REGULATION FOR THE CERTIFICATION ACTIVITIES OF PRESSURE EQUIPMENT/ASSEMBLIES

UNDER DIRECTIVE 2014/68/EU (PED)

Kiwa Cermet Italia S.p.A. - Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
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rev. no.	SUMMARY OF CHANGES	DATE
6	Clarifications added regarding unannounced verifications in § 6 and any production weld coupons in the ESR section of § 7	2026-07-03
5	Rebranding, edited fonts and Kiwa logo; edited Regulation code	2025-11-19
4	Corrected an inaccuracy in § 6.14.3 regarding the start of validity of the certificate for joining processes; rebranding (Kiwa font and logo)	2025-06-11

Verified by:

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1. SCOPE AND FIELD OF APPLICATION

This Regulation defines the rights and obligations, as well as the operating methodology governing the relationship between Kiwa Cermet Italia S.p.A. (hereinafter referred to as "Kiwa" for brevity) as a Notified Body and Customer Organisations, for the implementation of the Conformity Assessment procedures for "Pressure Equipment and Assemblies" (hereinafter referred to as "Pressure Equipment") in accordance with Directive 2014/68/EU (hereinafter referred to as the "Directive"), as transposed by Legislative Decree No. 26 of 15 February 2016, pursuant to Modules A2-B-C2-D-D1-E-E1-F-G-H-H1 of Annex III to the Directive. For the definition of "Pressure Equipment and Assemblies" covered by this Regulation, reference shall be made to Article 1 of the Directive.

Furthermore, this Regulation defines the principles, criteria and procedures, in accordance with the reference standards listed below, for the management of activities relating to the qualification, certification and subsequent maintenance of certification of technical personnel engaged in the production of permanent joints by means of suitable welding and/or brazing procedures on metallic components, and of the related joining processes applied to pressure systems, by Kiwa acting as a Notified Body in accordance with point 3.1.2 of Annex I to Directive 2014/68/EU.

Any form of consultancy provided to the Customer that could compromise the independence of the assessments performed is expressly excluded from the scope of the contract.

The requirements set out in this regulation form an integral part of the contract entered into with Kiwa (economic quotation, Kiwa Regulation for Certification and the *General Terms and Conditions of Kiwa Cermet Italia for the performance of the orders*, hereinafter referred to as the *General Terms and Conditions*, for brevity). These requirements apply solely to the aspects specifically related to the scope of the requested certification.

This Regulation is also available on the Kiwa website (www.kiwa.com).

The modules provided for in Annex III to the PED Directive, for which Kiwa carries out conformity assessment activities for Pressure Equipment, are listed below. These modules describe the procedures to be followed for the conformity assessment of pressure equipment and assemblies, both by the manufacturer and by Kiwa.

❑ Module A2	❑ Module B (type of production)	❑ Module B (design type)
❑ Module C2	❑ Module D	❑ Module D1
❑ Module E	❑ Module E1	❑ Module F
❑ Module G	❑ Module H	❑ Module H1

2. REFERENCE DOCUMENTS

2.1 General Requirements for the application of the PED Directive

- UNI CEI EN ISO/IEC 17065 – Requirements for bodies certifying products, processes and services
- EA-2/17 M – EA Document on Accreditation for Notification Purposes.

2.2 Requirements for the application of Module A2 (Internal production control combined with official pressure equipment checks carried out at random intervals, Annex III)

UNI CEI EN ISO/IEC 17020 – Conformity Assessment – Requirements for the operation of various types of bodies performing inspection.

2.3 Requirements for the application of Module H (conformity based on full quality assurance)

UNI CEI EN ISO/IEC 17021-1 – Conformity Assessment – Requirements for Bodies providing audit and certification of management systems – Part 1: requirements.

2.4 Requirements for the certification of welding and brazing personnel involved in the manufacture of category II, III and IV pressure equipment, Annex I, point 3.1.2

Document	Description
UNI CEI EN ISO/IEC 17024	Conformity Assessment – General requirements for bodies operating certification of persons
UNI EN ISO 9606-1	Welder qualification testing – Fusion welding – Part 1: Steels
UNI EN ISO 9606-2	Welder qualification testing – Fusion welding – Part 2: Aluminium and aluminium alloys
UNI EN ISO 9606-3	Welder qualification tests – Fusion welding – Part 3: Copper and copper alloys
UNI EN ISO 9606-4	Welding – Welder qualification tests – Fusion welding – Part 4: Nickel and nickel alloys
UNI EN ISO 9606-5	Welding – Welder qualification tests – Fusion welding – Part 5: Titanium and titanium alloys, zirconium and zirconium alloys
UNI EN ISO 14732	Welding personnel – Qualification testing of welding operators and welding setters for fully mechanised and automatic welding of metallic materials
UNI EN ISO 13585	Brazing – Qualification testing of brazers and brazing operators

2.5 Requirements for the certification of permanent joining processes used in the manufacture of category II, III and IV pressure equipment, Annex I, point 3.1.2

Document	Description
UNI CEI EN ISO/IEC 17020	Conformity assessment – Requirements for the operation of various types of bodies performing inspection
UNI EN 13134	Brazing – Procedure qualification
UNI EN 14276-1	Pressure equipment for refrigeration systems and heat pumps – Part 1: Vessels – General requirements
UNI EN ISO 15613	Specification and qualification of welding procedures for metallic materials – qualification based on pre-production welding tests
UNI EN ISO 15614-1	Specification and qualification of welding procedures for metallic materials – Welding procedure qualification test – Part 1: Arc and gas welding of steels and arc welding of nickel and nickel alloys
UNI EN ISO 15614-2	Specification and qualification of welding procedures for metallic materials – Welding procedure qualification test – Part 2: Arc welding of aluminium and its alloys
UNI EN ISO 15614-5	Specification and qualification of welding procedures for metallic materials – Welding procedure qualification test – Part 5: Arc welding of titanium, zirconium and their alloys
UNI EN ISO 15614-6	Specification and qualification of welding procedures for metallic materials - Welding procedure qualification test - Part 6: Arc and gas welding of copper and its alloys

UNI EN ISO 15614-7	Specification and qualification of welding procedures for metallic materials – Welding procedure qualification test – Part 7: Overlay welding
UNI EN ISO 15614-8	Specification and qualification of welding procedures for metallic materials – Welding Procedure Qualification Test – Welding of Tubes to Tube-Plate Joints
UNI EN ISO 15614-11	Specification and qualification of welding procedures for metallic materials – Welding procedure qualification test – Electron beam and laser beam welding

At the request of the Organisation, Kiwa may carry out the same certification/approval activities for Welding Processes/Procedures and Personnel/Welders in accordance with other recognised international standards and codes in addition to those listed above (e.g. ASME BPVC, API, Collection S (Italian "*Raccolta S*")).

The standards referenced in this Regulation shall be understood to mean the revision in force at the time the contract with Kiwa is signed (unless otherwise specified in writing, in the event of transition periods granted following revision of the aforementioned standards).

3. GENERAL PRINCIPLES AND GUARANTEES FOR THE CUSTOMER

In its certification activities, in addition to the provisions set out in the *General Terms and Conditions*, Kiwa applies the following principles:

a) Non-discrimination: access to certification services is granted to any Organisation requesting them, in compliance with this Regulation, without any discriminatory conditions of a commercial or financial nature, or relating to membership of particular associations

b) Impartiality and independence, ensured through formalised rules and controls, including:

- Certification activities are carried out by personnel having no interest in the Organisation subject to certification and who are required to comply with the rules of conduct and independence established by Kiwa. In this regard, Kiwa undertakes to accept any justified notifications raised by the Customer concerning potential engagement incompatibility that could compromise impartiality or independence of judgement.
- Strict application of formalised rules and procedures by all personnel involved in certification services, together with periodic consultation with appropriate interested parties interested regarding certification;
- Clear separation between personnel performing audit activities and personnel involved in certification decisions;
- Complete abstention from providing assistance in defining or implementing the requirements necessary to obtain Certification.

c) Proper handling of complaints and appeals, as defined in § 11 of this Regulation;

d) Confidentiality: in addition to the provisions of the General Terms and Conditions and the Kiwa Regulation for Certification, Kiwa requires all personnel, including its Auditors, to sign a confidentiality undertaking, as well as a document committing them to process any information obtained in compliance with applicable Privacy legislation;

e) Accreditations and Notifications: Kiwa undertakes to inform the Customer of any renunciation, suspension or withdrawal of accreditation and/or ministerial notification. In such cases, Kiwa shall in no way be liable for any damages suffered by the Customer as a result of such renunciation, suspension or withdrawal. In the aforementioned circumstances, the Customer shall be entitled to withdraw the contractual relationship with Kiwa without notice and without any additional charges.

4. ACCESS REQUIREMENTS FOR CERTIFICATION

4.1. General Requirements

Before commencing the Certification process with Kiwa, the Organisation shall meet the following requirements:

- Accept the conditions set out in this Regulation;
- Authorise access to premises, plants, areas and information necessary for carrying out the Audit;
- Appoint a Representative to act as the main contact for the Audit Team and ensure that any consultants present during the Audit act solely as observers;
- Be responsible for compliance with the applicable occupational health and safety requirements. In the absence of mandatory provisions, the Organisation undertakes to provide Kiwa with complete and detailed information regarding the specific risks existing in the environment in which Kiwa personnel will operate, as well as the personal protective equipment (PPE) required for the performance of the assignment, and to instruct Kiwa personnel on its correct use. To this end, the customer Organisation shall provide the personnel appointed by Kiwa with company documentation relating to occupational health and safety (risk assessment document (D.V.R.), safety plan, procedures, etc.), limited to the aspects of specific relevance. Should accidents occur or illnesses be contracted as a result of such omissions, no claim whatsoever may be brought against Kiwa for any reason.
- Accept, at no additional cost, the possible presence of Assessors from the Accreditation Body or supervisory Authorities acting as Observers. Such presence shall be notified by Kiwa together with a clear explanation of their roles. The purpose of such presence is to verify that the assessment methods adopted by Kiwa comply with accreditation requirements.
- Accept any assessments carried out by the Accreditation Body. In fact, in order to verify that the assessment methods adopted by Kiwa comply with the applicable standards, the Accreditation Body may require a visit, known as a Market Surveillance Visit, to be carried out at the certified Organisation directly by its own personnel. Such visit shall be notified by the Accreditation Body to Kiwa with seven working days' notice. Upon receipt of such notification, Kiwa shall inform the customer Organisation. The visit plan is prepared by the Accreditation Body and made available to Kiwa, which shall subsequently forward it to the customer Organisation. Should the Organisation refuse to grant approval for the visit, the validity of the certificate shall be suspended until such approval is granted, for a maximum period of 3 months. Upon expiry of this period, if approval has still not been granted, the certification shall be withdrawn. The Organisation shall make available to the Accreditation Body the documentation used as reference by Kiwa during previous audits. The Market Surveillance Visit does not replace the routine certification maintenance audits included in the audit programme. For details regarding the conduct of a Market Surveillance Visit, reference may be made to document IAF ID 04 (available free of charge from the IAF website: www.iaf.nu). The Accreditation Body may also adopt other monitoring methods to verify Kiwa's activities, such as unannounced verifications at the premises of certified organisations, requests for information from organisations or consultancy firms, or other control methods established by the accreditation body itself

5. GENERAL CONDITIONS

The manufacturer is responsible for the design and manufacture of a product covered by the Directive with a view to placing it on the Union market. The preparation of the technical documentation (the Technical File), the CE Marking and the issuance of the EU Declaration of Conformity are solely the responsibility of the manufacturer.

An importer or distributor shall be considered a manufacturer for the purposes of the Directive and shall be subject to the obligations of the manufacturer where it places pressure equipment on the market under its own name or trade mark, or modifies pressure equipment already placed on the market in such a way as to affect its conformity with the requirements of the Directive.

The authorised representative, established within the European Union, is formally appointed by the manufacturer and acts in the name and on behalf of the manufacturer with regard to the obligations laid down in the Directive.

A manufacturer wishing to use Kiwa for the CE marking of its Pressure Equipment is responsible for the intended use assigned to each item of Pressure Equipment and for its classification in accordance with Annex II to the Directive. Should any disagreement arise between the manufacturer and Kiwa as a result of the application of the classification rules, Kiwa, after informing the manufacturer, shall refer the matter to the Competent Authority responsible for taking any decision thereon.

In accordance with Annex II to the Directive, the manufacturer shall select the conformity assessment procedures required for affixing the CE marking to the Pressure Equipment on the basis of its classification. Accordingly, different conformity assessment Modules are available to the manufacturer, grouped by risk Category (II, III and IV), as set out in

Annex II to the Directive.

The various Modules referred to above may also involve the recognition by Kiwa of equivalent documents issued by other Notified Bodies. Acceptance of such documents shall always be subject to a formal review by Kiwa in accordance with the Directive.

Assessments and evaluations of the Quality System are carried out by Kiwa, which may also make use of testing laboratories or external assessment bodies qualified by Kiwa. Testing of Pressure Equipment shall be determined at the sole discretion of Kiwa and may be commissioned directly to Kiwa or to testing laboratories qualified by Kiwa.

Where testing laboratories or external bodies are used, the customer has the right to report any justified situations of incompatibility and to object to the testing laboratory/external body concerned. The same right shall apply to any objection regarding inspectors or technical experts.

Kiwa carries out surveillance visits, normally announced in advance, at the manufacturer's premises at least once a year in order to verify that the manufacturer maintains and applies the approved Quality System. Kiwa may carry out unannounced visits (which are mandatory in the cases provided for by the Directive).

The manufacturer undertakes to maintain its Organisation in compliance with the scope of the Certificates issued by Kiwa. The manufacturer shall notify Kiwa of any changes to the quality system and of any modifications to the Pressure Equipment manufactured, providing all documentation necessary for the assessment of such changes. Kiwa shall review the documentation relating to the changes and shall inform the manufacturer whether or not they are accepted, issuing, where appropriate, a new Certification replacing the previous one. In certain cases, acceptance of the changes may, at the sole discretion of Kiwa, be granted only following a successful additional inspection visit at the manufacturer's premises. The cost of such assessment shall be borne by the manufacturer, is not included in the Surveillance fee and is subject to payment of:

- the fee for the review of the documentation;
- the fee for any additional visits to the manufacturer's premises.

6. CONFORMITY ASSESSMENT PROCEDURES

For the purposes of this Regulation, and depending on the risk category of the Pressure Equipment, Kiwa applies the following conformity assessment modules:

Modules for Category II =	A2	D1	E1;		
Modules for Category III =	B (design type)		+ D	B (type of production) + F	
	B (type of production)		+ E	B (type of production) + C2	H;
Modules for Category IV =	B (type of production)		+ D	B (type of production) + F	
	G			H1	

For modules involving on-site verification activities, the following shall apply:

- any postponement of a planned and agreed verification, for reasons attributable to the Organisation, shall be notified to Kiwa at least two weeks before the scheduled date; otherwise, a penalty shall be charged in accordance with Article 15 of the General Terms and Conditions
- the performance of surveillance audits included within the certification cycle is subject to the Organisation having duly paid for all previous activities.

For modules D, D1, E, E1, H and H1, where it is not possible during surveillance visits to witness the performance of a final inspection, Kiwa shall carry out an unannounced visit at the first available opportunity, based on the production schedule provided by the manufacturer.

6.1 Module A2 – Internal production control and Surveillance of the final inspection

This module requires the manufacturer to keep production under internal control and to perform the final inspection of the pressure equipment under the surveillance of Kiwa during an unannounced verification.

Kiwa issues the manufacturer with an inspection report relating to the Pressure Equipment in accordance with the

conformity assessment procedure of the relevant Module A2 set out in Annex III to the Directive. Where the outcome of such inspections and verifications is positive, Kiwa issues the relevant certificate to the manufacturer.

The validity of the Certificate is subject to the performance of production surveillance visits by Kiwa at the frequency contractually agreed. Following each production surveillance visit, with a positive outcome, the Certificate is re-issued.

In the event of production being discontinued, the Manufacturer shall notify Kiwa in writing, indicating the identification details of the last item produced, and undertaking to inform Kiwa, with adequate notice, of any subsequent resumption of production.

6.2 Module B – EU-Type Examination – type of production

This module requires the manufacturer to make available to Kiwa all technical and evidential documentation relating to a type of Pressure Equipment, referred to as the "Type" (including design, production methods, final inspection, description of operation, etc.), and to provide Kiwa with a representative specimen of the "Type" production in order to verify and ascertain that such "Type specimen" complies with the provisions of the Directive.

Kiwa issues the manufacturer with a report on the review of the documentation and the tests carried out on the pressure equipment in accordance with the conformity assessment procedure of the relevant Module B set out in Annex III to the Directive. Where the outcome of such examinations and verifications is positive, Kiwa issues the manufacturer with the EU-Type Examination Certificate – type of production.

The manufacturer is also required to inform Kiwa without delay (which holds the technical documentation relating to the EU-Type Examination Certificate – type of production) of any modification to the approved pressure equipment. Such modifications shall be subject to further approval where they may affect conformity with the essential requirements or the prescribed conditions of use of the pressure equipment.

Further details regarding the operating procedures for the application of Module B (type of production) can be found in the attachment: "Alleg. REG 01-07-02-02-PED_Modulo B tipo produz."

6.3 Module B – EU-Type Examination – design type

This module requires the manufacturer to make available to Kiwa all technical and evidential documentation relating to the design of a pressure equipment in order to verify and ascertain that such Design complies with the provisions of the Directive.

Kiwa issues the manufacturer with a report on the review of the documentation carried out in accordance with the conformity assessment procedure of the relevant Module B set out in Annex III to the Directive. Where the outcome of such examinations and verifications is positive, Kiwa issues the manufacturer with the EU-Type Examination Certificate – type of design.

The manufacturer is required to inform Kiwa without delay (which holds the technical documentation relating to the EU-Type Examination Certificate – type of design) of any modifications to the design of the approved pressure equipment. Such modifications shall be subject to further approval where they may affect conformity with the essential requirements or the prescribed conditions of use of the pressure equipment.

Further details regarding the operating procedures for the application of Module B (type of design) can be found in the attachment: "Alleg. REG 01-07-02-03-PED_Modulo B tipo proget".

6.4 Module C2 – Conformity to Type

This module requires the manufacturer to make available to Kiwa all technical documentation relating to a type of pressure equipment covered by an EU-Type Examination Certificate (including design, production methods and final inspection, operating description, etc.), to make representative samples of its production available to Kiwa and to carry out the final inspection of the pressure equipment in order to verify and ascertain that such samples taken from production comply with the provisions of the Directive.

Kiwa issues a report on the analysis of the documentation and the tests performed on the pressure equipment, in accordance with the conformity assessment procedure of the relevant Module C2 set out in Annex III to the Directive. If the outcome of such examinations and verifications is positive, Kiwa issues the manufacturer with the Certificate of Conformity to type.

Further details on the operating procedures relating to the application of Module C2 are provided in the annex:

"Alleg. REG 01-07-02-04-PED_Modulo C2".

The validity of the Certificate is subject to the performance of visits at random intervals, with a frequency of at least once per year.

In the event of interruption of production, the Manufacturer shall notify Kiwa in writing, indicating the references of the last item produced and undertaking to inform Kiwa, with adequate notice, of any resumption of production.

6.5 Module D – Conformity to Type based on quality assurance of the production process

This module provides for the assessment of the company Quality Management System (QMS) for the production, inspection and testing of the finished product, for which a valid EU-Type Examination Certificate is available, and subject to surveillance by Kiwa, in order to ensure that the pressure equipment conforms to the type covered by the EU-Type Examination Certificate.

This module requires the manufacturer to adopt a recognised quality system for the production, final product inspection and testing of the pressure equipment concerned, subject to surveillance by Kiwa. The quality system ensures that the pressure equipment conforms to the type described in the EU-Type Examination Certificate and to the applicable requirements of the Directive.

The team appointed by Kiwa first evaluates the documentation supporting the quality system in order to determine whether it satisfies the applicable requirements and subsequently carries out periodic inspections at the production sites involved, in order to ascertain that the manufacturer maintains and applies the quality system. During such visits, the notified body may carry out, or have carried out, where necessary, tests on products in order to verify the proper functioning of the quality system.

Kiwa issues an audit report and a report on the analysis of the documentation and tests performed on the pressure equipment, in accordance with the conformity assessment procedure of the relevant Module D set out in Annex III to the Directive. If the outcome of such examinations and stage 1 and stage 2 audits is positive, Kiwa issues the manufacturer with the Type Certificate of the Quality Assurance System of the Production Process.

Further details on the operating procedures relating to the application of Module D are provided in the annex:

“Alleg. REG 01-07-02-05-PED_Modulo D”.

6.6 Module D1 – Quality assurance of the production process

This module provides for the assessment of the company QMS for the production, inspection and testing of the finished product, and subject to surveillance by Kiwa, in order to ensure that the pressure equipment complies with the requirements of the Directive.

This module requires the manufacturer to adopt a recognised quality system for the production, final product inspection and testing of the pressure equipment concerned, subject to surveillance by Kiwa. The quality system ensures that the pressure equipment complies with the requirements of the Directive applicable to it.

The team appointed by Kiwa first evaluates the documentation supporting the quality system in order to determine whether it satisfies the applicable requirements and subsequently carries out periodic inspections at the production sites involved, in order to ascertain that the manufacturer maintains and applies the quality system. During such visits, the notified body may carry out, or have carried out, where necessary, tests on products in order to verify the proper functioning of the quality system.

Kiwa issues an audit report and a report on the analysis of the documentation and tests performed on the pressure equipment, in accordance with the conformity assessment procedure of the relevant Module D1 set out in Annex III to the Directive. If the outcome of such examinations and stage 1 and stage 2 audits is positive, Kiwa issues the manufacturer with the Certificate of the Quality Assurance System of the Production Process.

Further details on the operating procedures relating to the application of Module D1 are provided in the annex:

“Alleg. REG 01-07-02-06-PED_Modulo D1”.

6.7 Module E – Conformity to Type based on Quality Assurance of pressure equipment

This module provides for the assessment of the company QMS for final inspection and testing of the finished product, for which a valid EU-Type Examination Certificate is available, and subject to surveillance by Kiwa, in order to ensure that the pressure equipment conforms to the type covered by the EU-Type Examination Certificate and to the requirements of the Directive.

This module requires the manufacturer to adopt a recognised quality system for final product inspection and testing of the pressure equipment concerned, subject to surveillance by Kiwa. The quality system ensures that the pressure equipment conforms to the type described in the EU-Type Examination Certificate and to the applicable requirements of the Directive.

The team appointed by Kiwa first evaluates the documentation supporting the quality system in order to determine whether it satisfies the applicable requirements and subsequently carries out periodic inspections at the production sites involved, in order to ascertain that the manufacturer maintains and applies the quality system. During such visits, the notified body may carry out, or have carried out, where necessary, tests on products in order to verify the proper functioning of the quality system.

Kiwa issues an audit report and a report on the analysis of the documentation and tests performed on the pressure equipment, in accordance with the conformity assessment procedure of the relevant Module E set out in Annex III to the Directive. If the outcome of such examinations and stage 1 and stage 2 audits is positive, Kiwa issues the manufacturer with the Type Certificate of the Quality Assurance System of pressure equipment.

Further details on the operating procedures relating to the application of Module E are provided in the annex:

“Alleg. REG 01-07-02-07-PED_Modulo E”.

6.8 Module E1 – Quality Assurance, inspection and testing of finished pressure equipment

This module provides for the assessment of the company QMS for final inspection and testing of the finished product, and subject to surveillance by Kiwa, in order to ensure that the pressure equipment complies with the requirements of the Directive.

This module requires the manufacturer to adopt a recognised quality system for final product inspection and testing of the pressure equipment concerned, subject to surveillance by Kiwa. The quality system ensures the conformity of the pressure equipment with the applicable requirements of the Directive.

The team appointed by Kiwa first evaluates the documentation supporting the quality system in order to determine whether it satisfies the applicable requirements and subsequently carries out periodic inspections at the production sites involved, in order to ascertain that the manufacturer maintains and applies the quality system. During such visits, the notified body may carry out, or have carried out, where necessary, tests on products in order to verify the proper functioning of the quality system.

Kiwa issues an audit report and a report on the analysis of the documentation and tests performed on the pressure equipment, in accordance with the conformity assessment procedure of the relevant Module E1 set out in Annex III to the Directive. If the outcome of such examinations and stage 1 and stage 2 audits is positive, Kiwa issues the manufacturer with the Certificate of the Quality Assurance System, inspection and testing of finished pressure equipment.

Further details on the operating procedures relating to the application of Module E1 are provided in the annex:

“Alleg. REG 01-07-02-08-PED_Modulo E1”.

6.9 Module F – Conformity to Type based on Product Verification

This module provides for product verification by means of examination and testing of each individual item of pressure equipment by Kiwa, in order to ensure that the pressure equipment conforms to the type covered by the EU-Type Examination Certificate and to the requirements of the Directive.

Kiwa issues a report on the analysis of the documentation and the tests performed on the pressure equipment, in accordance with the conformity assessment procedure of the relevant Module F set out in Annex III to the Directive. If the outcome of such examinations and verifications is positive, Kiwa issues the manufacturer with the Certificate of Conformity to Type based on the verification of pressure equipment.

Further details on the operating procedures relating to the application of Module F are provided in the annex:

“Alleg. REG 01-07-02-09-PED_Modulo F”.

6.10 Module G – Unit Verification

4.5.10.1 - This module provides for the examination of the design and manufacture of each item of pressure equipment and the performance, during manufacture, of the appropriate tests required by the standards by Kiwa, in order to ensure

that the pressure equipment complies with the requirements of the Directive.

4.5.10.2 - Kiwa issues a report on the analysis of the documentation and the tests performed on the pressure equipment, in accordance with the conformity assessment procedure of the relevant Module G set out in Annex III to the Directive. If the outcome of such examinations and verifications is positive, Kiwa issues the manufacturer with the unit verification Certificate of Conformity.

Further details on the operating procedures relating to the application of Module G are provided in the annex:

“Alleg. REG 01-07-02-10-PED_Modulo G”.

6.11 Module H – Total Quality Assurance

This module provides for Assessment of the company QMS for design, manufacture, final inspection and testing of the finished product, and subject to surveillance by Kiwa, in order to ensure that the pressure equipment complies with the requirements of the Directive.

This module requires the manufacturer to adopt a recognised quality system for design, manufacture, final product inspection and testing of the pressure equipment concerned, subject to surveillance by Kiwa. The quality system ensures conformity of the pressure equipment with the applicable requirements of the Directive.

The team appointed by Kiwa first evaluates the documentation supporting the quality system and the technical documentation relating to a model representative of each product type to be certified, in order to determine whether it satisfies the applicable requirements, and subsequently carries out periodic inspections at the production sites involved, in order to ascertain that the manufacturer maintains and applies the quality system. During such visits, the notified body may carry out, or have carried out, where necessary, tests on products in order to verify the proper functioning of the quality system.

Kiwa issues an audit report and a report on the analysis of the documentation and tests performed on the pressure equipment, in accordance with the conformity assessment procedure of the relevant Module H set out in Annex III to the Directive. If the outcome of such examinations and stage 1 and stage 2 audits is positive, Kiwa issues the manufacturer with the Total Quality Assurance System Certificate.

Further details on the operating procedures relating to the application of Module H are provided in the annex:

“Alleg. REG 01-07-02-11-PED_Modulo H”.

6.12 Module H1 – Total quality assurance with design examination

In addition to the requirements of Module H, this module requires Kiwa to carry out a Design Examination aimed at understanding the design, manufacturing process and operation of the pressure equipment, as well as verifying compliance with the applicable requirements of the Directive, and to perform surveillance through unannounced visits regarding the Final Verification of the pressure equipment, including Pressure Tests, Final Examination and Examination of Safety Devices.

This module requires the manufacturer to adopt a recognised quality system for the design, manufacture, final product inspection and testing of the pressure equipment concerned, subject to surveillance by Kiwa. The quality system ensures conformity of the pressure equipment with the applicable requirements of the Directive.

The team appointed by Kiwa first evaluates the documentation supporting the quality system in order to determine whether it satisfies the applicable requirements and subsequently carries out periodic inspections at the production sites involved, in order to ascertain that the manufacturer maintains and applies the quality system. During such visits, the notified body may carry out, or have carried out, where necessary, tests on products in order to verify the proper functioning of the quality system.

Kiwa issues an audit report and a report on the analysis of the documentation and tests performed on the pressure equipment, in accordance with the conformity assessment procedure of the relevant Module H1 set out in Annex III to the Directive. If the outcome of such examinations and verifications is positive, Kiwa issues the manufacturer with the Total Quality Assurance System Certificate with Design Examination.

The manufacturer is also required to promptly inform Kiwa (which holds the technical documentation relating to the EC Design-Examination Certificate) of any modifications to the approved design of the pressure equipment, which must receive further approval where such modifications may affect conformity with the essential requirements or the prescribed conditions of use of the pressure equipment.

Further details on the operating procedures relating to the application of Module H1 are provided in the annex:

“Alleg. REG 01-07-02-12-PED_Modulo H1”.

6.13 Classification of findings

Each finding identified during Audits is classified as follows:

Major Non-Conformity: deviation from, or total absence of, compliance with requirements, identified on the basis of objective evidence as a result of assessment activities.

Minor Non-Conformity: deviation from, or partial absence of, compliance with requirements, identified on the basis of objective evidence as a result of assessment activities.

Multiple minor nonconformities relating to the same requirement may, depending on their content and on the overall outcome of the audit, result in the issuance of a major NC.

Minor nonconformities that are not resolved and/or not addressed by the Organisation may result in the issuance of a major NC.

Opportunities for improvement: matters that do not fall within the definitions of nonconformity and which constitute a possible improvement to the effectiveness of the solutions adopted by the customer in order to achieve compliance with the requirements and prevent deviations.

6.14 Certification / approval activities for technical personnel performing permanent joining operations and related processes (point 3.1.2 of Annex I to the Directive)

6.14.1 Certification activities

To initiate the activity, in addition to countersigning the service quotation prepared by the sales function for acceptance, the manufacturer shall complete and sign the relevant certification application, attaching the reference documents (pWPS/pBPS), where applicable.

The qualification activity for permanent joining processes (welding/brazing) and the personnel assigned thereto is based on a practical test which may, at the manufacturer's request or on the basis of specific requirements of the applicable standard, be supplemented by a theoretical examination to assess the technical competence of the personnel involved.

The theoretical examination consists of a written test based on a multiple-choice questionnaire (selected in accordance with the operational fields of the welding processes and metallic materials relevant to the candidate), divided into the various subjects specified by the applicable standards (e.g. Annex B of UNI EN ISO 9606-1). The theoretical examination is considered passed when at least 80% of the answers are correct and the result is recorded by marking the appropriate field on the certificate.

The practical test requires each candidate to prepare the test specimens, or the designated personnel to prepare the specimens for qualification of the joining processes, in accordance with the activity programme included in the service quotation accepted by the manufacturer. Kiwa personnel supervise the preparation of the test specimens by verifying the identity of the candidates, in the case of personnel qualification, and by checking that the equipment, materials and operating parameters comply with the requirements of the applicable standards and other reference documents.

At the end of the practical test, the test programmes required by the applicable standards are performed on the test specimens using laboratories accredited in accordance with ISO/IEC 17025.

Where the test programmes provide positive results, Kiwa issues the corresponding qualification certificates containing the information required by the applicable reference standards.

6.14.2 Assessment of results and issuance of the certificate

On the basis of the results of the tests and qualification examinations, Kiwa issues the certificates. The issuance of the certificate attests the qualification of the person; however, it does not confer any authority to perform the activity. Such authority is granted by the employer in documented form, who assumes responsibility for the results of the inspection. If the certified person is self-employed or is an employer, he/she shall assume all responsibilities defined above for the employer. Certificates relating to permanent joining processes for pressure systems in categories II, III and IV make it possible to demonstrate the suitability of the methods adopted for their implementation, in accordance with paragraph 3.1.2 of Annex I to Directive 2014/68/EU.

6.14.3 Certificate validity

Personnel certificates are valid for the period specified in the applicable standards, starting from the date prescribed by the relevant standard, provided that they are signed every six months by the employer (including a temporary employer) or by the supervisor, as confirmation that the following conditions are satisfied:

- the welder/brazer/operator shall regularly perform the welding work for which he/she is qualified;
- no interruptions exceeding six months are permitted;
- the work performed by the welder/brazer/operator shall generally be in accordance with the welding conditions used during the qualification test;
- there shall be no specific reasons to question the skills and technical knowledge of the welder/brazer/operator.

Certificates relating to joining processes are valid from the date of issue and have no expiration date, provided that the applying Organisation maintains the capability to reproduce the operating and environmental conditions specified therein.

6.14.4 Certificates issued by another body

Where certificates have been issued by another body, the following 3 cases may arise:

a) The procedures and personnel qualifications have been issued by a notified body or by a recognised third-party organisation in accordance with harmonised standards. Kiwa shall verify, on the basis of a documentary review, the suitability of the welding procedures and personnel qualifications with respect to the characteristics of the pressure equipment being manufactured

b) The procedures and personnel qualifications have been certified by a notified body or by a recognised third-party organisation in accordance with non-harmonised standards. Kiwa shall verify, on the basis of a documentary review, the suitability of the welding procedures and personnel qualifications with respect to the characteristics of the pressure equipment being manufactured. Where the procedures or qualifications do not cover all the minimum requirements, Kiwa may require, in addition to the documentation already available, that the examinations and tests specified in the appropriate harmonised standards, or equivalent examinations and tests, be carried out

c) The procedures and personnel qualifications have not been certified or have been certified by a non-notified body. Kiwa shall require that the necessary qualifications be obtained in accordance with the provisions of the Directive.

7. REQUIREMENTS FOR THE MANUFACTURER

Without prejudice to the validity and binding nature of all provisions of the Directive and its annexes, the manufacturer is responsible for implementing all actions necessary to ensure that the Pressure Equipment complies with the requirements of the Directive, particularly with regard to the following matters of primary importance for the conformity assessment of pressure equipment:

- Risk Analysis (RA);
- Essential Safety Requirements (ESR);
- Conformity of base and filler Materials;
- Traceability of the materials used;
- Welding qualification procedures (WPAR and WPS);
- Qualifications of personnel performing welding and Non-Destructive Testing (NDT);
- Final pressure test.
- The manufacturer shall have appropriate equipment, together with an associated maintenance and calibration programme, ensuring metrological traceability.

Risk Analysis (RA)

The Risk Analysis (RA) relating to all life-cycle phases of the pressure equipment, and in particular to the production,

transport, installation, operation, maintenance and decommissioning phases, is a mandatory requirement that the manufacturer is required to fulfil.

The Risk Analysis (RA) shall be prepared and signed by the manufacturer and shall identify all foreseeable risks associated with the possible intended uses of the equipment, as well as all reasonably foreseeable cases of misuse.

For each risk identified in the Risk Analysis (RA), the manufacturer shall provide evidence of the most appropriate measure adopted in order to eliminate or substantially reduce the risk concerned.

The Risk Analysis (RA) is a document forming an integral part of the Technical File (TF), which shall be submitted to Kiwa and, where required, to the competent authority.

Essential Safety Requirements (ESR)

The manufacturer is responsible for complying with all Essential Safety Requirements (ESR) set out in Annex I to the Directive that are applicable to its Pressure Equipment.

The manufacturer shall prepare and sign a document listing all Essential Safety Requirements (ESR) of the Directive and, for each of them, shall provide evidence of how they have been taken into consideration and fulfilled.

The list of Essential Safety Requirements (ESR) of the Directive is a document forming an integral part of the Technical File (TF), which shall be submitted to Kiwa and, where required, to the competent authority.

In particular, the Manufacturer shall define the efficiency class of welded joints (ESR 7.2) and shall specify in the fabrication and inspection plan the type and extent of the controls to be performed, including destructive tests relating to any production weld coupons to be prepared (e.g. § 9 of EN 13445-4).

Regulatory changes and/or changes to certification requirements

Kiwa keeps itself informed of technological developments generally recognised as the state of the art, indicating whether the approved type may cease to comply with the applicable requirements of Directive 2014/68/EU, and determines whether such developments require further investigation. In such cases, Kiwa shall inform the manufacturer accordingly.

It nevertheless remains the responsibility of the manufacturer to verify that its test reports are updated to the latest available version of the applicable standard and/or are technically aligned with the state of the art, in order to ensure presumption of conformity with the essential requirements of the Directive.

Should the manufacturer fail to comply with such requirements, Kiwa shall proceed with withdrawal of the certificate.

8. SUBMISSION OF THE APPLICATION

The manufacturer shall submit the application by completing the relevant Kiwa form. In such form, the manufacturer shall specify the risk Category (II, III, IV) of the Pressure Equipment and, consequently, shall indicate which Modules are intended to be applied for the conformity assessment requested from Kiwa. Pursuant to the Directive, it is prohibited to submit similar certification applications for the same products to other Notified Bodies.

The manufacturer shall submit separate applications for the procedures provided for in the Annexes to the Directive, grouped in accordance with the various Modules.

Submission of an application for Modules D, D1, E, E1, H and H1, which require assessment of the company QMS, simultaneously entails activation of the surveillance procedures associated with the relevant Modules.

The pressure equipment covered by the application may also include variants, provided that they do not involve different types of risk with respect to the Essential Safety Requirements (ESR).

Acceptance of variants or of the criteria used to determine the homogeneity of Pressure Equipment families shall be subject to the sole discretion of Kiwa.

Each application shall be accompanied by a Technical File (TF) containing, in an orderly manner, all technical documentation required by the conformity assessment procedure adopted for affixing the CE marking, in accordance with the relevant Modules set out in Annex III to the Directive. EU-Type Examination Certificates, QMS Certificates and test reports demonstrating compliance with one or more ESRs may also be attached. Acceptance of such documents shall in any case remain at the sole discretion of Kiwa.

With regard to certification activities relating to technical personnel involved in permanent joining operations and the related processes (point 3.1.2 of Annex I to the Directive), the Organisation shall submit a specific certification application by completing the relevant Kiwa form together with the personnel certification application form, in the case of applications for certification of welders/brazers/operators.

Based on the information provided, and following a preliminary review to verify its completeness, Kiwa shall prepare a service quotation, which will be sent together with this regulation. The quotation shall also specify the conditions for the provision of the service, as well as the materials and documentation that the Organisation is required to make available during the examination:

- provision of the base materials for the preparation of the test specimens, with dimensions compliant with the requirements of the applicable standards;
- type 3.1 certificates in accordance with EN 10204 for base materials and filler materials;
- technical data sheets for any shielding gases;
- valid identification documents of the candidates;
- reference WPS/BPS.

Upon receipt of the accepted service quotation, Kiwa shall send the Organisation written confirmation of acceptance of the application.

9. USE OF THE CERTIFICATION AND APPLICATION OF THE CE MARKING

9.1 Use of the CE Marking

The CE marking shall be affixed by the manufacturer to each item of Pressure Equipment that has obtained certification in accordance with the applicable Modules referred to in section 4.5 of this Regulation, in accordance with the provisions of the Directive. The CE marking shall be accompanied by the number 0476, identifying Kiwa as the Notified Body.

In application of the Directive, the manufacturer shall unequivocally identify the Pressure Equipment bearing the CE marking from that which does not bear the CE marking. Other certification marks may be affixed, provided that such marks do not give rise to confusion with the CE marking.

Use of the CE marking and of the Certifications issued by Kiwa is strictly reserved to the Manufacturer and is not transferable, except in the event of transfer or transformation of the Manufacturer's company. In such cases, Kiwa shall be informed without delay. Kiwa shall record the change and initiate the procedures for updating the Certifications, repeating and/or carrying out additional assessment visits at the Manufacturer's premises, where deemed necessary.

The Manufacturer shall keep Kiwa informed of all modifications to its certified Pressure Equipment. Such modifications shall be subject to an additional assessment by Kiwa in order to determine whether they may affect compliance with the ESRs. Where the modifications affect compliance with the ESRs or the prescribed conditions of use, Kiwa shall carry out such additional tests and verifications as it deems necessary at its sole discretion.

The manufacturer shall maintain records of all incidents occurring during the use of the Pressure Equipment and of the corrective actions taken to remedy the situation, and shall inform Kiwa in all cases required by the Directive.

The manufacturer shall maintain records of all complaints and the actions taken in response relating to Pressure Equipment for which authorisation to affix the CE marking has been granted. Such information shall be reviewed by the Manufacturer in order to assess the effectiveness of the Risk Analysis performed.

9.2 Improper use of the certification and the CE Marking

Use of the certification or certificate is deemed improper when it may mislead the purchaser as to the nature, quality or origin of the pressure equipment, or when it is not used in accordance with this Regulation.

More specifically, use of the CE marking is deemed improper when it is applied to Pressure Equipment:

- for which the certification application has not yet been submitted or has been rejected;
- which does not correspond to the scope of the Certificates;
- for which the Certificates have been withdrawn.

The above cases are provided by way of example and are not exhaustive.

Where improper use of a specific Certification issued by Kiwa is reported, Kiwa shall withdraw from the Manufacturer the right to affix the CE Marking or to use such Certification and shall inform the competent Authority and the other Notified Bodies accordingly; in all cases, Kiwa shall take all measures necessary to protect its interests.

With regard to certification activities relating to technical personnel performing permanent joining operations (point 3.1.2 of Annex I to the Directive), the use of the relevant certification shall be such as to avoid any risk that certificates relating to personnel may be confused with, or associated with, the manufacturer's certification.

9.3 Use of the certification mark

Kiwa does not provide for the granting of the right to use either the Kiwa logo or the logo of the accreditation body.

10. RIGHT OF UNILATERAL WITHDRAWAL FROM THE CONTRACT AND RENUNCIATION OR WITHDRAWAL OF CERTIFICATION

Kiwa may freely withdraw from this contract by providing written notice to the customer Organisation at least six months prior to the effective date of withdrawal. The Organisation shall in any case remain liable to pay Kiwa the amounts due for the services performed during the notice period, in accordance with the latest valid quotation.

Should the Organisation wish to withdraw from the contract, unilateral withdrawal during the validity period of the Certification shall be subject to compliance with the notice periods specified in the *General Terms and Conditions*.

In the event of contract termination, Kiwa shall issue an invoice for the costs associated with closing the certification file, in accordance with the latest valid quotation.

In the event of renunciation, the Manufacturer shall, within no more than 15 days from the date of renunciation, communicate the stock of products bearing the CE marking.

Kiwa shall inform the competent Authority and the other Notified Bodies of the renunciation.

Kiwa reserves the right to withdraw the EU-Type Certificate and/or the QMS Certification, in addition to the reasons specified in the Kiwa regulation for certification, including in the event of the manufacturer’s bankruptcy.

In the event of withdrawal, the Manufacturer shall immediately cease application of the CE marking and remove all references thereto from catalogues and advertising material. At this stage, the Manufacturer undertakes to inform Kiwa of the stock of products already manufactured and covered by the withdrawn certification.

Kiwa may require modification of the product type references for which renunciation or withdrawal of the CE marking has occurred and may also perform a verification to determine the quantity of certified products remaining in stock.

Where a product for which the CE marking has been withdrawn is present on the market due to defects that may pose a risk to users, Kiwa shall require the manufacturer to withdraw all units of that product from the market within the period specified by Kiwa.

Kiwa shall not process applications relating to products for which the CE marking has been withdrawn due to non-compliance unless the manufacturer has demonstrated that all necessary measures have been taken to prevent recurrence of the non-compliance that gave rise to the withdrawal.

With regard to certification activities relating to technical personnel performing permanent joining operations and the related processes (point 3.1.2 of Annex I to the Directive), Kiwa may carry out monitoring or control activities concerning the work of qualified personnel within the scope of its institutional activities, such as:

- surveillance activities at construction sites and manufacturing workshops;
- certification or periodic visits relating to company quality systems in accordance with UNI EN ISO 9001;
- certification or periodic visits relating to products regulated under mandatory legislation (e.g. EU Directives);
- third-party certification activities.

Within the scope of these activities, Kiwa may proceed with withdrawal of certificates where:

- the conditions set out in Article 6 of the Kiwa regulation for certification are identified;

- documented objective evidence demonstrates that qualified personnel are no longer capable of maintaining the quality of execution demonstrated during qualification;
- documented objective evidence demonstrates that the Organisation has lost the capability to reproduce the operating and environmental conditions referenced in the issued process certificates.

Withdrawal of the certificate shall be notified in writing to the Organisation and the qualified personnel by certified e-mail (PEC) or registered letter and shall result in the removal of both the individual and the relevant Organisation from the list referred to in Section 12.

In the event of withdrawal of the certificate, the qualified personnel and the Organisation undertake to discontinue all use of it.

Withdrawal of certification shall result in automatic termination of the contract to which this regulation applies pursuant to Article 1456 of the Italian Civil Code, without prejudice, in any event, to compensation for any damages suffered by Kiwa.

Qualified personnel whose certificate has been withdrawn, and the Organisation, may not submit a new certification application before 6 months have elapsed from the date of withdrawal and only after the causes giving rise to the withdrawal decision have been removed or resolved.

In the event of suspension or withdrawal related to specific issues concerning products already placed on the market, Kiwa shall inform the competent Market Surveillance Authorities, the other Notified Bodies and the Accreditation Body, and reserves the right to communicate the suspension or withdrawal decision to other third parties submitting a justified request for information.

11. COMPLAINTS AND APPEALS

11.1 Complaints

The Manufacturer may submit a documented complaint concerning its contractual relationship with Kiwa in relation to certification activities.

Such complaint may arise from issues occurring during the certification process, such as delays in the completion of the various stages and/or improper conduct by Kiwa Auditors.

Kiwa shall record complaints, analyse them and inform the complainant of the actions taken within thirty working days from the date of receipt of the complaint.

In order to ensure impartiality, all complaints shall be handled by personnel not involved in the activities to which the complaints relate.

Kiwa shall agree with the complainant whether, and to what extent, the content of the complaint and its resolution are to be made public.

11.2 Appeals

Should the complainant not be satisfied with the response received, or wish to challenge a decision taken by Kiwa, he/she may submit an appeal in writing.

The appellant shall state the grounds for the appeal and, where the appeal relates to a decision taken by Kiwa (e.g. the issuance of a Major Non-Conformity), it shall be submitted to Kiwa within 10 working days from the date on which the decision was communicated.

Kiwa shall provide the appellant with a written response and shall notify any actions to be taken within 30 working days from the date of receipt of the appeal.

In order to ensure impartiality, appeals shall be handled by functions not involved in the activities to which the appeal relates.

Detailed information on the submission of complaints and appeals is available on the website www.kiwa.it.

12. LISTS OF ISSUED CERTIFICATIONS

Kiwa maintains an up-to-date list of products, personnel and companies for which Certification has been issued, in accordance with the respective conformity assessment modules provided for by the Directive.

Such lists are periodically made available to the Competent Authority.

13. UNILATERAL AMENDMENT OF THE CONTRACT

Kiwa reserves the right to amend this Regulation at any time.

Any new clauses and/or amendments shall become effective from the date on which they are communicated to the customer in writing.

Any Organisation that does not intend to accept such amendments may withdraw from the contract by giving written notice by registered letter with acknowledgement of receipt or certified e-mail within 30 calendar days, under penalty of forfeiture, from the day following communication of the amendments by Kiwa.

The withdrawal shall take effect on the last working day of the month in which the communication is received from the customer.