REGULATION FOR MANAGING PRODUCT CERTIFICATION ACTIVITIES

PED 2014/68/UE

TABLE OF REVISIONS				
Rev.	Date	DESCRIPTION of CHANGES	Drafted by	Approved by
00	06/06/11	New issue	Quality Manager	MANAGEMENT
01	09/12/11	Accredia Documentation Review	Quality Manager	MANAGEMENT
02	30/06/15	Transition to the Standards	QM	VRB-09-2015
03	30/10/15	Review and decision on certification	QM	VRB-15-2015
04	26/02/16	Full reissue for adaptation to the new format and new 2016/68/EU Directive	QM	VRB-06-2016
05	31/05/16	Addition of paragraph 9.14	QM	VRB-17-2016
06	13/09/16	Accredia documentation analysis	QM	VRB-21-2016
07	04/03/19	GDPR Reg. EU 679/2016	QM	VRB-04-2019

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1. Purpose

This Regulation defines the general practices adopted by ECO Certificazioni S.p.A. (hereafter ECO) for conducting conformity assessment activities on pressure equipment, as per Directive 2014/68/EU (hereafter Directive), that the Manufacturer or its Authorised Representative (hereafter Applicant) must follow to obtain and maintain EU product Certification.

ECO makes the latest updated version of the Regulation available on its website at www.eco-cert.it, at its premises, or upon the Applicant's request will send a copy in electronic format.

The amendments and additions to the Regulation are managed by issuing successive revisions, in which the modified portions of text are highlighted with vertical lines alongside them. The Regulation is an integral part of the contract signed between ECO and the Applicant. ECO always applies the last revision issued, and it is the Applicant's responsibility to check if any updates have been issued on the Body's website and adapt to them. ECO sends information to customers about the issue of a new revision of the regulation.

2. Field of application

ECO applies the Regulation to the conformity assessment activities for the fixed pressure equipment referred to in Article 1 of the Directive, according to the procedures referred to in the following modules:

- Module A2: Internal production control plus supervised pressure equipment checks at random intervals
- Module B: EU-Type Examination – Type of production
- Module B: EU-Type Examination – Type of design
- Module C2: Conformity to Type based on internal production control plus supervised pressure equipment checks at random intervals
- Module D: Conformity to Type based on quality assurance of the production process
- Module D1: Quality assurance of the Production process
- Module E: Conformity to Type based on pressure equipment quality assurance
- Module E1: Quality assurance of final pressure equipment inspection and testing
- Module F: Conformity to Type based on pressure equipment verification
- Module G: Conformity based on unit verification
- Module H: Conformity based on full quality assurance
- Module H1: Conformity based on full quality assurance plus design inspection

2.1 Conformity assessment of Fixed Pressure Equipment

The conformity assessment procedures are applicable to fixed pressure equipment according to the risk categories schema indicated in Article 14 of the Directive:

- Category I
  - module A (does not require the intervention of a Notified Body)
- Category II
  - module A2
  - module D1
  - module E1
- Category III
  - modules B (type of design) + D
  - modules B (type of design) + F
  - modules B (type of production) + E
  - modules B (type of production) + C2
  - module H
- Category IV
  - modules B (type of production) + D
  - modules B (type of production) + F
  - module G
  - module H1

The Regulation describes the commitments and responsibilities assumed by ECO and by the Applicant applying for conformity assessment.

ECO does not provide Applicants with consultancy services for preparing the technical documentation regarding the product to be certified, nor assistance in implementing and maintaining company management systems implemented by the manufacturer for production of the product.

3. Reference documents

The reference documents for ECO's certification activities in the scope of application of this Regulation are the following:

- Pressure Equipment Directive 2014/68/EU of the European Parliament and the Council of 15 May 2014 on the harmonisation of Member States' laws relating to making pressure equipment available on the market (recast);
- Legislative Decree 15 February 2016, No. 26 "Implementation of Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of Member States' laws relating to making pressure equipment available on the market (recast)";
- Legislative Decree 25 February 2000, No. 93 "Implementation of Directive 97/23/EC on pressure equipment and Directive 2014/68/EU on the harmonisation of Member States' laws relating to making pressure equipment available on the market (recast), which repeals the former";
- Guidelines issued by the European Community and Shared Opinions issued by the working groups of the European Commission;
- ISO/IEC 17065:2012 "Requirements for bodies certifying products, processes and services";
- ISO/IEC 17021:2011 "Conformity assessment – General requirements for bodies operating in the certification of persons"
- ISO/IEC 17024:2012 "Conformity assessment – General requirements for Bodies operating in the certification of personnel"
- UNI CEI EN ISO/IEC 17000:2005 "Conformity assessment – general vocabulary and principles";
- IAF GUIDES – Applicable EAs;
- General Regulations, Technical Regulations and provisions of the Accreditation Body (ACCREDIA), in the schemes and sectors covered by accreditation;
- UNI EN ISO 19011 "Guidelines for auditing Management systems for quality and/or Environmental Management".

The identification of binding rules and/or laws applicable to the product is the responsibility of the Applicant, who can refer to the standards and technical specifications issued by international standardisation committees such as UNI, EN, ISO, IEC, CEI, CEN and CENELEC. The harmonised standards referred to by the Directive, published and periodically updated by the European Commission, can be consulted at the following Internet address:

http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/pressure-equipment/index_en.htm

The Body will verify that the Applicant has defined and formalised both a method of identification and the methods for updating and implementing them, when applicable.

4. Definitions

For the purposes of this Regulation, the following definitions shall apply:

Pressure equipment: vessels, piping, safety accessories and pressure accessories, including, where applicable, elements attached to pressurised parts, such as flanges, nozzles, couplings, supports, lifting lugs;

Vessel: a housing designed and built to contain fluids under pressure, including its direct attachments up to the coupling point connecting it to other equipment. A vessel may be composed of more than one chamber;

Piping: components intended for the transport of fluids, when connected together for integration into a pressure system. Piping includes, in particular, a pipe or system of pipes, tubing, fittings, expansion joints, hoses, or other pressure-bearing components; heat exchangers consisting of pipes for the purpose of cooling or heating air shall be considered as piping;

Safety accessories: devices intended to protect pressure equipment from exceeding the permissible limits, including devices for direct pressure limitation, such as safety valves, rupture disc devices, crush bars, controlled safety devices (CSPRS) and limiting devices that activate the control systems or that turn off or turn off and deactivate the equipment, such as switches activated by pressure, temperature or fluid level and

measurement, control and regulation devices for safety (SRMCR); IT 27/06/2014 Official Journal of the European Union Law 189/173

Pressure accessories: devices with an operational function and having pressure-bearing housings;

Assemblies: several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole;

Pressure: pressure relative to atmospheric pressure, i.e. gauge pressure; as a consequence, vacuum is designated by a negative value;

Maximum allowable pressure (PS): means the maximum pressure for which the equipment is designed, as specified by the manufacturer, and defined at a location it specifies, being either the connection of protective and/or safety devices, or the top of equipment or, if not appropriate, any other point specified;

Minimum/maximum allowable temperature (TS): the minimum/maximum temperatures for which the equipment is designed, specified by the manufacturer;

Volume (V): the internal volume of a chamber, including the volume of nozzles to the first connection and excluding the volume of permanent internal parts;

Nominal size (DN): the numerical designation of size which is common to all components in a piping system other than components indicated by outside diameters or by thread size. It is a convenient round number for reference purposes and does not faithfully correspond to manufacturing dimensions. The nominal size is designated by DN followed by a number;

Fluids: gases, liquids and vapours in their pure state, as well as mixtures thereof; a fluid may contain a suspension of solids;

Permanent joints: joints that cannot be disconnected except by destructive methods;

European approval for materials: a technical document defining the characteristics of materials intended for repeated use in the manufacture of pressure equipment, which are not covered by any harmonised standard;

Making available on the market: the supply of pressure equipment or assemblies for distribution or use on the European Union market in the course of commercial activity, whether in return for payment or free of charge;

Placing on the market: the first time pressure equipment or assemblies are made available on the Union market;

Commissioning: the first use of pressure equipment or an assembly by its user;

Manufacturer: a natural or legal person who manufactures pressure equipment or an assembly, or has such equipment or assembly designed or manufactured, and markets them under their name or trademark or uses it for their own purposes;

Authorised representative: a natural or legal person established within the Union who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks;

Importer: a natural or legal person established in the European Union who places pressure equipment or assemblies originating from a third country on the market; Law 189/174 Official Journal of the European Union 27/06/2014

Distributor: a natural or legal person in the supply chain, other than the manufacturer or the importer, who makes pressure equipment or assemblies available on the market;

Economic operators: the manufacturer, the authorised representative, the importer and the distributor;

Technical specification: a document that prescribes technical requirements to be fulfilled by pressure equipment or assemblies;

Harmonised standard: harmonised standard as defined in Article 2, point 1, section c) of Regulation (EU) No. 1025/2012;

Accreditation: accreditation as defined in Article 2, point 10 of Regulation (EC) No. 765/2008;

National accreditation body: national accreditation body as defined in Article 2, point 11 of Regulation (EC) No. 765/2008;

Conformity assessment: the process demonstrating whether the essential safety requirements of this Directive relating to pressure equipment or assemblies have been fulfilled;

Conformity assessment body: a body that performs conformity assessment activities including calibration, testing, certification and inspection;

Recall: any measure aimed at achieving the return of pressure equipment or assemblies that have already been made available to consumers or other users;

Withdrawal: any measure aimed at preventing pressure equipment or assemblies in the supply chain from being made available on the market;

CE marking: a marking by which the manufacturer indicates that the pressure equipment or assembly is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

Union harmonisation legislation: any European Union legislation harmonising the conditions for marketing products.

Inspector (ISP): personnel who carry out certification activities or more generally assess the conformity of products;

Conformity assessment: the process to demonstrate compliance with the essential health and safety requirements laid down by the Decree, relating to equipment, an assembly or piping;

Verification: phase of the conformity assessment process conducted by the personnel appointed by the body, with the object of assessing compliance with the requirements applicable to the documentation prepared by the applicant or to the product they manufacture.

Findings: objective confirmation of an event or condition that highlights an NC or allows the expression of an Observation or a Comment;

Non-compliance (NC): failure by the Applicant to satisfy a requirement, referred to by a Directive, by a standard or by a law in force, applicable to the area in question, which affects the value of the CE attestation of Conformity in terms of effective and credible assurance of product compliance;

Observation (OBS): failure of the Applicant to satisfy a requirement which, although indicative of inadequate behaviour, does not jeopardise the continuation of the Inspection or Audit, but whose resolution by the Customer must however be verified by the Body before concluding the activities with a positive outcome;

Comment: Findings which are not configurable as the Applicant's failure to satisfy a requirement, but is aimed at preventing this situation from occurring, since it is potentially feasible.

Responsibility: burden assumed or deriving from conducting a process, from the execution of work, or from the management of a task (or duty) entrusted and to be carried out with due commitment.

Complaint: manifestation of dissatisfaction, either verbal or written, by entitled Parties (direct clients, indirect clients, Public Authorities, ACCREDIA), with regard to the services provided by the Body and, in general, to its operation;

Appeal: formal appeal, by Parties having specific cause, against decisions taken or assessments made, or attestations issued by the Body;

Any other definitions used in this document are shown in the documents referred to in paragraph 3.

5. Principles of impartiality and transparency

ECO grants all public or private entities equal access to the Certification services, without making any distinction based on Company size, membership of any organisation or association, or the number of Certificates obtained for the products manufactured. The only exception is made for companies subject to legal restrictions that prevent them from selling products subject to EU conformity Certification.

In order to guarantee the utmost correctness and transparency in the performance of conformity assessment and certification activities, ECO specifies, as well as through the signing of appropriate behaviour codes, that its managerial and technical personnel are not subject to undue internal or external pressures, commercial, financial or otherwise, which may negatively affect the work performed.

The personnel involved in conformity assessment activities aimed at issuing the EU conformity Certification are not involved in activities that could undermine confidence in their independence, impartiality or professional integrity. Furthermore, the Body does not carry out design activities either directly or in a consultancy form and does not market products and/or systems subject to inspections or EU conformity Certification, nor does it provide technical assistance services to parties subject to Assessments or Certifications, for the sectors covered by the Accreditation, or perform other activities that may compromise trust in its work.

6. Liability

This regulation details the mutual responsibilities and commitments that the Applicant and ECO are called upon to comply with in order to allow proper performance of the individual stages provided for by the Certification process, according to the procedures and timelines described in the following paragraphs and contractual documents signed by the parties.

ECO points out that some phases of the activity (e.g. tests and measurements) could be carried out by third parties (such as laboratories or other indicated or accredited parties, nonetheless qualified by ECO). The assignment of these activities is always subject to the Applicant's approval, upon written communication countersigned to show acceptance. Final responsibility for the activity remains exclusively with ECO.

7. Commitments of the Applicant

The Applicant shall provide maximum cooperation with ECO representatives during all the stages of the Certification process described in paragraph 9.0. It shall arrange any permissions and authorisations to allow access to the areas involved in the performance of conformity assessment activities, whether they are internal or external to the company being inspected. It allows access on site to, or provides copies of, all documents that ECO considers useful to examine for the purpose of granting the required conformity assessment.

Furthermore, the Applicant, before submitting the application to ECO for conformity assessment (Mod103 and Mod261) according to one of the methods set out in paragraph 2, has the responsibility to prepare at least the following in compliance with the requirements set by the Directive. All documentation provided by the Applicant in support of conformity assessment activities must be prepared in Italian (or alternatively in English, except for documents intended for products placed on the market in Italy, which must be in Italian).

7.1 Risk analysis

In compliance with the requirements set out in Annex I of the Directive[1], the Applicant must show that it has carried out a risk analysis to identify those risks related to the product, and that it has been designed and constructed keeping this analysis in mind. This analysis must be reflected in the technical documentation provided by the Applicant to the Body.

7.2 Technical documentation

In compliance with the requirements set out in the Annexes of the Directive describing the chosen conformity assessment procedure, the Applicant must provide evidence of having drafted the technical documentation required for the Fixed Pressure Equipment, in which compliance with the requirements of the Directive is demonstrated[2], as well as with any requirements referred to by the Directive or by the harmonised standards indicated for realisation of the same.

If the chosen conformity assessment procedure foresees it, the Applicant shall provide evidence of the adoption of a documented Quality Management System, which guarantees compliance with the Essential Safety Requirements defined by the Directive for the design, manufacture, testing and inspection of the product (as applicable), providing the Body with all related documentation.

If a Quality Management System is adopted, the Applicant must allow the Body's Auditors free access to all sites of design, manufacture, storage and testing etc., in order to allow them to carry out the appropriate checks and collect the necessary evidence and information to certify compliance with the requirements in place, including when accompanied by personnel from concessionary Authorities with recognition obtained from the Body or market surveillance Authorities.

7.4 EU Declaration of Conformity and CE Marking

As required by Article 17 of the Directive, the Applicant must prepare a document attesting the EU Declaration of Conformity.

The Declaration must have the required structure and contents as indicated in Annex IV of the Directive, and the elements specified in the relevant conformity assessment procedures set out in Annex III. Any information concerning data referring to the outcome of the Certification Process will have to be reported in draft, until positive conclusion of the Process. The Declaration must be translated into the language or languages required by the Member State in which the pressure equipment or assembly is placed or made available on the market,

[1] Paragraphs 3 and 4 of Annex I of the Directive, "Preliminary Observations"

[2] The requirements may refer to harmonised standards, mandatory laws or current regulations, or those referred to by other applicable Directives

and for pressure equipment and assemblies placed or made available on the Italian market it must be written in Italian.

Furthermore, in compliance with the requirements set forth in Article 18 of the Directive, the Applicant must provide for the CE marking of the Plant according to the general principles set out in Article 30 of Regulation 765/2008/EC, arranging to apply it after the positive conclusion of the certification process, in a visible, legible and indelible way on the equipment, on the plate and/or on the packaging, as indicated in Article 19 of the Directive.

7.5 Handling complaints

The Applicant must provide evidence of handling complaints[3] relating to fixed pressure equipment or assemblies subject to conformity assessment, in order to protect consumers' health and safety, by:

- recording the complaints
- handling complaints by conducting appropriate investigative activities, keeping track of their findings, the answers provided, and communications sent to distributors
- formalising and implementing any corrective actions as necessary following the complaint, appropriately recording the content and outcomes

If no complaints have been received regarding the fixed pressure equipment or assemblies subject to conformity assessment, the applicant must show that they have prepared what is necessary for potentially recording and handling them. The documentation, records relating to complaints and their processing must be made available to the ISPs who conduct the conformity assessment. If the Applicant does not consider it necessary to provide for the establishment of the record and the recording of any complaints, it must provide the Body with an assessment justifying said choice.

7.6 Compliance with the regulation and the contractual relationship

The Applicant shall comply with every point of this regulation and honour any further commitment required by the Certification process which derives from signing the contractual documents. It shall also ensure to:

- provide support to ECO representatives, making available its personnel responsible for the activities involved in conformity assessment activities during working hours and for the entire period involved in the Certification process;
- facilitate carrying out assessment activities at the times and in the ways agreed in official communications;
- facilitate the access of ECO representatives to all areas involved in assessments, to records (changes to technical documentation, resolving complaints etc.), to personnel involved in the design and manufacture, installation, etc.;
- prepare the authorisations necessary to allow access for ECO representatives, including if accompanied by internal or external observers, by the personnel of the competent Authorities, by the concessionary authorities with recognition from the Body, or ACCREDIA, to the places where construction sites are located or premises where the fixed pressure equipment or assemblies subject to conformity assessment are located.
- facilitate the resolution of the NCs that emerge during the Certification process, allowing ECO to verify their resolution through evidence of the corrective actions taken;
- not put fixed pressure equipment or assemblies subject to conformity assessment on the market until the positive conclusion of the Process;
- fulfil payments in the ways and times defined by the signed contractual documents;
- not to omit or neglect to communicate to ECO any information relevant to the Certification process or the fixed pressure equipment or assemblies subject to the conformity assessment requested;
- use and publicise the Certification exclusively within the limits for which it was granted, avoiding discrediting the Body;
- communicate to ECO any changes made to the products, production or welding processes or materials used in the manufacture of the products covered by the certificates issued by the body;
- allow the required checks to be carried out, including when communicated with minimum notice, by the personnel appointed by ECO, including when accompanied by personnel from ACCREDIA or the competent Authorities;
- allow ECO to perform additional checks motivated by serious reports concerning the certified product, including in conjunction with personnel from the competent Authorities or ACCREDIA. These checks can be

[3] ref. 4.1.2.2.c).1, 4.1.2.2.j).1 and 4.1.2.2.j).2 ISO/IEC 17065:2012 and Article 6, paragraph 4 of the Directive

carried out without notice or with a minimum of 2 working days' notice; refusal entails revocation of the Certification. It is not permitted to refuse the proposed inspectors[4];

- keep a copy of the EU Declaration of Conformity, of the Certificate issued by the Body and of the technical documentation for a minimum period of 10 years from the date when the fixed pressure equipment was placed on the market

8. Commitments of the Body

ECO shall make available the resources necessary to plan and carry out conformity assessment activities in accordance with the provisions of the Directive. It shall also make available the resources necessary to carry out any additional checks and all the activities required for monitoring and maintaining the Certification granted.

ECO also guarantees adequate insurance coverage with respect to the risks that could arise for the Applicant from the performance of the conformity assessment activities referred to in this Regulation.

8.1 Cases of force majeure

ECO cannot be held responsible for any non-fulfilments that may occur due to objectively unforeseeable circumstances, prior to taking on the assignment conferred by the Applicant for the conformity assessment of the fixed pressure equipment.

Equally, ECO cannot be held responsible for failure to comply with the agreed timings if it should be attributable to delays by the Applicant, or due to the occurrence of NC attributable to its actions.

9. Certification Process

The Certification process conducted by ECO involves carrying out the phases described in the following paragraphs. The process shall take place in accordance with the provisions of the Directive, the harmonised standards referred to in paragraph 3, and the binding laws on the matter. Each phase is conducted according to internal procedures and instructions prepared by ECO, which can be consulted by the Applicant at the Body's Head Office, limited to the section relating to Certification.

9.1 Access to conformity assessment services – Receipt of the Request

To access the conformity assessment services offered by ECO, the Applicant shall contact the Body by sending a quotation request or by contacting the commercial secretariat, which will record the same. The request (Mod258rev01 and Mod259rev00), completed in its entirety, provides the information necessary for defining the activities and sending the Proposal.

9.2 Reviewing the request and sending the proposal

Upon receipt of the request, ECO checks that it has been completed correctly with all the information required. If the documentation is missing some data or attachments, ECO will request them in writing.

Following the review, ECO sends the Applicant a proposal for the requested activities (Mod104 and Mod260). The proposal contains:

- the reference to the request sent to ECO
- the indication of the conformity assessment procedure to be adopted in accordance with the request
- the need to send all the technical documentation that the Applicant will have to provide to the Body, together with the Application to allow the start of the certification process
- the economic quantification for conformity assessment services in accordance with the related rate table
- compliance with the contents of this regulation
- the exclusions
- the contractual clauses

Together with the proposal, the Applicant is provided with the application form to be returned, completed in its entirety, if it accepts the Proposal. The same form can be found on the Body's website.

9.3 Acceptance of the Proposal, submission of the Application and technical documentation

Acceptance of the Proposal constitutes Order and Contract for the requested conformity assessment activities.

The Applicant, accepting the Body's proposal, shall also:

- provide the application form, completed in its entirety, and accompanied by the declaration of the Legal Representative stating that the application has not been submitted to another Certification Body[5];

[4] This applies to the conformity assessment procedures foreseen for it.

- provide all the technical documentation necessary for the conformity assessment of the fixed pressure equipment in accordance with the indicated procedure;
- consider this regulation as an integral part of the contractual relationship signed with the Body, respecting it for the entire duration of the certification process;
- accept all the clauses in the application and proposal documents, including the clauses identified as restrictive;

The application must be signed by the Applicant's legal representative, or by an appropriately authorised person[6].

In the event that the Applicant is the authorised representative of the manufacturer, ECO reserves the right to request that they prove the assignment of the mandate in writing.

The technical documentation must be provided to ECO upon acceptance of the Proposal. As long as all the technical documentation required by the conformity assessment form indicated in the request, proposal and application has not been received by the Body, the Head of the activities will not proceed with the definition of the certification process.

Depending on the conformity assessment form chosen, the technical documentation must contain the information in the following paragraphs:

9.3.1 The technical documentation related to the conformity assessment procedures for Type certification.

In any case in which the product is not already subject to EU Type Certification, the Applicant must provide a copy of the Technical Documentation (Technical File) containing:

- a general description of the equipment/assembly,
- design and manufacturing drawings, as well as diagrams of components, sub-units, circuits etc., of the equipment/assembly, accompanied by any calculation notes, test results, certificates, etc., enabling verification of the equipment/assembly's conformity with the essential safety requirements,
- the documentation on risk assessment, demonstrating the procedure followed, including:
  - a list of the essential health and safety requirements applicable to the equipment/assembly,
  - the protective measures implemented to eliminate the identified hazards or to reduce the risks and, where appropriate, the indication of the residual risks associated with the fixed pressure equipment,
- the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,
- the description and explanations necessary to understand the drawings and diagrams and the operation of the pressure equipment/assembly,
- a copy of the equipment/assembly instructions,
- a list of the standards referred to in Article 5 of the Directive, applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied,
- the results of the project calculations and examinations carried out etc., and the reports on the tests carried out,
- information concerning the tests provided for in manufacture
- information concerning the required qualifications or approvals, and in accordance with points 3.1.2 and 3.1.3 of Annex I of the Directive
- qualifications of the welding process and of welders
- in the case of mass production, the internal provisions that will be applied to maintain the conformity of the equipment/assembly with the provisions of the Directive,
- Facsimile of the CE Marking, in compliance with the requirements of the Directive and Article 30 of Regulation 765/2008/EC
- Facsimile of the EU Declaration of Conformity, in accordance with the provisions of the Directive

9.3.1.2 The technical documentation related to the conformity assessment procedures for the verification of conformity to the Type already certified must contain:

- a copy of the certificate and the EU declaration of conformity
- anything else required by the conformity assessment form indicated in the Application.

[5] The Directive explicitly requests this declaration from the Applicant to indicate that it will entrust the conformity assessment referred to in the application presented exclusively to ECO and not to any other Body.

[6] The signature of the Applicant's Legal Representative confirms its legal validity.

9.3.2 The technical documentation relating to the conformity assessment procedures for the conformity verification of the Quality Management System shall contain the QMS documentation set out by the conformity assessment form required with the Application, which in its most complete form must report at least the following:

- Quality Manual
- Written procedures and instructions describing how the QMS ensures the pressure equipment's conformity with the applicable requirements of the Directive, and which also provide an adequate description of:
  - the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product design and quality,
  - the technical design specifications, including standards that will be applied and, where the relevant harmonised standards will not be applied in full, the means that will be used to ensure that the essential safety requirements of this Directive are met,
  - the techniques for checking and verifying the design, processes and systematic interventions for the design of pressure equipment corresponding to the type in question, in particular as regards the materials, in accordance with point 4 of Annex I,
  - the corresponding manufacturing processes, the quality control and quality assurance techniques, the processes and systematic interventions that will occur, in particular the operational procedures for permanent joining of parts approved in accordance with point 3.1.2 of Annex I,
  - the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
  - quality records, such as inspection reports and test data and calibration data, reports on qualifications or approval of the personnel concerned, in particular those of personnel assigned to the permanent joining of parts and non-destructive tests on the basis of points 3.1.2 and 3.1.3 of Annex I, etc.,
  - the means of verifying the achievement of the required design and product quality and the effective operation of the quality system.

9.3.2.1 For each piece of equipment whose conformity is ensured by the application of the QMS, the Applicant must provide a copy of the following technical documentation (Technical File):

- a general description of the equipment/assembly,
- design and manufacturing drawings, as well as diagrams of components, sub-units, circuits etc., of the equipment/assembly, accompanied by any calculation notes, test results, certificates, etc., enabling verification of the equipment/assembly's conformity with the essential safety requirements,
- the description and explanations necessary to understand the drawings and diagrams and the operation of the pressure equipment/assembly,
- the documentation on risk assessment, demonstrating the procedure followed, including:
  - a list of the essential health and safety requirements applicable to the equipment/assembly,
  - the protective measures implemented to eliminate the identified hazards or to reduce the risks and, where appropriate, the indication of the residual risks associated with the fixed pressure equipment,
- a list of the standards referred to in Article 12, applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 12 have not been applied,
- a copy of the equipment/assembly instructions,
- the results of design calculations made, and examinations carried out,

9.4 Review of the Order and start of the Certification Process

ECO reviews the acceptance of the Offer, the Application and the declaration from the legal representative to verify that no changes have been made and that each field has been completed as required. If deficiencies or inaccuracies are found, additions and clarifications of the case will be required before starting the certification process.

The ECO representative in charge will open a new file and inform the Applicant of the acceptance of the assignment, indicating the names of the Inspector and/or the Auditor who will carry out the activity (Mod89). In the case of Modules D, D1, E, H and H1, the Triennial Certification Programme is prepared for planning the phases and the verifications they involve, as per paragraph 9.4.2 and the Audit Plan for Certification verification. The Audit Plan is sent to the customer following the communication of the GVI (Mod89).

The Applicant may reject the names indicated within 2 working days, explaining the reasons in writing[7]. If the reasons are well-founded, ECO will proceed to a new assignment, indicating the new names to the Applicant.

[7] Existence of well-founded conflicts of interest, previous unethical behaviour, etc.

If during the course of the certification process it is necessary to use equipment possessed by the applicant, or made available by one of its suppliers, the ILAC P10:01/2013 requirements must be verified before using it. This also applies to equipment used by the suppliers to whom the applicant entrusts the performance of tests and verifications whose reports/certificates will be assessed by the Body for the purpose of the Inspection. ECO will acquire a copy of the calibration documentation for all equipment that the applicant makes available during the process and for all equipment used during the activities carried out by its suppliers that is necessary for the product conformity assessment.

Prior to defining the process, the ECO Supervisor can request a copy of the calibration documentation for the equipment that will be made available to the applicant during the process.

9.4.1 Conformity assessment process for Modules A2, B, C2, F and G

Regardless of the conformity assessment procedure selected, the conformity assessment process essentially consists of two phases:

- analysis of the technical documentation
- inspection of the product to verify that it is constructed in accordance with that indicated in the technical documentation (in compliance with the Essential Safety Requirements), performing the leak test (hydraulic or gas, according to the specificity of the certified object) and checking the efficiency and functionality of any installed safety accessories.

9.4.2 Compliance assessment process for Modules D, D1, E, H and H1

Regardless of the conformity assessment procedure selected, the conformity assessment process consists of the following phases:

- Verification of Certification
- Verifications of annual Monitoring
- Verification of Renewal within the 3rd year

The times for carrying out the verifications on the manufacturer's premises are defined with reference to the relevant IAF documents (MD5), while the days are agreed with the Applicant, who has the right to request that the planned fulfilment date be moved.

The description of each stage of the Certification Process for Modules D, D1, E, H and H1 is reported in paragraph 9.14.

9.5 Verification of Documentation

The first phase of the Process consists of verifying the conformity of the documentation produced by the Applicant. The inspector appointed by ECO examines the documents contained in the technical file and any documentation for the Quality Management System if the Applicant has requested the application of one of the conformity assessment procedures of the quality management system.

9.5.1 Verification of technical documentation (Modules for conformity assessment of Type and to Type)

The inspector appointed by ECO evaluates the completeness of the technical documentation drawn up by the Applicant, who must satisfy the requirements of the conformity assessment procedure according to the Module of the Directive. The assessment is performed at the Body's offices unless otherwise agreed with the Applicant, and involves the following documents referred to in paragraph 9.3.1 and potentially 9.3.2.1.

9.5.2 Verification of technical documentation and QMS (Module for QMS conformity assessment)

In the event that the conformity assessment is to be carried out on the quality system applied by the manufacturer, the verification team appointed will carry out an examination of the documentation concerning the manufacturer's quality system and will subsequently make a visit to the manufacturer's premises to check the application of the procedures related to manufacturing, design (if applicable) and inspections, as required by the conformity assessment module referred to in the request, proposal and application.

The verifications are conducted by a QMS auditor and by an expert in the field and in the technology of the pressure equipment in question, with specific knowledge of the applicable requirements of the standards and the Directive.

The group in charge of the verification examines the technical documentation referred to in paragraph 9.3.2 and 9.3.2.1, verifying the Applicant's ability to identify the applicable requirements of the standards and the Directive and to carry out the tests aimed at ensuring the pressure equipment's conformity with these standards. The verification of the QMS documentation not provided will still take place on the manufacturer's premises during the Stage 1 Verification.

9.6 Outcome of the Documentation Verification and communication of the findings

If, at the end of the documentation verification referred to in paragraph 9.5.1, no Non-Conformity (NC) has emerged, ECO will proceed with the Functional verification of the Product. As for the verification of the documentation referred to in paragraph 9.5.2, the findings that emerged during Stage 1 must not impede carrying out the remaining phases of the Audit.

In case of serious deficiencies in the Technical documentation or Management System provided by the Customer, ECO will indicate the resolution of said deficiencies as a requirement for access to the next stage of the Certification Process, which provides for the verification of the Pressure Equipment and of the premises for manufacturing it, if required. The list of NCs is communicated in writing.

Following the communication, the Applicant can choose to adjust its own documentation or abandon the Process. In the latter case, the cancellation must be communicated to ECO by means of a registered letter with return receipt. The cancellation involves terminating the Certification Process and debiting the sums for the activities carried out (see paragraph 11.1).

If the Applicant decides to continue with the Certification, it can proceed to adjust its own documentation, resolving the findings, by notifying ECO within a period of time not exceeding six (6) months, otherwise the Certification Process will be closed with a negative outcome. The objective evidence of the requested adjustments is evaluated by ECO during the functional verification.

If the number of NCs and their extension do not allow normal continuation of the Process, ECO will inform the Applicant of the need to carry out a new Documentation Verification following the resolution of the findings that emerged. The relevant sums indicated for the items in the proposal will be debited again on the occasion of the new Verification.

9.7 Functional Assessment

The verification at the manufacturing premises begins with the initial meeting between the verification team, the Management (or its representative) and the production and design managers (if applicable) for a brief mutual introduction, clarifying and specifying the methods for carrying out the activity and verifying/clarifying the information received.

Should any discrepancies arise that may affect the expected fulfilment times, the manager of the verification team must immediately inform ECO Certificazioni S.p.A. in order to agree on the methods for continuing.

Once the activities foreseen by the conformity assessment procedure covered by the contract have been carried out, the verification team informs the manufacturer of the results and conclusions of said activities and formalises and illustrates any non-conformities (NC) that may have been detected during the verification in the field.

In the event of reservations or exceptions expressed by the manufacturer regarding the results of the activities, the work of the verification team, the findings and/or anything else, the team manager records them and sends them to the Sector Manager.

The activities generally include:

- Verification of any adjustments to documentation following the NC and Observations that emerged during the documentation verification of the technical file or the QMS documentation (stage 1);
- The examination of the representative sample of the "Type" indicated in the application, for correspondence with that stated in the technical file;
- The examination of the design, manufacturing, final inspection and testing processes implemented on the Applicant's premises, to verify that the fixed pressure equipment complies with what is stated in the technical file and with the applicable requirements set out by the Directive, by the applicable standards according to the solutions indicated in the risk analysis, if a procedure has been chosen that involves the adoption of a QMS according to the methods foreseen by the Module of the applied directive.

If Findings such as NCs, Observations and/or Comments emerge, ECO will indicate their resolution as a requirement for issuing the conformity Certificate, within a maximum period of six (6) months.

In the course of the activities, the Body's personnel shall document the preparation of the tests and their outcomes with photographic images, in addition to any other situation for which it should be necessary to produce such evidence. The Applicant must ensure that they have carried out the procedures are necessary to certify the conformity of the product being assessed. For this reason, it will have to arrange the activity in areas which do not preclude acquiring photographic evidence.

9.8 Additional Verifications

On all occasions in which it is necessary to check the Applicant's compliance with the requirements, both during the certification process and after the Certificate is granted, ECO reserves the right to carry out additional verifications. These verifications are usually carried out on the Applicant's premises and are communicated and justified by ECO in writing. The costs for carrying out the additional verification activities are expected to be borne by the Applicant and communicated by means of an appropriate economic proposal.

9.9 Review and decision on certification

At the end of all the assessments and fulfilments, ECO will review the contents of the file and decide on the Certification. The decision is made by a specially appointed Committee, comprised of members who are not involved in the conformity assessment activities subject to deliberation.

In the event of a positive decision from the Committee, ECO shall send the applicant the Certificate, containing at least the following information:

- The Certificate number and the revision index where necessary;
- Reference to the Directive (where necessary)
- The Applicant/Authorised Representative
- The Manufacturer
- The Product Type (if applicable)
- The factory number (if applicable)
- Reference to other Type certificates (if applicable)
- The reference of the Manufacturer's Registered Office and the production facilities
- The technical file
- Reference to the procedures adopted to verify conformity as defined by the Directive (if applicable)
- The number of the ECO file opened by the Body following the order/application
- Inspection reports and other documentation attesting conformity
- The reference standards applicable to the product
- The pertinent information concerning the validity of the Manufacturer's obligations to report changes
- The period for the Manufacturer to keep the documentation
- Reference to the invalidity of the Attestation/Certificate without the technical annex (if applicable)
- The dates of first issue, current issue and expiry where relevant
- ECO and the Accreditation body's logos;
- the reference of the Body to be contacted for accurate information on the validity of the certificate;

The Certificate is signed by a legal representative of the Body and/or proxy of the Chairman of the Board. The delivery of the document takes place only after payment of the remaining amounts agreed for the verification activities performed[8].

The Applicant may use the Certificate received only for the purposes specified in the Directive and in reference to the type of fixed pressure equipment for which it was issued by ECO, including the necessary data on the declaration of conformity that will be attached to it, and for all expected requirements for placing the equipment on the market.

The Certificate authorises the Applicant to affix the CE marking, according to the provisions of the Directive, exclusively on the fixed pressure equipment referable to the Types described in the technical annex that may be attached to the Certificate.

9.10 CE Marking

The Applicant, after obtaining the Certificate, shall proceed to affix the CE marking in accordance with the provisions of Article 30 of Regulation 765/2008/EC and Article 19 of the Directive. If required, it must indicate the number 0714 identifying the appointed Body to the European Commission.

9.11 Negative outcome of the conformity assessment

If the Applicant fails to comply within the deadlines set for resolving the Findings that emerged following the documentation verification or following the verification of the products and production sites, the Committee will not be able to proceed with a positive decision on the Certification. ECO will inform the Applicant of the negative conclusion of the Certification process by registered letter with return receipt[9], indicating the reasons

[8] This condition also applies in the case of transfer, renewal or modification of the Certificate

[9] Alternatively, a contracted courier or other form may be used that provides for proof of delivery (e.g. delivering letters by hand)

for the decision in a report, providing the communications required by the Directive and debiting the costs for the activities carried out. The Applicant may submit a new application for Certification or lodge a justified appeal according to the procedures set forth in paragraph 12. The communication is forwarded to the other Bodies, to the relevant ministry and to Accredia for their information, as well as to the other Authorities involved.

9.12 List of Certifications

ECO prepares and keeps an updated list of the certifications issued. This list, showing the company name of the Applicant and its address, the identification of the certified product, the number of the attestation or certificate issued, with the relative issue and expiry date, is included in the list of Certificates for public consultation on their validity, on the Body's website. The competent Ministry can consult the list of certifications and related information through restricted access.

Furthermore, if applicable, ECO shall inform ACCREDIA of the data of the certified Organisations in the sectors for which ECO is accredited, in compliance with what is outlined in the applicable Regulation.

9.13 Storage of the Documentation

The Applicant shall keep a copy of the technical documentation, a copy of the Certificates including their annexes and the EU Declaration of Conformity for a period of ten (10) years from the date when the fixed pressure equipment is placed on the market. ECO keeps a copy of the documentation drawn up during the Certification process in compliance with the provisions of its QMS.

9.14 Description of the certification process phases for Modules D, D1, E, H and H1

As indicated in paragraph 9.4.2, the following is a description of the three phases planned for the certification process for the Manufacturer's Quality Management System.

9.14.1 Initial verification for issuing the Certification

This phase consists of two sub-phases called Stage 1 Audit and Stage 2 Audit.

The Stage 1 Audit involves examining the completeness of the documentation required by the Management System adopted by the Manufacturer, in accordance with the provisions of the Directive and the ISO 9001 reference standard. The verification is usually carried out at the Body's offices. If NCs or OBSs emerge, these must be resolved before the start of the Stage 2 Audit.

The Stage 2 Audit involves complete verification of the contents of the system documentation and its adoption in the activities carried out by the Manufacturer. The audit involves checking the production and verification processes required by the Directive, as well as the proper management of tools and equipment. For Module H1, the processes related to the Design are also verified.

If NCs emerge, these must be resolved before the Certificate is issued. Any OBSs must be resolved by the next surveillance audit, following a declaration of action sent to the Body.

The certificate is valid for three years, provided the surveillance checks are concluded successfully.

9.14.2 Annual Surveillance Verifications

The surveillance verifications are performed to verify the resolution of the observations that emerged in the previous verifications, and the Manufacturer's system's continued compliance with requirements. The surveillance verifications may involve activities on one or more products covered by the certificate. In the event of NCs, the certificate is suspended until ECO can verify their resolution. In the event of the certificate being suspended, the Applicant must cease the activities it refers to.

9.14.3 Verification of Renewal within the 3rd year

The renewal verification has the same characteristics as the surveillance verification, but involves all activities carried out for all types of products covered by the certificate. In the event of NCs, the certificate is suspended until ECO can verify their resolution. In the event of the certificate being suspended, the Applicant must cease the activities it refers to. The renewal of the certificate has a duration of three years.

9.14.4. Commitments of the applicant

As indicated in paragraph 7, the Applicant must guarantee ECO ISPs free access to production sites, documentation and products, including when accompanied by observers from the Accreditation authority. Furthermore, production of the products involved must cease in cases where the certificate is suspended or revoked.

The Applicant must provide ECO with a complete list of the products for which Certification is required, providing copies of the products' technical files containing all the data required by the applicable standards, the Directive or the forms provided by the Body.

The Applicant must comply with the applicable requirements on the calibration of tools, with particular reference to the ILAC P10 and the product and production standards. This commitment is to be considered a fundamental requirement for obtaining and keeping the Certificate.

10. Validity and Renewal of the Certification and the Contract

The contracts signed between ECO and the Applicant have a duration equal to the validity of the Certification. The Applicant has the right to withdraw from the contract in accordance with the procedures set out in paragraph 21.1.

10.1 Certificates of conformity of Type and to Type

The certificates' validity is indicated in the relevant conformity assessment module for the certification of fixed pressure equipment. ECO shall inform the Applicant of any significant change that affects the Certificate's validity, such as the issuing of new harmonised standards or new updates to the Directive.

10.2 Certificate of conformity of the QMS

ECO periodically conducts surveillance visits, usually yearly if there are no critical factors that require a higher frequency. The surveillance visits ensure a complete re-assessment of the Applicant's QMS every 3 years, to ensure its maintenance and adaptation over time. Renewal visits are usually performed with prior notice, but ECO reserves the right to make unannounced visits for compliance assessment modules that require this. When the Certificate's validity expires, the Applicant must present a renewal application to ECO.

11. Renunciation, Suspension and Revocation of Certification

11.1 Renunciation

The Applicant may renounce the Certification at any time and for any reason, in accordance with the following procedures:

- Renunciation in Itinere
- Renunciation of the Certification obtained from ECO

In the first case, the Certification Applicant renounces continuing the Certification procedure, with a registered letter with return receipt sent to ECO and provides for the payment of the amount due for the activities carried out by ECO. The Body shall inform the parties concerned of the negative outcome of the assessment process.

In the second case, the Applicant must communicate the renunciation by registered letter with return receipt, sent to ECO at least three (3) months before the date scheduled for the renewal of the contract. Furthermore, the Applicant is obligated to return ECO the original copy of the Certificate ECO emitted. The renunciation of the Certification entails the end of its validity. The Body will inform the parties concerned.

11.2 Suspension

The validity of the Certification can be suspended:

- on the Applicant's request[10]
- on ECO's unquestionable judgement, if it becomes aware of:
  - the continued existence of unresolved findings
  - serious reports from the market
  - improper use of the Attestation or Certificate, in any way not in compliance with the provisions of the Directive[11]
  - failure to comply with the contractual obligations (including the requirements laid down in this Regulation), the requirements of the Directive, the economic conditions and payment deadlines signed with ECO

The suspension measure is communicated to the Applicant by registered letter with return receipt and advance fax, signed by the Body's legal representative. The communication reports the reason for the suspension and the time limits within which the Applicant must implement the corrective actions required. The Applicant has five (5) days to communicate to ECO its taking charge of the matter, the adaptation to the provisions of paragraph 11.2.1 of this Regulation, and any other information useful to inform ECO about the methods of resolving the challenged findings. The communication must be made by registered letter with return receipt and advance fax.

[10] In the case of voluntary suspension of the Certification, the Applicant must communicate the reasons for suspension, the adaptation to the requirements of paragraph 11.2.1 of this Regulation, and any other information, such as the estimated period of suspension, etc.

[11] For example, using the Certificate in reference to fixed pressure equipment not belonging to the certified Type, or in reference to fixed pressure equipment which has been modified without notifying ECO, etc.

If the Applicant does not comply with the requested communications or does not resolve the challenged causes for suspension within the indicated period[12], ECO will revoke the validity of the Certification, publicising it in the manner provided for by the Directive and the ACCREDIA regulations.

The suspension measure ceases when the Applicant eliminates the causes that generated it, providing ECO with proof.

11.2.1 Effects of Suspension

The suspension of the Certification involves the prohibition of placing fixed pressure equipment on the market, starting from the date of suspension. In the most serious cases, ECO reserves the right to request that the Applicant recall the equipment from the market, including that stored in warehouses.

Following suspension, the Applicant:

- loses the right to affix the CE marking and must stop using the Certificate
- must refrain from publicising the Certification until the end of the suspension period.

The suspensions are made public by ECO in the ways provided for by the Directive and ACCREDIA regulations.

The costs incurred by ECO to carry out any verifications or activities resulting from suspension measures are borne by the Applicant.

11.3 Revocation

The Revocation measure adopted by ECO consists of the definitive withdrawal of a Certificate granted to the Applicant, with the consequent loss of validity of the Certification.

ECO provides notification of the revocation of the Certification following the Suspension measure, in the event that the Applicant has not complied with the provisions of this regulation and in particular those of paragraph 11.2 and 11.2.1. Furthermore, ECO shall provide notification of the revocation of the Certification in all cases ordered by the competent authorities or in which it finds objective evidence of:

- fraudulent and illegitimate use of the Certification;
- serious failure to comply with this Regulation,
- significant and systematic non-conformity of the product manufactured or in production, compared to the technical documentation presented to ECO and/or the Essential Safety Requirements established by the Directive;
- failure to adapt the fixed pressure equipment to the requirements of the new editions of the applicable standards, both due to the intrinsic shortcomings of the Applicant's facility and to its obvious lack of will;
- the adoption of significant modifications to the Applicant's fixed pressure equipment without ECO's prior involvement;
- confirmed and repeated arrears towards ECO,
- misleading use of the Certification and/or the mark, such as to bring damages or discredit upon ECO;
- repeated hindrance to the fulfilment of surveillance visits conducted by ECO, alongside any personnel from ACCREDIA or other competent Authorities.

The revocation of the Certification, decided by the Certification Resolution Committee, is notified to the Applicant by registered letter with return receipt and advance fax, signed by the Body's Legal Representative, containing information on the reasons for the measure adopted, and has immediate effect.

Revocations are made public by ECO in the ways provided for by the Directive and ACCREDIA regulations, and are always communicated:

- to the competent Ministry and the other Appointed Bodies;
- to ACCREDIA in the time and manner established by them (if applicable);
- to any other competent Authorities, in the time and manner established by them.

Following the revocation, the Applicant must:

- Stop marketing fixed pressure equipment covered by the revoked Certification and cease to affix the CE marking
- Return the original Certificate to ECO, and any copies thereof;
- Refrain from publicising and using the revoked Certification by removing the logo and ECO references from the documentation in use.

If the Certification has been issued for the application of a conformity assessment procedure regarding the Applicant's QMS, its revocation involves the expiry of conformity of the QMS, and the prevention of marketing

[12] the period for the adaptation is indicated by ECO and, except in exceptional cases assessed by ECO, cannot exceed six (6) months.

all fixed pressure equipment produced after the revoked Certification. The Applicant must provide the Body with a complete list of the equipment subject to certification placed on the market up to the date of the revocation measure.

12. Complaints and Appeals

The Applicant can lodge a complaint regarding the activities carried out by ECO. The Body shall analyse the content of the complaint to identify the actions necessary for its management and resolution in accordance with the internal procedures adopted. ECO always provides a written and justified reply to the complaints received, whether these are found to be groundless or well-founded. In the latter case, it proposes actions to resolve them.

ECO does not take into consideration complaints presented anonymously. The PG13 for the management of complaints and appeals adopted by ECO is available for consultation on its website.

If the Applicant is not satisfied with ECO's response to the complaint sent or does not agree with the outcome of the decisions taken by the Body, it can proceed to formalise an appeal against it. The appeal must be presented in writing, by means of a registered letter with return receipt, detailing the reasons for the appeal and the evidence necessary to support the claim. The appeal must be filed within fifteen (15) working days from the notification of the decision against which it is lodged.

Within five (5) working days following receipt of the appeal, ECO communicates by fax the implementation of the Appeal and the names of the persons entrusted with its management and resolution. The implementation and management of the appeal do not suspend the validity of the decisions taken by ECO until the conclusion of the related process.

If the Applicant is not satisfied with the resolution of the appeal or the complaint, it can always resort to litigation against ECO.

13. Disputes

For any disputes that should arise between the parties regarding the interpretation, implementation, execution, validity and effectiveness of the Regulation for the Certification, the Court of Ravenna is exclusively competent.

14. Confidentiality

The activities carried out by ECO cannot disregard the evaluation of data and documents that represent sensitive elements of Company know-how and/or information subject to guaranteeing the privacy of the Applicant. In order to guarantee the necessary confidentiality, ECO adopts the provisions of Legislative Decree 30 June 2003, No. 196 and EU Regulation no. 679/2016 on the processing of data provided by the Applicant. It also adopts measures aimed at the protection of data and information obtained during conformity assessment, testing and/or measurement activities, and more generally during all phases involving processes related to the provision of services offered.

ECO does not disclose the data and information referred to above, except where expected or required by law[13], requesting consent in any case or producing written notice to the Applicant concerned, and extends the obligation of confidentiality to all internal and external personnel involved in the activities referred to in this Regulation, and adopts appropriate measures for control, management and storage of information transmitted on electronic media.

The Applicant explicitly approves that the information and documents pertaining to the Certification are accessible to ACCREDIA and to the ECO Certification Committee for the control activities required by the reference standards.

15. Certification Registration Data

If the Applicant changes its company name or address, it must promptly communicate the changes to ECO in writing, by registered letter with return receipt, sending:

- a copy of the new certificate of registration to the Chamber of Commerce, or an equivalent document;
- a copy of the notarial deed attesting to the aforementioned change.

Once all the necessary checks have been completed, ECO will issue a new Attestation/Certificate, cancelling the previous one. ECO reserves the right to carry out additional verifications to check the safeguarding of the requisites necessary to maintain the validity of the Certification issued. In all other cases, ECO will proceed with the revocation of the Certification.

[13] e.g. in the cases provided for in paragraph 7 of Annex IX of the Directive, or at the request of the judiciary

16. Clause for safeguarding the Certifications issued

In order to protect the certified fixed pressure equipment, in the event that legal responsibilities deriving from its operations can have serious consequences from the point of view of the Certification Body's survival, ECO shall sign agreements with other Certification Bodies of equal qualification to guarantee the validity of the certifications issued without increasing costs for the certified companies, until the natural expiration of the contracts signed with them.

This process will be initiated only with the prior written consent of the Organisations certified by ECO which, alternatively, have the right to renounce the Certification.

17. Modification of Fixed Pressure Equipment or QMS

The Applicant has the obligation to communicate in writing the modifications it intends to make to the fixed pressure equipment, to the internal manufacturing control process or its own QMS, by sending ECO all the documentation useful for assessing them, as indicated in paragraph 7.6.

ECO will carry out the necessary verifications, reserving the right to carry out additional verifications on the Applicant's premises, the costs for which are expected to be borne by the Applicant. If the changes made affect the conformity to the requirements of the Directive or the applicable standards, ECO will suspend the validity of the Certification until the Applicant makes the necessary adjustments.

In the case of positive assessments that do not compromise the validity of the Certification, ECO will issue a confirmation of validity of the existing Certification or issue a new one to the Applicant.

18. Extension/Reduction of Certification

If the Applicant communicates to ECO its intention to Extend or Reduce[14] the scope of the Certification, the Body will evaluate the content of the request in order to determine whether the extension or reduction[15] can be granted.

Once the assessment procedure to be carried out has been defined, ECO formalises the decision to the Applicant by issuing a specific proposal based on what is specified in the rate table. The verification activity of extensions/reductions follows the phases described for the Certification process.

In the case of reducing the Certification, the Applicant shall revise all publicity material.

19. Changes to Certification requirements

The issuance of new editions of the harmonised standards, or changes in the legislative framework concerning fixed pressure equipment, may modify the requirements for obtaining and maintaining the Certification.

ECO shall promptly notify the Applicant of the need to transpose the new requirements, also informing it of the deadline for adaptation to the new provisions, and to formalise a detailed economic proposal for the performance of additional verifications necessary to check the Applicant's adaptation to the new requirements.

If, as a result of the verifications performed, ECO detects the Applicant's failure to adapt, it will activate the suspension procedure for the Certification as per paragraph 11. In the event that the Applicant expresses its intention not to comply with the new requirements, or refuses the proposed verification activities, ECO will revoke the Certifications granted on the date the new provisions enter into force.

20. Changes to the Regulation

The continuous updating of the standards and legislative framework applicable to the activities conducted by ECO and involved in this regulation may require the modification of one or more of its paragraphs.

ECO shall make the latest updated version of the Regulations available on its website and at its offices or will send an electronic copy upon customer request.

The Applicant shall comply with the new conditions established by the Regulations, as indicated in paragraph 1. The updating of the Regulations cannot be considered a reason for withdrawal from the contract signed with ECO.

[14] e.g. including new types of fixed pressure equipment or excluding types of fixed pressure equipment that are obsolete or no longer produced

[15] In some cases, reducing the scope of the Certification could invalidate it overall

21. Economic Conditions

The economic conditions indicated in the Proposal, drawn up by ECO for the activities referred to in this regulation, are based on the information contained in the Application sent by the Applicant (Mod26 as per paragraph 9.2) and refer to the Rate Table items[16], defined by the Body's Management.

If Applicant wants to access the Certification services, they must accept ECO's Proposal, following the procedures indicated in paragraph 9.3, and shall comply with the payment terms contained therein.

21.1 Changes to the Proposal, the Rate Table and the Right of Withdrawal

Changes to the economic conditions signed by the Applicant can be applied by ECO if it becomes aware of any discrepancy between the data communicated by the Applicant at the time of completing the Application and that found during the subsequent verification activities required by the Certification Process. Or they may occur following revisions of the Rate Table.

21.1.1 Changes to the Proposal

In the event that conditions differing from those declared in the Application are found and they require an additional verification activity, ECO informs the Applicant of the necessary financial additions, suspending the Certification Process until they are accepted.

If the Applicant refuses the financial additions presented, ECO announces the interruption of the Certification Process, quantifying the amounts only for the activities already carried out.

21.1.2 Changes to the Rate Table

The Rate Table applied by ECO is periodically reviewed by the Body's Management. In the event of variations compared to the economic conditions signed, ECO informs the Applicant of the new amounts applied to the verification activities, by fax, e-mail or regular post.

The Applicant has the right to refuse the new economic conditions within one (1) month from the date of communication. When refusing the new amounts, the Applicant will see the Certification's validity expire at the natural expiration of the contract or at the time of the first surveillance verification.

For any activities already carried out during the month envisaged for the renunciation, ECO will apply the economic conditions prior to the change to the Rate Table.

21.1.3 Withdrawal and notice

The Applicant may withdraw from the contract signed with ECO by giving written notice not less than three (3) months from the expiry date of the Certification.

If the Applicant does not fulfil the economic commitments undertaken with ECO, the Body reserves the right to issue a letter of formal notice that may lead to suspension or revocation of the Certifications granted.

[16] The Rate Table can be consulted at the Body's offices following a written request from the applicant's legal representative.

Annex A - Publicity and use of the Certification

The Applicant may disclose and publicise, in the manner deemed most appropriate, their obtaining Certification of the product, fully reproducing the Attestation or Certificate obtained, enlarging or reducing it, in colour or black and white, provided that it remains legible and does not undergo any alteration.

Solutions other than those defined in this paragraph must be authorised in writing by ECO.

The Manufacturer must avoid misleading or ambiguous use of the Certification issued by ECO and must prevent the Certification from being considered as extended to products which are not covered by the certificate issued by ECO.

In the case of non-compliant use of the certificate with respect to that indicated in this section, ECO reserves the right to take appropriate measures against the manufacturer, including the use of appropriate legal actions and revocation of the Certification granted.

The use of the Body's Trademark and the Accredia Trademark, on the publicity documentation prepared by the Applicant, must be approved by ECO, following the procedures indicated in RG02 "Regulation for use of the Trademark".

The Annex is an integral part of the Regulation.

Information pursuant to Article 13, Legislative Decree 30/06/2003 No. 196 and EU Regulation no. 679/2016

Dear Customer,
Following the entry into force of the Code on the processing of personal data (Legislative Decree No. 196/2003), and following the entry into force of EU Regulation no. 679/2016, in compliance with that governed by Article 13 of the provisions of the law in question, we wish to inform you of the following:

Purpose of the data processing:
Your personal data freely communicated and acquired by us as a result of the activity carried out by ECO CERTIFICAZIONI S.p.A. will be treated in a lawful and correct manner for the following purposes: administrative, accounting, commercial.
Your data will not concern data of a so-called "sensitive" nature but may concern "judicial" data in the event of dispute.
In this regard, it is recalled that sensitive data means: "any personal data suitable for revealing racial and ethnic origin, religious, philosophical or other beliefs, political opinions, membership of parties, trade unions, associations or organizations of a religious, philosophical, political or trade union nature, as well as personal data capable of revealing the state of health, biometric data and data suitable for revealing sexual habits ".
Judicial data means: "personal data suitable to reveal measures pursuant to art. 3 paragraph 1 letters from a) to o) and from r) to u), of DPR 313/2002, concerning criminal records, the register of administrative penalties depending on the offense and the relative pending charges, or the quality of defendant or investigated, pursuant to articles 60 and 61 of the criminal procedure code.

Data processing methods:
Your data will be processed, in compliance with the necessary security and confidentiality, through the following methods: collection of data directly from the interested party or electronically (for example e-mail). Data will be collected and recorded for specific, explicit and legitimate purposes and used in further processing operations in terms compatible with these purposes. The processing will be carried out with and without the aid of electronic and automated tools, the storage of data will take place in a form that allows the identification of the data subject for a period of time not exceeding the period indicated below.

Processing legal basis:
The processing legal basis of your personal data is based on a contract signed between the parties or on contract proposals (commercial offer).

Legitimate interests pursued by the Data Controller:
Pursuant to art. 6 the lawfulness of the processing is based on the express consent of the interested party.

Mandatory or optional nature of providing data and consequences of a refusal to answer:
The nature of your provision of data is mandatory for the delivery of the required products, in case of refusal, it will be impossible to supply from us.

Communication of data to third parties:
Your data may be disclosed during inspections or controls (if requested to us), to all inspection bodies responsible for inspections and controls concerning the regularity of legal obligations.
Your data may also be disclosed to companies / professional firms that provide assistance, advice in accounting, administrative, tax, legal, tax and financial, for accounting.

Storage times:
Your personal data will be stored for n. 10 (ten) years from the termination of the supply relationship, unless otherwise specified by specific legislation applied.

Existence of an automated decision-making process:
There is no automated decision-making process; the data are not subject to profiling.

Controller intention:
The controller will not transfer your personal data to a third country or to an international organization.

Data controller and processor:
The controller is ECO CERTIFICAZIONI S.p.A., with registered office in Faenza (RA), via Mengolina n. 33, in the person of Farina Carlo.
Controller contacts, email: info@eco-cert.it
The person in charge of processing designated for replying to the interested party in case of exercise of the rights, is Mr. Minguzzi Stefano.
The interested party may at any time exercise the rights reserved to him or her, sanctioned by art. 7 of which the full text is reported.

Art. 7 D.Lgs. 196/2003 and art. 15 EU Regulation no. 679/2016 - Right to access personal data and other rights
The interested party has the right to obtain confirmation of the existence or not of personal data concerning him or her, even if not yet registered, and their communication in intelligible form.
The interested party has the right to obtain the indication: of the origin of personal data; the purposes and methods of processing; the logic applied in case of treatment carried out with the aid of electronic instruments; the identification details of the controller, of the person in charge and of the designated representative pursuant to art. 5 paragraph 2; the subjects or the categories of subjects to whom the personal data may be communicated or who can learn about them as appointed representative in the territory of the State, managers or agents.
The interested party has the right to obtain: the updating, rectification, or, when there is interest, the integration of data; the cancellation, transformation into anonymous form or blocking of data processed unlawfully, including data whose retention is unnecessary for the purposes for which the data were collected or subsequently processed; the attestation that the operations, referred to in letter a. and b., have been brought to the attention, even as regards their content, of those to whom the data have been communicated or disseminated, except in cases where such fulfilment is found to be impossible or involves a use of means manifestly disproportionate to the protected right.
The interested party has the right to object in whole or in part: for legitimate reasons to the processing of personal data concerning him or her, even though they are relevant to the purpose of the collection; to the processing of personal data concerning him or her for the purpose of sending advertising or direct sales material or for carrying out market research or commercial communication.
In particular, the data subject may at any time ask the controller for access to personal data and for correction or deletion of the same or the limitation of the processing that concern him or her or to oppose their treatment, in addition to the right to the portability of data.
The data subject has the right to withdraw the consent at any time without prejudice to the lawfulness of the treatment based on the consent given prior to the revocation and has the right to lodge a complaint with a supervisory authority.
The deletion of data is not allowed in cases where the applied legislation provides for its maintenance for a specified period.

The exercise of rights can be exercised by writing to the e-mail address: info@eco-cert.it

The Controller