APPROVED
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INSTRUCTION
GENERAL REQUIREMENTS FOR CERTIFICATION WITHIN DIRECTIVES 2014/32/EU – MEASURING INSTRUMENTS (annex II, sections 2, 3, 10, 11, 12) AND 2014/31/EU - NON - AUTOMATIC WEIGHING INSTRUMENTS (annex II, sections 1, 4, 5, 6)

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1. SCOPE and FIELD

The instruction describes the general requirements and the stages of the conformity assessment process/ products certification, performed by MRC, according to the requirements of EN ISO/CEI 17065:2013 standard – Conformity assessment. Requirements for bodies that certify products, processes and services.

The present *"General requirements"* have the purpose to offer a guidance for MRC clients when they make a request for certification and also to define the principles and the structures of certification schemes applied for specific activities performed for:

a) Conformity assessment according to:

- Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast), transposed into national legislation through GD no. 711/2015 on establishing the putting on the market the measuring instruments, defined in the specific annexes that concern:
  - Water meters – annex III (MI-001);
  - Gas meters and volume conversion devices – annex IV (MI-002);
  - Active electrical energy meters – annex V (MI-003);
  - Thermal energy meters – annex VI (MI-004);
  - Measuring systems for the continuous and dynamic measurement of quantities of liquids other than water – annex VII (MI-005);
  - Automatic weighing instruments – annex VIII (MI-006);
  - Taximeters – annex IX (MI-007);
  - Material measures – annex X (MI-008);
  - Dimensional measuring instruments – annex XI (MI-009);
  - Exhaust gas analysers – annex XII (MI-010).

- Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (recast), transposed into national legislation through GD no. 710/2015 on establishing the putting on the market the non-automatic weighing instruments.

Modules (procedures) of conformity assessment are described in the Directive 2014/32/EU (GD no. 710/2015) in annexes II, section 2, section 3, section 10, section 11, section 12) and in the Directive 2014/31/EU (GD no. 710/2015) in annexes II, section 1, section 4, section 5, section 6 and are:

Module A2 – Internal control of production and supervised verifications of the measuring instruments at random intervals (only for MID);

Module B – EU type examination;

Module F – Conformity to type based on product verification;

Module F1 – Conformity based on product verification;

Module G – Conformity based on unit product verification.

2. GENERAL CONDITIONS

2.1 General

Base conditions for obtaining a conformity certificate are that the applicant (producer or his authorized representative) to apply the general rules provided in the harmonized standards or in OIML and, if the case, the relevant guidelines agreed by the Group of Notified Bodies.
The present General Conditions describe the way MRC applies specific schemes and procedures of certification and define the relationships between the applicant and / or owner of certification and MRC throughout the evaluation process.

MRC assigned tasks for conformity certification of a product is based on documented requirements in specific modules of the directive, as follows:

Module A2 – Internal control of production and supervised verifications of the measuring instruments at random intervals (only for MID);

Module B – EU type examination;

Module F – Conformity to type based on product verification;

Module F1 – Conformity based on product verification;

Module G – Conformity based on unit product verification.

The conformity attestation of a product from MRC is confirmed by issuing the Certificate of Conformity.
MRC makes available to its certification services to all applicants whose products are included in its field of competence and notification (according to section 1.A of this document), without discrimination, regardless of whether they reside in Romania or in another state.
Certification is not conditioned by the size of the production locations of the applicants or their belonging to various associations or groups, nor the number of certificates already issued.
At the submission of the application for certification to MRC, applicants will inform MRC if they previously addressed to other notified body for the EC certification of the same product or family of products.
MRC treats the information obtained during the development of certification process regarding to a particular product or supplier, as being confidential.
In order to ensure that MRC does not require excessive financial conditions to its customers, the certification fees apply to all applicants in an absolutely discriminatory manner and are conditioned solely by the complexity and volume of activities undertaken in this sense by MRC.

The certification costs depend on:

- the volume of certification work performed (initiated and/ or additional and/ or assessments);
- the number of product types (product families) for which the certification is requested;
- number of locations of production;
- distance between MRC and the locations of production of the applicant;
- the specific requirements of the applicant (for example, the request to perform a preliminary visit).

The certification costs are agreed with the applicants before signing the certification contract, through the specification for certification which is annex to the certification contract.

The official attestation of the products conformity is expressed by issuing a Conformity certificate, of whose form and content comply with the specific procedure.

2.2 Choosing the conformity assessment procedure

The conformity assessment of a measuring instrument with the appropriate essential requirements is performed, at the producer`s choice, by applying one of the conformity assessment procedures provided in the specific annex of the measuring instrument, as follows:

No.crt.	Product/ group of products	Annex of Directive
1	Water meters - annex MI 001	B; F
2	Gas meters and volume conversion devices - annex MI 002	B; F
3	Active electrical energy meters – annex MI 003	B; F
4	Heat meters – annex MI 004	B;F
5	Measuring systems for the continuous and dynamic measurement of quantities of liquids other than water - annex MI-005	B; F; G
6	Automatic weighing instruments - annex MI-006 - for mechanical assemblies; - for electromechanical devices; - for electronic systems or systems containing software.	 B; F, F1, G B, F, G B, F, G
7	Taximeters – annex MI-007	B; F
8	Material measures – annex MI-008 - material measures of length; - capacity serving measures.	 B,F1, G A2, B, F1
9	Dimensional measuring instruments - annex MI-009 - for mechanical or electromechanical devices; - for electronic systems or systems containing software.	 B, F, F1, G B, F, G
10	Exhaust gas analysers – annex MI 010	B; F
11	Non automatic weighing instruments	B; F; G

2. STAGES OF CERTIFICATION

The certification process is developed according to the stages described below and with the flow chart presented in Annex 1.

3.1. Requesting certification

The initial request is made through fax, phone, letter or directly in MRC office. MRC sends the forms of certification request to the applicant and the preliminary assessment questionnaire, the scheme with the stages of the certification process and also, other informative materials with the purpose of obtaining the necessary date for making the certification offer.

3.2. Procuring the folder of informative documents

The folder of informative documents includes:

- General requirements for certification;
- Preliminary assessment questionnaire;
- Official request for certification.

The certification request is completed on a special form, where the applicant (producer or his authorized representative) refers to the specific product or the group of products (family of products) for which he requests the certification.
The certification request is completed with all required information and it is sent to MRC together with the technical documentation of the product.

3.3. Elaborating the certification offer

Based on the analysis of the certification request, of the preliminary assessment questionnaire and of the other documents provided by client, MRC decides if the certification process requested can be initiated and establishes the certification program, calculates the costs based on the List of fees and rates, sends the price offer to the applicant and in case of acceptance, elaborates the certification contract.
The certification process itself is initiated only after agreeing and signing the contractual documents by both parties.

3.4. Concluding the contract

MRC elaborates the certification contract based on the offer accepted by the applicant, on the official request of certification and on the preliminary assessment questionnaire and then sends it to the applicant.
The current requirements for certification are part of the contract.
After analyzing the contract by the applicant, any objections on it are submitted to MRC.
The contract is signed by both parties after solving them.
The certification process is initiated after signing the contract by both parties.

3.5.Transmission of required documents to MRC

The applicant submits to MRC all the required technical documentation of the product.

3.6. Preliminary assessment

The responsible of the file checks if the documentation received from the applicant is completed. Moving on to the next stage is made only after all the required documention is at MRC headquarters.

3.7. Performing the documentation examination and preparation of assessment

3.7.1. The client will send to MRC the technical documentation of the product that is about to be assessed, in order to be certified.

3.7.1.1. For products that comply with the Directive 2014/32/EU, the content of the technical documentation must meet the following provisions:

(1) The technical documentation describes the design, fabrication and operation of the measuring instrument in an intelligible manner and allows its conformity assessment with the applicable requirements of the current directive.
(2) The technical documentation is enough detailed to ensure meeting the following requirements:
a) definition of the metrological characteristics;
b) the reproducibility of the metrological performances of measuring instruments manufactured, when they are properly adjusted, with appropriate means;
c) the integrity of the measuring instruments.
(3) Whether is relevant for the assessment and the type identification and/or of the measuring insutruments, the technical documentation includes the following information:
a) a general description of the measuring instrumentl
b) design drawings and of manufacturing and the schemes of components, subassemblies, circuits, etc.;
c) manufacturing procedures to ensure an homogeneous production;
d) if applicable, a description of electronical devices, with drawings, schemes and flow diagrams of logical elements and of the general information about features and operation of software;
e) descriptions and necessary explanations for understanding the information mentioned at sections (b), (c) and (d), including the operation of the measuring instrument;
f) list of harmonized standards and/or normative documents reffered to in article 14, applied in full or in part, of whose references have been published in the Official Journal of European Union;
g) description of the solutions taken in order to meet the essential requirements, in case the harmonized standards and/or normative documents reffered to in article 14 have not been applied, including a list of other relevant technical specifications applied;
h) results of design calculations, of examinations etc.;

i) if necessary, the results of appropriate tests, in order to demonstrate that the type and/or measuring instruments meet:

- the requirements of the current directive under declared nominal operation conditions and with exposure to the specified environmental disturbances;
- durability specifications for gas meters, water and heat meters, as well as for liquids other than water;

j) EU type examination certificates or EU project examination certificates, regarding the measuring instruments that include parts identical of those from the project.

(4) The producer mentions the places where seals and markings have been applied.

(5) The producer indicates, if applicable, the compatibility requirements with the interfaces and subassemblies.

3.7.1.2. For products that comply with 2014/31/EU, the content of the technical documentation must correspond to the following provisions:

- the technical documentation allows the device assessment in terms of compliance with the applicable requirements of this Directive and shall include an adequate analysis and a risk(s) assessment;
- the technical documentation specifies the applicable requirements and covers, as far as it is relevant for assessment, the design, manufacturing and operation of the device.

The technical documentation includes, where applicable, at least the following elements:

(i) a general description of the device;

(ii) design drawings and of manufacturing and the component schemes, subassemblies, circuits, etc.;

(iii) descriptions and necessary explanations for understanding the drawings and the respective schemes and also of the operation of the device;

(iv) list of harmonized standards applied in full or in part, of whose references have been published in the Official Journal of European Union and in case these harmonized standards have not been published, a description of the solutions taken for meeting the essential requirements of the current directive, including a list of other relevant technical specification applied. In case of some harmonized standards which are partially applied, the technical documentation shall mention those parts that have been applied;

(v) results of design calculations, of the performed examination, etc.

3.7.1.3. Analysis of documentation

The assessment team of MRC examinates the documentation from the technical file of the product, in order to check if it is complete, if it is adequate for the applicable certification scheme and the specific characteristics of the product are complied with the requirements of the normative document(s) or with specific guidance of the respective product.

The technical documentation is examined in order to check the conformity with applicable requirements, under the aspects that can or are necessary to be checked based on technical documentation. This verification is specially adequate in case of some complex requirements, such as integrity of software, management of error codes, configuration methods of the measuring instruments or compability of component elements of the measuring instruments.

- The technical documentation is checked in order to see if it is conducted at the level of detail required by MID and NAWI, to ensure the adequate verification of compliance to the measuring instrument type;
- It is followed to see if the documentation submitted allows the unequivocal identification of the product type, complete characterization according to the essential requirements and from applicable standards, if contains enough elements for understanding the projects, plans and schemes and also the operation manner of the device and that all information presented refer to that product type;
- Are identified the elements that have been designed according to the applicable provisions from the harmonized standards or normative documents, as the case, and also the elements that have been designed without applying the provisions of those documents.
  On this occasion, the evaluation team can make recognition proposals of some tests which were previously performed based on test/ evaluation reports submitted by the client. At the same time, the evaluation team can make recognition proposals of the documents issued by notified bodies or by metrology national bodies from countries gathered in the OIML certification system.
  The evaluation team establishes the number of copies of representative products for the production provided (complete copy or copies of one or more critical components of the measuring instrument), that the producer must submit, based on the evidene analysis that allow determining the adequacy of the technical design of those components of the measuring instrument.
- The technical documentation is examined in order to ensure that the producer has suitable means to ensure an uniform production. The examination of the measuring instrument subject to assessment will be made through the possible difficulties encountered during the assessment process.
  This requirement is considered fulfilled if the producer has a quality system approved for similar applications.

In case the producer did not choose for applying the indicated solutions in the relevant documents (situation that happens for example in case of new technologies), the following additional information are requested:

- reasons for which the producer did not use the harmonized standard/ normative documents mentioned in the directive;
- which requirements from the relevant documents are not necessary for the specific application;
- which additional requirements or tests are necessary in case the producer would use new technologies;
- demonstration of equivalence of the technical solutions;
- if the producer did not use the standardized testing methods, remarks on the used methods if they represent an adaptation of standardized methods or are even developed by the producer.

Any new testing or of evaluation method of the measuring instrument must be documented by the producer in order to demonstrate their adequacy.

The possible observations occurred in the technical documentation are submitted to the producer in order to be solved. In such cases, the measures that the applicant intends to take in order to eliminate non-conformities, must be sent to MRC for a new examination of the documentation before proceeding to the next stage from the certification program.

Following the analysis of the documentation, the evaluation team prepares an analysis report and sends it to the contract responsible together with the documentation received.

It gets proceeded to the next stage if the analysis report of the documentation is favorable.

3.7.2. Examination and subcontracting the testing laboratory

Following the official confirmation of accepting a certification request and signing the contract documents, according to the assessment program, MRC makes the necessary arrangements with the applicant in order to perform the stages of the assessment process, according to the rules of the applicable certification scheme. This activity is carried out based on an evaluation plan, agreed in a suitable manner with the applicant, taking responsibility that all works performed by him are carried out in an appropriate way.

For module A2 of MID

The control of the product, with the purpose of checking the internal controls of the product, is performed by the technical expert at the fabrication location or at the product`s timber of the importer, according to the specific procedure.
The technical expert makes the project of the control plan. This will be submitted to approval by the contract responsible. The approved project is then sent to the applicant, by the good care of the contract responsible, in order to be accepted.

After its acceptance by the applicant, the testing plan project is approved by the Executive Director of MRC, becoming the official testing plan.
Tests are carried out by the technical expert of MRC or by a subcontracted laboratory. The test reports resulted after performing the control are sent to MRC, where are being analyzed and assessed in order to take the decision on certification.

For modules B, F, F1 and G

MRC does not have its own laboratories to perform tests, but subcontracts this activity to subcontracting laboratories (accepted), whose list is available for different applicants.
The “acceptance” criteria are those mentioned in Directive 2014/31/EU, Directive 2014/32/EU and also by meeting the requirement of EN ISO/CEI 17025 standard, which underlines the impartiality and the absence of interests conflict.

For any recourse to a subcontracted laboratory, MRC obtains the consent of the applicant (producer).
Conversely, MRC may accept a proposal for a testing laboratory from applicants (which is not yet included in the list of laboratories), with the condition that this laboratory to fulfill the established criteria and to agree to collaborate with MRC in this regard.
MRC ensures itself that laboratories performing tests are accredited, authorized or appointed by any other form by the competent authorities of EU Member States.

MRC maintains direct and continuous connections with all testing laboratories included in the list of subcontracted laboratories, in order to ensure that:

- their notification, accreditation, appointment or authorization is maintained;
- tests are carried out in accordance with the testing program, respectively with the harmonized European standard and the specific guidance established by the group of notified bodies on applicable product specifications, taking into consideration the requirements of EN ISO/CEI 17025;
- test reports issued are analyzed and assessed by MRC;
- a representative of MRC can be present within the laboratory before or/and during the tests performance requested by MRC or by the producer;
- MRC takes all responsibility for the tests performed by the accepted testing laboratories.

Within the assessment procedures for modules B, F, F1 and G, the chief assessor makes the testing plan project. This will be submitted to the approval of the Certification Director. The approved project is then sent, by the care of the contract responsible, to the applicant for acceptance. After its acceptance by the applicant, the testing plan project is approved by the Executive Director of MRC, becoming the official testing plan. Tests can be carried out by the evaluation team designated or by a subcontracted laboratory.

MRC, through the contract responsible, contacts the agreed testing laboratory, from the list of subcontracted laboratories and sends the order together with a copy of the product documentation – the part that contains necessary data for examination and testing – and the testing plan, as well.
The contract responsible informs the client on the date of starting the tests.

EU type examination (module B) is the part of the conformity assessment procedure through which MRC examinates the technical concept with relevant requirements from directives.
EU type examination can be performed through any of the below methods and afterwards MRC decides which is the most appropriate method and the needed samples:

- Examination of a complete measuring instrument sample, representative for the expected production (production type);
- Assessment of the adequacy of the technical project of the measuring instrument by examinating the technical documentation and the justificate documents, and also by examinating some representative samples for the considered production or one or more important parts of the measuring instrument (combination between the production type and the projected type);
- Assessment of the adequacy of the technical project of the measuring instrument by examinating the technical documentation and justificate documents, without examination of a sample (projected type).

Specific tests for EU type examination are performed by the assessment team designated by MRC or in laboratories subcontracted by MRC (accredited laboratories or accepted in appropriate manner by MRC).
MRC may accept tests to be performed using testing facilities (equipments) of the producer, with or without using the producer`s personnel, considering the conditions:

- these testing installations to be calibrated and to ensure traceability of the standards used;
- tests to be performed in strict accordance with the testing plan made by MRC;
- MRC to coordinate the tests or to attend them, in case are performed by the producer`s personnel;
- MRC to decide weather to take or not into consideration the test results.

In order to minimize costs for producers and to reduce the duration of the certification process (particularly in the case of applicants and foreign producers), MRC can agree that tests performance to be requested at testing laboratories agreed directly by the applicant (producer).

Tests specific to the type examination must include all product features required for evaluation and demonstration of its compliance with the specific essential requirements.
After completing the tests, a copy of each test report must be sent to MRC and then the file responsible shall examinate if:

- the forms of the test reports and their structure are in compliance with the requirements of EN ISO/IEC 17025:2005;
- all tests required by the testing program and by the harmonized standard, by OIML or other applicable harmonized specifications have been performed under the established conditions;
- the test results confirm (or not) that the tested products are in compliance with the requirements established by the harmonized European standard or by other applicable harmonized specifications.

In case the test reports are validated, it is estimated that the results confirm that the tested product meet the requirements of the harmonized standard or other applicable harmonized specifications. Otherwise, if the test results show nonconformities in relation to the requirements of the specific harmonized standard or other applicable harmonized specifications, MRC may agree with the producer to repeat in full or partial the tests at his own expense.

3.7.3 Evaluation report

Based on examinations/ tests/ inspections, test reports and report of documentation analysis prepared by the evaluation team (in case of type examination), the chief assessor elaborates the evaluation report, document endorsed by the Certification Director and approved by the Executive Director of MRC. The evaluation report contains, at least, information on:

- testing plan;
- conclusions on the test results;
- conclusions on the technical documentation (when the case);
- laboratories that have performed the tests (when the case);
- reference document to which the conformity is established with;
- experts that have analyzed the documentation and/ or have performed the examinations/ tests/ controls.

3.7.4. Decision of the Certification Committee

The final evaluation report, the specific test reports, together with all other documents included in the certification file are reviewed by the Certification Committee, which decides to accept or reject the proposal of the chief assessor, on certification.
In this regard, the Certification Committee considers as support of its decision, the results of all examinations, tests and other activities carried out in order to assess the product compliance with the requirements of Directive and the requirements specified in the applicable harmonized European standards.
If the certification was granted, MRC informs the applicant about this and issues a conformity certificate.
When MRC refuses to issue a certificate, it offers to the applicant detailed reasons for its refusal. A documented procedure for contestation and appeal can be make available on request to any interested party.

3.7.5. Certificate issuance

The certificate signed by the Executive Director of MRC or by the person empowered by him, is registered with unique number and is sent to the client.
In case of any special conditions, these will be annexed to the certificate.

3.7.6. Withdrawal and cancellation of the certificate

Situations that result in withdrawal and cancellation of the certificate:

- the organization does not pay the fees for performing activities previous to certification or for performing surveillance activities;
- the organization does not apply the requirements arising from the change of MRC certification documents, about which has been informed;
- the organization fraudulently apply the notified body number (i.g: on products not subject to certification, on products that have suffered changes towards the certified product, etc.);
- the organization violates the contractual requirements;
- the organization is abolished or in bankruptcy.

3.7.7. Appeals, complaints and contestations

Applicants may claim/ appeal the activities performed by the certification body (its decisions, breaking the contractual obligations), as it follows:

- reporting/ claiming the activity and behavior of assessment teams;
- not maintaining confidentiality by the MRC personnel;
- non-discriminatory access to information and certification procedures;
- contesting the nonconformities formulated and the assessment team's recommendation, within 15 days from the communication date;
- contesting the decision of the Certification Committee within 15 days from the communication date.

The applicant may present the arguments of his complaint formally to MRC.
The complaint/ appeal can be made to the Executive Director of MRC. In case the CEO was involved in the contested work, it can be filled up an appeal at the upper level.
Appeals, complaints and contestations may be made by applicants for certification, by certified organizations and all stakeholders in the certification process.
Appeals have in consideration the certification decision. If the operator considers unjust the decision of the Certification Committee, he may contest it by addressing to the Committee of Professional Ethics and Appeals of MRC.

OTHER SPECIFICATIONS

MRC makes public on the www.mrco.ro website, by these general rules, the following information:
- detailed description of certification activity, the initial and as well the granting process, maintenance, restriction, extending, suspending, withdrawing certification and recertification;
- normative requirements on certification;
- certification requirements for potential customers:

MRC informs customers through the contract, on the corresponding fees on certification and on its maintenance.
At the request of any interested party, MRC makes public information regarding the client and its certified products and also undertakes to confirm in writing by fax or e-mail, or by telephone, the validity of a certification granted.
In exceptional cases, at the request of the client, access to some information may be limited.
MRC can provide to a third party information on client only with his prior consent, except the cases provided by law.

The procedure shall enter into force after its approval by the Executive Director of MRC, starting with the date of obtaining accreditation.

Stages of the products certification activity

applicable depending on the product category, the conformity assessment manner, respectively the Directive:

1. Providing to client the informative documents, the application for the the preliminary assessment questionnaire.
2. Completion and submission of the application form and of the preliminary assessment questionnaire to MRC.
3. Official registration of certification request.
4. Sending to MRC the product documentation.
5. Preliminary analysis of the request and issuance of price offer.
6. Concluding the certification contract.
7. Examination of the technical documentation.
8. Performing the examination report of the technical documentation.
9. Performing the testing program.
10. Examination of evidences that allow establishing the adequacy of the technical design.
11. Performing tests.
12. Performing the test report.
13. Performing the evaluation report.
14. Analysis of the certification file.
15. Decision on granting the certification.

CERTIFICATION SCHEME