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Rev.	Description of changes	Date
7	Added reference to new Kiwa Regulation and relevant alignments (removed parts described in the Regulation). Introduction of Market Surveillance Visit and Accredia findings transposition	2018-02-26
6	Added reference to Legislative Decree no. 84 of 19/05/2016	2016-05-19

Checked by:

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1. SCOPE AND PURPOSE

This Regulation defines the rights and duties, as well as the operational methodology that governs the relationships between Kiwa Cermet Italia S.p.A. (hereinafter referred to as Kiwa Cermet) and the Customer Organisations, in the provision of the Certification services pursuant to Legislative Decree no. 84 of 19/05/2016, implementing Directive 2014/32/EU (hereinafter referred to as the "Directive") of the European Parliament and of the Council of 26 February 2014 on measuring instruments to be used for legal metrology and of Legislative Decree 22/2007.

The requirements stated in this Regulation are an integral part of the agreement stipulated with Kiwa Cermet (quotation, *The Kiwa Regulation for Certification* and *General Terms and Conditions of Kiwa Cermet Italia for the performance of orders* – hereinafter *General Terms and Conditions*). These requirements refer solely to the aspects specifically connected with the scope of the requested certification.

These Regulations set out the rules for putting into effect the procedures to be used for assessing the conformity of measuring instrument types according to the Directive in relation to the Conformance Assessment Forms for which Kiwa Cermet is authorised by the Competent Authority as a Notified Body.

The contract expressly excludes any form of consultancy to the Customer that could jeopardise the nature of independence of the carried out assessments.

This Regulation is also available on the Kiwa Cermet website (www.kiwacermet.it).

2. GENERAL PRINCIPLES AND GUARANTEES FOR THE CUSTOMER

In its certification processes, as well as the *General Terms and Conditions*, Kiwa Cermet applies the following principles:

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

b) Impartiality and independence: ensured through the following measures:

- Certification procedures are assigned to personnel with no interests in the Organisation being certified, bound to observe the rules of conduct and independence set by Kiwa Cermet; regarding this aspect Kiwa Cermet undertakes to investigate any justified concerns of the Customer concerning the existence of incompatibility of the duty assigned which could compromise the impartiality or independence of judgement. Impartiality is furthermore guaranteed by the involvement of dedicated bodies that govern the way in which the services of Kiwa Cermet are administered;
- On time implementation of formalised rules and procedures in use by all personnel certification and periodic consultation with certification stakeholders;
- Separation between the personnel carrying out audits and the personnel responsible for the certification decision;
- Total abstention from the performance of assistance activities in the definition and application of the requirements for obtaining the Certification.

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

d) In addition to what is regulated in the General Terms and Conditions and the Kiwa Regulation for Certification, Kiwa Cermet undertakes to make all staff, including its auditors, a commitment to confidentiality, as well as a document in which the staff undertakes to process any data entered in possession in compliance with the provisions of the Privacy Act.

e) Accreditation and Notifications: Kiwa Cermet undertakes to inform the client of any rejection, suspension or withdrawal of the accreditation and/or ministerial notification; in such cases Kiwa Cermet will be in no way responsible for any damages caused to the client by rejection, suspension or withdrawal of the accreditation or notification; in the aforementioned cases, the client has the right to opt out of the contractual relationship with Kiwa Cermet, without the need for prior notification and without any additional costs.

3. REQUIREMENTS FOR THE CERTIFICATION

3.1 General requirements

Before embarking upon the Certification process with Kiwa Cermet, the Organisation must satisfy the following requirements:

- Accept the conditions set out in this Regulation;
- Authorise access to offices, factories, areas and information needed to perform the Audit;
- Designate their own Representative as the main contact person for the Audit Team and make any consultants present during the Audit play the role of observer;
- Be responsible for applying the requirements prescribed by the laws in force on matters of safety in the workplace. In the absence of binding provisions, the Organisation agrees to provide Kiwa Cermet with complete and detailed information regarding the specific risks existing at the facilities where Kiwa Cermet personnel is expected to operate and PPE necessary for carrying out the appointment, informing Kiwa Cermet personnel concerning their correct use. In this regard, the Organisation has to provide appointed Kiwa Cermet personnel the Company documentation concerning the workplace safety (D.V.R., safety plan, procedures, etc.), limited to aspects of specific interest. If for such omissions, injuries occur or illnesses are contracted, no charges may be made, for any reason against Kiwa Cermet;
- Accept, without additional costs, the possible presence of Auditors from the accreditation or Competent Authority, as observers during the audit. Kiwa Cermet will inform the Organisation with regard to the possible presence of these auditors with a clear introduction of roles. Their presence has the aim of assessing that the evaluation methods used by Kiwa Cermet are compliant with the requirements for accreditation.
- Accept possible controls carried out by the Accreditation Body. In addition, in order to ensure that the assessment procedures adopted by Kiwa Cermet comply with the applicable standards, the Accreditation Body may require to conduct a visit, called Market Surveillance Visit, directly through the use of their personnel at the certified Organisation. This potential visit, is communicated by the Accreditation Body to Kiwa Cermet with 7 working days notice. Upon receipt of such communication Kiwa Cermet will inform the Organisation. The audit plan is prepared by the Accreditation Body, which it will make available to Kiwa Cermet; then Kiwa Cermet will send it to the Client Organisation. If the Organisation does not grant its approval, the validity of the certificate is suspended until it has not accepted the visit, for a maximum period of 3 months. After 3 months, in the absence of approval for the visit, the certification is withdrawn. The Organisation shall make available to the Accreditation Body the documentation that Kiwa Cermet has taken as a reference during the previous audits. The Market Surveillance Visit does not replace the normal maintenance certification audit provided by the Audit Programme. The Market Surveillance Visit procedures are indicated in the IAF ID 04 document (free download from the IAF website: www.iaf.nu). Other methods of control can be adopted by the accreditation Body, in order to verify the activities of Kiwa Cermet, e.g. unannounced audit at the premises of certified subjects, request of information to Organisations or Consulting Company, or other methods of control established by the accreditation body.

3.2 Classification of issues

Each issue found during the course of the Audits is classified in the following way:

Major non-conformity: a deviation or total absence of conformity to the requirements, found on the basis of objective evidence, as a result of the assessment activities.

Minor non-conformity: a deviation or partial absence of conformity to the requirements, found on the basis of objective evidence, as a result of the assessment activities.

Several minor conformities pertaining to the same requirement, depending on the content and the general outcome of the Audit, can lead to a major NC being issued.

Minor non-conformities not resolved and/or not taken in hand by the Organisation can lead to the issuing of a major NC.

Opportunities for improvement: anything not coming within the definitions of non-conformities and which constitutes a potential improvement in the effectiveness of the solutions adopted by the client, to ensure conformity with requirements and to prevent deviations.

4. ASSESSMENT PROCESS REQUIREMENTS

4.1 Introduction

The activities of Kiwa Cermet are carried out in compliance with all the requirements that must be possessed by Notified Bodies, in accordance with what is prescribed at national level by the Competent Authority.

The manufacturer is responsible for the design and manufacture of a product covered by the Directive, in view of making it available on the Community market. The drafting of technical documentation, the CE marking and the issuance of the EU Declaration of Conformity fall within its exclusive competence. The CE marking and the issuance of the EU Declaration of Conformity can be carried out by the authorised representative if explicitly provided for in the mandate.

An importer or a distributor shall be considered a manufacturer for the purposes of the Directive and shall be subject to the related obligations when the latter makes available on the market a measuring instrument under its own name, or based on a trademark, or modifies a measuring instrument already available on the market, in such a way as to affect its compliance with the provisions of the Directive.

The authorised representative shall be established within the European Union and shall be formally appointed by the manufacturer, acting in the name and on behalf of the latter at a minimum as specified in the mandate and as required by Article 9, paragraph 2 of the Directive.

The manufacturer shall choose, in accordance with Article 17 of the Directive, the procedures for assessing conformity of a measuring instrument to the essential requirements pertaining to it, as listed in the specific Annex for the measuring instrument, the Forms and the measuring instruments of the Directive for which Kiwa Cermet is authorised to operate by the Competent Authority.

Conformity assessment procedures:

Form B* *EU Type Examination*

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

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

Form E *Declaration of type conformity based on the quality assurance of the tools;*

Form F* *Declaration of type conformity based on product verification;*

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

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

Form H *Declaration of conformity based on full quality assurance;*

Form H1 *Declaration of conformity based on full quality assurance plus design examination.*

The forms marked with an (*) do not constitute a procedure for attesting conformity on their own

MEASURING TOOLS:

- **MI – 005**: Measuring Systems for the 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-up of the certification process

The manufacturer (or its authorised representative) submits a request for certification to Kiwa Cermet specifying the measuring instrument category/categories for which it intends to obtain certification, the option chosen for assessing the measuring instrument and makes available the following documentation in Italian, eventually accompanied by examples of instruments:

- *(for all Forms)* **Chamber of Commerce Registration Certificate** (simple, not requiring any duty stamp) or an equivalent document for foreign use;
- *(for Forms B, D1, F1, G, H1)* **The technical documentation described in Article 18 of the Directive:** the documentation must make it possible to ascertain the conformity of the measuring instrument with the relative requirements of the Directive; it includes an adequate analysis and assessment of risks, the design, manufacture and operation of the instrument, to the extent in which it is pertinent for the purposes of assessment;
- *(for only Form B)* **Specimens** that represent the production envisaged, as requested by Kiwa Cermet in relation to the provisions indicated in the Directive;
- *(for Forms F, F1)* **Specimens** to be subjected to verification of type conformity as requested by Kiwa Cermet (these instruments may be made available at the manufacturer's premises, at Kiwa Cermet's premises or at the installation site).
- *(for Forms B, H1)* **Documentary evidence proving the adequacy of the technical** design of the parts of the measuring instrument for which no specimens are requested;
- *(for Forms D, D1, E, H, H1)* **Documentation on the quality system:** Quality Manual and main procedures;
- *(for Forms D, E, F)* **Technical documentation on the type approved and a copy of the EU type-examination certificate.**

Under the terms of the Directive, it is forbidden to submit similar requests for certification of the same measuring instrument category/categories to other Notified Bodies.

4.3 Verification of Certification Conformity with the Directive

4.3.1 EU Type Examination - Form B

The EU Type examination consists of technical assessments that are carried out by Kiwa Cermet in order to ascertain whether the technical design of a measuring instrument satisfies the pertinent stipulations of the Directive.

To this end, the assessment activities carried out by Kiwa Cermet are as follows:

- type testing;
- documental analysis of the technical documentation (technical file);
- review for decision and issuing of the EU Type examination certificate.

The type-examination can be carried out in one of the following ways:

- the examination of one complete specimen of the measuring instrument representative of the production considered (production type);
- the examination of specimens of one or more critical parts of the measuring instrument representative of the production envisaged. In this case, during the document analysis stage, the adequacy of the technical design of the other parts of the measuring instrument is also assessed, through a review of the technical documentation and supporting evidence (combination of production type and project type);
- an assessment of the adequacy of the technical design of the measuring instrument, through a review of the technical documentation and supporting evidence, without examination of a specimen (design type).

4.3.1.1 Type testing

Type tests are carried out directly by the Kiwa Cermet laboratory, once the representative specimens to be tested have been identified, according to the measuring instruments for which certification is being sought and the applicable reference standards (OIML - Organisation Internationale de Métrologie Légale). 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 qualified Kiwa Cermet personnel.

The tests are conducted in conformity with procedures set by the laboratory based on the applicable reference regulations (OIML).

In the event of Non-conformities, modifications must be made to the measuring instrument by the manufacturer (or its authorised representative) and Kiwa Cermet arranges for a repeat of the tests deemed necessary, following the modifications made.

At the end of the test session, a test report is written which is then sent to the client.

4.3.1.2 Analysis of the technical file

The analysis of the technical documentation generally takes place on completion of the tests, but it may be carried out before or during testing by staff with the necessary technical competence for the scheme and type of measuring instrument to be certified.

On completion of the technical file examination, a report with a summary of the results is issued to the client.

According to the results of the documentation examined, the manufacturer (or its authorised representative) has to make the necessary modifications or additions. Kiwa Cermet may request the modified documents to be submitted for a new evaluation before moving on to the next stage.

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

The EU Type examination certificate is valid for 10 years from the date of issue.

4.3.2 Assessment of the Recognised Quality System - Forms D, D1, E and H

The conformity assessment regarding the approval of the manufacturer's Quality System (QS) is applicable to the following Forms:

- ***Form D:*** for a Recognised Quality System covering the production process and final product inspection and testing;
- ***Form E:*** for Recognised Quality System covering the final product inspection and testing;
- ***Form H:*** for a recognised Quality System, concerning the design, manufacture, inspections and final tests carried out on the product;
- ***Form D1:*** for a Recognised Quality System covering the production process and final product inspection and testing.

For Forms D and E it is essential that the measuring instrument has already been Certified according to Form B *EU Type examination* (§ 4.3.1) by a Notified Body.

The assessments carried out by Kiwa Cermet, in relation to the aforementioned Forms, are:

- Preliminary Audit (optional);
- Stage 1;
- Verification of certification or Stage 2.

4.3.2.1 Preliminary Audit

At the request of the manufacturer (or its authorised representative), once the service has been activated, a preliminary (optional) verification can be carried out, with the aim of evaluating the level of adequacy of the QS in relation to the Directive, for the type of measuring instruments to be certified. The results of this Audit are only expressed in terms of Non-conformities, they do not require the manufacturer (or its authorised representative) to notify Kiwa Cermet of the corrective actions it intends to take and they are not subject to examination for the purposes of issuing certification.

4.3.2.2 Stage 1

Stage 1 is the first stage of certification verification and also includes analysis of the documentation. Stage 1 is generally conducted on the premises of the Organisation, by staff with the necessary technical competence for the scheme and type of measuring instrument to be certified. The documents to be submitted for analysis are the Quality Manual and correlated Procedures/Instructions. In addition, for Form D1, the technical file will also need to be submitted for analysis.

The results of Stage 1 are documented and promptly communicated to the client Organisation; the Audit Team then agrees with the Organisation the details for Stage 2, also dealing with the planning of it.

Following Stage 1, if any modifications to the data and company activities are found compared to what was communicated by the Customer at the time of drawing up the quotation, the methods and duration of Stage 2 and of the subsequent surveillance Audits may differ from what was initially put forward in the quotation.

The client must provide Kiwa Cermet with an approved and updated copy of the Quality Manual and make it available on request, for the entire period of the assessment contract with Kiwa Cermet and during the assessment activities.

Depending on the results of Stage 1, before being able to proceed, the manufacturer must make the necessary modifications or additions to the documentation assessed. Kiwa Cermet may request the modified documents to be submitted for a new evaluation before moving on to the next stage.

If within 60 calendar days of the end of Stage 1, the Customer has not received any communication, or received notification of Stage 2 from Kiwa Cermet, the review report may be considered automatically confirmed. On the contrary if, following internal examination, Kiwa Cermet considers that any modifications need to be made to the content of the report, it will give formal notification to Organisation, providing explanations for each variation made and indications of the subsequent actions.

4.3.2.3 Verification of Certification or Stage 2

The purpose of the Stage 2 is to evaluate the implementation, as well as the effectiveness, of the Customer Management System.

Stage 2 is planned to take place within a certain time period after Stage 1, in such a way as to allow the Organisation to resolve the issues that emerged in Stage 1 and for Stage 2 to be planned efficiently by Kiwa Cermet.

The maximum time that can elapse between Stage 1 and Stage 2 will be decided by Kiwa Cermet and must be such as to guarantee that the results of Stage 1 are still valid. The product certification system, the Organisation and the regulatory and legislative context must not therefore undergo significant variations between the two stages.

In exceptional circumstances and for substantiated reasons, decided by Kiwa Cermet, the two stages may be carried out consecutively. In such instances if the result of Stage 1 is negative, the initial certification review will be completed just the same, but a new Stage 2 Audit will need to be undertaken.

The Stage 2 Audit always takes place on the premises where the processes that are the subject of the certification are carried out. This Audit extends to all requirements of the Directive and depends on the type of measuring instrument being certified.

At the start of Audit, the resolution of any issues notified in Stage 1 is assessed.

At the end of the Audit, the Audit Team issues a copy of the Audit report to the client, who signs it.

For any Non conformities found in Stage 2, the manufacturer must send Kiwa Cermet, on the relevant forms, its proposal for making the corrections and taking the corrective actions agreed (along with an analysis and formalisation of the causes that generated them), with a timescale for implementation.

On receiving the Audit report, and following the relative examination, Kiwa Cermet will confirm to the manufacturer (or its authorised representative) the result of the Audit and will give notification of the subsequent actions. In this phase, Kiwa Cermet may ask the manufacturer (or its authorised representative) to make any additions or modifications necessary in relation to the contents of the report issued by the Audit Team.

The process cannot be examined for the final decision until the proposal for resolving and taking the corrective actions for the Non-Conformities has been received. Furthermore, before certification is released, it must also be verified that major Non-conformities have been resolved, according to the assessment methods set by Kiwa Cermet (audit on the client's premises and/or through documented evidence, where possible). This assessment must take place no later than 6 months following the Stage 2 review; beyond this deadline, it will be at the discretion of Kiwa Cermet to evaluate the consequent actions to be taken.

The assessment of the implementation and effectiveness of the corrections and corrective actions concerning minor non-conformities is carried out by Kiwa Cermet in the subsequent periodic surveillance Audit.

If the certification decision is positive, the manufacturer (or its authorised representative) receives the CE certification and applies the number 0476, which identifies Kiwa Cermet as the Notified Body, to the measuring instruments covered by the approved Quality System.

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

Any requests for changes to the content of the certificate must be sent to Kiwa Cermet in writing and prior to the first useful verification review.

4.3.3 Assessment of Full Quality Assurance System and Design examination – Form H1

This conformity assessment concerns approval of the manufacturer's full quality assurance system for the design, production process, final product inspection and testing and the design examination.

To this end, the assessment activities carried out by Kiwa Cermet are as follows:

- Stage 1;
- Verification of certification or Stage 2.
- Design examination.

4.3.3.1 Preliminary Audit

See the information given in § 4.3.2.1.

4.3.3.2 Stage 1

See the information given in § 4.3.2.2.

4.3.3.3 Verification of Certification or Stage 2

See the information given in § 4.3.2.3.

4.3.3.4 Design examination.

The design examination consists of an analysis of the technical documentation (technical file and Design plan) and is conducted, unless otherwise agreed by the parties, on the premises of Kiwa Cermet by staff with the necessary technical skills for the scheme and type of measuring instrument to be certified.

If there are any Non-conformities, the process will not continue until the manufacturer (or its authorised representative) has sent Kiwa Cermet an updated technical file and/or Design plan demonstrating resolution of the Non-conformities found.

Following the positive outcome of the documental analysis of the Quality System documentation, the on-site audit and the design examination, the manufacturer (or its authorised representative) receives the certification and applies the number 0476, which identifies Kiwa Cermet as the Notified Body, to the measuring instruments covered by the approved quality system.

The Certificate for the Approved Quality System, is valid for 3 years from the date of issue.

The Certificate for the design examination assessed is valid for 10 years from the date of issue.

4.3.4 Product Verification Assessment - Form F

This conformity assessment is conducted depending on the type of Certificate according to Form B (§ 4.3.1) and the essential requirements of the Directive that apply. It is therefore essential that the measuring instrument has already been certified in accordance with Form B, by Kiwa Cermet or by another Notified Body.

To this end, the assessment activities carried out by Kiwa Cermet are as follows:

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

4.3.4.1 Examinations and tests

Depending on the type of instrument, the requirements of point 5.3 of Form F, the specific Form referring to the type of instrument (MI-XX) and any applicable standards (OIML and Welmec), Kiwa Cermet decides whether to carry out the tests and examinations on each individual instrument rather than on a statistical basis; Kiwa Cermet also decides whether to carry out the tests and examinations on the site where the measuring system is installed, fixed and in the position where it will be put into service, or in other places as well (for example the production facility).

It is the manufacturer's (or its authorised representative's) responsibility to provide Kiwa Cermet with all the relevant useful information for the final use of the measuring instrument, including supplying the specific measuring device and any test instruments.

In the event of statistical verification, it is also the manufacturer's (or its authorised representative) responsibility to present their measuring instruments in homogenous batches and to take all necessary measures to ensure the manufacturing process guarantees the homogeneity of each batch of measuring instruments produced.

The purpose of the examinations is to assess whether the measuring system being verified is consistent with the Type Certificate issued in conformity with Module B.

The purpose of the tests is to assess whether the measuring system conforms to the metrological requirements. These tests are conducted using the specific material that the measuring instrument will be used for, and are based on the tests described in the paragraph entitled *Initial verification* of the corresponding OIML standard that applies.

When the outcome of all the aforementioned verifications is positive, the Audit Team seals the metrologically important parts with seals marked Kiwa Cermet, according to the legalisation plan indicated in the Certificate issued in conformity with Form B.

At the end of the test session, the Lead Auditor writes a report on the verification, which is given to the client.

Where Non-conformities are discovered, the process only continues once the manufacturer (or its authorised representative) has resolved the Non-conformities identified and Kiwa Cermet has conducted a new audit (repeating the examinations and/or tests not passed) in order to assess the conformity of the new measuring instrument configuration.

In the event of statistical verification, if a batch is accepted, all the measuring instruments in that batch are approved, with the exception of those 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 its authorised representative) undertakes not to release it on the market and to dispose of it.

Following positive outcome of the analysis of the aforementioned activities, the manufacturer (or its authorised representative) receives the certification and may apply the notification number 0476, which identifies Kiwa Cermet as the Notified Body, to the measuring instruments covered by the verified product.

4.3.5 Product Verification assessment – Form F1

The purpose of this conformity assessment is to ascertain whether the measuring instruments conform to the requirements of the Directive.

To this end, the assessment activities carried out by Kiwa Cermet are as follows:

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

Depending on the type of measuring instrument and the size of the batch, the examination may be conducted in the following ways:

- complete tests on all the measuring instrument specimens or;
- complete tests on one measuring instrument specimen; all the other measuring systems are subjected to the same tests described in the paragraph entitled Initial verification of the corresponding applicable OIML standard and to examinations that verify whether these measuring instruments are manufactured in the same way as the instrument on which the complete tests were carried out;
- complete testing of a statistical sample of the measuring instruments.

Where tests are carried out on a statistical sample of measuring instruments, the sampling criterion is decided on the basis of the requirements of point 6.4 of Form F1, the specific MI-XXX Annex and any applicable regulations.

Kiwa Cermet also decides whether to carry out the tests and examinations on the site where the measuring system is installed, fixed and in the position where it will be put into service, or in other places as well (for example the production facility).

It is the manufacturer's (or its authorised representative) responsibility to provide Kiwa Cermet with all the relevant useful information for the final use of the measuring instrument, including supplying the specific measuring device and any test instruments.

In the event of statistical verification, it is also the manufacturer's (or its authorised representative) responsibility to present their measuring instruments in homogenous batches and to take all necessary measures to ensure the manufacturing process guarantees the homogeneity of each batch of measuring instruments produced.

4.3.5.1 Complete tests on one specimen

Complete tests on one specimen of the measuring instrument are carried out directly by the Kiwa Cermet Laboratory. The tests are conducted in conformity with procedures set by the laboratory based on the applicable reference regulations (OIML).

In the event of Non-conformities, the measuring instrument must be modified by the manufacturer (or its authorised representative). Kiwa Cermet repeats the tests deemed necessary following the modifications made.

At the end of the test session, a test report is written which is then sent to the client.

4.3.5.2 Examinations and tests on other specimens

The purpose of examinations is to assess whether the measuring system being verified is consistent with the specimen on which the complete tests have been carried out.

The purpose of tests is to assess the conformity of the measuring system with the metrological requirements. These tests are conducted using the specific material that the measuring instrument will be used for, and are based on the tests described in the paragraph entitled *Initial verification* of the corresponding OIML standard that applies.

When the outcome of all the aforementioned verifications is positive, the Audit Team seals the metrologically important parts with seals marked Kiwa Cermet.

At the end of the test session, the Lead Auditor writes a report on the verification, which is given to the client.

Where Non-conformities are found, the process only continues once the manufacturer (or its authorised representative) has resolved the Non-conformities found and Kiwa Cermet has conducted a new audit (repeating the examinations and/or tests not passed) in order to assess the conformity of the new measuring instrument configuration.

In the event of statistical verification, if a batch is accepted, all the measuring instruments in that batch are approved, with the exception of those 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 its authorised representative) undertakes not to release it on the market and to dispose of it.

4.3.5.3 Analysis of the technical file

The analysis of the technical documentation generally takes place on completion of the tests, but it may be carried out before or during testing by staff with the necessary technical skills for the scheme and type of measuring instrument to be certified.

For some parts of the measuring instrument, the adequacy of the technical design may be ascertained through an examination of the technical documentation and of the supporting evidence.

On completion of the technical file examination, a report with a summary of the results is issued to the client.

Depending on the results of the aforementioned documentation analysis, the manufacturer (or its authorised representative) will have to make any necessary modifications or additions. Kiwa Cermet may request the modified documents to be submitted for a new evaluation before moving on to the next stage.

Following positive outcome of the aforementioned assessment activities, the manufacturer (or its authorised representative) receives the CE certification and may apply the notification number 0476, which identifies Kiwa Cermet as the Notified Body, to the measuring instruments covered by the verified product.

4.3.6 Unit verification - Form G

The purpose of this conformity assessment is to ascertain whether a single specimen of a measuring instrument conforms to the requirements of the Directive.

To this end, the assessment activities carried out by Kiwa Cermet are as follows:

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

4.3.6.1 Comprehensive tests at the Unit level

Complete tests on one specimen of the measuring instrument are carried out directly by the Kiwa Cermet Laboratory.

Parts of these activities can also be contracted out to authorised third party laboratories.

Tests are conducted in conformity with procedures set by the laboratory based on the reference standards (OIML).

In the event of Non-conformities, modifications must be made to the measuring instrument by the manufacturer (or its authorised representative) who arranges for a repeat of the tests deemed necessary, following the modifications made.

At the end of the test session, a test report is written which is then sent to the client.

When the outcome of all the tests is positive, the Audit Team seals the metrologically important parts with seals marked Kiwa Cermet.

4.3.6.2 Analysis of the technical file

See the information given in § 4.3.5.3.

4.4 Maintenance audit

Forms B, F, F1, G and H1 (in relation to the design examination) are not subject to surveillance activities.

The Quality System approval certificates (Forms: D, D1, E, H. H1) are however subject to periodic audits, generally conducted annually, in order to ensure that the manufacturer (or its authorised representative) maintains and applies the approved quality system.

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

Kiwa Cermet additionally reserves the right to carry out Audits without prior notice and to conduct tests or have tests conducted on the product.

4.4.1 Surveillance audits according to Forms D, D1, E, H, and H1 of the Directive

Surveillance Audits are conducted in the place where the activities are carried out that are subject to the Approved Quality System covered by the certification.

Surveillance Audits take place once a year with reference to the month the certificate expires[1]. They are always conducted on the premises where the processes covered by the certified Approved Quality System, take place.

During the course of the surveillance Audits, an assessment is made of the resolution of the Non-conformities that emerged in previous Audits, as well as an assessment of the implementation and effectiveness of the corrective actions taken by the manufacturer (or its authorised representative).

At the end of the Audit, the Kiwa Cermet Audit Team issues a copy of the Audit report to the client who signs it.

The report can be considered confirmed if within 60 calendar days no further notification is given to the Organisation.

In the event of Non conformities, the Organisation must send Kiwa Cermet, within 20 working days and on the relevant forms, its proposal for the treatment and taking the corrective actions agreed (along with an analysis and formalisation of the causes that generated them), with a timescale for implementation. If within 30 working days of sending this the Organisation has not received any communication, it may consider automatically accepted the treatments and the plan of action set out.

In the event of major Non-conformities, Kiwa Cermet will notify the manufacturer (or its authorised representative) of the consequent actions: Audit on the client's premises and/or Audit through documented evidence where possible. The deadlines for these audits will be set by Kiwa Cermet depending on the seriousness and number of Non-conformities reported.

If the manufacturer (or its authorised representative) does not implement the agreed actions to resolve the issues within the time period specified, the certification may be suspended or withdrawn at the decision of Kiwa Cermet.

The postponement of an already scheduled and agreed Audit, for reasons attributable to the Organisation, must be notified to Kiwa Cermet at least 30 days before the scheduled date, otherwise a penalty of 50% of the cost involved will be invoiced, along with any expenses incurred.

Carrying out the Surveillance Audits prescribed in the certification cycle is conditional upon the Organisation being up to date with payments for all previous services supplied.

As well as the on site Audits, surveillance activities may also include by way of example:

a. requests to the manufacturer regarding aspects pertaining to the certification;
b. a review of the manufacturer's declarations for his own business activities (for example advertising materials and website);
c. requests to the manufacturer to provide documents and registrations (on paper or by electronic means).

These other forms of monitoring can be applied by Kiwa Cermet depending on: information received from external sources, results of the Audits, input from the Accreditation Body or the Competent Authority etc.

As part of the maintenance activities for the certification issued in conformity with the reference Directive, Kiwa Cermet keeps the manufacturer (or its authorised representative) with a certified product informed of any important changes that may have implications on the validity of the EU Type examination certificate.

4.4.2 Renewal Audits according to Forms D, D1, E, H, and H1 of the Directive

By the date the certification expires, Kiwa Cermet conducts a renewal audit on the manufacturer's (or its authorised representative) premises for the main purpose of assessing, including in terms of documentation, that the manufacturer (or its authorised representative) is maintaining the Approved Quality System in conformity with the requirements of the Directive.

The Renewal Audit is planned in such a way as to take into account all the requirements of the reference Directive.

[1]The date of the first Surveillance Audit following Stage 2 must not exceed 12 months from the date of the certification decision.

At the end of the Audit, the Audit Team issues a copy of the Audit report to the client, who signs it. The report is submitted for internal examination and approval by Kiwa Cermet, in order for the certification decision to be made.

As regards the management of any Non-conformities and the certification decisional phase, what was indicated in the previous § 4.3.2.3 applies.

The Renewal Audit, including correct management of any Non-conformities found, must be concluded by the time the Certificate expires. The Certificate will then be valid for a further 3 years.

4.5 Verification of Modifications made by the manufacturer

For certification issued in conformity with the Directive, depending on the type of conformity certification issued, the manufacturer (or its authorised representative) undertakes to inform Kiwa Cermet of all modifications made to the measuring instrument or to the approved design that could affect its conformity with the essential requirements, the conditions of validity for the certificate or the conditions envisaged for use of the measuring instrument and all the ensuing modifications to the approved quality system. Depending on these modifications, Kiwa Cermet assesses which supplementary assessment activities will need to be undertaken.

Please also refer to the information provided in point 5.2 of the *Kiwa Regulation for Certification*.

Depending on the type of modification, a quotation is provided, the contractual conditions are reviewed and the technical activities are planned as prescribed in the preceding paragraphs. Each product modification is approved by review of the decision and issuing of the modified Certificate.

4.6 Communications with Competent Authorities

Kiwa Cermet provides the Competent Authorities with a list of Certificates issued, modified, suspended, withdrawn or refused. Kiwa Cermet keeps available for inspection by the Competent Authorities all the documentation pertaining to issue of the certification.

5. SUSPENSION, WITHDRAWAL OR REDUCTION OF THE CERTIFICATION

The certification can be suspended, withdrawn or reduced in scope for the reasons mentioned in *the Kiwa Regulation for Certification* or on request of the manufacturer (or its authorised representative).

Kiwa Cermet reserves the right to consider, based on the reasons that led to suspension/withdrawal/reduction:

- Whether or not to allow the manufacturer (or its authorised representative) to continue to sell the measuring instruments already manufactured on the date of the suspension/withdrawal/reduction.

Apart from exceptional circumstances (in any case decided by Kiwa Cermet or by the Competent Authority) the suspension period may not last beyond 6 months, otherwise the certification will be withdrawn.

During the period of suspension the manufacturer (or its authorised representative) forfeits the right to use the CE metrological marking and the Certificate. The conditions for restoring the suspended certification (including the necessary conformity Audits), will be set by Kiwa Cermet based on the reasons that led to the suspension and depending on the duration of the suspension.

If the manufacturer (or its authorised representative) does not put into practice the actions specified by Kiwa Cermet for restoring the suspended certification, the certification will be withdrawn or, where possible, its scope will be reduced.

Reduction of the certification involves a new Certificate being issued, stating the type of measuring instruments for which the certification is still valid, and surrender of the old Certificate.

The withdrawal of the certification determines the automatic resolution pursuant to Article 1456 of the Italian Civil Code of the agreement to which this Regulation applies, except, in any case, the compensation of any damages suffered by Kiwa Cermet.

Following withdrawal of the certification, the manufacturer (or its authorised representative) forfeits the right to use of the metrological and CE marking and the Certificate. The manufacturer (or its authorised representative) may embark upon the certification process again by making a new application.

Kiwa Cermet reserves the right to communicate the suspension, withdrawal or reduction to the accreditation bodies and/or to the competent authorities and/or to other third parties that may request it.

6. INCORRECT USE OF CERTIFICATION, CERTIFICATE AND CE MARKING

Use of the certification or certificate is deemed to be incorrect when it could mislead the market regarding the nature, quality and method of use of the measuring instrument.

In addition to what is set out in the *Kiwa Regulation for Certification*, the rules below shall apply.

The use of the CE marking is incorrect when:

1. the latter is applied on measuring instruments:
   - When an application for certification has not yet been presented or when an application for certification has been refused;
   - That do not conform to those described in the certificates;
   - For which certificates have been withdrawn/suspended/reduced**;**
2. When the certificate has expired and has not yet been renewed;
3. When the manufacturer (or its authorised representative) has not implemented changes requested by Kiwa Cermet.

Where incorrect use of the certification, the certificate and/or the CE marking is discovered, Kiwa Cermet withdraws the right of the manufacturer (or its authorised representative) to apply the CE marking and to use the certification, at the same time notifying the Competent Authority.

In the most serious cases (e.g. illicit marking) Kiwa Cermet will also inform the Public Prosecutor's Office.

7. MANUFACTURER'S OBLIGATIONS

By accepting these regulations, as well as the content of the *General Terms and Conditions and of the Kiwa Regulation for Certification*, the manufacturer (or its authorised representative) must in the certification application phase, commit to comply with the following obligations:

- Must not have presented a similar request for certification for the same category/categories of measuring instrument to other Notified Bodies;
- Inform Kiwa Cermet of all the places where the measuring instrument is manufactured, especially if these places are different from the manufacturer's (or its authorised his representative) operational headquarters;
- Inform Kiwa Cermet of all the possible modifications made to the instrument (to the type approved in Form B) and/or to the Approved Quality System, subsequent to certification being issued by Kiwa Cermet;
- undertake to affix the CE marking to each measuring instrument which meets the relevant requirements of the Directive, the supplementary metrological marking and, when required by the Directive, the Kiwa Cermet identification number as a notified body;
- Have the EU Declaration of Conformity available for a period of 10 years, starting from the date the instrument is placed on the market;
- Ensure that the measuring instrument conforms to the applicable EC Directives.
- Make available to Kiwa Cermet auditors one or more measuring instruments covered by the certification to verify the inspections and calibration checks for Surveillance and Renewal Audits.

Only for assessments pertaining to Form B of the Directive

Keep a copy of the EU Type-examination certificate, the annexes and the relative supplements and modifications, together with the technical documentation for a period of ten years starting from the date the last measuring instrument was manufactured.

Only for assessments pertaining to Forms D, D1, E and H of the Directive

- Keep available for a period of ten years from the date the last measuring instrument was manufactured:
  1. the documentation submitted during the application stage, referred to in point 3.1 of Forms D, E, H and point 5.1 of Form D1 of the Directive;
  2. the changes and the related approvals, referred to in point 3.5 of Forms D, E, H and point 5.5 of Form D1 of the Directive;
  3. the decisions and the reports sent, referred to in points 3.5, 4.3 and 4.4 of Forms D, E, H and points 5.5, 6.3 and 6.4 of Form D1 of the Directive.

Only for assessments pertaining to Forms F, F1 and G of the Directive

- Keep available the conformity certificates for a period of ten years after the instrument is certified.
- Keep available the technical documentation for a period of ten years from the date the last measuring instrument was manufactured (only for Module F1).

Only for assessments pertaining to Form H1 of the Directive

- Keep a copy of the EU design examination certificate as well as the relative annexes and supplements together with the technical documentation for a period of ten years starting from the date the last measuring instrument was manufactured;
- Keep available for a period of ten years from the date the last measuring instrument was manufactured:
  1. the documentation submitted during the application phase, referred to in point 3.1 of Form H1;
  2. the updates referred to in point 3.5 of Form H1, and relative approval;
  3. the decisions and reports referred to in points 3.5, 5.3 and 5.4 of Form H1.

8. COMPLAINTS, APPEALS AND DISPUTES

8.1 Complaints

The Manufacturer may present documented complaints regarding his dealings with the certification activities provided by Kiwa Cermet.

Such complaints may arise from problems encountered during the certification process, such as for example, delays in completing the various phases and/or incorrect conduct by the Body Auditor.

Kiwa Cermet records all complaints, examines them and informs the claimant of the actions taken, within thirty days of receiving the complaint.

Kiwa Cermet will establish with the claimant whether and to what extent the content of the complaint and its resolution should be made public.

8.2 Appeals

If the claimant is not satisfied with the response received, or intends to appeal against the decision of Kiwa Cermet, the latter can present an appeal in writing.

The petitioner must state the grounds for his appeal and, where the appeal refers to a decision made by Kiwa Cermet (e.g. the expression of a Major non-conformity), it must be presented to Kiwa Cermet within 10 calendar days of the decision being communicated.

Kiwa Cermet will give the petitioner a written reply and will give notification of any actions to be taken within 30 days of the date of receiving the appeal.

A detailed description of how to present complaints and appeals is given on the Kiwa Cermet website www.kiwacermet.it.

8.3 Disputes

If the result of the appeal is not accepted by the complainant, any dispute between the Customer and Kiwa Cermet shall be managed in compliance with Article 18 paragraph 1 of the *General Terms and Conditions of Kiwa Cermet Italia for the performance of orders.*

9. CHANGES OF THE CERTIFICATION SCHEME

Where any substantial changes are made to the rules/requirements of the certification scheme, Kiwa Cermet informs the Organisations either certified or being certified, taking into consideration any observations made by them; these changes can pertain to:

- The Reference standard or directive;
- This Regulation;
- Additional requirements by the Accrediting Body or the Competent Authority.

Kiwa Cermet will communicate these variations in writing to the Customer Organisations, indicating the type of variation, the methods and terms by which the Organisation must comply with.

If the Organisation does not accept the changes, it may withdraw from the certification by giving written notification to Kiwa Cermet.

10. RIGHT OF UNILATERAL WITHDRAWAL FROM THE AGREEMENT

Kiwa Cermet may freely withdraw from the Agreement with the Customer Organisation by giving written communication to the Customer Organisation with a notice of six months from the effective date of withdrawal. The withdrawal by Kiwa Cermet determines the withdrawal of the issued certification. The Organisation is in any case obliged to pay Kiwa Cermet the amounts due for the services received during the notice period, as established in the last valid quotation.

In the case the Organisation wishes to terminate the agreement, the unilateral withdrawal, during the period of Certification validity, requires the respect of notice times established in General *Terms and Conditions of Kiwa Cermet Italia for the performance of orders* and in the *Kiwa Regulation of Certification.*

In particular, for notice of less than three months and more than two weeks from the scheduled Audit, the Customer must pay 50% of the amount relative to the cost foreseen for the subsequent activity as agreed upon in the Agreement. For periods of prior notification of less than two weeks, the conditions specified in the *General Terms and Conditions shall apply.*

In case of termination of the Agreement, Kiwa Cermet shall issue an invoice for the closing expenses of the certification procedure, in accordance with the last valid quotation.

11. UNILATERAL CHANGE OF THE CONTRACT

Kiwa Cermet reserves the right to modify this Regulation at any time. Any new clauses/changes shall be effective from the time they are communicated to the customer in writing.

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

The withdrawal shall be effective from the last business day of the month the customer receives the notice.