REGULATION FOR CERTIFICATION OF PRODUCTS IN ACCORDANCE WITH REGULATION (EU) 2016/426 ON APPLIANCES BURNING GASEOUS FUELS AND DIRECTIVE 92/42/EEC ON EFFICIENCY REQUIREMENTS FOR WATER BOILERS FIRED WITH LIQUID OR GASEOUS FUEL

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rev. no.	SUMMARY OF CHANGES	DATE
19	Integration of § 3.6.1, § 5.1 and § 13.1; correction of some errors	2026-09-10
18	Elimination of the requirements on the use of trademarks and inclusion in a specific Regulation; edited Regulation code	2025-11-19

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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 Organisation (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 efficiency 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 authorisation 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* for brevity). 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 Organisation

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 formalised rules and controls, including:

- Performance of certification activities assigned to personnel who do not have any interest with 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 the existence of any incompatibility relating to the assignment that may compromise the impartiality or independence of judgment.
- Strict application of formalised rules and procedures used by all 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 certification decisions.
- Complete abstention from providing consultancy or assistance in the definition and implementation of the requirements necessary to obtain Certification. Kiwa Italia is not directly involved in the production, representation, marketing, maintenance or installation of products or materials subject to certification, nor does it provide consultancy in the design and development phase of the product itself, nor does it have affiliated entities carrying out such activities, in accordance with the applicable legislation in force.

c) Prompt management of complaints and appeals, as defined in paragraph 13 of this Regulation;

d) Confidentiality: in addition to what is regulated in the *General Terms and Conditions* and in the *Kiwa Regulation for Certification*, 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 it comes into possession, in compliance with the provisions of the law on Privacy.

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

[2] Products that conform to harmonised 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.

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 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.

Authorised Representative: a natural or legal person established within the European Union who has received a written mandate from a Manufacturer authorising 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 below.

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 water boilers fired with liquid or gaseous fuel;
- Regulation (EU) no. 813/2013 of 02 August 2013 for Ecodesign of space heaters and combination heaters;
- EU Commission Guidelines on “New Approach” Directives
- Guidelines and documents issued by the group NBGA_Open applicable to the relevant products
- Applicable EN harmonised technical standards.

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

1.5 Manufacturer’s requirements

The Manufacturer, who commissioned Kiwa Italia to carry out the EC/EU Type examination, shall 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 appliance to be tested, as well as the certifications relating to the components constituting the appliance 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 EC/EU Type Examination Certificates, relating to products under Kiwa Italia's surveillance, are suspended or withdrawn by the Notified Body, if the EC/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 confirmation tests on the product or to carry out such verification activities directly on site,
- keep the technical reports relating to the EC/EU type examinations always available for any possible verification, in order to verify the correspondence between the tests carried out and the products to be certified,

- keep Kiwa Italia informed of any Regulatory, product modifications and/or any adaptation of the quality system (where applicable) made necessary, for example, by new technologies and new quality concepts, which shall be subject to evaluation by Kiwa Italia,
- accept, without additional costs, the possible presence during audits of Assessors from the Accreditation Body, whose participation shall be communicated by Kiwa Italia together with a clear explanation of their roles. Such presence is intended to ascertain that the assessment methods adopted by Kiwa Italia comply with the accreditation requirements,
- allow Kiwa Italia access, for inspection purposes, to production, inspection, testing and storage facilities and to provide all necessary information, in particular:
  - quality system documentation, including records such as complaints
  - quality records, such as inspection reports and test data, calibration data and qualification reports of the personnel involved,
- be responsible for the application of the requirements laid down by the applicable legislation regarding workplace health and safety. In the absence of mandatory provisions, the Manufacturer undertakes to provide Kiwa Italia with complete and detailed information concerning the specific risks existing in the environment in which Kiwa Italia personnel are required to operate and the personal protective equipment (PPE) necessary for the performance of the activities, informing Kiwa Italia personnel of their correct use. For this purpose, the Manufacturer shall provide the personnel appointed by Kiwa Italia with the company documentation relating to occupational health and safety (Risk Assessment Document (DVR), safety plan, procedures, etc.), limited to the items of specific relevance. Should accidents occur or illnesses be contracted as a result of such omissions, no claim whatsoever may be brought against Kiwa Italia for any reason.

Where the conformity assessment procedure chosen by the Manufacturer requires the implementation of a quality system, such system shall contain an adequate description covering, in whole or in part, the following aspects:

- Quality objectives, organisational chart, responsibilities of management personnel and their authority with regard to the quality of the appliances;
- Manufacturing processes, quality control and quality assurance techniques to be used, and the systematic actions to be implemented;
- Examinations and tests carried out before, during and after manufacture, indicating the frequency with which they are intended to be performed;
- Inspections and tests to be carried out after manufacture;
- Means of monitoring the achievement of the required appliance quality and the effective operation of the quality system.

Paragraph 16 provides the list of the minimum number of inspections that the Manufacturer shall include in its quality plan, as specified in Guideline C5 issued by the NBGA-Open group. Where necessary, the Manufacturer shall also provide for additional tests relating to EMC, life tests, material tests, etc.

Furthermore, in order to ascertain that the assessment methods adopted by Kiwa Italia comply with the applicable standards, the Accreditation Body may require the performance of a visit, referred to as a Market Surveillance Visit, at the Manufacturer's premises, directly through the use of its own personnel. Such visit, where required, shall be communicated by the Accreditation Body to Kiwa Italia with 7 working days' notice. Upon receipt of such notification, Kiwa Italia shall inform the Manufacturer. The visit plan shall be prepared by the Accreditation Body and made available to Kiwa Italia, which shall subsequently forward it to the Manufacturer. Should the Manufacturer refuse to grant its consent, the validity of the certificate shall be suspended until consent for the visit is granted, for a maximum period of 3 months. Upon expiry of the three-month period, if consent for the visit has still not been granted, the certification shall be withdrawn. The Manufacturer shall make available to the Accreditation Body the documentation that Kiwa Italia used as a reference during previous audits. The Market Surveillance Visit does not replace the routine certification maintenance audits provided for in the audit programme. For the arrangements governing the conduct of the Market Surveillance Visit, reference may be made to document IAF ID 04 (available free of charge from the IAF website: www.iaf.nu). The Accreditation Body may also adopt other control methods to verify the operation of Kiwa Italia, such as unannounced assessments at the premises of certified entities, requests for information from organisations or consultancy companies, or other control methods established by the Accreditation Body itself.

2. EC/EU TYPE EXAMINATION

2.1 General requirements

The EC/EU Type Examination, where the term Type means a representative specimen of the production, by Kiwa Italia consists in the assessment of the technical documentation to verify the adequacy of the technical design, in the assessment of the "Type" product to ascertain that it is in conformity with the technical documentation assessed, and in the performance of examinations and any tests, as necessary, in order to ascertain conformity with the essential requirements of the Regulation and the Directive. If the "Type" satisfies the provisions of the Regulation and the Directive, Kiwa Italia issues to the manufacturer an EC/EU Type Examination Certificate.

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

The Manufacturer intending to request a quotation for EC/EU Type certification shall send to Kiwa Italia the MOD-01b GAS *Information Questionnaire – EC (EU) Type Examination*, completed in all its parts, necessary for the preparation of the quotation.

Kiwa Italia, after having verified the completeness of the information reported in form MOD-01b GAS, the availability of the means to perform all assessment activities and the availability of personnel with the competence and capability to perform them, prepares the quotation detailing: the procedure, the costs, the applicable technical regulations and sends it to the Manufacturer attaching this Regulation, the Kiwa Regulation for Certification and the General Terms and Conditions.

The return of the quotation accepted and signed by the Legal Representative of the Manufacturer or by a delegated person, represents the official application for certification and the contract governing the relationship between Kiwa Italia and the Manufacturer; the latter thereby confirms that it has read, understood and accepted, as a binding condition, this Regulation, the Kiwa Regulation for Certification and the General Terms and Conditions.

Should the quotation be returned amended by the Manufacturer, Kiwa Italia may request clarifications or further amendments before activating the certification process, or communicate the impossibility of such start-up, stating the reasons to the Manufacturer.

Should inconsistencies emerge during the subsequent assessment phases with respect to what was declared in the information questionnaire, the quotation may be subject to revision by Kiwa Italia.

2.3 Planning and performance of the EC/EU Type examination

Where verification of the "Type" product requires the performance of tests, Kiwa Italia agrees with the Manufacturer the place and dates on which the examinations and tests shall be carried out; the Manufacturer is also requested to make available, in due time, a specimen of product representative of the intended production. Kiwa Italia reserves the possibility of requesting other specimens of the same type, where necessary for the execution of the test programme.

The Manufacturer shall send to Kiwa Italia all documents required by the Regulation and the Directive. Kiwa Italia carries out the analysis of the documentation received, in order to assess its adequacy and, upon receipt of the sample, verifies that such sample has been manufactured in conformity with the technical documentation received.

The technical assessments and tests relating to the EC/EU Type Examination may be conducted with reference to the applicable EN Technical Standards harmonised with the Regulation and the Directive and to technical standards representing the current "state of the art" for product conformity verification. Where the Manufacturer does not follow the requirements indicated in the harmonised technical standards, but adopts other solutions, Kiwa Italia shall verify that such solutions equally satisfy the essential requirements relating to the Regulation and the Directive.

Where tests are carried out, the tests relating to the essential requirements concerning gas aspects (therefore excluding hazards of an electrical and electromagnetic nature) may be carried out:

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 conformity with ISO/IEC 17025 and is recognised by Kiwa Italia in accordance with the internal procedure of Kiwa Italia;

c) by a third-party laboratory holding ISO/IEC 17025 accreditation issued by an EA/ILAC-recognised Accreditation Body for the specific tests to be carried out and belonging to a GAR and/or BED notified body, or recognised by Kiwa Italia in accordance with to the internal procedure of Kiwa Italia;

d) by a third-party laboratory not accredited to ISO/IEC 17025 for the specific test to be carried out, but capable of operating in conformity with ISO/IEC 17025 and recognised by Kiwa Italia in accordance with the internal procedure of Kiwa Italia.

The tests relating to hazards of an electrical and electromagnetic nature may be carried out, in addition to the entities indicated above, also by a third-party laboratory recognised within the international IECEE scheme as a CBTL, whose activity has previously been assessed as conforming to ISO/IEC 17025 by Kiwa Italia.

The performance of the tests shall take place on the basis of the operating instructions available in the laboratory and in conformity with the applicable technical standards. Personnel assigned to perform the tests shall possess the appropriate qualification.

At the end of the EC/EU Type Examination, Kiwa Italia prepares a technical report, including the technical assessments, any tests carried out, the equipment used and the results of the assessments performed.

2.4 Certification decision for the issuance of the EC/EU Type examination certificate

On the basis of the positive results of the technical assessments carried out, Kiwa Italia issues an EC/EU Type Examination Certificate relating to the family of products represented by the tested sample.

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

Kiwa Italia informs the notifying authority of the EC/EU Type Examination Certificates that it issues, making available to that authority the list of such certificates.

Reproduction (including colour reproduction) of conformity certificates issued by Kiwa Italia is permitted, provided that they reproduce the original in its entirety; partial reproduction is not permitted.

In the event of a negative outcome of the tests carried out, or where it is found that the characteristics of the product do not correspond to those reported in the technical documentation, Kiwa Italia shall not be able to issue any certificate and shall provide detailed reasons for such refusal to the Manufacturer so that the latter may request the return of the product and undertake the appropriate corrective actions (product modification, project closure).

3. ASSESSMENT OF CONFORMITY TO TYPE (Surveillance of the Notified Body in accordance with Modules D, E, C/C2)

3.1 General Requirements

Once EC/EU Type certification has been obtained, the Manufacturer shall apply for certification relating to one of the assessment of Conformity to Type Modules provided for by the Regulation and the Directive, in order to provide assurance that the conformity requirements of the products for which the EC/EU Type Examination Certificate has been issued are maintained.

For this purpose, the Manufacturer shall define, document and maintain a permanent production control system and/or a quality management system (in accordance with the selected assessment module) and identify the areas of responsibility in order 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) shall include procedures, regular inspections, tests and/or assessments that the Manufacturer shall carry out to monitor product conformity.

Assessment of Conformity to Type requires Kiwa Italia to perform an initial visit (audit) at the Manufacturer’s premises and annual visits to carry out checks on products and ascertain that they conform to the certified Type.

For each audit, Kiwa Italia shall send the Manufacturer an audit plan in advance, indicating the members of the Audit Team; where conflicts of interest exist, the Manufacturer may request the replacement, within 3 working days, of one member or of the entire Audit Team, stating the reasons. Kiwa Italia shall assess such reasons and, where justified, shall modify the audit team.

3.2 Classification of findings and their management

Findings resulting from the assessment activities of Conformity to Type are classified by Kiwa Italia as follows.

Major Nonconformity (NC): failure to fulfil a certification requirement which affects the capability of the product to ensure conformity with the essential requirements applicable to it. It may concern:

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

Minor Nonconformity (NC): failure to fulfil, or partial fulfilment of, a certification requirement, not falling within the cases of major nonconformities described above, which, although requiring correction, does not affect the capability of the product to ensure conformity with the essential requirements applicable to it.

Several minor nonconformities relating to the same requirement, depending on their content and on the overall result of the assessment, may lead to the issuance of a major NC.

Minor nonconformities not resolved and/or not addressed by the Customer Organisation may lead to the issuance of a major NC.

Element of Improvement/Observation: anything that does not fall within the definitions of nonconformity and which constitutes a possible improvement in the effectiveness of the solutions adopted by the Manufacturer in order to achieve conformity with the certification requirements.

The Manufacturer is not obliged to address improvement elements/Observations; however, it shall analyse them and justify the decision taken.

The corrections and corrective actions (CA) necessary to eliminate the nonconformities identified during the initial or periodic surveillance audit activities shall be defined by the Manufacturer and communicated to Kiwa Italia within 20 working days from the audit, by completing each individual nonconformity form/report in the section relating to the "proposed/implemented corrective actions", indicating methods, timeframes and responsibilities for implementation. Each form shall be signed by the Manufacturer's Representative.

The Lead Auditor shall assess the proposed corrective actions and, should comments or clarifications be necessary, shall communicate them in writing to the Manufacturer.

The positive or negative outcome of the assessment of the CA shall be recorded in the nonconformity report in the relevant section and approved by the Lead Auditor.

The effective implementation of the CA and the closure of minor NCs shall be assessed by the Lead Auditor during the subsequent surveillance audit; in the case of major NCs, the assessment shall be carried out through an additional audit (therefore additional to the periodic surveillance audits); such additional audit shall be at the Manufacturer's expense.

3.3 Application for the issue of the Conformity to Type Certificate

The Manufacturer intending to request a quotation for certification shall send Kiwa Italia the form *MOD-01a GAS Information Questionnaire – Surveillance*, completed in all its parts, necessary for the preparation of the quotation.

After having verified the completeness of the information reported in MOD-01a GAS, the availability of the means to perform all assessment activities and the availability of personnel with the competence and capability to perform them, Kiwa Italia issues a quotation for carrying out Type assessment activities at the production site. Such quotation may be:

- included in the quotation already issued for the performance of the EC/EU Type Examination, if both certifications have been requested from Kiwa Italia simultaneously by the Manufacturer;
- issued only for the assessment activity of Conformity to Type, 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 indicate the conformity assessment procedure selected by the Manufacturer:

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

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

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

The return of the quotation signed by the Legal Representative of the Manufacturer or by a delegated person represents the official application for certification.

Should the quotation be returned amended by the manufacturer, Kiwa may request clarifications or further amendments before considering the contract, and therefore the certification process, activated, or may communicate the impossibility of such activation, stating the reasons to the customer.

Should inconsistencies emerge during the subsequent assessment phases with respect to what was declared in the information questionnaire, the quotation may be subject to revision by Kiwa Italia.

3.4. Conclusion of the contract (Surveillance Agreement)

Following acceptance of the quotation, the *Surveillance Agreement* is concluded with the Manufacturer, in which the rights and obligations of both parties are defined, together with the selected assessment procedure, the complete list of products under surveillance and the sites subject to verification.

The Surveillance Agreement shall be signed by both parties.

3.5 Initial assessment of Conformity to Type (Initial surveillance)

3.5.1 Initial surveillance audit

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

The initial surveillance audit is carried out by the Kiwa Italia audit team on the basis of the assessment procedure/module selected by the Manufacturer and indicated in the contract.

The Manufacturer shall present all products and relevant information for the purpose of a thorough and valid assessment by Kiwa Italia and shall allow the Kiwa Italia auditor, if required, to take samples to be sent to the laboratory for product testing.

The Manufacturer shall always keep the technical reports relating to the EC/EU Type Examinations permanently available for any verification, in order to verify the correspondence 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, may:

- examine an adequate number of appliances and carry out appropriate tests defined in the applicable standards or equivalent tests in order to ascertain conformity of the appliances with the essential requirements of the Regulation and the Directive.
- ascertain that the Manufacturer maintains and applies a production control system (and/or a quality system) ensuring conformity of the appliances with the type described in the EC/EU Type Examination Certificate and with the essential requirements set out in the Regulation and the Directive;
- ascertain that the Manufacturer maintains and applies a production control system (and/or a quality system) for the final inspection and testing of appliances.

As regards Modules D and E, the *initial* surveillance is based on the requirements of UNI CEI EN ISO/IEC 17021-1 standard and provides for an audit structured in 2 Stages: Stage 1 audit and Stage 2 audit.

In Stage 1, Kiwa Italia assesses the Manufacturer's quality system, with particular reference to the documents making up the system; such system shall ensure conformity of the products with the Type described in the EC/EU Type Examination Certificate and with the essential requirements of the GAR Regulation and the BED Directive. Based on the outcome of Stage 1, the Manufacturer shall make any necessary amendments or additions. Kiwa Italia may request the amended documents for a further review before proceeding with 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 implemented and effective as required by the GAR Regulation and the BED Directive. Stage 2 may only be performed after successful completion of Stage 1.

The maximum time that may elapse between Stage 1 and Stage 2 shall be such as to ensure that the results of Stage 1 remain valid; therefore, the system, the products and the regulatory and legislative context shall not undergo changes between the two stages. If, during the period between Stage 1 and Stage 2, significant changes occur which may impact the assurance 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 prepares an audit report, comprising the results of the assessment, ensuring that the Manufacturer's signature is obtained for the relevant parts.

Kiwa Italia reserves the right to sample an appliance to be tested at the Kiwa Italia laboratory by drawing up a specific sampling record.

Should any NCs be identified following the audit, they shall be managed as indicated in § 3.2 above. Kiwa Italia shall not be able to proceed with the certification decision until the receipt of the proposed resolutions and corrective actions accepted by the Lead Auditor. Furthermore, in the case of major NCs, the certificate shall not be issued until the implementation of the corrections and corrective actions has also been verified through an additional conformity assessment as indicated 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 shall be carried out within a maximum of 6 months from the last day of Stage 2. Otherwise, once the 6 months have elapsed, but within 12 months from the last day of Stage 2, it shall be necessary to conduct another Stage 2 before proceeding with the certification process. Beyond 12 months, it shall 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 the laboratory tests and, in the event of a positive outcome, authorises the issue of the Conformity to Type Certificate, which has a validity of three years (from the date of first issue, which may never be earlier than the certification decision date).

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

Once the certificate has been received, the Manufacturer is authorised to affix the identification number of Kiwa Italia as Notified Body on the certified products.

In the event that the certificate is denied, Kiwa Italia shall send a communication to the Organisation reporting what has been established during the Certification Decision phase and the related consequent actions.

3.6 Periodic assessment of Conformity to Type (Periodic Surveillance)

3.6.1 Periodic surveillance audit

The surveillance audit shall be carried out at the Manufacturer's premises with a random frequency, considering an interval varying 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, depending for example on the results of previous audits.

For Modules D and E, in the year in which the certification expires, the periodic surveillance audit shall be planned in due time to allow re-issuance of the certificate with the new validity period before its expiry.

For Modules C/C2, should it not be possible to plan the audit in good time (e.g. due to a lack of samples available for testing), in accordance with the Surveillance Agreement in place with the manufacturer – which guarantees Kiwa's ongoing monitoring of conformity to type – if the last visit to the manufacturer's premises took place no more than 6 months previously or a new visit has been scheduled within 3 months of the certificate's expiry date, renewal may be carried out on the basis of documentation. If it is not possible to carry out the scheduled visit within this timeframe, the certificate shall be suspended as described in § 9.

The periodic surveillance audit shall be performed in a manner similar to that defined in § 3.5.1; Kiwa Italia reserves the right to carry out these audits without prior notice.

In the case of unannounced audits, the Lead Auditor shall explain the detailed audit plan to the Manufacturer and agree the details at the beginning of the audit. If the Manufacturer does not make itself available for such audits, Kiwa Italia reserves the right to suspend or withdraw (in the cases considered more serious) the issued certification.

The number of products to be sampled by Kiwa Italia shall be calculated according to the product types and the total annual production (number of products/year).

For Modules C and C2 (GAR), in the event of prolonged periods without production activity, surveillance may nevertheless be carried out by verifying products in stock; in the absence of such products, the Manufacturer may request an extension by sending a written request signed by a Company Representative, stating the reasons. Such request shall be assessed by the Scheme Manager who may grant an extension of up to a maximum of 3 months from the scheduled audit date. Upon expiry of the extension, if it has not been possible to carry out the surveillance audit, the certificate shall be suspended as described in § 9.

At the end of the audit, the Audit Team leaves a copy of the audit report with the Manufacturer, who signs it. The report is submitted for internal review and approval by Kiwa Italia. The report shall be considered confirmed if no further communication is sent to the Organisation within 60 calendar days. Conversely, if following internal review Kiwa Italia considers amendments to the contents of the report appropriate, it shall formally notify the Manufacturer, providing explanations for each amendment made and indications regarding subsequent actions.

In the event of NCs, they shall be managed as indicated in § 3.2 above. In the case of major NCs, the Manufacturer shall promptly implement corrective actions, which must be approved by the Lead Auditor and shall be implemented and verified by Kiwa Italia within a maximum period of 2 months from their recording; products subject to the major NC shall not be placed on the market before resolution of the major NC and the Manufacturer shall also provide for any recall of products already distributed, depending on the criticalities identified. Any request for extension of these implementation periods shall be justified in writing and approved by Kiwa Italia; if the established time is exceeded, the Manufacturer shall be subject to suspension or (in more serious cases) withdrawal or reduction of certification, as indicated in § 9 of this Regulation.

For modules D and E, where major nonconformities have been identified in the year of certificate expiry and it is not possible to verify their resolution before the certificate expiry date, Kiwa Italia shall decide on suspension of certification or, in more serious cases, reduction or withdrawal of certification.

The postponement or cancellation of an Audit already planned and agreed, for reasons attributable to the Manufacturer, shall be communicated to Kiwa Italia at least two weeks before the planned date and shall be managed in accordance with Article 15 of the General Terms and Conditions.

The performance of the surveillance Audits provided for within the certification cycle is subject to the regular payment by the Manufacturer of the previous activities.

3.6.2 Confirmation of certification

Kiwa Italia reviews the surveillance audit documentation and the correct management of findings and, in the event of a positive assessment, confirms the validity of the certification.

In the event of a negative outcome, Kiwa Italia shall establish the actions necessary to restore conformity and communicate them to the Manufacturer; if such actions are not implemented within the established timeframes, Kiwa Italia shall apply the suspension, reduction or withdrawal measures indicated in § 9. For Modules D and E, in the event of a negative assessment in the year of certificate renewal, the actions for restoration of conformity shall be implemented before the expiry of the certificate; otherwise, the certificate shall not be renewed and the Manufacturer shall be charged the amounts due, including expenses.

4. EXTRAORDINARY AUDITS

Kiwa Italia reserves the right, stating the reasons in writing to the Manufacturer, to perform extraordinary audits relating to the certified product for the reasons indicated in the *Kiwa Regulation for Certification* or for requests arising during the certificate issuance phase.

The costs of the above audit activities shall be borne by the Manufacturer and shall neither replace nor modify the process and frequency of the Periodic Surveillance Audits.

5. CONFORMITY BASED ON PRODUCT VERIFICATION OR VERIFICATION OF A SINGLE UNIT
(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 manufactured in well-defined and limited batches, or are manufactured as a single unit.

5.1 Module F: Conformity to Type based on product verification

Pursuant to Annex III – Module F, Kiwa Italia carries out the appropriate examinations and tests in order to verify the conformity of the appliances or accessories with the approved type described in the EC/EU Type Examination Certificate and with the relevant requirements of the GAR Regulation.

The manufacturer shall choose one of the following options to carry out the examinations and tests to verify compliance of the appliances or accessories with the relevant requirements:

- in accordance with point 5.4 of the GAR Regulation, i.e. by examining and testing each appliance or accessory, or
- in accordance with point 5.5 of the GAR Regulation, i.e. by examining and testing the appliances or accessories on a statistical basis. Kiwa Italia takes a number of products from each batch in accordance with a sampling scheme that complies with the provisions of point 5.5.3 of Annex III to the GAR Regulation.

On the basis of the positive results of the technical assessments carried out on the batch subject to verification, Kiwa Italia affixes, or has affixed, its Notified Body number to each appliance and provides a certificate. All appliances in the batch may be placed on the market, with the exception of any samples in which NCs have been identified.

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

5.2 Module G: Conformity based on verification of a single unit

Pursuant to Annex III – Module G, conformity based on verification 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 ensures 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 requirements of the GAR Regulation applicable to it.

Kiwa Italia examines the appliance and carries out, or has carried out, the appropriate tests, taking into account the design documentation of the product in order to verify its conformity with the essential requirements of the GAR Regulation.

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

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

6. MODIFICATIONS TO CERTIFICATION REQUIREMENTS

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

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

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

In the event of extensions of families, or introduction of new denominations, Kiwa Italia shall issue a new EC Type Examination Certificate.

7. CERTIFICATION FOR A PRIVATE LABELLER (OBL)

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

Where a Physical Producer intends to apply for an EC/EU Type Examination for a Private Labeller, it shall send the application for a certification quotation to Kiwa Italia through the form “MOD-01b GAS Information Questionnaire EC-EU Type Examination”.

In order to satisfy this request, it is necessary that a specific agreement in written form be stipulated between the Physical Producer and the Private Labeller, so as to clearly regulate the relationship between the two parties. Such agreement shall specify that all technical documentation and technical reports held by the Physical Producer, supporting the conformity verification of certified products, are fully available to the Private Labeller. Furthermore, such agreement shall indicate that the certification of the Private Labeller ceases to be valid if the certification of the Physical Producer ceases to be valid.

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

Where an EC/EU Type Examination Certificate is issued to a Private Labeller, the latter (with the written consent of the parties) may request to be included in the original technical report issued by Kiwa Italia or to have a technical report issued in its own name.

The extension of the original technical report to the Private Labeller, or the issue of a new technical report in the name of the Private Labeller, may be carried out by Kiwa Italia without performing further tests (therefore only on the basis of the technical documentation submitted) provided that the product does not undergo any modification compared to the sample originally tested.

On the basis of such technical report, an EC/EU Type Examination Certificate relating to the products marketed by the Private Labeller shall be issued.

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

7.2 Assessment of conformity to Type for a Private Labeller (OBL)

Where the Physical Producer supplies its certified products to a Private Labeller, the latter may apply for certification in its own name following the process referred to in the previous paragraphs.

For the purposes of certification of conformity to Type, where the entire production process is carried out at the Physical Producer without the certified product being modified and/or altered, the technical documentation and the reports of inspections carried out at the Physical Producer may be used (with the written consent of the parties).

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

Also in this case, the provisions specified in the previous point regarding the agreement to be stipulated between the parties shall apply. In addition to the above, such agreement shall indicate that the Private Labeller must be informed of all aspects related to the manufacturing process and/or the quality system for assuring conformity of the appliances and that the certification of the Private Labeller ceases to be valid if the certification of the Physical Producer ceases to be valid; the Private Labeller shall inform the Physical Producer of any complaints relating to the certified products.

For Module D, an audit activity is also required at the premises of the Private Labeller.

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

8. CHANGES TO REGULATIONS AND/OR CERTIFICATION REQUIREMENTS

Kiwa Italia keeps itself updated on technological progress generally acknowledged as the state of the art, indicating whether the approved type may cease to conform to the requirements applicable to Regulation 2016/426 (GAR), and decides whether such progress requires further investigations. In such case, Kiwa Italia shall inform the Manufacturer.

It nevertheless remains the responsibility of the Manufacturer to verify that its products and the related documentation are updated to the latest available version of the applied standard and/or are, from a technical point of view, at the same level as the "state of the art", in order to ensure the presumption of conformity with the essential requirements of the Regulation and the Directive.

9. SUSPENSION, WITHDRAWAL OR REDUCTION OF THE CERTIFICATION

Certification may be suspended, reduced or withdrawn for the reasons indicated in the *Kiwa Regulation for Certification* or upon customer request.

Except in exceptional cases (in any case established by Kiwa Italia or by the Competent Authority), the suspension period may not last longer than 6 months; otherwise, the certification shall be reduced or withdrawn.

The communication relating to the measure to be adopted shall be sent to the Manufacturer by registered letter with acknowledgement of receipt or certified electronic mail (PEC) and shall contain at least: the reason, the duration and the conditions under which the measure may be withdrawn, as well as the limitations on the use of the certificate.

During the suspension period, the customer Organisation loses the right to affix the CE marking and loses the right to use or advertise the certificate by any means. The conditions for restoring 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.

Should the customer Organisation fail to implement the actions indicated by Kiwa Italia for the restoration of suspended certification, the certification shall be withdrawn or, where possible, its scope shall be reduced.

Reduction of certification entails the issue of a new certificate indicating the type of product for which certification remains valid and the withdrawal of the previous certificate.

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

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

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

In the event of suspension or withdrawal related to specific critical issues concerning products already placed on the market, Kiwa Italia shall inform the competent Market Surveillance Authorities (as defined pursuant to Article 17 of Regulation (EC) No 765/2008, referred to by Article 36 of the GAR) in order to give effect to the provisions of Article 37 of the GAR *"national procedure for appliances and accessories presenting a risk"*.

It is understood that, where a contractual agreement exists between the Private Labeller and the Physical Producer, a suspension/withdrawal/reduction measure affecting the certification of the Physical Producer's products also implies the suspension/withdrawal/reduction of the certificates issued in the name of the Private Labeller, with Kiwa Italia being released from any liability connected with the contractual obligations assumed by the Physical Producer.

In the event of withdrawal, the Manufacturer (or authorised representative) may activate the certification process again by submitting a new application.

10. CONFIDENTIALITY

Kiwa Italia ensures the utmost confidentiality regarding all information acquired by its personnel involved in the certification process in the performance of their duties.

In addition to what is regulated in the *General Terms and Conditions* and in the *Kiwa Regulation for Certification*, this confidentiality obligation is ensured through the application of specific procedures complying with the applicable international standards and current legal provisions.

In this regard, Kiwa Italia requires all personnel, including its Auditors, to sign a confidentiality commitment, as well as a document by which personnel undertake to process any data coming into their possession in compliance with Privacy legislation.

This obligation shall cease where Kiwa Italia is required to publicly communicate the granting, suspension or withdrawal of an Organisation's certificate due to legal obligations and/or other requirements.

11. PUBLICITY

Once the certificate has been obtained, the Manufacturer has the right to make public the certification for the products covered by the certification. In any case, the Manufacturer shall ensure that its publications and advertising do not contain misleading references to the products covered by the certification.

12. USE OF THE CERTIFICATION MARK AND THE CE MARKING

12.1 Use of certification marks and logos

Use of the CE marking is governed by Reg. (EU) No. 2016/426 § (6) and by Directive 92/42 EEC Annex I.

The customer with a product certified by Kiwa Italia may choose whether or not to use the certification mark granted for use by Kiwa Italia.

When using the certification mark, the customer Organisation shall comply with all applicable rules indicated in the *"Kiwa Regulation for Certification"* and in the *Regulation for the use of the mark*, to which reference is made (www.kiwa.it).

12.2 Improper use of certification, certificate and CE Marking

In addition to what is indicated in *the Kiwa Regulation for Certification*, the following rules apply.

The use of the certification or certificate is considered incorrect when it can mislead the market on the nature, quality and methods of use of the products subjected to certification.

It is incorrect to use the CE marking when it is applied to products:

- with an application for certification not yet submitted or with an application for certification refused;
- which do not conform to the scope reported in the certificates;
- whose certificate has expired and has not yet been renewed;
- for which the Manufacturer (or authorised representative) has not implemented modifications required by Kiwa Italia.

Where improper use of certification, the certificate or the CE Marking is identified, Kiwa Italia may withdraw from the Manufacturer (or authorised representative) the right to affix the CE Marking and to use the certification, giving notice thereof to the Competent Authority.

Use of the mark and certificate in a manner that differs from the applicable requirements or is misleading, as well as misuse thereof, constitute prohibited conduct giving rise to the liabilities provided for by law and by contract. In the above-mentioned cases of non-compliant use and/or misuse, Kiwa Italia may contest the breaches to the Customer and require the Customer to immediately implement corrective actions to restore compliance with the applicable legal requirements.

In the most serious cases (e.g. improper marking), Kiwa Italia shall also inform the Public Prosecutor's Office.

13. COMPLAINTS AND APPEALS

13.1 Complaints

The Manufacturer may submit a documented complaint concerning certification activities with Kiwa Italia.

Such complaint may arise from inconveniences occurring during the certification process, such as, for example, delays in carrying out the various phases and improper behaviour by the auditors of the Body.

Complaints may be submitted by any party with an interest in the certification.

Kiwa Italia shall record the complaints, analyse them and inform the complainant of the actions undertaken within thirty days from the date of receipt of the complaint; the assessment and any approval shall be carried out by personnel not involved in the process subject to the complaint.

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

Kiwa Italia shall establish with the complainant whether and to what extent the content of the complaint and its resolution shall be made public.

13.2 Appeals

Should a customer organisation wish to challenge a decision made by Kiwa Italia, it may submit an appeal in writing.

The appellant shall state the reasons for the appeal and, where such appeal relates to a decision of Kiwa Italia (e.g. recording of a Major Non-conformity), it shall be submitted to Kiwa Italia within 10 calendar days from the date of communication of the decision.

Appeals are handled by functions not involved in the activities subject to the appeal.

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

Detailed arrangements for the submission of complaints and appeals are available on the websitewww.kiwa.it

The submitting of an appeal does not suspend the validity of the decision against which it is submitted.

14. RIGHT OF UNILATERAL WITHDRAWAL FROM THE CONTRACT

Kiwa Italia may freely withdraw from the contract by giving written notice to the Customer Organisation with six months' notice prior to the effective date of the withdrawal. Withdrawal by Kiwa Italia results in withdrawal of the certification issued. The Organisation is in any case required to pay Kiwa Italia the amounts due for the services received during the notice period, in accordance with the latest valid quotation.

Should the Organisation wish to withdraw from the contract, unilateral withdrawal during the validity period of the Certification requires compliance with the notice periods provided for in the *General Terms and Conditions* and in the *Kiwa Regulation for Certification*.

In the event of withdrawal from the Surveillance Agreement by the Organisation, Kiwa Italia has the right to carry out a final audit if more than 6 (six) months have elapsed since the previous audit.

In particular, for notice periods shorter than three months prior to the scheduled Audit and longer than two weeks, the Customer shall pay 50% of the amount relating to the fee envisaged for the next activity provided for by the contract. For notice periods of less than two weeks, the provisions of the *General Terms and Conditions* apply.

In the event of closure of the contract, Kiwa Italia shall issue an invoice relating to the costs of closing the certification file, in accordance with the latest valid quotation.

15. UNILATERAL AMENDMENT OF THE CONTRACT

Kiwa Italia reserves the right to amend this Regulation at any time. Any new clauses/changes made will be effective from the moment they are communicated to the customer in written form.

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

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

16. MINIMUM CHECKS TO BE PERFORMED BY THE MANUFACTURER

16.1 Gas appliances:

Test *Tipo di controllo*	**Frequency/*Frequenza***
Gas circuit soundness/ *Tenuta circuito gas*	100%
Heat capacity / *Portata termica*	100%
Burner ignition/ *Accensione*	100%
Visual appearance flame/ *Controllo visivo fiamma*	100%
Burner x lighting / *Bruciatore d'accensione*	100%
Earth continuity/ *Continuità di terra*	100%
Dielectric strength / *Rigidità dielettrica*	100%
Flame supervision device/ *Dispositivo controllo fiamma*	100%
Combustion /*Combustione*	S
Surface temperature/ *temperature superficiali*	S
Thermostats/ *Termostati*	S
Pressure limit switches/ *Pressostati limite*	100%
Fan operation/ *Funzionamento ventilatore*	100%
Combustion circuit soundness/ *Tenuta circuito combustione*	S
Flue gas leaks / Fughe gas incombusti	S
Thermal down draught diverter/ *Cappa rompi tiraggio*	S
CO_2 detection device/ *Dispositivo controllo* CO_2	S
Water circuit soundness/ *tenuta circuito acqua*	100%
Electrical safety tests / *Controlli elettrici sicurezza*	100%
Temperature limits (switches)/ *Termostati limite temperatura*	S
Efficiency/ *Rendimento*	S

100% = *tests performed on each CE marked product*

S = *tests performed on a regular statistical basis, daily, weekly, etc., at the Manufacturer's discretion*

16.2 Components:

Controls/ *Controlli*	**Gas soundness/ *Tenuta gas***	**Functional safety/ *Sicurezza funzionale***	**Electrical safety/ *Sicurezza elettrica***
Gas valves, cocks/ *valvole gas, rubinetti*	100%	100%	100%
Electr. Temperature controllers/ *Controlli elettrici temperatura*	N/A	100%	100%
Mechanical (gas) temperature controllers/ *controlli meccanici temperatura (gas)*	100%	100%	100%
Air flow and pressure level controllers/ *flussimetri e pressostati aria*	N/A	100%	100%
Gas pressure switches/ *pressostati gas*	100%	100%	100%
Igniters, sensors/ *Dispositivi accensione, sensori*	N/A	100%	100%
Safety electronics/ dispositivi sicurezza elettronici	N/A	100%	100%