

DECLARATION OF CONFORMITY

OFFICIAL JOURNAL OF TOY SAFETY
DIRECTIVE (2009/48/EC)

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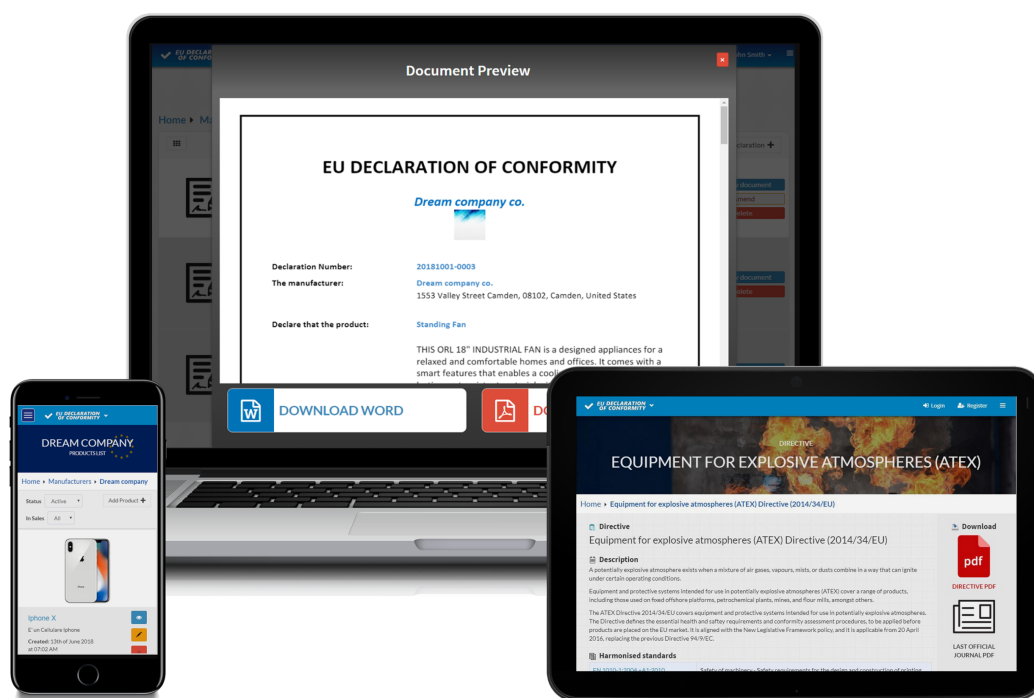
DECLARATION OF CONFORMITY

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COMMISSION IMPLEMENTING DECISION (EU) 2021/1992**of 15 November 2021****on harmonised standards for toys drafted in support of Directive 2009/48/EC of the European Parliament and of the Council**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ⁽¹⁾, and in particular Article 10(6) thereof,

Whereas:

- (1) In accordance with Article 13 of Directive 2009/48/EC of the European Parliament and of the Council ⁽²⁾, toys which are in conformity with harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, are to be presumed to be in conformity with the requirements covered by those standards or parts thereof set out in Article 10 of Directive 2009/48/EC and Annex II to that Directive.
- (2) Directive 2009/48/EC lays down, in Part I of Annex II thereto, specific requirements on physical and mechanical properties (including provisions aimed at ensuring that toys are manufactured in such a way as to avoid causing burns, scalds or other physical injury) and in Part II of Annex II thereto, specific requirements in order to ensure a high level of toy safety with regard to flammability hazards. Directive 2009/48/EC also lays down, in Part III of Annex II thereto, specific requirements in order to ensure that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain. Moreover Article 10(2) lays down the general safety requirement, Article 11(2) lays down requirements for warnings on toys, and Annex V to Directive 2009/48/EC lays down warnings for toys, including specific warning for chemical toys.
- (3) By letter M/445 ⁽³⁾ of 9 July 2009 the Commission made a request to the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) for the drafting of new and the revision of existing harmonised standards in support of Directive 2009/48/EC.
- (4) On the basis of the request M/445 of 9 July 2009, CEN revised harmonised standard EN 71-2:2011+A1:2014 'Safety of toys – Part 2: Flammability', the reference of which was published by Commission Implementing Decision (EU) 2021/867 ⁽⁴⁾. This resulted in the adoption of harmonised standard EN 71-2:2020.
- (5) Harmonised standard EN 71-2:2020 is clearer and more precise than its predecessor EN 71-2:2011+A1:2014. It includes: further definitions, thus describing better to which toys the standard's specifications apply; clearer, more precise wording; new specifications for toy disguise costumes which contain loose stuffing; additional specifications to wash or cleanse (or not) toy disguise costumes prior to testing; specifications on the testing of smaller parts of toys by combining them, as well as the testing of fillings, trims and embellishments; illustrative examples of disguise toys (such as face masks or helmets) and toy disguise costumes and indications on how to test them; flowcharts showing how to obtain test specimens from toy disguise costumes.

⁽¹⁾ OJ L 316, 14.11.2012, p. 12.

⁽²⁾ Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1).

⁽³⁾ M/445 of 9 July 2009 on a standardisation mandate addressed to CEN and CENELEC within the framework of Directive 2009/48/EC revising Directive 88/378/EEC concerning the safety of toys.

⁽⁴⁾ Commission Implementing Decision (EU) 2021/867 of 28 May 2021 on harmonised standards for toys drafted in support of Directive 2009/48/EC of the European Parliament and of the Council (OJ L 190, 31.5.2021, p. 96).

- (6) On the basis of the request M/445 of 9 July 2009, CEN also revised harmonised standard EN 71-3:2019 ‘Safety of toys - Part 3: Migration of certain elements’, the reference of which was published by Implementing Decision (EU) 2021/867. This resulted in the adoption of harmonised standard EN 71-3:2019+A1:2021.
- (7) Harmonised standard EN 71-3:2019+A1:2021 updates its list of legal limit values, taken from Directive 2009/48/EC, for the elements in toys. The update concerns aluminium, for which strengthened limit values were to be applied as of 20 May 2021 ⁽⁵⁾. It also concerns chromium-VI, for which a previous limit value was deleted. The mathematical formula to calculate the chromium-VI migration of a toy sample has been adapted to the test procedure. All other changes are editorial.
- (8) On the basis of the request M/445 of 9 July 2009, CEN further revised harmonised standard EN 71-4:2013 ‘Safety of toys - Part 4: Experimental sets for chemistry and related activities’, the reference of which was published by Implementing Decision (EU) 2021/867. This resulted in the adoption of harmonised standard EN 71-4:2020.
- (9) Harmonised standard EN 71-4:2020 is clearer than its predecessor EN 71-4:2013, due to quite a number of editorial changes. Also, pictograms and signal words of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽⁶⁾ have been used more abundantly and more consistently. Furthermore, the specifications for child-resistant containers now rely on an established international standard, taken over by CEN. Eye protection is now required for certain experimental sets. Finally, more explanations on the rationale of the specifications have been included.
- (10) On the basis of the request M/445 of 9 July 2009, CEN revised harmonised standard EN 71-13:2014 ‘Safety of toys - Part 13: Olfactory board games, cosmetic kits and gustative games’, the reference of which was published by Implementing Decision (EU) 2021/867. This resulted in the adoption of harmonised standard EN 71-13:2021.
- (11) The specifications of harmonised standard EN 71-13:2021 are more clearly linked to the requirements of Directive 2009/48/EC. In particular, the specifications related to specific warnings and indications set out in Annex V, Part B, to Directive 2009/48/EC have been extended and more clearly relate to olfactory board games, cosmetic kits and gustative games that contain certain allergenic fragrances. Furthermore, the specifications for child-resistant closures of containers in the concerned games and kits are now based on an international standard, referred to as EN ISO 8317:2015 Child-resistant packaging – Requirements and testing procedures for reclosable packages. The test method in EN ISO 8317:2015 replaces the previous test method set out in EN 71-13:2014. Finally, references to Union legislation have been updated, in particular to food safety legislation.
- (12) The Commission together with CEN has assessed whether harmonised standards EN 71-2:2020, EN 71-3:2019+A1:2021, EN 71-4:2020 and EN 71-13:2021 drafted by CEN comply with the request M/445 of 9 July 2009. The four harmonised standards satisfy the requirements which they aim to cover and which are set out in Directive 2009/48/EC. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.
- (13) Harmonised standards EN 71-2:2020, EN 71-3:2019+A1:2021, EN 71-4:2020 and EN 71-13:2021 replace harmonised standards EN 71-2:2011+A1:2014, EN 71-3:2019, EN 71-4:2013 and EN 71-13:2014, respectively. It is therefore necessary to withdraw the references of those standard from the *Official Journal of the European Union*. In order to allow toy manufacturers sufficient time to adapt their products to the revised specifications in harmonised standards EN 71-2:2020, EN 71-3:2019+A1:2021, EN 71-4:2020 and EN 71-13:2021, it is necessary to defer the withdrawal of the reference of harmonised standards EN 71-2:2011+A1:2014, EN 71-3:2019, EN 71-4:2013 and EN 71-13:2014.

⁽⁵⁾ Commission Directive (EU) 2019/1922 of 18 November 2019 amending, for the purposes of adaptation to technical and scientific developments, point 13 of part III of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards aluminium (OJ L 298, 19.11.2019, p. 5).

⁽⁶⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

- (14) In the interests of clarity, rationality and simplification, a complete list of references of harmonised standards drafted in support of Directive 2009/48/EC and satisfying the requirements they aim to cover should be published in a single act. The references of harmonised standards drafted in support of Directive 2009/48/EC are currently published by Commission Implementing Decisions (EU) 2021/867 and 2019/1728 ⁽⁷⁾. Consequently, it is necessary to replace Implementing Decision (EU) 2021/867 by a new decision.
- (15) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the date of its publication,

HAS ADOPTED THIS DECISION:

Article 1

The references of the harmonised standards for toys drafted in support of Directive 2009/48/EC, listed in Annex I to this Decision, are hereby published in the *Official Journal of the European Union*.

Article 2

Implementing Decision (EU) 2021/867 is repealed.

However, Article 1 of Implementing Decision (EU) 2021/867 shall continue to apply to the references of the harmonised standards for toys drafted in support of Directive 2009/48/EC, listed in Annex II to this Decision, until the dates set out in that Annex.

In addition, Article 1 of Implementing Decision (EU) 2019/1728 shall continue to apply to the references of the harmonised standards for toys drafted in support of Directive 2009/48/EC, listed in Annex III to this Decision, until the dates set out in that Annex.

Article 3

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 15 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁷⁾ Commission Implementing Decision (EU) 2019/1728 of 15 October 2019 on harmonised standards for toys drafted in support of Directive 2009/48/EC of the European Parliament and of the Council (OJ L 263, 16.10.2019, p. 32).

ANNEX I

No	Reference of the standard		
1.	EN 71-1:2014+A1:2018 Safety of toys — Part 1: Mechanical and physical properties		
2.	EN 71-2:2020 Safety of toys — Part 2: Flammability		
3.	EN 71-3:2019+A1:2021 Safety of toys — Part 3: Migration of certain elements		
4.	EN 71-4:2020 Safety of toys — Part 4: Experimental sets for chemistry and related activities		
5.	EN 71-5:2015 Safety of toys — Part 5: Chemical toys (sets) other than experimental sets		
6.	EN 71-7:2014+A3:2020 Safety of toys — Part 7: Finger paints — Requirements and test methods		
7.	EN 71-8:2018 Safety of toys — Part 8: Activity toys for domestic use		
8.	EN 71-12:2016 Safety of toys — Part 12: N-Nitrosamines and N-nitrosatable substances <i>Informative note:</i> The limit values in point (a) of Table 2 of clause 4.2 of standard 'EN 71-12:2016 Safety of toys — Part 12: N-Nitrosamines and N-nitrosatable substances' are lower than the limit values to be complied with set in point 8 of part III of Annex II to Directive 2009/48/EC. In particular those values are as follows:		
	Substance	Standard EN 71-12:2016	Directive 2009/48/EC
	N-nitrosamines	0,01 mg/kg	0,05 mg/kg
	N-nitrosatable	0,1 mg/kg	1 mg/kg.
9.	EN 71-13:2021 Safety of toys — Part 13: Olfactory board games, cosmetic kits and gustative games		
10.	EN 71-14:2018 Safety of toys — Part 14: Trampolines for domestic use		
11.	EN IEC 62115:2020 Electric toys — Safety EN IEC 62115:2020/A11:2020		

ANNEX II

No	Reference of the standard	Date of withdrawal
1.	EN 71-2:2011+A1:2014 Safety of toys — Part 2: Flammability	15 May 2022
2.	EN 71-3:2019 Safety of toys — Part 3: Migration of certain elements	15 May 2022
3.	EN 71-4:2013 Safety of toys — Part 4: Experimental sets for chemistry and related activities	15 May 2022
4.	EN 71-13:2014 Safety of toys — Part 13: Olfactory board games, cosmetic kits and gustative games	15 May 2022

ANNEX III

No	Reference of the standard	Date of withdrawal
1.	<p>EN 71-7:2014+A2:2018</p> <p>Safety of toys — Part 7: Finger paints – Requirements and test methods</p> <p><i>Note:</i> For the allowed preservative Climbazole (entry 22 in Table B.1 of Annex B to this standard) the presumption of conformity applies up to a maximum allowed concentration of 0,2 % (not: 0,5 %). This is based on the ‘ADDENDUM to the Opinion on Climbazole (P64) ref. SCCS/1506/13’ of the Scientific Committee on Consumer Safety (SCCS) that was adopted after the publication of the standard by CEN.</p> <p>https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_212.pdf</p>	28 November 2021
2.	<p>EN 71-12:2013</p> <p>Safety of toys — Part 12: N-Nitrosamines and N-nitrosatable substances</p>	28 November 2021
3.	<p>EN 62115:2005</p> <p>Electric toys – Safety (IEC 62115:2003 (Modified) + A1:2004)</p> <p>EN 62115 :2005/A2:2011 (IEC 62115:2003/A2:2010 (Modified))</p> <p>EN 62115:2005/A2:2011/AC:2011</p> <p>EN 62115:2005/A11:2012</p> <p>EN 62115:2005/A11:2012/AC:2013</p> <p>EN 62115:2005/A12:2015</p>	21 February 2022