REGULATION FOR CERTIFICATION

OF PRODUCTS IN COMPLIANCE WITH REGULATION (EU) 2016/426 ON APPLIANCES BURNING GASEOUS FUELS

AND DIRECTIVE 92/42/EEC ON BOILER EFFICIENCY

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Rev. No.	SUMMARY OF CHANGES	DATE
18	Elimination of the requirements on the use of trademarks and inclusion in a specific Regulation; edited Regulation code	2025-11-19
17	Improvement of the document's structure and paragraphs, introduction of a section on definitions, inclusion of details on stages 1 and 2, rules for OBL and OEM; other minor changes	2024-10-03

Verified by:
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1. GENERAL REQUIREMENTS

1.1 Scope and field of application

This Regulation defines the rights and obligations, as well as the operational methodology that governs the relationship between Kiwa Cermet Italia S.p.A. (hereinafter referred to as "Kiwa Italia" or "Kiwa") and the Customer Organization (hereinafter also referred to as "Manufacturer") in the implementation of conformity assessment procedures aimed at issuing product certification[1], in accordance with Regulation (EU) 2016/426 (hereinafter also referred to as the Regulation or GAR Regulation) on appliances burning gaseous fuels and Directive 92/42/EEC (hereinafter also referred to as the Directive or BED Directive) on the performance of water boilers fired by liquid or gaseous fuels, as amended by Regulation (EU) No 813/2013[2].

In accordance with the aforementioned Regulations and Directive, Kiwa Italia operates as a "**Notified Body**" under authorization from the competent national authority.

The requirements expressed in this regulation are an integral part of the contract entered into with Kiwa Italia (economic quotation, Surveillance Agreement (if applicable), *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 only refer to the aspects specifically connected to the field of application of the requested certification.

Any form of advice to the Customer, which could undermine the nature of independence of the assessments is expressly excluded from the subject of the contract entered into with Kiwa Italia.

This regulation is also available on the Kiwa Italia website (www.kiwa.it).

1.2 General principles and guarantees for the customer Organization

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

a) Non-discrimination: any requesting Manufacturer may access certification services in accordance with this regulation, without any discrimination based on commercial or financial grounds or membership of specific organisations.

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

- Certification activities are assigned to personnel who do not have any interest wih the Manufacturer subject to certification, who shall comply with the rules of conduct and independence established by Kiwa Italia. Therefore, Kiwa Italia agrees to accept any justified reports by the Customer concerning conflicting tasks that may compromise the impartiality or independence of judgment.
- Exact application of official rules and procedures used by the certification service personnel and periodic consultation with relevant certification stakeholders.
- Clear separation between the personnel carrying out audits and tests and the personnel taking part in decisions about certification.
- Avoiding any support to define and apply the requirements to obtain certifications. Kiwa Italia is not directly involved in the production, representation, marketing, maintenance, installation of products or materials relating to certification, nor does it offer consultancy in the design and development phase of the product itself, nor does it have any related structures that carry out these activities, in accordance with the provisions of current legislation on the matter.

c) Prompt management of complaints and appeals, as defined in paragraph 13 of this regulation.

d) Confidentiality: in addition to what is provided for in the *General Terms and Conditions* and *Kiwa Regulation for Certification*, Kiwa Italia requires all its personnel, including its Auditors, to sign a confidentiality agreement and a document in which they commit to treat any information that comes into their possession in accordance with the provisions of the Privacy Act.

e) Accreditations and Notifications: Kiwa Italia undertakes to inform the Manufacturer of any renunciation, suspension or withdrawal of accreditation and/or ministerial notification; in such cases Kiwa Italia is in no way responsible for

[1] Generic term to indicate appliances and/or related devices.

[2] Products that conform to harmonized standards, or parts thereof, the references of which are published in the Official Journal of the European Union, are presumed to conform to the essential requirements of the GAR Regulation and the BED Directive.

any damage caused to the Customer by the renunciation, suspension or withdrawal of accreditation or notification; in the aforementioned cases, the Manufacturer has the right to renounce the contractual relationship with Kiwa Italia, without notice and without additional charges.

1.3 Definitions

Manufacturer: A natural or legal person who manufactures a product/appliance/accessory, or has designed and manufactured them and who markets them by affixing their own name or trademark, or uses the appliance for their own purposes.

Authorized Representative: A natural or legal person established within the European Union who has received a written mandate from a Manufacturer authorizing them to carry out specific tasks on their behalf.

Private Labeller or OBL (Own Brand Labeller): A natural or legal person who can have a product designed and manufactured by another Manufacturer, assemble, package, transform or label it in order to place it on the market under their own name or brand, thus assuming the same obligations as a Manufacturer.

Physical Producer or OEM (Original Equipment Manufacturer): A natural or legal person who designs and manufactures a product that will be placed on the market by a Private Labeller under the latter's name or brand. The Physical Producer may also market such products under their own name or brand, thus becoming a Manufacturer.

Based on the provided definitions, all obligations of the Manufacturer as indicated in this regulation also apply to the OBL and/or OEM when they assume the role of Manufacturer.

For all other definitions, please refer to the applicable legislation cited in paragraph 1.4.

1.4 References for the Manufacturer

- Regulation (EU) 2016/426 of 9 March 2016 on appliances burning gaseous fuels
- Directive 92/42/EEC on efficiency requirements for new hot water boilers fired with liquid or gaseous fuel
- Regulation (EU) no. 813/2013 of 02 August 2013 for the eco design requirements for space heaters and combination heaters
- Guidelines of the EU Commission on the "New Approach" Directives
- Guidelines and documents issued by the group NBGA_Open applicable to the relevant products
- Applicable EN harmonized technical standards

The aforementioned standards/external documents without a date are to be understood in their current revisions.

1.5 Manufacturer’s obligations

The manufacturer, who commissioned Kiwa Italia to carry out the EC/(EU) type examination, must not have given a similar task to another Notified Body.

The Manufacturer shall also

- ensure compliance with Regulation (EU) 2016/426 and Directive 92/42/EEC for the purpose of affixing and maintaining the CE marking on products,
- provide Kiwa Italia with all the technical documentation relating to the design of the device to be tested, as well as the certifications relating to the components making up the device itself,
- make available all relevant products and information for the purpose of a careful and valid evaluation by Kiwa Italia,
- notify Kiwa Italia in the event that one or more CE/EU Type Examination Certificates, relating to products under Kiwa Italia's surveillance, are suspended or withdrawn by the Notified Body, if the CE/EU Type Examination Certificate was issued by a Notified Body other than Kiwa Italia,
- allow the Kiwa Italia auditor, if requested, to take samples to be sent to the laboratory for the feedback tests on the product or to carry out such feedback directly on site,
- keep available, for any feedback, the technical reports relating to the EC/(EU) Type Exams, in order to be able to verify the compliance of the tests carried out with the products to be certified,
- keep Kiwa Italia informed of any regulatory change, change in product and/or adaptation of the quality system (if applicable) made necessary, for example, by new technologies and new quality concepts that will be evaluated by Kiwa Italia,

- accept, at no additional cost, any auditors from the accreditation body during audits, who will be communicated by Kiwa Italia with a clear illustration of their roles. The purpose of their presence is to verify that the assessment methods adopted by Kiwa Italia are in compliance with the accreditation requirements,
- allow Kiwa Italia to access the production, control, testing and storage premises for inspection purposes and provide all necessary information, in particular:
  - documentation of the quality system including records such as complaints,
  - the quality records made, such as inspection reports and test data, calibration data, reports on the qualifications of personnel,
- be responsible for the application of the requirements laid down by the regulations in force on safety in the workplace. In the absence of mandatory provisions, the manufacturer undertakes to provide Kiwa Italia with complete and detailed information on the specific risks existing in the environment in which Kiwa Italia personnel and the PPE necessary for carrying out the assignment, are intended to operate, informing Kiwa Italia personnel on their correct use. In this regard, the Manufacturer must provide the personnel appointed by Kiwa Italia 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 Italia.

If the conformity assessment procedure chosen by the Manufacturer involves the implementation of a quality system, such system must contain an adequate description of all or part of the following aspects:

- Quality objectives, the organization chart and the responsibilities of the managers and their powers as regards the quality of the equipment;
- Manufacturing processes and quality control and assurance techniques that will be used and the systematic interventions that will be implemented;
- Examinations and tests carried out before, during and after manufacturing, with indication of the frequency with which they are to be carried out;
- Checks and tests that must be carried out after manufacturing;
- Means by which to control the achievement of the required quality of the appliance and the effective functioning of the quality system;

Paragraph 16 lists the minimum number of checks that the manufacturer must provide in his quality plan, as specified in the guideline C5 issued by the group NBGA-Open. If necessary, the Manufacturer shall add other EMC related tests, life tests, material tests, etc.

Furthermore, in order to verify that the assessment methods adopted by Kiwa Italia comply with the reference standards, the Accreditation Body may request a visit, called Market Surveillance Visit, to be carried out at the Manufacturer, directly through the use of own personnel. This eventual visit is communicated by the Accreditation Body to Kiwa Italia with a 7 working days' notice. Upon receipt of this communication, Kiwa Italia will inform the Manufacturer. The visit plan is prepared by the Accreditation Body, which will make it available to Kiwa Italia, then Kiwa Italia will send it to the Manufacturer. If the Manufacturer 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 withdrawn. The Manufacturer must make the documentation that Kiwa Italia 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 Italia, for example. unannounced checks at the offices of certified subjects, requests for information from organizations or consulting firms, or other control methods established by the accreditation body itself.

2. EC/EU TYPE EXAMINATION

2.1 General requirements

The CE/EU Type Examination, where Type refers to a representative sample of the production, conducted by Kiwa Italia, consists of the evaluation of the technical documentation to verify the adequacy of the technical design, the assessment of the "Type" product to ensure that it conforms to the analyzed technical documentation, and the performance of tests,

as necessary, to verify compliance with the essential requirements of the Regulation and Directive. If the "Type" meets the provisions of the Regulation and Directive, Kiwa Italia issues a CE/EU Type Examination Certificate to the Manufacturer.

2.2 Application for the issue of the EC/EU type certificate

The Manufacturer who intends to request a quotation for CE/EU Type certification, shall send to Kiwa Italia the form MOD-01b GAS Information Questionnaire - EC (EU) type examination thoroughly filled out necessary for the preparation of the quotation.

After verifying the completeness of the information reported in the form MOD-01b GAS, the availability of the means to carry out all the evaluation activities, and availability of competent and skilled personnel to perform it, Kiwa Italia elaborates a quotation detailing the procedure, costs and the applicable technical standard, and sends it to the Manufacturer attaching this Regulation, Kiwa Regulation for Certification, and the General Terms and Conditions of Kiwa Cermet Italia.

The return of the quotation, accepted and signed by the Legal Representative of the Manufacturer or by a designated representative, constitutes the official application for certification and the contract that will govern the relationship between Kiwa Italia and the Manufacturer. Therefore, the Manufacturer confirms that they have read, understood and accepted, as a binding condition, this Regulation, the Kiwa Regulation for Certification and the General Terms and Conditions.

If the quotation is returned modified by the Manufacturer, Kiwa Italia may request clarifications or further modifications before initiating the certification process, or may communicate the impossibility of such initiation, providing the Manufacturer with the reasons.

Should any inconsistencies arise between the information provided in the questionnaire and the findings of subsequent assessments, Kiwa Italia reserves the right to revise the quotation.

2.3 Planning and carrying out the EC/EU type examination

If the verification of the "Type" product involves testing, Kiwa Italia will agree with the Manufacturer on the location and dates for the examinations and tests. The Manufacturer is also required to provide, in a timely manner, a representative sample of the intended production. Kiwa Italia reserves the right to request additional samples of the same type, if necessary to carry out the test program.

The Manufacturer must send to Kiwa Italia all documents required by the Regulation and Directive. Kiwa Italia will analyze the received documentation to assess its adequacy and, upon receipt of the sample, will verify that the sample has been manufactured in accordance with the technical documentation received.

Technical assessments and tests related to the CE/EU Type Examination may be conducted with reference to applicable EN Technical Standards, harmonized with the Regulation and Directive, and to technical standards that represent the current "state of the art" for verifying product conformity. If the Manufacturer does not follow the requirements indicated in the harmonized technical standards but adopts other solutions, Kiwa Italia will verify that these solutions also meet the essential requirements of the Regulation and Directive.

In the case of tests, tests related to the essential requirements concerning gas aspects (excluding electrical and electromagnetic hazards) may be performed:

a) by laboratories belonging to Kiwa Italia

b) by the Manufacturer, under the responsibility of Kiwa Italia, if the laboratory where the tests are carried out operates in compliance with ISO/IEC 17025 and is recognized by Kiwa Italia under Kiwa Italia internal procedure;

c) by a third-party laboratory that has ISO/IEC 17025 accreditation granted by a EA/ILAC recognized accreditation body, for the specific tests to be performed and belongs to a GAR and/or BED notified body or has been acknowledged by Kiwa Italia according to the Kiwa Italia internal procedure;

d) by a third-party laboratory which is not accredited for ISO/IEC 17025 as to the specific test to be performed, but can operate in compliance with the ISO/IEC 17025 standard and has been acknowledged by Kiwa Italia under Kiwa Italia internal procedure.

Tests related to electrical and electromagnetic hazards may be performed, in addition to the aforementioned entities, by a third-party laboratory recognized as a CBTL within the international IECEE circuit, whose operations have been previously assessed by Kiwa Italia as conforming to ISO/IEC 17025.

The tests must be carried out on the basis of the specific operating instructions available in the laboratory and in compliance with the applicable technical standards. The personnel responsible for conducting the tests must have the appropriate qualifications.

Upon completion of the CE/EU Type Examination, Kiwa Italia draws up a technical report, encompassing the technical assessments, any performed tests, the used equipment, and the results of the conducted evaluations.

2.4 Certification decision and issuance of the CE/EU Type examination certificate

Following positive results from the technical assessments, Kiwa Italia issues a CE/EU Type Certificate for the product family represented by the tested sample.

The CE/EU Type Certificate is drawn up in accordance with the provisions of the Regulation and/or Directive and shall have a maximum validity of 10 years from the date of issue.

Kiwa Italia informs the notified body of the issued CE/EU Type Certificates, providing a list of such certificates.

It is permitted the reproduction (including color) of the certificates of conformity issued by Kiwa Italia, as long as it reproduces the original in full. Partial reproduction is not permitted.

In the event of negative test results, or if the product's characteristics do not correspond to those reported in the technical documentation, Kiwa Italia shall not issue any certificate and shall provide the Manufacturer with a detailed explanation of such refusal, allowing the Manufacturer to request the return of the product and undertake appropriate corrective actions (product modification, project closure, etc.).

3. TYPE EXAMINATION ASSESSMENT (Notified Body Surveillance according to Modules D, E, C/C2)

3.1 General requirements

Once the CE/EU Type Certificate has been obtained, the Manufacturer must request certification according to one of the Conformity Assessment modules provided for by the Regulation and Directive, in order to guarantee the maintenance of the conformity requirements of the products for which the CE/EU Type Certificate has been issued.

To this end, the Manufacturer must define, document, and maintain a permanent production control system and/or a quality management system (based on the chosen assessment form) and identify the areas of responsibility to ensure that the products placed on the market conform to the characteristics of the certified “Type”. The production control system (and/or quality management system) must include procedures, regular inspections, tests, and/or evaluations that the Manufacturer must carry out to monitor product conformity.

The Type conformity assessment involves an initial visit (audit) by Kiwa Italia to the Manufacturer's premises, followed by annual visits to carry out product checks and verify that they conform to the certified Type.

For each audit, Kiwa Italia sends an audit plan to the Manufacturer in advance, communicating the names of the Audit Team; if there are conflicts of interest, the Manufacturer may request, within 3 working days, the replacement of a member or the entire Audit Group, providing reasons. Kiwa Italia will evaluate these reasons and, if they are justified, will modify the audit team.

3.2 Classification of findings and their management

The findings resulting from the Type conformity assessment activities are classified by Kiwa Italia as follows.

Major Non-Conformity (NC): failure to meet a certification requirement, which compromises the product's capability of ensuring compliance with the essential requirements applicable to it. This may concern:

- deviation or total absence of conformity with respect to a specified requirement, found on the basis of objective evidence;
- failure to comply with applicable legal requirements.

Minor Non-Conformity (NC): failure or partial fulfillment of a certification requirement, not falling within the category of major non-conformities described above, which, although requiring correction, does not affect the product's capability of ensuring compliance with the essential requirements applicable to it.

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

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

Improvement element/observation: situations which do not fall within the definitions of non-conformity and constitute a potential improvement in the effectiveness of the solutions adopted by the Manufacturer, to achieve compliance with the certification requirements.

The Manufacturer is not obliged to implement the improvement elements/Observations, however, they must analyse them and justify the decision taken.

The corrections and corrective actions (CAs) necessary to eliminate the non-conformities identified during the initial or periodic surveillance audit must be defined by the Manufacturer and communicated to Kiwa Italia within 20 working days of the audit, by completing each non-conformity form/report, in the section related to "proposed/implemented corrective actions" indicating the methods, timing and responsibilities of the implementation. Each form must be signed by the Manufacturer's Representative.

The Lead Auditor evaluates the proposed corrective actions and, in the case of comments or the need for clarification, notifies the Manufacturer in written form.

The positive or negative outcome of the CA assessment is noted on the non-compliance report in the relevant part and approved by the Lead Auditor.

The actual implementation of the CAs and the closure of minor NCs will be evaluated by the Lead Auditor in the subsequent surveillance audit; in the case of major NCs, the assessment will take place through an additional audit (in addition to the periodic surveillance audits), and this additional audit will be at the expense of the Manufacturer.

3.3 Application for the issuance of the Type conformity Certificate

The Manufacturer who intends to request a quotation for certification shall send to Kiwa Italia the form MOD-01a GAS Information Questionnaire – Surveillance thoroughly filled out, necessary for the preparation of the quotation.

Kiwa Italia, after verifying the completeness of the information reported in MOD-01a GAS, the availability of the means to carry out all the assessment activities and the availability of competent and skilled personnel to perform it, issues a quotation for carrying out the type assessment activities at the production site. Such quotation can be:

- included in the quotation already issued for carrying out the EC/EU Type Examination, if the two certifications have been requested from Kiwa Italia simultaneously by the Manufacturer;
- issued only for the Type conformity assessment activity, if the Manufacturer has received the EC/EU Type Examination from another Notified Body, or has previously requested it from Kiwa Italia.

The quotation shall also include the conformity assessment procedure chosen by the Manufacturer:

a. Mod. C2 Reg. (EU) 2016/426 Ann. III – Mod. C Dir. 92/42/CEE Ann. IV

b. Mod. D Reg. (EU) 2016/426 Ann. III – Mod. D Dir. 92/42/CEE Ann. IV

c. Mod. E Reg. (EU) 2016/426 Ann. III – Mod. E Dir. 92/42/CEE Ann. IV

The return of the quotation signed by the Manufacturer's Legal Representative or their delegate, constitutes the official application for certification.

If the Manufacturer returns a modified quotation, Kiwa may request clarifications or further modifications before considering the contract activated and the certification process initiated, or may communicate the impossibility of such initiation, providing the Customer with a reasoned explanation.

Should any inconsistencies arise during the subsequent evaluation phases compared to what was declared in the information questionnaire, the quotation may be subject to review by Kiwa Italia.

3.4 Entering into agreement (Surveillance Agreement)

Following the acceptance of the quotation, the Surveillance Agreement is entered into with the Manufacturer, defining the rights and duties of both parties, as well as the chosen evaluation procedure, the complete list of products under surveillance, and the sites to be audited.

The Surveillance Agreement must be signed by both parties.

3.5 Initial Type conformity assessment (Initial surveillance)

3.5.1 Initial surveillance audit

Following the signing of the Surveillance Agreement, Kiwa Italia proceeds with the planning of the initial surveillance audit at the Manufacturer's premises, communicating the planned dates and locations to the Manufacturer.

The initial surveillance audit is conducted by the Kiwa Italia audit team based on the evaluation procedure/module chosen by the Manufacturer and specified in the contract.

The manufacturer must present all relevant products and information for the purpose of a careful and valid evaluation by Kiwa Italia in order to allow the Kiwa Italia auditor, if requested, to take the samples to be sent to the laboratory for testing the product.

The manufacturer must always keep available, for any feedback, the technical reports relating to the EC/EU Type Examination, in order to be able to verify the compliance of the tests carried out with the products to be certified.

The Kiwa Italia audit team, depending on the assessment procedure/module requested by the Manufacturer, can:

- examine an adequate number of appliances and carry out appropriate tests defined in the applicable standards or equivalent tests to verify compliance of the appliances with the essential requirements set out in the Regulation and Directive;
- ensure that the Manufacturer maintains and applies a production control system (and/or a quality system) which guarantees conformity of the appliances with the type described in the CE/EU Type certificate and with the essential requirements set out in the Regulation and Directive;
- ensure that the Manufacturer maintains and applies a production control system (and/or a quality system) for the final inspection of the appliances and for the tests.

Regarding modules D and E, the initial surveillance is based on the requirements of UNI CEI EN ISO/IEC 17021-1 and provides for a structured audit in 2 phases: Stage1 and Stage2.

In Stage 1, Kiwa Italia assesses the Manufacturer's quality system, with particular reference to the constituent documents. This system must ensure the conformity of products to the Type described in the EC/EU Type Certificate and to the essential requirements of the GAR Regulation and the BED Directive. Based on the results of Stage 1, the Manufacturer is required to make any necessary modifications or additions. Kiwa Italia may request the modified documents for further analysis before proceeding with the subsequent activities. Depending on the results of Stage 1, Kiwa Italia may decide to postpone or cancel Stage 2.

In Stage 2, Kiwa Italia verifies that the Manufacturer's quality system is correctly applied and effective as specified in the GAR Regulation and the BED Directive. Stage 2 can only be conducted after the successful completion of Stage 1.

The maximum time that may elapse between Stage 1 and Stage 2 must be such as to ensure that the results of Stage 1 remain valid. Therefore, the system, products, and the normative and legislative context must not undergo any variations between the two stages. If significant changes occur between Stage 1 and Stage 2 that would impact the guarantee of conformity with the essential requirements of the Regulation and the Directive, Kiwa Italia may require the repetition of all or part of Stage 1.

At the end of each audit, the Lead Auditor draws up an audit report, which includes the results of the assessment. The Manufacturer is required to sign the relevant sections of the report.

Kiwa Italia reserves the right to sample an appliance for testing at Kiwa Italia's laboratory, drawing up a specific sampling report.

Any non-conformities identified following the audit must be handled as outlined in § 3.2. Kiwa Italia cannot proceed with the certification decision until it receives the proposed corrective actions, which must be accepted by the Lead Auditor. Furthermore, in the case of Major NCs, the certificate cannot be issued until the implementation of corrections and corrective actions has been verified through a supplementary conformity assessment, as described in § 3.2.

In the case of Modules D and E, if Major NCs are identified at the end of Stage 2, the additional assessment for their closure must be completed within a maximum of 6 months from the last day of Stage 2. If, on the other hand, the 6-month period has elapsed but it is within 12 months of the last day of Stage 2, it will be necessary to conduct another Stage 2 before proceeding with the certification process. Beyond 12 months, it will be necessary to restart from Stage 1.

3.5.2 Certification decision

Kiwa Italia reviews the audit documentation produced by the Lead Auditor, the results of laboratory tests, and, in case of a positive outcome, authorizes the issuance of the Type Certificate, which is valid for three years (from the date of first issuance, which cannot be prior to the date of the certification decision).

If Kiwa Italia's final decision differs from that proposed by the Lead Auditor, the reasons will be communicated in writing to the Manufacturer.

Upon receipt of the certificate, the Manufacturer is authorized to affix Kiwa Italia's identification number as a Notified Body to the certified products.

In the event of certificate denial, Kiwa Italia will send a notification to the Organization, which will outline the details of the Certification Decision and the subsequent actions.

3.6 Periodic Type Conformity Assessment (Periodic Surveillance)

3.6.1 Periodic surveillance audit

The surveillance audit will be conducted at the Manufacturer's premises on a “random” basis, considering a variable interval between 9 months and one year for Modules C and C2 (GAR) and an annual frequency for Modules D and E.

Kiwa Italia may establish a higher frequency for these audits, based for example on the results of previous audits.

For modules D and E, in the year of certificate expiration, the periodic surveillance audit will be scheduled in a timely manner to allow for the re-issuance of the certificate with the new validity period, prior to its expiration.

For modules C/C2, Kiwa Italia will update the certificate upon expiration, provided that the Surveillance Agreement with the Manufacturer is valid and the required activities are progressing as planned.

The periodic surveillance audit shall be conducted in a manner similar to that defined in section 3.5.1; Kiwa Italia reserves the right to conduct these audits without prior notice.

In the event of an unannounced audit, the Lead Auditor shall present the detailed audit plan to the Manufacturer and agree on the specifics at the beginning of the audit. Should the Manufacturer be unable to accommodate such audits, Kiwa Italia reserves the right to suspend or withdraw (in more serious cases) the issued certification.

The number of products to be sampled by Kiwa Italia will be calculated based on the product types and total annual production (number of products per year).

For modules C and C2 (GAR), in case of prolonged periods of production inactivity, surveillance can still be conducted by inspecting products in stock. If no products are available in stock, the Manufacturer may request an extension by submitting a written request, signed by a Company Representative, justifying the reasons. This request will be evaluated by the Division Manager who may grant an extension of up to 3 months from the due date of the audit.

At the conclusion of the audit, the Audit Team shall provide the Manufacturer with a copy of the audit report, which the Manufacturer shall sign. The report will be subject to internal review and approval by Kiwa Italia. The report shall be deemed confirmed if no further communication is received by the Organization within 60 calendar days. Conversely, if, following an internal review, Kiwa Italia considers it necessary to make changes to the report, it shall formally notify the Manufacturer, providing explanations for any changes made and indicating the subsequent actions.

Any NCs shall be handled in accordance with the provisions of section 3.2. For major NCs, the Manufacturer must promptly implement corrective actions, which must be approved by the Lead Auditor and implemented and verified by Kiwa Italia within a maximum of 2 months from the verbalization; products subject to a major NC cannot be placed on the market until the major NC has been resolved; furthermore, the Manufacturer must consider a possible recall of products already distributed, depending on the identified criticalities. Any requests for an extension of these implementation times must be justified in writing and approved by Kiwa Italia; in case of exceeding the established time, the Manufacturer will be subject to the measure of suspension or (in more serious cases) withdrawal or reduction of the certification, as indicated in paragraph 9 of this Regulation.

For modules D and E, if major non-conformities are identified in the year of certificate expiration and cannot be resolved by the certificate expiration date, Kiwa Italia will decide to suspend the certification or, in more serious cases, reduce or withdraw the certification.

The postponement or cancellation of a previously scheduled and agreed-upon audit, for reasons attributable to the manufacturer, must be communicated to Kiwa Italia at least two weeks prior to the planned date and will be managed as per Article 15 of the General Terms and Conditions.

The performance of the surveillance audits foreseen in the certification cycle is subject to the regular payment of previous activities by the manufacturer.

3.6.2 Certification confirmation

Kiwa Italia reviews the surveillance audit documentation, the correct management of findings, and, if the evaluation is positive, confirms the validity of the certification.

In case of a negative outcome, Kiwa Italia will determine the actions to restore conformity, which will be communicated to the Manufacturer; if these actions are not implemented within the specified time, Kiwa Italia will take the measures of suspension, reduction, or withdrawal as indicated in § 9. For modules D and E, in case of a negative evaluation in the year of certificate renewal, the actions to restore conformity must be implemented before the certificate expires, otherwise the certificate will not be renewed and the Manufacturer will be charged for all due costs, including expenses.

4. EXTRAORDINARY AUDITS

Kiwa Italia reserves the right, motivated in writing to the Manufacturer, to carry out extraordinary audits relating to the certified product for the reasons indicated in the *Kiwa Regulation for Certification* or for requests that emerged during the issue of the certificate, etc.

The costs of the aforementioned audit activities shall be borne by the Manufacturer and do not replace or modify the process and frequency of periodic surveillance audits.

5. CONFORMITY BASED ON THE PRODUCT VERIFICATION OR ON A SINGLE UNIT VERIFICATION (Regulation (EU) 2016/426)

Pursuant to Regulation (EU) 2016/426, EU certification of products is possible without carrying out periodic surveillance activities by a Notified Body if, under certain conditions, the products are made in batches well defined and limited or made in a unit.

5.1. Module F: Conformity to type based on product verification

Pursuant to Annex III – Module F, Kiwa Italia conducts the necessary examinations and tests to verify the conformity of the appliances or accessories with the approved type described in the EU-type examination certificate and with the relevant requirements of the GAR Regulation. The Manufacturer may choose to conduct the examinations and tests to verify conformity with the relevant requirements of the appliances or accessories pursuant to point 5.4 of the GAR Regulation - i.e. by examining and testing each appliance or accessory - or pursuant to point 5.5 of the GAR Regulation - i.e. by examining and testing the appliances or accessories on a statistical basis.

Based on the positive results of the technical assessments carried out on the batch subject to verification, Kiwa Italia affixes or causes to be affixed its Notified Body number on each appliance and provides a certificate. All appliances in the batch may be placed on the market, except for any samples in which NCs have been found.

In the event of a negative outcome of the tests carried out, or if it is found that the product characteristics do not correspond to the certified Type, Kiwa Italia cannot issue any certificate and will provide a detailed justification for such refusal to the Manufacturer so that the latter may request the return of the product and take appropriate corrective actions (modification of the product, project closure).

5.2. Module G: Conformity based on the unit verification

Pursuant to Annex III – Module G, conformity based on the examination of a single unit is the conformity assessment procedure whereby the Manufacturer fulfils the obligations set out in points 6.2, 6.3 and 6.5 of the GAR Regulation and guarantees and declares, under its sole responsibility, that the appliance or accessory concerned, to which point 6.4 of the GAR Regulation has been applied, conforms to the applicable requirements of the GAR Regulation.

Kiwa Italia examines the appliance and carries out or arranges for the carrying out of the necessary tests, taking into account the product's design documentation, to verify its conformity with the essential requirements of the GAR Regulation.

Based on the positive results of the technical assessments carried out on the single unit subject to verification, Kiwa Italia affixes or causes to be affixed its Notified Body number on the approved appliance and provides a certificate.

In the event of a negative outcome of the tests carried out, Kiwa Italia cannot issue any certificate and will provide a detailed justification for such refusal to the Manufacturer so that the latter may request the return of the product and take appropriate corrective actions (modification of the product, project closure).

6. MODIFICATIONS OF CERTIFICATION REQUIREMENTS

The Manufacturer must inform Kiwa Italia of any modifications to the certified product that may affect its conformity with the essential requirements of the Regulation and Directive, or the conditions of validity of the certification.

If the Manufacturer requests an extension and/or communicates a modification, since modifications have been made or extensions have been introduced to the product families already tested, Kiwa Italia will issue a new quotation.

Depending on the extension/modification, Kiwa Italia may carry out supplementary tests or, in the case of negligible modifications to the product, proceed to an update of the technical report previously issued, based on the analysis of documentary evidence.

In the case of extensions of families or the introduction of new denominations, Kiwa Italia will issue a new CE-Type Examination Certificate.

7. CERTIFICATION FOR A PRIVATE LABELLER (OBL)

7.1 CE/EU Type Examination for a Private Labeller (OBL)

Should a Physical Producer intend to request a CE/EU Type Examination for a Private Labeller, they must send the certification quotation request to Kiwa Italia using the form “MOD-01b GAS Information Questionnaire for CE/EU Type Examination”.

In order to fulfill this request, it is necessary to enter into a specific written agreement between the Physical Producer and the Private Labeller, in order to clearly regulate the relationship between the two parties. This agreement must specify that all technical documentation and technical reports in the possession of the Physical Producer, in support of the conformity verification of the certified products, are fully available to the Private Labeller. Furthermore, this agreement must state that the certification of the Private Labeller will lapse if the certification of the Physical Producer lapses.

A copy of this agreement must be attached to the certification application together with confirmation of having read, understood and accepted, as a binding condition, this Regulation, the Kiwa Regulation for Certification and the General Terms and Conditions.

In the event of the issuance of a CE/EU Type Examination Certificate to a Private Labeller, they may (with the written consent of the parties) request to be included in the original technical report issued by Kiwa Italia or to have a technical report in their own name.

The extension of the original technical report to the Private Labeller, or the issuance of a new technical report in the name of the Private Labeller, may be carried out by Kiwa Italia without further testing (therefore only on the basis of the technical documentation presented) only on the condition that the product undergoes no modifications compared to the sample originally tested.

Based on this technical report, a CE/EU Type Examination Certificate will be issued for the products marketed by the Private Labeller.

The certificate issued to the Private Labeller will have the same expiry date as the certificate issued to the Physical Producer, regardless of the date of issue.

7.2 Type conformity assessment for a Private Labeller (OBL)

Should a Physical Producer supply its certified products to a Private Labeller, the latter may request certification under its own name by following the procedure outlined in the preceding paragraphs.

For the purpose of Type conformity certification, where the entire production process is carried out at the Physical Producer without any modifications and/or alterations to the certified product, the technical documentation and reports of inspection visits conducted at the Physical Producer's premises may be used (with the written consent of both parties).

The Private Labeller undertakes not to make any documentary or technical changes to the products supplied by the Physical Producer.

The provisions specified in the preceding paragraph regarding the agreement to be drawn up between the parties also apply in this case. Additionally, this agreement must stipulate that the Private Labeller shall be informed of all aspects related to the manufacturing process and/or the quality system for ensuring the conformity of the appliances. The Private Labeller's certification shall lapse if the certification of the Physical Producer lapses. The Private Labeller must inform the Physical Producer of any complaints regarding the certified products.

With regard to Module D, an audit activity is also planned at the Private Labeller's premises.

The certificate issued to the Private Labeller shall have the same expiry date as the certificate issued to the Physical Producer, regardless of the date of issue.

8 CHANGES TO REGULATIONS AND/OR CERTIFICATION REQUIREMENTS

Kiwa Italia monitors technological advancements generally recognized as state-of-the-art, to assess whether the approved type may cease to comply with the requirements of Regulation 2016/426 (GAR) and determines whether these advancements require further investigation. In such cases, Kiwa Italia informs the Manufacturer.

However, it remains the Manufacturer's responsibility to verify that their products and related documentation are updated to the latest version of the applicable standard and/or are technically at the same level as the state of the art, in order to guarantee the presumption of conformity with the essential requirements of the Regulation and Directive.

9 SUSPENSION, WITHDRAWAL OR REDUCTION OF THE CERTIFICATION

The Certification can be suspended, withdrawn or reduced for the reasons indicated in the *Kiwa Regulation for Certification* or at the request of the customer.

Except in exceptional cases (as determined by Kiwa Italia or the Competent Authority), the suspension period cannot exceed 6 months; otherwise, the certification will be reduced or withdrawn.

The communication regarding the measure to be taken is sent to the Manufacturer by registered letter with acknowledgment of receipt or certified email and must include at least: the reason, the duration, and the conditions under which the measure may be revoked, as well as the limitations on the use of the certificate.

During the suspension period the Organization loses the right to affix the CE marking and loses the right to use or advertise the certificate by any means. The conditions for the restoration of the suspended certification (including the necessary conformity assessment activities), will be established by Kiwa Italia based on the reasons that led to the suspension, and based on the duration of the suspension.

If the customer Organization does not implement the actions indicated by Kiwa Italia to restore the suspended certification, the certification will be withdrawn or, in possible cases, its scope will be reduced.

The reduction of the certification involves the issue of a new certificate, indicating the type of product for which the certification has remained valid, and the withdrawal of the old certificate.

Withdrawal of the certification involves automatic termination of the contract to which this regulation applies pursuant to art. 1456 of the Italian Civil Code, without prejudice, in any case, to compensation for any damage suffered by Kiwa Italia.

Following the withdrawal of the certification, the Manufacturer (or authorized representative) loses the right to use the CE marking and the certificate, Kiwa Italia informs the Manufacturer that the product can no longer be placed on the market with the CE marking and will inform other Notified Bodies.

On the basis of the reasons that led to the suspension/withdrawal/reduction of the certification Kiwa Italia reserves the right to request the list of stocks in the warehouse, of the products covered by certification, on the date of the suspension/withdrawal/reduction decision.

In the case of suspension or withdrawal due to specific critical issues on products already placed on the market, Kiwa Italia will inform the competent Market Supervisory Authorities (as defined pursuant to Article 17 of Regulation EC 765/2008, article 36 of the GAR) in order to comply with the provisions of art. 37 of the GAR “procedure at national level for devices and accessories that present risks”.

Please note that in the event of a contractual agreement between the Private Labeller and the Physical Producer, a suspension/withdrawal/reduction of the certification of the Physical Producer's products shall also imply the suspension/withdrawal/reduction of the certificates issued in the name of the Private Labeller, with Kiwa Italia being exempted from any liability related to the contractual obligations assumed by the Physical Producer.

In case of withdrawal, the Manufacturer (or authorized representative) will be able to activate the certification process again by submitting a new application.

10 CONFIDENTIALITY

Kiwa Italia ensures maximum confidentiality on all information acquired by its personnel, involved in the certification process, in the performance of their functions.

In addition to what is regulated in the *General Terms and Conditions* and in the *Kiwa Regulation for certification*, this confidentiality bond is ensured by applying specific procedures in compliance with the relevant international legislation and current legal provisions.

In this regard, Kiwa Italia 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 they come into possession of in compliance with the provisions of the law on Privacy.

This constraint ceases to apply when Kiwa Italia is obliged to publicly communicate the issuance, suspension, or withdrawal of an Organization's certificate due to legal obligations or other requirements.

11 ADVERTISING

Once the Manufacturer has obtained the certificate, they have the right to make the news public for the products covered by the certification. In any case, the manufacturer must pay attention to ensure that in publications and advertising there are no misleading references to the products subject to certification.

12 USE OF THE CERTIFICATION MARK AND CE MARKING

12.1 Use of certification marks and logos

The use of the CE marking is regulated by Regulation (EU) n° 2016/426 § (6) and by Directive 92/42 EEC Annex I.

The use of the Kiwa logo is optional; however, if the customer Organization wishes to use this option, this regulation is binding.

When using the certification mark, the customer Organization shall comply with all applicable rules stated in *Kiwa Regulation for Certification* and and the Regulations for Use of the Mark, to which reference is made (www.kiwa.it).

13 COMPLAINTS AND APPEALS

13.1 Complaints

The Manufacturer can file a documented complaint, concerning the certification activities with Kiwa Italia.

This complaint may arise from issues occurring during the certification process, such as, for example, delays in carrying out the various phases and incorrect behavior by the Body's auditors.

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

In order to ensure impartiality all complaints are dealt with by personnel which is not involved in the activities subject to the complaints.

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

13.2 Appeals

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

The appellant must justify the reasons for his appeal and, in the case that this appeal relates to a decision by Kiwa Italia (e.g. recording a major Non-Conformity), it must be presented to Kiwa Italia within 10 days calendar from the date of communication of the decision.

Appeals are dealt with by functions which are not involved in the activities subject to the appeal.

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

The detailed procedures for submitting complaints and appeals are shown on the website www.kiwa.it.

14 RIGHT OF UNILATERAL WITHDRAWAL FROM THE CONTRACT

Kiwa Italia may freely withdraw from this contract by giving written notice to the customer organization with six months' notice of the effective date of the withdrawal. Withdrawal by Kiwa Italia involves the withdrawal of the certification issued. The Organization is in any case required to pay Kiwa Italia the amounts due for the services received during the notice period, as established in the last valid quotation.

If the Organization wishes to withdraw from the contract, the unilateral withdrawal during the period of validity of the Certification requires compliance with the notice times provided for in the *General Terms and Conditions and in Kiwa Regulation for Certification*.

In the event that the Organization terminates the Surveillance Agreement, Kiwa is entitled to conduct a final inspection visit if more than six months have elapsed since the previous audit.

In particular, for notice of less than three months with respect to the scheduled Audit and more than two weeks, the Customer will have to 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 Italia will issue an invoice, in relation to the costs of closing the certification file, as established in the last valid quotation.

15 UNILATERAL AMENDMENT OF THE CONTRACT

Kiwa Italia reserves the right to amend this Regulation at any time. Any new clauses/amendments shall become effective from their written notification to the customer.

If the Organisation does not accept the amendments, it may terminate the contract by giving written notice by registered letter with return receipt or certified e-mail within 30 calendar days, under penalty of forfeiture, from the day after the communication to Kiwa Italia.

The termination shall become effective from the last working day of the month in which the Customer’s notice is received.

16 MINIMUM CHECKS TO BE PERFORMED BY THE MANUFACTURER

16.2 Gas appliances:

Test	Frequency
Gas soundness	100%
Flow rate	100%
Burner ignition	100%
Visual appearance flame	100%
Burner x lighting	100%
Earth continuity	100%
High voltage	100%
Flame supervision device	100%
Combustion	S
Surface temperature	S
Thermostat	S

Pressure limit switches	100%
Fan operation	100%
Combustion circuit soundness	S
Flue gas spillage	S
Thermal down draught diverter	S
CO_2 detection device	S
Water circuit soundness	100%
Electric control safety	100%
Temperature limits (switches)	S
Efficiency	S

100% = *test carried out on each CE marked product.*

S = *test carried out on a regular statistical basis, daily, weekly, etc. at the discretion of the manufacturer.*

17 GAS APPLIANCE COMPONENTS:

Controls	**Gas soundness**	**Functional safety**	**Electrical safety**
Gas valve, cocks	100%	100%	100%
Electr. Temperature controllers	N/A	100%	100%
Mechanical (gas) temperature controllers	100%	100%	100%
Air flow and pressure levels controllers	N/A	100%	100%
Gas pressure switches	100%	100%	100%
Igniters, sensors	N/A	100%	100%
Safety electronics	N/A	100%	100%