



<b>Title:</b>	<b>Product Certification Regulation</b>	
<b>File Name:</b>	RG-05 Rev. 01 – Product Certification Regulation	

## ***PRODUCT CERTIFICATION REGULATION***

### **1 General**

#### ***1.1 Principles***

This Regulation defines the operational methodology that regulates the relationship between KIWA Italy SpA (hereinafter "KIWA") and organizations (companies) in the services of product certification in accordance with the requirements of the UNI CEI EN 45011.

In its certification activities KIWA apply the following principles:

- a) the policies, strategies, procedures are not discriminatory: Access to the certification is granted to any company that requests it in compliance with these Regulations, without any discriminatory conditions related to commercial or financial aspects, or based on the belonging to particular associations.
- b) Kiwa is absolutely impartial and independent. Ensures that condition by an organization that ensures full respect for all phases of the certification process.

KIWA, furthermore, doesn't provide assistance to organizations in defining and implementing the requirements to obtain the certification of the product, nor have the propriety of any structures engaged in these activities in accordance with the provisions of the "Regulations for the accreditation of certification bodies"

#### ***1.2 Definition***

##### ***Product certification***

In this Regulation, the term "certification" means all activities carried out by KIWA and, according to which states, with an high degree of confidence, that a product clearly described, or process, or service meets all the requirements of certification scheme, established in an "assessment guideline" (Technical Document) or other normative document, declared applicable by KIWA itself for certification purpose.

The terms refer to the definitions listed in:

ISO 9000:2005  
UNI CEI EN ISO/IEC 17000:2005  
UNI CEI EN 45020:2007  
Documenti Tecnici di riferimento


#### ***1.3 Reference***

UNI CEI EN 45011 Ed. 1999  
IAF GD5:2006  
ISO/IEC Guide 67 :2004  
UNI CEI EN ISO/IEC 17025:2005  
Requirement for Accreditation Bodies  
Reference Technical Documents (DT KI-04xx)

#### ***1.4 Scope***

This Regulation applies to the activities of:

- a) product certification in accordance with mandatory laws and regulations;
- b) product certification according to national/international voluntaries standards;
- c) certification of products according to specific technical documents on a voluntary basis.

<b>Title:</b>	<b>Product Certification Regulation</b>	
<b>File Name:</b>	RG-05 Rev. 01 – Product Certification Regulation	

## **2 Initial Certification**

### **2.1 Certification request**

The Company that intends to request a certification sends a request for quotation to KIWA.

KIWA, after collecting the necessary information, prepare an offer, specifying the procedure, the costs and the reference DT-KI-04xx and send it to the client with the attached Request for Certification.

In case of acceptance of the offer, the company returns to KIWA the Certification Request, signed by the legal representative, that represents the contract that will regulate the relationship between this company and KIWA, during the phase of initial type testing and initial audit, while the following phase of the grant of the mark, will be regulated with a dedicated contract.

### **2.2 Audit planning**

KIWA send a detailed audit program to the Company indicating the names of the GA in charge of the audit, with a minimum notice of 3 days.

The Company may appeal within three days, against the appointment of a member or the entire Audit Group, with a clear and valid explanation of the reasons.

The Company is also required to provide access to inspectors of the Accreditation Body to carry out the accompanying audit with the KIWA inspectors.

The Company shall also provide all necessary assistance to the GA and make available to KIWA all the necessary documentation


### **2.3 Laboratory test**

#### *2.3.1 General*

The certification tests performed by KIWA will be based on the requirements of the certification scheme related to the product under certification process, on the reference Technical Document (based on the reference standard) and on the type of product to be certified. This test include:

- test (laboratory test on the sample) to ensure that products meet the technical requirements;
- evaluation of production process;
- evaluation of Quality system and/or of the Internal Quality Control scheme (IQC-Scheme);
- evaluation of the supplier procedure.

The Company shall provide all products and information relevant to a thorough and valid assessment by KIWA, allowing the KIWA auditor to take the samples to be sent to the laboratory for tests as specified by the applicable Standard/Technical document in accordance to the sampling plan shown in the IQC scheme.

<b>Title:</b>	<b>Product Certification Regulation</b>	
<b>File Name:</b>	RG-05 Rev. 01 – Product Certification Regulation	

### 2.3.2 *Acceptance of the test report submitted by the supplier*

If the Company submit test reports conducted in accordance with the requirements of the applicable Standard/Technical Document to demonstrate that the requirements for certification have been met, KIWA accept these reports as if they were the results of their certification test, as long as they have been approved by an accredited Product Certification Body. Of course, the test have been carried out on the same products for which the Company has submitted the application for certification

The laboratory has to work in accordance to the UNI CEI EN ISO/IEC 17025 Ed. 2005 and it has to be approved by Kiwa with and audit, or has to be accredited by a Body signer of MLA in ambit EA for the required type of test.

### 2.3.3 *Verification of the technical requirements*

KIWA has to verify the products under certification process, with reference to the technical requirements as defined by the reference Technical Document (D.T. KI-04xx)

To do this, KIWA has to take the necessary samples from ongoing production and / or from the warehouse.

In case the initial tests are not passed, they are to be repeated until there is a positive feedback (passing the initial tests). The practice will not be submitted to the Certification Officer until the initial tests are not passed by the customer. The costs will all charged to the customer until the positive feedback (cost of the new sampling and of the new test)

## 2.4 *Audit to the producer*

The assessment of compliance to the applicable requirements of the Technical Document (TD-04xx KI) is performed on the basis of the document "IQC-Scheme" which sets out and defines what elements are to be verified on the basis of existing procedures in the company, and which shall be filled in and signed by the applicant and that it will be used during all audits.


The elements to be examinees are:

- measuring instruments and calibration method (internal or external);
- raw materials or purchased components;
- assessment of the production process (control of semi-finished and process parameters);
- checks on finished products to ensure that they meet the technical requirements;
- examination procedures for the management of non-compliance and/or waste (if any corrective actions and claims);
- examination procedures for transport, storage and packaging of finished products.

For each of these elements, the producer must register giving evidence:

- the type of control;
- the method of control used;
- the monitoring frequency;
- the method used to record the audit results.

The LA delivers the original reports of non-compliance (RGS 030) and/or Observations (RGS 029) to the Managers of the Company, taking care to collect the signatures of the parties involved, taking a copy for himself.

<b>Title:</b>	<b>Product Certification Regulation</b>	
<b>File Name:</b>	RG-05 Rev. 01 – Product Certification Regulation	

## 2.5 *Corrective action (AC)*

Corrections and corrective actions necessary to eliminate the non-compliance find, must be determined by the Company and sent to KIWA within three weeks by the audit, filling in every single report of non-compliance, in the part of competence of the "corrective actions proposed / implemented "pointing out method, timing and responsibility for implementation.

Each form must be signed by the Representative of the Company

The LA shall evaluate the proposed corrective action and, if he doesn't agree or if he highlight comments or clarification need, he shall inform in writing the Company.

No communication is, however, sent in case of acceptance of them.

The success or failure of the AC evaluation is noted on the evaluation of non-conformity report on the part of competence and approved by LA.

Effective implementation of the AC and the closure of the NC will be assessed by the LA in the following surveillance audit; in case of serious NC the assessment will be made through an additional audit.

The management of observations will be evaluated in the field during the following surveillance audit.

## 2.6 *Classification of the non-compliances (NC)*


Each non-compliance found during the audit is classified as follows:

- ***Serious non-compliance:*** *is considered a serious non-compliance, which undermines the effectiveness of the product and concerns:*
  - a systematic or intentional failure to fulfill specific requirements of the applicable certification scheme or of the regulations/processes related to them;
  - a failure in fulfilling the legal requirements applicable to the product/service within the certification scope;
  - a lack of one or more requirements related to the products/services under certification procedure;
  - more minor non-conformities related to the same requirement of the Standard/Technical Document having a direct influence on product / service
  - an intentional failure in the implementation of corrective actions to correct a found non-compliance
  - incorrect or misleading references to the certification and/or to the use of the certificate/mark.

The presence of one or more serious non-compliance, if not corrected in the right time, can lead to missed certification or its suspension.

- ***Minor non-compliance:*** *is considered a minor non-compliance any lack of system/product subject to certification, not already covered in the series of serious non-compliance, as described above*
- ***Observation:*** *is considered an observation any situation found during the audit that can give rise to an improvement of the management system or of the product/service subject to certification.*

Observations should be recorded on the form (RGS 029), a copy of which will be issued because to the Company, for information.

<b>Title:</b>	<b>Product Certification Regulation</b>	 <b>kiwa</b>
<b>File Name:</b>	RG-05 Rev. 01 – Product Certification Regulation	

Observations should be considered as an element of assessment for the planning and conduction of the following audit; however, the applicant/licensing company is not required to provide any evidence about the treatment of comments made by KIWA.

## **2.7 Certification decision**

The Certification Officer review the audit documentation produced by the LA, the results of laboratory tests and, if successful, authorize the issuance of the Certificate of Compliance.

If the Certification Officer's final decision differs from the one proposed by the LA, the reasons shall be given in writing to the Company.

The Certificate of Compliance is valid for an indefinite period and will expire at the end of the certification contract between KIWA and the Company.

## **2.8 Certification mark and logos**

The Company has obligation to apply on the certified products certification mark. For those products for which it is not possible to apply the label on the product or packaging, it should be applied on the shipping documents in accordance to the Regulations RG-02 "Use of Certification Mark"

KIWA monitor the proper use of the certification mark on the occasion of the audits and, if used incorrectly, take the necessary action which may include serious/minors non-compliances issue and appropriate legal action

# **3 Maintaining – periodical audit**

## **3.1 Audit planning**

A surveillance audit has to be carried out at regular intervals, as indicated in the D.T. KI-04xx.

The planning modality are indicated in the § 2.2

## **3.2 Surveillance Audit**

The surveillance audit includes laboratory test and audit to the produce as defined in the § 2.3 ÷ 2.6.


## **3.3 Certification confirmation**

The Certification Officer examine the documentation of the surveillance and the laboratory test results and, if successful, confirm the validity of the certification.

In case of non-compliance elements, he inform the customer about the decisions.

# **4 Additional Audit**

KIWA reserves itself the right, communicating in writing to the Company, to perform additional audits and /or tests on the certificated product, in order to verify the implementation of corrective actions following a serious non-compliance, or following to requests raised during the certificate issue, or for the withdrawal of the suspension of the certificate, or on receipt of complaints associated with the product certificated, or for the misuse of certificate or of the mark, etc. .. The cost of these additional audits and/or tests shall be sustained by the customer.

<b>Title:</b>	<b>Product Certification Regulation</b>	 <b>kiwa</b>
<b>File Name:</b>	RG-05 Rev. 01 – Product Certification Regulation	

## **5 Modification to the certification**

### **5.1 Extension of the certification**

If the Company requests an extension of the existing certification, KIWA will issue a new offer and it will follow the same procedure described in § 2.1 for the certification audit.

### **5.2 Certification's modifications**

The Company must inform KIWA about changes that are (or can be) directly related to the quality of its products. *(These changes may include changes in product specifications or changes in the structure, management of the supplier's company, or in the supply or production processes, etc.)*

KIWA, therefore, must determine whether it's needed an additional test and inform the Company.

If it's required an additional test, KIWA may forbid to the Company to issue as certificates the products manufactured under conditions different than those defined in the certificate.

The prohibition ends as soon as KIWA has informed the Company on the positive results of the test

If the tests show a negative results, these are repeated until they reach a positive outcome at the expense of the customer (the company cannot issue as certificates the products manufactured in those conditions, not defined in the certificate, until the test will have positive result)

KIWA must indicate the type, scope and cost of any additional tests

If the Company does not accept the proposed amendments or further testing, they should inform KIWA via formal communication (e.g., letter, fax or e-mail) within thirty days. In this case, the certificate loses its validity from the date on which it will applied the modified requirements for the certification, or at the end of the transition period, if it exist.

If the Company accept the modification and the results of test are positive, they will receive a new certificate.

If, otherwise, the results are negative, the certificate loses its validity from the date on which it will applied the modified requirements for the certification, or at the end of the transition period, if it exist.


### **5.3 Modification to the regulation and/or to the certification's requirement**

Changes to regulations, standards and criteria for certification shall be formally communicated (e.g., letter, fax or e-mail) from KIWA to customers at least four months prior to their entry into force, unless otherwise specified in the notice of warning.

The Company can accept the changes and comply with the provisions of KIWA in order to maintain the certification within ten days following the forwarding of the communication, or may explicitly reject them, within ten days, giving up, if necessary, to be certified at the expiring date, or at the end of the transition period, if it exist.

In case no reply is received within the before mentioned time limits, it means that the company has tacitly accepted the changes and will comply with the relevant requirements.

If the changes have influence on the contractual arrangements entered into by the parties, they, by law, remain in force until the expiring of the contract

<b>Title:</b>	<b>Product Certification Regulation</b>	 <b>kiwa</b>
<b>File Name:</b>	RG-05 Rev. 01 – Product Certification Regulation	

## **6 Suspension/withdrawal/abandon of the certification**

### **6.1 Suspension/reactivation of the certification**

The certification can be suspended when:

- The company has not implemented adequate and effective corrective action on the expected time to solve "serious" non-compliance found in the surveillance audits.
- The company hasn't allowed KIWA to perform the surveillance audits on time and in the manner planned with tolerance up to one month;
- The Company doesn't accept the additional audit required and fully justified by KIWA
- The Company doesn't give up the improper use of the certification mark and of the certificate of conformity on time planned by KIWA.
- The Company doesn't adapt itself to the new rules of the scheme of certification after they have been accepted

Decisions on suspension shall be taken by KIWA in the same manner as for the certification issue (§ 2.7), the measure has a defined temporal validity and determine the conditions under which this suspension may be reversed.

The communication regarding the suspension of certification, sent to the company by registered A/R letter, includes the motivation and the duration and the conditions under which the order may be reversed and restrictions on the use of the certificate and certification mark


At the end of the suspension period, KIWA make a supplementary audit at the company in order to check the overtake of the conditions that led to the suspension

This audit must be completed within six months from the date of suspension and have to be successful, otherwise the certificate will be revoked; the charges for the audit shall be paid by the Company and doesn't change the programming of the surveillance audits already planned

### **6.2 Withdrawal of the certification**

The certification can be revoked when:

- The company hasn't eliminated the conditions that led to the suspension of certification;
- The company communicate with writing notice the waving of the certification;
- The company doesn't comply to the KIWA certification scheme;
- The company give up the activity for more the none calendar year or is put on liquidation;
- The company fails to honor its financial commitments with KIWA after the second reminder.

<b>Title:</b>	<b>Product Certification Regulation</b>	 <b>kiwa</b>
<b>File Name:</b>	RG-05 Rev. 01 – Product Certification Regulation	

Decisions on withdrawal shall be taken by KIWA in the same manner as for the certification issue (§ 2.7).

The communication regarding the withdrawal of certification, sent by KIWA with registered A/R letter, contains the reasons of the decision, the effective date of termination of validity of the certificate, the withdrawal of the certificate and of the use of the mark, and references to legal action of KIWA in its protection.

The company has 15 working days to return the certificate of conformity and all its copies to KIWA.

KIWA has the right to publish, in the manner it considers appropriate, withdrawal of certification of the company.

The withdrawal is effective from the moment of cancellation of certificate.

### **6.3 Abandon of the certification**

The Company may waive the certification in their possession when they occur at least one of the following conditions:

- Presentation by the customer of formal cancellation of the contract, with notice of at least three months before the periodic surveillance. If this terms are respected no payment will be required to customer. Otherwise, with notice of less than three months with respect to the periodic surveillance, it will be invoiced to the company the 50% on the annual maintenance fee
- Modification of the Standards/Technical Documents used for certification;
- In case of modification of this Regulation;

The Company shall provide to give written notice of its decision to waive KIWA that will communicate, with its acceptance, the effective date of termination of validity of the certificate and the date of the withdrawal of the use of the certificate and of the mark

The company has 15 working days to return the certificate of conformity and all its copies to KIWA.

KIWA has the right to publish, in the manner it considers appropriate, withdrawal of certification of the company.


The withdrawal is effective from the moment of cancellation of certificate.

## **7 Confidentiality**

KIWA ensure strict confidentiality of all information acquired in the performance of their functions by its personnel involved in the certification process. Such confidentiality is ensured by applying the appropriate procedures in conformity with international standards and with reference to current legislation.

In order to do it, the staff of KIWA , including its auditors, subscribe a commitment to confidentiality, as well as a document in which the staff will treat any information which comes into possession in accordance with the provisions of the Privacy Law.

This commitment cease if KIWA is obliged to publicly communicate the existence or the withdrawal of a certificate of a company, or if Kiwa decide to communicate the suspension of the certificate of a company, and/or for legal obligations and/or for other prescriptions.

<b>Title:</b>	<b>Product Certification Regulation</b>	 <b>kiwa</b>
<b>File Name:</b>	RG-05 Rev. 01 – Product Certification Regulation	

## **8 Advertising**

The company, after the issue of certificate of conformity, has the right to publish the news of the authorization to use the mark or certificate of conformity for products covered by certification. In any case, the organization must pay attention to in its publications and in its advertising there aren't misleading references to products subject to certification.

## **9 Complaints, appeals and legal argument**

### **9.1 Complaints**

The Company may present a documented complaint to KIWA, having as object its contractual relationship with KIWA.

This complaint may arise from incidents occurring in the course of the certification process, such as, for example, delays in carrying out various steps and patterns of behavior by the auditor of the Body.

KIWA shall record complaints, to analyze and to inform the company about the actions taken within fifteen days from the date of the complaint.

### **9.2 Appeals**

The appeal may arise from disagreement of the company against a decision taken by KIWA as a part of the certification process and can relate to the issue, not issuance, suspension, etc. of the certification.

The appeal must reach in writing within 30 days from the date of the document or activity to which it refers, and should include details of the applicant, the name of the person against whom it is presented and the motivation supported by objective evidence.

KIWA examine the appeal and expressed their views in writing within 30 days of receipt of it.

### **9.3 Legal arguments**

If the outcome of the appeal is not accepted by the Company, the dispute arising from it will be decided by a committee made up of one representative from Kiwa, a representative of the Company and a representative, which act as President, appointed by the two parties to review the appeal and reach an amicable settlement of dispute.

If the dispute is not resolved amicably, the same dispute may be referred to the decision of an "Arbitro Unico" (a sole arbitrator) to be appointed in accordance with the Rules of the Arbitration Court of Treviso. The parties expressly declare to know and accept the said Rules of Arbitration.

The Arbitro Unico decide as a ritual in equity, in accordance with the mandatory provisions of the Italian Code of Civil Procedure.

The costs will be sustained by the losing party for the 75%