APPROVED
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GENERAL REQUIREMENTS FOR CERTIFICATION WITHIN DIRECTIVE 2009/48/CE – SAFETY OF TOYS

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I. PURPOSE AND SCOPE

1.1 The instruction describes the general requirements to be met by an organisation applying to MRC for conformity assessment of products under the Toy Safety Directive 2009/48/EC. The procedure shall be applied by MRC for the conformity assessment and certification of products in accordance with the requirements of SR EN ISO 17065:2013 and the conformity assessment module B of Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.

These rules apply to certification, recertification, extension, restriction, suspension and withdrawal of certification activities and are an integral part of the certification contract with MRC.

1.2 The Certificate of Conformity is issued by MRC for the following categories of toys according to ONR CR 14379:2002:

- Activity toys - category A
- Aquatic toys - category B
- Art, crafts and related items - category C
- Audio-visual equipment - category D
- Books of entertainment value - category E
- Construction toys and puzzles - category F
- Costumes, costumes and masks (imitative) - category G
- Stuffed soft toys and dolls - category H
- Experimental toys - category I
- Functional toys - category J
- Play sets - category K
- Mechanical and/or powered vehicles - category L
- Play sets and constructed models - category M
- Projectiles with a launch device - category N
- Push and pull toys and walking aids - category O
- Role-playing toys - category P
- Water toys - sand - category Q
- Skill development toys - category R
- Cosmetic toys - category S
- Musical instrument toys - category T
- Sports equipment toys and balls - category T
- Children's toys for looking, grasping and/or squeezing - category V
- Toys intended to support a child's table - category W
- Toys for children to climb into - category X

The Certificate of Conformity is the document attesting that, from a safety point of view, the toy ensures the conformity of the product with the relevant (general essential and specific) applicable requirements of Directive 2009/48/EC transposed into national law by GD 74/2011.

2. REFERENCE DOCUMENTS

- Government Decision No 74/2011 on the safety of toys;
- Directive 2009/48/EC of the European Parliament and of the Council of 26.06.2011 on the safety of toys.
- SR EN ISO/IEC 17065:2013 - Conformity assessment. Requirements for bodies certifying products, processes and services.
- RS-7.18 ON- Specific RENAR accreditation regulation in the field covered by GD 74/2011 on toy safety, transposing Directive 2009/48/EC.

3. DEFINITIONS and ABBREVIATIONS

3.1 Definitions

Applicable terminology and definitions from:

- SR EN ISO/IEC 17065:2013 - Conformity assessment. Requirements for bodies certifying products, processes and services;
- SR EN ISO/IEC 17020:2012 - Conformity assessment - Requirements for the operation of various types of bodies performing inspections;
- SR EN ISO/IEC 17025:2018 - General requirements for the competence of testing and calibration laboratories;
- Directive 2009/48/EC of the European Parliament and of the Council of 26.06.2011 on the safety of toys;
- Government Decision No 74/2011 on the safety of toys;
- EA-2/17 M:2020 - EA Guide on accreditation for notification;
- https://ec.europa.eu/growth/sectors/toys/safety/guidance_en :
- Documents implementing the Directive issued by the European Commission and the notified bodies coordination group;
- RS-7.18 ON- Specific RENAR accreditation regulation in the field covered by GD 74/2011 on toy safety, transposing Directive 2009/48/EC.

In addition the following definitions apply:

3.1.1. Non-conformity - absence or lack of capability to implement or maintain one or more of the requirements of the Directive applicable to the design, production, final inspection control system in the factory.

3.1.2. Observation - deviation from the requirements, which does not pose a risk to the effective operation of the design, production, final inspection control system in the factory, but which by repetition could lead to non-conformity.

3.1.3. Observer = person who accompanies the assessment team but does not carry out assessments.

3.1.4. Guide = person appointed by the customer to assist the assessment team.

3.1.5. EC Certificate = means the document issued at the end of the relevant conformity assessment procedure.

3.1.6. CE marking = mandatory marking affixed to a product/toy to indicate conformity with the essential procedures and requirements of the Directive.

3.1.7. Competent Authority = the body designated by the Government of a Member State and entrusted with the administration of the application of a given Directive by that Member State.

3.1.8. Conformity assessment procedure = services carried out by a notified body in accordance with the Directive.

3.1.9. Notified body = a body designated by the Government of a Member State and notified by the European Commission in accordance with a Directive to provide a specific range of conformity assessment procedures.

3.1.10. Placing on the market = the first time a product is supplied or made available for supply in the European Economic Area.

3.2 Abbreviations

ETC = Evaluation Team Leader

CPEA = College of Professional Ethics and Appeal

4. RESPONSIBILITIES

The responsibilities are shown in the process diagram in Annex 2.

5. GENERAL CONDITIONS

5.1. MRC - conformity assessment body is organised in accordance with the requirements of SR EN ISO/IEC 17065:2013 and operates in the European area.

5.2. The general requirements contain in addition to general information also specific requirements of MRC to inform applicants about:

- obtaining certification
- prolongation, extension or withdrawal of certification.

Conformity assessment is described in chap. IV of Directive 2009/48/EC - Conformity Assessment.

5.3. REQUIREMENTS OF THE DIRECTIVE

All elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner. The technical documentation relating to the toy, submitted by the manufacturer to the certification body, must contain the documents specified in Annex IV to Directive 2009/48/EC and GD 74/2011.

5.4. STAGES OF CERTIFICATION

5.5.1. General requirements

- MRC's attestation of conformity of a product is confirmed by issuing the Certificate of Conformity.
- MRC makes its certification services available to all applicants whose products fall within its scope of competence and notification (see point 1.a of this document), on a non-discriminatory basis, regardless of whether they are domiciled in Romania or elsewhere.

- Certification is not conditional on the size of the applicants' production sites or their membership of various associations or groups, nor on the number of certificates already issued.
- When submitting the application for certification to MRC, applicants shall inform MRC if they have previously applied to another notified body for EC certification of the same product or family of products.
- MRC treats information obtained during the course of the certification process concerning a particular product or supplier as confidential.
- In order to ensure that MRC does not impose unreasonable financial conditions on its clients, certification fees are applied to all applicants on a completely non-discriminatory basis and are exclusively conditioned by the complexity and volume of the work carried out for this purpose by MRC. Certification costs depend on:

- volume of certification work carried out (initial and/or additional and/or assessments)
- number of product types (product families) for which certification is requested;
- specific requirements of the applicant (e.g. request for a preliminary visit).

- Certification costs are agreed with applicants before certification contracts are signed, by means of the certification estimate annexed to the certification contract.
- he official attestation of conformity of the products is expressed by the issue of an EC Type Certificate, the form and content of which comply with the specific procedure.

5.5.2. Application for certification

- The initial request is made by telephone, fax, e-mail, letter or directly to MRC office;
- Procurement of the information document map, which contains:

- general requirements for certification
- preliminary assessment questionnaire
- official application/order for certification

- MRC sends the applicant the preliminary assessment questionnaire and certification order forms, the scheme with the steps of the certification process and other information material in order to obtain the data necessary to prepare the certification offer.
- The certification application and the pre-assessment questionnaire shall be filled in on the special forms by the certification applicant (manufacturer or its authorised representative) with all the required information concerning the toy(s) for which certification is requested and submitted to MRC together with the technical documentation of the product.
- - Upon receipt of the certification order and documentation, MRC shall carry out its analysis and determine the duration of the evaluation, based on the information provided by the applicant and taking into account:

- Complexity of the toy and identified safety risks
- Complexity of the toy manufacturing technology
- Number of products with the same technology..

5.5.3. Development of the certification offer

On the basis of the analysis of the certification application, the preliminary assessment questionnaire and the other documents provided by the client, MRC decides whether the requested certification process can be initiated and establishes the certification programme,

calculates the costs on the basis of the Fee and Tariff Schedules, submits the price offer to the applicant and, if the offer is accepted, draws up the certification contract.

5.5.4. Conclusion of contract

MRC draws up the certification contract on the basis of the offer accepted by the applicant, the formal application for certification and the preliminary assessment questionnaire and sends it to the applicant. These certification requirements form an integral part of the contract.

After review of the contract by the applicant, any objections are forwarded to MRC. Once they have been resolved, the contract is signed by both parties.

The established contractual conditions become invalid if the organisation starts the certification within 6 months from the date of conclusion of the contract. If this period is exceeded, the organisation is obliged to update the certification/recertification order, taking into account any changes that may occur. In this situation MRC has the right to modify the terms of the contract.

5.5.5. Submission of the requested documentation to MRC

The applicant shall submit all technical documentation of the product to MRC.

5.5.6. Preliminary assessment

The File Manager checks the completeness of the documentation received from the applicant. The next step is taken when all the requested documentation is at MRC.

5.5.7. Carrying out the analysis of the documentation and preparing the evaluation

The client submits the technical documentation of the product to be assessed to MRC for certification.

For products covered by Directive 2009/48/EC, the technical documentation shall include at least the elements specified in Annex IV to Directive 2009/48/EC, namely:

a) a detailed description of the design and manufacture, including the components and materials used to make the toy and the safety data sheet of the chemicals to be used (obtained from the manufacturers of the chemicals);
b) safety assessment of the toy;
c) test reports and description of the means by which the manufacturer ensures conformity of production with the harmonised standards;
d) list of harmonised standards applied in full or in part, the references of which have been published in the Official Journal of the European Union, and, where these harmonised standards have not been applied, a description of the solutions adopted to meet the essential requirements of the Directive, including a list of other relevant technical specifications applied. In the case of partially applied harmonised standards, the technical documentation shall mention those parts which have been applied;
e) the EC type-examination certificate (where appropriate).

MRC assessment team reviews the documentation in the technical file of the product to verify that it is complete, that it is appropriate to the applicable certification scheme, and that the specific characteristics of the product are in accordance with the toy safety requirements of the normative document(s) or guidance specific to the product in question and that appropriate measures have been taken to eliminate the identified risks.

The technical documentation shall be examined to verify compliance with the applicable requirements of those aspects that can, or need to, be further verified. This verification is particularly appropriate in the case of certain toy safety requirements:

- Verification that the technical documentation is drawn up to the level of detail required by Directive 2009/48/EC to ensure adequate subsequent verification of the toy's compliance with the safety requirements.
- Checking that the documentation submitted enables the category of the toy to be unambiguously identified, that it is fully characterised in accordance with the essential requirements and the applicable standards, that it contains sufficient elements for the understanding of the designs, plans and diagrams and the use of the toy and that all the information submitted relates to the type of product concerned;
- The elements which have been designed in accordance with the applicable provisions of, where appropriate, harmonised standards or normative documents, as well as the elements which have been designed without applying the provisions of those documents, shall be identified. On this occasion, the assessment team may make proposals for the recognition of tests previously carried out on the basis of test/assessment reports submitted by the customer. The assessment team may also propose recognition of documents issued by other notified bodies.
- The evaluation team shall determine the number of specimens of products representative of the production envisaged to be submitted by the manufacturer on the basis of the analysis of the evidence of the adequacy of the technical design of those parts of the measuring instrument.
- The technical documentation shall be examined to ensure that the manufacturer has adequate means to ensure uniform production. The examination of the toy under assessment shall be carried out in the light of any difficulties encountered during the assessment process.

If the manufacturer has not chosen to apply the solutions indicated in the relevant documents (which may be the case e.g. for new technologies), the following additional information is required:

- the reasons why the manufacturer has not used the harmonised standard(s) referred to in the Directive;
- which requirements in the relevant documents are not necessary for the specific application;
- which additional requirements or tests are necessary if the manufacturer would use new technologies;
- demonstration of equivalence of technical solutions;
- if the manufacturer has not used standardised test methods, details of the methods used, whether they are an adaptation of standardised methods or developed by the manufacturer himself.

Any new method of testing or evaluating the toy must be documented by the manufacturer to demonstrate its suitability.

Any comments arising from the technical documentation shall be forwarded to the manufacturer for resolution. In such cases, the measures that the applicant intends to take in

order to eliminate non-conformities shall be forwarded to MRC for further examination of the documentation before proceeding to the next stage of the certification programme.

Following the review of the documentation, the assessment team prepares a review report and sends it together with the received documentation to the contract manager.

If the documentation analysis report is favourable, then the next step is taken.

5.5.8. Examination and sub-testing of the test laboratory

Following formal confirmation of acceptance of an application for certification and the signing of the contractual documents in accordance with the evaluation programme, MRC makes the necessary arrangements with the applicant to carry out the steps of the evaluation process in accordance with the rules of the applicable certification scheme. This activity is carried out on the basis of an assessment/assessment plan, appropriately agreed with the applicant, taking responsibility for ensuring that all work undertaken by the applicant is carried out correctly.

As MRC does not have its own laboratories to perform testing for Module B, this activity is outsourced to subcontracted laboratories (accredited according to the requirements of SR EN ISO/IEC 17025/SR EN ISO/IEC 17020 whose accreditation scope covers the activities performed under subcontract or only with laboratories assessed by laboratory assessors with technical competence for SR EN ISO/IEC 17025 and recognised by MRC, including test method standards), whose list is available to certification applicants.

The acceptance criteria are those mentioned in Directive 2009/48/EC, accreditation according to the requirements of EN ISO/IEC 17025, emphasising impartiality and absence of conflicts of interest.

For any use of a subcontracted laboratory MRC obtains the agreement of the applicant (manufacturer).

Reciprocally, MRC may accept a proposal for a testing laboratory from the applicant (which is not yet included in its list of laboratories), provided that this laboratory is accredited/assessed by MRC and agrees to collaborate with MRC in this regard.

MRC maintains direct and ongoing liaison with all testing laboratories on its list of subcontracted laboratories to ensure that:

- their accreditation/assessment is maintained;
- tests are carried out in accordance with the test programme, i.e. the harmonised European standard and the specific guidance established by the Notified Bodies Group on applicable product specifications, taking into account the requirements of SR EN ISO/IEC 17025;
- the test reports issued are reviewed and evaluated by MRC;
- a representative of MRC may be present in the laboratory prior to and/or during the performance of tests commissioned by MRC or the manufacturer;
- MRC assumes full responsibility for the tests performed by accepted test laboratories.

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As part of the assessment procedure for Module B the assessor shall draw up the draft test plan. It will be submitted to the Certification Director for endorsement. The endorsed draft is

then forwarded by the Contract Manager to the applicant for acceptance. After acceptance by the applicant, the draft test plan is approved by MRC Executive Director and becomes the official test plan.

Tests may be performed by the designated evaluation team or by a sub-contracted laboratory.

MRC, through the Contract Manager, contacts the approved testing laboratory from the list of sub-contracted laboratories and submits the order together with a copy of the product documentation - the part containing the necessary examination and testing aspects - and the test plan.

The contract manager shall notify the customer of the test start date.

EC type-examination (module B) is the part of the conformity assessment procedure whereby MRC examines the technical design of a toy, ensures and declares the conformity of the technical design with the relevant requirements of Directive 2009/48/EC on the safety of toys.

EU type examination can be carried out by any of the methods below, after MRC decides on the appropriate method and the required samples:

- assessment of the adequacy of the technical design of the toy by examining the technical documentation and supporting documents and by examining representative samples of the intended production (combination of production type and designed type);

The specific tests for EC type examination shall be carried out by the assessment team designated by MRC or in laboratories subcontracted by MRC (laboratories accredited/assessed and accepted by MRC).

MRC may accept tests to be performed using the manufacturer's test facilities (equipment) if the manufacturer has an accredited/assessed laboratory to perform those tests specified in the assessment plan, with or without the use of the manufacturer's personnel, provided that:

- these test facilities are calibrated and ensure the traceability of the standards used;
- the tests are carried out strictly in accordance with the test plan drawn up by MRC;
- MRC co-ordinates or assists the tests, if carried out by the manufacturer's personnel;
- MRC decides whether or not to take the test results into account.

In order to minimise costs for manufacturers and to reduce the duration of the certification process (especially in the case of foreign applicants and manufacturers), MRC may agree that tests are commissioned from accredited testing laboratories agreed with the applicant (manufacturer).

The specific type examination tests must cover all the characteristics of the product necessary to assess and certify its conformity with the specific essential requirements.

After completion of the tests, a copy of each test report shall be sent to MRC and the certification file manager shall examine whether:

- the test report forms and their structure are in accordance with the requirements of EN ISO/IEC 17025:2005;

- all tests required by the test programme and the harmonised standard, or other applicable specifications, have been carried out as required;
- the test results confirm (or not) that the products tested are in conformity with the toy safety requirements.

If the test reports are validated, it is assumed that the results confirm that the tested product meets the safety requirements. Otherwise, if the test results show non-conformity with the applicable requirements, MRC may agree with the manufacturer to repeat all or part of the tests at the certification applicant's own expense.

5.5.9. Evaluation report

On the basis of the examinations/tests/controls, test reports and documentation review report prepared by the assessment team, the assessor shall prepare the assessment report (F.MRC.OCS.12.05), which is endorsed by the Certification Manager and approved by the Executive Director of MRC.

The evaluation report contains, at least, information on:

- number and date of issue of the evaluation report;
- the identification data of the manufacturer and the applicant;
- toy name, category, unique identification number (code), age category, product characteristics;
- certification scheme
- assessment period
- proposal of the evaluation team (technical assessor) for certification
- test plan;
- conclusions on the technical documentation;
- conclusions on test results;
- type of verification (sampling or not)
- the laboratories that performed the tests;
- relevant test reports
- reference document against which conformity is established;
- final conclusions;
- name and signature of the members of the assessment team (technical assessor), who reviewed the documentation and/or carried out the examinations/tests/checks.
- annexes

5.5.10. Decision in 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 whether or not to accept the assessor's proposal for certification.

In doing so, the Certification Committee shall take into account in support of its decision the results of all examinations, tests and other activities carried out to assess the conformity of the product with the requirements of Directive 2009/48/EC and the requirements specified in the applicable harmonised European standards or other regulatory documents.

If a decision has been taken to grant certification, MRC shall inform the applicant accordingly and issue a Certificate of Conformity.

Where MRC refuses to issue a Certificate, it shall provide the applicant with detailed reasons for its refusal.

A documented appeals and complaints procedure is available to any interested party upon request and is posted on the website – www.mrco.ro.

5.5.11. Issuance of the certificate

The certificate, signed by the Executive Director of MRC or his authorised representative, is registered with a unique number and sent to the client.

The numbering of the certificate of conformity is as follows:

RO-*notified body number*-SJ-YZ00X, where:
RO = Romania
notified body number = identification number of the notified body
SJ = safety of toys
YZ = last two digits of the year of issue of the certificate
00X = serial number of the certificate

If the space reserved in the certificate is insufficient, it will be continued in an annex. If there are any limitations, these shall be entered in an annex to the certificate.

The certificate issued by MRC is sent to the customer (the manufacturer or his authorised representative) after which the holder of the certificate has the following rights and obligations:

a) Issuance of the EC declaration of conformity by the organisation

During the period of validity of the certificate of conformity, the organisation is obliged to complete the Declaration of Conformity and affix the CE conformity marking only on the certified toys (cf. Art. 15, respectively Art. 15 of Directive 2009/48/EC).

The declaration of conformity is issued under the sole responsibility of the manufacturer, is identified by a unique number and refers at least to:

- The model of the toy (product number, type, batch or serial number);
- Name and address of the manufacturer and, where appropriate, of his authorised representative;
- Subject of the declaration (identification of the toy, allowing traceability; addition of a coloured picture of the toy);
- Relevant harmonised standards used or references to other technical specifications in relation to which conformity is declared;
- Notified Body that carried out the assessment and issued the certificate;
- The number of the certificate issued by MRC;
- Additional information;
- Relevant harmonisation legislation.

b) Application of the CE conformity marking

- The CE marking shall be affixed visibly and legibly to the toy. Where this is not possible or justified on grounds of the nature of the size of the toy, the markings shall be affixed on the accompanying documents and, where appropriate, on the packaging.
- When removed, the CE marking shall self-destruct.

- If the toy consists of a set of parts/parts that function together, the CE marking shall be affixed to the main body/part of the toy.
- The CE marking shall be affixed before the toy is placed on the market.
- The CE marking may be affixed to the toy during the manufacturing process if justified.
- The certificate holder must ensure, upon the expiry of all or part of the CE certificate, whichever occurs, the immediate cessation of the application of the CE marking or a specific symbol to new products/toys and the removal of the CE marking or a specific symbol, if required, from any product/toy in its possession and the discontinuation of the use of all others or references to it, including all references to the CRM in all advertising, media and other promotional material.

The correct issue of EC declarations of conformity and the correct application of EC conformity markings are verified by the designated market surveillance bodies and are also subject, among other things, to verification by MRC following market complaints.

The affixing of markings on the toy which are likely to mislead third parties as to the meaning and/or form of the CE marking is prohibited, but any other marking, warning, etc. may be affixed provided that it does not reduce the visibility and legibility of the CE marking.

c) Registrations

The certificate holder must keep, for any toy for which a EC certificate has been issued, all documents and data relating to the conformity of the toy with the essential requirements of Directive 2009/48/EC on the safety of toys, legible, retrievable and in an acceptable form, for a minimum period of 10 years as defined in the Directive, after cessation of manufacture of the product/toy concerned.

5.6. Appeals and complaints

Applicants may appeal/claim the activities carried out by the certification body (its decisions, non-compliance with contractual obligations, etc.) as follows:

- the activities and behaviour of the assessment teams
- failure of MRC staff to maintain confidentiality
- non-discriminatory access to certification information and procedures
- non-conformities raised and assessment team recommendations within 15 days from the date of communication
- decisions of the Certification Committee.

Complaints/appeals must be made by the client within 15 days from the date of the activity or communication of the contested decision.

The applicant may present their complaint arguments formally to MRC.

Complaints can be made to the Executive Director of MRC. If they were involved in the activity being challenged, a complaint may be made to the next level up.

Appeals and complaints can be made by applicants for certification, certified organisations as well as all stakeholders in the certification process.

Appeals concern the certification decision. If the certification applicant is aware that the decision of the Certification Committee is unfair, he/she may appeal it to MRC Professional Ethics and Appeals Committee.

5.7. Validity of the Certificate of Conformity

The EC Type Examination Certificate is valid for 5 years from the date of issue, subject to the maintenance of the requirements against which certification was granted and will be reviewed, however, every 5 years.

Any change in the design, manufacture, materials, equipment and technology of the toy that alters the initial conditions considered when certifying the toy must be notified by the manufacturer, and MRC will carry out a new assessment to verify whether the changes affect compliance with the safety requirements of the toy, in which case the initial certificate will lose its validity and a new certificate will be issued.

If the essential and specific requirements are still met, the original certificate is maintained.

5.8. Additional assessments

Additional assessments shall be carried out in the following situations:

- to assess the changes communicated by the organisation, on which occasion MRC will decide whether the general and specific requirements are still met,
- in case of complaints or at the request of the competent designating authority.

Additional assessments shall be notified in advance to the certified organisations.

If non-conformities are found in the additional assessments, the deadline for resolution is 2 months. If the 2-month period is exceeded before resolution, certification will be suspended.

In this case, MRC notifies the Competent Authority and the client within 24 hours of the suspension of certification.

From that moment the organisation is no longer entitled to use the certificate and the CE conformity marking in dealings with third parties for the toy.

If it is found that non-conformities have not been resolved within 3 months, the certification is withdrawn.

5.9. Revision of the EC type-examination certificate

The start of the revision process shall be initiated by the organisation at least 3 months before the expiry of the certificate.

The organisation must submit a firm recertification order to MRC for the conclusion of the recertification contract in order to review and issue the certificate.

The re-examination covers all the referential requirements, includes the analysis of the documents submitted by the client as at the initial certification and the tests set out in the assessment plan.

The decision to re-certify is made in the same way as the certification decision, based on the evidence from the recertification assessment.

A new certificate is issued after the certification decision has been taken by the Certification Committee.

5.10. Extension

The extension (inclusion of a new product/toy) is requested by the client by submitting an order which is reviewed by MRC and an Additional Act to the existing Certification Contract is concluded.

The evaluation for extension (inclusion of a new product/toy) is carried out in the same way as the certification evaluation.

In case a manufacturer applies for extension of certification and if the technical documentation review for the extension shows that the product complies with the requirements of the Directive (no additional testing is required compared to the certification of the already certified product or the previous extension), the assessor completes the report on the review of the documentation for the certification of conformity and recommends the extension of certification (or not).

The decision to extend certification is taken by the Certification Committee.

5.11. Restriction

Restriction takes place at the request of the customer, e.g. due to a narrowing of the range of products/products manufactured or the relocation of a production site.

The customer's request is considered by MRC and an Additional Act to the existing Certification Contract is concluded.

5.12. Suspension

Situations leading to suspension of certification are:

- non-conformities have been found and the product no longer meets the requirements of the reference standard
- incorrect use of the certificate and CE conformity marking
- failure to inform MRC of significant changes made which may affect the quality of the product
- the certified customer voluntarily requests suspension.

During the period of suspension the right to use the certificate of conformity and CE conformity marking is prohibited.

In case of suspension, MRC shall send an official notification to the organisation specifying the reasons for the decision as well as the deadline for the revocation of the suspension and the measures to be taken by the certificate holder which may be as appropriate:

- withdrawal of certified products, possibly non-compliant, from users, the retail market or places of distribution and their return to the place of manufacture or other acceptable place for correction/corrective action;
- removal of the CE conformity marking from withdrawn products, reworking or replacement of withdrawn products.

MRC shall notify the competent authority of the suspension of the certificate within 24 hours.

5.13. Withdrawal and cancellation of the certificate

Situations resulting in withdrawal and cancellation of the certificate:

- the organisation does not apply the requirements resulting from the amendment of MRC certification documents, which have been brought to their attention;

- the organisation fraudulently uses the notified body number (e.g. on EC declarations of conformity accompanying products not covered by the certification or products that have undergone changes compared to the certified product, etc.);
- the organisation violates contractual requirements;

5.14. Notification of changes

5.14.1. Changes made by the organisation

The organisation shall notify MRC at least 30 days in advance of:

- design changes
- - changes in technology
- - changes in technological developments
- - changes in materials used, etc.

The organisation must not supply products manufactured with modifications announced as certified without a written agreement from MRC.

MRC will review the nature of each change made by the organization and if it may affect the already certified product, will schedule an additional evaluation.

6. PRIVACY

MRC guarantees the confidentiality of information obtained during certification activities, unless otherwise required by law.

MRC staff as well as collaborating staff (assessors/contracted experts) sign a confidentiality pledge, which commits them not to disclose information collected during the assessment process to a third party without written authorisation from the organisation.

7. MANAGEMENT OF COMPLAINTS AND APPEALS

The organisation has the right to make written complaints or appeals with full identification of contact details.

The appeal is the organisation's refusal to accept decisions made by MRC regarding assessment and certification activities. Disputes arise from the organisation's refusal to accept MRC's decision on an appeal.

The appeal shall be made in writing and submitted to MRC no later than 15 days from the date the notification of the decision was received.

An acknowledgement of receipt of the appeal is sent to the appellant. MRC reviews all documented sources on the subject.

After obtaining all necessary information MRC communicates the decision to the appellant.

If the appeal is justified, MRC orders the necessary corrections/corrective actions and ensures that they have been implemented.

The timeframe for resolving the appeal is 30 days from receipt by MRC, unless there are objective reasons that require an extension.

If the customer is dissatisfied with the response received, they may appeal MRC's decision. In this case, the Executive Director of MRC is obliged to bring the appeal to the attention of the EAPC. The Commission will make an independent investigation and analysis and its decision will be final.

The costs of the investigation will be borne by the appellant if the CPEA finds the appeal to be unfounded and orders in favour of MRC, and if the CPEA decides that the appeal is meritorious and rules in favour of the appellant, all costs of conducting the investigation will be borne by MRC. Necessary expenses of the investigation means all expenses incurred for the purpose of disposing of the appeal (e.g. costs of the CPEA, experts, etc.).

If, following the resolution given by the CPEA, the appellant considers himself wronged, he may apply to the competent courts, initiating a dispute which will be settled according to the provisions of the Romanian legislation in force.

The complaint concerns the organisation's dissatisfaction with the administrative or technical performance of MRC.

Complaints shall be registered by MRC which:

- acknowledges receipt of the complaint to the complainant;
- informs the complaining client of the receipt of the complaint.

MRC reviews the complaint and all related data.

If the complaint is founded and has been made within the time limit, MRC determines the necessary actions and informs the complainant.

Certification by MRC does not include certification of facilities. MRC does not assume any liability for damage or accidents caused by faulty or negligent operation of processes and facilities within the organisations or for defective products. As a result, complaints in these categories do not fall within the competence of MRC as a certification body.

The decision on the complaint resolution is determined/approved by persons not previously involved in the subject of the complaint. The complaint resolution period is 30 days from receipt by MRC, unless there are objective reasons that require an extension.

8. OTHER INFORMATION

MRC publishes these general requirements for certification on the website www.mrco.ro.

MRC informs clients, by means of the contract, of the fees for certification and its maintenance.

At the request of any interested party, MRC shall make public the information concerning the client and the certified products and at the same time undertakes to confirm in writing, by fax or e-mail, or by telephone on request, the validity of a certification granted.

In exceptional cases, access to certain information may be limited at the request of the customer.

MRC may make information concerning the client available to a third party only with the client's prior consent, except in cases expressly provided for by law.

The Instruction shall become effective upon approval by the Executive Director of the MRC, as of the date of accreditation.

9. ANNEXES

Annex 1 - Stages of the toy certification process under Directive 2009/48/EC

Annex 2 - Certification process

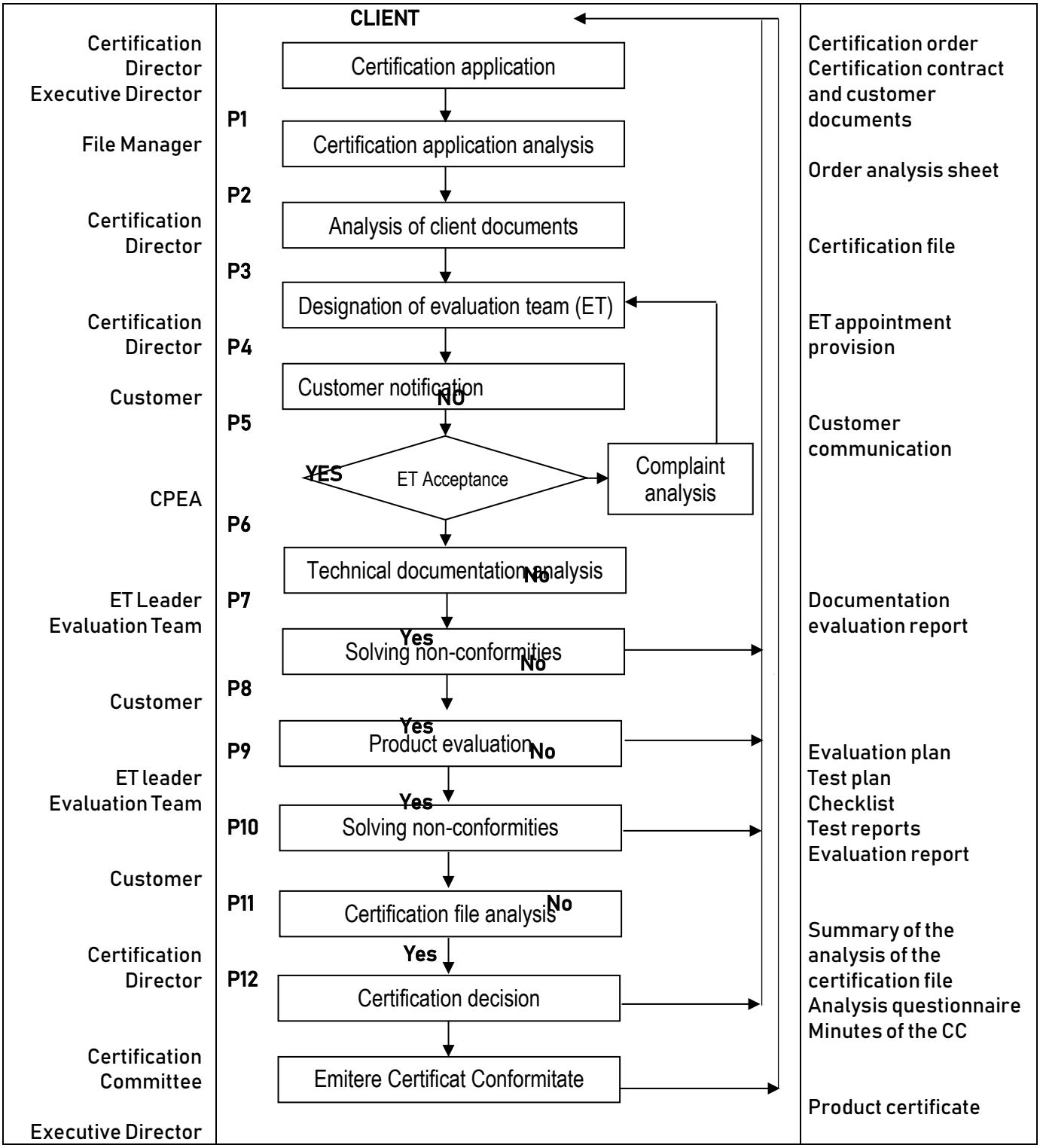
Annex 1

Stages of the product certification process

1. Stages of the product certification process
2.
3. Provision of information documents, model application and preliminary assessment questionnaire to the client
4. Completion and submission to MRC of the model application and preliminary assessment questionnaire
5. Official registration of the certification application
6. Submission of the product documentation to MRC
7. Preliminary analysis of the application and issue of the price offer
8. Conclusion of the certification contract
9. Examination of technical documentation
10. Preparation of the technical documentation analysis report
11. Preparation of test programme
12. Examination of evidence to establish adequacy of technical design
13. Carrying out tests
14. Preparation of test report
15. Preparation of Certification File Analysis Report
16. Decision to grant certification

Annex 2

Manager	Process diagram	Documents and Records


CLIENT
Certification Director
Executive Director
Certification application
Certification order
Certification contract and customer documents
P1
File Manager
Certification application analysis
Order analysis sheet
P2
Certification Director
Analysis of client documents
Certification file
P3
Designation of evaluation team (ET)
Certification Director
P4
ET appointment provision
Customer notification
Customer
NO
P5
Customer communication
YES
ET Acceptance
Complaint analysis
CPEA
P6
Technical documentation analysis
No
ET Leader
Evaluation Team
P7
Documentation evaluation report
Yes
Solving non-conformities
No
Customer
P8
Yes
Product evaluation
No
P9
Evaluation plan
Test plan
Checklist
Test reports
Evaluation report
ET leader
Evaluation Team
Yes
P10
Solving non-conformities
Customer
P11
Certification file analysis
No
Summary of the analysis of the certification file
Analysis questionnaire
Minutes of the CC
Yes
Certification Director
P12
Certification decision
Certification Committee
Emitere Certificat Conformitate
Product certificate
Executive Director