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Rev.	Description of changes	Date
8	Addition of reference to new Kiwa Regulation and relevant alignments (removed parts described in the Regulation). Addition of Market Surveillance Visit.	2018-02-26
7	Addition of references to transposition and authorisation decrees	2016-07-26

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1. SCOPE AND PURPOSE

This Regulation sets out the rights and duties, as well as the operating methods that regulate the relationship between Kiwa Cermet Italia S.p.A. (hereinafter referred to as "Kiwa Cermet") and the Client Organisations, for putting into effect the procedures to be used for the Assessment of Conformity of "Pressure equipment and assemblies" (hereinafter referred to as "Pressure Equipment"), provided for in Directive 2014/68/EU (hereinafter referred to as the "Directive"), referred to in Legislative Decree no. 26 of 15 February 2016 as a Notified Body, according to the provisions of Modules / Forms A2-B-C2-D-D1-E-E1-F-G-H-H1 of Annex III of the Directive. The definition of "Pressure equipment and assemblies" referred to in this Regulation is the same as in the specifications of Article 1 of the Directive.

Moreover, this Regulation defines the principles, criteria and procedures, in accordance with the reference standards indicated below, for the management of activities related to the qualification, certification and subsequent maintenance of the certification of technical staff responsible for the creation of permanent joints using suitable welding and/or brazing procedures on metal components and of the related joining processes applied to pressure systems, as a Notified Body, pursuant to point 3.1.2. of Annex I of Directive 2014/68/EU.

The requirements stated in this Regulation are an integral part of the agreement stipulated with Kiwa Cermet (quotation, *The Kiwa Regulation for Certification* and *General Terms and Conditions of Kiwa Cermet Italia for the performance of orders* - hereinafter *General Terms* and Conditions). These requirements refer solely to the aspects specifically connected with the scope of the requested certification.

Reference documentation for the qualification of junction processes

For the certification of welding and brazing personnel:

Document	Description
UNI EN ISO 9606-1	Welders qualification tests - Fusion welding - Part 1: Steels
UNI EN ISO 9606-2	Welders qualification tests - Fusion welding - Part 2: Aluminium and aluminium alloys
UNI EN ISO 9606-3	Welders qualification tests - 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 for welding operators and welding preparators for fully mechanised and automatic welding of metallic materials
UNI EN ISO 13585	Strong brazing - Qualification of brazers and strong brazing operators

For the approval of permanent joining processes used in the manufacture of pressure systems and of qualified personnel, in addition to the above standards:

Document	Description	Scope
UNI EN 13134	Strong brazing - Qualification of the procedure	Qualification of process
UNI EN 14271-1	Pressure equipment for refrigeration systems and for heat pumps - Part 1: Recipients - General requirements	Qualification of process and brazor/preparer
UNI EN ISO 15613	Specification and qualification of welding procedures for metallic materials - Qualification based on pre-production welding tests	Qualification of process and welder/operator
UNI EN ISO 15614-1	Specification and qualification of welding procedures for metallic materials - Welding procedure qualification tests - Part 1: Arc welding and gas welding of steels and arc welding of nickel and nickel alloys	Qualification of process and welder/operator
UNI EN ISO 15614-2	Specification and qualification of welding procedures for metallic materials - Welding procedure qualification tests - Part 2: Arc welding of aluminium and its alloys	Qualification of process and welder/operator
UNI EN ISO 15614-4	Specification and qualification of welding procedures for metallic materials - Welding procedure qualification tests - Part 4: Finishing welding of aluminium castings	Qualification of process and welder/operator

Document	Description	Scope
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	Qualification of process and welder/operator
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	Qualification of process and welder/operator
UNI EN ISO 15614-7	Specification and qualification of welding procedures for metallic materials - Welding procedure qualification tests - Part 7: Overlay by welding	Qualification of process and welder/operator
UNI EN ISO 15614-8	Specification and qualification of welding procedures for metallic materials - Welding procedure qualification tests - Welding of tubes to tube-plate joints	Qualification of process
UNI EN ISO 15614-11	Specification and qualification of welding procedures for metallic materials - Welding procedure qualification tests - Electron and laser beam welding	Qualification of process and operator
UNI EN ISO 15620	Welding - Friction welding of metallic materials	Qualification of process

However, if requested by the Organisation, Kiwa Cermet is entitled to carry out the same certification/approval activities of welding processes/procedures and of personnel/welders on the basis of other recognised international standards and codes (for example: ASME, AWS, API, etc.).

The standards referred to in this Regulation must be understood in their revision in force at the time of the signing of the contract with Kiwa Cermet (unless otherwise specified in writing, in case of transitional measures granted following the updating of the aforementioned standards).

For the purposes of this Regulation, the term EU Certification of Pressure equipment shall refer to all the Conformity assessment activities involving the issuance of specific compliance certification documents by Kiwa Cermet.

The contract expressly excludes any form of consultancy to the Customer that could jeopardise the nature of independence of the carried out assessments.

This Regulation is also available on the Kiwa Cermet website (www.kiwacermet.it).

2. GENERAL PRINCIPLES AND GUARANTEES FOR THE CUSTOMER

In its certification processes, as well as the *General Terms and Conditions*, Kiwa Cermet applies the following principles:

a) Non-discrimination*:* certification services are accessible to any Organisation requesting them, in accordance with this Regulation, without any discrimination of a commercial or financial nature or regarding membership of particular associations.

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

- Certification procedures are assigned to personnel with no interests in the Organisation being certified, bound to observe the rules of conduct and independence set by Kiwa Cermet; regarding this aspect Kiwa Cermet undertakes to investigate any justified concerns of the Customer concerning the existence of incompatibility of the duty assigned which could compromise the impartiality or independence of judgement.
- On time implementation of formalised rules and procedures in use by all personnel certification and periodic consultation with certification stakeholders;
- Separation between the personnel carrying out audits and the personnel responsible for the certification decision;
- Total abstention from the performance of assistance activities in the definition and application of the requirements for obtaining the Certification.

Prompt 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 Regulation for Certification*, Kiwa Cermet undertakes to request all staff, including its auditors, to subscribe to a commitment to confidentiality, as well as to a document in which the staff undertakes to process any data of which they become aware in compliance with the provisions of the applicable Privacy Act;

d) Accreditation and Notifications: Kiwa Cermet undertakes to inform the client of any rejection, suspension or withdrawal of the accreditation and/or ministerial notification; in such cases Kiwa Cermet will be in no way responsible for any damages caused to the client by rejection, suspension or withdrawal of the accreditation or notification; in the aforementioned cases, the client has the right to opt out of the contractual relationship with Kiwa Cermet, without the need for prior notification and without any additional costs.

3. ACCESS REQUIREMENTS FOR THE CERTIFICATION

3.1 General requirements

Before embarking upon the Certification process with Kiwa Cermet, the Organisation must satisfy the following requirements:

- Accept the conditions set out in this Regulation;
- Authorise access to offices, factories, areas and information needed to perform the Audit;
- Designate their own Representative as the main contact person for the Audit Team and make any consultants present during the Audit play the role of observer;
- Be responsible for the application of the requirements provided for by the occupational safety laws in force. In the absence of binding provisions, the Organisation agrees to provide Kiwa Cermet with complete and detailed information regarding the specific risks existing at the facilities where Kiwa Cermet personnel is expected to operate and PPE necessary for carrying out the appointment, informing Kiwa Cermet personnel concerning their correct use. In this regard, the Organisation has to provide appointed Kiwa Cermet personnel the Company documentation concerning the workplace safety (D.V.R., safety plan, procedures, etc.), limited to aspects of specific interest. If for such omissions, injuries occur or illnesses are contracted, no charges may be made, for any reason against Kiwa Cermet.
- Accept, without additional costs, the possible presence of auditors from the Accreditation or Control Body as observers, which shall be communicated by Kiwa Cermet with a clear illustration of their roles. Their presence has the aim of assessing that the evaluation methods used by Kiwa Cermet are compliant with the requirements for accreditation.
- Accept possible controls carried out by the Accreditation Body. In addition in order to ensure that the assessment procedures adopted by Kiwa Cermet comply with the applicable standards, the Accreditation Body may require to conduct a visit, called Market Surveillance Visit, directly through the use of their personnel at the certified Organisation. This potential visit, is communicated by the Accreditation Body to Kiwa Cermet with 7 working days notice. Upon receipt of such communication Kiwa Cermet will inform the Organisation. The audit plan is prepared by the Accreditation Body, which it will make available to Kiwa Cermet; then Kiwa Cermet will send it to the Client Organisation. If the Organisation does not grant its approval, the validity of the certificate is suspended until it has not accepted the visit*,* for a maximum period of 3 months. After 3 months, in the absence of approval for the visit, the certification is withdrawn. The Organisation shall make available to the Accreditation Body the documentation that Kiwa Cermet has taken as a reference during the previous audits. The Market Surveillance Visit does not replace the normal maintenance certification audit provided by the Audit Programme. The Market Surveillance Visit procedures are indicated in the IAF ID 04 document (free download from the IAF website: www.iaf.nu). Other methods of control can be adopted by the accreditation Body, in order to verify the activities of Kiwa Cermet, e.g. unannounced audit at the premises of certified subjects, request of information to Organisations or Consulting Company, or other methods of control established by the accreditation body.

3.2 Classification of issues

Each issue found during the course of the Audits is classified in the following way:

Major non-conformity: a deviation or total absence of conformity to the requirements, found on the basis of objective evidence, as a result of the assessment activities.

Minor non-conformity: a deviation or partial absence of conformity to the requirements, found on the basis of objective evidence, as a result of the assessment activities.

Several minor conformities pertaining to the same requirement, depending on the content and the general outcome of the Audit, can lead to a major NC being issued.

Minor non-conformities not resolved and/or not taken in hand by the Organisation can lead to the issuing of a major NC.

Opportunities for improvement: anything not coming within the definitions of non-conformities and which constitutes a potential improvement in the effectiveness of the solutions adopted by the client, to ensure conformity with requirements and to prevent deviations.

4. GENERAL CONDITIONS

4.0 - The manufacturer is responsible for the design and manufacture of a product covered by the Directive, in view of making it available on the Community market. The drafting of technical documentation (technical file), the CE Marking and the issuing of an EU Declaration of Conformity are within its exclusive competence.

An importer or a distributor shall be considered a manufacturer for the purposes of the Directive and shall be subject to the related obligations as manufacturer when they make available on the market pressure equipment under their own name, or based on a trademark, or modify pressure equipment already available on the market, in such a way as to affect its compliance with the provisions of the Directive.

The authorised representative shall be established within the European Union and shall be formally appointed by the manufacturer, acting in the name and on behalf of the latter in relation to the obligations imposed by the Directive.

4.1 - A manufacturer wishing to use the services of Kiwa Cermet for CE marking its Pressure equipment, is responsible for the intended use assigned to each piece of pressure equipment and the relative classification according to what is stated in Annex II of the Directive. If there is any disagreement between the manufacturer and Kiwa Cermet arising from application of the classification rules, after giving notification to the manufacturer Kiwa Cermet will report the terms of the disagreement to the Competent Authorities involved for all decisions on the matter.

4.2 - The manufacturer chooses, in accordance with Annex II of the Directive, the conformity assessment procedures in order to apply the CE marking to the Pressure equipment in relation to its classification. The manufacturer is presented with different conformity assessment Forms grouped into risk categories (II - III - IV) stated in Annex II of the Directive.

4.3 - The various Forms cited may also involve recognition by Kiwa Cermet of equivalent documents issued by other Notified Bodies, the acceptance of which always implies a formal audit by Kiwa Cermet, in accordance with the provision of the Directive and notification to the Competent Authority.

4.4 - The verifications and assessments of the QA system are carried out by Kiwa Cermet, which may also use external test laboratories or assessment bodies authorised by Kiwa Cermet. Tests on the Pressure equipment are set at the incontestable discretion of Kiwa Cermet and may be commissioned directly to Kiwa Cermet or to Test laboratories authorised by Kiwa Cermet.

Where external test laboratories or bodies are used, the client has the right to highlight any substantiated situations of incompatibility and to challenge the external laboratory/body; the same right applies to any challenge of auditors or technical experts.

4.5 - Conformity assessment procedures:

For the purposes of this Regulation, depending on the risk category of the Pressure equipment, Kiwa Cermet applies the following forms for the Conformity assessment:

Category II Forms =	A2	D1	E1;		
Category III Forms =	B (design type)		+ D	B (design type) + F	
	B (production type)		+ E	B (production type) + C2	H;

Category IV Forms =	B (production type) + D		B (production type) + F
	G		H1

For forms in which on-site verification activities are planned, the following are valid:

- the postponement of an already scheduled and agreed Audit, for reasons attributable to the Organisation, must be notified to Kiwa Cermet at least 30 days before the scheduled date, otherwise a penalty of 50% of the cost involved will be invoiced, along with any expenses incurred.
- Carrying out the Surveillance Audits prescribed in the certification cycle is conditional upon the Organisation being up to date with payments for all previous services supplied.

4.5.1 Form A2 - Internal production control and Surveillance of the final verification

4.5.1.1 - This form entails the manufacturer keeping the internal production under control and carrying out the final assessment on the Pressure equipment under the surveillance of Kiwa Cermet, during an audit without any prior notice.

4.5.1.2 - Kiwa Cermet provides the manufacturer with an analysis report of the documentation and of the tests carried out on the Pressure equipment according to the Conformity assessment procedure for the relative Form A2 stated in Annex III of the Directive. If the outcome of such inspections and audits is positive, Kiwa Cermet issues the manufacturer the Certificate of Authorisation of internal production control.

4.5.2 Form B - EU type - production type Examination

4.5.2.1 - This form entails the manufacturer making available to Kiwa Cermet all the Technical Documentation for a type of Pressure equipment, called the "Type" (ranging from the design, the production methods and final assessment, to the description of how it works etc.). He provides Kiwa Cermet with a representative specimen of its "Type" production in order to ascertain and attest that this "Type specimen" satisfies the regulations set out in the Directive.

4.5.2.2 - Kiwa Cermet provides the manufacturer with an analysis report of the documentation and of the tests carried out on the Pressure equipment according to the Conformity assessment procedure for the relative Form B stated in Annex III of the Directive. If the outcome of these examinations and assessments is positive, Kiwa Cermet issues the manufacturer the EU type - production type Examination Certificate

4.5.2.3 - The manufacturer is also obliged to inform promptly Kiwa Cermet (who holds the Technical Documentation pertaining to the EU type - production type Examination Certificate) of all modifications to the approved pressure equipment, which must receive additional approval where the modifications could affect conformity with the essential requirements or the prescribed conditions for use of the pressure equipment.

4.5.3 Form B - EU type - design type Examination

4.5.3.1 - This form entails the manufacturer making available to Kiwa Cermet all the Technical and Evidential Documentation pertaining to the design of an item of pressure equipment in order to ascertain and attest that the design satisfies the requirements of the Directive.

4.5.3.2 - Kiwa Cermet provides the manufacturer with an analysis report of the documentation carried out according to the Conformity assessment procedure for the relative Form B stated in Annex III of the Directive.If the outcome of these examinations and assessments is positive, Kiwa Cermet issues the manufacturer the EU type - design type Examination Certificate.

4.5.3.3 - The manufacturer is obliged to promptly inform Kiwa Cermet (who holds the Technical Documentation for the EU type - design type Examination Certificate) of all modifications to the design of the approved pressure equipment, which must receive additional approval where the modifications could affect conformity with the essential requirements or the prescribed conditions for use of the pressure equipment.

4.5.4 Corm C2 - Conformity to type

4.5.4.1 - This form entails the manufacturer making available to Kiwa Cermet all the Technical Documentation for a type of Pressure equipment described in the EU type Examination Certificate, (ranging from the design, the production methods and final assessment, to the description of how it works etc.). The manufacturer must make available to Kiwa Cermet representative specimens of its production and carry out the Final assessment on the Pressure equipment in order to ascertain and attest that these specimens taken from the production satisfy the requirements of the directive.

4.5.4.2 - Kiwa Cermet provides an analysis report of the documentation and of the tests carried out on the Pressure equipment according to the Conformity assessment procedure for the relative Form C2 stated in Annex III of the

Directive. If the outcome of these examinations and assessments is positive, Kiwa Cermet issues the manufacturer the type Certificate of conformity.

4.5.5 Form D - Type conformity based on quality assurance of the production process

4.5.5.1 - This form entails the assessment of the Quality management system (QMS) for production, inspection and testing of the finished product, and is subject to monitoring by Kiwa Cermet, in order to ensure that the pressure equipment conforms to the type described in the EU type Examination Certificate.

4.5.5.2 - Kiwa Cermet provides an audit and analysis report of the documentation and of the tests carried out on the Pressure equipment according to the Conformity assessment procedure for the relative Form D stated in Annex III of the Directive.If the outcome of these examinations and of the stage 1 and stage 2 audits is positive, Kiwa Cermet issues the manufacturer the Production Process Quality Assurance System Type Certificate.

4.5.6 Form D1 - Quality assurance of the production process

4.5.6.1 - This form entails an assessment of the Company QA system for the manufacture, final inspection and testing of the product, and is subject to monitoring by Kiwa Cermet, in order to ensure that the pressure equipment conforms to the requirements of the Directive.

4.5.6.2 - Kiwa Cermet provides an audit and analysis report of the documentation and of the tests carried out on the Pressure equipment according to the Conformity assessment procedure for the relative Form D1 stated in Annex III of the Directive.If the outcome of these examinations and of the stage 1 and stage 2 audits is positive, Kiwa Cermet issues the manufacturer the Production Process Quality Assurance System Certificate.

4.5.7 Form E - Type conformity based on quality assurance of pressure equipment

4.5.7.1 - This form entails the assessment of the Approved Company QA system for final inspection and testing of the product, and is subject to monitoring by Kiwa Cermet, in order to ensure that the pressure equipment conforms to the type described in the EU type Examination Certificate and to the requirements of the Directive.

4.5.7.2 - Kiwa Cermet provides an audit and analysis report of the documentation and of the tests carried out on the Pressure equipment according to the Conformity assessment procedure for the relative Form E stated in Annex III of the Directive.If the outcome of these examinations and of the stage 1 and stage 2 audits is positive, Kiwa Cermet issues the manufacturer the Quality Assurance System Type Certificate relating to the pressure equipment.

4.5.8 Form E1 - Quality Assurance and warranty of the inspection and of the testing of the finished pressure equipment

4.5.8.1 - This form entails the assessment of the Company QA system for final inspection and testing of the product, and is subject to monitoring by Kiwa Cermet, in order to ensure that the pressure equipment conforms to the requirements of the Directive.

4.5.8.2 - Kiwa Cermet provides an audit and analysis report of the documentation and of the tests carried out on the Pressure equipment according to the Conformity assessment procedure for the relative Form E1 stated in Annex III of the Directive.If the outcome of these examinations and of the stage 1 and stage 2 audits is positive, Kiwa Cermet issues the manufacturer the Quality Assurance System Certificate relating to the inspection and testing of the finished pressure equipment.

4.5.9 Form F - Type conformity based on product verification

4.5.9.1 - This form provides for verification on the product by examining and testing each individual piece of pressure equipment by Kiwa Cermet, in order to ensure that the pressure equipment conforms to the type described in the EU type Examination Certificate and to the requirements of the Directive.

4.5.9.2 - Kiwa Cermet provides an analysis report of the documentation and of the tests carried out on the Pressure equipment according to the Conformity assessment procedure for the relative Form F stated in Annex III of the Directive. If the outcome of these examinations and assessments is positive, Kiwa Cermet issues the manufacturer the Type Certificate of Conformity based on the verification of pressure equipment.

4.5.10 Form G - Unit verification.

4.5.10.1 - This form entails an examination of the design and manufacturing process of each item of pressure equipment and the carrying out by Kiwa Cermet of appropriate tests during manufacture as prescribed by the standards, in order to ensure that the pressure equipment conforms to the requirements of the Directive.

4.5.10.2 - Kiwa Cermet provides an analysis report of the documentation and of the tests carried out on the Pressure equipment according to the Conformity assessment procedure for the relative Form G stated in Annex III of the

Directive. If the outcome of these examinations and assessments is positive, Kiwa Cermet issues the manufacturer the Certificate of conformity of verification of the unit.

4.5.11 Form H - Total Quality Assurance

4.5.11.1 - This form entails the assessment of the Company QA system for the design, manufacture, final inspection and testing of the finished product, and is subject to monitoring by Kiwa Cermet in order to ensure that the pressure equipment conforms to the requirements of the Directive.

4.5.11.2 - Kiwa Cermet provides an audit and analysis report of the documentation and of the tests carried out on the Pressure equipment according to the Conformity assessment procedure for the relative Form H stated in Annex III of the Directive.If the outcome of these examinations and of the stage 1 and stage 2 audits is positive, Kiwa Cermet issues the manufacturer the Total Quality Assurance System Certificate.

4.5.12 - Form H1 - Total quality assurance with design control

4.5.12.1 - This form entails, in addition to the requirements of form H, Kiwa Cermet carrying out an examination of the design and monitoring, by means of visits without giving prior notice, on the Final assessment of the pressure equipment, including pressure tests, the Final Examination and examination of the safety devices.

4.5.12.2 - Kiwa Cermet provides an audit and analysis report of the documentation and of the tests carried out on the Pressure equipment according to the Conformity assessment procedure for the relative Form G stated in Annex III of the Directive. If the outcome of these examinations and assessments is positive, Kiwa Cermet issues the manufacturer the Certificate of the Total Quality Assurance System with design control

4.5.12.3 - The manufacturer is also obliged to promptly inform Kiwa Cermet (who holds the Technical Documentation for the EU Design examination certificate) of all modifications to the design of the approved pressure equipment, which must receive additional approval where the modifications could affect conformity with the essential requirements or the prescribed conditions for use of the pressure equipment.

4.6 Certification activities of technical staff responsible for the creation of permanent junctions and related processes (point 3.1.2 of Annex I of the Directive)

4.6.1 - The qualifying examination is based on a practical welding test, which, at the request of the Organisation or based on specific requirements of the reference standard, can be combined with a theoretical test for the assessment of technical skills. The practical test requires that each candidate carries out the testing as per the activity programme contained in the service proposal accepted by the Organisation. The examiner will have to supervise the testing, verifying that the equipment, materials and operating parameters comply with the requirements of the standard and to the other reference documents (WPS/BPS). At the end of the practical test the trials must be sent to a laboratory operating according to the ISO/IEC 17025 standard, after these have positively passed a visual examination of the weldings according to the UNI EN ISO 17637standard. The laboratory shall carry out the test plan specified by the Inspector on the appropriate form. The exam is passed with the passing of the practical test, based on the results of the laboratory tests. A candidate who fails the practical test can repeat the test once, without the need for specific training. The theoretical test will consist of a written exam based on a questionnaire containing 20 multiple choice questions (to be selected based on the specific operational areas of the welding processes for the metallic materials of interest to the candidate) divided into the various topics set out by the reference standards (e.g. Annex B of the UNI EN ISO 9606-1 standard). The theoretical test is passed by answering at least 80% of the questions correctly and is annotated by marking the spaces provided on the certificate.

4.6.2 - Certificates issued to personnel are valid for the period set out in the various applicable regulations starting from the date prescribed by the relevant legislation, provided they are signed every six months by the employer (even temporary) or supervisor, to certify that the following conditions are met:

- the welder/operator must regularly perform the welding job for which he/she is qualified;
- interruptions for a period longer than six months are inadmissible;
- the work of the welder/operator should generally be carried out 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/operator.

Certificates for joining processes are valid starting from the date the examinations are carried out, and have no expiry, as long as the requesting Organisation maintains the ability to replicate the operational and environmental conditions reported therein.

4.6.3 - Based on the results of the tests and of the qualification exams Kiwa Cermet provides for the issuance of certificates. With the issue of the certificate, the person's qualification is attested, but this does not provide them

with the authority to operate. This is provided for by the employer with a written certificate, based on the operator's competence, as specified by the certificate, which takes responsibility for the results of the verification. If the certified person is self-employed, an employer must assume all the responsibilities defined above for the employer. Certificates for permanent joining processes for categories II, III and IV pressure systems make it possible to demonstrate the suitability of the methods adopted for their realisation, pursuant to paragraph 3.1.2 of Annex I of Directive 2014/68/EU.

5. REQUIREMENTS FOR THE MANUFACTURER

5.1 - The validity and binding nature of all the provisions of the Directive and its annexes being understood, the manufacturer is responsible for implementing all the actions necessary to guarantee conformity of the Pressure equipment to the requirements of the Directive, especially aspects concerning following matters of primary importance for the purposes of conformity assessment of the pressure equipment:

- Risk assessment (RA);
- Essential Safety Requirements (ESR);
- Conformity of raw and filler materials;
- Traceability of materials used;
- Welding qualification procedures (WPAR and WPS);
- Qualifications of welding staff and Non-destructive testing (NDT);
- Final pressure testing.

5.2 Risk assessment (RA)

5.2.1 - The Risk assessment (RA) concerning all the phases of the life of the pressure equipment, and especially the phases of manufacture, transportation, installation, operation, maintenance and decommissioning, is a binding requirement to be satisfied by the manufacturer.

5.2.2 - The Risk assessment (RA) must be prepared and undertaken by the manufacturer and must highlight all the foreseeable risks in the possible conditions of use for the equipment and also in the event of all reasonably foreseeable instances of incorrect use.

5.2.3 - For each risk highlighted in the Risk assessment (RA), the manufacturer must provide evidence of the most suitable counter-measure adopted in order to eliminate or significantly reduce the risk in question.

5.2.4 - The Risk assessment (RA) document is an integral part of the Technical File (TF) which is presented to Kiwa Cermet and, if requested, to the Competent Authority.

5.3 Essential Safety Requirements (ESR)

5.3.1 - The manufacturer is responsible for satisfying all the Essential Safety Requirements (ESR) prescribed by Annex I of the Directive, that apply to its Pressure equipment.

5.3.2 - The manufacturer must prepare and undertake a document in which it lists all the Essential Safety Requirements (ESR) of the Directive and for each one provides evidence of how these have been taken into consideration and observed.

5.3.3 - The list of Essential Safety Requirements (ESR) of the Directive document is an integral part of the Technical File (TF) which is presented to Kiwa Cermet and, if requested, to the Competent Authority.

5.4 Regulatory changes and/or certification requirements

Kiwa Cermet shall keep up to date on technological progress generally recognised as state of the art, indicating whether the approved type may cease to comply with the applicable requirements of Directive 2014/68/EU and shall decide whether such progress requires further investigation. In this case, Kiwa Cermet shall inform the manufacturer.

Nonetheless, it is the responsibility of the manufacturer to make sure its test reports are updated to the latest version of the standard applied and/or that they are, from a technical standpoint, at the same "state of the art" level, in order to guarantee the assumption of conformity to the essential requirements of the Directive.

In the event that the manufacturer does not follow up on these requests, Kiwa Cermet shall withdraw the certificate.

6. PRESENTING THE APPLICATION

6.1 - The manufacturer must present the application by filling in the relevant Kiwa Cermet form. On this form it must specify the Risk Category (II, III, IV) of the Pressure equipment and consequently must indicate which Forms (A2, B - design type, B – production type, C2, D, D1, E, E1, F, G, H, H1) it intends to apply in assessing the Conformity requested from Kiwa Cermet. Under the terms of the Directive, it is forbidden to present similar applications for certification, for the same products, to other Notified Bodies.

6.2 - The manufacturer must present separate applications for the procedures provided for by the Annexes of the Directive grouped into the various Forms.

6.3 - Presenting the application for Forms D, D1, E, E1, H and H1 which involve an assessment of the Company QA system, entail simultaneously activation of the surveillance procedure according to the corresponding Forms.

6.4 - The pressure equipment for which application is made may also include variants as long as they do not involve different types of risk from the Essential Safety Requirements (ESR).

6.5 - Acceptance of the variants or criteria for determining the homogenous nature of the families of Pressure equipment is strictly at the incontestable discretion of Kiwa Cermet.

6.6 - Each application must include a Technical File (TF) that gathers together in an ordered manner all the Technical Documentation prescribed by the Conformity assessment procedure adopted for applying the CE marking according to the pertinent Forms of Annex III of the Directive. Any EU type examination certificates, Quality Assurance system certificates or Test Reports able to demonstrate compliance with one or more Essential Safety Requirements (ESR) may also be included, but their acceptance is in any case at the incontestable discretion of Kiwa Cermet.

6.7 - As regards to the certification activities of technical staff responsible for the creation of permanent joints and related processes (point 3.1.2 of Annex I of the Directive), the Organisation shall submit a specific certification application to Kiwa Cermet, which must contain at least the following:

- Name of applicant organisation;
- Regulations/reference technical specifications;
- Type and thickness of base material;
- Type of welding positions subject to certification;
- Number of welders/operators to be qualified, if applicable;
- Number of joining processes to be qualified, if applicable;
- Requested period for the execution of the qualification exam;
- Possible request to verify the technical knowledge of the candidates during the examination;
- Possible modes of extension for the validity of the certificates.

Based on this information and following a preliminary examination to verify the completeness of the information provided, Kiwa Cermet shall formulate a proposal for services, which will be sent together with this Regulation. This proposal shall also indicate the conditions for carrying out the service, as well as the materials and documentation that the Organisation must make available during the examination:

- provision for the basic materials for carrying out the testing, with dimensions conforming to what set out in the reference standards;
- 3.1 type certificates according to the EN 10204 standard for basic materials and support materials;
- technical data sheets for any eventual blanket gases;
- valid identity documents for all candidates;
- reference WPS/BPS.

Upon receipt of the acceptance of the proposed service, Kiwa Cermet shall send the Organisation a written confirmation of the acceptance of the application.

7. USING THE CERTIFICATION AND APPLYING THE CE MARKING

7.1 - To each item of Pressure equipment that has obtained CE certification in accordance with the relevant Forms stated in point 4.5 of this Regulation, the manufacturer applies the CE marking, in accordance with the provisions of the Directive. The CE marking must be associated with the number 0476, which identifies Kiwa Cermet as the European Notified Body.

7.2 - In keeping with the Directive, the manufacturer is obliged to differentiate unambiguously the Pressure equipment with the CE marking from the equipment that does not have it. The application of markings from other types of certification is permitted as long as these markings cannot be confused with the CE marking.

7.3 - Use of the CE marking, the Declarations and the Certifications issued by Kiwa Cermet is strictly reserved for the manufacturer and is not transferrable, except in the event of the manufacturer's company being sold or transformed, in which case prompt notification must be given to Kiwa Cermet, who will then register the variation and initiate the procedure for updating the Declarations or Certifications, where necessary repeating, and/or carrying out supplementary assessment visits on the manufacturer's premises.

7.4 - Kiwa Cermet makes surveillance visits, normally giving prior notice, to the manufacturer's premises, at least once per year to make sure the manufacturer maintains and applies the QA system already approved. Kiwa Cermet can make unannounced visits (mandatory in cases provided for by the Directive).

7.5 - Following these visits Kiwa Cermet shall release, depending on the applicable Forms of the Directive, an audit report and a report pertaining to the documentation analysis and tests performed on the pressure equipment.

7.6 - The manufacturer undertakes to maintain its Organisation compliant with the items described in the Certifications issued by Kiwa Cermet. The manufacturer must notify Kiwa Cermet of any modifications to the QA system and variations in the Pressure equipment manufactured, providing all the documentation necessary for assessing such modifications. Kiwa Cermet examines the documentation regarding the modifications and informs the manufacturer whether or not they are acceptable, at the same time issuing, if necessary, a new Certification which replaces the previous one. In some cases acceptance of the modifications can take place, at the incontestable discretion of Kiwa Cermet, only following a supplementary audit with positive outcome on the manufacturer's premises. The cost of this audit is to be borne by the manufacturer, is not included in the Surveillance cost and is subject to payment being received for:

- the cost of examining the documentation;
- the cost of any supplementary visits to the manufacturer's premises.

7.7 - The Manufacturer must keep Kiwa Cermet informed regarding all modifications to its certified Pressure equipment. These modifications must be covered by an additional examination by Kiwa Cermet to check whether these will have any effect on compliance with the Essential Safety Requirements (ESR). Where the modifications affect compliance with the Essential Safety Requirements (ESR) or the prescribed conditions of use, Kiwa Cermet carries out the additional tests and verifications at its own incontestable discretion.

7.8 - The manufacturer must keep a log of all accidents occurring while using the Pressure equipment and of the relative measures taken to remedy the problem and must inform Kiwa Cermet in all cases prescribed by the Directive.

7.9 - The manufacturer must keep a log of all complaints and of the relative actions taken regarding the Pressure equipment for which CE marking authorisations have been granted and must remedy the problems. This information must be subjected to an in-depth examination by the Manufacturer to evaluate the effectiveness of the Risk assessment carried out.

8. RIGHT OF UNILATERAL WITHDRAWAL FROM THE CONTRACT OR WITHDRAWAL OF THE CERTIFICATION

8.1 - Kiwa Cermet may freely withdraw from the Agreement with the Customer Organisation by giving written communication to the Customer Organisation with a notice of six months from the effective date of withdrawal. The withdrawal by Kiwa Cermet determines the withdrawal of the issued certification. The Organisation is in any case obliged to pay Kiwa Cermet the amounts due for the services received during the notice period, as established in the last valid quotation. In the case the Organisation wishes to terminate the agreement, the unilateral withdrawal, during the period of Certification validity, requires the respect of notice times established in *General Terms and Conditions* of Kiwa Cermet Italia for the performance of orders and in the *Kiwa Regulation of Certification*. In particular, for notice of less than three months and more than two weeks from the scheduled Audit, the Customer must pay 50% of the amount relative to the cost foreseen for the subsequent activity as agreed upon in the Agreement. For periods of prior notification of less than two weeks, the conditions specified in

the *General Terms and Conditions* shall apply. In case of termination of the Agreement, Kiwa Cermet shall issue an invoice for the closing expenses of the certification procedure, in accordance with the last valid quotation.

8.2 - In the event of termination, the manufacturer must provide notification, within a time period of no longer than 15 days from the date of the termination, of the stocks of products still held that carry the CE marking.

8.3 - Kiwa Cermet informs the Competent Authority and the other Notified Bodies of the termination.

8.4 - Kiwa Cermet reserves the right to withdraw the EU Type Compliance Certificate and/or the Quality Management System Certification in all cases specified in the Kiwa Regulation for Certification and in the following cases:

- The manufacturer being declared bankrupt;
- Failure to observe the commitments taken on to maintain the certification in compliance with the schemes applied.

8.5 - In the event of withdrawal, the manufacturer must immediately desist from applying the CE marking and remove all references from catalogues and advertising in general. In this phase the manufacturer undertakes to notify Kiwa Cermet of the stocks still held of products already manufactured and covered by the withdrawn certification.

8.6 - Where a product for which the CE marking has been withdrawn because of defects that could compromise the users is present on the market, Kiwa Cermet will ask the manufacturer to withdraw from sale all units of that product, within the timeframe indicated by Kiwa Cermet.

8.7 - Kiwa Cermet has the right to request changes to the references of the product type for which the CE marking has been terminated or withdrawn, as well as carrying out an audit to ascertain the numbers of certified items held in stock as per point 8.5 above.

8.8 - Kiwa Cermet will not process applications for products for which the CE marking has been withdrawn due to failure to comply, unless the manufacturer in the meantime has demonstrated that it has put in place all the measures necessary to prevent a repetition of the breach that originally gave cause for the withdrawal.

8.9 - As regards to the certification activities of technical staff responsible for the creation of permanent joints and related processes (point 3.1.2 of Annex I of the Directive), Kiwa Cermet may engage in monitoring or control of the work of qualified personnel as part of his/her institutional activities such as:

- supervision at construction sites and production workshops;
- certification or periodic visits on corporate QA systems according to the UNI EN ISO 9001 standard;
- certification or periodic visits on regulated products under a binding regime (e.g. EU Directives);
- third party certification activities.

As part of these activities, Kiwa Cermet can proceed to withdraw a certificate if:

- the conditions set out in Article 6 of the *Kiwa Regulation for Certification are met;*
- it is found that the conditions set out in section 9.4 are not fulfilled;
- as a result of documented objective evidence testifying the incapacity of qualified personnel to maintain the quality of execution demonstrated during qualification;
- as a result of documented objective evidence testifying that the Organisation has lost the ability to replicate the operating and environmental conditions referred to in the process certificates issued.

The withdrawal of the certificate shall be notified in writing by registered letter to the organisation and to the qualified personnel and shall imply the relative removal of the individual and of the organisation in question from the list referred to in section 12.

In the event of a withdrawn certificate, the qualified personnel and the organisation undertake not to publicise the certification and to return the certificate issued.

The withdrawal of the certification determines the automatic resolution pursuant to Article 1456 of the Italian Civil Code of the agreement to which this Regulation applies, except, in any case, the compensation of any damages suffered by Kiwa Cermet.

The qualified personnel from whom the certificate has been withdrawn and the related Organisation may not re-apply for certification for at least 6 months from the date of withdrawal, on the condition that the causes that trigger the withdrawal decision have been eliminated or resolved.

The qualified personnel and the Organisation shall not be able to make use of the certificate(s) and its/their copies when the certification in question is withdrawn.

Kiwa Cermet reserves the right to communicate the suspension or withdrawal to the accreditation bodies and/or to other third parties that may request it.

Based on the motivations that led to the suspension/withdrawal/reduction of the certification, Kiwa Cermet reserves the right to request a list of all current stocks and/or of the products covered by the certification on the date of the suspension/withdrawal/reduction decision.

In the event of suspension or withdrawal of a certificate related to specific issues for products already available on the market, Kiwa Cermet shall inform the Market Surveillance Authorities accordingly.

9. INCORRECT USE OF THE CERTIFICATION

In addition to what is set out in the *Kiwa Regulation for Certification*, the rules below shall apply.

9.1 - Use of the CE marking, for a QA system certificate is incorrect when it could deceive the purchaser as to the nature, quality or origin of the Pressure equipment, or when it is not used in compliance with this Regulation.

9.2 - More specifically, the CE marking is used incorrectly when it is applied to Pressure equipment:

- for which the certification application has not yet been presented or has been refused;
- that does not correspond with the equipment described in the Certificates or the Declarations of Conformity;
- for which the Certificates or the Declarations of Conformity have been withdrawn.

The above instances are stated by way of example but not limitation.

9.3 - As soon as incorrect use is notified, if Kiwa Cermet has issued a specific Certification it withdraws the manufacturer's right to apply the CE marking or to use the Certification and informs the Competent Authority and the other Notified Bodies of this; if this is not possible, it takes all the measures necessary to protect its own interests.

9.4 - As regards to the certification activities of technical staff responsible for the creation of permanent joints and related processes (point 3.1.2 of Annex I of the Directive), there should be no risk that the certificate, referring to the specific technician, may be confused or associated with the certification of the manufacturer other than for the individual professional.

10. COMPLAINTS, APPEALS AND DISPUTES

10.1 Complaints

The Manufacturer may present documented complaints regarding his dealings with the certification activities provided by Kiwa Cermet.

Such complaints may arise from problems encountered during the certification process, such as for example, delays in completing the various phases and/or incorrect conduct by the Body Auditor.

Kiwa Cermet records all complaints, examines them and informs the claimant of the actions taken, within thirty days of receiving the complaint.

Kiwa Cermet will establish with the claimant whether and to what extent the content of the complaint and its resolution should be made public.

10.2 Appeals

If the claimant is not satisfied with the response received, or intends to appeal against the decision of Kiwa Cermet, the latter can present an appeal in writing.

The petitioner must state the grounds for his appeal and, where the appeal refers to a decision made by Kiwa Cermet, it must be presented to Kiwa Cermet within 10 calendar days of the decision being communicated.

Kiwa Cermet will give the petitioner a written reply and will give notification of any actions to be taken within 30 days of the date of receiving the appeal.

A detailed description of how to present complaints and appeals is given on the website www.kiwacermet.it.

10.3 Disputes

If the result of the appeal is not accepted by the complainant, any dispute between the Customer and Kiwa Cermet shall be managed in compliance with Article 18 paragraph 1 of the *General Terms and Conditions of Kiwa Cermet Italia for the performance of orders.*

11. PUBLICATION OF CERTIFICATIONS ISSUED

Kiwa Cermet keeps an updated list of products, personnel and companies with Certification issued, in accordance with the relative Conformity assessment forms prescribed by the Directive.

These lists are periodically made available to the Competent Authority and can be sent to any interested party, based on the reasoned request presented to Kiwa Cermet.

12. RETENTION OF TECHNICAL AND CERTIFICATION-RELATED DOCUMENTATION

All the Technical Documentation regarding an item of pressure equipment designed and/or built and subject to the assessment of Kiwa Cermet, must be collected together in an ordered manner into a Technical File.

The EU Conformity declarations written by the manufacturer and the Declarations/Certificates issued by Kiwa Cermet, must be kept by the manufacturer, together with the Technical Documentation collected in a Technical File, for at least **10 years** from the date the last Pressure equipment was manufactured and remain available to the competent national authorities for the necessary checks/inspections.

For the above purposes, also the documentation regarding the company Quality Assurance system (QA) and any updating of it, plus the documentation for the inspection and surveillance visits must be kept for 10 years.

13. FORMS

The following is a summary of the forms prescribed by Annex III of the Pressure Equipment Directive (PED) for which Kiwa Cermet carries out Pressure equipment Conformity assessment. These forms describe the procedures to be followed for the Conformity assessment of pressure equipment and assemblies by both the manufacturer and Kiwa Cermet.

In order to assist manufacturers of Pressure equipment in understanding the assessment procedures to be followed, as well as for the preparation of the Technical Documentation to be presented to Kiwa Cermet in a Technical File, copies of the forms/annexes re-drafted by Kiwa Cermet are delivered to the manufacturer.

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

14. UNILATERAL CHANGE OF THE CONTRACT

Kiwa Cermet reserves the right to modify this Regulation at any time. Any new clauses/changes shall be effective from the time they are communicated to the customer in writing.

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

The withdrawal shall be effective from the last business day of the month the customer receives the notice.