# REGULATION FOR CE CERTIFICATION UNDER THE MACHINERY DIRECTIVE

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## 1. SCOPE AND FIELD OF APPLICATION

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 for brevity) and the Customer Organisations, 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 machinery, implemented in Italy with Legislative Decree n. 17 of 27 January 2010.

The requirements stated in this regulation are an integral part of the contract entered into with Kiwa Italia (economic 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* for brevity). 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 referred to in Annex IV of the Directive 2006/42/EC, related to the ***EC type-examination*** referred to in Annex IX.

The categories of machinery referred to in Annex IV of Directive 2006/42/EC for which Kiwa Italia is authorised are listed in Article 1 of the Authorisation Decree for CE Certification issued by the Competent Authority, available on the Kiwa Italia website (www.kiwa.it).

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 ORGANISATION

In its certification activities, in addition to what is provided for by 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, financial nature or regarding membership of particular associations.

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

- Carrying out certification activities assigned to personnel with no interests in the Organisation subject to certification, bound to observe the rules of conduct and independence set by Kiwa Italia; regarding this aspect Kiwa Italia undertakes to accept any justified reports from the Customer concerning the existence of incompatibility of the duty assigned which could compromise the impartiality or independence of judgement;
- Strict implementation of formalised rules and procedures in use by all certification services personnel and periodic consultation with appropriate certification stakeholders;
- Clear separation between the personnel carrying out audit activities and personnel participating in certification decision;
- Total abstention from carrying out assistance activities in the definition and application of the requirements for obtaining Certification.

c) Prompt handling 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 arranges for all personnel, including its Auditors, to sign a confidentiality undertaking, as well as a document in which the personnel undertakes to process any data coming into his/her possession in compliance with the provisions of the Privacy legislation;

e) Accreditation and Notifications: Kiwa Italia undertakes to notify the Customer of any renunciation, suspension or withdrawal of the accreditation and/or ministerial notification; in such cases Kiwa Italia shall be in no way liable for any damages caused to the Customer by the renunciation, suspension or withdrawal of the accreditation or notification; in the aforementioned cases, the Customer has the right to withdraw from the contractual relationship with Kiwa Italia, without prior notice and without any additional charges.

## 3. ACCESS REQUIREMENTS FOR CERTIFICATION

### 3.1 General requirements

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

- Accept the conditions set out in this Regulation;
- Authorise access to offices, plants, 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 mandatory provisions, the Organisation undertakes to provide Kiwa Italia with complete and detailed information regarding the specific risks existing in the environment where Kiwa Italia personnel is expected to operate and PPE necessary for carrying out the appointment, informing Kiwa Italia personnel on their correct use. In this regard, the Customer organisation shall provide the appointed Kiwa Italia personnel the Company documentation concerning the workplace safety (Risk Assessment Document (D.V.R.), safety plan, procedures, etc.), limited to aspects of specific interest. If for such omissions, injuries occur or illnesses are contracted, no claim or liability may be brought, for any reason, against Kiwa Italia;
- Accept, without additional costs, the possible presence of Assessors from the accreditation Body or Competent Authority, as Observers, who shall be notified by Kiwa Italia together with a clear explanation of their roles. This presence has the aim of ascertain that the evaluation methods used by Kiwa Italia are compliant with the accreditation requirements;
- Accept possible controls carried out by the Accreditation Body. In fact, in order to ascertain 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 customer Organisation. The audit plan is prepared by the Accreditation Body, which will make it available to Kiwa Italia; subsequently Kiwa Italia will send it to the Customer Organisation. If the Organisation 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 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 (downloadable free of charge from the IAF website: www.iaf.nu). Other methods of control may be adopted by the accreditation Body, in order to verify the activities of Kiwa Italia, e.g. unannounced audits at the premises of certified entities, request of information to organisations or consulting company, or other methods of control established by the accreditation body itself.

### 3.2 Classification of findings

Each finding reported during Audits is classified in the following way:

**Non-conformity**: a deviation or partial or total absence of compliance with the requirements, found on the basis of objective evidence, as a result of the assessment activities.

*[text removed]*

## 4. REQUIREMENTS OF THE ASSESSMENT PROCESS

### 4.1 Introduction

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

The manufacturer (or authorised representative) of a machinery, which intends to use Kiwa Italia for the CE marking of its machinery, shall ensure that a risk assessment is carried out to establish the safety and health protection requirements for the machinery. Furthermore, the machinery shall have been designed and manufactured 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 objectives that these requirements define may not be achieved. In this case the machinery shall, as far as possible, be designed and manufactured in order to achieve those objectives.

The manufacturer (or authorised representative) chooses, if the machinery is covered by Annex IV, in accordance with the provisions of Article 12 of the Directive, the conformity assessment procedures enabling the CE marking to be affixed to the machinery, in relation to one of the following Annexes to the Directive:

- EC type-examination referred to in Annex IX;

The documents issued by Kiwa Italia for the purposes of CE marking and its maintenance, in accordance with the assessment procedures above mentioned, are as follows:

- EC-type Examination certificate as per Annex IX of the Directive;

### 4.2 Start the Certification process

The manufacturer (or authorised representative) applies for certification to Kiwa Italia specifying the type(s) of machinery(ies) for which it intends to obtain CE certification, the option chosen for the assessment of the machinery(ies) 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 shall 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: shall be a document that allows to analyse 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 provide evidence on 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 be put into service in safe conditions.

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### 4.3 Type conformity assessment

*4.3.1 Assessment of the conformity of the type (or final verification) in accordance with Ann. IX of the Directive.*

The assessment 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 file, the report summarizing the outcome is issued to the manufacturer (or authorised 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 file analysed, carrying out for this purpose, if necessary, checks, measurements and tests.

Where Kiwa Italia accepts test reports performed by the manufacturer, obtained together with the technical file, such reports shall satisfy the following requirements in order to ensure that the tests have been performed in accordance with ISO/IEC 17025:

- 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 acceptance of such test reports is subject to the repetition of such tests (partially or fully) and to the achievement of equivalent/comparable results.
Alternatively, tests may be carried out by at third-party laboratory, which is accredited against ISO/IEC 17025 for specific tests to be performed or by a third-party laboratory, not accredited under ISO/IEC 17025 for the specific test to be performed, but which is capable of operating in accordance with ISO/IEC 17025. In the latter case, Kiwa may require for the repetition of such tests on site, using qualified professionals or reserve the right to verify this laboratory's qualification.

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 file is evaluated.

At the end of the verification, the Audit Team leaves a copy of the audit report, which the customer signs. The audit report shows the list of any findings that the customer shall resolve, the report is subjected to analysis and internal approval by Kiwa Italia, for the certification decision.

The customer shall send the correct technical file to Kiwa Italia. The application cannot be reviewed for the certification decision, 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 audit in accordance with Annex IX of the Directive*

Before the certification expires, the manufacturer (or authorised 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 reports.

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 shall be carried out before the certificate expires.

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

Where the machinery has undergone modifications, the manufacturer (or authorised representative) shall also send to Kiwa Italia, together with the aforementioned application, all the information relating to such modifications.

The Kiwa Italia Scheme Manager shall evaluate whether such modifications affect or not the validity of the EC Type examination certificate and, with a positive outcome, establishes any verification activities to be carried out prior to the expiry of the certificate. Such additional activities are defined in the renewal quotation issued by Kiwa Italia and performed in accordance with the provisions set in the previous points for the applicable parts.

### 4.4 Verification 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 authorised representative) to the approved type, these modifications shall be approved by Kiwa Italia. Depending on their criticality and extent, Kiwa Italia evaluates which assessment activities need to be performed.

*[Text removed]*

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

### 4.5 Changes to standards and/or certification requirements

Kiwa Italia keeps abreast of technological developments generally recognised as state of the art, indicating whether the approved type can cease to comply with the requirements applicable to Directive 2006/42/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 (e.g. harmonised technical Standard) that had an implication on the validity of the certificate. The notified body withdraws the certificates which are no longer valid.

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

### 4.6 Communications with Competent Authorities

Kiwa Italia shall communicate to the Competent Authority the list of CE Certificates issued, amended, suspended and withdrawn. Kiwa Italia shall keep available for the Competent Authority all documentation relating to the granting of 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 upon 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 authorised representative) to recall the machines already placed on the market (including those stored in the warehouse);
- Whether or not to allow the manufacturer (or its authorised representative) to continue placing the machinery on the market 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 customer forfeits the right to affix the CE marking and forfeits the right to use and to publicize the certificate by any means. The conditions for reinstating the suspended certification (including the necessary conformity assessment activities), 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 customer does not put into practice the actions specified by Kiwa Italia for reinstating 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 withdrawal of the old Certificate.

The withdrawal of the certification determines the automatic resolution pursuant to Article 1456 of the Italian Civil Code of the contract 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 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 shall inform the competent Market Surveillance Authorities, the other Notified Bodies and the Accreditation Body of any suspension, withdrawal or reduction decision.

## 6. INCORRECT USE OF CERTIFICATION, CERTIFICATE AND CE MARKING

### 6.1. Use of the CE marking

The CE marking shall be affixed by the manufacturer to every machinery that has obtained certification visibly, legibly and indelibly, in accordance with this Regulation.

The manufacturer shall ensure the unambiguous identification of machinery bearing the CE marking and distinguish it from machinery not bearing such marking. Other certification marks may be affixed, provided that such marks do not create confusion with the CE marking and do not impair its visibility, legibility and meaning.

The use of the CE marking and Certifications issued by Kiwa is strictly reserved to the Manufacturer and is not transferable.

### 6.2. Incorrect use of the certification and CE 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 subject to certification.

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:
   - with an application for certification that has not yet been submitted or when an application for certification has been refused;
   - that do not conform to the scope stated 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, the CE marking is discovered, Kiwa Italia may withdraw the right of the manufacturer (or its authorised representative) to affix the CE marking and to use the certification, notifying the Competent Authority.

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

The Manufacturer may reproduce the Certificate exclusively in its entirety, ensuring its legibility and without making any modification to the original.

### 6.3. Use of the certification mark

Kiwa Italia does not provide for the right to use of either the Kiwa logo or the accreditation body logo.

## 7. MANUFACTURER'S (OR AUTHORISED REPRESENTATIVE) OBLIGATIONS

By accepting this regulation, in addition to what is provided for by the *General Terms and Conditions* and in *the Kiwa Regulation for Certification*, the manufacturer (or its authorised representative) shall, when applying for certification (acceptance of the quotation), undertake to comply with the following requirements:

- provide Kiwa Italia with the name and address of the Manufacturer (or the authorised representative);
- declare that it has not submitted a similar application 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 programme 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 file and all significant documents concerning it;
- notify 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

Any interested party may submit a documented complaint concerning its relations connected with certification activities with Kiwa Italia or concerning machinery certified by Kiwa Italia. Such complaint 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 Auditors.

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 subject of the complaint.

To ensure impartiality, all 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

Where a Customer organisation intends to contest a decision made by Kiwa Italia, it may submit a written appeal.

The petitioner shall state the grounds for his appeal and, where the appeal refers to a decision made by Kiwa Italia (e.g. the raising of a major Non-conformity), it shall be submitted to Kiwa Italia within 10 calendar days from the date the decision was communicated.

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

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

In order to ensure impartiality, appeals are handled by functions not involved in the activities that are the subject of the appeal.

Detailed information on how to submit complaints and appeals is available on the website www.kiwa.it.

The submission of an appeal does not suspend the validity of the measure against which the appeal has been lodged.

## 9. RIGHT OF UNILATERAL WITHDRAWAL FROM THE CONTRACT

Kiwa Italia may freely withdraw from this contract 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 withdraw from the contract, the unilateral withdrawal during the period of Certification validity, requires compliance with the notice periods established in *General Terms and Conditions* 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 shall pay 50% of the amount relating to the cost foreseen for the subsequent activity as agreed upon in the Contract. 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 contract, Kiwa Italia shall issue an invoice for the closing expenses of the certification procedure, in accordance with the last valid quotation.

## 10. UNILATERAL AMENDMENT 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 working day of the month in which the notice was received from the customer.