

REGULATION FOR THE ISSUE OF EC / EU TYPE EXAMINATION CERTIFICATE

ISSUE 6.0

1.0 PURPOSE

This Regulation defines all the activities and the necessary elements to issue product certifications according to Directive 2009/48/EC and Regulation (EU) 2016/425 and the procedures that customers must follow to obtain and maintain this certification according to ISO/IEC 17065:2012 requirements.

2.0 SCOPE

This regulation binds the EC Type Area and the Customer to comply with what is here described. It means fully known and accepted by the customer once signed and sent to the reference CS.

This regulation defines the conditions for the granting, extension, revocation and renunciation of the EC / EU type examination certificate to Customers, with reference to the assessment and certification procedures adopted by the EC Type Area.

Any changes to the regulations will be notified to the Customer through publication in the reserved area of the website and through specific communication.

3.0 DEFINIZIONI / DEFINITIONS

EC-TYPE EXAMINATION CERTIFICATE

Document issued by IISG attesting the conformity of an item after evaluating the essential requirements of European Directive 2009/48/EC adopted by the Council of The European Communities.

EU-TYPE EXAMINATION CERTIFICATE

Document issued by IISG attesting the conformity of Personal Protective Equipment after evaluating the essential requirements established by Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016.

TECHNICAL FILE

Collection of technical documentation certifying the criteria adopted to meet the safety requirements and to minimize the residual risk. It is prepared by the customer.

CUSTOMER

The Manufacturer or an authorized representative resident in the European Union.

CS

Customer Service

EC Type Area

IISG internal office responsible for the evaluation of test reports and all documentation and information relating to certification practices, before sending it to the certification committee.

4.0 RESPONSIBILITY

- EC Type Area Manager: supervises the verification of the completeness of the certification procedures completed by the EC Type Area Technician before sending to the certification committee
- EC Type Area Technician/Inspector: evaluates the completeness of the documentation and information relating to certification practices, including the technical files received from customers;
- Certification Committee: is responsible for the issue of EC type certifications
- Quality Staff: supports the EC Type Area in the preparation of system documentation and in the organization of certification activities.

5.0 GENERAL CONDITIONS FOR OBTAINING AND MAINTAINING THE EC/EU TYPE EXAMINATION CERTIFICATE

In addition to what is provided below, in order to obtain and maintain the EC/EU Type Examination Certificate, the Customer shall:

- Satisfy over time the requirements of certification, and in particular:
 - observe the contents of Directive and Regulation for the issue of EC/EU type;
 - proceed with the payment of fees;
 - give prompt notice of any changes to the certified product or production method;
 - give timely notice of changes to the organization, the legal, commercial, or property, contact addresses and production sites;
 - implement the appropriate changes communicated by the Notified Body (eg in the case of the certification scheme change)
- Provide a description of the control and test systems applied in the manufacturing plant.
- Provide a copy of the information note that the manufacturer intends to attach to the article placed on the market.
- Commit to not use the product certification incorrectly, or likely to bring discredit to IISG.

6.0 ASSESSMENT PROCESS

6.1 SUBMISSION OF THE APPLICATION FOR THE EC/EU TYPE EXAMINATION CERTIFICATE

The Manufacturer or an Authorized Representative resident in the European Union (hereinafter referred to as the "Customer") may submit a request for the issue of the EC/EU Type Certificate.

In order to access the product certification services offered by IISG, the Customer shall prepare the following documentation:

6.1.1 Application Form available on the CRS website <https://crs.ul.com/it/resources/> or sent by IISG upon request – filled in by the customer in all its part and signed by the Legal Representative or his delegate, containing:

- A statement certifying that the application for EC/EU certification is submitted by the manufacturer or his representative resident in the European Union

- Declaration certifying that the application for certification is presented to a single notification body for each model of article, and the product has not previously been subject to any refusal, withdrawal or revocation.
 - Declaration the Customer agree with, to comply with the requirements of IISG and confirms its willingness to provide all the information that it believes necessary to carry out the EC / EU type-examination.
 - Name, company name and address of the manufacturer, if different from requester
 - Details on the place of manufacture of the item subject to certification
- 6.1.2 N 4 representative samples of the expected production, including the packaging used and any leaflets and information sheets attached (a greater number of samples may be required depending on the characteristics of the product and the verification to be carried out);
- 6.1.3 Copy of the technical documentation including the description of the control and test systems applied in the production plant and copy of the information note that the Manufacturer intends to attach to the item placed on the market which it requests the EC / EU Type Certificate for. The Customer can present, with the technical documentation of the product to be certified, the test reports containing the chemical and physical mechanical tests already carried out in other laboratories.

Furthermore, by signing this regulation, the Customer agrees to the authority responsible for assessing the Certification Body (ACCREDIA - Italian Accreditation Body) to attend the certification activities and witness the tests on their articles, as required by the ACCREDIA Regulation RG-01 point 1.1.2, under penalty of failure to issue the certification by IISG.

6.2 DOCUMENTAL REVIEW AND ISSUE OF THE OFFER

The document review phase begins when the EC Type Area receives from the Customer the documentation indicated in point 6.1.

The EC Type Area verifies the completeness of the information received, requesting any additions if necessary.

The CS informs the Customer about the acceptance of the application requesting, if necessary, any corrections and / or additions. After verifying the completeness of the documentation received, CS proceeds with the issue of the offer that must be signed for acceptance by the Customer and sent back to IISG. Without the offer confirmed, it is not possible to proceed with the certification process.

The activities are planned and carried out by qualified personnel, taking into account customer's needs and the constraints relating to contingent needs related to the verification of the products subject to certification.

6.3 CONFORMITY ASSESSMENT

The conformity assessment of the technical file and the adequacy of the tests carried out are the responsibility of the technicians / inspectors of the EC Type Area, the final approval of the file is the responsibility of the Head of the EC Type Area.

Regarding the tests, there are the following possibilities:

- Tests can be carried out in IISG Laboratories or in the group's qualified laboratories. Some tests can be subcontracted to external laboratories (subject to the stipulation of an agreement between IISG and the laboratory to which the subcontract is entrusted), in compliance with the requirements of the ISO / IEC 17025 standard and the accreditation requirements, subject to prior information to the customer and his acceptance
- The customer can present with the technical documentation of the product to be certified the test reports containing the tests carried out by other laboratories. Where the customer submits test reports from internal laboratories or other laboratories - if not ISO / IEC 17025 accredited - the customer must ensure that these laboratories operate in compliance with ISO / IEC 17025 or shall provide evidence of third party verifications.

The customer is informed by the EC Type Area of any non-conformities and / or findings found during the certification process; at the same time the request is put "on hold" by the Customer Service. In the event that the customer expresses interest in continuing with the certification process, IISG shall provide the customer with a list of non-conformities and / or findings found, such as the need to integrate the technical file or any other requests for further information. These are managed by e-mail with the involvement of the Customer Service department.

If the customer agrees to carry out the additional assessment tasks, the EC Type Area must ensure that all information and documents are satisfactory.

If the customer is unable to resolve the non-conformities found or is unable to send adequate documentation for the resolution of the findings, IISG will refuse the issue of the EC / EU type examination certificate and will inform the Authority of Notification and the other Notified Bodies. At the end of the evaluation activity, the EC Type Area Manager informs and involves the Certification Committee about the need to evaluate the practice for issuing the EC / EU Type.

6.4 ISSUE OF THE EC / EU CERTIFICATE

After the issue, the EC / EU Type Examination Certificate is sent to the Customer by the Customer Service in one of the following ways :

- sending the PDF of the EC / EU type examination certificate to the email address indicated by the Customer;
- sending the original paper Certificate by mail / courier to the Customer if requested;
- uploading the Certificate on the customer's website (where required).

A copy of the EC / EU Type Certificate is kept for at least 10 years on paper or electronic media. The relative samples are also kept for at least 10 years.

6.5 CHECK ON THE USE OF THE CERTIFICATE

IISG as a Notified Body can use Accredia trademark combined with the IISG S.r.l. Logo for all certificates that fall within the scope of accreditation as defined in the Regulation Document for the use of the Accredia trademark (RG-09).

The issuance of a Certification does not authorize the Owners to use IISG trademark.

Incorrect references to the certification or misleading use of IISG trademark by the Owners may lead to the adoption of measures to suspend or revoke the certification.

7.0 SUBSEQUENT REQUESTS TO THE ISSUE OF THE CERTIFICATE

7.1 MODIFICATIONS AND EXTENSION OF THE CERTIFICATION

Changes to the certification of an already certified product could be:

1. If the holder of the certification decides to modify the product, it could request certification's changes by forwarding a prior request to the reference CS. In this case, the EC Type Area carries out the assessment activities, according to the procedures previously described in paragraph 6.2, and, based on the outcome, it communicates whether the requested modification or extension can be granted.

The modifications / extensions of the certification may concern formal modifications of the data present on the certificate; any other request of modification is evaluated by the technicians and by the EC Type Area Manager with the involvement of the certification manager.

The "corrected" Certificate maintains the same number as the previous one and contains the wording "Revised", the new issue date and the reason for the revision. The new Certificate is sent to the customer who must return the previous canceled version and destroy any copies. The same procedure is used in the case of changes or corrections to the EC Type Examination Certificates already sent to the Notification Authority.

2. Due to internal causes - errors on the part of the Body (such as in the identification of the article): in this case, proceed as indicated above with the reissue of a certificate that cancels and replaces the previous one of the same number with the wording "Revised".
3. Finally, changes could be consequent at the entry into force of new legislative provisions and / or new harmonized technical standards (as defined in point 7.1 of Annex V of EU Regulation 2016 425 for PPE), IISG follows the evolution of the state of the art and evaluates the need to proceed with in-depth analysis.

This request does not apply to Toys as Directive 2009/48 / EC does not make this specification and for toys the manufacturer is required to keep up to date on regulatory updates.

The changes can be made on the proposal of the Certification Committee after involving, if appropriate, the Representative Committee of the Parties and must follow the procedure described starting from § 6.2. Once this approval has been obtained, which must concern both the contents of the changes and the date of entry into force of the same, IISG will:

- inform the Entities holders or applicants for certification;
- take into consideration any observations from Entities holders or applicants;
- specify the required adjustment actions, granting the time necessary for their implementation.

If the Entities holders or applicants fail to adapt to the established measures, within the agreed time frame, may result in the adoption of measures to suspend or revoke the certification.

7.2 RENEWAL OF THE EC-TYPE CERTIFICATE

The EC / EU type examination certificate is valid for 5 years, after this period it must be revised. This verification has the purpose of allowing an effective review, also document related, of the continuous compliance of the product with the requirements of the reference standards.

8.0 SUSPENSION, REVOCATION OF THE CERTIFICATION

If non-compliant uses of an EC / EU Type Examination Certificate issued are highlighted, the EC Type Area shall convene the holder of the Certificate in advance, to remedy such behavior, if and as far as possible.

In case of impossibility of resolution of this behaviors, then Notified Body could adopt the suspension or, in the most serious cases, of revocation the certification.

Decision relating to the suspension rather than the revocation of the certification is taken by the certification committee based on the severity of the behavior.

The measures of suspension or revocation of the certification are communicated through PEC (Certified Mail) with the reasons for the provision.

In the event of revocation the former holder must return the Certificate and must stop using the certificate in any form and location; he is also ordered to stop production, destroy the samples in the warehouse, recall the samples on the market.

The Notification Authority and others Notified Bodies, operating on the Toys Directive or on the PPE Regulation, are informed of any refusal, limitation, suspension, revocation or withdrawal of EC type examination certificates and, where applicable, of the measures adopted.

9.0 COMPLAINTS RELATING TO CERTIFIED PRODUCTS

IISG requires the Customer to provide for:

- a. keep a record of all complaints of which it is aware relating to the compliance of certified products, with the requirements of the reference standard, and make these records available upon request of the certification body itself.
- b. adopt the appropriate corrective actions following such complaints or any deficiency found in the products or services that affect compliance with the certification requirements;
- c. provide documentation relating to the actions taken.

10.0 MANAGEMENT OF COMPLAINTS, APPEALS AND LITIGATIONS

10.1 COMPLAINTS

IISG S.r.l. takes into consideration all complaints regarding certification activities received from customers or other interested parties.

Complaints relating to the product certification activity can be sent to IISG in the following ways:

- Sending the complaint to the following e-mail address: <https://www.ul.com/contact-us>
- By communicating to Customer Advocacy at the following e-mail address: [customer experience survey](#)
- Contacting the IISG staff directly

In the event that the complaint is well founded, the necessary corrective actions are taken, vice versa in the event of an unfounded complaint, the quality office promptly informs the complainant in writing of the grounds for the groundlessness of the complaint. The analysis of the complaint is carried out by the function in charge which must not be the subject of the complaint.

10.2 RECOURSES AND APPEALS

Recourses (or appeals) against decisions taken or acts carried out by IISG as a product Certification Body, are managed as described below, but do not suspend the validity of such acts until the related discussion is concluded.

Appeals must be submitted by registered letter with return receipt or by PEC (Certified Mail (iisg@legalmail.it)) within 15 (fifteen) working days, from the notification of the deed against which it is appealed.

IISG S.r.l. confirm within the following 15 (fifteen) working days, by e-mail or certified e-mail, the receipt and taking charge of the appeal.

Management of recourses (or appeals) is always carried out by the personnel in charge, different from those involved in the decisions against which the applicant has lodged a recourse (or appeal), with the assistance of the quality office.

This management must ensure that all phases of activity are correctly recorded and that all applicable treatments and corrective actions are defined and proposed.

The final decisions regarding the appeal are taken by the Certification Committee on the proposal of the managers involved.

Within 3 months following the submission of the appeal, IISG S.r.l. provides for the closure and notification of the outcome of the same to the appellant by registered letter with return receipt or PEC (Certified Mail).

10.3 CONTENTIOUS

For any dispute that may arise between the parties regarding the interpretation, implementation, execution, validity and effectiveness of the activity carried out by IISG as a product certification body, the Court of Como (Italy) is exclusively competent.

11.0 INFORMATION TO CUSTOMERS AND AUTHORITIES

11.1 CUSTOMERS

The Regulations and Forms to be used to request EC Type certificates are made available in the Customer Area on the website <https://crs.ul.com/it/resources/>



11.2 AUTHORITIES

IISG shall notify to the competent authorities, an IT access to its database so that they can at any time have information relating to the certifications issued, withdrawn, suspended or denied. Certificates issued by IISG in relation to the Directives / Regulations concerning Toys and Personal Protective Equipment are made available to the *Ministero dello Sviluppo Economico* on the [UL CRS](#) website in the reserved area which can be accessed using a username and password which have been duly communicated to the representative of the *Ministero*.

12.0 CONFIDENTIALITY OF INFORMATION

IISG, as responsible for the management of all information obtained or produced during the execution of the certification activities, undertakes to maintain the confidentiality of the information owned by the Customer, through confidentiality agreements and letters of appointment that are signed by all the personnel involved in the certification activity.

Place and date:

Function and signature for acceptance

.....

.....