



TITLE	Technical regulation for certification under the Toys Directive 2009/48/EC
CODE	RG-PC-GIO-01-01
REVIEW	0.9
DATE	22.06.2026

CONTROLLED COPY	☒
UNCHECKED COPY	☐

Rev.	Date	Written by	Verified by	Approved by	Description of changes
0.0	02.11.2018	GIO Scheme Manager	Quality Manager	Quality Manager	First issue
0.1	09.08.2019	GIO Scheme Manager	Quality Manager	Quality Manager	Updated following ED-PRD Accredia
0.2	07.04.2022	GIO Scheme Manager	GIO Scheme Manager	Technical Director	Updated following deletion of English language
0.3	24.05.2022	GIO Scheme Manager	Quality Manager	Quality Manager	Updated due to typos
0.4	05.09.2022	GIO Scheme Manager	Quality Manager	Quality Manager	Update following internal audit findings
0.5	01.03.2023	GIO Scheme Manager	Quality Manager	Quality Manager	Updated following ED-PRD Accredia
0.6	15.09.2023	GIO Scheme Manager	Quality Manager	Quality Manager	Updated following ED-PRD Accredia
0.7	30.05.2025	GIO Scheme Manager	Quality Manager	Quality Manager	Updated following ED-PRD Accredia
0.8	19.11.2025	GIO Scheme Manager	Quality Manager	Quality Manager	Eliminated \$5 OBL following ED-PRD Accredia
0.9	18.06.2026	GIO Scheme Manager	Quality Manager	Quality Manager	Update \$6

1 Table of Contents

2	FOREWORD.....	4
3	PURPOSE AND SCOPE	4
3.1	REFERENCE DOCUMENTS	4
3.2	TERMS AND DEFINITIONS	5
	<i>DANGER: A POTENTIAL SOURCE OF HARM;</i>	5
3.3	AFFILIATES AND SUBCONTRACTORS	5
4	CERTIFICATION PROCESS	6
4.1	GENERAL	6
4.2	REPORTING OBLIGATION.....	7
4.3	AUTHORISED REPRESENTATIVE OR AUTHORISED REPRESENTATIVE.....	7
4.4	VALIDITY AND RENEWAL OF CERTIFICATION	7
4.5	MAINTAINING CERTIFICATION.....	8
4.6	CERTIFICATE MODES AND EXTENSION.....	8
4.7	WAIVER, SUSPENSION AND REVOCATION OF CERTIFICATION	8
4.7.1	<i>Waiver.....</i>	9
4.7.2	<i>Suspension</i>	9
4.7.3	<i>Revocation</i>	<i>Errore. Il segnalibro non è definito.</i>
5	ADVERTISING – USE FOR CE MARKING PURPOSES	10
6	PRESERVATION OF SAMPLES AND DOCUMENTATION.....	11
7	USE OF TRADEMARKS AND LOGOS.....	11
8	CONFORMITY ASSESSMENT PROCEDURES.....	11
8.1	APPLICATION FOR CERTIFICATION	11
8.2	REVIEW OF THE APPLICATION	12
8.3	PLANNING AND EXECUTION OF EVALUATIONS/TESTS	12
8.4	EQUIPMENT USED	13
8.5	REQUIREMENTS FOR TESTING LABORATORIES AND RELATED REPORTS	13
8.6	LANGUAGE.....	13
9	CONFORMITY ASSESSMENT PROCEDURES.....	13
9.1	EC TYPE-EXAMINATION	13
9.2	EVALUATION REPORT	15
9.3	CERTIFICATION ISSUANCE.....	16

2 Foreword

This regulation binds MTIC and the applicant organization to comply with the provisions of this regulation. It is considered fully known and accepted by the Organization, following the signing of the contract represented by the certification application submitted and the acceptance of the economic offer.

This Regulation defines the conditions for the granting, extension, revocation and renunciation of the EC-type examination certificate to Organisations, with reference to the assessment and certification procedures adopted by MTIC.

All the documentation necessary for certification must be submitted to MTIC in Italian or English.

For the general terms and conditions of the contract, please refer to document RG-GQ-01-01 published on the website www.mtic-group.org to section "Who we are" .

3 Purpose and scope

This regulation defines the rules and methods for providing the certification service implemented by MTIC in accordance with the provisions of Directive 2009/48/EC (hereinafter the Toys Directive) in the following areas:

- Module B (EC Type Examination)

For all the activities specified in this Regulation, MTIC applies the provisions of the mandatory legislation issued by the competent authorities.

This Regulation applies to conformity assessment procedures under Directive 2009/48/EC.

Any changes to the regulations themselves will be communicated by e-mail when they are published on the website.

Such changes are deemed to be accepted unless explicitly communicated by the customer.

3.1 Reference documents

In general, the reference documents cited are applicable in the latest valid edition and/or revision.

- Directive 2009/48/EC on the safety of toys
- Legislative Decree No. 54 of 11 April 2011 Implementation of Directive 2009/48/EC on the safety of toys.
- Guidelines issued by the European Community and Shared Opinions issued by the working groups of the European Commission.

The Standards referred to and/or harmonized pursuant to Directive 2009/48/EC will be applied as published in the Official Journal.

- UNI CEI EN ISO/IEC 17065 Requirements for Bodies that certify products, processes and services.
 - UNI CEI EN ISO/IEC 17067 Fundamental Elements of Product Certification and Guidelines for Product Certification schemes.
 - EN 71 Series
 - IEC 62115 - Electric toys. Safety
 - UNI CEI EN ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
- RG-GQ-01-01 General Terms and Conditions

The documents cited are for explanatory but not exhaustive purposes

3.2 Terms and definitions

For the purposes of these Regulations, all the definitions set out in Article 3 of Directive 2009/48/EC shall apply, in particular and/or in addition to the following:

Making available on the market: the supply of a toy for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;

Placing on the market: the first making available of a toy on the Community market;

Manufacturer: natural or legal person who manufactures a toy, or has it designed or manufactured, and markets it under his or her own name or trademark;

Authorised Representative: a natural or legal person established in the Community who has received a written mandate from a Manufacturer authorising him to act on his behalf in relation to certain tasks;

Importer: a natural or legal person established in the Community who places on the Community market a toy originating in a third country;

Distributor: a natural or legal person in the supply chain, other than the Manufacturer or importer, who makes a toy available on the market;

Harmonised standard: a standard adopted by one of the European standardisation organisations listed in Annex I to Directive 98/34/EC on the basis of a request submitted by the Commission in accordance with Article 6 of that Directive;

Community harmonization legislation: Community legislation that harmonizes the conditions under which products are marketed;

Accreditation: the same meaning as in Regulation (EC) No 765/2008;

Conformity assessment: the process of demonstrating whether the specific requirements relating to a toy have been met;

Conformity assessment body: a body that carries out conformity assessment activities, including calibrations, tests, certifications and inspections;

Recall: any measure aimed at obtaining the return of a toy that has already been made available to the end user;

Revocation: any measure aimed at preventing a toy from being made available on the market in the supply chain;

Market surveillance: the activities carried out and the measures taken by public authorities to ensure that toys comply with the applicable requirements laid down in Community harmonisation legislation and do not adversely affect health, safety or any other aspect of the protection of the public interest;

CE marking: a marking by which the Manufacturer indicates that the toy complies with the applicable requirements established in the Community harmonisation legislation that provides for its affixing of the toy;

Damage: physical injury or any other damage to health including long-term health effects;

Hazard: A potential source of harm;

Risk: the probability of the occurrence of a hazard that is a source of damage and the severity of the damage;

Company: Organization that requires (or has obtained) the Certification;

TM: Technical Director of the body;

Establishment: site where the Manufacturer produces its products subject to certification;

Approval: recognition, through a specific procedure, that a particular skill (knowledge and experience) is suitable for a specific product/activity.

3.3 Affiliates and subcontractors

If MTIC intends to entrust, in part or in full, the certification activities to affiliates and/or subcontractors, the Organization will be informed in advance and explicit consent will be requested.

In any case, MTIC retains responsibility for the certification decision.

Conformity assessment bodies shall ensure that the activities of their affiliates or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

4 Certification Process

4.1 General

Manufacturers wishing to obtain certification for the Type they intend to place on the market must send by fax, post or e-mail a specific request (form F-PC-GIO-01-01 Rev. 0.0_Scheda Data collection for request for quotation) containing the information necessary for the formulation of the service proposal.

The Manufacturer is solely responsible for the conformity of the toy which he certifies with the issue of the Declaration of Conformity (Art. 15 and Annex III of the Directive).

MTIC accepts applications without discrimination, prejudice or favourable conditions, deriving from membership in particular associations and/or categories.

MTIC carries out a preliminary examination to verify whether the information provided is sufficient to formulate a service proposal, reserving the right, if necessary with reference also to what is reported in these Regulations, to request further details.

Where the Manufacturer has applied the harmonised standards, the references of which have been published in the Official Journal of the European Union, concerning all toy safety requirements, the Manufacturer shall follow the internal production control procedure set out in Module A of Annex II to Decision No 768/2008/EC.

The toy shall be subject to an EC type-examination referred to in Article 20 together with the conformity to type procedure provided for in Module C of Annex II to Decision No 768/2008/EC in the following cases published in the Official Journal of the European Union, covering all toy safety requirements:

- a) when the harmonised standards referred to in letter a) exist, but the Manufacturer has not applied them or has applied them only partially;*
- (b) where one or more harmonised standards referred to in point (a) have been published with a restriction;*
- c) when the Manufacturer considers that the nature, design, construction or intended use of the toy requires recourse to verification by third parties.*

On the basis of these indications, a proposal for services (offer) is formulated, with reference to these Regulations, which will be sent together with the Application for Certification. This regulation and the application for certification constitute contractual documents to all intents and purposes.

Upon receipt of the duly completed Certification Application, where the manufacturer declares that he has not submitted an application for certification for the same product to another Notified Body, and of the countersigned offer for acceptance of the service proposal issued, MTIC will have 10 working days to submit comments to these requests or reject them.

After this deadline without which comments or observations have been made, the request must be considered automatically accepted and therefore the MTIC INTERVENTIONS carried out according to these Regulations must be considered contractually formalized.

From the positive review of the certification application, after the **six-month period** without a positive conclusion of the assessment and without communication from the manufacturer, MTIC can consider the certification file closed and formalize a refusal to certification. MTIC will proceed to charge the time and expenses incurred up to that moment. In such cases, the Manufacturer may not submit a new application for certification for the same product.

The aforementioned time limits may in particular cases be varied upon reasoned request by the Manufacturer, in the opinion of MTIC.

Upon successful completion of all the examinations and tests required by the certification procedures and by these Regulations, the technical secretariat sends the file complete with all the documentation to one or more competent and independent technicians (deliberation committee) for the complete review of the same and the decision on the granting of the certification. Following the positive outcome of the decision of the deliberation committee, MTIC will issue the required certificate.

4.2 Reporting obligation

MTIC has the obligation to inform the Notifying Authority:

- any refusal, restriction, suspension or withdrawal of a certificate;
- any requests for information they have received from market surveillance authorities in relation to conformity assessment activities;
- upon request, the conformity assessment activities carried out as part of their notification and any other activities, including cross-border and subcontracting activities.

In addition, it has the obligation to provide access to the list of certified organizations.

MTIC has the obligation to provide other notified bodies with relevant information on issues related to negative and, upon request, positive results of conformity assessments.

The European Commission, Member States and other Notified Bodies may obtain, upon request, a copy of the Type Examination Certificates and/or their supplements. The European Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by MTIC upon justified request.

4.3 Authorised representative

The Manufacturer may appoint, by means of a written mandate, an authorised representative. The mandate must respect the limits and prerogatives set out in Directive 2009/48/EC. The mandate must allow the authorised representative to carry out at least the following tasks:

- keep the EU declaration of conformity and technical documentation available to national market surveillance authorities for a period of ten years from the last date of placing the toy on the market;
- following a reasoned request from a national competent authority, provide the latter with all the information and documentation necessary to demonstrate the compliance of the toy;
- if the competent national authorities so request, cooperate with them in any action taken to eliminate the risks presented by the toy within its mandate.

Therefore, if the Manufacturer has identified an authorised representative, MTIC will require evidence that the mandate contains at least the above.

The authorised representative may submit the EC Type Examination Application and generally fulfil the administrative obligations provided for in Directive 2009/48/EC on behalf of the Manufacturer, provided that they are specified in the mandate.

The obligations referred to in Article 4, paragraph 1 of the Directive and the obligations to create the Technical Manufacturing Documentation referred to in Annex IV to Directive 2009/48/EC, which are the responsibility of the Manufacturer, do not fall within the mandate.

For the purposes of these Technical Regulations, any reference to "the Manufacturer" or "the Organisation" shall read as "the Manufacturer or its authorised representative".

4.4 Validity and renewal of certification

The validity of the certifications issued by MTIC is defined by the reference Directive, in particular for the Toys Directive the validity of the certifications issued is five years, except for changes to the product and/or to the standards applicable to the manufacture of the product.

At the end of the five years, in order to keep the certificate active, the manufacturer must make a formal request to MTIC which will issue an appropriate offer; upon acceptance of the same, the body will evaluate the documentation relating to the product and if it does not find any changes, it will confirm the validity of the certificate for the same period.

However, MTIC keeps up to date with technological progress and regulatory updates, particularly regarding project approvals. If there are substantial changes that affect compliance with the Directive, MTIC informs the Manufacturer so that it can make the necessary adjustments.

4.5 Maintaining certification

The Manufacturer must maintain the conformity of the products with the applicable reference standards, is required to periodically check the state of the art, as well as changes to the legislation in force or to the harmonized standards to which conformity is declared.

The Manufacturer undertakes to notify MTIC of any significant changes that may affect the requirements that led to the certification.

The Manufacturer must keep records of any complaints received from its customers regarding the products covered by the certificate and the related corrective actions taken and must make them available to MTIC.

MTIC reserves the right to carry out additional checks at the Manufacturer's premises in the event of complaints or reports, considered particularly significant, relating to the non-compliance of the products with the requirements of the reference standards and with these Regulations, or in order to verify the conformity of the product following the changes communicated by the Manufacturer. In the event of refusal, without valid reasons, by the Manufacturer, MTIC may initiate the process of suspending the certification.

In the event that complaints and reports are deemed justified by MTIC, the cost of carrying out further tests is borne by the Manufacturer.

The manufacturer undertakes to accept, if requested, the presence of Accredia inspectors during the conformity assessment, otherwise MTIC reserves the right to proceed with the suspension of the certificate and if the situation persists to revoke it.

If, during the period of validity of the certificate, changes occur to the certification requirements required by the applicable standards, MTIC will notify the Manufacturer in order to define the actions to be taken.

4.6 Certificate and Extension

In the event of changes to the certification requirements, made necessary as a result of changes or updates to the legislative landscape and by this Regulation, these changes will be promptly communicated in writing by MTIC to the manufacturers concerned, indicating the date on which they will enter into force.

For all regulatory changes or updates, it is the responsibility of the Manufacturer to adapt its products to the new requirements.

Adaptation to the new provisions will be mandatory by the date of entry into force of the same. If necessary, the certifications issued and the manufacturers holding them may be verified for a supplementary assessment by that date.

If the outcome of the checks certifies that the products have been adapted to the new applicable requirements and therefore comply with the requirements of the reference standard, MTIC will maintain the pre-existing certificate of conformity. Otherwise, it will revoke the same (paragraph 3.6.3)

The applicant is also required to notify MTIC of the intention to put into production products of new conception or with modifications, compared to the certified ones, which may require the adaptation of certification and production. MTIC will conduct laboratory and/or documentary checks for the assessment of conformity of the new variants to the Type or the modified Type

If the outcome of the verifications certifies that the variants or the modified type comply with the requirements of the reference standard, MTIC grants an extension of the pre-existing Type certificate.

Extension requests related to:

- certificates of a different gender than the original one;
- new applicants than the one indicated in the original certificate;
- conformity of a single product or a different project;

are treated as new certification applications.

4.7 Waiver, Suspension and Withdrawal of Certification

In the event of suspension, withdrawal or waiver of the Certificate, the Manufacturer must notify MTIC of the presence of the products already manufactured ready to be placed on the market, whose marketing authorisation will be subject to specific assessment by MTIC.

In the event of withdrawal, suspension and reactivation of existing certificates, the technical deliberation committee will be convened.

4.7.1 Waiver

The organization may renounce the Product Certification in its possession, giving formal notice with 6 months' notice:

- if you do not agree to any revisions to this document;
- in the event of non-acceptance of the changes to the economic-contractual conditions established by MTIC Intercert srl
- for reasoned withdrawal of the Contract (e.g. cessation of production of the product, forfeiture of the contract, etc.).

Following the renunciation, the organization undertakes to:

- return the original of the Certificate of Conformity;
- not to use any copies or reproductions;
- immediately suspend, giving written confirmation, the use of any type of graphic characterization (letterhead, technical and advertising documentation, forms, etc.) containing the trademark and/or references to the certification;

The waiver of the Certification entails, by MTIC Intercert:

- the cancellation of the Certificate of Conformity;

The Manufacturer provides MTIC with a list of the products in stock.

The Manufacturer also undertakes not to allow certifications relating to the same product issued by different Notified Bodies to coexist.

MTIC Intercert reserves the right to publish the information of waiver of the Certification.

If the waiver is communicated after MTIC Intercert has started the certification process, the cancelling organization will have to pay a file closure fee equal to 50% of the contract amount; in this case, MTIC Intercert will give notice of waiver to the competent authorities and to all the notified bodies for the toys directive.

4.7.2 Suspension

A product certification may be suspended due to situations that may compromise the conformity of the product with the relevant directive or the legislative instrument applied, the decision is always taken by the deliberation committee, for example, for the following reasons:

- any well-founded reports by market surveillance authorities;
- the improper use of the Certification, the Registration documents and the Trademark;
- the use of its certification in a way that brings MTIC into disrepute;
- issuing statements, documentation or marks about its certification that may be considered misleading or abusive;
- repeated failures to comply with this document or MTIC's procedures;
- conditions of arrears in payments.

The suspension can be accepted if requested by the customer.

The Manufacturer will be notified in writing of the suspension of the certification. The disclosure will contain the reasons for the suspension and the temporary expiration date for any corrective actions.

The time taken to resolve the non-conformities that gave rise to the suspension ranges from a minimum of 30 to a maximum of 180 calendar days.

After six months without any solution, the certification will be automatically revoked (see next paragraph).

The customer who believes that he has resolved all the non-conformities asks for verification to confirm the resolution; MTIC carries out the assessment or appoints competent figures in order to take the decision, notifying the Manufacturer.

The reinstatement of the certification is subject to the verification of the elimination of the deficiencies that had caused the suspension itself through the verification of the product and the Manufacturer to ascertain their compliance with all the requirements of the reference standard.

It shall be notified in writing to the Manufacturer and made publicly known by MTIC if the notice of the suspension had been made public at the time.

4.7.3 Withdrawal

MTIC, following the decision of the deliberation committee, may withdraw a Certificate of Conformity for the following reasons, in brackets is given the maximum time within which to resolve non-conformities to avoid revocation:

- 1) The product does not comply with the requirements of Article 10 and Annex II of the Toys Directive.
- 2) Failure to comply with the Regulations and contractual conditions (30 days);
- 3) Exceeding the suspension period of 180 days (none);
- 4) Serious non-compliance in the manufacture of the product and/or raw materials that may affect the safety of the product (immediate);
- 5) For any other serious reason, in the opinion of MTIC such as, for example, but not limited to, the proven inability of the system to pursue its objectives of compliance with legislative or contractual constraints or product safety (in the opinion of MTIC);
- 6) Non-payment of the certification invoice, partial or total.

MTIC will always communicate the revocation of certifications:

- To the Notifying Authority responsible for market surveillance;
- To the National Accreditation Body (if required);
- To all other Notified Bodies.

The Manufacturer may request the withdrawal of the certification in writing, accompanied by objective reasons.

The Manufacturer whose certification has been revoked must:

- Return the revoked certificate by notifying the Body. If the certificate is not received within 30 days, MTIC will consider the certificate destroyed under the responsibility of the Manufacturer;
- Remove all references to certification;
- If applicable, remove all references to the ACCREDIA mark granted to certified Organizations (see RG-09 on the website www.accredia.it for details);
- Do not use copies and/or reproductions of the revoked certificate.

The Manufacturer who, after the revocation, intends to access the certification again, must submit a new application following the entire procedure provided for by these Regulations.

The Manufacturer may request the withdrawal of the certification in writing, accompanied by objective reasons.

MTIC, following the decision of the resolution committee, will issue a resolution sheet for which the revocation of the certificate will be made official.

From the date of revocation, the manufacturer must suspend the affixing of the CE marking to his products and the products in stock cannot be put on the market unless previously verified.

The manufacturer must suspend any publicity actions relating to the certification of the toy.

5 Advertising – use for CE marking purposes

The Manufacturer may disclose in the most appropriate ways the obtaining of the certification by MTIC. The Manufacturer must in any case clearly indicate any limitations and conditions imposed by MTIC at the time of issuing the aforementioned certification.

The Manufacturer may reproduce the Certificate in its entirety, enlarging or reducing it, provided that it remains legible and is not altered in any way.

In using the Certificate, the Manufacturer must avoid that the certification can be understood as extended to products not included in those covered by the certification issued by MTIC.

In the event of use of the Certificate that does not comply with the above points or in the event of their unlawful use, MTIC will take appropriate measures against the Manufacturer, including the use of appropriate legal action.

6 Preservation of samples and documentation

MTIC ensures the correct handling of samples during testing.

Storage at MTIC or at the manufacturer's premises of samples already subjected to verification is not required.

MTIC ensures the storage of the tested toys for a period of at least 6 (six) months from the date of issue of the EU Type Examination Certificate and unless otherwise agreed will dispose of the same

Any disposal costs are borne by the Manufacturer.

The Manufacturer must ensure their traceability and safekeeping in order to maintain their integrity and keep them for a period of at least 10 years from the date of the last placing on the market of the toy covered by the EU Type Examination Certificate.

In the event of a dispute during the period in which the toy is marketed, the Manufacturer must make available to MTIC all the toys described above sealed.

Copies of the certificates and the significant files of technical documentation listed in the certificates are kept by MTIC for the time provided for by current legislation. At the end of this period, the documentation, if on paper, is digitized and stored together with the relevant documentation already in digital format.

The Manufacturer is asked to return the paper documents, in case of no response within 30 days, the documents are destroyed. Digital documents are archived and stored until the entity exists.

7 Use of trademarks and logos

MTIC does not provide for the granting of the use of its certification mark for conformity assessment activities conducted in the notified area.

The use of the ACCREDIA mark is only possible in combination with the MTIC certification mark, for the terms of use of the ACCREDIA mark please refer to the RG09 regulation at the latest revision available on the website www.accredia.it.

The methods of affixing the marking are regulated by the Directive itself.

8 Conformity Assessment Procedures

8.1 Application for certification

After the first contact with the customer (telephone or email), all the information necessary to start the certification process is requested.

The customer will be sent a special form (F-PC-GIO-01-01 Rev. 0.0_Scheda Data collection for request for quotation), which he must fill in in its entirety, necessary for the formulation of the service proposal

Once the information has been obtained, MTIC prepares, on the basis of the price list, an economic offer for testing and certification activities and sends it to the interested customer together with the forms necessary for the submission of the application.

Certification can only be requested by the Manufacturer of the product or by a person or organization in possession of specific authorization from the Manufacturer.

If the application is submitted by the authorised representative established in the Community, it must contain, in addition to the name and address of the manufacturer, place of production, description of the type of product and the intended use, also the name and address of the authorised representative.

The applicant must submit the application by filling in the form provided by MTIC in its entirety, filling in one form for each model or for each homogeneous series of products.

If the application and the documents provided are incomplete, MTIC requests the necessary additions necessary to continue with the certification process.

The documentation provided by the applicant shall include, in accordance with the applicable attestation of conformity systems:

- Detailed description of the product, technical specifications and safety data sheets of the materials used and other data deemed necessary;
- List of characteristics/requirements falling within the field of interest of the conformity assessment activity and the list of reference documents (standards, etc.);
- Detailed drawings of the product (general design and manufacturing drawings, diagrams of components, sub-assemblies, circuits, etc.; including descriptions and explanations necessary for the understanding of these drawings and diagrams and of the operation of the product);
- Assembly and operating instructions;
- Available test reports and certificates relating to the product, technical documentation regarding the materials procured, etc.;

Where applicable, the application for certification must be accompanied by a sufficient number of samples for the appropriate assessments.

Upon acceptance of the offer by the Customer and upon receipt of the completed application, the application itself is reviewed and a file number is assigned.

8.2 Review of the application

The review of the certification application is the phase by which the conformity assessment procedure is initiated. The review of the application for certification takes into consideration the conditions and information on the basis of which the economic offer was prepared and verifies its continued existence through the application itself, the documentation and the samples received, if any.

Upon receipt of the certification application duly completed for acceptance of the service proposal issued, MTIC will have 10 working days to submit comments on said requests or reject them.

If the application for certification is not accompanied by the elements necessary for the start of activities, MTIC requests integration and the conformity assessment procedure is put on hold until the conditions are met.

If these conditions are not met, MTIC shall reject the application received and inform the competent bodies accordingly

8.3 Planning and execution of evaluations/tests

The activities envisaged for the products are carried out by MTIC, based on the requirements of the applicable assessment procedures (modules) described in detail later in these Regulations.

MTIC will communicate to the Manufacturer the name of the person in charge of the practice and the persons in charge who will carry out the evaluations; the Manufacturer may object in writing to the appointment of such technicians, justifying the reasons within five days of receipt of the communication.

Upon successful completion of all the examinations and tests provided for and specified in the service proposal sent to the Manufacturer and accepted by him, the technical secretariat sends the file, complete with all the documentation, to one or more competent and independent technicians of MTIC (deliberation committee), for review and resolution.

Following the positive outcome of this verification and the approval of the relevant certification proposal, MTIC will issue the certificate required by the chosen assessment module and will send it to the Manufacturer following payment of the relevant invoice.

In the event of a negative outcome, MTIC shall notify the Manufacturer of this outcome and agree with the Manufacturer on the modalities for any re-evaluation. Any refused certification is also communicated to the Authority in charge of market surveillance and other notified bodies-

8.4 Equipment used

MTIC has internal laboratories for carrying out certification and control tests. If MTIC does not have the tools, it may proceed with subcontracting as provided for in the following paragraph.

8.5 Requirements for testing laboratories and related reports

Applicants may submit to MTIC test reports in their possession, if issued by laboratories accredited according to ISO/IEC 17025 for the standards/tests relevant to the ongoing certification process.

In addition, test reports from laboratories that have been qualified by MTIC for the standards/tests relevant to the ongoing certification process are accepted.

If the test reports relating to the tests conducted on the representative sample of the product, submitted by the applicant to MTIC, should show a date of execution of the same, prior to the date of submission of the application for EU Type Examination or renewal of the certificate, the body will reserve the right to accept the same only following verification that:

- no changes to the reference standards for these tests have been necessary;
- the Manufacturer can demonstrate that no changes have been made to the materials, the production process, or other changes to the product subject to certification, with respect to the sample subject to the test reports presented.
- The test reports are NOT older than six months from the date of submission of the certification application and the technical standards underlying the tests must still be valid

MTIC reserves the right to use laboratories accredited by ISO/IEC 17025 or qualified by the Body for the execution of the required tests on the products. In such circumstances, MTIC will include in the bidding document the reference to the subcontracted laboratory.

8.6 Language

The documents and correspondence relating to the conformity assessment of a toy and/or the quality system must be in Italian or English. The Technical Documentation and/or the Quality System Documentation may contain, if necessary, some parts in different languages as long as they are also provided in Italian or English. In particular, the instructions for use are always evaluated in the Italian language only, and only in the absence of this are they evaluated in the English language.

For other Community languages, an additional offer for the translation of documents will be produced, if necessary.

Please note that compliance with the obligations regarding the language to be used for the instructions for use and for the EC declaration of conformity of toys placed on the European market is the responsibility of the Manufacturer. MTIC may examine how this is properly handled during type verification where applicable.

9 Conformity Assessment Procedures

9.1 EC type-examination

The EC-type examination is the part of a conformity assessment procedure by which MTIC examines the technical design of a product, as well as verifies and certifies that the technical design of the product complies with the applicable requirements.

The EC-type examination is carried out through an assessment of the adequacy of the technical design of the product, carried out by examining the documentation, together with the examination of samples, representative of the planned production, of one or more critical parts of the product (combination of type of production and type of design).

The Manufacturer submits the request for EC-type examination to a notified body of his choice.

The application must contain:

- name and address of the Manufacturer and, if the request is made by the authorised representative, also the name and address of the latter,

- a written statement that the same application has not been submitted to any other notified body (Application for certification),
- the technical documentation referred to in Article 21 of the Directive listed below.

The technical documentation referred to in Article 21 shall in particular contain, to the extent that it is relevant to the assessment, the following documentation:

- a detailed description of the design and manufacture, including a list of the components and materials used in the toys, as well as safety data sheets for the chemicals used to be requested from suppliers of the substances;
- the safety assessment(s) carried out in accordance with Article 18;
- a description of the conformity assessment procedure followed;
- a copy of the EC declaration of conformity;
- the address of the places of manufacture and storage;
- test reports and description of the means by which the Manufacturer has ensured the conformity of production with the harmonised standards in the event that the Manufacturer has made use of the internal production control procedure referred to in Article 19(2);

MTIC for the product:

- examines the technical documentation and evidence to assess the adequacy of the technical design of the product,

MTIC for Samples:

- verify that the samples have been manufactured on the basis of the technical documentation, and identify the elements designed in accordance with the relevant provisions of the relevant harmonised standards and/or technical specifications as well as the elements designed without applying the relevant provisions of those standards;
- carries out or has carried out appropriate examinations and tests to check whether, where the Manufacturer has chosen to apply the solutions referred to in the relevant harmonised standards and/or technical specifications, these solutions have been correctly applied;
- agrees with the Manufacturer on a place where the examinations and tests will be carried out.

MTIC draws up an evaluation report listing the initiatives undertaken and their results. Without prejudice to its obligations to the notifying authorities, MTIC shall make public the entire content of the report, or part thereof, only with the agreement of the Manufacturer.

If the type meets the applicable requirements, MTIC issues the Manufacturer with an EC type-examination certificate. The certificate shall indicate the name and address of the manufacturer, the conclusions of the examination, the conditions of validity and the data necessary to identify the approved type. The certificate may have one or more attachments.

The certificate and its annexes shall contain all relevant information enabling the conformity of the products manufactured with the type examined to be assessed and the product in operation to be checked.

If the type does not meet the applicable requirements: As provided for in Article 35(3) of Directive 2009/48/EC, if it is found that the requirements set out in Article 10d of Annex II or the corresponding harmonised standards have not been complied with by the manufacturer, the manufacturer shall be asked to take the appropriate corrective measures as a precondition for the issue of the EC-type examination certificate referred to in Article 20(4).

If the customer considers it inconvenient to intervene on the toy, the negative assessment report is issued, without issuing the EC type examination certificate and the procedure established by Article 36 of Directive 2009/48/EC is carried out (Article 27 of Legislative Decree 58).

If the customer deems it appropriate to make the necessary changes to resolve the non-conformities, the deadline is established within which the modified samples must be submitted again for tests or, in the case of the technical documentation, to make the required changes/additions.

For the findings that emerged during laboratory tests, they must be resolved with modifications to the prototype under examination, while for the findings that emerged during the evaluation of the technical documentation, they must be resolved within 15 working days and subjected to a new evaluation.

MTIC admits up to 3 re-evaluations to be completed within 6 months of the certification application. If the samples or documentation resolve the non-conformities found, the assessment report and the EC type-examination certificate are issued; otherwise, unless otherwise agreed, there is no provision for the issuance of a test report in the event of a negative outcome of the tests, the results of which are communicated in writing to the customer, by e-mail and the procedure established by Article 36 of Directive 2009/48/EC (Article 27 of Legislative Decree 58) is carried out.

MTIC follows the evolution of generally recognised technological progress and assesses whether the approved type no longer complies with the applicable requirements. It decides whether such progress requires further investigation. In this case, the notified body shall inform the Manufacturer accordingly.

The Manufacturer shall inform MTIC, holder of the technical documentation relating to the EC type-examination certificate, of any changes to the approved type that may affect the conformity of the product with the applicable requirements or the conditions of validity of the certificate. Such amendments require further type-approval, in the form of a supplement to the original EC type-examination certificate.

MTIC shall inform its notifying authorities of EC type-examination certificates and/or supplements issued or withdrawn by it and shall periodically or on request make available to the notifying authorities the list of certificates and/or supplements that have been rejected, suspended or otherwise restricted.

MTIC shall inform other notified bodies of EC type-examination certificates and/or supplements which it has rejected, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or supplements issued by MTIC.

The Commission, the Member States and other notified bodies may obtain, on request, copies of EC-type examination certificates and/or their supplements. The Commission and the Member States may obtain, upon request, a copy of the technical documentation and the results of the examinations carried out by MTIC. MTIC shall keep a copy of the EC type-examination certificate, the annexes and the supplements, as well as the technical archive containing the documentation submitted by the Manufacturer, until the expiry of the validity of the certificate.

The Manufacturer shall keep a copy of the EC Type Examination Certificate, the Annexes and the Supplements together with the technical documentation available to the national authorities for ten years from the date on which the product was placed on the market.

The authorized representative of the Manufacturer may submit the request and carry out the obligations envisaged, provided that they are specified in the mandate.

9.2 Evaluation report

At the end of the evaluations and upon their positive outcome, the results of the above evaluations are finalized and documented in one or more test reports, which are delivered to the Manufacturer at the same time as the EC Type Examination Certificate.

Unless otherwise agreed, a test report will not be issued in the event of a negative outcome of the tests, the results of which are in any case communicated in writing to the customer, by e-mail.

In the event of an unsatisfactory outcome of the above assessments, based on the applicable situations, MTIC may require the Manufacturer to carry out the necessary actions to resolve the non-compliance situation, including:

- modify/integrate the technical documentation prepared;
- review and modify the design of the toy as appropriate;
- provide a new sample to carry out the repetition of unsuccessful tests.

In general, and without prejudice to a case-by-case assessment, in the event of a negative outcome of the assessments conducted during the EC Type Examination phase, MTIC admits up to 3 reassessments to be completed within 6 months of the application for certification.

If the condition of non-compliance persists despite the actions of the Manufacturer, MTIC refuses to issue an EU Type Examination Certificate and informs the Notifying Authority and the Notified Bodies for the same type of product, as well as the Manufacturer, giving detailed reasons for its refusal.

9.3 Certification issuance

If all the evaluation activities have been concluded with a positive outcome, the person in charge of the file may submit the same to the resolution committee.

In the event of a negative outcome, MTIC shall inform the Manufacturer of the reasons that led to the refusal of the certification.

Any refusal shall be communicated to the competent authority and to the other notified bodies, in accordance with the Directive.

If the organization deems it appropriate, there is a procedure for appeal, as indicated in the General Terms and Conditions (RG-GQ-01-01) published on the www.mtic-group.org website.