REGULATION FOR CE CERTIFICATIONS PURSUANT TO THE MID MEASURING INSTRUMENT DIRECTIVE

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Rev. No.	SUMMARY OF CHANGES	DATE
12	Rebranding, edited fonts and Kiwa logo; edited Regulation code	2025-11-19
11	Deletion of references to modules E, E1 and H1 and introduction of clarifications regarding modules B and D-D1; other minor changes	2025-02-05

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1. PURPOSE AND AREA OF APPLICATION

This Regulation defines the rights and duties, as well as the operating methodology that regulates the relations between Kiwa Cermet Italia S.p.A. (hereinafter Kiwa Italia or Kiwa) and the Customer Organizations, in the provision of certification services pursuant to Legislative Decree 2 February 2007 n ° 22 which transposes Directive 2004/22/EC, as amended by Legislative Decree 19/05/2016, n. 84 of the transposition in Italy of Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 relating to measuring instruments to be used in the field of legal metrology (hereinafter referred to as the "Directive").

The requirements expressed in this regulation are an integral part of the contract stipulated with Kiwa Italia (economic quotation *Kiwa Regulation for Certification and General Terms and Conditions of Kiwa Cermet Italia for carrying out the assignments* - hereinafter *General Terms and Conditions* for brevity). These requirements refer only to the aspects specifically connected to the area of application of the requested certification.

This Regulation establishes the rules for the implementation of the procedures to be used for the conformity assessment on the types of measuring instruments of the Directive in relation to the conformity assessment modules for which Kiwa Italia is authorized by the Competent Authority as a Notified Body.

Any form of advice to the Client, which could undermine the nature of independence of the assessments carried out, is expressly excluded from the subject of the contract.

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

2. GENERAL PRINCIPLES AND GUARANTEES FOR THE CUSTOMER

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

a) Absence of discrimination: access to certification services is allowed to any Organization that requests it, in compliance with these Regulations, without any discriminatory conditions of a commercial, financial nature or membership of particular associations.

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

- Carrying out of the certification activities assigned to personnel having no interest in the organization subjected to certification, required to observe the rules of conduct and independence established by Kiwa Italia; on this point, Kiwa Italia undertakes to accept any justified reports from the Customer, relating to the existence of incompatibility of assignment, which could compromise impartiality or independence of judgment. Impartiality is also guaranteed by the involvement of specific bodies assigned to control the methods of providing Kiwa Italia services;
- Punctual application of formalized rules and procedures, in use by all the personnel of the certification services and periodic consultation with appropriate parties interested in the certification;
- Clear separation between the personnel performing the audit activities and those participating in the certification decision;
- Total abstention from carrying out assistance activities in the definition and application of the requirements to obtain the Certification.

c) Punctual management of complaints and appeals, as defined in § 8 of these Regulations.

d) Confidentiality: in addition to what is regulated in the General Terms and Conditions and in the Kiwa Certification Regulations, Kiwa Italia arranges for all personnel, including its Auditors, to sign a commitment to confidentiality, as well as a document in which the personnel undertakes to process any data it comes into possession in compliance with the provisions of the privacy law.

e) Accreditations and Notifications: Kiwa Italia undertakes to inform the Customer of any renunciation, suspension or revocation of accreditation and/or ministerial notification; in such cases Kiwa Italia is in no way responsible for any damage caused to the Customer by the renunciation, suspension or revocation of accreditation or notification; in the aforementioned cases, the Customer has the right to renounce the contractual relationship with Kiwa Italia, without notice and without additional charges.

3. ACCESS REQUIREMENTS FOR CERTIFICATION

3.1 General Requirements

Before embarking the certification process with Kiwa Italia, the Organization must meet the following requirements:

- Accept the conditions set out in these Regulations;
- Authorize access to the premises, plants, areas and information necessary to carry out the Audit;
- Designate its own Representative as the main interlocutor of the Audit Group and have any consultants present during the Audit play the role of observer;
- Be responsible for the application of the requirements laid down by current workplace safety regulations. In the absence of mandatory provisions, the Organization undertakes to provide Kiwa Italia with complete and detailed information on the specific risks existing in the environment in which Kiwa Italia personnel and the PPE necessary for carrying out the assignment are intended to operate, informing Kiwa Italia personnel on their correct use. In this regard, the customer organization must provide the personnel appointed by Kiwa Italia with company documentation relating to safety in the workplace (D.V.R., safety plan, procedures, etc.), limited to items of specific interest. When, due to such omissions, accidents occur or illnesses are contracted, no charge can be made for any reason to Kiwa Italia;
- Accept, at no additional cost, the possible presence of Evaluators from the accreditation body or the competent Authority, as Observers, who will be notified by Kiwa Italia with a clear illustration of roles. This presence is intended to ensure that the assessment methods adopted by Kiwa Italia comply with the requirements for accreditation.
- Accept any inspections by the Accreditation Body. In fact, in order to assess that the evaluation methods adopted by Kiwa Italia comply with the reference standards, the Accreditation Body may request a visit, called Market Surveillance Visit, to be carried out at the certified Organization, directly through the use of own personnel. This eventual visit is communicated by the Accreditation Body to Kiwa Italia with 7 working days notice. Upon receipt of this communication, Kiwa Italia will inform the customer organization. The audit plan is prepared by the Accreditation Body, which will make it available to Kiwa Italia, then Kiwa Italia will send it to the client organization. If the Organization 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 revoked. The Organization must make the documentation that Kiwa Italia used as a reference during previous audits available to the Accreditation Body. The Market Surveillance Visit does not replace the normal certification maintenance audits required by the audit program. For the procedures for carrying out the Market Surveillance Visit, refer to the document IAF ID 04 (which can be downloaded free of charge from the IAF website: www.iaf.nu). Other control methods may be adopted by the Accreditation Body, to verify the operation of Kiwa Italia, for example unannounced visits at the offices of certified subjects, requests for information from organizations or consulting companies, or other control methods established by the accreditation body itself.

3.2 Remarks classification

Each remark found during the Audits is classified as follows:

Major Non-Conformity: deviation or total absence of compliance with requirements, found on the basis of objective evidence, following the assessment activities.

Minor Non-Conformity: deviation or partial absence of compliance with requirements, found on the basis of objective evidence, following the assessment activities.

Several minor non-conformities, inherent to the same requirement, depending on the contents and the general result of the audit may result in the issuance of a major NC.

Minor non-conformities not resolved and/or not taken over by the Organization may result in the issuance of a major NC.

Elements of improvement: anything not covered by the definitions of non-compliance and which constitutes a possible improvement in the effectiveness of the solutions adopted by the customer, to achieve compliance with the requirements and prevent deviations.

4. REQUIREMENTS OF THE EVALUATION PROCESS

4.1 Premise

Kiwa Italia's activity is carried out in compliance with all the requirements that must be possessed by the Notified Bodies, as prescribed at national level by the Competent Authority.

The manufacturer is responsible for the design and manufacture of a product covered by the Directive, with a view to its placing on the Community market. The drafting of the technical documentation, the CE Marking and the issuance of the EU Declaration of Conformity for each model of measuring instruments are its sole responsibility, the CE Marking and the issuance of the EU Declaration of Conformity can be carried out by the authorized representative if explicitly provided for in the mandate.

An importer or distributor is considered to be a manufacturer for the purposes of the Directive and is subjected to the related obligations when he places on the market a measuring instrument with his own name, or trademark, or modifies a measuring instrument already placed on the market, in such a way as to be able to condition compliance with the requirements of the Directive.

The authorized representative, established within the European Union, is formally appointed by the manufacturer and acts in the name and on behalf of the latter in relation at least to what is specified in the mandate and as required by paragraph 2 of art. 9 of the Directive.

The manufacturer chooses, in accordance with the provisions of Article 17 of the Directive, the procedures for assessing the conformity of a measuring instrument with the essential requirements relevant to it listed in the specific Annex of the measuring instrument, the Modules and measuring instruments of the Directive for which Kiwa Italia is authorized to operate by the Competent Authority.

Conformity assessment procedures:

Module B* *EU-type examination*;

Module D *Declaration of conformity to type based on the quality assurance of the production process;*

Module D1 *Declaration of conformity based on the quality assurance of the production process;*

Module F* *Declaration of conformity to type based on product verification*

Module F1 *Declaration of conformity based on product verification;*

Module G *Declaration of conformity based on unit verification;*

The modules marked with (*) do not alone constitute a procedure for attesting conformity.

MEASUREMENT INSTRUMENTS:

- **MI – 005:** Measuring instruments for continuous and dynamic measurement of quantities of liquids other than water**;**
- **MI – 006**: Automatic weighing instruments;
- **MI – 008**: Materialized measures;
- **MI – 009**: Size measuring instruments.

4.2 Start of the certification process

The manufacturer (or authorized representative) submits an application for certification to Kiwa Italia specifying the category(ies) of the measuring instrument for which he intends to obtain certification, the option chosen for the evaluation of the measuring instrument, and provides the following documentation in Italian or English, possibly accompanied by specimens of instruments:

- *(for all Modules)* **Chamber of Commerce registration certificate** (copy on plain paper) or equivalent document for abroad;
- *(for Modules B, D1, F1, G)* **Technical documentation described in article 18 of the Directive:** the documentation must enable the conformity of the measuring instrument to be assessed with the relevant requirements of the Directive and includes an adequate risk analysis and assessment, the design, manufacture and operation of the instrument, in to the extent that this is relevant for the purpose of the assessment;
- *(for Module B)* **Samples**, representative of the expected production requested by Kiwa Italia in relation to the requirements indicated in the Directive;
- *(for Modules F, F1)* **Samples** to be subjected to verification of conformity to the type required by Kiwa Italia (these tools can be made available at the manufacturer's premises, that of Kiwa Italia or that of the place of installation);

- *(for Modules B)* **Evidence documentation certifying the adequacy of the technical design** of the parts of the measuring instrument of which no specimen is required;
- *(for Modules D, D1)* **Documentation relating to the quality system:** Quality Manual and main procedures;
- *(for Modules D, F)* **Technical documentation relating to the approved type and a copy of the EU type certificate.**

Pursuant to the Directive, it is forbidden to submit similar applications for certification, for the same category(ies) of the measuring instrument to other Notified Bodies.

4.3 Certification Verification of Conformity to the Directive

4.3.1 EU Type Examination - Module B

The EU-type examination consists of the technical assessments that are performed by Kiwa Italia in order to ascertain that the technical design of a measuring instrument meets the relevant provisions of the Directive.

For this purpose, the assessment activities that Kiwa Italia carries out are as follows:

- type tests;
- documentary analysis of the technical documentation (technical file);
- review by resolution and issue of the EU Type Examination Certificate.

Type examination can be done in one of the following methods:

- examination of a sample of the complete measuring instrument that is representative of the production considered (type of production);
- examination of specimens of one or more essential parts of the measuring instrument that are representative of the relevant production. In this case, in the document analysis phase, the adequacy of the technical design of the other parts of the measuring instrument is ascertained, by examining the technical documentation and additional documentation (combination of type of production and type of project);
- ascertaining the adequacy of the technical design of the measuring instrument, by examining the technical documentation and supplementary documentation, without examining a specimen (project type).

4.3.1.1 Type tests

The type tests are performed directly by the Kiwa Italia laboratory, once the representative specimens to be tested have been identified, on the basis of the measuring instruments subjected to the application for certification and the applicable regulatory references (OIML - International Organization of Legal Metrology). Part of these activities can also be entrusted to qualified third party laboratories or carried out at the manufacturer's site under the supervision of Kiwa Italia qualified personnel.

If the tests are entrusted to an external laboratory accredited according to ISO/IEC 17025, Kiwa Italia:

- Informs the manufacturer of its choice of testing laboratory and obtains its acceptance
- Verifies that the test program has been correctly implemented by the chosen laboratory
- Verifies that the test results reported in the test report comply with all the essential requirements of the MID and, where applicable, with the relevant harmonised standard or normative document (in case of presumption of conformity), and are not based solely on a general declaration of conformity.

The tests are performed in accordance with procedures defined by the laboratory on the basis of the applicable regulatory references (OIML).

In case of Non-Conformity the modification of the measuring instrument must be carried out by the manufacturer (or authorized representative). Kiwa Italia repeats the tests deemed necessary, following the modification.

At the end of the test session, a test report is drawn up and delivered to the customer.

4.3.1.2 Analysis of the technical file

The analysis of the technical documentation is generally carried out at the conclusion of the tests, but it is possible that it is also carried out before or during the execution of the tests by personnel with the necessary technical competence relating to the scheme and type of measuring instrument to be certified.

At the end of the analysis of the technical file, the report that summarizes the outcome is released to the customer.

Based on the result of the analysis of the documentation, the manufacturer (or authorized representative) is required to make any necessary changes or additions. Kiwa Italia can request the modified documents to be subjected to a new analysis, before proceeding to the following activities.

Following the positive outcome of the results of the type tests and the technical file, the manufacturer (or authorized representative) receives the certification.

The EU-type Examination Certificate is valid for 10 years from the date of issue and may be renewed for successive periods of 10 years each.

4.3.2 Evaluation of the recognized Quality System - Modules D, D1

The conformity assessment concerning the approval of the manufacturer's Quality System (QMS) is applicable to the following Modules:

- ***Module D:*** conformity to type based on quality assurance of the production process
- **Module D1:** quality assurance of the production process

Quality assurance of the production process means that the manufacturer operates an approved quality system that covers the manufacture, testing of the measuring instrument during the production process, and final product inspection. Therefore, the manufacturer demonstrates a priori the ability to consistently provide a compliant product that meets the appropriate requirements of the MID, in the case of Module D1, or conforms to the approved type and meets the appropriate requirements of the MID, in the case of Module D.

For Module D it is essential that the measuring instrument has already been certified according to Module B *EU-type examination* (§ 4.3.1) by a Notified Body.

The assessment activities carried out by Kiwa Italia, in relation to the aforementioned Modules, are:

- Preliminary audit (optional);
- Stage 1;
- Certification check or Stage 2.

4.3.2.1 Preliminary Audit

At the request of the manufacturer (or authorized representative), after the activation of the service, it is possible to carry out a preliminary check (optional), with the aim of assessing the degree of adequacy of the QMS, with respect to the Directive, for the type of measure subject to certification. The results of this verification are expressed only in terms of Non-Conformity, they do not imply by the manufacturer (or authorized representative) the communication to Kiwa Italia of the corrective actions it intends to undertake and are not subjected to analysis in order to issue of the certification.

4.3.2.2 Stage 1

Stage 1 represents the first phase of the certification verification and also includes the analysis of the documentation. Stage 1 is generally performed at the Organization, by personnel with the necessary technical expertise relating to the scheme and type of measuring instrument to be certified. The documentation to be subjected to documentary analysis is represented by the Quality Manual and Related Procedures/Instructions. Furthermore, for Module D1, it will also be necessary to submit the technical file to documentary analysis.

The results of Stage 1 are documented and promptly communicated to the Client Organization; the Audit Group therefore agrees with the Organization the details for Stage 2, also providing for the planning of the latter.

Following the performance of Stage 1, in the case that changes to company data and activities are found, from what was communicated by the Client at the time of preparation of the Offer, the methods and duration of stage 2 and subsequent surveillance audits , may differ from those initially proposed in the quotation.

The customer must provide Kiwa Italia with an updated copy of the Quality Manual and make it available upon request, for the entire period of validity of the evaluation contract with Kiwa Italia and during the evaluation activities.

Based on the result of Stage 1, before being able to proceed with subsequent activities, the manufacturer is required to make any necessary changes or additions to the assessed documentation. Kiwa Italia can request the modified documents, to be subjected to a new analysis, before proceeding to the following activities.

If within 60 calendar days from the end of Stage 1, the Customer does not receive any communication, or if Kiwa Italia receives the Stage 2 notification, the audit report can be considered automatically confirmed. On the other hand, if

following internal analysis, Kiwa Italia deems appropriate changes to the contents of the report, it will formally notify the Organization, providing explanations for any changes made and indications regarding subsequent actions.

4.3.2.3 Certification Verification or Stage 2

The purpose of the Stage 2 audit is to evaluate the implementation, including the effectiveness, of the customer's Management System.

Stage 2 is planned at a distance of time from Stage 1, such as to allow the Organization to resolve the findings that emerged in Stage 1 and the correct planning of Stage 2 by Kiwa Italia.

The maximum time between Stage 1 and Stage 2 will be established by Kiwa Italia and must be such as to ensure that the results of Stage 1 remain valid, therefore the product certification system, the Organization, the context regulatory and legislative must not undergo significant variations between the two stages.

In exceptional and adequately motivated cases, established by Kiwa Italia, the two stages can be organized in consecutive moments, in such cases if the outcome of Stage 1 is negative, the initial certification verification will still be completed, but it will be necessary to carry out a new Stage 2 check.

Stage 2 is always performed at the places where the activities subjected to certification take place. This verification is extended to all the requirements of the Directive and in relation to the type of measuring instrument subject to certification.

In the initial phase of the verification, the resolution of any findings notified in the Phase 1 phase is evaluated.

At the end of the audit, the Audit Group leaves a copy of the report on the activity carried out to the customer who signs it.

In the face of any Non-Conformities found in Stage 2, the manufacturer must send Kiwa Italia, on the appropriate form, the proposal relating to the corrections and corrective actions established (against the analysis and formalization of the causes that generated them), with the timing of implementation.

Upon receipt of the inspection report and following its analysis, Kiwa Italia will confirm to the manufacturer (or authorized representative) the result of the inspection and will communicate the subsequent actions. In this phase Kiwa Italia can ask the manufacturer (or authorized representative) for any additions or changes to the contents of the report issued by the Audit Group.

The file cannot be analyzed for the resolution, until the proposals for resolution and corrective actions of the Non-Conformities are received. Furthermore, before the certification is issued, the resolution of all major Non-Conformities must also be verified, according to the assessment methods established by Kiwa Italia (audit at the customer's and/or through documentary evidence where possible). This assessment must be carried out no later than 6 months after the Stage 2 verification; beyond this time, it will be at the discretion of Kiwa Italia to evaluate the consequent actions.

Verification of the implementation and effectiveness of corrections and corrective actions related to minor non-conformities is carried out by Kiwa Italia during the subsequent periodic surveillance audit.

Upon successful completion of the certification resolution, the manufacturer (or authorized representative) receives the certification and applies the number 0476, which identifies Kiwa Italia as a Notified Body, on the measuring instruments referred to the approved quality system.

The Kiwa Italia Certificate is valid for 3 years from the date of issue.

Any requests for changes to the contents of the certificate must be sent to Kiwa Italia in written form and in advance of the first useful verification activity.

4.3.3 Product Verification Assessment – Module F

This conformity assessment is performed in relation to the type certified according to Module B (§ 4.3.1) and the applicable essential requirements of the Directive. Consequently, it is essential that the measuring instrument has already been certified according to Form B, by Kiwa Italia or another Notified Body.

For this purpose, the assessment activities that Kiwa Italia carries out are as follows:

- Exams and tests;
- Sealing of metrologically relevant parts (e.g. plate).

4.3.3.1 Examination and tests

Depending on the type of instrument, the requirements of point 5.3 of Module F, the specific Module referred to the type of instrument (MI-XXX) and any applicable standards (eg. OIML and Welmec), Kiwa Italia decides whether to carry out the tests and examinations on each single instrument rather than on a statistical basis; Kiwa Italia also decides whether to carry out the tests and examinations at the installation site of the measurement system, fixed and installed in the position where it will be put into service or also in other places (for example the production plant).

It is the responsibility of the manufacturer (or authorized representative) to provide Kiwa Italia with all useful information regarding the final use of the measuring instrument, including the supply of the specific product being measured and any test equipment.

In the case of statistical checks, it is also the responsibility of the manufacturer (or authorized representative) to present their measuring instruments in homogeneous batches and take all necessary measures so that the manufacturing process guarantees the homogeneity of each batch of measuring instruments produced.

The exams have the purpose to assess that the measurement system being verified is consistent with the certified type issued in accordance with Module B.

The tests have the purpose to assess the compliance of the measurement system with the metrological requirements. These tests are performed using the specific material that will be treated by the measuring instrument and based on the tests described in the *Initial verification* paragraph of the corresponding applicable OIML standard.

When the outcome of all the above checks is positive, the Audit Group proceeds with the sealing of metrologically relevant parts with seals marked Kiwa Italia, according to the legalization plan indicated in the Certificate issued in accordance with Form B.

At the end of the test session, the Leas Auditor of the Audit Team draws up a report on the verification which is delivered to the customer.

In the presence of Non-Conformities, the procedure proceeds only after the manufacturer (or authorized representative) has resolved the non-conformities found and Kiwa Italia has performed a new audit (repetition of the examinations and/or tests that have not been passed) in order the compliance of the new configuration of the measuring instrument.

In the case of statistical control, if a batch is accepted, all the measuring instruments of the lot are approved, with the exception of the instruments of the sample found to be non-compliant within the limits allowed by the applicable standards. If a batch is rejected, the manufacturer (or authorized representative) undertakes not to place it on the market, providing for its elimination.

Following a positive outcome of the analysis of the above activities, the manufacturer (or authorized representative) receives the certification and can apply the notification number 0476, which identifies Kiwa Italia as a Notified Body, on the measuring instruments related to the verified product.

4.3.4 Product Verification Assessment – Module F1

This conformity assessment aims to ascertain that the measuring instruments comply with the requirements of the Directive.

To this purpose, the assessment activities that Kiwa Italia carries out are as follows:

- documentary analysis of the technical documentation (technical file);
- examination of measuring instruments.

Depending on the type of measuring instrument and the size of the batch, the exam can be developed as follows:

- complete tests on all examples of measuring instruments or;
- complete tests on a statistical sample of the measuring instruments.

In the case in which the tests are carried out on a statistical sample of the measuring instruments, the sampling criterion is decided based on the requirements of point 6.4 of Module F1, of any applicable guides (WELMEC 8.10).

Kiwa Italia also decides where to carry out the tests and examinations (at its own laboratory, at the manufacturer's premises, or at another site agreed upon by the parties).

It is the responsibility of the manufacturer (or authorized representative) to provide Kiwa Italia with all useful information regarding the final use of the measuring instrument, including the supply of the specific product being measured and possibly test equipment.

In the case of statistical checks, it is also the responsibility of the manufacturer (or authorized representative) to present their measuring instruments in homogeneous batches and take all necessary measures so that the manufacturing process guarantees the homogeneity of each batch of measuring instruments produced.

4.3.4.1 Examinations and tests on the specimens

The purpose of the examinations and tests is to assess that the instruments being verified comply with the requirements applicable for the type of instrument considered (Annex X MID-008).

At the end of the test session, the Lead Auditor of the Audit Group draws up a test report, which is delivered to the customer.

In the event of non-conformities that do not exceed the required quality level, the batch may be declared compliant, with the exclusion of instruments found to be non-compliant. If the batch does not meet the required quality level, the batch shall be declared non-compliant.

If a batch is rejected, the manufacturer (or authorized representative) undertakes not to place it on the market, providing for its elimination.

4.3.5 Unit Verification – Module G

This conformity assessment aims to ensure that a single sample of measuring instrument complies with the requirements of the Directive.

For this purpose, the assessment activities that Kiwa Italia carries out are as follows:

- Documentary analysis of the technical documentation (technical file);
- Complete tests of the measuring instrument.

4.3.5.1 Complete tests on the Unit

The complete tests on a sample of the measuring instrument are carried out directly by the Kiwa Italia laboratory.

Parts of these activities can also be outsourced to qualified third party laboratories.

If the tests are entrusted to an external laboratory accredited according to ISO/IEC 17025, Kiwa Italia:

- Informs the manufacturer of its choice of testing laboratory and obtains its acceptance
- Verifies that the test program has been correctly implemented by the chosen laboratory

Verifies that the test results reported in the test report comply with all the essential requirements of the MID and, where applicable, with the relevant harmonised standard or normative document (in case of presumption of conformity), and are not based solely on a general declaration of conformity.

The tests are performed in accordance with procedures defined by the laboratory on the basis of the reference standards (OIML).

In case of Non-Conformity, the modification of the measuring instrument must be carried out by the manufacturer (or authorized representative) who repeats the tests deemed necessary, following the modification.

At the end of the test session, a test report is drawn up and delivered to the customer.

When the outcome of all tests is positive, the Audit Group proceeds with the sealing of the metrologically relevant parts with seals marked Kiwa Italia.

4.3.6.1 Analysis of the technical file

See what indicated in § 4.3.5.3.

4.4 Maintenance Audit

Modules B, F, F1 and G (in relation to the examination of the project) are not subject to surveillance activities.

The quality system approval certificates (Modules: D, D1) are instead subject to periodic audits, generally on an annual basis, in order to ensure that the manufacturer (or authorized representative) maintains and applies the approved quality system.

The manufacturer (or authorized representative) undertakes to keep the Quality System adequate and efficient.

Kiwa Italia also reserves the right to carry out audits without prior notice and, on this occasion, carry out or have tests carried out on the product.

The need and frequency of such unannounced visits are determined by Kiwa Italia after considering the initial assessment of the quality system, previous information regarding the manufacturer, relevant economic operators, the instruments manufactured and any complaints received.

4.4.1 Surveillance Audit according to Modules D, D1 of the Directive

The surveillance audits are carried out at the places where the activities related to the approved Quality System, subject to certification, are carried out.

Surveillance Audits are carried out once a year with reference to the month of expiry of the certificate. They are always carried out at the places where the activities related to the approved Quality System, subject to certification, are carried out.

During the surveillance audits, the assessment of the resolution of the Non-Conformities emerged in the previous audits is carried out, as well as the evaluation of the implementation and effectiveness of the corrective actions implemented by the manufacturer (or authorized representative).

At the end of the audit, the Kiwa Italia Evaluation Group leaves a copy of the audit report to the customer who signs it.

The report will be considered confirmed if no further communications to the Organization follow within 60 calendar days.

In the case of Non-Conformity, the manufacturer must send Kiwa Italia, within 20 working days and on the appropriate form, the proposal relating to the corrections and corrective actions established (against the analysis and formalization of the causes that generated them), with the timing of implementation. If within 30 working days of sending, the Organization does not receive any communication, it will be able to consider automatically accepted the treatments and the defined action plan.

In the case of major non-conformities, Kiwa Italia will notify the manufacturer (or the authorized representative) of the consequent actions: audit at the customer's and/or verification through documentary evidence where possible. The timing of this verification will be established by Kiwa Italia based on the severity and number of reported non-conformities.

In the case in which the manufacturer (or authorized representative) does not implement the actions agreed to resolve the findings within the permitted terms, the certification may be suspended or revoked upon decision of Kiwa Italia.

The postponement of an Audit already planned and agreed, for reasons attributable to the Organization, must be communicated to Kiwa Italia at least 30 days before the scheduled date, otherwise a penalty equal to 50% of the expected fee will be invoiced, in addition to any expenses incurred.

The performance of the surveillance audits provided for in the certification cycle is subjected to the regular payment of the previous activities by the Organization.

Surveillance activities, in addition to on-site audits, may include, for example:

a. Requests to the manufacturer about aspects relating to certification;

b. Review of the manufacturer’s declarations regarding its activities (e.g. promotional material, website);

c. Requests to the manufacturer to provide documents and records (on paper or electronic means).

These other forms of monitoring can be applied by Kiwa Italia, depending on: information received from outside, the outcome of the audits, input from the Accreditation Body or the competent authority, etc.

As part of the maintenance of the certification issued in compliance with the reference Directive, Kiwa Italia keeps the manufacturer (or authorized representative) with certified product informed of any significant change that had an implication on the validity of the examination certificate UE of the type.

4.4.2 Renewal Audit according to Modules D, D1 of the Directive

Within the expiration of the certification, Kiwa Italia performs a renewal audit at the manufacturer's (or authorized representative's) headquarters which aim is to assess, also at a documentary level, that the manufacturer (or authorized representative) maintains the approved Quality System valid, in accordance with the provisions of the Directive.

The Renewal audit is planned in order to examine all the requirements of the relevant Directive.

At the end of the audit, the Audit Team leaves a copy of the audit report to the customer who signs it. The audit report is subjected to internal analysis and approval by Kiwa Italia, for the approval of the certification.

As regards the management of any non-conformities and the approval phase of the certification, what is indicated in the preceding § 4.3.2.3 applies.

The renewal activity, including the correct management of the non-conformities that have emerged, must be completed by the expiry of the certificate. The validity period of the certificate will again be 3 years.

4.5 Verification of the changes made by the manufacturer

In the case of certification issued in compliance with the Directive, depending on the type of certificate of conformity issued, the manufacturer (or authorized representative) undertakes to communicate to Kiwa Italia all the changes made to the measuring instrument or to the approved project that may affect conformity of the same with the essential requirements, the conditions of validity of the certificate or the conditions foreseen for the use of the measuring instrument and all the planned modifications to the approved quality system. On the basis of these changes, Kiwa Italia assesses which additional evaluation activities need to be carried out.

See also what is reported in the Kiwa Regulations for Certification at point 5.2.

Depending on the type of changes, an offer is drawn up, the contractual conditions are reviewed and the technical activities are planned as prescribed in the previous paragraphs. Each product modification is approved by review for the resolution and issue of the modified Certificate.

The certificate must be revised as soon as the measuring instrument no longer meets at least one aspect of the description included in the certificate and/or its annexes.

For the EU-type examination certificate, when the name of the manufacturer or its authorized representative changes, Kiwa Italia amends the existing EU-type examination certificate. This amendment requires additional approval in the form of an addition, or a revision of the original EU-type examination certificate. The design characteristics of the type remain unchanged, therefore the evaluation of the measuring instrument is not necessary. The recipient of the EU-type examination certificate is in any case the manufacturer.

4.6 Communications with Competent Authority

Kiwa Italia makes the list of certificates issued, modified, suspended, revoked or refused available to the Competent Authorities.

The Commission, Member States and other notified bodies may, upon request, obtain a copy of the EU-type examination certificates and/or additions thereto.

Upon request, the Commission and Member States may obtain a copy of the technical documentation and the results of the examinations carried out by Kiwa Italia.

Kiwa Italia keeps all the documentation relating to the issue of certification available to the Competent Authorities.

5 SUSPENSION, REVOCATION OR REDUCTION OF THE CERTIFICATION

The Certification can be suspended, revoked or reduced for the reasons indicated in the Kiwa Regulations for Certification or at the request of the Manufacturer (or authorized representative).

Kiwa Italia reserves the right to evaluate on the basis of the reasons that led to the suspension/revocation/reduction:

- Whether to allow the manufacturer (or authorized representative) to continue with the marketing of the measuring instruments already made on the date of suspension/revocation/reduction.

Except in exceptional cases (established in any case by Kiwa Italia or the Competent Authority) the suspension period cannot last more than 6 months, otherwise the certification will be revoked.

During the suspension period the manufacturer (or authorized representative) loses the right to use the EC metrology marking and the certificate. The conditions for restoring the suspended certification (including the necessary conformity assessment activities) are established by Kiwa Italia based on the reasons that led to the suspension and based on the duration of the suspension.

If the manufacturer (or authorized representative) does not implement the actions indicated by Kiwa Italia to restore the suspended certification, the certification will be revoked or, in possible cases, the scope of application will be reduced.

The reduction of the certification involves the issue of a new certificate, indicating the type of measuring instruments for which the certification has remained valid, and the withdrawal of the old certificate.

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

Following the revocation of the certification, the manufacturer (or authorized representative) loses the right to use the metrology and CE marking and the certificate. The manufacturer (or authorized representative) will be able to activate the certification process again by submitting a new application.

Kiwa Italia will inform the competent Market Supervisory Authorities, other Notified Bodies and the Accreditation Body of the suspension, revocation or reduction.

6 INCORRECT USE OF THE CERTIFICATION, THE CERTIFICATE AND THE CE MARKING

6.1 Incorrect use of the certification and EC marking

The use of the certification or certificate is considered incorrect when it can mislead the market as to the nature, quality and methods of use of the measuring instrument.

In addition to what is indicated in the *Kiwa Certification Regulations*, the following rules apply.

The use of the CE marking is incorrect when:

1. This applied on measuring instruments:
   - With an application for certification not yet submitted or with an application for certification refused;
   - Non-compliant with the object reported in the certificates;
   - For which certificates have been revoked/suspended/reduced**;**
2. When the certificate had expired and not yet renewed;
3. When the manufacturer (or authorized representative) has not implemented the changes requested by Kiwa Italia.

If an incorrect use of the certification, certificate and/or CE marking is found, Kiwa Italia revokes the manufacturer (or authorized representative) the right to affix the CE marking and use the certification, notifying the Competent Authority.

In the most serious cases (e.g. undue marking) Kiwa Italia also informs the Public Prosecutor's Office.

6.2 Use of the certification mark

Kiwa Italia does not grant the use of the Kiwa logo or the logo of the accreditation body.

7 MANUFACTURER'S OBLIGATIONS

With the acceptance of this regulation, in addition to everything provided in the *General Terms and Conditions* and in the *Kiwa Regulations for Certification*, the manufacturer (or authorized representative) must undertake to comply with the following requirements when applying for certification:

- Not having submitted a similar application for certification for the same category (s) of the measuring instrument to another Notified Body;
- Communicate to Kiwa Italia all the places where the measuring instrument is manufactured, in particular if these places do not correspond to the operational headquarters of the manufacturer (or authorized representative);
- Notify Kiwa Italia of any changes introduced to the instrument (to the approved type in the case of Module B) and/or to the approved Quality System, subsequent to the release of the certification by Kiwa Italia;
- undertake to affix the CE marking on each measuring instrument that meets the relevant requirements of the Directive, the supplementary metrology marking and, when required by the Directive, the identification number 0476 of Kiwa Italia as a notified body;
- Keep the EU Declaration of Conformity available for a period of 10 years starting from the placing on the market of the instrument;
- Ensure that the measuring instrument complies with all applicable Community Directives.
- Make one or more measuring instruments subject to certification available to Kiwa Italia inspectors to verify the execution of verifications and calibration checks during surveillance and renewal audits.

- The manufacturer shall have suitable equipment with a related maintenance and calibration program that ensures metrological traceability, for the modules that provide for the manufacturer to independently carry out the final checks and tests for placing on the market.

Only for assessments with respect to Module B of the Directive

Keep a copy of the EU-type examination certificate, its annexes and its additions and amendments, together with the technical documentation for a period of ten years after the last measuring instrument has been manufactured.

Only for assessments with respect to Modules D, D1 of the Directive

- Keep it available for a period of ten years from the manufacture of the last instrument:
  1. the documentation presented during the application phase referred to in point 3.1 of Module D and 5.1 of Module D1 of the Directive;
  2. the amendments and related approvals referred to in point 3.5 of Module D, E, and 5.5 of Module D1 of the Directive;
  3. the decisions and reports submitted pursuant to points 3.5, 4.3 and 4.4 of Module D and 5.5, 6.3 and 6.4 of Module D1 of the Directive.

Only for assessments with respect to Modules F, F1 and G of the Directive

- Keep the certificates of conformity available for a period ending ten years after the certification of the instrument.
- Keep the technical documentation available for a period of ten years starting from the manufacture of the last instrument (only for Module F1).

8 COMPLAINTS AND APPEALS

8.1 Complaints

The Manufacturer may submit a documented complaint, concerning its relations relating to the certification activities with Kiwa Italia.

This complaint may arise from problems occurring during the certification process, such as, for example, delays in carrying out the various phases and/or incorrect behaviour by the Body's Auditors.

Kiwa Italia records the complaints, analyses them and informs the complainant about the actions taken, within thirty days from the date of receipt of the complaint; the assessment and eventual approval are carried out by personnel not involved in the process, the subject of the complaint.

To ensure impartiality, all complaints are handled by personnel not involved in the activities covered by the complaints themselves.

Kiwa Italia will establish with the complainant if and to what extent, the content of the complaint and its resolution must be made public.

8.2 Appeals

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

The appellant must justify the reasons for his appeal and, in the case in which this appeal relates to a decision by Kiwa Italia (e.g. record of major Non-Conformity), it must be presented to Kiwa Italia within 10 days from the date of communication of the decision.

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

Kiwa Italia will provide the applicant with a written reply and notify any action to be taken within 30 working days from the date of receipt of the appeal.

The detailed procedures for submitting complaints and appeals are shown on the website www.kiwa.it.

9 MODIFICATION OF THE CERTIFICATION SCHEME

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

It is in any case the responsibility of the manufacturer to verify that its technical product documentation and related procedures are updated to the latest available version of the standard applied and/or that they are, from a technical point of view, at the same level as the state of the art, in order to guarantee the presumption of conformity with the essential requirements of the Directive.

If the manufacturer does not comply with these requests, Kiwa Italia will withdraw the certificate.

If substantial changes are made to the rules/requirements of the certification scheme, Kiwa Italia informs the certified or certified Organizations, taking into consideration any observations submitted by them; these changes may concern:

• The reference standard or directive;

• This Regulation;

• Additional requirements of the Accrediting Body or Competent Authority.

Kiwa Italia will communicate these changes in written form to the client Organizations, indicating the type of variation, the methods and terms within which the Organization must comply.

In case of non-acceptance, the Organization may renounce the certification by giving written notice to Kiwa Italia.

10 RIGHT OF UNILATERAL WITHDRAWAL FROM THE CONTRACT

Kiwa Italia may freely withdraw from this contract by giving written notice to the customer organization with six-month notice of the effective date of the withdrawal. Withdrawal by Kiwa Italia involves the revocation of the certification issued. The Organization is in any case required to pay Kiwa Italia the amounts due for the services received during the notice period, as established in the last valid offer.

If the Organization wishes to withdraw from the contract, the unilateral withdrawal during the period of validity of the Certification requires compliance with the notice times provided for in the General Terms and Conditions and in the Kiwa Regulations for Certification.

In particular, for notice of less than three months with respect to the scheduled Audit and more than two weeks, the Customer will have to pay 50% of the amount relating to the amount foreseen for the subsequent activity provided for in the contract. For notice periods of less than two weeks, the provisions of the General Terms and Conditions apply.

In case of termination of the contract, Kiwa Italia will issue an invoice, in relation to the costs of closing the certification file, as established in the last valid offer.

11 UNILATERAL MODIFICATION OF THE CONTRACT

Kiwa Italia reserves the right to modify these Regulations at any time. Any new clauses/changes made will be effective from the moment they are communicated to the customer in written form.

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

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