REGULATION FOR CERTIFICATION PURSUANT TO THE MID DIRECTIVE ON MEASURING INSTRUMENTS

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1. SCOPE AND FIELD OF APPLICATION

This Regulation defines the rights and duties, as well as the operating methodology that regulates the relationships between Kiwa Cermet Italia S.p.A. (hereinafter Kiwa Italia or Kiwa) and the Customer Organisations, 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 Italia for the performance of orders* - hereinafter *General Terms and Conditions* for brevity). These requirements refer only to the aspects specifically connected to the field 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 authorised by the Competent Authority as a Notified Body.

Any form of advice to the Customer, 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 Organisation that requests it, in compliance with this Regulation, without any discriminatory conditions of a commercial, financial nature or membership of particular associations.

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

- Carrying out of the certification activities assigned to personnel having no interest in the Organisation 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;
- Strict application of formalised rules and procedures in use by all the personnel of the certification services and periodic consultation with appropriate certification stakeholders;
- Clear separation between personnel performing audit activities and those participating in the certification decision;
- Total abstention from carrying out assistance activities in the definition and implementation of the requirements to obtain Certification.

c) Timely management of complaints and appeals, as defined in § 8 of this Regulation.

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

e) Accreditations and Notifications: Kiwa Italia undertakes to inform the Customer of any renunciation, suspension or withdrawal 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 withdrawal of accreditation or notification; in the aforementioned cases, the Customer has the right to withdraw from the contractual relationship with Kiwa Italia, without notice and without additional charges.

3. ACCESS REQUIREMENTS FOR CERTIFICATION

3.1 General Requirements

Before embarking on the Certification process with Kiwa Italia, the Organisation shall meet the following requirements:

- Accept the conditions set out in this Regulation;
- Authorise access to the premises, facilities, areas and information necessary to carry out the Audit;
- Designate its own Representative as the main contact person for the Audit Team 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 Organisation undertakes to provide Kiwa Italia with complete and detailed information on the specific risks existing in the environment in which Kiwa Italia personnel are intended to operate and the PPE necessary for carrying out the assignment, informing Kiwa Italia personnel on their correct use. In this regard, the Customer organisation shall provide the personnel appointed by Kiwa Italia with company documentation relating to safety in the workplace (Risk Assessment Document (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 claim or liability whatsoever may be brought against Kiwa Italia for any reason;
- Accept, at no additional cost, the possible presence of Assessors 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 ascertain 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 ascertain 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 Organisation, directly through the use of its own personnel. This potential 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 Organisation. The visit plan is prepared by the Accreditation Body, which will make it available to Kiwa Italia; subsequently, Kiwa Italia will send it to the customer Organisation. Should the Organisation not grant its approval, the validity of the certificate shall be 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 shall be withdrawn. The Organisation shall make available to the Accreditation Body the documentation that Kiwa Italia used as a reference during previous audits. The Market Surveillance Visit does not replace the normal certification maintenance audits required by the audit programme. For the procedures for carrying out the Market Surveillance Visit, reference may be made to document IAF ID 04 (available free of charge from the IAF website: www.iaf.nu). Other monitoring methods may be adopted by the Accreditation Body to verify the operation of Kiwa Italia, for example unannounced audits at the premises of certified organisations, requests for information from organisations or consultancy companies, or other monitoring methods established by the Accreditation Body itself.

3.2 Classification of findings

Each finding raised during Audits is classified as follows:

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

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

Several minor non-conformities related to the same requirement may, depending on their content and the overall audit result, may lead to the issuance of a Major NC.

Minor non-conformities that have not been resolved and/or addressed by the Organisation may lead to the issuance of a Major NC.

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

4. REQUIREMENTS OF THE EVALUATION PROCESS

4.1 Introduction

Kiwa Italia's activity is carried out in compliance with all the requirements that shall 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 instrument are its sole responsibility; the CE Marking and the issuance of the EU Declaration of Conformity may be carried out by the authorised 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 subject to the related obligations when placing a measuring instrument on the market under its own name or trademark, or when modifying a measuring instrument already placed on the market in such a way as to affect its conformity with the requirements of the Directive.

The authorised 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 Article 9 of the Directive.

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

Conformity assessment procedures:

Module B* *EU-type examination*

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

Module D1 *Declaration of conformity based on 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 in themselves constitute a conformity assessment procedure.

MEASURING INSTRUMENTS:

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

4.2 Start of the certification process

The manufacturer (or authorised representative) submits an application for certification to Kiwa Italia specifying the category(ies) of the measuring instrument for which certification is sought, the option chosen for the assessment of the measuring instrument, and makes available the following documentation in Italian or English, possibly accompanied by instrument specimens:

- *(for all Modules)* **Chamber of Commerce registration certificate** (copy on plain paper) or equivalent document for foreign organisations;
- *(for Modules B, D1, F1, G)* **Technical documentation described in Article 18 of the Directive:** the documentation shall enable to ascertain the conformity of the measuring instrument with the relevant requirements of the Directive and shall include an adequate risk analysis and assessment, the design, manufacture and operation of the instrument, insofar as this is relevant for the purpose of the assessment;
- *(for Modules B)* **Specimens**, representative of the intended production, as required by Kiwa Italia in accordance with the requirements set out in the Directive;

- *(for Modules F, F1)* **Specimens** to be subjected to verification of conformity to type, as required by Kiwa Italia (such instruments may be made available at the manufacturer's premises, at Kiwa Italia's premises or at the place of installation).
- *(for Modules B)* **Evidence documentation attesting the adequacy of the technical design** of those parts of the measuring instrument for 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 Examination Certificate.**

Pursuant to the Directive, it is forbidden to submit similar applications for certification for the same category(ies) of 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 for certification decision and issue of the EU-Type Examination Certificate.

Type examination may be carried out in one of the following methods:

- examination of a sample of the complete measuring instrument that is representative of the production considered (production type);
- 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 production type and design type);
- ascertaining the adequacy of the technical design of the measuring instrument, by examining the technical documentation and supplementary documentation, without examining a specimen (design 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 subject to the application for certification and the applicable regulatory references (OIML - International Organization of Legal Metrology). Part of these activities may also be entrusted to qualified third-party laboratories or carried out at the manufacturer's site under the supervision of qualified Kiwa Italia personnel.

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

- Informs the manufacturer of its choice of testing laboratory and obtains its acceptance
- Verifies that the test programme 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 the 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 the event of Non-Conformity, the modification of the measuring instrument shall be carried out by the manufacturer (or authorised 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 may also be 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 summarising the outcome is issued to the customer.

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

Following the positive outcome of the type tests and technical file assessment, the manufacturer (or authorised 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 Recognised Quality System - Modules D, D1

The conformity assessment concerning the approval of the manufacturer's Quality System (QS) 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 in accordance with 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 verification or Stage 2.

4.3.2.1 Preliminary Audit

At the request of the manufacturer (or authorised representative), after activation of the service, it is possible to carry out a preliminary audit (optional), with the aim of assessing the degree of adequacy of the QS with respect to the Directive, for the type of measuring instruments subject to certification. The results of this audit are expressed only in terms of Non-Conformities; they do not require the manufacturer (or authorised representative) to communicate to Kiwa Italia any corrective actions it intends to undertake and are not subject to analysis for the purpose of issuing 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 Organisation by personnel with the necessary technical competence relating to the scheme and type of measuring instrument to be certified. The documentation to be subjected to documentary analysis consists of the Quality Manual and related Procedures/Instructions. Furthermore, for Module D1, the technical file shall also be subjected to documentary analysis.

The results of Stage 1 are documented and promptly communicated to the Customer Organisation; the Audit Team therefore agrees with the Organisation the details for Stage 2 and also plans the latter.

Following the performance of Stage 1, if changes in company data and activities are identified compared to what was communicated by the Customer when preparing the Quotation, the methods and duration of Stage 2 and subsequent surveillance audits may differ from those initially proposed in the Quotation.

The customer shall provide Kiwa Italia with a controlled-update copy of the Quality Manual and make it available upon request throughout the validity period of the assessment contract with Kiwa Italia and during assessment activities.

Based on the results of Stage 1, before proceeding with subsequent activities, the manufacturer is required to make any necessary amendments or additions to the assessed documentation. Kiwa Italia may request the amended documents to be submitted to a further analysis before proceeding with subsequent activities.

If, within 60 calendar days from completion of Stage 1, the Customer receives no communication, or if a Stage 2 notification is received from Kiwa Italia, the audit report shall be considered automatically confirmed. Conversely, if, following internal analysis, Kiwa Italia considers amendments to the contents of the report appropriate, it shall formally notify the Organisation, providing explanations for each amendment 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 an interval from Stage 1 sufficient to allow the Organisation to resolve the findings identified during Stage 1 and to allow Kiwa Italia to properly plan Stage 2.

The maximum period that may elapse between Stage 1 and Stage 2 shall be established by Kiwa Italia and shall ensure that the results of Stage 1 remain valid. Therefore, the product certification system, the Organisation and the regulatory and legislative context shall not undergo significant changes between the two stages.

In exceptional and duly justified cases established by Kiwa Italia, the two stages may be organised consecutively. In such cases, should Stage 1 have a negative outcome, the initial certification audit will nevertheless be completed, but a new Stage 2 audit will be required.

Stage 2 is always performed at the sites where the activities subject to certification are carried out. This audit covers all the requirements of the Directive relevant to the type of measuring instrument subject to certification.

During the initial phase of the audit, the resolution of any findings raised during Stage 1 is evaluated.

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

In the event of Non-Conformities identified during Stage 2, the manufacturer shall submit to Kiwa Italia, using the appropriate forms, proposals for the corrections and corrective actions established (following analysis and formalisation of the causes that generated them), together with the implementation timescales.

Upon receipt of the audit report and following the relevant analysis, Kiwa Italia shall confirm to the manufacturer (or authorised representative) the outcome of the audit and communicate the subsequent actions. At this stage, Kiwa Italia may request from the manufacturer (or authorised representative) any additions or amendments to the contents of the report issued by the Audit Team.

The file cannot be reviewed for certification decision until the proposals for resolution and corrective actions relating to the Non-Conformities have been received. Furthermore, before certification is granted, the resolution of all Major Non-Conformities shall also be verified according to assessment methods established by Kiwa Italia (audit at the customer's premises and/or through documentary evidence where possible). Such assessment shall be carried out within a maximum of six months from the Stage 2 audit; beyond this limit, Kiwa Italia shall decide on any consequent actions.

Verification of the implementation and effectiveness of corrections and corrective actions relating to Minor Non-Conformities is carried out by Kiwa Italia during the subsequent periodic surveillance Audit.

Following a positive certification decision, the manufacturer (or authorised representative) receives CE certification and applies the number 0476, identifying Kiwa Italia as the Notified Body, to the measuring instruments covered by the approved quality system.

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

Any requests for amendments to the certificate contents shall be submitted to Kiwa Italia in writing prior to the first available verification activity.

4.3.3 *Product Verification Assessment - Module F*

This conformity assessment is performed in relation to the type certified in accordance with 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 in accordance with Module B, by Kiwa Italia or another Notified Body.

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

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

4.3.3.1 Examinations 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 (e.g. OIML and Welmec), Kiwa Italia decides whether to carry out the tests and examinations on each individual 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 measuring system, fixed and installed in the position where it will be put into service, or at other locations (for example, the production plant).

It is the responsibility of the manufacturer (or authorised 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 authorised representative) to present the measuring instruments in homogeneous batches and to take all necessary measures to ensure that the manufacturing process guarantees the uniformity of each batch of measuring instruments produced.

The examinations are intended to assess that the measuring system subject to verification is consistent with the certified type issued in accordance with Module B.

The tests are intended to assess the conformity of the measuring system with the metrological requirements. These tests are performed using the specific material that will be processed by the measuring instrument and are based on the tests described in the Initial Verification section of the corresponding applicable OIML standard.

When the outcome of all the above verifications is positive, the Audit Team proceeds with the sealing of metrologically relevant parts using seals marked Kiwa Italia, in accordance with the legalisation plan indicated in the Certificate issued in accordance with Module B.

At the end of the test session, the Lead Auditor draws up an audit report, which is delivered to the customer.

In the presence of Non-Conformities, the process proceeds only after the manufacturer (or authorised representative) has resolved the identified Non-Conformities and Kiwa Italia has carried out a new audit (repetition of the failed examinations and/or tests) in order to assess the conformity of the new configuration of the measuring instrument.

In the case of statistical control, if a batch is accepted, all measuring instruments in the batch are approved, except for the instruments in the sample found to be non-conforming within the limits permitted by the applicable standards. If a batch is rejected, the manufacturer (or authorised representative) undertakes not to place it on the market and to arrange for its disposal.

Following a positive outcome of the assessment of the activities described above, the manufacturer (or authorised representative) receives certification and may affix notification number 0476, identifying Kiwa Italia as the Notified Body, to the measuring instruments relating 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.

For 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 examination may be carried out as follows:

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

In the event that the tests are carried out on a statistical sample of the measuring instruments, the sampling criterion is determined on the basis of the requirements of point 6.4 of Module F1 and any applicable guidance documents (WELMEC 8.10).

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

It is the responsibility of the manufacturer (or authorised 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, where applicable, the necessary test equipment.

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

4.3.4.1 Examinations and Tests on Specimens

The purpose of the examinations and tests is to assess that the instruments subject to verification comply with the requirements applicable to the type of instrument under consideration (Annex X MID-008).

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

In the event of Non-Conformities that do not exceed the prescribed quality level, the batch may be declared compliant, excluding the instruments found to be non-compliant. If the batch does not meet the prescribed quality level, the batch shall be declared non-compliant.

If a batch is rejected, the manufacturer undertakes not to place it on the market and shall arrange for its disposal.

4.3.5 Unit Verification - Module G

This conformity assessment aims to ascertain that a single specimen of a 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 specimen of the measuring instrument are carried out directly by the Kiwa Italia laboratory.

Parts of these activities may also be entrusted to qualified third-party laboratories.

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

- Informs the manufacturer of its choice of testing laboratory and obtains its acceptance
- Verifies that the test programme 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 reference standards (OIML).

In the event of Non-Conformity, the modification of the measuring instrument shall be carried out by the manufacturer (or authorised representative), who shall repeat 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 Team proceeds with the sealing of the metrologically relevant parts using seals marked Kiwa Italia.

4.3.6.1 Analysis of the Technical File

See § 4.3.5.3.

4.4 Maintenance Audits

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

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

The manufacturer (or authorised representative) undertakes to maintain the Quality System in an adequate and effective condition.

Kiwa Italia also reserves the right to carry out audits without prior notice and, on such occasions, to perform or have tests performed on the product.

The need for and frequency of such unannounced audits are determined by Kiwa Italia after taking into consideration the initial assessment of the quality system, previous information relating to the manufacturer, relevant economic operators, instruments manufactured and any complaints received.

4.4.1 Surveillance Audits in accordance with Modules D, D1 of the Directive

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

Surveillance Audits are carried out once a year with reference to the month of expiry of the certificate[1]. They are always conducted at the locations where the activities related to the approved Quality System subject to certification are performed.

During surveillance audits, the resolution of Non-Conformities raised during previous audits is assessed, together with the implementation and effectiveness of corrective actions undertaken by the manufacturer (or authorised representative).

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

The report shall be deemed confirmed if no further communication is received by the Organisation within 60 calendar days.

In the event of Non-Conformity, the manufacturer shall submit to Kiwa Italia, within 20 working days and using the appropriate forms, the proposed corrections and corrective actions established (following analysis and formalisation of the causes that generated them), together with the related implementation timescales. Should the Organisation receive no communication within 30 working days from submission, the defined treatment and action plan shall be deemed automatically accepted.

In the case of Major Non-Conformities, Kiwa Italia shall communicate to the manufacturer (or authorised representative) the consequent actions to be taken: audit at the customer's premises and/or verification through documentary evidence where possible. The timing of such verification shall be established by Kiwa Italia according to the severity and number of the recorded Non-Conformities.

Should the manufacturer (or authorised representative) fail to implement the agreed actions for resolving the findings within the permitted timeframes, certification may be suspended or withdrawn by decision of Kiwa Italia.

The postponement of an Audit that has already been planned and agreed, for reasons attributable to the Organisation, shall be communicated to Kiwa Italia at least 30 days before the scheduled date; otherwise, a penalty equal to 50% of the planned fee, in addition to any expenses incurred, shall be charged.

The performance of the surveillance audits provided for in the certification cycle is subject to payment of all previous activities by the Organisation.

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

a. requests to the manufacturer concerning aspects related 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 (paper or electronic).

These other forms of monitoring may be applied by Kiwa Italia depending on: information received from external sources, audit results, input from the Accreditation Body or the competent authority, etc.

Kiwa Italia may also carry out unannounced surveillance Audits at the manufacturer's facilities, taking into consideration the following factors:

[1] The date of the first surveillance audit following Stage 2 shall not exceed 12 months from the date of the certification decision.

- type of instruments manufactured;
- results of previous surveillance and renewal audits
- any Non-Conformities identified during surveillance and renewal audits
- need to ensure control of corrective measures (e.g. Corrective Actions)
- where applicable, special conditions associated with approval of the QS
- significant changes in the Manufacturer's organisation (e.g. production/manufacturing techniques, test techniques and methods, controls and Final Verifications).

During such unannounced audits, Kiwa Italia may perform tests in order to ascertain the actual and correct implementation of the company QS and final verification activities.

At the end of each audit, Kiwa Italia issues an Audit Report containing any Non-Conformities identified, together with the methods and timescales for their resolution or for the implementation of Corrective Actions.

As part of the maintenance of certification issued in accordance with the applicable Directive, Kiwa Italia keeps the manufacturer (or authorised representative) of the certified product informed of any significant change that may affect the validity of the EU-type Examination Certificate.

4.4.2 Renewal Audit in accordance with Modules D, D1 of the Directive

Before certification expiry, Kiwa Italia performs a renewal audit at the manufacturer's (or authorised representative's) premises, the main purpose of which is to assess, including through documentation review, that the manufacturer (or authorised representative) continues to maintain valid an approved Quality System in compliance with the provisions of the Directive.

The Renewal Audit is planned in such a way as to cover all the requirements of the applicable 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 then submitted for internal review and approval by Kiwa Italia for certification decision.

As regards the management of any Non-Conformities and the certification decision phase, the provisions of § 4.3.2.3 above shall apply.

The renewal activity, including the proper management of any Non-Conformities identified, shall be completed before expiry of the certificate. The certificate validity period shall again be three years.

4.5 Verification of 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 authorised representative) undertakes to communicate to Kiwa Italia all changes made to the measuring instrument or to the approved design that may affect its conformity with the essential requirements, the conditions of validity of the certificate or the intended conditions of use of the measuring instrument, and all planned modifications to the approved quality system. On the basis of these changes, Kiwa Italia assesses which supplementary assessment activities need to be carried out.

See also the provisions of *the Kiwa Regulation for Certification*, point 5.2.

Depending on the type of changes, a quotation is prepared, the contractual conditions are reviewed and the technical activities are planned in accordance with the provisions of the preceding paragraphs. Each product modification is approved through review for certification decision and issue of the amended Certificate.

The certificate shall be revised as soon as the measuring instrument no longer complies with 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 authorised representative changes, Kiwa Italia amends the existing EU-type Examination Certificate. Such amendment requires additional approval in the form of a supplement or a revision to the original EU-type Examination Certificate. The design characteristics of the type remain unchanged; therefore, assessment of the measuring instrument is not required. The recipient of the EU-type Examination Certificate shall in all cases be the manufacturer.

4.6 Communications with the Competent Authority

Kiwa Italia makes the list of certificates issued, modified, suspended, withdrawn 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 any additions thereto.

Upon request, the Commission and the 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 documentation relating to the issuance of certification available to the Competent Authorities.

5 SUSPENSION, WITHDRAWAL OR REDUCTION OF CERTIFICATION

Certification may be suspended, withdrawn or reduced for the reasons specified in *the Kiwa Regulation for Certification* or at the request of the Manufacturer (or authorised representative).

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

- Whether to allow the manufacturer (or authorised representative) to continue placing on the market the measuring instruments already manufactured at the date of suspension/withdrawal/reduction.

Except in exceptional cases (in any event determined by Kiwa Italia or by the Competent Authority), the suspension period may not exceed six months, otherwise the certification shall be withdrawn.

During the suspension period, the manufacturer (or authorised representative) loses the right to use the CE metrological marking and the certificate. The conditions for reinstating suspended certification (including the necessary conformity assessment activities) shall be established by Kiwa Italia according to the reasons that led to the suspension and the duration of the suspension.

Should the manufacturer (or authorised representative) fail to implement the actions specified by Kiwa Italia for the reinstatement of suspended certification, the certification shall be withdrawn or, where applicable, its scope shall be reduced.

Reduction of certification entails the issue of a new certificate indicating the types of measuring instruments for which certification remains valid and the withdrawal of the previous certificate.

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

Following withdrawal of certification, the manufacturer (or authorised representative) loses the right to use the metrological marking, the CE marking and the certificate. The manufacturer (or authorised representative) may restart the certification process by submitting a new application.

Kiwa Italia shall inform the competent Market Surveillance Authorities, the other Notified Bodies and the Accreditation Body of any suspension, withdrawal or reduction measure.

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

6.1 Incorrect Use of the Certification and CE Marking

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

In addition to the provisions of *the Kiwa Regulation for Certification*, the following rules shall apply.

The use of the CE marking is considered incorrect when:

1. it is affixed to measuring instruments:
   - For which an application for certification has not yet been submitted or for which the application has been rejected;
   - Which do not conform to the scope covered by the certificates;
   - for which the certificates have been withdrawn/suspended/reduced**;**
2. Where the certificate has expired and has not yet been renewed;
3. Where the manufacturer (or authorised representative) has not implemented the modifications required by Kiwa Italia.

Should any incorrect use of the certification, certificate and/or CE marking be identified, Kiwa Italia shall withdraw from the manufacturer (or authorised representative) the right to affix the CE marking and to use the certification, and shall notify the Competent Authority accordingly.

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

6.2 Use of the certification mark

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

7 MANUFACTURER'S OBLIGATIONS

By accepting this regulation, and in addition to all provisions contained in *the General Terms and Conditions* and *in the Kiwa Regulation for Certification*, the manufacturer (or authorised representative) shall, when applying for certification, undertake to comply with the following requirements:

- Not to have submitted a similar application for certification for the same category(ies) of measuring instrument to another Notified Body;
- Communicate to Kiwa Italia all locations where the measuring instrument is manufactured, particularly where such locations do not correspond to the operational premises of the manufacturer (or authorised representative);
- Communicate to Kiwa Italia any modifications introduced to the instrument (to the approved type in the case of Module B) and/or to the approved Quality System following the granting of certification by Kiwa Italia;
- undertake to affix the CE marking to each measuring instrument complying with the applicable requirements of the Directive, the supplementary metrological marking and, where required by the Directive, the identification number 0476 of Kiwa Italia as Notified Body;
- Keep the EU Declaration of Conformity available for a period of ten years from the placing on the market of the instrument;
- Ensure that the measuring instrument complies with all applicable European Directives;
- Make available to Kiwa Italia inspectors one or more measuring instruments covered by certification in order to verify the performance of checks and calibration verifications during surveillance and renewal audits;
- The manufacturer shall possess suitable equipment together with an associated maintenance and calibration programme ensuring metrological traceability, for those modules requiring the manufacturer to independently perform final checks and tests for placing products on the market.

Only for assessments relating to Module B of the Directive

Keep a copy of the EU-type Examination Certificate, its annexes, supplements and amendments, together with the technical documentation, for a period of ten years from the manufacture of the last measuring instrument.

Only for assessments relating to Modules D, D1 of the Directive

Keep the following available for a period of ten years from the placing on the market of the last instrument:

1. the documentation submitted during the application stage referred to in point 3.1 of Module D and point 5.1 of Module D1 of the Directive;
2. the modifications and related approvals referred to in point 3.5 of Module D and point 5.5 of Module D1 of the Directive;
3. the decisions and reports transmitted pursuant to points 3.5, 4.3 and 4.4 of Module D and points 5.5, 6.3 and 6.4 of Module D1 of the Directive.

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

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

8 COMPLAINTS AND APPEALS

8.1 Complaints

Any interested party may submit a documented complaint concerning its relationships pertaining to certification activities with Kiwa Italia.

Such complaint may arise from problems occurred during the certification process, such as delays in carrying out the various phases and/or inappropriate conduct by the Body's Auditors.

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

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

Kiwa Italia shall determine together with the complainant whether, and to what extent, the content of the complaint and its resolution shall be made public.

8.2 Appeals

Where a customer Organisation intends to challenge a decision taken by Kiwa Italia, it may submit an appeal in writing.

The appellant shall state the grounds for the appeal and, where the appeal relates to a decision taken by Kiwa Italia (e.g. the recording of a Major Non-Conformity), it shall be submitted to Kiwa Italia within 10 calendar days from the date on which the decision was communicated.

The assessment and any approval are carried out by personnel not involved in the process that is the subject of the appeal.

Kiwa Italia shall provide the appellant with a written response and shall notify any actions to be taken within 30 working days from receipt of the appeal.

To ensure impartiality, appeals are managed by functions not involved in the activities that are the subject of the appeal.

Detailed procedures for submitting complaints and appeals are available on the website www.kiwa.it.

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

9 MODIFICATION OF THE CERTIFICATION SCHEME

Kiwa Italia keeps abreast of technological developments generally recognised as state of the art, indicating whether the approved type may cease to comply with the applicable requirements of the Directive, and determines whether such developments require further investigation. In such cases, Kiwa Italia shall inform the manufacturer accordingly.

It remains, however, the responsibility of the manufacturer to verify that its technical product documentation and related procedures are updated to the latest available version of the applied standard and/or are, from a technical perspective, 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.

Should the manufacturer fail to comply with such requests, Kiwa Italia shall withdraw the certificate.

Where substantial changes are made to the rules/requirements of the certification scheme, Kiwa Italia shall inform certified Organisations or Organisations undergoing certification, taking into account any observations submitted by them. Such changes may concern:

- The applicable Standard or Directive;
- This Regulation;
- Additional requirements of the Accreditation Body or the Competent Authority.

Kiwa Italia shall communicate such changes in writing to customer Organisations, indicating the nature of the change, the methods and the deadline by which the Organisation shall comply.

If the changes are not accepted, the Organisation may renounce certification by providing 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 Organisation at least six months before the effective date of withdrawal. Withdrawal by Kiwa Italia entails the withdrawal of the certification issued. The Organisation shall in any case be required to pay Kiwa Italia the amounts due for the services provided during the notice period, as established in the latest valid quotation.

Should the Organisation wish to withdraw from the contract, unilateral withdrawal during the validity period of the Certification shall be subject to compliance with the notice periods established in the *General Terms and Conditions* and in *the Kiwa Regulation for Certification*.

In particular, where notice of less than three months but more than two weeks is given before the scheduled Audit, the Customer shall be required to pay 50% of the amount relating to the fee due for the next activity provided for under the contract. For notice periods of less than two weeks, the provisions of the *General Terms and Conditions* shall apply.

In the event of contract termination, Kiwa Italia shall issue an invoice in respect of the costs associated with closing the certification file, in accordance with the latest valid quotation.

11 UNILATERAL AMENDMENT OF THE CONTRACT

Kiwa Italia reserves the right to amend this Regulation at any time. Any new clauses and/or amendments introduced shall become effective from the date on which they are communicated to the customer in writing.

Any Organisation that does not intend to accept the amendments may withdraw from the contract by giving written notice by registered letter with acknowledgement of receipt or certified email within 30 calendar days, failing which the right shall lapse, starting from the day following communication to Kiwa Italia.

The withdrawal shall become effective on the last working day of the month in which the communication from the customer is received.