

TABLE OF REVISIONS

Rev.	Date	DESCRIPTION of CHANGES	Drafted by	Approved by
00	09/01/2024	Translation and new issuing	HoD	PCA

CONTENTS

1	PURPOSE	4
1.1	CONFORMITY ASSESSMENT OF FIXED PRESSURE EQUIPMENT	4
1.2	EVALUATION PROCEDURES ADOPTED	5
2	REFERENCE DOCUMENTS.....	5
3	DEFINITIONS	6
4	PRINCIPLES OF IMPARTIALITY AND TRANSPARENCY.....	7
5	LIABILITY.....	8
6	COMMITMENTS OF THE APPLICANT	8
6.1	GENERAL.....	8
6.2	RISK ANALYSIS	8
6.3	TECHNICAL DOCUMENTATION.....	8
6.4	EU DECLARATION OF CONFORMITY AND CE MARKING.....	9
6.5	HANDLING COMPLAINTS	9
6.6	COMPLIANCE WITH THE REGULATION AND THE CONTRACTUAL RELATIONSHIP	9
7	COMMITMENTS OF THE BODY.....	10
8	CERTIFICATION PROCESS	10
8.1	GENERAL.....	10
8.2	ACCESS TO CONFORMITY ASSESSMENT SERVICES – RECEIPT OF THE REQUEST	10
8.3	REVIEWING THE REQUEST AND SENDING THE PROPOSAL	10
8.4	ACCEPTANCE OF THE PROPOSAL, SUBMISSION OF THE APPLICATION AND TECHNICAL DOCUMENTATION	11
8.4.1	<i>General.....</i>	<i>11</i>
8.4.2	<i>The technical documentation related to the conformity assessment procedures for Type certification.</i>	<i>11</i>
8.4.3	<i>Documentation relating to the conformity assessment procedures for the verification of conformity of the Management System.....</i>	<i>12</i>
8.5	REVIEW OF THE ORDER AND START OF THE CERTIFICATION PROCESS	13
8.5.1	<i>Review of the Order.....</i>	<i>13</i>
8.5.2	<i>Conformity assessment process for Module A2</i>	<i>13</i>
8.5.3	<i>Conformity assessment process for Module B (Type of design)</i>	<i>13</i>
8.5.4	<i>Conformity assessment process for Modules B (Type of production), C2, F, G, H1</i>	<i>13</i>
8.5.5	<i>Compliance assessment process for Modules D, D1, E, H and H1</i>	<i>14</i>
8.6	DOCUMENTS EXAMINATION.....	14
8.6.1	<i>General.....</i>	<i>14</i>
8.6.2	<i>Examination of technical documentation</i>	<i>14</i>
8.6.3	<i>Examination of technical documentation and QMS.....</i>	<i>14</i>
8.7	OUTCOME OF THE DOCUMENT EXAMINATION AND COMMUNICATION OF THE FINDINGS	14
8.8	FUNCTIONAL ASSESSMENT	15
8.9	ADDITIONAL CHECKS	15
8.10	REVIEW AND DECISION ON CERTIFICATION	15
8.11	CE MARKING	16
8.12	NEGATIVE OUTCOME OF THE CONFORMITY ASSESSMENT	16
8.13	LIST OF CERTIFICATIONS	16
8.14	STORAGE OF THE DOCUMENTATION	16
8.15	DESCRIPTION OF THE CERTIFICATION PROCESS PHASES FOR MODULES D, D1, E, H AND H1.....	17
8.15.1	<i>Initial audit for issuing the Certification</i>	<i>17</i>
8.15.2	<i>Annual Surveillance Audit.....</i>	<i>17</i>
8.15.3	<i>Unannounced surveillance audits.....</i>	<i>17</i>
8.15.4	<i>Renewal audit within the 3rd year</i>	<i>17</i>
9	VALIDITY AND RENEWAL OF THE CERTIFICATION	17
10	WAIVER, SUSPENSION AND REVOCATION OF CERTIFICATION	18

10.1	WAIVER	18
10.2	SUSPENSION	18
10.2.1	General	18
10.2.2	Effects of Suspension	18
10.3	REVOCATION.....	18
11	COMPLAINTS AND APPEALS	19
11.1	COMPLAINTS.....	19
11.2	APPEALS.....	19
12	DISPUTES	20
13	CONFIDENTIALITY	20
14	TRANSFER OF CERTIFICATION	20
15	CLAUSE FOR SAFEGUARDING THE CERTIFICATIONS ISSUED	20
16	MODIFICATION OF PRESSURE EQUIPMENT OR MANAGEMENT SYSTEM	20
17	EXTENSION/REDUCTION OF CERTIFICATION	20
18	CHANGES TO CERTIFICATION REQUIREMENTS.....	21
19	CHANGES TO THE REGULATION	21
20	ECONOMIC CONDITIONS	21
20.1	CHANGES TO THE PROPOSAL, THE RATE TABLE AND THE RIGHT OF WITHDRAWAL.....	21
20.2	CHANGES TO THE OFFER, PRICE LIST AND RIGHT OF WITHDRAWAL	21
20.3	CHANGES TO THE PRICE LIST	21
21	PUBLICITY AND USE OF THE CERTIFICATION	22

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.

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

1.1 *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.

1.2 Evaluation procedures adopted

In consideration of the entry into force of the EA 2/17 M:2020 document, the certification requirements provided for by international standards apply to the modules (certification procedures) listed above as per the following list:

- ISO/IEC 17020:
 - Module A2,
 - res 3.1.2 approval of the permanent joint operating methods;
- ISO/IEC 17065:
 - Module B (type of production),
 - Module B (type of design),
 - Module C2,
 - Module D,
 - Module D1,
 - Module E,
 - Module E1,
 - Module F,
 - Module G,
 - Module H1;
- ISO/IEC 17021:
 - Module H;
- ISO/IEC 17024:
 - res 3.1.2: Permanent joint workers,
 - res 3.1.3: Non-destructive testing workers.

2 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 17020:2012 "Conformity assessment - Requirements for the operation of various types of bodies performing inspection";
- ISO/IEC 17021-1:2015 "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 17000:2020 "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.

3 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.

4 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.

5 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.

6 COMMITMENTS OF THE APPLICANT

6.1 General

The Applicant shall provide maximum cooperation with ECO representatives during all the stages of the Certification process described in paragraph 8.0. 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 is responsible for preparing at least the following in compliance with the requirements set by the Directive, before forwarding the conformity assessment application to ECO, using the forms on the ECO website (possibly also available on request from the office via e-mail) or through its own document compliant with the provisions of the chosen and applicable conformity assessment form. All documentation provided by the customer to support 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 or, if in market other than the Italian one, in the language of the country in which they will be placed).

It is also necessary that:

- the personnel responsible for permanent joints and related procedures are certified in accordance with the provisions of res 3.1.2 of Annex I to the Directive;
- the personnel assigned to non-destructive testing is certified in accordance with the provisions of res 3.1.3 of Annex I to the Directive;
- that the instrumentation used (e.g. pressure gauges) is equipped with a valid calibration certificate¹, as required by the ILAC P10 document.

6.2 Risk analysis

In compliance with the requirements set out in Annex I of the Directive², 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.

6.3 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

¹ The term calibration certificate implies that it must be issued by a laboratory accredited for this activity.

² Paragraphs 3 and 4 of Annex I of the Directive, "Preliminary Observations"

Pressure Equipment, in which compliance with the requirements of the Directive is demonstrated³, 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.

6.4 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, 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.

6.5 Handling complaints

The Applicant must provide evidence of handling complaints⁴ 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.

6.6 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.

³ The requirements may refer to harmonised standards, mandatory laws or current regulations, or those referred to by other applicable Directives

⁴ Ref. Article 6, paragraph 4 of the Directive

- 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 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 inspectors⁵;
- 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.

7 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.

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.

8 CERTIFICATION PROCESS

8.1 General

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 1.3, 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.

8.2 Access to conformity assessment services – Receipt of the Request

To access the conformity assessment services offered by ECO, the customer contacts the Body by sending a request for quotation or by contacting the sales back office which will register it. The request completed in its entirety provides the information necessary for defining the activities and sending the offer. The request can also be forwarded via e-mail to the technical back offices, specifying all the information necessary to define the offer. If it is not sufficient or clear, additional information will be requested before preparing the offer.

8.3 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. The proposal contains:

- descriptive data of the product for which the offer is requested;

⁵ This applies to the conformity assessment procedures foreseen for it.

- the indication of the conformity assessment procedure to be adopted in accordance with the request;
- the indication of the site for assessment;
- 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;
- the reference to the privacy policy pursuant to EU regulation 2679/2016 GDPR.

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.

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

8.4.1 General

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

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

- to provide the application form completed in its entirety and accompanied by the declaration of the Legal Representative, or delegated person, certifying that the application has not been submitted to another certification body (this declaration is explicitly required by the Directive to guarantee that the applicant will entrust the conformity assessment, referred to in the application, exclusively to ECO and to no other body);
- 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;
- declaration of having read and accepted the privacy information on the ECO website

The application must be signed by the Applicant's legal representative, or by an appropriately authorised person⁶.

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.

8.4.2 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,

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

- 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

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.

8.4.3 Documentation relating to the conformity assessment procedures for the verification of conformity of the Management System

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.

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,

8.5 Review of the Order and start of the Certification Process

8.5.1 Review of the Order

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 back office will open a new job 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, through a pre-filled email sent by the online system. 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 8.5.5 and the Audit Plan for Certification verification. The Audit Plan is sent to the customer following the communication of the GVI.

The Applicant may reject the names indicated within 2 working days, explaining the reasons in writing⁷. If the reasons are well-founded, ECO will proceed to a new assignment, indicating the new names to the Applicant.

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 P10:07 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 Head of the Department can request a copy of the calibration documentation for the equipment that will be made available to the applicant during the process.

8.5.2 Conformity assessment process for Module A2

The conformity assessment process essentially consists of two phases which can both be carried out on site:

- 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.

8.5.3 Conformity assessment process for Module B (Type of design)

The certification process involves the examination of the technical documentation (project) without on-site verification, which will be carried out according to the conformity assessment process combined with the project Module B and defined by the applicant on the basis of Article 14 of the Directive.

8.5.4 Conformity assessment process for Modules B (Type of production), C2, F, G, H1

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

- analysis of the technical documentation (project examination) – for Modules C2 and F, the examination of the project is carried out with the conformity assessment of the Module B chosen by the applicant, on the basis of Article 14 of the Directive;
- inspection of the product to verify that it is built in accordance with what is indicated in the technical documentation (in compliance with the Essential Safety Requirements), carry out the leak test (hydraulic or with gas, based on the specificities of the certified product) and verify the efficiency and functionality of any safety accessories installed.

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

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

Regardless of the conformity assessment procedure chosen, the conformity assessment process essentially consists of the following phases (for Module H1 only, the project examination must also be followed as indicated in paragraph 8.5.5)::

- Certification Audit;
- Annual Monitoring Audits;
- Unannounced surveillance audits;
- Renewal audit within the 3rd year from the date of issue of the certificate and continues with a new three-year certification period.

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 8.15.

8.6 Documents Examination

8.6.1 General

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.

8.6.2 Examination of technical documentation

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 8.4.2 and potentially 8.4.3.

8.6.3 Examination of technical documentation and QMS

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 team in charge of the verification examines the technical documentation referred to in the previous paragraphs, verifying the customer's ability to identify the requirements applicable to the standards and the directive and to carry out the examinations required to guarantee compliance of the pressure equipment with these standards. The verification of the QMS documentation will be checked at the manufacturer's headquarters during the audit.

8.7 Outcome of the Document Examination and communication of the findings

If no findings have emerged at the end of the document check, ECO will proceed with the field check on the product.

If serious deficiencies occur in the technical documentation, ECO will indicate the times within which the customer must provide a resolution program for the same and a deadline for their resolution, as a requirement for access to the next phase of the certification process, which involves the verification of the pressure equipment and its manufacturing premises if applicable. The list of NCs is communicated in written form.

Following the communication, the customer can choose to adapt their documentation or renounce the continuation of the process. In the latter case, the waiver must be communicated to ECO by certified email. The waiver involves the closure of the certification process and the charging of the amounts relating to the activities carried out (see par. 10.1).

If the applicant decides to continue with the certification, he/she will be able to proceed to adapt his/her documentation, resolving the findings that have emerged, communicating this to ECO within a period of time not exceeding six (6) months, under penalty of negative closure of the process of certification. The objective evidence of the required adjustments is evaluated by ECO during the functional verification.

If the number of NCs and their extension do not allow the normal continuation of the process, ECO will inform the customer of the need to carry out a new document check following the resolution of the findings that have emerged. The expected amounts referred to in the offer items will be charged again upon the new verification.

8.8 Functional Assessment

The assessment 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 Head of the Department.

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 documents;
- Examination of the equipment indicated in the application, to verify correspondence with what is declared in the technical file or in the type certificate presented;
- 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 it has been chosen a procedure that involves the adoption of a QMS according to the methods foreseen by the Module of the applied directive.

If findings emerge, such as NC, Observations and/or Comments, ECO will indicate the times within which the customer must provide a resolution program for the same and a deadline for the resolution of the same, as a requirement for issuing the certificate of conformity, such period cannot exceed six (6) months or go beyond the expiry of the certificate in case of renewal if less than six months.

During the activities, the Organization's staff will document with photographic images the setup of the tests and their outcome as well as any other situation for which it may be necessary to produce such evidence. The customer must ensure that these practices are carried out, which is necessary to certify the conformity of the product being evaluated. For this reason, it will be necessary to set up the activity in areas where acquiring photographic evidence is not precluded.

8.9 Additional checks

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.

8.10 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
- The Applicant/Authorised Representative
- The Manufacturer
- The Product Type
- The serial number (if applicable)
- Reference to other Type certificates (if applicable)
- Reference of the Manufacturer's Registered Office and the production facilities

- Reference to the procedures adopted to verify conformity as defined by the Directive (if applicable)
- The number of the ECO job 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 notification number of ECO Certificazioni S.p.A. 0714 and the accreditation certificate
- the reference of the Body to be contacted for accurate information on the validity of the certificate;

The certificate is signed by a person with legal representation of the Body and/or delegation of the Presidency of the Board of Directors. The document is sent only after payment of the residual amounts agreed for the verification activity performed⁸.

The customer will be able to use the certificate received only for the purposes envisaged by the Directive and in reference to the equipment / assembly for which it was issued, entering the necessary data on the declaration of conformity that he will draw up for all the obligations required for placing it on the market.

The certificate authorizes the customer to affix the CE marking, according to the requirements set by the Directive, exclusively on the pressure equipment attributable to the certificate.

8.11 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.

8.12 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 receipt⁹, indicating the reasons 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 11.2. 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.

8.13 List of Certifications

ECO prepares and keeps an updated list of the certifications issued. This list, showing the company name of the Applicant, 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.

8.14 Storage of the Documentation

The applicant undertakes to keep a copy of the technical documentation, a copy of the certificates including their attachments and the EU Declaration of Conformity for a period of ten (10) years starting from the date of placing the pressure equipment / assembly on the market. ECO keeps a copy of the documentation drawn up during the certification process in compliance with the provisions of its management system and for a minimum period of 10 years as required by the Directive.

⁸ This condition also applies in the case of transfer, renewal or modification of the certificate

⁹ Alternatively, an approved courier or another form that requires proof of delivery can be used (e.g. short manual receipt)

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

8.15.1 Initial audit for issuing the Certification

This phase is made up of two sub-phases called Stage 1 Audit and Stage 2 Audit. For further details regarding the methods of carrying out audits on the company management system, consult Regulation RG01 on the ECO website www.eco-cert.it. During the Stage 1 Audit, the completeness of the documentation required by the management system adopted by the Manufacturer is examined, according to the provisions of the Directive and the reference standard ISO 9001. The verification is carried out at the manufacturer's headquarters. If NC or OBS emerge, these must be resolved before the start of the stage 2 Audit.

During the Stage 2 Audit, a complete verification of the contents of the system documentation is conducted and its adoption in the activities conducted by the Manufacturer. The audit involves the verification of the production and verification processes required by the Directive, as well as the adequate management of tools and equipment. For Module H1, the processes relating to Design are also verified.

If NCs emerge, these must be resolved before issuing the certificate. Any OBS or COMM must be resolved by the next surveillance audit, following a treatment declaration sent to the Body.

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

8.15.2 Annual Surveillance Audit

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.

In the case of production in a single sample of category III pressure vessels and equipment based on the procedure referred to in module H, ECO carries out the final evaluation referred to in Annex I point 3.2 for each individual example.

8.15.3 Unannounced surveillance audits

The customer provides production data in order to allow ECO to establish and quantify the unannounced visits, as provided for in point 4.4 of modules D, E and H as well as in point 5.4 of module H1, for the pressure equipment referred to in categories III and IV.

8.15.4 Renewal audit 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.

To avoid interruptions in production, the renewal check must be conducted 6 months before the certificate expires. Regardless of the issue date, the new deadline will be kept three years from the previous one.

ECO will send communication adequately in advance; however, it will be the customer's responsibility to submit a formal renewal request.

9 VALIDITY AND RENEWAL OF THE CERTIFICATION

The contracts signed between ECO and the customer have a duration equal to the validity of the certification. The customer has the right to withdraw from the contract according to the methods set out in par. 20.2, the renewal of certification requires the submission of the certification application and the issuing of a new offer and involves the same steps referred to in paragraph 8.

- Form A2 → formally does not expire but automatically lapses in the absence of the surveillance foreseen and communicated by ECO;
- Production module B Project module B → 10 years;
- Form C2 → formally does not expire but automatically lapses in the absence of the surveillance foreseen and communicated by ECO;
- Modules D, D1, E, E1, H, H1 → 3 years;
- res 3.1.2 permanent joint operating methods → see RG19 published on the website www.eco-cert.it;
- res 3.1.2 permanent joint workers → see RG19 published on the website www.eco-cert.it;
- res 3.1.3 non-destructive testing personnel → see RG24 published on the website www.eco-cert.it.

10 WAIVER, SUSPENSION AND REVOCATION OF CERTIFICATION

10.1 Waiver

The customer can renounce the ongoing certification at any time and for any reason; it is therefore necessary to communicate the renouncement via PEC to be sent to the address certification@pec.ecocertificazioni.eu and pay the amount due for the activities carried out by ECO.

If the waiver is due to the failure to resolve non-conformities on the documentation and/or on the product, ECO will inform the interested parties of the negative outcome of the evaluation process pursuant to Art. 36 of the Directive.

10.2 Suspension

10.2.1 General

The validity of the certification can be suspended:

- at the customer's request by sending a PEC to the address certification@pec.ecocertificazioni.eu;
- at the sole discretion of ECO, if it finds:
 - 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
 - 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 customer via PEC. The communication reports the reason for the suspension and the time deadlines within which the customer must implement the requested corrective actions. The customer has five (5) days to communicate to ECO the acceptance of the measure and the compliance with the provisions referred to in par. 10.2.2 of this Regulation and any other useful information to inform ECO on how to resolve the disputed findings. Communication must take place via PEC.

If the Applicant does not comply with the requested communications or does not resolve the challenged causes for suspension within the indicated period¹⁰, 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.

10.2.2 Effects of Suspension

The suspension of the certification entails the prohibition of placing on the market of the pressure equipment / assemblies covered by the suspended certificate, starting from the date of suspension. In more serious cases, ECO reserves the right to ask the customer to recall them from the market, including those 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.

10.3 Revocation

The revocation measure adopted by ECO consists in the definitive withdrawal of a certificate. ECO notifies the revocation of the certification following the suspension provision, in the event that the customer has not complied with the provisions of this regulation and in particular par. 10.2.2. Furthermore, ECO will notify the revocation of certification in all cases ordered by the competent authorities or in which it finds objective evidence:

- 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;

¹⁰ The period for the adaptation is indicated by ECO and, except in exceptional cases assessed by ECO, cannot exceed six (6) months.

- 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 Decision Committee, is notified to the customer by certified email and contains the reasons for the measure adopted, and has immediate effect.

The Revocations are made public by ECO in the ways provided for by the Directive and by the 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 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.

11 COMPLAINTS AND APPEALS

On the website www.eco-cert.it, in the Communications section, the Complaints and Appeals Management Procedure (PG13) adopted by ECO is available for consultation.

All direct customers, customers of customers, other subjects who meet ECO staff during the performance of their activities on behalf of ECO, staff of accreditation bodies, concessionaire bodies, of the bodies responsible for market supervision and institutional bodies in general.

11.1 Complaints

Legitimate subjects can present a complaint both in written and verbal form, as long as it is not anonymous and provided that the verbal complaint is followed by written communication in the forms provided for by the PG13 procedure.

Having received the Complaint, the Body analyzes its content and identifies the actions necessary for the management and resolution of the same, in accordance with the internal procedures adopted by it (PG13). Following the management of the Complaint, ECO always provides the complainant with a written and reasoned response, whether the Complaint is unfounded or well-founded. In this latter case, ECO proposes the resolution actions of the same, making the complainant aware of it and keeping him informed on the progress and results.

11.2 Appeals

The subjects entitled to appeal are identifiable exclusively as direct customers (or their representatives) as the decisions taken by the body at the end of the activities carried out rarely involve third parties.

Appeals can be submitted by registered letter with return receipt. or alternatively by PEC to the address certification@pec.ecocertificazioni.eu within 15 (fifteen) working days from notification of the act/decision against which you are appealing, specifying the reasons for the same and the evidence necessary to support your thesis, indicating always a PEC address at which to receive communications relating to the management of the Appeal.

Within 10 working days of receipt, ECO confirms by certified email to the address provided that the Appeal has been received and taken care of, at the same time communicating all the contact details of whoever is managing it.

It then informs the appellant about the progress of the appeal.

ECO will manage and close the appeal within a maximum of 3 (three) months from its receipt, notifying the outcome to the appellant at the PEC address provided.

The presentation and pending nature of the Appeal do not suspend the validity of the decisions taken by ECO.

If the decision taken as a result of the Appeal does not satisfy the appellant, it may be challenged in litigation with ECO.

Any costs for the review following the Appeal are borne by the losing party.

12 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.

13 CONFIDENTIALITY

The activities carried out by ECO cannot ignore the evaluations of data and documents that represent sensitive elements of the Company's know-how and/or information subject to a guarantee of the Customer's privacy. To guarantee the necessary confidentiality on the same, ECO adopts the provisions of the Legislative Decree of 30 June 2003, n. 196 and Regulation (EU) 2016/679 GDPR, regarding the processing of data provided by the customer. It also adopts measures aimed at protecting the data and information obtained during conformity assessment activities, testing and/or measurement activities and more generally during all phases involving the processes relating to the provision of the services offered.

The terms of processing are available on the website www.eco-cert.it.

ECO does not reveal the above data and information, except where required or required by law, by producing written information to the Customer concerned unless otherwise indicated by the judicial authority, it extends the obligation of confidentiality to all internal staff and external involved in the activities referred to in this Regulation and adopts appropriate control, management and conservation measures of the information conveyed on IT media.

The Client explicitly approves that the information and documents relating to the certification are accessible to ACCREDIA, the Certification Committee and the Impartiality Safeguarding Mechanism, for the control activities required by the reference standards.

14 TRANSFER OF CERTIFICATION

If the customer changes his company name or address, he must promptly communicate the changes in writing by registered letter with return receipt or by certified e-mail to certification@pec.ecocertificazioni.eu, 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.

15 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.

16 MODIFICATION OF PRESSURE EQUIPMENT OR MANAGEMENT SYSTEM

The customer has the obligation to communicate in writing the changes he intends to make to the pressure equipment / assemblies, to the internal manufacturing control process or to his management system, sending to ECO all the documentation useful for the evaluation of the same as indicated in the par. 8.6.

ECO proceeds to carry out the necessary checks, reserving the right to carry out additional checks at the customer's premises, the costs of which are intended to be borne by the customer. If the changes made jeopardize compliance with the requirements of the Directive or the applicable standards, ECO will proceed to suspend the validity of the certification until the customer makes the necessary adjustments.

In case of positive evaluations that do not jeopardize the validity of the certification, ECO proceeds to issue a confirmation of its validity or to issue a new one.

17 EXTENSION/REDUCTION OF CERTIFICATION

If the Applicant communicates to ECO its intention to Extend or Reduce the scope of the Certification, the Body will evaluate the content of the request in order to determine whether the extension or reduction 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.

18 CHANGES TO CERTIFICATION REQUIREMENTS

The issuing of new editions of the harmonized standards, or the changing legislative landscape relating to pressure equipment / assemblies, may modify the requirements for obtaining and maintaining certification.

ECO undertakes to promptly communicate to the customer the need to implement the new requirements, also informing them of the deadline for adaptation to the new provisions and formalizing a detailed economic proposal for carrying out additional checks necessary to verify compliance with the new requirements.

If, following the checks carried out, ECO finds that there has been no compliance, it will activate the certification suspension procedure referred to in par. 10.2. In the event that the customer expresses the intention not to adapt to the new requirements, or refuses the proposed verification activities, ECO will arrange for the revocation of the certifications granted on the date of entry into force of the new provisions.

19 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.

20 ECONOMIC CONDITIONS

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

The economic conditions reported in the Offer drawn up by ECO for the activities referred to in this regulation are based on the information contained in the offer request sent by the customer and refer to the items in the Price List¹¹, defined by the Management of the Organisation.

The customer who wants to access the certification services must accept ECO's offer, according to the methods reported in par. 8.4, also undertaking to respect the payment conditions contained therein.

If the customer does not fulfil the economic commitments undertaken with ECO, the Organization reserves the right to issue a letter of formal notice which may lead to the suspension or revocation of the certifications granted.

20.2 Changes to the Offer, Price List and right of withdrawal

Changes to the economic conditions signed by the customer may be applied by ECO if it detects discrepancies between the data communicated when completing the request and those found during the subsequent verification activities envisaged by the certification process. Or following revisions of the Price List.

In the event that conditions are found that differ from those declared in the request and in the subsequent certification application which justify additional verification activities, ECO will communicate to the customer the necessary financial additions, suspending the certification process until they are accepted.

To the customer who refuses the economic integration presented, ECO communicates the interruption of the certification process, quantifying the amounts only for the activities already carried out.

20.3 Changes to the Price List

The tariff applied by ECO is periodically reviewed by the Management of the Organisation. In the event of variations with respect to the economic conditions signed, in particular for the modules that provide for surveillance at regular intervals and/or without notice, ECO communicates to the customer the new amounts applied to the verification activities, by e-mail or certified e-mail.

¹¹ The Price List can be consulted at the headquarters of the Body following a written request from the legal representative of the customer.

The customer has the right to refuse the new economic conditions within one (1) month from the date of communication. By refusing the new amounts, the customer will see the validity of the certification lapse upon the natural expiry of the contract or on the occasion of the first surveillance audit.

For any activities already carried out during the month foreseen for the waiver, ECO will apply the economic conditions prior to the change in the price list.

21 PUBLICITY AND USE OF THE CERTIFICATION

The customer can make known and publicize, in the ways he deems most appropriate, the obtaining of product certification, reproducing the obtained certificate in full, enlarging or reducing it, in colour or black and white, as long as it remains legible and does not undergo alterations. any.

Solutions different from those defined in this paragraph must be authorized in writing by ECO.

The customer must avoid misleading or ambiguous uses of the certification obtained and must prevent the certification from being considered extended to products not covered by the certificate issued by ECO.

In the event of non-compliant use of the certificate with respect to what is indicated in this paragraph, ECO reserves the right to take appropriate measures against the manufacturer, including the use of appropriate legal action and the revocation of the certification granted.

The use of the Body's logo and the ACCREDIA logo, on the advertising documentation prepared by the customer, must be approved by ECO, according to the methods indicated by RG02 "Regulations for use of the Logo".