REGULATION FOR CERTIFICATION ACTIVITIES OF PRESSURE EQUIPMENT/ASSEMBLIES

Rev.	Summary Edit	Date
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
3	Better description of Module A2, Module C2 and Module H. Minor changes	2023-10-18

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1. PURPOSE AND AREA OF APPLICATION

This Regulation defines the rights and duties, as well as the operating methodology that governs the relations between Kiwa Cermet Italia S.p.A. (hereinafter "Kiwa" for the sake of brevity) as notified body and the Customer Organizations, for the implementation of the procedures for the Conformity Assessment of "Pressure Equipment and Assemblies" (hereinafter referred to as "Pressure Equipment") provided for by Directive 2014/68/EU (hereinafter referred to as the "Directive"), implemented by Legislative Decree 15 February 2016, no. 26 as a Notified Body, in accordance with the provisions of Forms A2-B-C2-D-D1-E-E1-F-G-H-H1 of Annex III of the Directive itself. For the definition of "Pressure equipment and assemblies" covered by this Regulation, the provisions of Article 1 of the Directive apply.

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

Any form of consultancy to the Client that could undermine the independent nature of the assessments carried out is expressly excluded from the scope of the contract.

The requirements expressed in this regulation are an integral part of the contract stipulated with Kiwa (economic quotation, *Kiwa Regulation for Certification and General Terms and Conditions of Kiwa Cermet Italia for carrying out the assignments* - hereinafter *General Terms and Conditions* for brevity). These requirements refer only to the aspects specifically connected to the field of application of the requested certification.

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

Here below are the modules defined by Annex III of the PED Directive for which Kiwa performs the conformity assessment of Pressure equipment. Such modules describe the procedures to be followed both by the manufacturer and Kiwa to assess the conformity of pressure equipment and assemblies.

❑ Module A2	❑ Module B (type of production)	❑ Module B (type of project)
❑ 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 to apply 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 to apply Module A2 (Internal production control and official checks of pressure equipment performed randomly, Annex III)

- UNI CEI EN ISO/IEC 17020 - Conformity assessment – Requirements for various inspection bodies

2.3 Requirements to apply Module H (conformity based on total quality guarantee)

- UNI CEI EN ISO/IEC 17021-1 - Conformity assessment – Requirements for Bodies providing audits and certifications for management systems – Part 1: requirements

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

Document	Description
UNI CEI EN ISO/IEC 17024	Conformity assessment – General requirements for bodies certifying persons
UNI EN ISO 9606-1	Qualification tests for welders - Fusion welding - Part 1: Steels
UNI EN ISO 9606-2	Qualification tests for welders - Fusion welding - Part 2: Aluminum and aluminum alloys
UNI EN ISO 9606-3	Qualification tests for welders - Fusion welding - Part 3: Copper and copper alloys
UNI EN ISO 9606-4	Welding - Welders qualification tests - Fusion welding - Part 4: Nickel and nickel alloys
UNI EN ISO 9606-5	Welding - Welders qualification tests - Fusion welding - Part 5: Titanium and titanium alloys, zirconium and zirconium alloys
UNI EN ISO 14732	Welding personnel - Qualification tests of welding operators and welding preparers for fully mechanized and automatic welding of metallic materials
UNI EN ISO 13585	Brazing - Qualification of brazers and operators for brazing

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

Document	Description
UNI CEI EN ISO/IEC 17020	Conformity assessment – Requirements for various inspection bodies
UNI EN 13134	Brazing - Qualification of the procedure
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 tests - 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 tests - Part 2: Arc welding of aluminum and its alloys

Document	Description
UNI EN ISO 15614-5	Specification and qualification of welding procedures for metallic materials - Welding procedure qualification tests - 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 tests - 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 tests - Part 7: Overlay by welding
UNI EN ISO 15614-8	Specification and Qualification of Welding Procedures for Metallic Materials - Welding Procedure Qualification Tests - Welding of tubes to tubesheet
UNI EN ISO 15614-11	Specification and qualification of welding procedures for metallic materials - Welding procedure qualification tests - Electron beam and laser beam welding

If requested by the Organization, Kiwa has the right to carry out the same certification/approval activities of the Welding Processes/procedures and of the Personnel/Welders on the basis of other recognized international standards and codes besides the abovementioned ones (for example ASME BPVC, API , Collection S).

The regulations mentioned in this Regulation must be understood in their revision in force at the time of signing the contract with Kiwa (unless otherwise specified in written form, in case of transients granted following the updating of the aforementioned regulations).

Any form of advice to the Customer, which could undermine the nature of independence of the performed assessments, is expressly excluded from the subject of the contract.

3. GENERAL PRINCIPLES AND GUARANTEES FOR THE CUSTOMER

In its certification activity, in addition to the provisions of the *General Terms and Conditions*, Kiwa applies the following principles:

a) Absence of discrimination: access to certification services is allowed to any Organization that requests it, in compliance with these Regulations, without any discriminatory conditions of a commercial, financial nature or membership of particular associations

b) Impartiality and independence, ensured by the following measures:

- Carrying out the certification activities assigned to personnel having no interest in the organization subjected to certification, required to observe the rules of conduct and independence established by Kiwa; on this point, Kiwa undertakes to accept any justified reports from the Customer, relating to the existence of incompatibility of the assignment, which could compromise impartiality or independence of judgment;
- Punctual application of formalized rules and procedures, in use by all the personnel of the certification services and periodic consultation with appropriate parties interested in the certification;
- Clear separation between the personnel performing the audit activities and those participating in the certification decision;

- Total abstention from carrying out assistance activities in the definition and application of the requirements to obtain the Certification.

Punctual management of complaints, appeals and disputes, as defined in § 10 of this Regulation;

c) Confidentiality: in addition to what is regulated in the *General Terms and Conditions* and in the *Kiwa Regulations for Certification*, Kiwa ensures that all personnel, including its Auditors, sign a commitment to confidentiality, as well as a document in which the personnel undertakes to process any data it comes into possession in compliance with the provisions of the Privacy law;

d) Accreditations and Notifications: Kiwa undertakes to inform the Customer of any renunciation, suspension or revocation of accreditation and/or ministerial notification; in such cases Kiwa is in no way responsible for any damage caused to the Customer by the renunciation, suspension or revocation of accreditation or notification; in the aforementioned cases, the Customer has the right to renounce the contractual relationship with Kiwa, without the need for notice and without additional charges.

4. ACCESS REQUIREMENTS FOR CERTIFICATION

4.1 General Requirements

Before embarking on the certification process with Kiwa, the Organization must meet the following requirements:

- Accept the conditions set out in this Regulation;
- Authorize access to the premises, plants, areas and information necessary to carry out the Audit;
- Designate its own Representative as the main interlocutor of the Audit Group and have any consultants present during the Audit play the role of observer;
- Be responsible for the application of the requirements laid down by current workplace safety regulations. In the absence of mandatory provisions, the Organization undertakes to provide Kiwa with complete and detailed information on the specific risks existing in the environment in which Kiwa personnel and the PPE necessary for carrying out the assignment are intended to operate, informing Kiwa personnel on their correct use. In this regard, the customer organization must provide the personnel appointed by Kiwa with company documentation relating to safety in the workplace (D.V.R., safety plan, procedures, etc.), limited to items of specific interest. When, due to such omissions, accidents occur or illnesses are contracted, no charge can be made for any reason to Kiwa.
- Accept, at no additional cost, the possible presence of Auditors of the accreditation body or Control Authority, as Observers, who will be notified by Kiwa with a clear illustration of roles. This presence is intended to ensure that the assessment methods adopted by Kiwa comply with the requirements for accreditation.
- Accept any verification by the Accreditation Body. In fact, in order to ascertain that the assessment methods adopted by Kiwa comply with the reference standards, the Accreditation Body may request a visit, called Market Surveillance Visit, to be carried out at the certified Organization, directly through the use of their own personnel. This eventual visit is communicated by the Accreditation Body to Kiwa with 7 working days' notice. Upon receipt of this communication, Kiwa will inform the customer organization. The visit plan is prepared by the Accreditation Body, which will make it available to Kiwa, then Kiwa will send it to the customer organization. If the Organization does not grant its approval, the validity of the certificate is suspended, until approval for the visit is granted, for a maximum period of 3 months. After 3 months, in the absence of approval for the visit, the certification is revoked. The Organization must make the documentation that Kiwa used as a reference during previous audits available to the Accreditation Body. The Market Surveillance Visit does not replace the normal certification maintenance audits required by the audit program. For the procedures for carrying out the Market Surveillance Visit, reference can be

made to the document IAF ID 04 (which can be downloaded free of charge from the IAF website: www.iaf.nu). Other control methods may be adopted by the Accreditation Body, to verify the operation of Kiwa, for example. unannounced visits at the offices of certified subjects, requests for information from organizations or consulting 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, in order to be placed on the Community market. The drafting of the technical documentation (the Technical File), the CE marking and the issuance of the EU Declaration of Conformity are its sole responsibility.

An importer or distributor is deemed to be a manufacturer for the purposes of the Directive and subjected to the obligations of the manufacturer when they place pressure equipment on the market under their own name or trademark or modify pressure equipment already placed on the market in such a way that they condition compliance with the requirements of the Directive.

The authorized representative, established within the European Union, is formally appointed by the manufacturer and acts in the name and on behalf of the latter in relation to the obligations under the Directive.

The manufacturer who intends to use Kiwa for the "CE" marking of their pressure equipment, is responsible for the intended use assigned to each pressure equipment and its classification as set out in Annex II of the Directive. If there is a disagreement between the manufacturer and Kiwa resulting from the application of the classification rules, Kiwa, after informing the manufacturer, reports the terms of the disagreement to the Competent Authority to which it responds for any decision on the matter.

The manufacturer chooses, in accordance with Annex II of the Directive, the conformity assessment procedures to be able to affix the "CE" marking on the pressure equipment in relation to the classification of the same. Therefore, different conformity assessment modules are presented for the manufacturer grouped by risk category (II - III - IV) listed in Annex II of the Directive.

The various modules mentioned may also entail the recognition, by Kiwa, of equivalent documents issued by other notified bodies, the acceptance of which always implies a formal verification by Kiwa, in accordance with the provisions of the Directive.

The checks and assessments of the Quality System are carried out by Kiwa which may also make use of test laboratories or external assessment bodies qualified by Kiwa. Tests on pressure equipment are established at the absolute discretion of Kiwa and can be commissioned directly to Kiwa or to Kiwa qualified test laboratories.

In case of use of test laboratories or external bodies, it is the customer's right to report any justified incompatibility situations and to object to the external laboratory/body, the same right applies to any refusal of inspectors or technical experts.

Kiwa carries out surveillance visits, usually announced, at the manufacturer, at least once a year to ensure that the manufacturer maintains and applies the already approved Quality System. Kiwa can make visits without notice (compulsory in the cases provided for by the Directive).

The manufacturer undertakes to keep its organization compliant with the subject of the Certificates issued by Kiwa. The manufacturer must notify Kiwa of any changes to the quality system and changes in the pressure equipment produced, providing all the documentation necessary for the assessment of such changes. Kiwa examines the documentation concerning the changes and informs the manufacturer of their acceptance or not, simultaneously issuing, if necessary, a new Certification which replaces the previous one. In some cases, the acceptance of the changes may take place, at

Kiwa's unquestionable judgment, only following a successful additional inspection visit at the manufacturer. The cost of this verification is borne by the manufacturer, is not included in the Surveillance amount and is subjected to payment of:

- the amount for the examination of documents;
- the amount of any additional visits to the manufacturer.

6. CONFORMITY ASSESSMENT PROCEDURES

For the purposes of this Regulation, according to the risk category of the Pressure Equipment, for the assessment of conformity, Kiwa applies the following modules:

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

The following is valid for the modules in which on-site verification activities are envisaged:

- The postponement of the verification already scheduled and agreed, for reasons attributable to the Organization, must be communicated to Kiwa at least two weeks before the scheduled date, otherwise a penalty as provided for in Article 15 of the General Terms and Conditions
- Carrying out the surveillance inspections provided for in the certification cycle is subjected to the regular payment of the previous activities by the Organization.

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 carry out the final check on the pressure equipment under the supervision of Kiwa during an unannounced visit.

Kiwa issues the manufacturer an inspection report of the pressure equipment according to the conformity assessment procedure of the relevant Module A2 reported in Annex III of the Directive. If the outcome of these inspections and verifications is positive, Kiwa issues the manufacturer with the relevant certificate.

The validity of the certificate depends on the production surveillance audits by Kiwa Italia according to the schedule defined in the contract. After each successful production surveillance audit the Certificate is re-issued.

If the production is suspended, the Manufacturer shall give notice of it to Kiwa in writing by specifying details of the last manufactured specimen and committing to informing Kiwa of any production restart with suitable notice.

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

This module requires the manufacturer to make available to Kiwa all the technical and evidential documentation relating to a type of pressure equipment, called "Type" (ranging from design, production methods and final verification, description of operation, etc.) and make available to Kiwa a representative sample of its "Type" production in order to verify and ascertain that this "Type sample" meets the provisions of the Directive.

Kiwa issues the manufacturer with an analysis report of the documentation and tests carried out on the pressure equipment according to the conformity assessment procedure of the relevant Module B reported in Annex III of the Directive. If the outcome of these examinations and verifications is positive, Kiwa issues the manufacturer with the "EU" Type Examination Certificate - type of production.

The manufacturer is also obliged to promptly inform Kiwa (which holds the technical documentation relating to the "EU" type - production type Examination Certificate) of all changes to the approved pressure equipment, which must receive a further approval, where such changes may affect compliance with the essential requirements or prescribed manner of use of the pressure equipment.

Further details on the operating procedures relating to 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 – type of project

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

Kiwa issues the manufacturer with an analysis report of the documentation carried out according to the conformity assessment procedure of the relevant Module B reported in Annex III of the Directive. If the outcome of these examinations and verifications is positive, Kiwa issues the manufacturer with the "EU" Type Examination Certificate - type of project.

The manufacturer is obliged to promptly inform Kiwa (which holds the technical documentation relating to the "EU" Type Examination Certificate – type of project) of all changes to the design of the approved pressure equipment, which must receive a further approval, where such changes may affect compliance with the essential requirements or prescribed manner of use of the pressure equipment.

Further details on the operating procedures relating to the application of Module B (type of project) 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 the technical documentation relating to a type of pressure equipment subjected to an "EU" Type Examination Certificate, (ranging from design, production methods and final verification, to description of operation, etc.), make representative samples of its production available to Kiwa and carry out the final check on the pressure equipment in order to verify and ascertain that these samples taken from production meet the provisions of the Directive.

Kiwa issues an analysis report of the documentation and tests carried out on the pressure equipment, according to the conformity assessment procedure of the relevant Module C2 reported in Annex III of the Directive. If the outcome of these examinations and verifications is positive, Kiwa issues the manufacturer with the Certificate of Conformity to the type.

Further details on the operating procedures relating to the application of Module C2 can be found in the attachment “Alleg. REG 01-07-02-04-PED_Modulo C2”.

The validity of the certificate depends on the audits with random frequency at least once a year.

If the production is suspended, the Manufacturer shall give notice of it to Kiwa in writing by specifying details of the last manufactured specimen and committing to informing Kiwa of any production restart with suitable notice.

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

This module provides for the assessment of the company's 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 subjected to surveillance by Kiwa, 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 recognized quality system for the production, finished product inspection and testing of the pressure equipment concerned, subjected to surveillance by Kiwa. The quality system ensures that the pressure equipment conforms to the type described in the EU type examination certificate and the requirements of the Directive applicable to it.

The group appointed by Kiwa first evaluates the documentary apparatus supporting the quality system, to determine if it meets the applicable requirements, and subsequently carries out periodic inspections at the production sites involved, to ensure that the manufacturer maintains and applies the quality system. During such visits, the notified body may test products or have them tested, if necessary, to verify the correct functioning of the quality system.

Kiwa issues an audit report and an analysis report of documentation and tests carried out on pressure equipment, according to the conformity assessment procedure of the relevant Module D reported in Annex III of the Directive. If the outcome of these 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 can be found in the attachment “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, inspections and tests on the finished product, and subjected 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 recognized quality system for the production, finished product inspection and testing of the pressure equipment concerned, subjected to surveillance by Kiwa. The quality system ensures that the pressure equipment complies with the requirements of the Directive that apply to it.

The group appointed by Kiwa first evaluates the documentary apparatus supporting the quality system, to determine if it meets the applicable requirements, and subsequently carries out periodic inspections at the production sites involved, to ensure that the manufacturer maintains and applies the quality system. During such visits, the notified body may test products or have them tested, if necessary, to verify the correct functioning of the quality system.

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

Further details on the operating procedures relating to the application of Module D1 can be found in the attachment “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 the final inspection and tests on the finished product, for which a valid EU-type examination certificate is available, and subjected to surveillance by Kiwa, in order to ensure that the pressure equipment conform to the type covered by the «EU» Examination Certificate, the type and the requirements of the Directive.

This module requires the manufacturer to adopt a recognized quality system for the finished product inspection and testing of the pressure equipment concerned, subjected to surveillance by Kiwa. The quality system ensures that the pressure equipment conforms to the type described in the EU type examination certificate and the requirements of the Directive applicable to it.

The group appointed by Kiwa first evaluates the documentary apparatus supporting the quality system, to determine if it meets the applicable requirements, and subsequently carries out periodic inspections at the production sites involved, to ensure that the manufacturer maintains and applies the quality system. During such visits, the notified body may test products or have them tested, if necessary, to verify the correct functioning of the quality system.

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

Further details on the operating procedures relating to the application of Module E can be found in the attachment “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 tests on the finished product, and subjected 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 recognized quality system for the finished product inspection and testing of the pressure equipment concerned, subjected to surveillance by Kiwa. The quality system ensures the conformity of the pressure equipment with the requirements of the Directive applicable to it.

The group appointed by Kiwa first evaluates the documentary apparatus supporting the quality system, to determine if it meets the applicable requirements, and subsequently carries out periodic inspections at the production sites involved, to ensure that the manufacturer maintains and applies the quality system. During such visits, the notified body may test the products or have them tested, if necessary, to verify the correct functioning of the quality system.

Kiwa issues an audit report and an analysis report of the documentation and tests carried out on the pressure equipment, according to the conformity assessment procedure of the relevant Module E1 reported in Annex III of the Directive. If the outcome of these 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 the finished pressure equipment.

Further details on the operating procedures relating to the application of Module E1 can be found in the attachment “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 examination and testing of each individual 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 an analysis report of the documentation and tests carried out on the pressure equipment, according to the conformity assessment procedure of the relevant Module F reported in Annex III of the Directive. If the outcome of these examinations and verifications is positive, Kiwa issues the manufacturer with the Certificate of Conformity to the Type based on the verification of the pressure equipment.

Further details on the operating procedures relating to the application of Module F can be found in the attachment “Alleg. REG 01-07-02-09-PED_Modulo F”.

6.10 Module G – Verification of the unit

4.5.10.1 - This module provides for the examination by Kiwa of the design and production of each pressure equipment and carrying out at the time of manufacturing, the appropriate tests required by the standards, to ensure that the pressure equipment complies with the requirements of the Directive.

4.5.10.2 - Kiwa issues an analysis report of the documentation and tests carried out on the pressure equipment, according to the conformity assessment procedure of the relevant Module G reported in Annex III of the Directive. If the outcome of these 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 can be found in the attachment "Alleg. REG 01-07-02-10-PED_Modulo G".

6.11 Module H – Total Quality Assurance

This module provides for the evaluation of the company QMS for the design, manufacturing, final inspection and testing of the finished product, and subjected 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 recognized quality system for the design, manufacturing, finished product inspection and testing of the pressure equipment concerned, subjected to surveillance by Kiwa. The quality system ensures compliance of the pressure equipment with the applicable requirements of the Directive.

The group appointed by Kiwa first evaluates the documentary apparatus supporting the quality system and the technical documents of a sample, to determine if it meets the applicable requirements, and subsequently carries out periodic inspections at the production sites involved, to ensure that the manufacturer maintains and applies the quality system. During such visits, the notified body may test the products or have them tested, if necessary, to verify the correct functioning of the quality system.

Kiwa issues an audit report and an analysis report of the documentation and tests carried out on the pressure equipment, according to the conformity assessment procedure of the relevant Module H reported in Annex III of the Directive. If the outcome of these 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 can be found in the attachment "Alleg. REG 01-07-02-11-PED_Modulo H".

6.12 Module H1 – Total Quality Assurance with design control

In addition to the requirements of Module H this module provides that Kiwa carries out the Design Examination aimed at understanding the design, manufacturing process and operation of the pressure equipment, as well as ascertaining compliance with the requirements of the Directive that apply to it, and the surveillance with unannounced visits on the Final Verification of the pressure equipment, including the Pressure Tests, the Final Examination and the Examination of the safety devices.

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

The group appointed by Kiwa first evaluates the documentary apparatus supporting the quality system, to determine if it meets the applicable requirements, and subsequently carries out periodic inspections at the production sites involved, to ensure that the manufacturer maintains and applies the quality system. During such visits, the notified body may test the products or have them tested, if necessary, to verify the correct functioning of the quality system.

Kiwa issues an audit report and an analysis report of documentation and tests carried out on pressure equipment, according to the conformity assessment procedure of the relevant Module H1 reported in Annex III of the Directive. If the outcome of these examinations and verifications is positive, Kiwa issues the manufacturer with the Total Quality Assurance System Certificate with design control.

The manufacturer is also obliged to promptly inform Kiwa (which holds the technical documentation relating to the "CE" design examination certificate) of all changes to the design of the approved pressure equipment, which must receive further approval, where such modifications may affect compliance with the essential requirements or prescribed manner of use of the pressure equipment.

Further details on the operating procedures relating to the application of Module H1 can be found in the attachment “Alleg. REG 01-07-02-12-PED_Modulo H1”.

6.13 Classification of findings

Each finding found during the Audits is classified as follows:

Major Non-Conformity: deviation or total absence of compliance with requirements, found on the basis of objective evidence, following the assessment activities.

Minor Non-Conformity: deviation or partial absence of compliance with requirements, found on the basis of objective evidence, following the assessment activities.

Several minor non-conformities for the same requirement, depending on the contents and the general result of the audit may result in the issuance of a major NC.

Minor non-conformities not resolved and/or not taken over by the Organization may result in the issuance of a major NC.

Elements of Improvement: anything not covered by the definitions of non-compliance and which constitutes a possible improvement in the effectiveness of the solutions adopted by the customer, to achieve compliance with the requirements and prevent deviations.

6.14 Certification/approval activities of the technical personnel involved in the construction of permanent joints and related processes (item 3.1.2. of Annex I of the Directive)

6.14.1. Certification activities

To start the activity, in addition to countersigning for acceptance the service proposal prepared by the commercial function, the manufacturer fills in and signs a specific application for certification, attaching, if necessary, the reference documents (pWPS/pBPS).

The qualification activity of the permanent joining processes (welding/brazing) and of the personnel assigned to them is based on a practical test, to which, at the request of the manufacturer or on the basis of specific requirements of the reference standard, a theoretical test can be combined to ascertain technical skills of the personnel involved.

The theoretical test consists of a written exam based on a questionnaire with multiple choice questions (to be selected according to the operational areas of the welding processes for the metal materials of interest to the candidate) divided into the various topics indicated by the reference standards (e.g. Appendix B of the UNI EN ISO 9606-1 standard). The theoretical test is successful with at least 80% of correct answers, and is noted by marking the appropriate slots in the certificate.

The practical test requires each candidate to carry out the test pieces, or the designated personnel to carry out the assays for the qualification of the joining processes, as per the activity program contained in the service proposal accepted by the manufacturer. Kiwa’s personnel supervises the execution of the test pieces by checking the identity of

the candidates, in the case of qualification of personnel in charge, and verifying that the work equipment, materials and operating parameters comply with the requirements of the standards and other reference documents.

At the end of the practical test, the test programs referred to in the reference standards are performed on the test pieces, preferably using laboratories accredited according to the ISO/IEC 17025 standard.

When test programs give positive results, Kiwa issues the corresponding qualification certificates, which contain the information required by the various applied reference standards.

6.14.2. Result assessment and certificate issue

Based on the results of the tests and qualification exams, Kiwa issues the certificates. The certificate issue proves the qualification of the person, but this does not give any authority to operate. This is conferred by the employer with a written document, taking responsibility for the results of the control. If the certified person is self-employed or an employer, he/she must take all responsibilities defined above for the employer. The certificates for permanent joining processes for pressure systems of categories II, III and IV allow demonstrating the suitability of the methods adopted for their implementation, pursuant to par. 3.1.2 of Annex I of Directive 2014/68/EU.

6.14.3. Certificate validity

Personnel certificates are valid for the period indicated in the various standards starting from the date prescribed by the reference standards, provided that they are signed every six months by the employer (even temporary) or supervisor, to certify that the following conditions are met:

- the welder/brazer/operator must regularly carry out the welding work for which he is qualified;
- interruptions for a period longer than six months are not permitted;
- the work of the welder/brazer/operator must generally be in accordance with the welding conditions used in the qualification test;
- there must be no particular reasons to question the skills and technical knowledge of the welder/brazer/operator.

The certificates for joining processes are valid from the date of the issue date, and do not expire, provided that the requesting Organization maintains the ability to replicate the operational and environmental conditions reported therein.

6.14.4. Certificates issued by another body

In the case of certificates issued by another body, there may be 3 cases:

a) The procedures and qualifications of personnel have been issued by a notified body or by a third party recognized in accordance with harmonized standards. Kiwa verifies on a documentary basis the suitability of welding procedures and personnel qualifications with respect to the characteristics of the pressure equipment being manufactured.

b) The procedures and qualifications of personnel have been issued by a notified body or by a third party recognized in accordance with harmonized standards. Kiwa verifies on a documentary basis the suitability of welding procedures and personnel qualifications with respect to the characteristics of the pressure equipment being manufactured. If the procedures or qualifications do not cover all the minimum requirements, in addition to what is already available, Kiwa may request to have the examinations and tests carried out provided for in the appropriate harmonized standards, or equivalent examinations and tests carried out.

c) Personnel procedures and qualifications have not been certified or are certified by a non-notified body. Kiwa requires the necessary qualifications to be made in accordance with the provisions of the directive.

7. REQUIREMENTS FOR THE MANUFACTURER

Without prejudice to the validity and compulsoriness of all the provisions of the Directive and its annexes, the manufacturer is responsible for the implementation of all the actions necessary to ensure compliance of the Pressure Equipment with the requirements of the Directive, in particular with the aspects related to the following pivotal topics 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 the personnel who carry out the welding and non-destructive tests (NDT);
- Final pressure test.
- The manufacturer must have adequate instruments with relative maintenance and calibration program that guarantees metrological traceability.

Risk Analysis (RA)

The Risk Analysis (RA) connected to all the life stages of the pressure equipment, and in particular to the stages of production, transport, installation, operation, maintenance and disposal, is a mandatory requirement that the manufacturer has to meet.

The Risk Analysis (RA) must be prepared and signed by the manufacturer and must highlight all foreseeable risks in the possible methods of use of the equipment and in all reasonably foreseeable methods of incorrect use as well.

For each risk highlighted in the Risk Analysis (RA), the manufacturer must provide evidence of the most suitable countermeasure adopted to eliminate or significantly reduce the relevant risk.

The Risk Analysis (RA) is a document that is an integral part of the Technical File (TF) which must be submitted to Kiwa and, if requested, to the competent authority.

Essential Safety Requirements (ESR)

The manufacturer is responsible for the fulfilment of all the Essential Safety Requirements (ESR), provided for in Annex I of the Directive, applicable to his own pressure equipment.

The manufacturer must prepare and sign a document which lists all the Essential Safety Requirements (ESR) of the Directive and gives evidence for each of them of how they have been taken into consideration and met.

The list of Essential Safety Requirements (ESR) of the Directive is a document that is an integral part of the Technical File (TF) which must be submitted to Kiwa and, if requested, to the competent authority.

Regulatory changes and/or changes in certification requirements

Kiwa keeps up with technological advances generally recognized as the state of the art and indicating whether the approved type can cease to comply with the applicable requirements of Directive 2014/68/EU and decides whether such progress requires further investigation. If so, Kiwa informs the manufacturer accordingly.

In any case, it is the responsibility of the manufacturer to verify that its test reports are updated to the latest available version of the applied standard and/or that they are technically at the same level as the "state of the art", in order to guarantee presumption of conformity with the essential requirements of the Directive.

If the manufacturer does not comply with such requests, Kiwa will withdraw the certificate.

8. SUBMISSION OF THE APPLICATION

The manufacturer must submit the application by filling out the specific Kiwa form. In this form he must specify the Risk Category (II, III, IV) of the Pressure Equipment and indicate which Modules (A2, B - type of project, B - type of production, C2, D, D1, E, E1 , F, G, H, H1) intends to apply in the conformity assessment requested to Kiwa. Pursuant to the directive, it is forbidden to submit similar applications for certification, for the same products, to other Notified Bodies.

The manufacturer must submit separate applications for the procedures provided for in the Annexes of the Directive grouped according to the various Modules.

The submission of the application for Modules D, D1, E, E1, H, H1, which provide for the assessment of the company QMS, simultaneously implies the activation of the surveillance procedures according to the corresponding Modules.

The pressure equipment listed in the application may include variants as long as they do not involve different types of risk with respect to the Essential Safety Requirements (ESR).

The acceptance of the variants or criteria for determining the homogeneity of the families of pressure equipment is subjected to the unquestionable judgment by Kiwa.

Each application must be accompanied by a Technical File (TF) that collects in an orderly manner all technical documents required by the conformity assessment procedure adopted for the "CE" marking, according to the relevant Forms of Annex III of the Directive. Any "EU" type Examination Certificates, QMS Certificates, Test Reports designed to demonstrate compliance with one or more Essential Safety Requirements (ESR), whose acceptance is in any case at Kiwa's discretion, can also be attached.

As to the certification activities of technical personnel involved in the construction of permanent joints and related processes (item 3.1.2. of Annex I of the Directive), the Organization prepares a specific certification application by filling in Kiwa relevant form together with the application form for certification of personnel in charge in the case of certification application for welders/brazers/operators.

Based on such indications, after a preliminary examination to verify the completeness of the information provided, Kiwa formulates a service proposal that will be sent together with this regulation. This proposal also lists the conditions for carrying out the service, the materials and documents that the Organization must make available during the examination:

- finding the base materials for the realization of the test pieces with dimensions compliant with what is indicated in the reference standards;
- 3.1 type certificates according to EN 10204 standard for base and filler materials;
- technical data sheets of any protective gases;
- valid identity documents of candidates;
- reference WPS/BPS.

Upon receipt of the acceptance of the service proposal, Kiwa sends the written confirmation of application acceptance to the Organization.

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

9.1 Use of CE marking

Each pressure equipment that has obtained the certification according to the Modules indicated in item 4.5 of this Regulation is given the CE marking by the manufacturer in accordance with the Directive. The CE marking must be associated with the number 0476, which is the identification of Kiwa as a Notified Body.

In accordance with the Directive, the manufacturer is required to unequivocally identify pressure equipment bearing the CE marking, compared to those which do not. Other certification marks can be applied as long as such marks do not lead to confusion with the CE marking.

The use of the CE marking, Certificates and Certifications issued by Kiwa is strictly reserved to the manufacturer and is not transferable, except for transfer or transformation of the manufacturer's company, for which prompt notice must be given to Kiwa, which records the change and instructs the procedures to update the Certificates or Certifications, repeating, if deemed necessary, and/or carrying out additional evaluation visits to the manufacturer.

The Manufacturer keeps Kiwa informed of all changes to its Certified Pressure Equipment. Such changes must be subjected to an additional examination by Kiwa to verify if they can affect compliance with ESRs. If changes affect compliance with ESRs or the conditions of use provided, Kiwa will carry out additional tests and checks at its sole discretion.

The manufacturer must keep a record of all accidents occurring during the use of pressure equipment and the related actions taken to remedy them and must inform Kiwa in all cases provided for by the Directive.

The manufacturer must keep a record of all complaints and related actions taken in relation to the Pressure Equipment for which the CE marking authorizations have been granted and remedy them. Such information must be investigated by the Manufacturer to assess the effectiveness of the Risk Analysis carried out.

9.2 Improper use of the certification and CE marking

It is incorrect to use the CE marking or the certificate, when it can mislead the buyer as to the nature, quality, origin of the pressure equipment, or when it is not used in accordance with this Regulation.

Specifically, it is incorrect to use the CE marking when it is applied to pressure equipment:

- for which the certification application has not yet been submitted or has been refused;
- which does not correspond to the subject of the Certificates or Attestations of Conformity;
- for which the Certificates or Attestations of Conformity have been withdrawn.

The above-mentioned cases are for indicative and non-limiting purposes.

In case an incorrect use is reported, if Kiwa has issued a specific Certification, it revokes the manufacturer's right to apply the CE marking or use such Certification and informs the competent Authority and other notified bodies; in any case it will be taken all necessary measures to protect its interests.

As to the certification activities of the technical personnel involved in the construction of permanent joints (item 3.1.2. of Annex I of the Directive), the use of the relevant certification must be such as not to generate the risk that the personnel certificates shall never be confused or associated with the certification of the manufacturer.

9.3 Use of the conformity certification mark

Kiwa Italia does not grant the use of Kiwa logo and Accredia logo.

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

Kiwa may freely withdraw from this contract by giving to the customer organization a written six-month notice as of the effective date of the withdrawal. The Organization is in any case required to pay to Kiwa the amounts due for the services received during the notice period, as established in the last valid quotation.

If the Organization resolves to withdraw from the contract, the unilateral withdrawal during the period of validity of the Certification requires compliance with the notice time provided for in the *General Terms and Conditions* and in the *Kiwa Regulation for Certification*. In particular, for a notice of less than three months with respect to the scheduled Audit and

longer than two weeks, the Customer shall pay 50% of the amount relating to the amount foreseen for the subsequent activity provided for in the contract. For notice periods of less than two weeks, the provisions of the *General Terms and Conditions* apply.

In case of termination of the contract, Kiwa will issue an invoice for the costs of closing the certification file, as established in the last valid quotation.

In case of renunciation, the manufacturer shall communicate, within a period not exceeding 15 days from the date of renunciation, the stocked products bearing the CE marking.

Kiwa informs the competent Authority and other notified bodies of the renunciation.

Kiwa reserves the right to withdraw the EU Type Conformity Certificate and/or the QMS, in addition to the reasons indicated in the General Certification Regulation, also in the following cases:

- bankruptcy of the manufacturer;
- Non-compliance with the commitments undertaken in maintaining the certification in compliance with the applied schemes.

In the case of withdrawal, the manufacturer is required to immediately cease applying the CE marking and to eliminate any reference in catalogs and advertisements. At this stage, the manufacturer undertakes to communicate to Kiwa the stocked products already manufactured, subjected to the withdrawn certification.

Kiwa has the right to request the modification of the type references of the product for which the CE marking has been renounced or withdrawn, as well as to perform a verification to assess the amount of stocked certified products referred to in the previous paragraph.

In the case of a marketed product for which the CE marking has been withdrawn due to defects that may be detrimental to users, Kiwa requires the manufacturer to withdraw every single product from the market within a term set by Kiwa.

Kiwa will not investigate the products for which the CE marking has been withdrawn due to non-compliance, unless the manufacturer proves that he/she has taken, in the meantime, all measures to avoid non-compliance which resulted in the withdrawal.

As to the certification activities of the technical personnel involved in the construction of permanent joints and related processes (item 3.1.2. of Annex I of the Directive), Kiwa can carry out monitoring or control activities on the work of qualified personnel within its institutional activities such as:

– surveillance at construction sites and production workshops;
– certification or periodic visits of company quality systems according to UNI EN ISO 9001 standard;
– certification or periodic visits of products regulated in mandatory regime (e.g. EU Directives);
– third-party certification activities.

As part of these activities, Kiwa may proceed with the withdrawal of certificates,

– if the conditions indicated in art. 6 of the Kiwa Regulation for certification occur;
– if the conditions of § 9.4 are not met;
– as a result of documented objective evidence that proves the inability of qualified personnel to maintain the quality of execution demonstrated during qualification;
– as a result of documented objective evidence proving that the Organization cannot replicate the operational and environmental conditions anymore referred to in the issued process certificates.

The certificate withdrawal will be notified in written form by registered letter to the Organization and qualified personnel and will involve the relative cancellation of the person and the relevant Organization from the list referred to in chapter 12.

In the case of a certificate withdrawal, the qualified personnel and the Organization undertake not to use the certificate anymore.

Certification withdrawal involves automatic termination of the contract to which this regulation applies, pursuant to art. 1456 of the Italian Civil Code, without prejudice to compensation for any damage incurred by Kiwa.

Qualified personnel, whose certificate has been withdrawn, and the Organization can re-apply for certification no earlier than 6 months from the withdrawal date, provided that the causes giving rise to the withdrawal have been removed or resolved.

In the case of suspension or withdrawal related to specific critical issues of products already marketed, Kiwa will inform the competent Market Supervisory Authorities, other notified bodies and the Accreditation Body and reserves the right to communicate the suspension or withdrawal to third parties who request it.

11. COMPLAINTS, APPEALS AND LITIGATION

11.1 Complaints

The Manufacturer may submit a documented complaint concerning its relations with Kiwa relating to certification activities.

Such complaint may arise from issues occurring during the certification process, such as delays in carrying out the various phases and/or incorrect behaviour by Kiwa's Auditors.

Kiwa records the complaints, analyses them and informs the complainant about the actions taken, within 30 working days from the date of receipt of the complaint; the assessment and approval are carried out by personnel not involved in the process subject of the complaint.

To ensure impartiality all complaints are managed by personnel who are not involved in the activities subject to the complaints.

Kiwa will establish with the complainant if and to what extent the content of the complaint and its resolution must be made public.

11.2 Appeals

If the complainant is not satisfied with the response received, or intends to oppose a decision by Kiwa, he can appeal in written form.

The appellant must justify the reasons for his appeal and, if such appeal relates to a decision by Kiwa, it must be presented to Kiwa within 10 working days from the date of communication of the decision.

Appeals are managed by functions who are not involved in the activities subject to appeals.

Kiwa will provide the appellant with a written reply and notify any action to be taken within 30 working days from the date of receipt of the appeal.

11.3 Litigations

Any dispute between the Customer and Kiwa will be handled as provided for in art. 18 paragraph 1 of *Kiwa Cermet Italia General Terms and Conditions for the performance of the assignments*.

12. LISTS OF ISSUED CETIFICATIONS

Kiwa updates lists of products, personnel and companies with issued Certification, according to 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 modify this Regulation at any time.

Any new clauses/changes will be effective from the moment they are communicated to the customer in written form.

The Organization that does not intend to accept the changes, may withdraw from the contract by giving written notice by registered letter with return receipt or certified mail within 30 calendar days, under penalty of forfeiture, from the day following the communication to Kiwa.

The withdrawal will be effective from the last working day of the month of receipt of the communication from the customer.