



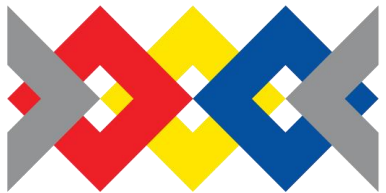
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EU rules on children's products 欧盟关于儿童产品的规则

11-04-2024
2024年4月11日

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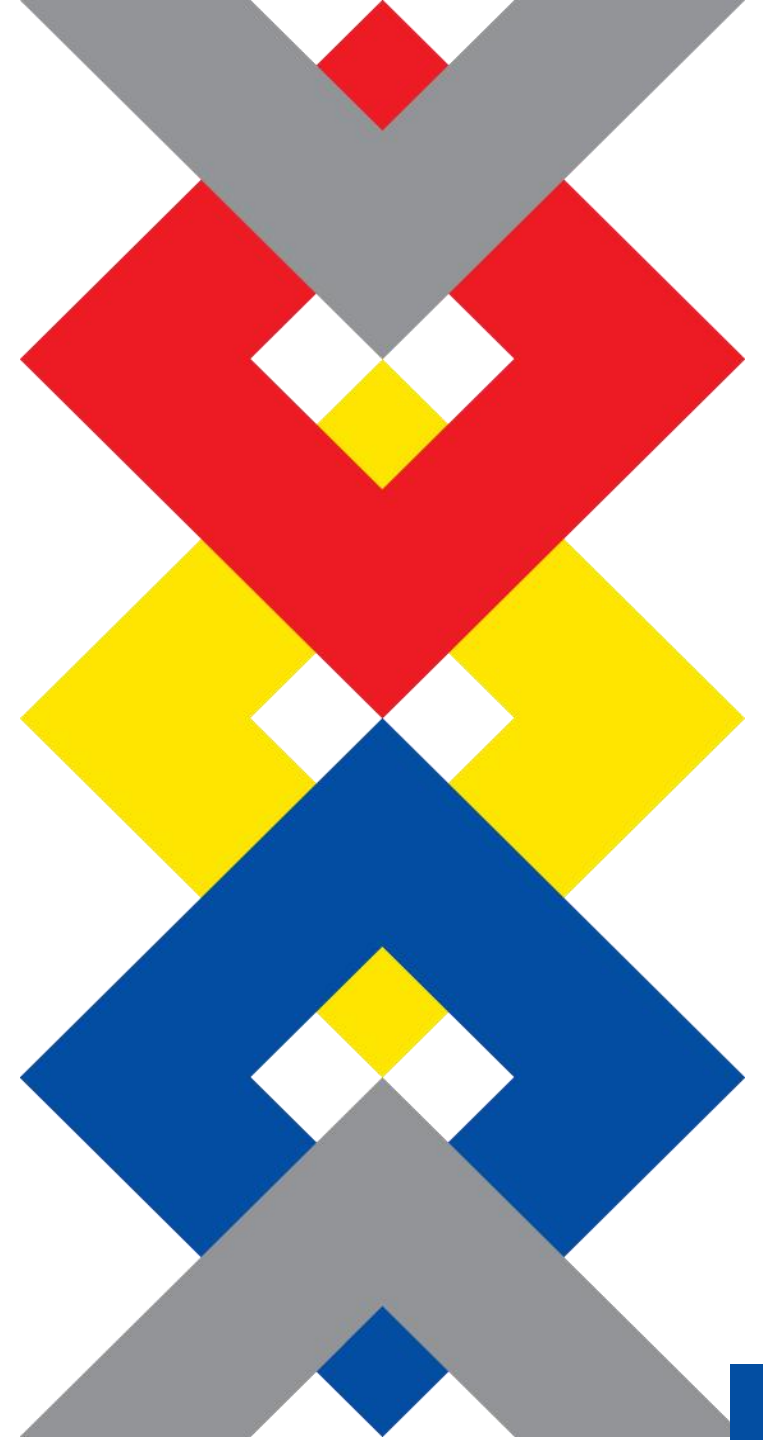
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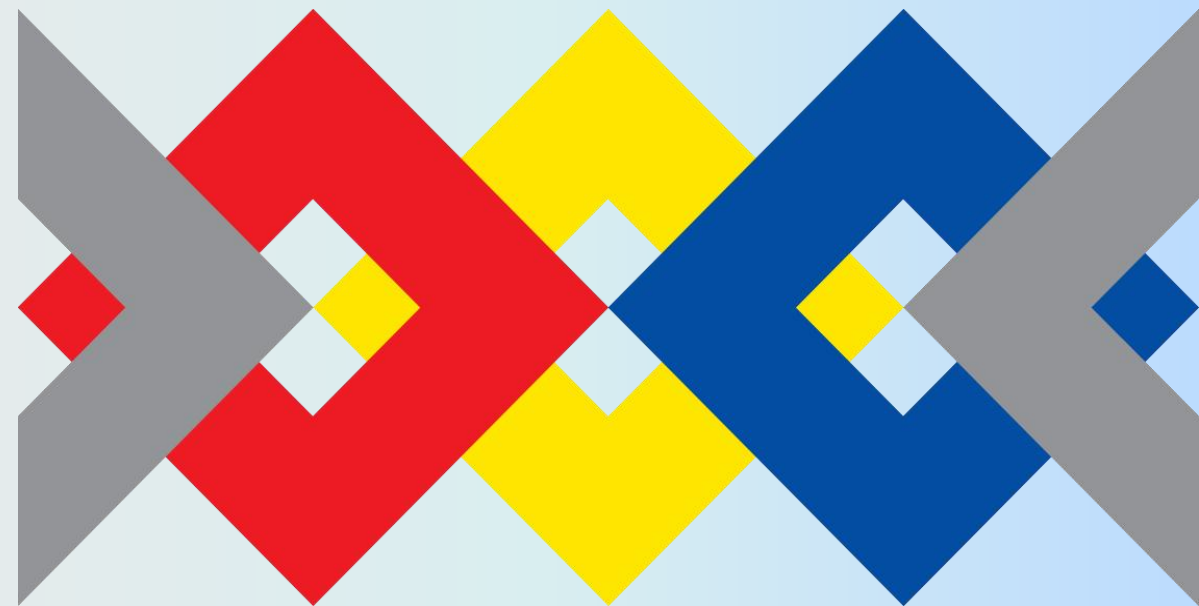


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- Introduction to product safety in the EU
欧盟产品安全介绍
- The new General Product Safety Regulation
新版《通用产品安全法规》
- How to make compliant children care products
如何制造符合要求的儿童护理产品

Introduction to product safety in the EU

欧盟产品安全介绍



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Introduction to product safety in the EU 欧盟产品安全介绍

Product safety and consumer protection are important
产品安全和消费者保护至关重要

All actors in the supply chain are responsible for the safety of the product
供应链中的所有参与方都对产品的安全负责

供应链中的所有参与方都对产品的安全负责

No EU-wide body that approves products prior to selling them
欧盟范围内没有机构会在产品售卖之前批准该产品

EU Member States check that all actors meet their responsibility
欧盟各成员国确保所有参与方各负其责

This also applies to products sold online

上述内容同样适用于网络销售的产品





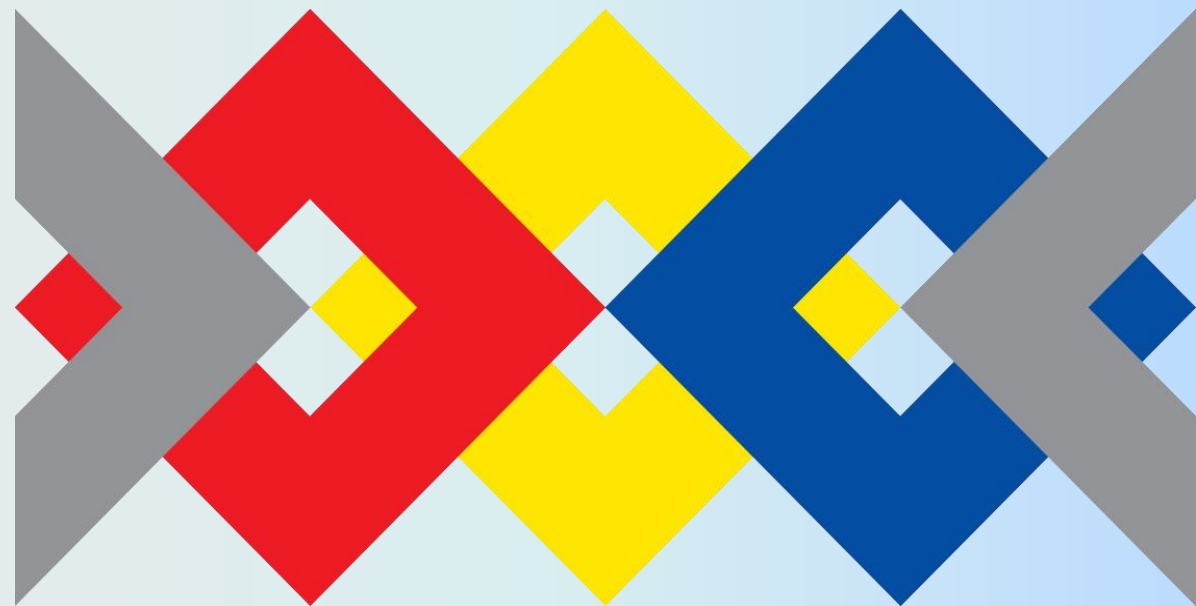
The EU's market surveillance system 欧盟市场监管体系

- Market surveillance is undertaken by EU's Member States
由欧盟各成员国负责市场监管
- Products are sampled and tested
对产品进行抽样和检验
- Main tasks: 主要职责:
 - monitor the market; 监管市场;
 - check that marking and documentation requirements are respected
检查是否符合标识和文档方面的要求
 - check that products comply with EU requirements
检查产品是否符合欧盟要求
 - check that businesses follow up on complaints and monitor accidents
核查商事主体是否跟进投诉并监控事故



The New General Product Safety Regulation

新版《通用产品安全法规》



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The New General Product Safety Regulation (GPSR) **新版《通用产品安全法规》（GPSR）**

Full legal text => <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0988>
法律全文 => <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0988>

Purpose 目的

- Provide a high level of consumer protection
提供高层次的消费者保护
- Establish essential rules for safety of consumer products
制定关于消费品安全的基本规则
- Complimentary to rules laid down in other legislation
对其他法律规定的规则进行补充
- Fully applicable from December 2024
自2024年12月起完全生效



The new GPSR – what is new? 新版GPSR - 有哪些新内容?

- Establishes aspects to be taken into account when assessing the safety of products
确定产品安全评估时应考虑的方面
- Obligation to undertake risk analysis before products are placed on the market
履行在产品投放市场前进行风险分析的义务
- Obligation to compile a technical documentation
履行编写技术文档的义务
- Describes recall notice
描述召回通知
- Introduces the “Authorised representative”
引入“授权代表”
- Obligation to have a responsible economic operator based in the EU
履行在欧盟设立可承担责任的经济运营者的义务



Authorised representative 授权代表

Written mandate 书面授权

Must include these tasks: 义务如下:

- Provide the technical file to an EU market surveillance authority during a period of at least 10 years.
向欧盟市场监管部门提供至少10年的技术文件。
- Inform the manufacturer if the product is unsafe.
如果产品不安全，通知制造商。
- Inform the market surveillance authority if actions are taken
如果采取措施，通知市场监管部门。
- Cooperate with the market surveillance authorities or take action himself to remove unsafe products from the market.
与市场监管部门合作，或自行采取行动，从市场上下架不安全产品。





The responsible economic operator 可承担责任的经济运营者

Products can only be sold on the EU market if there is a responsible economic operator established in the EU

只有在欧盟设立了可承担责任的经济运营者的情况下，产品才能在欧盟市场上销售

Can be: 可以是:

- Manufacturer established in the EU 设立在欧盟的制造商
- The importer 进口商
- Authorised representative 授权代表
- Fulfilment service provider 产品履行服务提供商





Mandatory to identify the responsible economic operator 必须确定可承担责任的经济运营者

The contact details of the responsible economic operator must be indicated on the product

产品上必须注明可承担责任的经济运营者的联系方式

Name, trademark, postal address

(Email address or website is not sufficient)

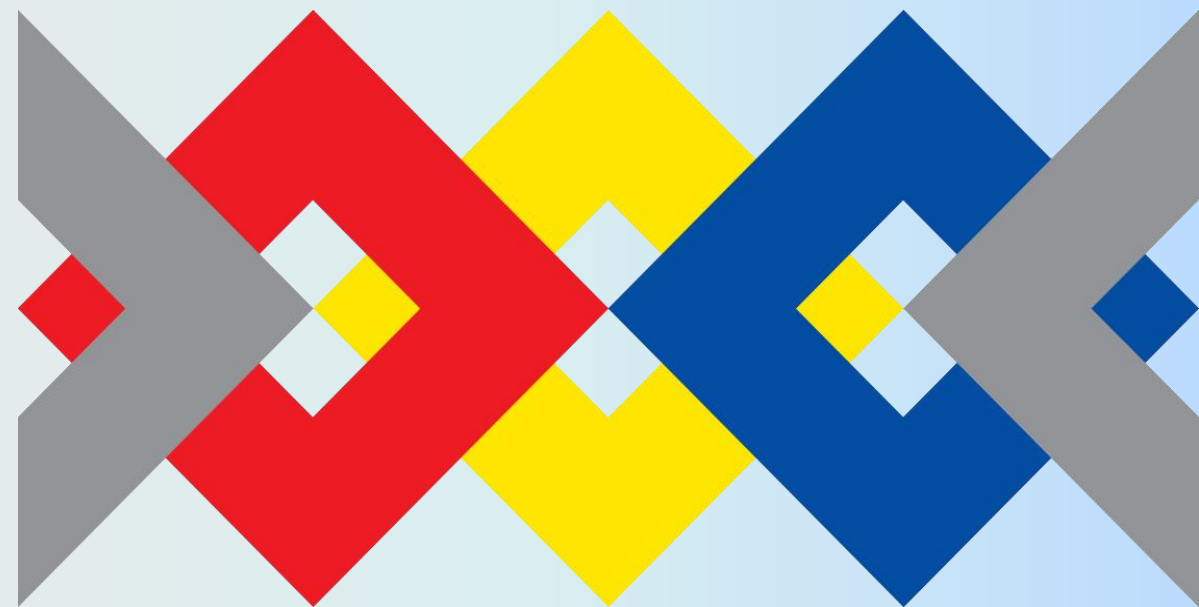
名称、商标、通讯地址

(仅提供电子邮件地址或网站还不够)



How to make compliant children care products

如何制造符合要求的儿童护理产品



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The EU approach to safety - a 2-layer scheme 实现安全的欧盟方法 - 双层方案

Product safety legislation:
产品安全法律:

- Products must be safe
产品必须是安全的
- Essential Health and Safety Requirements
基本健康和安全要求

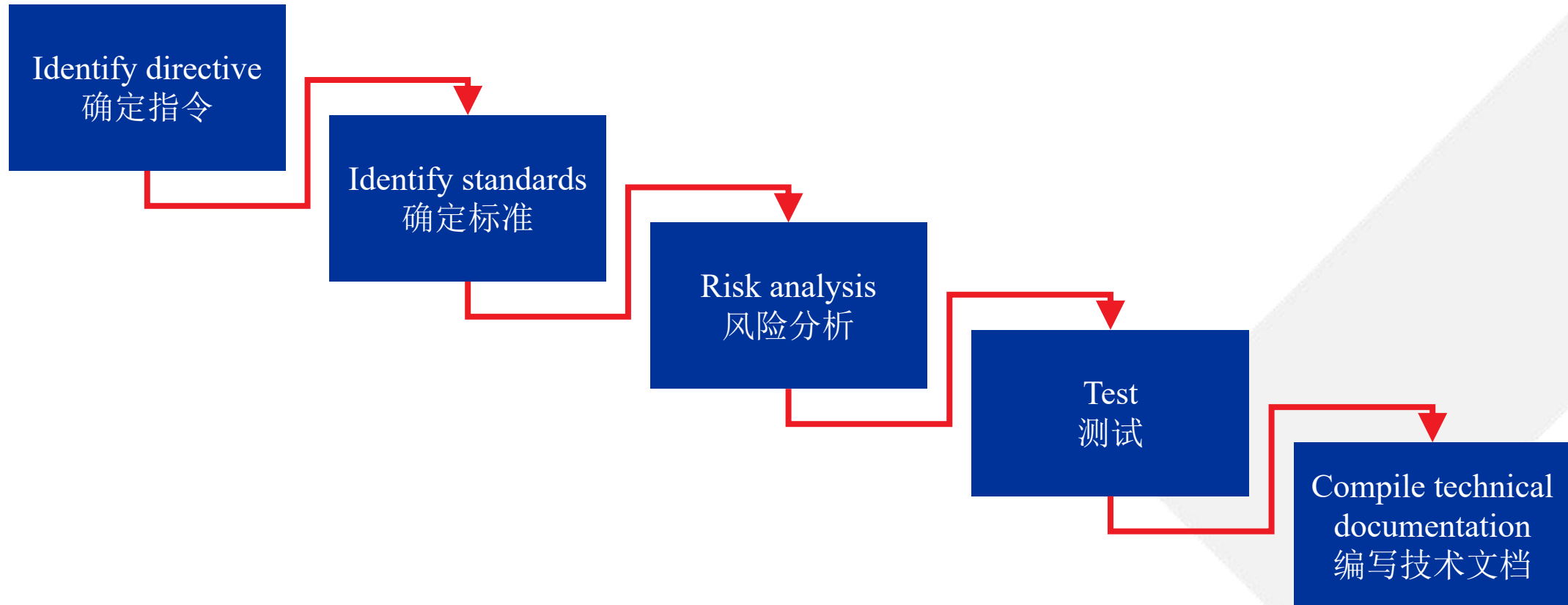
Harmonised standards:
协调标准:

- How to comply with the Essential Health and Safety Requirements
如何遵守基本健康和安全要求





Making safe children care products 制造安全的儿童护理产品





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Finding the applicable directive 查找适用的指令

European Commission's website with overview
of directives

欧盟委员会网站上有指令的概述

<https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/en>

The screenshot shows the European Commission website page for Harmonised Standards. At the top, there is the European Commission logo and a search bar. The main navigation bar includes links for Home, Single market and standards, Industry, Entrepreneurship and SMEs, Access to finance for SMEs, Sectors, and Tools and databases. The breadcrumb trail reads: European Commission > Internal Market, Industry, Entrepreneurship and SMEs > Single market and standards > European standards > Harmonised Standards. The main heading is "Harmonised Standards". Underneath, there is a section for "Formal objections" which states that the page contains a list of European Commission decisions taken on the basis of formal objections raised against publication of the references of harmonised standards in the Official Journal of the European Union (OJEU). Below this, there is a paragraph explaining that a harmonised standard is a European standard developed by a recognised European Standards Organisation: CEN, CENELEC, or ETSI. It is created following a request from the European Commission to one of these organisations. Manufacturers, other economic operators, or conformity assessment bodies can use harmonised standards to demonstrate that products, services, or processes comply with relevant EU legislation. Another paragraph states that the references of harmonised standards must be published in the Official Journal of the European Union. The purpose of this website is to provide access to the latest lists of references of harmonised standards and other European standards published in the Official Journal of the European Union (OJEU). The main heading for the next section is "References of harmonised standards and of other European standards published in the OJEU". Underneath, there is a section for "Accessibility" with a link to "Websites and mobile applications of public sector bodies". Below that, there is a section for "Chemicals" with links to "Chemical substances (REACH)", "Explosives for civil uses", and "Pyrotechnic articles".



Finding the harmonised standards (1) 查找协调标准(1)

General Product Safety Directive 通用产品安全指令



References of harmonised standards and of other European standards published in the OJEU

Accessibility

- [Websites and mobile applications of public sector bodies](#)

Chemicals

- [Chemical substances \(REACH\)](#)
- [Explosives for civil uses](#)
- [Fertilising products](#)
- [Pyrotechnic articles](#)

Conformity assessment and management systems

- [New Legislative Framework \(NLF\) and Eco-Management and Audit Scheme \(EMAS\)](#)

Construction

- [Construction products \(CPD/CPR\)](#)

Consumers and workers protection

- [Cosmetics products](#)
- [General product safety](#)
- [Personal protective equipment \(PPE\)](#)
- [Toys safety](#)

Energy efficiency

- [Ecodesign and energy labelling](#)

Electric and electronic engineering

- [Electromagnetic compatibility \(EMC\)](#)



Finding the harmonised standards (2) 查找协调标准(2)

List of harmonised standards in PDF or
XLS format
PDF或XLS格式的协调标准列表

List of European standardisation bodies =>
<https://standards.cencenelec.eu/dyn/www/f?p=CEN:5>
欧洲标准化机构列表 =>
<https://standards.cencenelec.eu/dyn/www/f?p=CEN:5>



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General product safety

Directive 2001/95/EC

Short name:	General product safety
Base:	Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety OJ No L 11 of 15 January 2002
Modification:	Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council



Summary list of titles and references of European standards under Directive 2001/95/EC for General Product Safety

The summary below consolidates the references of European standards published by the Commission in the Official Journal of the European Union (OJ). It reproduces information already published in the L or C series of the OJ. It contains all references which, when the summary was generated, still provided a presumption of safety together with references already withdrawn from the OJ.

The Commission services provide this summary for information purposes only. Although they take every possible precaution to ensure that the summary is updated regularly and is correct, errors may occur and the summary may not be complete at a certain point in time. The summary does not as such generate legal effects.

- [Summary list as pdf document](#)
- [Summary list as xls file](#)

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No harmonised standard – what to do? 没有协调标准- 怎么办?

Look for other European standards:
查找其他欧洲标准:

- The standardisation bodies' websites
标准化机构网站
- Seek advice from test lab or product safety advisor
征求检测实验室或产品安全顾问的建议
- Check notifications on the EU Safety Gate
检查欧盟安全门的通知
- SPEAC Finder factsheets
SPEAC Finder说明书





Pre-production risk assessment 生产前风险评估

Table with three columns:
三列表格:

- First column lists all the potential hazards
第一列列出所有潜在危险
- Second column is used for indicating whether the hazard is relevant
第二列用于说明危险是否相关
- Third column contains a short description of how the risk has been reduced
第三列简述如何降低风险





Testing 测试

The pre-market risk management will produce list of test requirements (third column in table)
上市前风险管理会产生测试要求的清单（表中第三列）

Involving test lab means extra control of risk assessment
让检测实验室参与意味着对风险评估的额外控制

Not obligatory for child care articles
对于儿童护理产品这并非强制性要求





Documentation – the technical file (1) 文档 - 技术文件 (1)

Contents内容

1. An assessment of the risks with the product.
产品风险评估
2. A general description of the product, any variants, and its intended use. This could be marketing material.
相关产品、类似产品及其预期用途的基本描述。上述内容可能作为营销材料。
3. Construction drawings including the bill of materials.
结构图，包括物料清单。
4. Those explanations that are necessary to understand the information mentioned under item 3 (if any).
为理解第3项所述信息（如有）而必需做出的解释。
5. Results of calculations, investigations and the like (if any).
计算的结果和调研等（如有）。





Documentation – the technical file (2) 文档 - 技术文件 (2)

Contents (continued) 内容（续）

6. Test reports 检测报告

7. Evidence (e.g. test reports, safety data sheets or declarations) demonstrating that the product complies with the chemical requirements

证明产品符合化学品要求的证据（如检测报告、安全技术说明书或声明）

8. A list of the harmonised standards and other technical specifications that have been applied.

一份使用的协调标准和其他技术规范的列表。

9. A copy of the user manual and the marking plate. 用户手册和产品铭牌的副本。

10. A description of the production control measures that the manufacturer has implemented.

一份制造商实施的生产控制方法的说明。





Marking标签

- Name and address of manufacturer plus importer or EU representative - full contact details.
制造商以及进口商或欧盟授权代表的名称和地址——详细的联系方式。
- Product name, model name or type number plus serial number, batch number or another timestamp.
产品名称、型号名称或型号，以及序列号、批次号或其他时间戳。
- Marking must be permanent.
采用耐久性标签。
- Correct language.
使用正确的语言。





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Declaration of Conformity? 符合性声明?

Declaration of Conformity only required for CE-marked products
仅CE认证产品需要符合性声明



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Thank you for listening
感谢聆听