

# REGULATION FOR THE CERTIFICATION OF MATERIALS AND PRODUCTS IN CONTACTS WITH WATER INTENDED FOR HUMAN CONSUMPTION

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### REGULATION FOR THE CERTIFICATION OF MATERIALS AND PRODUCTS IN CONTACTS WITH WATER INTENDED FOR HUMAN CONSUMPTION



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### REGULATION FOR THE CERTIFICATION OF MATERIALS AND PRODUCTS IN CONTACTS WITH WATER INTENDED FOR HUMAN CONSUMPTION



### 1. SCOPE AND APPLICATION FIELD

This Regulation defines the rights and duties and the operational methodology that regulates the relationship between Kiwa Cermet Italia S.p.A. (hereinafter Kiwa Italia or Kiwa) and the Customer Organization (hereinafter also Manufacturer or Company) in the provision of the product certification service.

This Regulation applies to the certification (issue and/or maintenance of a certificate) of materials and products in contacts with water intended for human consumption, with reference to toxicological aspects, based on indications of the Italian law D.M. 174/2004 (ref. tests per product).

The requirements stated in this Regulation form an integral part of the Agreement (economic offer, *Kiwa Regulations for Certification and General Terms and Conditions of Kiwa Cermet Italia for carrying out the tasks* - hereinafter the *General Terms and Conditions* for brevity) between Kiwa Italia and the Customer. These requirements only refer to the aspects specifically related to the scope of the required certification.

Any form of consultancy to the Customer, that could fail the independence of the carried out assessments, is expressly excluded from the scope of the agreement.

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

#### 2. GENERAL PRINCIPLES AND GUARANTEES FOR THE CUSTOMER ORGANIZATION

In its certification activity, in addition to the provisions of the General Terms and Conditions, Kiwa Italia applies the following principles:

- Non-discrimination: access to certification services is allowed to any Organization that requests it, in compliance with this Regulation, without any discriminatory condition of a commercial, financial or belonging to particular associations;
- b) Impartiality and independence: ensured through formalized rules and controls, including:
  - conduction of certification activities assigned to personnel with no interest in the Organization subject to certification, required to observe the behavioural and independence rules established by Kiwa Italia; on this point, Kiwa Italia undertakes to accept any justified reports from the Customer regarding the existence of incompatibility of the assignment, which could compromise the impartiality or independence of judgment;
  - precise application of formalized rules and procedures, in use by all personnel of certification services and periodic consultation with appropriate Parties interested in certification;
  - clear separation between the staff performing the auditing activities and the one participating in the certification decision;
  - avoiding any support to define and apply the requirements to obtain certifications. Kiwa Italia is not directly involved in the production, representation, marketing, maintenance, installation of products or materials relating to certification, nor does it offer consultancy in the design and development phase of the product itself, nor does it have any related structures that carry out these activities, in accordance with the provisions of current legislation on the matter.
- c) Precise management of complaints and appeals, as defined in § 14 of this Regulations;
- d) Confidentiality: In addition to what is regulated in the General Terms and Conditions and in the Kiwa Certification Regulations, Kiwa Italia will arrange for all personnel, including their Auditors, to sign a commitment to confidentiality, as well as a document in which the staff undertakes to treat any data that comes into its possession in compliance with the provisions of the law on Privacy;
- e) Accreditations (only in case of service covered by accreditation): Kiwa Italia undertakes to inform the Customer of the eventual renunciation, suspension or revocation of the accreditation, as well as to support the Client in the phase of transition to another accredited Body; in such cases Kiwa Italia is in no way responsible for any damage caused to the Customer by the waiver, suspension or revocation of the accreditation; in the aforementioned cases, the Customer has the right to renounce the contractual relationship with Kiwa Italia, without prior notice and without additional charges.

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### 3. MANDATORY REQUIREMENTS AND LEGALITY CONTROL LIMITS

The legislative compliance related to the certification scope will be considered by Kiwa Italia an essential prerequisite for the issue of the certification. However, the certificate issued by Kiwa Italia only concerns compliance with this only regulation therefore it is not a guarantee of compliance with the mandatory requirements, that is a specific responsibility of the Customer, which remains the solely liable, to itself and third parties, for the legislative fulfilments related to certified products.

For this reason, Kiwa Italia audit activities shall not be considered as a release towards any audit performed by Competent Authorities and Customer recognizes that no other express or implied warranty is given by Kiwa Italia, including, but not limiting, fitness as certification under Directive (EU) 2020/2184.

### 4. **DEFINITION**

Material: A solid, semi-solid or liquid that is used to manufacture a product/component and consists of:

- a) an organic composition (plastic or elastomeric), prepared with one or more starting substances;
- b) a cementitious composition, prepared with one or more constituents;
- c) a composition of metal, ceramic, enamel or other inorganic material.

Product/component: manufactured product made with a single or different materials, which can be divided into:

- single-material product: the entire product is made with a single material;
- multilayer product: the different materials form the different layers, not physically separable, of the finished product;
- assembled product: the product is assembled with different independent components that are joined during the assembly phase.

Family/series: set of artefacts made with the same material/materials (e.g. polymer, metal alloy, ...).

### 5. QUALITY SYSTEM REQUIREMENTS FOR THE PRODUCTION OF CERTIFIED PRODUCTS

### 5.1 General

This chapter outlines the requirements that must be satisfied by the quality system of the Manufacturer and the methods used by Kiwa Italia for the evaluation of it.

### 5.2 Internal quality control (of the Manufacturer)

As part of its quality system, the Manufacturer must have a scheme of internal quality control (IQC scheme) that shall include:

- the aspects that are subject to inspection;
- inspection methods adopted;
- the frequency of inspections;
- the procedures for recording and archiving of results.

The Manufacturer shall prepare and adopt a plan for internal quality control of its production, as defined in the table reported on this document, with relation to each product and make it available to the inspector during the performance of audits.

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IQS aspects
Calibration or verification of measuring equipment
Verification of purchased materials and components
Verification of used components in finished product
Monitoring of production process
Control of non-conformities and/or rejected products
Verification of used components in finished product
Handling and storage
Management of Costumer complaints
Training / Competence personnel

The client Company shall identify and formalize the corporate functions responsible for carrying out the activities listed into the above table.

### 6. REQUIREMENTS FOR THE CERTIFIED PRODUCTS

### 6.1 Metallic materials and components

Ref.	Metallic materials and components	ІТТ	BRT and PVT	ATs	Lab
Annex I DM 174	Verification of PLs	Х			
	Verification of 3.1 certificates of incoming goods material in contact with DW	Х			
	Verification of the drawings	Х			
	Verification of BOM and supply chain*	Х	Х	Х	
Annex II)M 1/4	Metallographic analysis (only in case the 3.1 certificates are not available)	Х			
	Global migration test	Х			Х
	Specific migration test (only for Stainless steel)	Х			
	Verification of 3.1 or 2.2 certificates of incoming goods material in contact with DW		х	Х	

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### 6.2 Plastic materials, elastomers and multilayer products

Ref.	Plastic materials, elastomers and multilayer products	ITT	BRT and PVT	ATs	Lab
Annex I DM 174	Verification of PLs	Х			
	Verification of BOM and supply chain*	Х	Х	Х	
	Verification of 3.1 certificates of incoming goods material in contact with DW	Х			
	Global migration test	Х			Х
	Specific migration test (if required)	Х			
	Verification of 3.1 or 2.2 certificates of incoming goods material in contact with DW		х	Х	

# 6.3 Materials based on hydraulic binders, including those containing organic constituents, porcelain enamels, ceramics and glass

Ref.	Materials based on hydraulic binders	ITT	BRT and PVT	ATs	Lab
Annex II DM 174, section I	Verification of PLs	Х			
	Verification of 3.1 certificates of incoming goods material in contact with DW	Х			
	Verification of BOM and supply chain*	Х	Х	Х	
	Global migration test (only for organic constituents)	Х			Х
	Specific migration test (if required, only for organic, cast iron and stainless steel fibers)	Х			
	Verification of 3.1 or 2.2 certificates of incoming goods material in contact with DW		Х	Х	

Ref.	Porcelain enamels, ceramics and glass	IΠ	BRT and PVT	ATs	Lab
Annex II DM 174, section II	Verification of PLs (except glass)	Х			
	Verification of 3.1 certificates of incoming goods material in contact with DW	Х			

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Ref.	Porcelain enamels, ceramics and glass	Ιπ	BRT and PVT	ATs	Lab
	Verification of BOM and supply chain*	Х	Х		
	Global migration test (only for glass)	Х			Х
	Specific migration test (only for porcelain enamels and ceramics)	Х			
	Verification of 3.1 or 2.2 certificates of incoming goods material in contact with DW		Х	х	

<sup>\*</sup>This information will be collected by Kiwa personnel directly from suppliers and eventual sub-supplier and won't be disclosed to anyone except the owner of information (recipe, sub-recipe) and Kiwa involved personnel.

#### NOTE:

ITT = initial type testing

BRT = batch release test

PVT =process verification test

AT's= items verified by the auditor

Lab = test for which samples are sent to laboratories

### 6.4 Assembled products

In case of assembled products, each component must be assessed in accordance with this Regulation for certification purposes.

The requirements are listed in the above tables.

If supplier/s of plastic and elastomeric materials aren't certified themselves according to this Regulation, an audit every two year at the supplier/s will be necessary.

### 6.5 Sampling

Samples required for ITT and LAB be selected by the auditor/audit team from production line or from the stock but cannot be older than 12 months.

In case won't be possible select the necessary samples in annual surveillance:

- 1) an extra surveillance at cost of Manufacturer will be planned within 3±1 months since the annual surveillance in order to samples products not older than 12 months
- 2) if it is not possible to carry out sampling within the timeframes indicated in point 1, Kiwa will have to suspend the certificate which will be reactivated following the carrying out of a sampling audit (at the manufacturer's cost) and consequent positive results of the tests carried out on the samples.

### 7. INITIAL CERTIFICATION

### 7.1 General

The Company, before undertaking the certification process with Kiwa Italia, should meet the following requirements:

- having verified that the product complies with the requirements for which certification is requested and undertake to maintain compliance with these requirements;
- accept the conditions set forth in this Regulation;

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- authorize access to the premises, establishments, areas and information necessary to perform the audit;
- provide complete collaboration to the Audit Team, making the necessary documentation available;
- indicate its own Representative as the main interlocutor of the Audit Team and let play to any eventual consultants present during the audit the role of observer;
- be responsible for the application of the requirements lay down in the current regulations regarding safety in the workplace. In the absence of binding provisions, the Company undertakes to provide Kiwa with complete and detailed information regarding the specific risks existing in the environment in which the Kiwa staff are destined to operate and about the personal protective equipment necessary for carrying out the assignment, informing Kiwa staff about their correct use. In this regard, the client Company must provide the personnel appointed by Kiwa with the company documentation relating to workplace safety (D.V.R., safety plan, procedures, etc.), limited to items of specific interest. If for such omissions, accidents occur or illnesses are contracted, no charge can be made for any reason at Kiwa.

### 7.2 Application for certification

The Company, that means to request a certification, applies for an offer to Kiwa Italia.

Kiwa Italia, after having collected the necessary technical information, verified the availability of the means to carry out all the assessment activities and to have the competence and ability to perform it, draws up an offer detailing the procedure and the costs and send it to the Company, attaching this Regulation, Kiwa Regulation for Certification and the General Terms and Conditions of Kiwa Cermet Italia.

In case of acceptance, the Company sends to Kiwa Italia the accepted offer, signed by the Legal Representative or by his delegate, which represents the contract that will regulate the relations between the Company and Kiwa Italia.

In case of any changes to the offer by the Customer, before starting the certification process, Kiwa Italia will be allowed to ask for further details or may communicate the impossibility of such initiation, providing the Customer with the reasons.

Contract review is performed by Kiwa Italia.

Should any inconsistencies arise between the information provided in the questionnaire and the findings of subsequent assessments, Kiwa Italia reserves the right to revise the quotation or to not activate the certification services.

If the Company intends to terminate the contract before having obtained the Certificate of Conformity, it will be required to pay the already incurred expenses (e.g. audits or test already performed) adding the cost for the certification procedure closing, as established in the last valid offer.

### 7.3 Planning of the initial certification audit

Kiwa Italia agrees with the Company the date of the initial certification audit and sends the audit plan to the Customer; if there are conflicts of interest, the Company may request replacement within three working days of a member or of the entire Audit Team, giving the reasons for this. Kiwa reserves the right to evaluate whether to modify the audit team based on the reasons given by the Company.

### 7.4 Certification process

### 7.4.1 General requirements

The certification audit performed by Kiwa Italia will be based on the requirements of this product certification regulation and they include:

- analysis of the recipe and/or verification of the composition of the alloy in order to verify that the raw materials used are permitted for use with drinking water and determine the necessary set of tests;
- tests (laboratory tests on samples) to verify that the products meet the technical requirements of the product and/or of the manufacturing;
- evaluation of the production process;
- evaluation of the System and / or the Internal Control scheme;
- evaluation of company procedures relating to the definition and control of the production process of the products subject to certification.

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The Company shall present all the products and relevant information for a careful and valid assessment by Kiwa Italia, allowing the Kiwa Italia auditor to take samples to be sent to the laboratory for the tests required, in accordance with the sampling plan.

### 7.4.2 Items covered by the certification and possibly subject to testing

The items covered by the certification are the number of products/components in contact with water intended for human consumption (drinking water) and/or the materials of which products/components are made, for which analyses and possible initial testing are carried out and which lead to the certification decision.

To define how many products and/or materials must be analysed and subjected to initial testing, the following criteria are applied:

#### Different materials:

- different type of material;
- · same type of material but supplied by different suppliers;
- same type of material, supplied by the same supplier, but made with a different recipe, different production method, different production site.

**Elements not relevant** to define how many products and/or materials there are for which analyses and any initial testing must be performed: geometries of the products or components.

Based on the above elements, all products/components made with different materials are selected. **These products/components are 100% selected** (sampling is not allowed) for initial analysis and possible testing.

The certification will therefore cover the products/components and families/series that use the materials analysed and possibly tested.

The certification of the raw material, in any case, will always be considered a pre-product certification and does not imply at all that the final products/components made with this certified material are automatically certified.

### 7.4.3 Acceptance of the test reports presented by the Company

If the Company submits test reports conducted in accordance with the requirements of the applicable parts of the D.M. 174 in order to demonstrate that the requirements for certification have been met, Kiwa Italia will accept these reports, provided they have been issued by an accredited Product Certification Body or by a competent Laboratory (see below). Naturally, the tests must have been carried out on the same products for which the Company has presented the certification request to Kiwa Italia.

The toxicological aspects to be verified and the quantity of material necessary for such tests will be determined following the analysis of the recipe/verification of the composition of the alloys and the necessary samples will have to be selected by the auditor/audit team as above mentioned and verified as specified in the D.M. 174.

The tests shall be performed by:

- accredited test laboratory according to ISO/IEC 17025;
- if a laboratory with accredited tests is not available: a laboratory of which Kiwa Italia has verified skills and abilities to carry out testing according to ISO/IEC EN 17025 and that is competent to perform test in accordance to this Regulation.

Kiwa remains the right to perform a topic audit to the test laboratory and/or perform witness testing.

The test laboratory delivers a test report according in which the test results are presented.

### 7.5 Verification of product and / or manufacturing requirements

Kiwa Italia must verify the products to be certified, with reference to the product and manufacturing requirements defined by this Regulation.

To this end, Kiwa Italia must have the necessary samples, taken from the production in progress and / or from the warehouse.

If the initial tests are not passed, these can be repeated at the request of the Company and all costs will be borne by the Company.

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### 7.6 Initial Audit at the Company

The assessment of compliance with the requirements of this Regulation is carried out on the basis of specific Kiwa check lists.

The main elements to be examined are:

- a) measurement tools and calibration method (internal or external);
- b) raw materials or components purchased;
- c) evaluation of the production process (control of the semi-finished and process parameters);
- d) checks on finished products in order to verify that they respect the technical requirements of the product and/or manufacturing;
- e) examination of internal procedures for the management of Non-Conformities (possible corrective actions and complaints);
- f) examination of internal procedures for transport, storage and packaging of finished products.

For items from a) to d), the Company must record, giving evidence of it:

- · type of control;
- · control method;
- frequency of control;
- · the method in which the control results are recorded and stored.

The Lead Auditor (LA) digitally delivers the Audit Report, the reports of Non-compliance and/or improvement elements to the Company representative.

Before the type testing, Kiwa Italia will perform an Initial Factory Inspection of the manufacturing sites. During the initial factory inspection will be checked the aspect as per Chapter 4 of this document.

The Initial Factory Inspection shall be performed by an auditor/audit team which is qualified by Kiwa Italia.

The auditor/audit team delivers a Factory Inspection report.

To take a positive certification decision the Initial Factory Inspection shall show the following status:

- I. All major Non-conformities shall be closed by the auditor/audit team;
- II. Corrective measures to resolve minor Non-conformities shall be approved by the auditor/audit team. The verification of correct implementation of the corrective measure shall find place during the next scheduled audit.

### 7.7 Corrective actions (CAs)

Corrections and corrective actions, necessary to eliminate the Non-conformities that have emerged during the initial or periodic factory inspection audit must be defined by the Company and communicated to Kiwa Italia within 30 days of the audit, filling in each individual non-conformity report, in the part relating to the "suggested/implemented corrective actions" indicating the methods, timing and responsibility for implementation. Each module that provides it must be signed by the Company Representative.

The LA evaluates the proposed corrections and the corrective actions and by acceptance or in case comments or clarifications are needed, it communicates them in writing to the Company.

The positive or negative outcome of the evaluation of the CAs is noted on the Non-compliance report in the relevant part and approved by the LA.

The actual implementation of the CAs and the closure of the NCs will be assessed by the LA in the subsequent surveillance audit; in the case of major NCs, the evaluation will take place through an additional audit.

The treatment of the observations/improvement elements will be evaluated in the field, during the subsequent surveillance audit.

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### 7.8 Classification of findings (NCs) and their management

The findings resulting from the Type conformity assessment activities are classified by Kiwa Italia as follows.

Major Non-Conformity: failure to meet a certification requirement, which compromises the product's efficacy or safety. This may concern:

- deviation or total absence of compliance with a specified requirement, found on the basis of objective evidence;
- failure to comply with legal requirements applicable to the product subject to certification.

**Minor Non-Conformity:** failure or partial fulfilment of a certification requirement which does not fall within the case of the major non-conformities described above, although requiring correction, does not affect the product's efficacy or safety.

More minor Non-conformities, inherent to the same requirement depending on the contents and the general result of the audit can lead to the issue of a major NC.

Minors Non-conforming not resolved and/or not taken over by the Company may result in the issuing of a Major NC.

**Improvement Element (Observations)**: situation detected during the audit which can provide ideas for an improvement of the process subject to certification. The Company is not obliged to implement the improvement elements/Observations, however, they must analyse them and justify the decision taken.

### 7.9 Certification decision

Kiwa Italia examines the result of recipe analysis and/or the verification of the composition, the audit documentation produced by the LA, the results of the laboratory tests and, in the event of a positive outcome, authorizes the issuance of the Certificate of Conformity. If the final decision differs from that proposed by the LA, the reasons are communicated in writing to the Company.

In case of a negative outcome (major NC), Kiwa Italia is not able to issue any certificate and it will provide detailed reasons for this refusal to the Company so that it can undertake appropriate corrective actions.

The validity of the Certificate of Conformity is 5 years and it is subject to the positive outcome of periodic surveillance visits.

It is permitted the reproduction (including color) of the certificates of conformity issued by Kiwa Italia, as long as it reproduces the original in full. Partial reproduction is not permitted.

### 7.10 Kiwa Certificate and Certification mark

The Company is authorized to apply the certification mark on the certified products as defined by this Regulation.

For those products for which it is not possible to apply the mark on the product itself or on the packaging, this can be applied to promotional or technical documents in compliance with the provisions present within this Regulation and always taking care to clearly highlight the reference with the product model to which the mark has been granted.

Kiwa Italia monitors the correct use of the certification mark during surveillance audits and, in the event of incorrect use, undertakes the necessary actions that may include the issue of Major/minor non-conformities and appropriate legal actions.

Based upon the granting of the Kiwa Certification the Manufacturer is allowed to use the Kiwa mark shown below on packaging, label, brochure, website, etc., but with clear reference to the products approved.



Certificate N° Kiwa Regulation RG 05 DWH rev. \_\_\_\_

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The dimensions of Kiwa logo may be increased or decreased uniformly, keeping the ratio of the size and if the writing remains legible. The logo may be used only for the products certified by Kiwa, on letterhead, advertising material and / or promotion. Cannot be used in a misleading manner and cannot be interpreted as a certification system.

Together to Kiwa Logo the Certificate number and the present Kiwa Regulation shall be reported clearly.

The Kiwa Logo shall be used with the colours of the above figure (Pantone 300); alternatively, black can be used.

If used on transport or handling systems, the rules above indicated shall be respected.

Kiwa reserves the right to take legal action to protect its image if the mark or the certificate is used in a manner inconsistent with the contractual and / or to bring disrepute to the image Kiwa.

It is possible to reproduce (even in colour) the Kiwa certificate of conformity as long as the original is reproduced in its entirety.

The certificate will be made public by Kiwa.

### 8. MAINTENANCE - PERIODIC SURVEILLANCE

### 8.1 Surveillance Audit

Annually, a surveillance audit must be performed at the Company premises.

Surveillance audits can be performed without prior notice.

The surveillance audit includes the test phases at the laboratory according to the provisions of this Regulation and audit at the Company premises with the same procedures defined by  $\$ 7.3 \div \$ 7.8$ .

At the conclusion of the audit, the Audit Team shall provide the Company with a copy of the audit report. The report will be subject to internal review and approval by Kiwa Italia. The report shall be deemed confirmed if no further communication is received by the Company within 60 calendar days. Conversely, if, following an internal review, Kiwa Italia considers it necessary to make changes to the report, it shall formally notify the Company, providing explanations for any changes made and indicating the subsequent actions.

Any NCs shall be handled in accordance with the provisions of section 7.8. For major NCs, the Company must promptly implement corrective actions, which must be approved by the Lead Auditor and implemented and verified by Kiwa Italia within a maximum of 2 months from the verbalization; products subject to a major NC cannot be placed on the market until the major NC has been resolved; furthermore, the Company must consider a possible recall of products already distributed, depending on the identified criticalities. Any requests for an extension of these implementation times must be justified in writing and approved by Kiwa Italia; in case of exceeding the established time, the Company will be subject to the measure of suspension or (in more serious cases) withdrawal or reduction of the certification, as indicated in paragraph 9 of this Regulation.

As regards the postponement of the audit already planned and agreed, point 15.2 of the General Terms and Conditions of Kiwa Cermet Italia is applicable for the performance of the assignments.

The execution of the surveillance audits foreseen in the certification cycle is subject to the regular payment of the previous activities by the Company.

### 8.2 Sampling criteria for maintaining certification

For the purposes of maintaining certification, it is possible to apply sampling, the following formula is applied to define the number of products/components to be sampled:

$$S = \frac{x}{5}$$

S = Number of samples to be collected during surveillance

X = items covered by the certification and subject to testing

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Rounding should be done upwards to the next higher number.

The criterion of division by 5 is due to the duration of the certificate, expected as 5 years, before the possible renewal, therefore In the five-year validity of the certification all the elements covered by the certification and subjected to initial testing shall be re-examined.

The samples must be selected and sampled by the audit team on the basis of the Surface/Volume ratio (S/V); those with the highest S/V ratio must be taken and the samples have to be sent at the laboratory for the annual test.

#### 8.3 Certification Confirmation

Kiwa Italia examines the surveillance audit documentation and any laboratory tests, the correct management of findings (if applicable) and, in the event of a positive outcome, confirms the validity of the certification.

#### 9. CERTIFICATION RENEWAL

In the year of certificate expiration, the periodic surveillance audit will be scheduled in a timely manner to allow for the renewal of the certificate with the new validity period.

Prior to the certificate expiration, Kiwa will contact the Company in order to confirm necessary data to draw up a renewal offer.

The renewal process shall be conducted in the same way of § 7 (included the eventual migration testing based on the result of recipe analysis).

#### 10. ADDITIONAL AUDITS

Kiwa Italia reserves the right, motivated in writing to the Company, to perform audits and / or additional tests related to the certified product, for the reasons indicated in the Kiwa Regulations for Certification or for requests emerged in the Certification Decision phase.

These additional audits, at the expense of the Company, do not replace and do not modify the procedures and frequencies of the periodic surveillance audits.

### 11. CHANGES TO CERTIFICATION

### 11.1 Extension of certification

If the Company requests an extension of the existing certification, Kiwa Italia will issue a new offer and the same procedure described in § 7 will be followed for the certification audit.

### 11.2 Changes made by the Company

The Company must inform Kiwa Italia of the changes that are (or may be) directly related to the quality of its products (these changes may involve: variations in product specifications or changes in the structure, in the management of the supplier company, in the production or procurement processes, etc.).

Kiwa Italia consequently must determine whether an additional evaluation and/or test is necessary and inform the Company, communicating its nature, purpose and related costs.

If a supplementary evaluation and/or test is required, Kiwa Italia may not authorize the Company to issue products that were manufactured under conditions other than those defined at the time the certificate was issued as certificates.

The authorization is restored when the evaluation and/or positive test results are available.

If, on the other hand, the evaluation and/or tests show a negative result, in order to confirm the validity of the certificate, they are repeated at the customer's expense, jointly Kiwa Italia opens an NC to the Company for the management of the consequent actions.

### 11.3 Extension of the certification to a third company (OBL - Own Brand Labeller)

If the client company (company "a" or OEM - Original Equipment Manufacturer) were to supply their certified products to a third-party company (company "b" or OBL - Own Brand Labeller), with the aim of placing such products

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on the market with the name of the company "b", the latter company may request certification in its own name following the procedure described in the previous paragraphs.

For the purpose of certification, if the entire production process, including the final packaging, ready to be issued on the market, is carried out at the company "a", without the certified product being modified and/or altered, it can be used (with the consent of the parties expressed in writing) the technical documentation and the reports of the inspections carried out at the company "a".

Companies "a" and "b" declare to Kiwa the existence of an agreement between the parties, in addition to the fact that the surveillance for the products of the company "b" are carried out at the company "a" which undertakes to allow such audits and that the products are not modified in any way by the company "b".

The certification of company "b" expires if the certification of "a" is no longer valid; the Company "b" must inform the Company "a" of any complaints regarding the certified products.

### 12. SUSPENSION, REDUCTION OR WITHDRAWAL OF THE CERTIFICATION

The Certification may be suspended, withdrawn or reduced for the reasons indicated in the *Kiwa Certification Regulations* or at the request of the client. Kiwa Italia reserves the right to evaluate based on the reasons that led to the suspension/ reduction/withdrawal:

- The possibility of requesting the Company to recall products already placed on the market (including those in stock):
- If granting to the Company to continue with the marketing of products already made within the date of suspension/reduction/withdrawal.

Except in exceptional cases (established in any case by Kiwa Italia) the suspension period cannot last more than 12 months, otherwise the certification will be reduced or withdrawn.

During the suspension period, the Company loses the right to use the Kiwa Italia Certification Mark and the certificate and is deleted from the lists of Companies with certified product.

If the Company does not implement the actions indicated by Kiwa Italia for the restoration of the suspended certification, the certification will be withdrawn or, in possible cases, the field of application will be reduced.

The certification reduction involves the issue of a new certificate, indicating the field of application for which the certification has remained valid, and the withdrawal of the old certificate. The customer must also promptly adapt all forms of communication and advertising relating to the certification with reference to the new reduced field of application.

Following withdrawal of the certification, the Company loses the right to use the Kiwa Italia Certification Mark and is deleted from the lists of certified Companies.

Following withdrawal, as regards the part of the year covered by the Certification, the Company must pay Kiwa Italia the annual maintenance cost already defined, proportionally to the period of validity of the certificate itself. Visiting costs and maintenance tests, if already performed, will be fully invoiced.

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

Kiwa Italia reserves the right to communicate the suspension, withdrawal or reduction measure to the accreditation bodies (for certification covered by accreditation) and / or to other third parties that request it.

In the event of a contractual agreement between the OBL and the OEM, a suspension/withdrawal/reduction of the certification of the OEM's products shall also imply the suspension/withdrawal/reduction of the certificates issued in the name of the OBL, with Kiwa Italia being exempted from any liability related to the contractual obligations assumed by the OEM.

### 13. ADVERTISING

The Company, once obtained the Certificate, has the right to make public the news of the authorization to use the mark or the certificate of conformity for the products covered by the certification. In any case, the Company must

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pay attention so that in its publications and in its advertising, there are no misleading references to the products covered by the certification.

### 14. COMPLAINTS AND APPEALS

### 14.1 Complaints

The Company may file a documented complaint concerning to the certification activities with Kiwa Italia.

This complaint may arise from inconveniences occurring during the certification process, such as, for example, delays in completing the various phases and / or incorrect behaviour on the part of the Body's Auditors.

Kiwa Italia will register the complaints, analyse them and inform the complainant about the actions taken, within thirty days from the date of receipt of the complaint.

In order to ensure impartiality all complaints are dealt with by personnel which is not involved in the activities subject to the complaints.

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

### 14.2 Appeals

If the complainant is not satisfied with the response received, or intends to oppose a decision by Kiwa Italia, he can file an appeal in writing.

The appellant must justify the reasons for his appeal and, if this appeal refers to a decision by Kiwa Italia (for example, minutes of major non-conformity), it must be presented to Kiwa Italia within a period of 10 calendar days from the date of notification of the decision.

Appeals are managed by functions which are not involved in the activities subject to appeals.

Kiwa Italia will provide the applicant with a written reply and will notify any actions to be taken within 30 working days of receiving the appeal.

Detailed methods for submitting complaints and appeals can be found on the website www.kiwa.it.

### 15. RIGHT OF UNILATERAL WITHDRAWAL FROM THE CONTRACT

Kiwa Italia can freely withdraw from this contract by giving written notice to the client Company with six months' notice with respect to the effective date of withdrawal. Withdrawal by Kiwa Italia involves the withdrawal of the certification issued. However, the client Company is obliged to pay Kiwa Italia the amounts due for the services received during the notice period, as established in the last valid offer.

If the Company wishes to withdraw from the contract, the unilateral withdrawal during the period of validity of the Certification, foresees the observance of the notice periods foreseen in the *General Terms and Conditions and in the Kiwa Certification Regulations*.

In the event of termination of the Contract, Kiwa Italia will issue an invoice for the coverage of the remaining certification period in relation to the costs of closing the certification procedure, as established in the last valid offer.

### 16. UNILATERAL AMENDMENT OF THE CONTRACT

Kiwa Italia reserves the right to amend this Regulation at any time. Any new clauses/amendments shall become effective from their written notification to the Client Company.

If the Company does not accept the amendments, it may terminate the contract by giving written notice by registered letter with return receipt or certified e-mail within 30 calendar days, under penalty of forfeiture, from the day after the communication to Kiwa Italia.

The termination shall become effective from the last working day of the month in which the Customer's notice is received.

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