REGULATION FOR CE CERTIFICATION ACCORDING TO MACHINERY DIRECTIVE

Kiwa Italia Italia S.p.A. – Single-member company subject to management and coordination by Kiwa Italia Holding S.r.l.
Headquarters: Via Cadriano 23, 40057 - Granarolo dell'Emilia (BO), Italy – Registered at the Chamber of Commerce of Bologna with registration number and Fiscal code: 03502820370, REA: BO-295316, VAT n. 00627711203 - Share capital: € 1.000.000,00 paid-up
Tel. +39.051.4593.111 - Fax +39.051.763.382 – it.info@kiwa.com - PEC: kiwa@pec.kiwaitalia.com - www.kiwa.it

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Rev. No.	SUMMARY OF CHANGES	DATE
11	Rebranding, edited fonts and Kiwa logo; edited Regulation code	2025-11-19
10	Improved description of renewal audits according to Annex IX of the Directive, paragraph 4.3.1.3; minor changes	2024-10-21

Verified by:

Compliance Manager Dr. Laura Moro

Approved by:

Compliance and Legal Affairs Director Eng. Maria Anzilotta

1. SCOPE AND PURPOSE

This Regulation defines the rights and duties, as well as the operational methodology that governs the relationships between Kiwa Cermet Italia S.p.A. (hereinafter referred to as Kiwa Italia or Kiwa) and the Customer Organizations, in the provision of the Certification services pursuant to Directive 2006/42/EC of the European Parliament and of the Council of 17 may 2006 on machineries, implemented in Italy with Legislative Decree n. 17 of 27 January 2010.

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

This regulation establishes the rules for the implementation of the procedures to be used for the conformity assessment of the machinery categories listed in Annex IV of the Directive 2006/42/EC, related to the ***Type examination for the CE certification*** referred to in Annex IX.

The categories of machineries referred to Annex IV of Directive 2006/42/EC, for which Kiwa Italia is authorized, are listed in Article 1 of the Decree for the authorization of EC certification, issued by the Competent Authority.

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

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

2. GENERAL PRINCIPLES AND GUARANTEES FOR THE CUSTOMER ORGANIZATION

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

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

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

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

c) Prompt management of complaints and appeals, as defined in § 8 of this Regulation.

d) Confidentiality - in addition to what is regulated in the General Terms and Conditions and the Kiwa Regulation for Certification, Kiwa Italia undertakes to make all staff, including its auditors, a commitment to confidentiality, as well as a document in which the staff undertakes to process any data entered in possession in compliance with the provisions of the Privacy Act.

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

3. REQUIREMENTS FOR THE CERTIFICATION

3.1 General requirements

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

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

3.2 Classification of issues

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

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

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

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

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

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

4. ASSESSMENT PROCESS REQUIREMENTS

4.1 Introduction

The activities of Kiwa Italia are carried out in compliance with all the requirements that must be possessed by Notified Bodies, in accordance with what is prescribed at national level by the Competent Authority.

The manufacturer (or authorized representative) of a machinery, which intends to use Kiwa Italia for the CE marking of its machinery, must ensure that a risk assessment is carried out to establish the safety and health protection requirements for the machinery. The machinery must also have been designed and constructed taking into account the results of the risk assessment.

The essential safety and health protection requirements listed in Annex 1 of Directive 2006/42 / EC are mandatory. However, taking into account the state of the art, the targets that these requirements are set for can not be achieved. In this case the machinery must, as far as possible, be designed and built to tend towards these targets.

The manufacturer (or agent) chooses, if the machinery is covered by Annex IV, according to the provisions of Article 12 of the Directive, the conformity assessment procedures to be able to affix the CE marking on the machinery in relation to one of the following Attachments of the Directive:

- EC Type Examination referred to Annex IX;

The documents issued by Kiwa Italia for the purposes of CE marking and its maintenance, according to the assessment procedures indicated above, are as follows:

- EC type examination certificate according to Annex IX of the Directive;

4.2 Starting the certification process

The manufacturer (or authorized representative) applies for certification to Kiwa Italia specifying the type / s of machinery (s) for which it intends to obtain EC certification, the option chosen for the evaluation of the machinery (s) and forwards the following documentation:

- Certificate of registration of the Chamber of Commerce (simple paper copy) or equivalent document for foreign countries;
- Technical file: it must be a reference company document in which to collect and order all the constructive documentation of the product, following its history during its life from construction, its commissioning and disposal, which, among other things, includes:
  - Risk Assessment: must be a document that allows to analyze the risks associated with the product, in relation to its intended use, for each point of Annex I of the Directive;
  - Research and Test Reports: they constitute the collection of all the necessary documentation to show the conformity of the machinery to the requirements of the Directive and of the applicable technical standards and to determine if the machinery, as a result of its design or construction, can be assembled and commissioning in safe conditions.

4.2.1 Assessment of the technical file for comparison

If the manufacturer (or authorized representative) requests to Kiwa Italia to certify, with reference to Annex IX of the Directive, a type already certified by Kiwa Italia upon request of another manufacturer (or authorized representative), Kiwa Italia in order to issue the attestation of type examination certificate, performs an analysis of the applicant's technical file for comparison (or comparative) compared with the previously assessed technical file referring to the type already certified by Kiwa Italia, in order to ascertain that the technical contents of the document coincide or are equivalent.

4.3 Type conformity assessment

4.3.1 Evaluation of the conformity of the type (or final verification) according to the All. IX of the Directive.

The evaluation activities performed by Kiwa Italia, in relation to the aforementioned annex, are:

- Initial verification of the machinery;

- Technical file analysis;

- Final verification of the machinery.

4.3.1.1 Analysis of the technical file

The analysis of the technical file is carried out by personnel with the necessary technical skill related to the scheme and the category of machinery to be certified.

At the end of the analysis of the technical dossier, the report summarizing the outcome is issued to the manufacturer (or representative).

Based on the result of the analysis of the documentation, the customer is required to make any necessary changes or additions. Kiwa Italia can request the modified documents to be submitted to a new analysis, before proceeding to the following activities

4.3.1.2 Final verification of the machinery

The conformity assessment of the type (or final verification) is carried out at the location where it is possible to verify that the type has been manufactured in accordance with the technical dossier analyzed, carrying out, if necessary, checks, measurements and tests.

In case of acceptance by Kiwa Italia of test reports, carried out by the manufacturer, it must meet the following requirements:

• Competence of the technician performing the test;

• Correctness of the content of the test report;

• Management of the equipment used for the test and related metrological traceability.

The final verification is planned in such a way as to take into consideration all the requirements of the reference Directive.

In the initial phase of the verification, the resolution of any findings notified in the analysis of the technical dossier is evaluated.

At the end of the verification, the Evaluation Group leaves a copy of the report of the verification, which the customer subscribes. The report of the audit shows the list of any findings that the customer must resolve, the report is subjected to analysis and internal approval by Kiwa Italia, for the issuance of the certification.

The customer must send the correct technical file to Kiwa Italia. The practice can not be analyzed for the resolution, until receipt of the correct documentation and the closure of all the findings.

The Kiwa Italia Certificate is valid for 5 years from the date of issue

4.3.1.3 Renewal verification according to annex IX of Directive

Before the certification expires, the manufacturer (or authorized representative) shall submit a formal request for an extension of the validity of the EC type examination certificate, together with a declaration stating that the product has undergone no structural modifications and has not been the subject of any safety-related notifications.

Kiwa Italia reviews the validity of the issued EC type examination certificate and, if it determines that the certificate remains valid in light of the state of the art, extends the certificate's validity for an additional five years.

These checks and their extension must be carried out before the certificate expires.

If the validity of the EC type-examination certificate is not extended, the manufacturer (or authorized representative) must cease placing the machinery on the market.

4.4 Assessment of modifications made by the manufacturer

In the case of certification issued in compliance with Annex IX of the Directive, in the presence of modifications made by the manufacturer (or authorized representative) to the approved type, these modifications must be approved by Kiwa Italia. Depending on their criticality and extent, Kiwa Italia evaluates which assessment activities need to be performed.

Similarly, with reference to the certifications issued in compliance with Annex X of the Directive, in the event that the manufacturer (or authorized representative) has made significant changes to the approved Quality System and / or the certified machinery model, Kiwa Italia decides the type of checks to be carried out.

See also the contents of the Kiwa *Regulations for Certification in point 5.2.*

4.5 Standard modifications and/or certification requirements

Kiwa Italia updates on technological progress generally recognized as state of the art, indicating whether the approved type can cease to comply with the requirements applicable to Directive 2066/42/EC and decides whether such progress requires further investigation. In this case, Kiwa Italia informs the manufacturer

Kiwa Italia has a permanent responsibility to ensure that the EC type-examination certificate remains valid.

Kiwa Italia informs the manufacturer of any significant change (eg harmonized technical standard) that had an implication on the validity of the certificate. The notified body revokes the certificates which are no longer valid.

The manufacturer of the machinery has the permanent responsibility to ensure that the machinery complies to the corresponding state of the art; the lack of adaptation to the new technical standard will automatically determine the revocation of the certificate.

4.6 Communications with Competent Authorities

Kiwa Italia provides the Competent Authorities with a list of Certificates issued, modified, suspended, withdrawn or refused. Kiwa Italia keeps available for inspection by the Competent Authorities all the documentation pertaining to issue of the certification.

5. SUSPENSION, WITHDRAWAL OR REDUCTION OF THE CERTIFICATION

The certification can be suspended, withdrawn or reduced in scope for the reasons mentioned in *the Kiwa Regulation for Certification* or on request of the manufacturer (or its authorised representative).

Kiwa Italia reserves the right to consider, based on the reasons that led to suspension/withdrawal/reduction:

- The possibility to request the manufacturer (or agent) to recall the machineries already placed on the market (including those stored in the warehouse);
- Whether or not to allow the manufacturer (or its authorised representative) to continue to sell the machinery already manufactured on the date of the suspension/withdrawal/reduction.

Apart from exceptional circumstances (in any case decided by Kiwa Italia or by the Competent Authority) the suspension period may not last beyond 6 months, otherwise the certification will be withdrawn.

During the period of suspension the manufacturer (or its authorised representative) forfeits the right to use the CE metrological marking and the Certificate. The conditions for restoring the suspended certification (including the necessary conformity Audits), will be set by Kiwa Italia based on the reasons that led to the suspension and depending on the duration of the suspension.

If the manufacturer (or its authorised representative) does not put into practice the actions specified by Kiwa Italia for restoring the suspended certification, the certification will be withdrawn or, where possible, its scope will be reduced.

Reduction of the certification involves a new Certificate being issued, stating the type of machinery for which the certification is still valid, and surrender of the old Certificate.

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

Following withdrawal of the certification, the manufacturer (or its authorised representative) forfeits the right to use of the metrological and CE marking and the Certificate. The manufacturer (or its authorised representative) may embark upon the certification process again by making a new application.

Kiwa Italia reserves the right to communicate the suspension, withdrawal or reduction to the accreditation bodies and/or to the competent authorities and/or to other third parties that may request it.

6. INCORRECT USE OF CERTIFICATION, CERTIFICATE AND CE MARKING

6.1. Incorrect use of the certification, certificate and EC marking

Use of the certification or certificate is deemed to be incorrect when it could mislead the market regarding the nature, quality and method of use of the machinery.

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

The use of the CE marking is incorrect when:

1. It is applied on machinery:

- an application for certification has not yet been presented or when an application for certification has been refused;
- That do not conform to those described in the certificates;
- For which certificates have been withdrawn/suspended/reduced;

2. When the certificate has expired and has not yet been renewed;
3. When the manufacturer (or its authorised representative) has not implemented changes requested by Kiwa Italia.

Where incorrect use of the certification, the certificate and/or the CE marking is discovered, Kiwa Italia withdraws the right of the manufacturer (or its authorised representative) to apply the CE marking and to use the certification, at the same time notifying the Competent Authority.

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

6.2. Use of the certification mark

Kiwa Italia does not foresee the granting of the use of either the Kiwa logo or the accreditation body logo.

7. MANUFACTURER'S OBLIGATIONS (OR AUTHORISED REPRESENTATIVE)

By accepting these regulations, as well as the content of the *General Terms and Conditions and of the Kiwa Regulation for Certification*, the manufacturer (or its authorised representative) must in the certification application phase, commit to comply with the following obligations:

- provide Kiwa Italia with the name and address of the Manufacturer (or the agent);
- declare that it has not submitted a similar request for certification to another Notified Body;
- declare that the same application has not already been rejected by another Notified Body;
- make available a sample of the type to Kiwa Italia, Kiwa Italia may also request other samples, if the test program requires it;
- keep for fifteen years from the issuance of the EC type-examination certificate, and from the renewal of its validity, a copy of the same, the technical dossier and all significant documents concerning it;
- Inform Kiwa Italia, which holds the technical file of the EC type-examination certificate, about all modifications made to the approved type.

8. COMPLAINTS AND APPEALS

8.1 Complaints

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

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

Kiwa Italia records all complaints, examines them and informs the claimant of the actions taken, within thirty days of receiving the complaint; the evaluation and the possible approval are carried out by personnel not involved in the process object of the complaint.

Complaints are handled by personnel not involved in the activities that are the subject of the complaints.

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

8.2 Appeals

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

The petitioner must state the grounds for his appeal and, where the appeal refers to a decision made by Kiwa Italia (e.g. the expression of a Major non-conformity), it must be presented to Kiwa Italia within 10 calendar days of the decision being communicated.

Evaluation and possible approval are carried out by personnel not involved in the process object of the appeal.

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

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

9. RIGHT OF UNILATERAL WITHDRAWAL FROM THE AGREEMENT

Kiwa Italia may freely withdraw from the Agreement with the Customer Organisation by giving written communication to the Customer Organisation with a notice of six months from the effective date of withdrawal. The withdrawal by Kiwa Italia determines the withdrawal of the issued certification. The Organisation is in any case obliged to pay Kiwa Italia the amounts due for the services received during the notice period, as established in the last valid quotation.

In the case the Organisation wishes to terminate the agreement, the unilateral withdrawal, during the period of Certification validity, requires the respect of notice times established in *General Terms and Conditions of Kiwa Cermet Italia for the performance of orders* and in the *Kiwa Regulation for Certification*.

In particular, for notice of less than three months and more than two weeks from the scheduled Audit, the Customer must pay 50% of the amount relative to the cost foreseen for the subsequent activity as agreed upon in the Agreement. For periods of prior notification of less than two weeks, the conditions specified in the *General Terms and Conditions* shall apply.

In case of termination of the Agreement, Kiwa Italia shall issue an invoice for the closing expenses of the certification procedure, in accordance with the last valid quotation.

10. UNILATERAL CHANGE OF THE CONTRACT

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

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

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