REGULATION FOR PRODUCT CERTIFICATION UNDER DIRECTIVES 2014/30/UE AND 2014/53/UE

Kiwa Cermet Italia S.p.A. - Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
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rev. n°	SUMMARY OF CHANGES	DATA
14	Update following the merger of Kiwa Creiven in Kiwa Cermet; insertion of principles, reference to the other contract documents, clarification of the prohibition of trademark use and prohibition of the use of the number of Notified Body, removal of requirement already provided for by General Regulation or in the Kiwa T&C, insertion of the faculty of withdrawal and unilateral amendment of the contract.	2025-11-18
13	Last revision available with Company Name Kiwa Creiven	2025-03-25

Verification:

Management System Compliance Manager Dr. Diego De Rosa

Approval:

Compliance and Legal Affairs Director Ing. Maria Anzilotta

1. SCOPE AND FIELD OF APPLICATION

This Regulation describes the activities, as well as the operational methodology governing the relations between Kiwa Cermet Italia S.p.A. (hereinafter also referred to as "Kiwa") and the Customer Organisations, in the provisions of CE certification services pursuant to the following EU Directives:

- **2014/30/UE** Electromagnetic Compatibility Directive (**EMC**), transposed by the Legislative Decree nr. 194 of 6/11/2007, and modified by the Legislative Decree nr. 80 of 18/05/2016.
- **2014/53/EU** Radio Equipment Directive (**RED**),transposed by the Legislative Decree nr. 128 of 22/06/2016.

Kiwa carries out the following assessment activities:

- For the **EMC** Directive: Art. 14b: module B: UE-Type examination.
- For the **RED** Directive: Art. 17b: module B: UE-Type examination.

Kiwa, accredited pursuant to UNI CEI EN ISO/IEC 17065, is authorised to operate for the product certification; the accreditation status and the standards for voluntary certification can be verified consulting the Database on Accredia website, while the notification status can be verified on the European Commission NANDO website.

The requirements expressed in this regulation, form an integral part of the contract entered to with Kiwa (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*). Such requirements refer solely to aspects specifically linked to the field of application of the certification required.

Any form of consultancy for the Customer is expressly excluded from the subject matter of the contract, that may impair the independent nature of the assessments carried out.

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

2. GENERAL PROVISIONS

The EU Directive 2014/30/EU Electromagnetic Compatibility Directive (**EMC**), does not provide for mandatory certification from the Notified Body (N.B.) in order to affix the CE marking. The assessment by the Notified Body constitutes a means for the manufacturer to demonstrate that a recognized third party has assessed the respect of essential requirements of health and safety established by the same Directive. The assessment for certification activity applied consists of the evaluation of the project, represented by the Technical File and by evidences of the conformity status of the product (module B, annex III directive 2014/30).

The EU Directive 2014/53/EU Radio Equipment Directive (**RED**) applies the same principles set out above. However it provides for the mandatory certification by the Notified Body in order to affix the CE marking, in case the manufacturer does not applied the harmonised standards or has partially applied them. The assessment activity for certification applied by Kiwa consists of the project assessment consisting of the Technical File and the evidences of the conformity status of the product (module B, annex III directive 2014/53).

In case the necessity to carry out tests arises to assess the product conformity, the Customer is free to entrust them to the accredited Kiwa laboratory or to another accredited laboratory.

3. PRINCIPLES AND GUARANTEES FOR THE CUSTOMER

In its certification activities, in addition to what is provided for in General Terms and Conditions, Kiwa applies the following principles and commitments:

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

b) Impartiality and independence, ensured by suitable measures, including:

- on time implementation of formalised rules and procedures in use by all certification services personnel and periodic consultation with appropriate certification stakeholders;

- the conduction of certification activities assigned to personnel who do not have interest in the Organisation subject to certification, who are held to observe the rules of conduct, impartiality and independence established by Kiwa. On this point, Kiwa undertakes to accept any possible justified reports from the Organisation, concerning the existence of incompatibilities of the duty assigned that could compromise the impartiality or independence of judgment;
- clear separation between the personnel carrying out the assessment activities and personnel participating in the certification decision;
- total abstention from carrying out consulting activities in defining and applying the requirements for obtaining certification.

c) Prompt management of complaints and appeals, as per § 9 of this Regulation.

d) Confidentiality: in addition to thar provided for in General Terms and Conditions and in The Kiwa Regulation for Certification, all Customers data and information are treated with the utmost confidentiality, subject to that provided for otherwise by law. Kiwa requires all of its personnel, including its Auditors, to sign a confidentiality agreement and a document in which they commit to treat any information that comes into their possession in accordance with the provisions of the Privacy Act.

e) Accreditations and Notifications: Kiwa undertakes to inform the Manufacturer about any possible renunciation, suspension or withdrawal of the accreditation, in such cases Kiwa will be in no way responsible for any damages caused to the Customer by the renunciation, suspension or withdrawal of accreditation; in such cases, the Manufacturer has the right to opt out of the contractual relationship with Kiwa, without the need for prior notification and without additional costs.

4. CERTIFICATION PROCESS

4.1 Application and technical documentation

The application for access to service is made by submission of the appropriate “Application for the EU-Type examination” on the Kiwa form, that requires the following information:

- applicable Eu Directive;
- general information of the Manufacturer (company name, name, address, legal status, etc.);
- declaration attesting that the same application has not been submitted to another Body;
- technical documentation that shall allow the conformity assessment of the equipment to the applicable requirements.

The technical documentation to be provided with the Application corresponds to the Technical File, as per annex II of the Dir. 2014/30 EMC or Ann. V of the Dir. 2014/53 RED. The documentation consists at least of:

- general description of the equipment;
- software or firmware releases important for conformity to essential requirements;
- information for the users and installation instructions;
- design and manufacturing drawings, schemes of components, sub-assemblies, circuits;
- descriptions and explanations necessary to comprehend such design drawings and schemes and the functioning of the equipment;
- results of design calculations performed, of the tests carried out, etc.
- reports regarding the tests carried out;
- list of the harmonised standards completely or partially applied and, when they have not been applied, descriptions of the adopted solutions to meet the essential requirements of the relevant directive, including a list of the other technical specifications applied (in case of partial application of the harmonised standards the technical documentation shall specify the parts that have been applied);
- copy of the EU conformity declaration;

- example of CE Marking and any marking information required by the relevant directive.

The Application for EU-Type Examination has to be completed in all its sections and signed by a Legal Representative of the Manufacturer. The Manufacturer may delegate an Authorised Representative to act on its behalf in relation to certain tasks. The mandate shall be sent to Kiwa.

4.2 Quotation

The receipt of completed Application allows Kiwa to issue a quotation that reports at least the following information:

- description of the assessment service;
- detailed amount due, as per current Tariff, for the single activities required;
- the warning that, in case of negative outcomes, additional assessments are to be borne by the Manufacturer;
- invoicing and payment methods;
- agreed timelines for the provision of the service;
- the evaluator to whom the practice will be assigned.

The Manufacturer has three (3) working days form the receipt of the quotation to refuse the assignment of the evaluator, with justified reasons and in writing. In this case, Kiwa proposes a new evaluator or announces its renunciation of the certification process.

It remains Kiwa Italia's option to decide whether the formalised motivations are acceptable and involve the replacement of the evaluator, in case of impossibility to carry out such substitution Kiwa Italia communicates the renunciation to provide the certification service.

The contract between Kiwa and the Manufacturer is finalized upon receipt of the countersigned quotation (that includes also the acceptance of the conditions set out in this document) and after its review and the review of the data provided by the Manufacturer. With a positive outcome of such review, Kiwa Italia may activate the certification process. With a negative outcome, Kiwa has faculty to ask all the integrations or modifications necessary before the formal start of the process or notify the Customer of the impossibility to start such process giving the Manufacturer reasons therefor.

4.3 Type examination

The evaluator entrusted assesses the Application and the Technical File. The documentation shall be complete and representative of the Type to certificate; if the documentation received results to be incomplete, Kiwa shall provide to require an integration to the Manufacturer.

The Certification provides for evidences to demonstrate conformity.

The extension of the Type examination to a family of products is subject to specific assessment.

Kiwa acknowledges the report of testing issued by laboratories chosen by the Manufacturer as long as they are clearly referable to the Type and accredited for the tests in question by entities signatory to the EA/MLA, ILAC/MRA agreements, however Kiwa reserves the right to evaluate its validity over time depending on the object of the test, the state of the art of the technique and the Reference Standards. For these purposes, Kiwa accepts test reports issued up to a maximum of five (5) years before the conformity assessment of the Type.

At the end of the thorough assessment of the Technical File and testing documentation that supports it, if Kiwa expresses a positive opinion, the assessment proceeds with certificate issuance.

In case of a negative opinion, Kiwa shall sent to the Manufacturer the emerged findings in written, and the Manufacturer shall communicate how intends to intervene and which corrective actions intends to implement. In case of no reply by three (3) months from findings communication, or if the Manufacturer does not intend to implement modification to the product, Kiwa may decide to close the assessment with the "Refusal of certification" that shall be communicated to the Notifying Authorities and to the other European NBs (art. 36 RED; art.14vi EMC). The Manufacturer is requested to pay for the assessment activities carried out until that point.

If the Manufacturer complies with the findings, Kiwa assesses the correct implementation and effectiveness of the actions undertaken.

The certification cannot be issued until the non-conformities based on the findings have been removed and the supplementary assessment is concluded with a positive outcome.

The costs for carrying out the additional activities are understood to be borne by the Manufacturer and communicated through an appropriate quotation, as per current Kiwa Tariff.

4.4 Certificate issuance

On the basis of the positive results of the assessments carried out, the certificate is issued.

In case of a negative outcome of the assessments carried out, Kiwa shall not issue any certificate and shall give detailed reasons for such refusal to the Manufacturer.

5. VALIDITY OF THE CERTIFICATES AND MUTUAL OBLIGATIONS

5.1. Validity of certificates

The certificate does not have an expiring date.

The Certificates issued by Kiwa are in the name of the Manufacturer and shall not be transferable without the interventions and assessment of the case by Kiwa.

The Certificate ceases to be valid on the following circumstances:

- changes to Type configuration identified in the Technical File and documented during the tests;
- cessation of conformity with requirements specified in the Certificate due to regulatory, legislative and technological updates.

5.2. Certificate review

In the event the certificate is no longer valid the Manufacturer shall submit a new Application with the necessary documentation for the assessment, as already described in par. 4.

Kiwa assesses the case and issues a quotation based on the actual needs for documentary and technical evaluation.

The existing Certificate is cancelled and replaced by a new certificate.

5.3. Obligations of the Manufacturer

The Manufacturer shall undertake to:

- adopt all measures necessary with the aim that the manufacturing process and its controlling guarantee the conformity of the equipment to the Type;
- inform Kiwa in advance of the changes that intends to make to the products configuration;
- inform Kiwa of any transfer or transformation of company name;
- maintain the recording of the complaints relating to the conformity to certification requirements, and mantain the recording of the relevant corrective actions, as long as make this documentation available to Kiwa upon request;
- be responsible for the implementation of the requirements provided for by regulations in force, in the matter of safety at workplaces. The Organisation shall undertake to provide Kiwa with complete and detailed information relating to the specific risks existing in the environment in which the personnel of Kiwa are intended to operate and to provide the PPE necessary for the performance of the assignment, informing personnel of Kiwa of their correct use. In this regard, the customer Organisation shall provide the personnel appointed by Kiwa the company documentation relating to the safety on workplace (Risk Assessment, safety plan, procedures, etc.), limited to items of specific interest. When for such omissions, injuries occur or diseases are contracted, no charge may be brought against Kiwa for any reason.
- accept, at no additional cost, that conformity assessment activities be carried out in the presence of evaluators from the accreditation body, that shall be communicated by Kiwa with clear illustration of roles. This presence has the purpose to ascertain that the assessment methodologies adopted by Kiwa are compliance to the accreditations requirements.

5.4. Obligations of Kiwa

Kiwa shall promptly notify the Manufacturers that compliance with Essential Requirements has ceased due to legislative, regulatory or technological development, so that they can provide for the adaptation of the product in time. The Manufacturers have the power to accept the changes or renounce the certification.

Kiwa maintains the list of certificates and make it available to Notification Authority. Upon third parties request, Kiwa shall communicate only the validity status of the certificate.

In the case of Directive 2014/53/UE radio equipment (**RED**), Kiwa shall inform the competent authority and the Member States of the issued certificates respect to which the harmonised standards have not been applied or have been partially applied. The European Commission and Member States may request a copy of the certificates and of the technical file.

6. AFFIXING OF THE CE MARKING, USE OF CERTIFICATIONS AND OF TRADEMARKS

The Manufacturer shall affix the CE Marking, approved during assessment, according to the rules of the applicable Directive, and in particular following:

- The graphic form of the marking, compliant to the annex 2 of the Regulation 765/2008/CE.
- The provisions of the Decision nr. 768/2008/CE.

It is forbidden by the Directives to affix marks or inscriptions that could be confused with the CE Marking, misinterpret its meaning or mislead the user.

Use of the KIWA trademark is not permitted nor the use of the number of Notified Body of Kiwa.

The Manufacturer is allowed to use the Certificate issued by Kiwa but only if it is reproduced in its entirety. Its extracts, omissions or partial reproductions are prohibited; the same trademarks present within the certificate shall not be extracted from the certificate or used in any way.

7. RENUNCIATION, SUSPENSION AND WITHDRAWAL

The Certification may be suspended or withdrawn for the reasons given in *The Kiwa Regulation for Certification* or under Customer's request.

Kiwa shall notify the suspension, renunciation or withdrawal notice, of the CE Certificates to the competent Ministry for the notification on the market, as provided for by directives.

Every action of suspension, withdrawal or renunciation:

- commits the Manufacturer to cease use of the certificate and refrain from advertising the certification in any way and through any means;
- commits the loss of the possibility of affixing the CE marking and the consequent impossibility of placing the relevant products on the market, starting from the date of the effective date of the measure.

7.1. Renunciation

The Manufacturer may renounce the product certification obtained, in cases where:

- the Manufacturer does not accept the new prescriptions arising from updates to these conditions;
- the Manufacturer does not accept the decisions assumed by Kiwa regarding to the requests of documental integrations and/or testing due to legislative, regulatory or technical development;
- the Manufacturer decides to pass to the affixion of the CE marking without the intervention of the NB, if provided for by applicable directive.

The renunciation of certification shall be notified to Kiwa through certified mail or registered letter by 30 (thirty) days from the communication of the changes sent by Kiwa (see art. 5.2).

As from the date of renunciation, every reference and advertising of the CE certificate issued by Kiwa, and relevant certification intervention shall cease.

Kiwa shall notify the cancellation of the Certificate via certified mail or registered letter and update the list of

certificates.

7.2. Suspension

In addition to the reasons reported in *The Kiwa Regulation for Certification*, Kiwa shall suspend certificates also in the following cases:

- reports from market, subject to a finding of the relative seriousness;
- unlawfully affixing of the CE Marking.

Kiwa shall notify the Manufacturer of the imminent suspension of the certificate, granting ten (10) working days from the date of receipt of the communication, to transmit to Kiwa any reasons and documentation justifying its actions.

Kiwa shall notify the suspension notice specifying:

- the reasons for the suspension;
- the period of suspension that shall not exceed twelve (12) months;
- the condition the Manufacturer shall meet to be admitted again in the use of certification, eliminating the causes that determined the suspension.

The suspension status is communicated to the Notifying Authority and to the EU Notified Bodies for the same directives.

If the Manufacturer fails to comply with the requests or does not remove the contested causes for suspension, within the indicated period, Kiwa shall proceed with the withdrawal of the Certificate.

7.3. Withdrawal

In addition to the reasons given in *The Kiwa Regulation for Certification*, Kiwa withdrawals the certificates also in the following cases:

- fraudulent or illegitimate use of the CE Certification;
- significant and systematic product non-conformity;
- adoption of significant changes made to the product by the Manufacturer without prior involvement of Kiwa.

Kiwa shall notify the withdrawal notice, specifying the reasons.

The withdrawal is communicated to the Notifying Authority and to the EU Notified Bodies for the same directives.

8. CONSERVATION OF PROCEDURAL DOCUMENTS

The Notified Body conserves a copy of the Type Certificate, of the annexes, of the supplements and of the Technical File containing the documentation presented by the Manufacturer, for at least ten (10) years since the date in which the product has been placed on the market.

9. COMPLAINT AND APPEALS

It is possible to forward:

- a complain concerning the certification services by any means whatsoever;
- an appeal against a certification decision, by a registered letter with acknowledgement of receipt or by a certified mail to Kiwa@legalmail.it.

The Appeal shall be submitted within ten (10) days from the receipt of the contested decision.

A notification of acceptance for processing is sent by ten (10) days upon receipt to the sender with the commitment to give back a reply within thirty (30) working days.

The review of the objection is carried out by a responsible that did not take part in the contested decision; the decisions made after the re-examination are not appealable.

In the event of a report coming from a user, regarding the conformity of a product certified by Kiwa, the

Management shall notify without delay the Manufacturer and proceeds, thereafter, with the case assessments; moreover shall notify the reporter of the actions taken under its jurisdiction.

The detailed arrangements for the submission of complaints and appeals are set out on the website www.kiwa.it.

10. UNILATERAL RIGHT OF WITHDRAWAL

Kiwa may freely withdraw from the contract with the Manufacturer, giving with written notice with six months' notice of the effective date of withdrawal. The withdrawal by Kiwa involves revoking the certification issued. The Manufacturer is still required to pay Kiwa the amounts due for the services received during the notice period, as established in the last valid quotation.

If the Manufacturer wants to withdrawal from the contract, the unilateral withdrawal during the period of validity of the Certification provides for compliance with the notice periods provided for in the *General terms and Conditions* and in *The Kiwa Regulation for Certification*.

In the event of contract termination, Kiwa will issue an invoice, in relation to the costs of closing the certification process, as established in the last valid quotation.

11. UNILATERAL AMENDMENT OF THE CONTRACT

Kiwa reserves the right to amend these Regulations at any time. Any new clauses/variations made, will be effective from the moment they are communicated to the customer in writing.

The Organisation who does not intend to accept the variations may withdraw from the contract by giving written notice by registered letter, with acknowledgment of receipt, or certified mail within 30 (thirty) calendar days, under penalty of forfeiture, from the day following the communication to Kiwa.

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