
Special Certification Rules - Toys

Special Certification Rules

Toys



Scientific and Technical Centre of the Belgian Textile Industry

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1 Introduction

The European Regulation for toys 2009/48/EC requires the CE marking to be affixed to products that are used as toys. With this CE marking the manufacturer* declares that the toy is in conformity with the applicable essential health and safety requirements and that it has been placed on the market in accordance with the legislation. The technical requirements that these products must meet are described in the relevant harmonised European standards or technical specifications.

* *Manufacturer: any natural or legal person who manufactures a toy or has a toy designed or manufactured, and markets that toy under his name or trademark*

Centexbel is a notified body with number 0493 and is recognized for type examinations.

2 Definitions

See General certification rules

3 Certification procedure

Manufacturers shall, before placing a toy on the market, carry out an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene, and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards.

3.1 Module A: Internal production control

If the manufacturer has applied harmonised standards, the reference number of which has been published in the Official Journal of the European Union, covering all relevant safety requirements for the toy, he shall use the internal production control procedure set out in **Module A** of Annex II to Decision No 768/2008/EC.

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0048&from=EN>

3.2 Module B: EC-Type examination

In the following cases, the toy shall be submitted to **EC-type examination (module B)**, together with the conformity to type procedure set out in **Module C** of Annex II to Decision No 768/2008/EC:

- a) where harmonised standards, the reference number of which has been published in the Official Journal of the European Union, covering all relevant safety requirements for the toy, do not exist
- b) where the harmonised standards referred to in point a) exist but the manufacturer has not applied them or has applied them only in part

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- c) where one or more of the harmonised standards referred to in point a) has been published with a restriction
- d) when the manufacturer considers that the nature, design, construction, or purpose of the toy necessitate third party verification

After consultation with the applicant, *EC type-examination* shall be carried out. This verification is guided by the technical file, based on the requirements of Directive 2009/48/EC, in particular Annex II thereof, and the harmonised standards or other technical specifications used.

The manufacturer shall submit to the notified body the following documents:

- technical documentation (the application for EC type examination shall include a description of the toy and an indication of the place of manufacture, including the address)
- evidence of the adequacy of the technical design
- required samples representative of the production in question

During this examination, prototypes are also subjected to the tests provided for in the relevant harmonised standard or technical specification. These tests are performed in the CENTEXBEL laboratories or by an approved subcontractor in accordance with the requirements of ISO 17025.

Notified body:

- checks conformity with essential requirements
- shall examine technical documentation and supporting evidence to assess the adequacy of the technical design
- where necessary, shall carry out tests on one or more representative samples of one or more critical parts of the product (combination of production type and design type)
- grants EC-type examination certificate

The *product certifier* shall draw up a report of remarks and send it to the applicant. The applicant is requested to make the necessary clarifications and/or corrections as soon as possible. CENTEXBEL sets a maximum period of 6 months for this. If CENTEXBEL does not receive the missing documents within 6 months, the file will automatically be put on-hold and reopening the file after 6 months will result in a new certification fee. (ISO 17065 §7.4).

Only after all observations have been positively answered, the product certifier shall prepare a proposal for the granting of a type examination certificate and submits it to the manager of certification. If it is not possible to demonstrate conformity, the product certifier shall submit a proposal for refusal of the type-examination certificate to the manager of certification.

3.3 Module C: Conformity to type based on internal production control

“Conformity to type based on internal production control” is the part of a conformity assessment procedure whereby the manufacturer fulfils the following obligations and ensures and declares that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the relevant legislation.

— Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing and controlling process ensure conformity of the manufactured products with the approved type described in the EC-type examination certificate and with the requirements of the relevant legislation.

— Conformity marking and declaration conformity

The manufacturer shall affix the required conformity marking set out in the relevant legislation to each individual product that is in conformity with the type described in the EC-type examination certificate and satisfies the applicable requirements of the relevant legislation.

The manufacturer shall draw up a written declaration of conformity for a product model and keep it at the disposal of the national surveillance authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up. A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

4 Obligations of manufacturers

The manufacturer shall be presumed to comply with the applicable provisions of the European Directive on Toys 2009/48/EC. If the manufacturer relies on one or more harmonised standards or technical specifications giving presumption of conformity with the essential requirements of the equipment, he shall also comply with the provisions of those standards.

1. When placing their toys on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in Article 10 and Annex II.
2. Manufacturers shall draw up the required technical documentation in accordance with Article 21 and carry out or have carried out the applicable conformity assessment procedure in accordance with Article 19. Where compliance of a toy with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EC declaration of conformity, as referred to in Article 15, and affix the CE marking, as set out in Article 17 (1).
3. Manufacturers shall keep the technical documentation and the EC declaration of conformity for a period of 10 years after the toy has been placed on the market.
4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in toy design or characteristics and changes in the harmonised standards by reference to which conformity of a toy is declared shall be adequately taken into account. When deemed appropriate with regard to the risks presented by a toy, manufacturers shall, to

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protect the health and safety of consumers, carry out sample testing of marketed toys, investigate, and, if necessary, keep a register of complaints, of non-conforming toys and toy recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that their toys bear a type, batch, serial or model number or other element allowing their identification, or, where the size or nature of the toy does not allow it, that the required information is provided on the packaging or in a document accompanying the toy.
6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy or, where that is not possible, on its packaging or in a document accompanying the toy. The address shall indicate a single point at which the manufacturer can be contacted.
7. Manufacturers shall ensure that the toy is accompanied by instructions and safety information in a language or languages easily understood by consumers, as determined by the Member State concerned.
8. Manufacturers who consider or have reason to believe that a toy which they have placed on the market is not in conformity with the relevant Community harmonisation legislation shall immediately take the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the toy presents a risk, manufactures shall immediately inform the competent national authorities of the Member States in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.
9. Manufacturers shall, further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the toy, in a language easily understood by that authority. They shall cooperate with that authority, at its request, as regards any action taken to eliminate the risks posed by toys which they have placed on the market.