limits of use, remaining risks connected to use, identification of replaceable parts, documents necessary for a full understanding of these instructions).

Following this, RINA shall:

- examine and approve the documentation, perform any assessments required and send any comments;
- assess the materials used in relation to the function for which they are intended and to the compatibility with adjoining materials; where these are not in conformity with the relevant harmonized standards or with a European approval for pressure equipment materials, it shall issue a Particular Material Approval (PMA-PED form);
- perform the appropriate examinations to establish whether the solutions adopted by the manufacturer meet the essential safety requirements listed in Annex I of the Directive;
- perform the necessary examinations to establish whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied;
- approve the procedures for the permanent joining of pressure equipment parts, or check that they have been previously approved by a Notified Body or recognised third party, in accordance with section 3.1.2 of Annex I of the Directive;
- verify that the personnel undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved by a Notified Body or recognised third party, in accordance with sections 3.1.2 and 3.1.3 of Annex I of the Directive;

Where the design meets the provisions of the Directive, RINA will issue an EU type-examination certificate to the manufacturer. The certificate will contain the name and address of the manufacturer, the conclusions of the examination, conditions for its validity and the necessary data for identification of the approved design. A list of the relevant parts of the technical documentation is annexed to the certificate and a copy kept by the RINA.



The manufacturer to which RINA issued the EU type-examination certificate shall inform RINA of all modifications to the approved design; these are subject to additional assessment and approval where such changes may affect the conformity of the pressure equipment with the essential requirements of the Directive or the prescribed conditions for use of the pressure equipment. This additional approval shall be given in the form of a revision or an addition to the original EU type-examination certificate.

RINA shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, RINA shall inform the manufacturer accordingly.

ANNEX 3 MODULE C2 (CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRESSURE EQUIPMENT CHECKS AT RANDOM INTERVALS)

Within the context of this procedure, the manufacturer establishes and declares that the pressure equipment is in conformity with the type as described in the EU type-examination certificate and meets the requirements of the Directive.

This module may be used for category III pressure equipment or, if the manufacturer decides, for pressure equipment falling within risk category I or II.

The manufacturer shall send a CE marking authorisation application, following the procedures described in module C2 of the Pressure Equipment Directive and for each individual item of pressure equipment intended for CE marking, the manufacturer shall include the following documents:

- a) a general description of the pressure equipment;
- b) conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment;
- c) a list of the standards applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the Directive where the harmonised standards have not been applied;
- d) copy of the specifications and the reports qualifying the permanent joints (e.g. as regards WPS and WPAR welding) issued by Notified Body or Third Party Body;
- e) certificates qualifying personnel/operators undertaking the permanent joining of parts, issued by Notified Body or by Third Party Body;
- f) a copy of the EU type-examination certificate issued by a Notified Body.

RINA examines the documents produced and makes a preliminary visit to the manufacturer to verify the methods used to execute the final assessment; if the outcome of this visit is positive, RINA issues authorisation for CE marking.

The manufacturer carries out the final assessment of the pressure equipment under RINA's control, through unexpected inspections.

During the scheduled visits and the unexpected visits, the manufacturer shall provide RINA with the following documents:

- proof of EU-type examination certificate (Module B);
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment;
- list of materials used, with name of harmonised standard reference, or Particular Material Approval (PMA) issued by manufacturer or European Material Approval (EMA);
- certificates of origin of the basic materials and of the filler materials;
- traceability procedures;
- a copy of the specifications and the reports qualifying the permanent joints (e.g. as regards WPS and WPAR welding) issued by Notified Body or Third Party Body and approved by RINA;
- heat treatment procedures;
- heat treatment diagrams;
- reports of non-destructive tests carried out;
- reports of any destructive tests carried out (e.g. face bend and root bend welding tests);
- a copy of certificates qualifying personnel undertaking non-destructive tests approved by Third Party Body;
- certificates qualifying personnel/operators undertaking the permanent joining of parts, issued by Notified Body or by Third Party Body and approved by RINA;
- non-conformity reports issued in production and corresponding resolutions;
- operating instructions (installing and putting into service, use and maintenance, limits of use, remaining risks connected to use, identification of replaceable parts, documents necessary for a full understanding of these instructions);
- declaration of conformity (ref. Article 17 of directive 2014/68/EU).

During these inspections, RINA ascertains that the manufacturer actually performs the final assessment required by the Directive (Annex I, par. 3.2) and shall take a sample of pressure equipment from the manufacturing or storage premises in order to perform, or have performed, all or part of the final assessment of the pressure equipment samples; RINA will also ascertain that the CE marking is affixed correctly.

The frequency of the visits made by RINA shall be defined according to the average annual number of pressure equipment items manufactured, to the number of equipment types to certify and to the group of fluids contained.

Since these are unexpected visits, the manufacturer will communicate the intended schedule of production to RINA, so that visits can be made during final product assessment or in any case when product items are available for RINA inspections, for example during hydrostatic pressure tests, visual inspections and dimensional checks, non-destructive tests on permanent joints, examination of reports of tests performed.



If shortcomings to the final assessment system should emerge during these unexpected visits, RINA reserves the right to make other unexpected visits to verify whether the Organisation has remedied these non-conformities.

On the responsibility of RINA, the manufacturer shall affix the CE marking on each item of pressure equipment, indicating the identification number of RINA.

ANNEX 4 MODULE D (CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS)

Within the context of this procedure, the manufacturer shall adopt an approved Quality System for production, final inspection and testing as specified in "Quality System" and be subject to surveillance by RINA as specified in "Surveillance".

The manufacturer establishes and declares that the pressure equipment is in conformity with the type as described in the EU type-examination certificate and meets the requirements of the Directive.

The manufacturer shall affix the CE marking to each item of pressure equipment, indicating the identification number of RINA and draw up a Declaration of Conformity (ref. Article 17 of directive 2014/68/EU).

Quality system

The manufacturer shall lodge an application for assessment of his Quality System for the products concerned, in accordance with the procedures described in module D of the Pressure Equipment Directive and shall include the following documents:

- a) a general description of the pressure equipment;
- b) a copy of the quality documentation relevant for the purposes of the pressure equipment (this documentation is listed below and alternatively may be acquired and examined by RINA during the audit);
- c) a copy of the EU type-examination certificate or EC design-examination certificate (unless the assessment according to Module D is carried out at the same time as the EU type examination or EC design examination) and the corresponding technical documentation;
- d) a copy of ISO9001 certification.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This Quality System documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

The Quality System documentation shall contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment;
- the manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with section 3.1.2 of Annex I of the Directive;
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the joining of parts and the non-destructive tests in accordance with sections 3.1.2 and 3.1.3 of Annex I of the Directive;
- the means of monitoring the achievement of the required quality and the effective operation of the Quality System.

The Quality System shall guarantee conformity of the pressure equipment with the type as described in the EU type-examination certificate and with the requirements of the Directive.

It is essential for the manufacturer to have its own Quality System certified by an accredited body to UNI EN ISO 9001; cases other than these will be assessed individually.

When the manufacturer is sure that the documentation of its management Quality System is in line with the PED, it can request RINA to carry out the audit.

During the audit for first certification, RINA will assess the fundamental points of the Quality System in terms of what is required by the pressure equipment certificate, using an appropriate checklist; it will also assess the Quality System overall if this has been certified by a different body from RINA. At the end of the audit, RINA will issue a copy of the audit report.

The auditing team shall have at least one member with experience of assessing the pressure equipment production technology concerned. The assessment will include an inspection visit to the manufacturer's premises.

If the outcome of assessment activities is positive, in other words if not serious (type B) findings or simple recommendations emerge, RINA issues a Quality System Certificate of Conformity attesting to conformity with the requirements of Module D (production quality assurance) of the Directive. RINA will make another visit to verify that the changes agreed during the audit have been put into place within the agreed time.

If serious findings emerge or if the number of not serious findings prejudices compliance with the essential safety requirements, RINA will carry out a reassessment within the deadline indicated on the audit report (which allows the manufacturer to take action on its Quality System, integrating the changes required) and will not issue any Certificate of Conformity.

After the second audit is carried out, if the result is positive or falls within the limits above, RINA will issue the Certificate of Conformity.

The Quality System Certificate of Conformity is valid for three years.

If the second audit is not successful, RINA will inform the other notified bodies that it has denied certification of conformity.

The manufacturer undertakes to fulfil the obligations arising out of the Quality System as approved and to ensure that it remains satisfactory and efficient.

The manufacturer shall inform RINA of any intended adjustment to the Quality System.

RINA shall assess the proposed changes and decide whether the amended Quality System will still meet the requirements referred to above or whether a reassessment is required.

RINA shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance

The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved Quality System.

RINA carries out the Quality System surveillance by implementing a time schedule that includes a maintenance visit at the end of the first year, a maintenance visit at the end of the second year and a series of unexpected visits established on the basis of the criteria described below; product specialists will carry out the visits.

During each of the maintenance visits, RINA will carry out a complete review of the management Quality System or apply a review programme that leads to a full reassessment of the management Quality System during the two visits.

During the first year of production there shall be at least two unexpected visits for equipments categories III and IV cited at article 4, par. 1, comma a), point i), article 4, par. 1, comma a), point ii), first indent, and article 4, par. 1, comma b) (one of which may be carried out at the same time as the audit). For all other pressure equipments, and in general for all subsequent visits, the frequency of the unexpected visits and any general increase in their number is determined on the basis of the following criteria:

- ▶ the category of the equipment;
- ▶ the results of previous surveillance visits;
- ▶ the need to ensure implementation of the corrective actions;
- ▶ special conditions linked to the approval of the system, where applicable;
- ▶ significant changes in manufacturing organisation, policy or techniques.

Since these are unexpected visits, the manufacturer will communicate the intended schedule of production to RINA, so that visits can be made during final product assessment or in any case when product items are available for RINA inspections, for example during hydrostatic pressure tests, visual inspections and dimensional checks, non-destructive tests on permanent joints, examination of reports of tests performed.

During the scheduled visits and the unexpected visits, the manufacturer shall provide RINA with the following documents:

- the documentation relating to the Quality System;
- the internal inspection reports;
- results of design calculations made, examinations carried out, etc. for experimental designs;
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment;
- list of materials used, with name of harmonised standard reference, or Particular Material Approval (PMA) issued by the Notified Body that approved the type of pressure equipment or European Material Approval (EMA);
- certificates of origin of the basic materials and of the filler materials;
- traceability procedures;
- a copy of the specifications and the reports qualifying the permanent joints (e.g. as regards WPS and WPAR welding) issued by Notified Body or Third Party Body and approved by the Notified Body that issued the EU-type examination certificate;
- heat treatment procedures;
- heat treatment diagrams;
- reports of non-destructive tests carried out;
- reports of any destructive tests carried out (e.g. face bend and root bend welding tests);
- a copy of certificates qualifying personnel undertaking non-destructive tests approved by Third Party Body;
- certificates qualifying personnel/operators undertaking the permanent joining of parts, issued by Notified Body or by Third Party Body and approved by the Notified Body that issued the EU-type examination certificate;
- calibration certificates of test equipment;
- non-conformity reports issued in production and corresponding resolutions;

- operating instructions (installing and putting into service, use and maintenance, limits of use, remaining risks connected to use, identification of replaceable parts, documents necessary for a full understanding of these instructions);
- declaration of conformity (ref. Article 17 of directive 2014/68/EU).

During these inspections, RINA ascertains that the manufacturer actually performs the final assessment required by the Directive (Annex I, par. 3.2) and shall take a sample of pressure equipment from the manufacturing or storage premises in order to perform, or have performed, all or part of the final assessment of the pressure equipment samples.

RINA also establishes that the CE marking is correctly affixed.

When the result of these activities is positive, RINA issues a final assessment report.

The possible presence of high findings during surveillance visits or unannounced visits is managed by RINA as follows: In the presence of major non-conformities or other findings, whose number in the opinion of the evaluation group is such as to prejudice the manufacturing process, the Organization is subjected to an additional verification within the time established by RINA, in relation to the type of non-conformities themselves and, in any case, no later than three months from the end of the surveillance visit aimed at verifying the effectiveness of the corrections and corrective actions proposed.

If the non-conformities are not resolved within the established times 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 have been corrected. If the subsequent audit also had a negative outcome, RINA will proceed with the revocation of the Certificate of conformity.

When the certificate validity expires, the manufacturer shall send another application for assessment of its Quality System and RINA will make a thorough review of the whole management Quality System.

MODULE D1 (QUALITY ASSURANCE OF THE PRODUCTION PROCESS)

Within the context of this procedure, the manufacturer shall implement an approved Quality System for production, final inspection and testing of finished product as specified in "Quality System" and be subject to surveillance by RINA as specified in "Surveillance".

This module may be used for category II pressure equipment or, if the manufacturer decides, for pressure equipment falling within risk category I.

The manufacturer establishes and declares that the pressure equipment meets the requirements of the Directive.

The manufacturer shall affix the CE marking to each item of pressure equipment, indicating the identification number of RINA and draw up a Declaration of Conformity (ref. Article 17 of directive 2014/68/EU).

Quality system

The manufacturer shall lodge an application for assessment of his Quality System for the products concerned, in accordance with the procedures described in module D1 of the Pressure Equipment Directive and shall include the following documents:

- a) a general description of the pressure equipment with all useful technical information;
- b) conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment (this documentation is listed below and alternatively may be acquired and examined by RINA during the audit);
- c) results of design calculation made and a list of the standards applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the Directive where the harmonised standards have not been applied (this documentation is listed below and alternatively may be acquired and examined by RINA during the audit);
- d) a copy of the quality documentation relevant for the purposes of the pressure equipment (this documentation is listed below and alternatively may be acquired and examined by RINA during the audit);
- e) a copy of ISO9001 certification.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This Quality System documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

The Quality System documentation shall contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment;
- the manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with section 3.1.2 of Annex I of the Directive;

- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the joining of parts in accordance with section 3.1.2 of Annex I of the Directive;
- the means of monitoring the achievement of the required quality and the effective operation of the Quality System.

The Quality System shall ensure compliance of the pressure equipment with the requirements of the Directive.

It is essential for the manufacturer to have its own Quality System certified by an accredited body to UNI EN ISO 9001; cases other than these will be assessed individually.

When the manufacturer is sure that the documentation of his management Quality System is in line with the PED, it can request RINA to carry out the audit.

During the audit for first certification, RINA will assess the fundamental points of the Quality System in terms of what is required by the pressure equipment certificate, using an appropriate checklist; it will also assess the Quality System overall if this has been certified by a different body from RINA. At the end of the audit, RINA will issue a copy of the audit report.

The auditing team shall have at least one member with experience of assessing the pressure equipment production technology concerned. The assessment will include an inspection visit to the manufacturer's premises.

If the outcome of assessment activities is positive, in other words if not serious (type B) findings or simple recommendations emerge, RINA issues a Quality System Certificate of Conformity attesting to conformity with the requirements of Module D1 (production quality assurance) of the Directive. RINA will make another visit to verify that the changes agreed during the audit have been put into place within the agreed time.

If serious findings emerge or if the number of not serious findings prejudices compliance with the essential safety requirements, RINA will carry out a reassessment within the deadline indicated on the audit report (which allows the manufacturer to take action on its Quality System, integrating the changes required) and will not issue any Certificate of Conformity.

After the second audit is carried out, if the result is positive or falls within the limits above, RINA will issue the Certificate of Conformity.

The Quality System Certificate of Conformity is valid for three years.

If the second audit is not successful, RINA will inform the other notified bodies that it has denied certification of conformity.

The manufacturer undertakes to fulfil the obligations arising out of the Quality System as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorized representative established within the Community, shall inform the Notified Body that has approved the Quality System of any intended adjustment to the Quality System.

The Notified Body shall assess the proposed changes and decide whether the amended Quality System will still meet the requirements referred to above or whether a reassessment is required.

The Notified Body shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance

The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved Quality System.

RINA carries out the Quality System surveillance by implementing a time schedule that includes a maintenance visit at the end of the first year, a maintenance visit at the end of the second year and a series of unexpected visits established on the basis of criteria described below; product specialists will carry out the visits.

During each of the maintenance visits, RINA will carry out a complete review of the management Quality System or apply a review programme that leads to a full reassessment of the management Quality System during the two visits.

The frequency of the unexpected visits and any general increase in their number is determined on the basis of the following criteria:

- ▶ the category of the equipment;
- ▶ the results of previous surveillance visits;
- ▶ the need to ensure implementation of the corrective actions;
- ▶ special conditions linked to the approval of the system, where applicable;
- ▶ significant changes in manufacturing organisation, policy or techniques.

Since these are unexpected visits, the manufacturer will communicate the intended schedule of production to RINA, so that visits can be made during final product assessment or in any case when product items are available for RINA inspections, for example during hydrostatic pressure tests, visual inspections and dimensional checks, non-destructive tests on permanent joints, examination of reports of tests performed.

During the scheduled visits and the unexpected visits, the manufacturer shall provide RINA with the following documents:

- the documentation relating to the Quality System;
- the internal inspection reports;
- results of design calculations made, examinations carried out, etc. for experimental designs;
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment;
- list of materials used, with name of harmonised standard reference, or Particular Material Approval (PMA) issued by manufacturer or European Material Approval (EMA);
- certificates of origin of the basic materials and of the filler materials;
- traceability procedures;
- a copy of the specifications and the reports qualifying the permanent joints (e.g. as regards WPS and WPAR welding) issued by Notified Body or Third Party Body, approved by RINA;
- heat treatment procedures;
- heat treatment diagrams;
- reports of non-destructive tests carried out;
- reports of any destructive tests carried out (e.g. face bend and root bend welding tests)
- copy of certificates qualifying personnel undertaking non-destructive tests
- certificates qualifying personnel/operators undertaking the permanent joining of parts, issued by Notified Body or by Third Party Body and approved by RINA;
- calibration certificates of test equipment;
- non-conformity reports issued in production and corresponding resolutions;
- Operating instructions (installing and putting into service, use and maintenance, limits of use, remaining risks connected to use, identification of replaceable parts, documents necessary for a full understanding of these instructions);
- declaration of conformity (ref. Article 17 of directive 2014/68/EU).

During these inspections, RINA ascertains that the manufacturer actually performs the final assessment required by the Directive (Annex I, par. 3.2) and shall take a sample of pressure equipment from the manufacturing or storage premises in order to perform, or have performed, all or part of the final assessment of the pressure equipment samples.

RINA also establishes that the CE marking is correctly affixed.

When the result of these activities is positive, RINA issues a final assessment report.

The possible presence of high findings during surveillance visits or unannounced visits is managed by RINA as follows: In the presence of major non-conformities or other findings, whose number in the opinion of the evaluation group is such as to prejudice the manufacturing process, the Organization is subjected to an additional verification within the time established by RINA, in relation to the type of non-conformities themselves and, in any case, no later than three months from the end of the surveillance visit aimed at verifying the effectiveness of the corrections and corrective actions proposed.

If the non-conformities are not resolved within the established times 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 have been corrected. If the subsequent audit also had a negative outcome, RINA will proceed with the revocation of the Certificate of conformity.

When the certificate validity expires, the manufacturer shall send another application for assessment of its Quality System and RINA will make a thorough review of the whole management Quality System.

The manufacturer shall, for a period of ten years after the last of the pressure equipment has been manufactured, hold at the disposal of the national authorities:

- the documentation referred to from points a) to c) of the 'Quality System' section;
- the documentation referred to in point d) of the 'Quality System' section;
- the adjustments referred to in the Quality System;
- the decisions and reports from RINA and relative to the approval of the management Quality System, of the changes made and of the scheduled and unexpected visits made.

ANNEX 5 MODULE E (CONFORMITY TO TYPE BASED ON PRESSURE EQUIPMENT QUALITY ASSURANCE)

Within the context of this procedure, the manufacturer shall implement an approved Quality System for the final inspection and testing of the finished product as specified in "Quality System" and be subject to surveillance by RINA as specified in "Surveillance".

The manufacturer establishes and declares that the pressure equipment is in conformity with the type as described in the EU type-examination certificate and meets the requirements of the Directive.

The manufacturer shall affix the CE marking to each item of pressure equipment, indicating the identification number of RINA and draw up a Declaration of Conformity (ref. Article 17 of directive 2014/68/EU).

Quality system

The manufacturer shall lodge an application for assessment of his Quality System for the products concerned, in accordance with the procedures described in module E of the Pressure Equipment Directive and shall include the following documents:

- a) a general description of the pressure equipment;
- b) a copy of the quality documentation relevant for the purposes of the pressure equipment (this documentation is listed below and alternatively may be acquired and examined by RINA during the audit);
- c) a copy of the technical EU type-examination certificate (unless the assessment according to Module E is carried out at the same time as the EU type examination) and the corresponding technical documentation;
- d) a copy of ISO9001 certification.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This Quality System documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

The Quality System documentation shall contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment;
- the examinations and tests to be carried out after manufacture;
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the joining of parts and the non-destructive tests in accordance with sections 3.1.2 and 3.1.3 of Annex I of the Directive;
- the means of monitoring the effective operation of the Quality System.

The Quality System shall guarantee conformity of the pressure equipment with the type as described in the EU type-examination certificate and with the requirements of the Directive.

It is essential for the manufacturer to have its own Quality System certified by an accredited body to UNI EN ISO 9001; cases other than these will be assessed individually.

When the manufacturer is sure that the documentation of his management Quality System is in line with the PED, it can request RINA to carry out the audit.

During the audit for first certification, RINA will assess the fundamental points of the Quality System in terms of what is required by the pressure equipment certificate, using an appropriate checklist; it will also assess the Quality System overall if this has been certified by a different body from RINA. At the end of the audit, RINA will issue a copy of the audit report.

The auditing team shall have at least one member with experience of assessing the pressure equipment production technology concerned. The assessment will include an inspection visit to the manufacturer's premises.

If the outcome of assessment activities is positive, in other words if not serious (type B) findings or simple recommendations emerge, RINA issues a Quality System Certificate of Conformity attesting to conformity with the requirements of Module E (production quality assurance) of the Directive. RINA will make another visit to verify that the changes agreed during the audit have been put into place within the agreed time.

If serious findings emerge or if the number of not serious findings prejudices compliance with the essential safety requirements, RINA will carry out a reassessment within the deadline indicated on the audit report (which allows the manufacturer to take action on its Quality System, integrating the changes required) and will not issue any Certificate of Conformity.

After the second audit is carried out, if the result is positive or falls within the limits above, RINA will issue the Certificate of Conformity.

The Quality System Certificate of Conformity is valid for three years.

If the second audit is not successful, RINA will inform the other notified bodies that it has denied certification of conformity.

The manufacturer undertakes to fulfil the obligations arising out of the Quality System as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorized representative established within the Community, shall inform the Notified Body that has approved the Quality System of any intended adjustment to the Quality System.

The Notified Body shall assess the proposed changes and decide whether the amended Quality System will still meet the requirements referred to above or whether a reassessment is required.

The Notified Body shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance

The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved Quality System.

RINA carries out the Quality System surveillance by implementing a time schedule that includes a maintenance visit at the end of the first year, a maintenance visit at the end of the second year and a series of unexpected visits established on the basis of fixed criteria later on; product specialists will carry out the visits.

During each of the maintenance visits, RINA will carry out a complete review of the management Quality System or apply a review programme that leads to a full reassessment of the management Quality System during the two visits.

During the first year of production there shall be at least two unexpected visits for equipments categories III and IV cited at article 4, par.1, comma a), point i), article 4, par. 1, comma a), point ii), first indent, and article 4, par. 1, comma b) (one of which may be carried out at the same time as the audit). For all other pressure equipments, and in general for all subsequent visits, the frequency of the unexpected visits and any general increase in their number is determined on the basis of the following criteria:

- ▶ the category of the equipment;
- ▶ the results of previous surveillance visits;
- ▶ the need to ensure implementation of the corrective actions;
- ▶ special conditions linked to the approval of the system, where applicable;
- ▶ significant changes in manufacturing organisation, policy or techniques.

Since these are unexpected visits, the manufacturer will communicate the intended schedule of production to RINA, so that visits can be made during final product assessment or in any case when product items are available for RINA inspections, for example during hydrostatic pressure tests, visual inspections and dimensional checks, non-destructive tests on permanent joints, examination of reports of tests performed.

During the scheduled visits and the unexpected visits, the manufacturer shall provide RINA with the following documents:

- the documentation relating to the Quality System;
- the internal inspection reports;
- the technical documentation relative to the EC design-examination certificate and to the EU type-examination certificate (Module B-B1) issued by a Notified Body;
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment;
- list of materials used, with name of harmonised standard reference, or Particular Material Approval (PMA) issued by the Notified Body that approved the type of pressure equipment or European Material Approval (EMA);
- certificates of origin of the basic materials and of the filler materials;
- traceability procedures;
- a copy of the specifications and the reports qualifying the permanent joints (e.g. as regards WPS and WPAR welding) issued by Notified Body or Third Party Body and approved by the Notified Body that issued the EU-type examination certificate;
- heat treatment procedures;
- heat treatment diagrams;
- reports of non-destructive tests carried out;
- reports of any destructive tests carried out (e.g. face bend and root bend welding tests);
- a copy of certificates qualifying personnel undertaking non-destructive tests approved by Third Party Body;
- certificates qualifying personnel/operators undertaking the permanent joining of parts, issued by Notified Body or by Third Party Body and approved by the Notified Body that issued the EU-type examination certificate;
- calibration certificates of test equipment;
- non-conformity reports issued in production and corresponding resolutions;
- operating instructions (mounting and putting into service, use and maintenance, limits of use, remaining risks connected to use, identification of replaceable parts, documents necessary for a full understanding of these instructions);
- declaration of conformity (ref. Article 17 of directive 2014/68/EU).

During these inspections, RINA ascertains that the manufacturer actually performs the final assessment required by the Directive (Annex I, par. 3.2) and shall take a sample of pressure equipment from the manufacturing or storage premises in order to perform, or have performed, all or part of the final assessment of the pressure equipment samples.

RINA also establishes that the CE marking is correctly affixed.

When the result of these activities is positive, RINA issues a final assessment report.

In the event of serious findings or a number of findings that are not even serious enough to compromise compliance with the Essential Safety Requirements, RINA will re-perform a surveillance audit within the deadline indicated in the Inspection Report (such as to allow the manufacturer to act on its own quality system integrating the requested changes) suspending the Certificate of conformity.

If the subsequent audit also had a negative outcome, RINA will proceed with the revocation of the Certificate of conformity.

When the certificate validity expires, the manufacturer shall send another application for assessment of its Quality System and RINA will make a thorough review of the whole management Quality System.

The manufacturer shall, for a period of ten years after the last of the pressure equipment has been manufactured, hold at the disposal of the national authorities:

- the documentation referred to in point c) of the 'Quality System' section;
- the adjustments referred to in the Quality System;
- the decisions and reports from RINA and relative to the approval of the management Quality System, of the changes made and of the scheduled and unexpected visits made.

MODULE E1 (QUALITY ASSURANCE OF FINAL PRESSURE EQUIPMENT INSPECTION AND TESTING)

Within the context of this procedure, the manufacturer shall use an approved Quality System for the final inspection and testing of the finished product as specified in "Quality System" and be subject to surveillance by RINA as specified in "Surveillance".

This module may be used for category II pressure equipment or, if the manufacturer decides, for pressure equipment falling within risk category I.

The manufacturer establishes and declares that the pressure equipment meets the requirements of the Directive.

The manufacturer shall affix the CE marking to each item of pressure equipment indicating the identification number of RINA and draw up a Declaration of Conformity (ref. Article 17 of directive 2014/68/EU).

Quality system

The manufacturer shall lodge an application for assessment of his Quality System for the products concerned, in accordance with the procedures described in module E1 of the Pressure Equipment Directive and shall include the following documents:

- a) a general description of the pressure equipment with all useful technical information;
- b) conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment (this documentation is listed below and alternatively may be acquired and examined by RINA during the audit);
- c) results of design calculation made and a list of the standards applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the Directive where the harmonised standards have not been applied (this documentation is listed below and alternatively may be acquired and examined by RINA during the audit);
- d) a copy of the quality documentation relevant for the purposes of the pressure equipment (this documentation is listed below and alternatively may be acquired and examined by RINA during the audit);
- e) a copy of ISO9001 certification.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This Quality System documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

The Quality System documentation shall contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment;
- the operational procedures for the permanent joining of parts approved in accordance with the provisions set forth in point 3.1.2 of annex I of the Pressure Equipment Directive;
- the examinations and tests to be carried out after manufacture;

- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the joining of parts in accordance with section 3.1.2 of Annex I of the Directive;
- the means of monitoring the operation of the Quality System.

The Quality System shall ensure compliance of the pressure equipment with the requirements of the Directive.

It is essential for the manufacturer to have its own Quality System certified by an accredited body to UNI EN ISO 9001; cases other than these will be assessed individually.

When the manufacturer is sure that the documentation of its management Quality System is in line with the PED, it can request RINA to carry out the audit.

During the audit for first certification, RINA will assess the fundamental points of the Quality System in terms of what is required by the pressure equipment certificate, using an appropriate checklist; it will also assess the Quality System overall if this has been certified by a different body from RINA. At the end of the audit, RINA will issue a copy of the audit report.

The auditing team shall have at least one member with experience of assessing the pressure equipment production technology concerned. The assessment will include an inspection visit to the manufacturer's premises.

If the outcome of assessment activities is positive, in other words if not serious (type B) findings or simple recommendations emerge, RINA issues a Quality System Certificate of Conformity attesting to conformity with the requirements of Module E1 (production quality assurance) of the Directive. RINA will make another visit to verify that the changes agreed during the audit have been put into place within the agreed time.

If serious findings emerge or if the number of not serious findings prejudices compliance with the essential safety requirements, RINA will carry out a reassessment within the deadline indicated on the audit report (which allows the manufacturer to take action on its Quality System, integrating the changes required) and will not issue any Certificate of Conformity.

After the second audit is carried out, if the result is positive or falls within the limits above, RINA will issue the Certificate of Conformity.

The Quality System Certificate of Conformity is valid for three years.

If the second audit is not successful, RINA will inform the manufacturer and the other notified bodies that it has denied certification of conformity.

The manufacturer undertakes to fulfil the obligations arising out of the Quality System as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorized representative established within the Community, shall inform the Notified Body that has approved the Quality System of any intended adjustment to the Quality System.

The Notified Body shall assess the proposed changes and decide whether the amended Quality System will still meet the requirements referred to above or whether a reassessment is required.

The Notified Body shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance

The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved Quality System.

RINA carries out the Quality System surveillance by implementing a time schedule that includes a maintenance visit at the end of the first year, a maintenance visit at the end of the second year and a series of unexpected visits established on the basis of fixed criteria later on; product specialists will carry out the visits.

During each of the maintenance visits, RINA will carry out a complete review of the management Quality System or apply a review programme that leads to a full reassessment of the management Quality System during the two visits.

The frequency of the unexpected visits and any general increase in their number is determined on the basis of the following criteria:

- ▶ the category of the equipment;
- ▶ the results of previous surveillance visits;
- ▶ the need to ensure implementation of the corrective actions;
- ▶ special conditions linked to the approval of the system, where applicable;
- ▶ significant changes in manufacturing organisation, policy or techniques.

Since these are unexpected visits, the manufacturer will communicate the intended schedule of production to RINA, so that visits can be made during final product assessment or in any case when product items are available for RINA inspections, for example during hydrostatic pressure tests, visual inspections and dimensional checks, non-destructive tests on permanent joints, examination of reports of tests performed.

During the scheduled visits and the unexpected visits, the manufacturer shall provide RINA with the following documents:

- the documentation relating to the Quality System;
- the internal inspection reports;
- the design calculations of the pressure equipment;
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment;
- list of materials used, with name of harmonised standard reference, or Particular Material Approval (PMA) issued by the Notified Body that approved the type of pressure equipment or European Material Approval (EMA)
- certificates of origin of the basic materials and of the filler materials;
- traceability procedures;
- a copy of the specifications and the reports qualifying the permanent joints (e.g. as regards WPS and WPAR welding) issued by Notified Body or Third Party Body and approved by the Notified Body that issued the EU-type examination certificate;
- forming procedures;
- heat treatment procedures;
- heat treatment diagrams;
- reports of non-destructive tests carried out;
- reports of any destructive tests carried out (e.g. face bend and root bend welding tests);
- a copy of certificates qualifying personnel undertaking non-destructive tests approved by Third Party Body;
- certificates qualifying personnel/operators undertaking the permanent joining of parts, issued by Notified Body or by Third Party Body and approved by the Notified Body that issued the EU-type examination certificate;
- calibration certificates of test equipment;
- non-conformity reports issued in production and corresponding resolutions;
- operating instructions (installing and putting into service, use and maintenance, limits of use, remaining risks connected to use, identification of replaceable parts, documents necessary for a full understanding of these instructions);
- declaration of conformity (ref. Article 17 of directive 2014/68/EU).

During these inspections, RINA ascertains that the manufacturer actually performs the final assessment required by the Directive (Annex I, par. 3.2) and shall take a sample of pressure equipment from the manufacturing or storage premises in order to perform, or have performed, all or part of the final assessment of the pressure equipment samples.

RINA also establishes that the CE marking is correctly affixed.

When the result of these activities is positive, RINA issues a final assessment report.

The possible presence of high findings during surveillance visits or unannounced visits is managed by RINA as follows: In the presence of major non-conformities or other findings, whose number in the opinion of the evaluation group is such as to prejudice the manufacturing process, the Organization is subjected to an additional verification within the time established by RINA, in relation to the type of non-conformities themselves and, in any case, no later than three months from the end of the surveillance visit aimed at verifying the effectiveness of the corrections and corrective actions proposed.

If the non-conformities are not resolved within the established times 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 have been corrected. If the subsequent audit also had a negative outcome, RINA will proceed with the revocation of the Certificate of conformity.

When the certificate validity expires, the manufacturer shall send another application for assessment of its Quality System and RINA will make a thorough review of the whole management Quality System.

The manufacturer shall, for a period of ten years after the last of the pressure equipment has been manufactured, hold at the disposal of the national authorities:

- the documentation referred to from points a) to c) of the 'Quality System' section;
- the documentation referred to in point d) of the 'Quality System' section;
- the adjustments referred to in the Quality System;
- the decisions and reports from RINA and relative to the approval of the management Quality System, of the changes made and of the scheduled and unexpected visits made.

ANNEX 6 MODULE F (CONFORMITY TO TYPE BASED ON PRESSURE EQUIPMENT VERIFICATION)

Within the context of this procedure, the manufacturer establishes and declares that the pressure equipment subject to RINA surveillance and described in "product verification" is in conformity with the type as described in the EU type-examination certificate and meets the essential requirements of the Directive.

The manufacturer shall also take all steps required to ensure that the production process guarantees conformity of the equipment to the type described in the above certificates.

The manufacturer shall affix the CE marking to each item of pressure equipment and draw up a Declaration of Conformity (ref. Article 17 of directive 2014/68/EU).

The manufacturer shall send a CE marking authorisation application, following the procedures described in module F of the Pressure Equipment Directive and for each type of pressure equipment intended for CE marking, the manufacturer shall include the following documents:

- a) a general description of the pressure equipment;
- b) conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment;
- c) a copy of the EU type-examination certificate issued by the Notified Body with all relevant technical documentation attached.
- d) certificates qualifying personnel/operators undertaking the permanent joining of parts, issued by Notified Body or by Third Party Body and qualifying personnel undertaking non-destructive tests issued by Third Party Body;
- e) a copy of the certificates of origin issued by the materials manufacturer

RINA examines the documentation produced and sends its comments.

RINA performs the audit to check conformity of each item of pressure equipment with the relevant requirements of the Directive by examining and testing every product in accordance with the methods described in the next paragraph.

Product verification

RINA examines each item of pressure equipment individually and they undergo appropriate tests and examinations as set out in existing harmonised standards, or equivalent examinations and tests in order to verify that each product conforms to the type and to the requirements of the Directive.

In particular, for each product RINA shall:

- 1) verify that the personnel undertaking the permanent joining of parts and the non-destructive tests are qualified or approved in accordance with sections 3.1.2 and 3.1.3 of Annex I of the Directive.
- 2) verify the certificates of origin issued by the materials manufacturer in accordance with section 4.3 of Annex I of the Directive
- 3) carry out or have carried out the final inspection and proof test referred to in section 3.2 of Annex I and examine the safety devices, if applicable.

During the visits as set out in point 3) above, the manufacturer shall provide RINA with the following documents:

- results of design calculations made, examinations carried out for experimental designs;
- documents relative to the EC design-examination certificate or the EU type-examination certificate
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment;
- list of materials used, with name of harmonised standard reference, or Particular Material Approval (PMA) issued by manufacturer or European Material Approval (EMA)
- certificates of origin of the basic materials and of the filler materials;
- traceability procedures;
- copy of the specifications and the reports qualifying the permanent joints (e.g. as regards WPS and WPAR welding) approved by Notified Body or Third Party Body
- heat treatment procedures;
- heat treatment diagrams;
- reports of non-destructive tests carried out;
- reports of any destructive tests carried out (e.g. face bend and root bend welding tests)
- a copy of certificates qualifying personnel undertaking non-destructive tests approved by Third Party Body;
- certificates qualifying personnel/operators undertaking the permanent joining of parts, approved by Notified Body or by Third Party Body, or in lack thereof, RINA will approve them in compliance with the provisions of the supporting EU-type examination certificate;
- non-conformity reports issued in production and corresponding resolutions;

- operating instructions (installing and putting into service, use and maintenance, limits of use, remaining risks connected to use, identification of replaceable parts, documents necessary for a full understanding of these instructions);

If the results of these tests are satisfactory, RINA issues a Certificate of Conformity for each product and affixes its identification number or has it affixed to each item of pressure equipment approved.

The manufacturer shall make the certificates of conformity issued by RINA available on request.

ANNEX 7 MODULE G (CONFORMITY BASED ON UNIT VERIFICATION)

Within the context of this procedure, the manufacturer establishes and declares that pressure equipment which has been issued with the Certificate of Conformity by RINA meets the essential requirements of the Directive.

The manufacturer shall affix the CE marking to each item of pressure equipment and draw up a Declaration of Conformity (ref. Article 17 of directive 2014/68/EU).

The manufacturer shall send a CE marking authorisation application, following the procedures described in module G of the Pressure Equipment Directive and for each item of pressure equipment intended for CE marking, the manufacturer shall include the following documents:

- a) a general description of the pressure equipment;
- b) conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment;
- c) risk assessment;
- d) a list of the standards applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the Directive where the harmonised standards have not been applied;
- e) results of design calculations made and examinations carried out;
- f) test reports;
- g) list of materials used, with name of harmonised standard reference, or European Material Approval (EMA);
- h) copy of the specifications and the reports qualifying the permanent joints (e.g. as regards WPS and WPAR welding) issued by Notified Body or Third Party Body
- i) certificates qualifying personnel/operators undertaking the permanent joining of parts, issued by Notified Body or by Third Party Body
- j) manufacturing quality control plan (inspection plan);
- k) non-destructive test procedures;
- l) heat treatment procedures;
- m) copy of certificates qualifying personnel undertaking non-destructive tests
- n) drawing of plate
- o) operating instructions (installing and putting into service, use and maintenance, limits of use, remaining risks connected to use, identification of replaceable parts, documents necessary for a full understanding of these instructions).

After receiving this, during the design phase RINA carries out the following examinations and tests:

- examine and approve the documentation and make any assessments required;
- assess the materials used in relation to the function for which they are intended and to the compatibility with adjoining materials; where these are not in conformity with the relevant harmonized standards or with a European approval for pressure equipment materials, it shall issue a Particular Material Approval (PMA-PED form);
- perform the appropriate examinations to establish whether the solutions adopted by the manufacturer meet the essential safety requirements listed in Annex I of the Directive
- perform the necessary examinations to establish whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied
- after carrying out these examinations and tests, issue a design examination report
- approve the procedures for the permanent joining of pressure equipment parts, or check that they have been previously approved by a Notified Body or recognised third party, in accordance with section 3.1.2 of Annex I of the Directive;
- verify that the personnel undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved by a Notified Body or recognised third party ,in accordance with sections 3.1.2 and 3.1.3 of Annex I of the Directive;

During the production phase, RINA carries out, or has carried out, the tests or inspections required by the harmonised standards or by the relevant standard and according to the approved inspection plan, which are necessary to ensure that the pressure equipment complies with the essential safety requirements of the Directive; RINA will issue a test report for each test or inspection.

After production, RINA will carry out the final inspection as set out in point 3.2 of annex I of the Directive, and will issue a final inspection report.

If the results of the inspections and tests are positive, RINA will affix its identification number or have it affixed to the pressure equipment and will issue the manufacturer a Certificate of Conformity for the tests carried out.

ANNEX 8 MODULE H (CONFORMITY BASED ON FULL QUALITY ASSURANCE)

Within the context of this procedure, the manufacturer shall use an approved Quality System for design, manufacture, final inspection and testing of finished product as specified in "Quality System" and be subject to surveillance by RINA as specified in "Surveillance".

The manufacturer establishes and declares that the pressure equipment meets the directive essential safety requirements.

The manufacturer shall affix the CE marking to each item of pressure equipment, indicating the identification number of RINA and draw up a Declaration of Conformity (ref. Article 17 of directive 2014/68/EU).

Quality system

The manufacturer shall lodge an application for assessment of his Quality System for the products concerned, in accordance with the procedures described in module H of the Pressure Equipment Directive and shall include the following documents:

- a) a general description of the pressure equipment with all useful technical information;
- b) a copy of the quality documentation relevant for the purposes of the pressure equipment (this documentation is listed below and alternatively may be acquired and examined by RINA during the audit);
- c) a copy of ISO9001 certification.
- d) the technical documentation for one model of each type of pressure equipment intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements:
 - a general description of the pressure equipment,
 - conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
 - descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,
 - a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
 - results of design calculations made, examinations carried out, etc.,
 - test reports.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This Quality System documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

The Quality System documentation shall contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the design and to product quality;
- the technical design specifications, including standards, that will be applied and, where the harmonised standards are not applied in full, the means that will be used to ensure that the essential requirements of the Directive applicable to the pressure equipment will be met;
- the design control and design verification techniques, processes and systematic measures that will be used when designing the pressure equipment, particularly with regard to materials in accordance with section 4 of Annex I;
- the corresponding manufacturing, techniques, processes and systematic measures that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with section 3.1.2 of Annex I, in quality control and in quality assurance;
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with sections 3.1.2 and 3.1.3 of Annex I;
- the means of monitoring the achievement of the required pressure equipment design and quality and the effective operation of the Quality System.

The Quality System shall ensure compliance of the pressure equipment with the requirements of the Directive.

It is essential for the manufacturer to have his own Quality System certified by an accredited body to UNI EN ISO 9001; cases other than these will be assessed individually.

When the manufacturer is sure that the documentation of his management Quality System is in line with the PED, it can request RINA to carry out the audit.

During the audit for first certification, RINA will assess the fundamental points of the Quality System in terms of what is required by the pressure equipment certificate, using an appropriate checklist; it will also assess the Quality System overall if this has been certified by a different body from RINA. At the end of the audit, RINA will issue a copy of the audit report.

The auditing team shall have at least one member with experience of assessing the pressure equipment production technology concerned. The assessment will include an inspection visit to the manufacturer's premises.

If the outcome of assessment activities is positive, in other words if not serious (type B) findings or simple recommendations emerge, RINA issues a Quality System Certificate of Conformity attesting to conformity with the requirements of Module H (production quality assurance) of the Directive. RINA will make another visit to verify that the changes agreed during the audit have been put into place within the agreed time.

If serious findings emerge or if the number of not serious findings prejudices compliance with the essential safety requirements, RINA will carry out a reassessment within the deadline indicated on the audit report (which allows the manufacturer to take action on its Quality System, integrating the changes required) and will not issue any Certificate of Conformity.

After the second audit is carried out, if the result is positive or falls within the limits above, RINA will issue the Certificate of Conformity.

The Quality System Certificate of Conformity is valid for three years.

If the second audit is not successful, RINA will inform the other notified bodies that it has denied certification of conformity.

The manufacturer undertakes to fulfil the obligations arising out of the Quality System as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorized representative established within the Community, shall inform the Notified Body that has approved the Quality System of any intended adjustment to the Quality System.

The Notified Body shall assess the proposed changes and decide whether the amended Quality System will still meet the requirements referred to above or whether a reassessment is required.

The Notified Body shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance

The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved Quality System.

RINA carries out the Quality System surveillance by implementing a time schedule that includes a maintenance visit at the end of the first year, a maintenance visit at the end of the second year and a series of unexpected visits established on the basis of fixed criteria later on; product specialists will carry out the visits.

During each of the maintenance visits, RINA will carry out a complete review of the management Quality System or apply a review programme that leads to a full reassessment of the management Quality System during the two visits.

During the first year of production there shall be at least two unexpected visits for equipments categories III and IV cited at article 4, par.1, comma a), point i), article 4, par. 1, comma a), point ii), first indent, and article 4, par. 1, comma b) (one of which may be carried out at the same time as the audit). For all other pressure equipments, and in general for all subsequent visits, the frequency of the unexpected visits and any general increase in their number is determined on the basis of the following criteria:

- ▶ the category of the equipment;
- ▶ the results of previous surveillance visits;
- ▶ the need to ensure implementation of the corrective actions;
- ▶ special conditions linked to the approval of the system, where applicable;
- ▶ significant changes in manufacturing organisation, policy or techniques.

Since these are unexpected visits, the manufacturer will communicate the intended schedule of production to RINA, so that visits can be made during final product assessment or in any case when product items are available for RINA inspections, for example during hydrostatic pressure tests, visual inspections and dimensional checks, non-destructive tests on permanent joints, examination of reports of tests performed.

In the case of one-off production of fired or otherwise heated pressure vessels and equipment with the risk of overheating intended for generation of steam or super-heated water at temperatures higher than 110 °C having a volume greater than 2L, and all pressure cookers in Category III and subject to module H procedure, the Notified Body shall perform or have performed the final assessment (as referred to in Annex I 3.2.2 of the Pressure Equipment Directive) for each unit.

During the scheduled visits and the unexpected visits, the manufacturer shall provide RINA with the following documents:

- the documentation relating to the Quality System;

- the internal inspection reports;
- the design calculations of the pressure equipment;
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment;
- list of materials used, with name of harmonised standard reference, or Particular Material Approval (PMA) issued by manufacturer or European Material Approval (EMA);
- certificates of origin of the basic materials and of the filler materials;
- traceability procedures;
- a copy of the specifications and the reports qualifying the permanent joints (e.g. as regards WPS and WPAR welding) issued by Notified Body or Third Party Body, approved by RINA;
- heat treatment procedures;
- heat treatment diagrams;
- reports of non-destructive tests carried out;
- reports of any destructive tests carried out (e.g. face bend and root bend welding tests);
- copy of certificates qualifying personnel undertaking non-destructive tests;
- certificates qualifying personnel/operators undertaking the permanent joining of parts, issued by Notified Body or by Third Party Body and approved by RINA;
- calibration certificates of test equipment;
- non-conformity reports issued in production and corresponding resolutions;
- operating instructions (installing and putting into service, use and maintenance, limits of use, remaining risks connected to use, identification of replaceable parts, documents necessary for a full understanding of these instructions);
- declaration of conformity (ref. Article 17 of directive 2014/68/EU).

During these inspections, RINA ascertains that the manufacturer actually performs the final assessment required by the Directive (Annex I, par. 3.2) and shall take a sample of pressure equipment from the manufacturing or storage premises in order to perform, or have performed, all or part of the final assessment of the pressure equipment samples.

RINA also establishes that the CE marking is correctly affixed.

When the result of these activities is positive, RINA issues a final assessment report.

The possible presence of high findings during surveillance visits or unannounced visits is managed by RINA as follows: In the presence of major non-conformities or other findings, whose number in the opinion of the evaluation group is such as to prejudice the manufacturing process, the Organization is subjected to an additional verification within the time established by RINA, in relation to the type of non-conformities themselves and, in any case, no later than three months from the end of the surveillance visit aimed at verifying the effectiveness of the corrections and corrective actions proposed.

If the non-conformities are not resolved within the established times 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 have been corrected. If the subsequent audit also had a negative outcome, RINA will proceed with the revocation of the Certificate of conformity.

When the certificate validity expires, the manufacturer shall send another application for assessment of its Quality System and RINA will make a thorough review of the whole management Quality System.

The manufacturer shall, for a period of ten years after the last of the pressure equipment has been manufactured, hold at the disposal of the national authorities:

- the Quality System documentation referred to in point d);
- the adjustments referred to in the Quality System;
- the decisions and reports from RINA and relative to the approval of the management Quality System, of the changes made and of the scheduled and unexpected visits made.

MODULE H1 (CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION)

Within the context of this procedure, in addition to the requirements of module H, the manufacturer shall lodge an application for EU examination of the design with RINA.

This procedure applies to pressure equipment in category IV or, if the manufacturer decides, in a lower risk category.

The manufacturer lodges the application for EU examination of the pressure equipment design and includes the following documents:

- a) a general description of the pressure equipment;

- b) conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment;
- c) risk assessment;
- d) a list of the standards applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the Directive where the harmonised standards have not been applied;
- e) results of design calculations made and examinations carried out;
- f) list of materials used, with name of harmonised standard reference, or European Material Approval (EMA);
- g) copy of the specifications and the reports qualifying the permanent joints (e.g. as regards WPS and WPAR welding) issued by Notified Body or Third Party Body and corresponding RINA approval;
- h) certificates qualifying personnel/operators undertaking the permanent joining of parts, issued by Notified Body or by Third Party Body and corresponding RINA approval;
- i) non-destructive test procedures;
- j) heat treatment procedures;
- k) a copy of certificates qualifying personnel undertaking non-destructive tests approved by Third Party Body;
- l) drawing of plate;
- m) operating instructions (installing and putting into service, use and maintenance, limits of use, remaining risks connected to use, identification of replaceable parts, documents necessary for a full understanding of these instructions).

Following this, RINA shall:

- examine and approve the documentation, perform any assessments required and send any comments
- assess the materials used in relation to the function for which they are intended and to the compatibility with adjoining materials; where these are not in conformity with the relevant harmonized standards or with a European approval for pressure equipment materials, it shall issue a Particular Material Approval (PMA-PED form);
- perform the appropriate examinations to establish whether the solutions adopted by the manufacturer meet the essential safety requirements listed in Annex I of the Directive;
- approve the procedures for the permanent joining of pressure equipment parts, or check that they have been previously approved by a Notified Body or recognised third party, in accordance with section 3.1.2 of Annex I of the Directive;
- verify that the personnel undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved by a Notified Body or recognised third party, in accordance with sections 3.1.2 and 3.1.3 of Annex I of the Directive.

Where the design meets the provisions of the Directive, RINA will issue an EU design-examination certificate to the manufacturer. The certificate will contain the name and address of the manufacturer, the conclusions of the examination, conditions for its validity and the necessary data for identification of the approved design. A list of the relevant parts of the technical documentation is annexed to the certificate and a copy kept by the RINA.

The manufacturer to which RINA issued the EU design-examination certificate shall inform RINA of all modifications to the approved design; these are subject to additional assessment and approval where such changes may affect the conformity of the pressure equipment with the essential requirements of the Directive or the prescribed conditions for use of the pressure equipment. This additional approval shall be given in the form of an addition to the original EU design-examination certificate.

Final assessment as referred to in section 3.2 of Annex I of the Directive is subject to increased surveillance according to even stricter criteria than in module H, which means special manufacturing surveillance by RINA, in the form of unexpected visits. In the course of such visits, the Notified Body will conduct examinations on the pressure equipment

The number of unexpected visits required for the type of equipment referred to in module H1 depends on the number of items manufactured and on the complexity of the actual equipment.

If the outcome of assessment activities is positive, in other words if no serious (type B) findings or simple recommendations emerge, and when an EC design-examination certificate is issued for an item of equipment falling within risk category IV, RINA issues a Quality System Certificate of Conformity attesting to conformity with the requirements of Module H1 (production quality assurance) of the Directive.

The Certificate of Conformity issued according to module H1 also covers module H.

RINA follows the evolution of generally recognized technological progress and assesses whether the approved type is no longer compliant with the applicable provisions of the directive. RINA decides whether this progress requires further investigation and if so, informs the manufacturer

Annex 9 – Facsimile of Application for conformity assessment of pressure equipment in compliance with Pressure Equipment Directive

PRIVACY NOTICE

Pursuant to art 13 of Italian Legislative Decree n° 196 of 30.6.2003 (hereinafter, the “**Privacy Code**”) and art 13 of Regulation (EU) 2016/679 (hereinafter, the “**GDPR**”) and in relation to data provided by the Client or obtained by the Controller during the contractual or pre-contractual relations, the Client is hereby informed that its data will be processed by the following means and for the following purposes:

1. DATA CONTROLLER

The data controller is RINA S.p.A., whose registered office is in Genoa (Italy), via Corsica 12, Tax code and VAT n° 03794120109, as well as the Company(ies) in the RINA Group with which you have and/or may sign a services contract (hereinafter the “**Controller**”). The Controller can be contacted via the contact details shown on the www.rina.org website, or via the e-mail address for the Data Protection Officer rina.dpo@rina.org.

2. PURPOSE OF PROCESSING

The Controller processes the personal data (hereinafter, “**personal data**” or also “**data**”) provided by the Client:

- a.** Without having to obtain your explicit consent, for the following purposes:
- pre-contractual due diligence activities;
 - to submit offers and bids and other activities aimed at setting up a contractual relationship for the supply of services by the Controller;
 - to fulfil pre-contractual, contractual, and fiscal obligations arising from relations in force with you;
 - to fulfil the obligations imposed by law or by an order of the competent Authority;
 - to exercise the Controller’s rights, such as the right of defence in a lawsuit.
- b.** Only with your prior consent, for the following promotional purposes:
- to send you e-mails, post, sms and/or telephone calls, newsletters, commercial communications, and/or advertising materials on products or services offered by the Controller, and to measure the level of satisfaction with the quality of such services.

3. PROCESSING METHOD

The Controller will process personal data in accordance with the principles of lawfulness, fairness and transparency.

Your personal data are processed by means of the following operations: collection, recording, organisation, structuring, storage, consultation, adaptation or alteration, use, dissemination, disclosure by transmission, retrieval, alignment or combination, restriction, erasure or destruction of the data. Your personal details are subjected to both hard-copy and electronic processing.

The Controller will process the personal data for the time necessary to carry out the purposes indicated above and, in any case, for not more than 30 years from termination of contractual relations and not more than 2 years from collecting data for marketing purposes.

Once 10 years have passed since the contractual relations have ceased, access to the data will be limited to heads of departments.

Should the Controller have a documented need to store the data for a period longer than 30 years (e.g. if erasure could compromise its legitimate right to defence or in general, to safeguard its company assets), such further storage shall take place, limiting access to said data to the head of the legal department only, in order to guarantee the legitimate exercising of the right of defence of the Controller.

4. RECIPIENTS OF THE DATA

Your data may be made accessible for the purposes indicated in art 2.a and 2.b to the following recipients:

- affiliate companies or subsidiaries of RINA Group, in Italy and abroad, to the extent to which this is necessary for processing, in conformity to the binding corporate rules adopted by RINA Group;
- companies or other third entities (credit institutions, professional firms, consultants, insurance companies for providing insurance services, auditing companies, supervisory institutions, etc.) who carry out activities on an outsourcing basis, on the Controller’s behalf;
- public entities, for fulfilling legal obligations.

Without requiring your explicit consent, the Controller may communicate your data for the purposes indicated in art 2.a to supervisory bodies, judicial authorities, insurance companies for providing insurance services, as well as to entities to which communication is mandatory in terms of the law, for carrying out said purposes.

5. TRANSFERS OF DATA

Personal data are stored on servers located within the European Union. In any case, it is understood that, should this be necessary, the Controller will have the right to move the servers even outside the EU. In such a case, the Controller hereby guarantees that transfers of data outside the EU will be done in accordance with the applicable laws, also by means of including standard contractual clauses provided for by the European Commission, and adopting binding corporate rules for intra-group transfers.

6. CONSENT

The provision of data and related processing for the purposes indicated in art. 2.a is necessary in order to guarantee the Controller’s services you have requested, and for implementing the contract and any pre-contractual obligations. Any refusal will make it impossible for the Controller to provide the services covered by the contract.

Providing data for the purposes indicated in art. 2.b, on the other hand, is not mandatory. You may, therefore, decide not to provide any data or subsequently refuse processing of data already provided - the only consequence of any such refusal will be that receiving newsletters, commercial communications, and advertising materials related to the services offered by the Controller will not be possible. However, you will continue to have the right to the services indicated in art. 2.a.

Annex 9 – Facsimile of Application for conformity assessment of pressure equipment in compliance with Pressure Equipment Directive

7. RIGHTS OF THE DATA SUBJECT

As the data subject, you have the right to:

obtain confirmation of whether or not personal details regarding you are processed or not, as well as to obtain a copy of said data;

obtain an indication of: a) the source of the personal data; b) the purposes and means of processing; c) the logic involved in the case of processing done with the help of electronic instruments; d) the identity and the contact details of the controller, controller's representatives, processors and data protection officer; e) the recipients or categories of recipients to which the personal data can be communicated, or who can come to know the same as the designated representative within the territory of the State, processors, or employees who carry out processing;

obtain: a) updating, rectification, or completion of the data; b) erasure, transformation into an anonymous form or blocking of data processed in violation of laws; c) certification that the operations referred to in letters a) and b) have been made known, also in relation to their content, to those to whom the data have been communicated or disclosed by transmission, unless this is impossible or involves a disproportionate effort; d) a structured format, from the Controller, commonly used and provided in an intelligible and easily accessible form with the personal data related to you, and, where technically feasible, to obtain transmission of said data directly from one controller to another;

object to: a) processing of your personal data, even if pertinent to the purpose for which they were collected. b) processing of your personal data for the purposes of sending advertising or direct sales materials, or for carrying out market research or commercial communication, using automated telephone calling systems without an operator, by e-mail and or by means of traditional telephone and/or hard copy postal marketing methods. Such right of object may also be exercised only in part, thereby allowing the data subjects to choose whether to receive only communications using traditional means or only automated communications, or neither of the two types of communication.

Therefore, in your capacity as Data Subject, you have the rights pursuant to art 7 of the Privacy Code and art 15 – 21 of GDPR, as well as the right to lodge a complaint with the competent Authority pursuant to art 77 of GDPR.

8. PROCEDURE FOR EXERCISING RIGHTS AND COMMUNICATIONS

The Controller has appointed a Data Protection Officer, who can be contacted for all matters related to processing of your personal data and the exercising of related rights.

Therefore, you may contact the Data Protection Officer at any time, using the following procedure:

- by sending a registered letter with notification of receipt to RINA S.p.A., via Corsica 12, 16128 Genova, for the attention of the Data Protection Officer, or by
- by sending an e-mail message to rina.dpo@rina.org.

We wish to state that you have the right to withdraw the consent given at any time by writing to rina.dpo@rina.org.

Yours sincerely,

I declare that I have examined the notice and accept its contents (mandatory consent for providing the Controller's services).

(Signature of the Data Subject)

(Place & Date)

For the purpose of receiving e-mails, post, sms and/or telephone calls, newsletters, commercial communications, and/or advertising materials on products or services the Controller offers, and to measure the degree of satisfaction with the quality of such services (non mandatory consent).

I give my consent

I do not give my consent

(Signature of the Data Subject)

(Place & Date)

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Technical regulations