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# 《全球合规快讯》

GLOBAL COMPLIANCE EXPRESS

法规更新、召回案例解读

REGULATIONS & LAWS, RECALL CASES STUDY

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### 编辑团队联系方式

Dennis Zhang

电话: 021-53396292

邮箱: dennis.zhang@intertek.com

网址: www.intertek.com.cn



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## PART 1 Toys 玩具

## 1 Hong Kong - Proposed Updates to Safety Standards for Toys and Children Products (12/2/2020)

## 香港- 提议更新玩具和儿童产品的安全标准

The Commerce and Economic Development Bureau (CEDB) of Hong Kong has proposed to adopt up-to-date safety standards for toys and some children's products listed in Schedules 1 and 2 of the Toys and Children's Products Safety Ordinance (Cap. 424).

香港商务和经济发展局提议更新玩具和儿童产品安全条例（Cap.424）附录 1 和附录 2 列出的安全标准，以采用最新的标准版本。

The proposed changes to the standards are summarized below:

提议的标准变更总结如下：

Table 1: Proposed Updates to Standards for Toys listed in Schedule 1

表 1：提议更新的附录 1 中关于玩具的标准

Standard 标准	Current Version 当前版本	Updated Version 更新版本	Name of Standard 标准名称
International Standard 国际标准	ISO 8124-3:2010 + A2:2018	ISO 8124-3:2020	Safety of toys - Part 3: Migration of certain elements 玩具安全 第 3 部分:特定元素迁移
European Standard 欧洲标准	BS EN 71 - 7:2014 + A2:2018	BS EN 71 - 7:2014 + A3:2020	Safety of toys - Part 7: Finger paints – Requirements and test methods 玩具安全 第 7 部分:指画颜料-要求和测试方法



Table 2: Proposed Updates to Standards for Children's Products listed in Schedule 2

表 2：提议更新的附录 2 中关于儿童产品的标准

Children's Product 儿童产品	Current Version 当前版本	Updated Version 更新版本	Name of Standard 标准名称
Bunk beds for domestic use 家用双层床	ASTM F1427-13	ASTM F1427-19	Standard consumer safety specification for bunk beds  消费者安全规范-双层床标准
Children's high chairs and multi- purpose high chairs for domestic use 儿童高脚椅和多用途家用高脚椅	BS EN 14988:2017	BS EN 14988:2017 + A1:2020	Children's high chairs- Requirements and test methods  儿童高脚椅-要求和测试方法
Children's paints 儿童绘画涂料	ISO 8124-3:2010 + A2:2018	ISO 8124-3:2020	Safety of toys - Part 3: Migration of certain elements  玩具安全 第 3 部分:特定元素迁移



## 2 EU - Approved Amendment to Allergenic Fragrance Requirements under Toy Safety Directive 2009/48/EC (12/16/2020)

### 欧盟-批准修订玩具安全指令 2009/48/EC 中对致敏香料的要求

The European Commission has published Directives (EU) 2020/2088 and 2020/2089 to amend Annex II to Toy Safety Directive 2009/48/EC, regarding allergenic fragrances in toys. Member States shall apply the amendments from 5 July 2022. Here is the summary of the new requirements:

欧盟委员会发布了指令(EU) 2020/2088 和指令(EU) 2020/2089，修订玩具安全指令 2009/48/EC 的附件 II 中对玩具中致敏香料的要求。成员国应从 2022 年 7 月 5 日起执行该两项修订的要求。以下为要求的总结：

#### 1) Amendments to the list of allergenic fragrances which require labelling 对需进行标签的致敏香料清单的修订

According to the current requirement in Part III, Annex II to the Directive, the name of allergenic fragrance listed in Paragraph 3 of Point 11 shall be stated on a toy, on an affixed label, on the packaging or in an accompanying leaflet, if the fragrance is added to the toy or component at a concentration exceeding 100 mg/kg.

根据玩具安全指令 2009/48/EC 附件 II 第 III 部分的现行要求，第 11 点的第 3 段中表格所列致敏香料，若在玩具或其部件中添加的浓度超过 100 mg/kg，则应在玩具、加贴标签、包装或随附单页上列出该致敏香料的名称。





The Commission has approved to amend the list by:

**欧盟委员会已批准对此清单进行如下修订:**

A. Adding 2 CAS numbers to Citronellol, 1117-61-9 and 7540-51-4

香茅醇 (Citronellol, CAS 号: 106-22-9) , 增加 2 个 CAS 号 (1117-61-9 和 7540-51-4) ;

B. Adding 61 allergenic fragrances to the list, as below:

增加 61 种致敏香料, 详见下表:

No 序号	Name of the allergenic fragrance 致敏香料名称	CAS number CAS 号
(12)	Acetylcedrene 甲基柏木酮	32388-55-9
(13)	Amyl salicylate 水杨酸戊酯	2050-08-0
(14)	trans-Anethole 反式茴香脑	4180-23-8
(15)	Benzaldehyde 苯甲醛	100-52-7
(16)	Camphor 樟脑	76-22-2; 464-49-3
(17)	Carvone 香芹酮	99-49-0; 6485-40-1; 2244-16-8
(18)	beta-Caryophyllene (ox.) $\beta$ -石竹烯	87-44-5
(19)	Rose ketone-4 (Damascenone)大马酮	23696-85-7
(20)	alpha-Damascone (TMCHB)甲位二氢突厥酮(TMCHB)	43052-87-5; 23726-94-5
(21)	cis-beta-Damascone 乙位二氢突厥酮	23726-92-3
(22)	delta-Damascone 丁位突厥酮	57378-68-4
(23)	Dimethylbenzyl carbiny acetate (DMBCA)	151-05-3



	乙酸二甲基苄基原酯(DMBCA)	
(24)	Hexadecanolactone 氧杂环十七烷-2-酮	109-29-5
(25)	Hexamethylindanopyran 佳乐麝香	1222-05-5
(26)	(DL)-Limonene 双戊烯	138-86-3
(27)	Linalyl acetate 乙酸芳樟酯	115-95-7
(28)	Menthol 薄荷脑	1490-04-6; 89-78-1; 2216-51-5
(29)	Methyl salicylate 水杨酸甲酯	119-36-8
(30)	3-methyl-5-(2,2,3-trimethyl-3-cyclopenten-1-yl)pent-4-en-2-ol 3-甲基-5-(2,2,3-三甲基-3-环戊烯-1-基)-4-戊烯-2-醇	67801-20-1
(31)	alpha-Pinene $\alpha$ -蒎烯	80-56-8
(32)	beta-Pinene $\beta$ -蒎烯	127-91-3
(33)	Propylidene phthalide 3-丙亚基-1-异苯并呋喃酮	17369-59-4
(34)	Salicylaldehyde 水杨醛	90-02-8
(35)	alpha-Santalol $\alpha$ -檀香醇	115-71-9
(36)	beta-Santalol $\beta$ -檀香醇	77-42-9
(37)	Sclareol 香紫苏醇	515-03-7
(38)	alpha-Terpineol $\alpha$ -松油醇	10482-56-1; 98-55-5
(39)	Terpineol (mixture of isomers) 松油醇 (异构体混合物)	8000-41-7
(40)	Terpinolene 萜品油烯	586-62-9
(41)	Tetramethyl acetyloctahydro naphthalenes 龙涎酮	54464-57-2; 54464-59-4; 68155-66-8; 68155-67-9
(42)	Trimethyl benzenepropanol (Majantol) 美研醇	103694-68-4



(43)	Vanillin 香兰素	121-33-5
(44)	Cananga odorata and Ylang-ylang oil 衣兰油	83863-30-3; 8006-81-3
(45)	Cedrus atlantica bark oil 雪松油	92201-55-3; 8000-27-9
(46)	Cinnamomum cassia leaf oil 肉桂油	8007-80-5
(47)	Cinnamomum zeylanicum bark oil 锡兰肉桂树皮提取物	84649-98-9
(48)	Citrus aurantium amara flower oil 苦橙花油	8016-38-4
(49)	Citrus aurantium amara peel oil 酸橙提取物	72968-50-4
(50)	Citrus bergamia peel oil expressed 香柠檬果提取物	89957-91-5
(51)	Citrus limonum peel oil expressed 柠檬提取物	84929-31-7
(52)	Citrus sinensis (syn.: Aurantium dulcis) peel oil expressed 甜橙提取物	97766-30-8; 8028-48-6
(53)	Cymbopogon citratus/schoenanthus oils 香茅提取物	89998-14-1; 8007-02-01; 89998-16-3
(54)	Eucalyptus spp. leaf oil 桉叶油	92502-70-0; 8000-48-4
(55)	Eugenia caryophyllus leaf/flower oil 丁香油	8000-34-8
(56)	Jasminum grandiflorum/officinale 茉莉油	84776-64-7; 90045-94-6; 8022-96-6
(57)	Juniperus virginiana 柏木油	8000-27-9; 85085-41-2
(58)	Laurus nobilis fruit oil 月桂果油	8007-48-5
(59)	Laurus nobilis leaf oil 月桂叶油	8002-41-3
(60)	Laurus nobilis seed oil 月桂籽油	84603-73-6
(61)	Lavandula hybrida 杂薰衣草提取物	91722-69-9
(62)	Lavandula officinalis 薰衣草提取物	84776-65-8



(63)	Mentha piperita 辣薄荷叶提取物	8006-90-4; 84082-70-2
(64)	Mentha spicata 留兰香提取物	84696-51-5
(65)	Narcissus spp. 水仙提取物	Diverse, including 90064-25-8
(66)	Pelargonium graveolens 香叶天竺葵提取物	90082-51-2; 8000-46-2
(67)	Pinus mugo 欧洲山松提取物	90082-72-7
(68)	Pinus pumila 偃松提取物	97676-05-6
(69)	Pogostemon cablin 广藿香油	8014-09-3; 84238-39-1
(70)	Rose flower oil (Rosa spp.) 玫瑰油	Diverse, including 8007-01-0, 93334-48-6, 84696-47-9, 84604-12-6, 90106-38-0, 84604-13-7, 92347-25-6
(71)	Santalum album 檀香油	84787-70-2; 8006-87-9
(72)	Turpentine (oil) 松节油	8006-64-2; 9005-90-7; 8052-14-0

## 2) Prohibition of 3 allergenic fragrances 禁用 3 种致敏香料

The following 3 allergenic fragrances shall be banned:

以下 3 种致敏香料将被禁用：

No 序 号	Name of the allergenic fragrance 致敏香料名称	CAS number CAS 号
(56)	Atranol (2,6-Dihydroxy-4-methyl-benzaldehyde) 地衣醇 (2,6-二羟基-4-甲基苯甲醛)	526-37-4
(57)	Chloroatranol (3-Chloro-2,6-Dihydroxy-4-methyl-benzaldehyde) 氯冉醇	57074-21-2
(58)	Methyl heptine carbonate 2-辛炔酸甲酯	111-12-6





The above ban shall not apply to traces of the fragrances in which the presence is technically unavoidable under good manufacturing practice and does not exceed 100 mg/kg.

以上禁令不适用于在良好生产规范下无法从技术上避免的，痕量存在且含量不超过 100 mg/kg 的香料。

As methyl heptine carbonate has become a prohibited fragrance, it shall be removed from the list of allergenic fragrances which require labelling.

由于 2-辛炔酸甲酯 (Methyl heptine carbonate, CAS 号: 111-12-6) 已成为禁用致敏香料，它将在需进行标签的致敏香料的原表格中去除。



### 3 Korea - Proposed Amendments to Standards for Toys and School Things under Safety Confirmation System (12/16/2020)

#### 韩国 - 提议修订安全确认体系中的关于玩具和学习用品的标准

The Korean Ministry of Trade, Industry and Energy (MOTIE) has issued Announcement No. 2020-670, proposing to amend the standards for Toys (Annex 6) and School Things (Annex 11) under Safety Confirmation System for consultation. The proposed amendments are as follows:

韩国贸易、工业和能源部（MOTIE）日前发布第 2020-670 号公告，提议对安全确认制度下的玩具（附录 6）和学习用品（附录 11）标准进行修订征求意见。拟议的修正案如下：

#### 1) Annex 6: Toys 附件 6：玩具

- A. Products such as permanent stickers for interior decoration and name stickers are not considered as toys. However, the stickers for interior decoration such as luminous constellation stickers that children may use should be considered as toys.

室内装饰用永久贴纸和姓名贴等产品不被视为玩具。然而，用于室内装饰的贴纸，如儿童可能使用的夜光星座贴纸，应视为玩具。

- B. Newly added requirements for nitrosamines and nitrosatable substances for elastomeric children's products which is designed for use in or put into the mouth. The requirements shall follow the "Common Safety Standard for Children's Products".

新增亚硝胺和亚硝基物质要求，该要求针对于设计用于或放入口中的儿童产品中弹性体。该亚硝胺和亚硝基物质要求应依照《儿童产品通用安全标准》的规定。



- C. The total lead contents in substance shall be reduced from 300 mg/kg to 100 mg/kg. (The limits for paint and surface coating shall be still 90mg/kg or less. It has not been changed in the amendments of standard)

基材的总铅限量应从 300 mg/kg 降至 100 mg/kg. (油漆和表面涂层的限值仍应为 90mg/kg 或以下)。

- D. The requirements for phthalate plasticizers (DEHP, DBP, BBP, DINP, DIDP, DnOP) shall apply to synthetic resin products regardless of whether it is designed for use in the mouth. The total content of the six phthalates shall not exceed 0.1 %.

邻苯二甲酸酯增塑剂 (DEHP、DBP、BBP、DINP、DIDP、DnOP) 的要求适用于合成树脂产品, 无论其是否设计用于口腔接触。六种邻苯二甲酸酯的总含量不得超过 0.1%。

## 2) Annex 11: School Things 附件 11: 学习用品

- A. Removed users' ages for crayon and craypas from present standard. So that after amendment, crayon and craypas refer to a kind of art tool that includes crayons, crayon sharpeners, handles, and scrapers.

从现行标准中删除了油画棒和蜡笔的使用年龄。因此经修改后, 油画棒和蜡笔是指艺术工具, 包括蜡笔、蜡笔削笔刀、手柄和刮刀。

- B. Clay products are removed from school things and managed as toys.

粘土制品从学习用品中移除, 现作为玩具来监管。

- C. Flavors used in products shall be the items listed in Food Additives Code.

产品中使用的香精应当符合《食品添加剂规范》的规定。



- D. The acute oral toxicity value ( $LD_{50}$ ) shall be 2000mg/kg and more in the test. However, if submit internationally recognized toxicity data, toxicity testing can be omitted.

试验中急性经口毒性值 ( $LD_{50}$ ) 应为 2000mg/kg 及以上。但是，如果提交国际公认的毒性数据，则毒性试验可以省略。

- E. Newly added requirements for nitrosamines and nitrosatable substances for elastomeric children's products which is designed for use in or put into the mouth. It shall according to "Common Safety Standard for Children's Products".

新增亚硝胺和亚硝基物质要求，该要求针对于设计用于或放入口中的儿童产品中弹性体。该亚硝胺和亚硝基物质要求应依照《儿童产品通用安全标准》的规定。

- F. The total lead contents in substance shall be reduced from 300 mg/kg to 100 mg/kg. (The limits for paint and surface coating shall be still 90mg/kg or less. It has not been changed in the amendments of standard)

基材的总铅限量应从 300 mg/kg 降至 100 mg/kg。（油漆和表面涂层的限值仍应为 90mg/kg 或以下）。

- G. The requirements for phthalate plasticizers (DEHP, DBP, BBP, DINP, DIDP, DnOP) shall apply to synthetic resin products regardless of whether it is designed for use in the mouth. The total content of the six phthalates shall not exceed 0.1 %.

邻苯二甲酸酯增塑剂（DEHP、DBP、BBP、DINP、DIDP、DnOP）的要求适用于合成树脂产品，无论其是否设计用于口腔接触。六种邻苯二甲酸酯的总含量不得超过 0.1%。





## PART 2 Children products 儿童产品

### 4 Korea - Proposed Amendments to Guidelines for Children Products (12/11/2020)

#### 韩国-提议修订儿童产品指南

The Korean Agency for Technology and Standards (KATS) has issued announcement No. 2020-0386 proposing to amend the “Guideline for the Interpretation and Safety Management of Children Products” for consultation. This guideline aims to provide business operators guidance on factors that should be considered when evaluating what products shall be governed by the “Special Act on Children’s Product Safety” prior to market distribution. The appendix of the regulation provide the guidance for children’s products subject to “Supplier Conformity Confirmation” however without assigned standards (annexes). The proposed amendments are highlighted as follows:

韩国技术和标准局（KATS）发布了第 2020-0386 号公告，提议修订《儿童产品解释和安全管理指南》并征求公众意见。本指南旨在为经营者提供指导，说明在上市销售前评估哪些产品应受“儿童产品安全特别法”管辖时应考虑的因素。本法规的附录提供了受“供应商符合性确认”约束的儿童产品的指南，但未指定标准（附件）。拟议修正案重点如下：

#### 1) Definition and Scope 定义及范围

Children’s products are products (include parts or accessories) designed primarily for and intended for use by children under the age of 14. “for use” means that children physically interact with the product through normal use and reasonably foreseeable use. General purpose products that are designed not primarily for children under the age of 14, professional or having special purpose are not considered as children’s products. In addition, products for any intended age range (e.g. 8 years old to adult) must be designed suitable for its minimum age.



儿童产品是指主要为 14 岁以下儿童设计和使用的产品（包括零件或附件）。“使用”是指儿童通过正常使用和合理可预见的使用与产品进行身体互动。非主要为 14 岁以下儿童设计的通用产品、专业产品或具有特殊用途的产品不被视为儿童产品。此外，适用于任何预期年龄范围（如 8 岁至成人）的产品必须设计为适合其最低年龄。

## 2) Interpretation of Children's Products 儿童产品的解释

Children's products shall be further determined which system (Safety Certification, Safety Confirmation or Suppliers Conformity Confirmation) of the "Special Act on Children's Product Safety" should be under, through the definition and scope of the children product after having considered the following factors:

儿童产品应在考虑以下因素后，通过儿童产品的定义和范围，进一步确定其应归属的“儿童产品安全特别法”中的体系（安全认证、安全确认或供应商符合性确认）：

- Functions and Characteristics of Children's Products  
儿童产品的功能和特点
- Age of user of the product 产品使用者年龄
- Product advertisement and packaging 产品广告与包装
- General perception of consumers 消费者的总体认知
- Manufacturer's description 制造商说明
- Other elements, such as product price, design, usage  
其他要素，如产品价格、设计、用途等



### 3) Labelling for non-Children's Products 非儿童产品的标签

If it is possible to misuse a product as a children's product (people cannot distinguish the intended users of a product), the product shall be clearly indicated that it is not for children (e.g., "for adults", "not for children", "Available for use over the age of 14", etc.). Products without such label would be considered as children's products in principle. Unless they are distributed separately from places that mainly for children's products (e.g. toy stores, children's product sales areas in large shopping centers, etc.).

如果产品有可能被误用为儿童产品（人们无法区分产品的预期使用者），则应明确指出该产品不适合儿童使用（如“成人使用”、“不适合儿童使用”、“14 岁以上可使用”等）。无此标签的产品原则上视为儿童产品。除非与主要销售儿童产品的场所（如玩具店、大型购物中心的儿童产品销售区等）分开销售。

### 4) Checklist 检查清单

The checklist for helping to determine whether a product is children product can be found in the table of the Appendix in the guideline

帮助确定产品是否为儿童产品的检查表可在指南附录的表格中找到。



## 5 Taiwan - Approved Mandatory Inspection Requirements for Cribs and Cradles for Domestic Use (12/29/2020)

### 台湾- 批准家用婴儿床和摇篮的强制检验要求

The Bureau of Standards, Metrology and Inspection (BSMI) of Taiwan has approved the mandatory inspection requirements for cribs and cradles for domestic use under the BSMI Notice No. 10920008270, which shall be effective from 1 May 2021. The BSMI inspection service shall be available from 1 May 2021, and all products shall comply with the requirements from 1 November 2021. Here are the highlights:

台湾标准、计量和检查局（BSMI）已发布第 10920008270 号通知，批准家用婴儿床和摇篮的强制检验要求，自 2021 年 5 月 1 日起生效。BSMI 将自 2021 年 5 月 1 日起提供检验服务，2021 年 11 月 1 日起所有产品都必须符合相关要求。以下是主要内容：

#### 1) Scope and inspection standard 范围和检验标准

##### Scope 范围:

Cribs and cradles for domestic use 家用婴儿床和摇篮

##### Inspection standard 检验标准:

CNS 12990:2017 *Cribs and cradles for domestic use* 家用婴儿床和摇篮

#### 2) Conformity assessment requirements 合格评定要求

A. Products shall follow either 产品应符合以下任一条件：





- a. Batch-by-Batch Inspection (Type Approval); or  
逐批检查（型式认可）;或
- b. Module II and Module III of the Registration of Product Certification (RPC) Scheme, where:  
产品认证注册计划的模块 II 和模块 III，其中：
- Module II - Type Test Module: The applicant or the production premises shall submit technical documents together with the type samples and obtain a type-test report indicating that the types are in compliance with specified standards or relevant technical regulations from the BSMI or designated testing laboratories recognized by the BSMI.  
模块 II-型式检验模块：申请人或生产场所应将技术文件与型式样品一起提交，并获得型式试验报告，以表明该类型符合 BSMI 或其认可实验室的指定标准或相关技术法规。
  - Module III - Declaration of Conformity: The applicant shall declare and ensure that its production premises are registered under their consent, and are the actual factories manufacturing the registered commodities which comply with those types in Module II.  
模块 III-符合性声明：申请人应声明并确保其生产场所在其同意下进行注册，并且是生产符合模块 II 中那些类型的注册商品的实际工厂
- B. After passing the conformity assessment, products shall be labelled with the Commodity Inspection Mark on the prominent place of the product.  
通过合格评定后，产品应在产品显眼位置贴上商品检验标记。
- C. The product certificate shall be valid for 3 years. If the certificate is issued on or before 31 October 2021, it shall be valid from 1 November 2021 until 31 October 2024.



产品证书有效期为 3 年。如果证书颁布于 2021 年 10 月 31 日及之前，其有效期为 2021 年 11 月 1 日至 2024 年 10 月 31 日。

- D. Multifunctional cribs and cradles that fall within the scope of inspection shall comply with relevant inspection requirements. Any accessories of cribs and cradles which are included in the scope of inspection shall also comply with the relevant inspection requirements.

属于强制检查产品范围内的多用途婴儿床和摇篮应符合相关的检查要求。属于强制检查范围婴儿床和摇篮的任何附件也应符合相关的检查要求。

## 6 Taiwan - Approved Mandatory Inspection Requirements for Reclined Cradles (12/30/2020)

### 台湾—批准倾倒式摇篮的强制检查要求

The Bureau of Standards, Metrology and Inspection (BSMI) of Taiwan has approved the mandatory inspection requirements for reclined cradles for domestic use under the BSMI Notice No. 10920008230, which shall be effective from 1 May 2021. The BSMI inspection service shall be available from 1 May 2021, and all products shall comply with the requirements from 1 November 2021. Here are the highlights:



台湾标准、计量和检查局（BSMI）已发布第 10920008230 号通知，批准倾倒式摇篮的强制检验要求，自 2021 年 5 月 1 日起生效。BSMI 将自 2021 年 5 月 1 日起提供检验服务，2021 年 11 月 1 日起所有产品都必须符合相关要求。以下是主要内容：

### 1) Scope and inspection standard 范围和检验标准

Scope 范围:

Reclined cradles 倾倒式摇篮

Inspection standard 检验标准:

CNS 15982:2017 *Child use and care articles - Reclined cradles*

儿童使用和护理用品---倾倒式摇篮

### 2) Conformity assessment requirements 符合性评估要求

A. Products shall follow either 产品应符合以下任一条件：

- a. Type Approved Batch-by-Batch Inspection; or  
逐批检查（型式认可）;或
- b. Module II and Module III of the Registration of Product Certification (RPC) Scheme, where:  
产品认证注册计划（RPC）的模块 II 和模块 III，其中：



- Module II - Type Test Module: manufacturers or importers shall have their products type-tested by the BSMI or designated testing laboratories recognized by the BSMI before applying for registration of their products.

模块 II-型式检验模块：申请人或生产场所应将技术文件与型式样品一起提交，并获得型式试验报告，以表明该类型符合 BSMI 或其认可实验室的指定标准或相关技术法规。

- Module III - Declaration of Conformity: manufacturers or importers shall declare and ensure that all products made at their manufacturing facilities are in conformity with the prototypes submitted for type testing in Module II.

模块 III-符合性声明：申请人应声明并确保其生产场所在其同意下进行注册，并且是生产符合模块 II 中那些类型的注册商品的实际工厂。

B. After passing the conformity assessment, products shall be labelled with the Commodity Inspection Mark on the prominent place of the product.

通过合格评定后，产品应在产品显眼位置贴上商品检验标记。

C. The product certificate shall be valid for 3 years. If the certificate is issued on or before 31 October 2021, it shall be valid from 1 November 2021 until 31 October 2024.

产品证书有效期为 3 年。如果证书颁布于 2021 年 10 月 31 日及之前，其有效期为 2021 年 11 月 1 日至 2024 年 10 月 31 日。



## 7 Taiwan - Approved Mandatory Inspection Requirements for Playpens for Domestic Use (12/30/2020)

### 台湾-批准家用游戏围栏的强制检验要求

The Bureau of Standards, Metrology and Inspection (BSMI) of Taiwan has approved the mandatory inspection requirements for playpens for domestic use under the BSMI Notice No. 10920008780, which shall be effective from 1 June 2021. The BSMI inspection service shall be available from 1 June 2021, and all products shall comply with the requirements from 1 December 2021. Here are the highlights:

台湾标准、计量和检查局（BSMI）已发布第 10920008780 号通知，批准家用游戏围栏的强制检验要求，自 2021 年 6 月 1 日起生效。BSMI 将自 2021 年 6 月 1 日起提供检验服务，2021 年 12 月 1 日起所有产品都必须符合相关要求。以下是主要内容：

#### 1) Scope and inspection standard 范围及检验标准

##### Scope 范围：

Playpens for domestic use 家用游戏围栏

##### Inspection standard 检验标准:

CNS 16004:2017 Child use and care articles – Playpens for domestic use

CNS 16004:2017 儿童使用和护理用品-家用游戏围栏



## 2) Conformity assessment requirements 符合性评估要求

A. Products shall follow either:

产品应符合以下任一条件：

- a. Type Approved Batch-by-Batch Inspection; or  
逐批检查（型式认可）;或
- b. Module II and Module III of the Registration of Product Certification (RPC) Scheme, where:  
产品认证注册计划（RPC）的模块 II 和模块 III，其中：

- Module II - Type Test Module: manufacturers or importers shall have their products type-tested by the BSMI or designated testing laboratories recognized by the BSMI before applying for registration of their products.  
模块 II-型式测试模块：制造商或进口商应在其产品注册之前，由 BSMI 或 BSMI 认可的指定测试实验室对其产品进行型式测试。
- Module III - Declaration of Conformity: manufacturers or importers shall declare and ensure that all products made at their manufacturing facilities are in conformity with the prototypes submitted for type testing in Module II.

模块 III-符合性声明：申请人应声明并确保其生产场所在其同意下进行注册，并且是生产符合模块 II 中那些类型的注册商品的实际工厂。



B. After passing the conformity assessment, products shall be labelled with the Commodity Inspection Mark on the prominent place of the product.

通过合格评定后，产品应在产品显眼位置贴上商品检验标记。

C. The product certificate shall be valid for 3 years. If the certificate is issued on or before 30 November 2021, it shall be valid from 1 December 2021 until 30 November 2024.

产品证书有效期为 3 年。如果证书颁布于 2021 年 11 月 30 日及之前，其有效期为 2021 年 12 月 1 日至 2024 年 11 月 30 日。

D. Multifunctional playpens that fall within the scope of inspection shall comply with relevant inspection requirements.

属于检查范围的多功能家用游戏围栏应符合相关的检查要求。



## 8 Taiwan - Approved Mandatory Inspection Requirements for Children's Chairs and Stools (12/30/2020)

### 台湾-批准儿童椅及凳的强制检验要求

The Bureau of Standards, Metrology and Inspection (BSMI) of Taiwan has approved the mandatory inspection requirements for children's chairs and stools under the BSMI Notice No. 10920008760, which shall be effective from 1 June 2021. The BSMI inspection service shall be available from 1 June 2021, and all products shall comply with the requirements from 1 December 2021. Here are the highlights:

台湾标准、计量和检查局（BSMI）已发布第 10920008760 号通知，批准儿童椅及凳的强制检验要求，自 2021 年 6 月 1 日起生效。BSMI 将自 2021 年 6 月 1 日起提供检验服务，2021 年 12 月 1 日起所有产品都必须符合相关要求。以下是主要内容：

#### 1) Scope and inspection standard 范围及检验标准

##### Scope 范围：

Children's chairs and stools with a seat height of less than 38 cm, excluding children's potty and chairs and stools using in public places, without rigid frames, or with restraint systems.

座椅高度小于 38 厘米的，无刚性框架或约束系统的儿童椅和凳子。儿童便盆和用于公共场所的椅子和凳子除外。

##### Inspection standard 检验标准：

CNS 16045:2018 *Child use and care articles –Children's chairs and stools*

CNS 16045:2018 儿童使用和护理用品-儿童椅及凳





## 2) Conformity assessment requirements 符合性评估需求

A. Products shall follow either:

产品应符合以下任一条件：

a. Type Approved Batch-by-Batch Inspection; or

逐批检查（型式认可）；或

b. Module II and Module III of the Registration of Product Certification (RPC) Scheme, where:

产品认证注册计划（RPC）的模块 II 和模块 III，其中：

- Module II - Type Test Module: manufacturers or importers shall have their products type-tested by the BSMI or designated testing laboratories recognized by the BSMI before applying for registration of their products.

模块 II-型式测试模块：制造商或进口商应在其产品注册之前，由 BSMI 或 BSMI 认可的指定测试实验室对其产品进行型式测试。

- Module III - Declaration of Conformity: manufacturers or importers shall declare and ensure that all products made at their manufacturing facilities are in conformity with the prototypes submitted for type testing in Module II.

模块 III-符合性声明：申请人应声明并确保其生产场所在其同意下进行注册，并且是生产符合模块 II 中那些类型的注册商品的实际工厂。

B. After passing the conformity assessment, products shall be labelled with the Commodity Inspection Mark on the prominent place of the product.

通过合格评定后，产品应在产品显眼位置贴上商品检验标记。



- C. The product certificate shall be valid for 3 years. If the certificate is issued on or before 30 November 2021, it shall be valid from 1 December 2021 until 30 November 2024.

产品证书有效期为 3 年。如果证书颁布于 2021 年 11 月 30 日及之前，其有效期为 2021 年 12 月 1 日至 2024 年 11 月 30 日。

- D. Multifunctional children's chairs and stools that fall within the scope of inspection shall comply with relevant inspection requirements. Any accessories of chairs and stools which are included in the scope of inspection shall also comply with the relevant inspection requirements.

属于强制检查产品范围内的多用途儿童椅和凳子应符合相关的检查要求。  
属于强制检查范围儿童椅和凳子的任何附件也应符合相关的检查要求。



### PART 3 Electrical products 电子电气产品

## 9 Saudi Arabia - Draft Technical Regulation for the Restriction of Hazardous Substances in Electrical and Electronic Equipment (12/10/2020)

### 沙特阿拉伯- 提议电子电气设备中有害物质限制的技术法规

Saudi Standards, Metrology and Quality Organization (SASO) has proposed a technical regulation for the Restriction of Hazardous Substances in Electrical and Electronic Equipment. Here are the highlights:

沙特标准、计量和质量组织（SASO）提议了关于电子电气设备中有害物质限制的技术法规草案。以下是要点：

#### 1) Scope 范围

This regulation applies to electrical and electronic equipment in the following categories, which are placed and available in the Kingdom's markets, manufactured inside the Kingdom or imported from abroad:

本规定适用于如下在沙特国内制造或从国外进口、在沙特市场使用的电子电气设备：

- Large household appliances 大型家用电器
- Small household appliances 小型家用电器
- IT and telecommunications equipment 信息技术及通讯设备



- Lighting equipment 照明设备
- Electrical and electronic tools (except large-scale stationary industrial tools) 电动及电子工具(大型固定工业工具除外)
- Toys, leisure and sports equipment 玩具、休闲和运动器材
- Monitoring and control instruments 监控仪器
- Electrical and electronic equipment (May be a typographical error of the draft which shall be subject to change)

电气及电子设备（可能提案草稿的编辑错误，后续应会被修订）

\*All medical devices are excluded from the scope of this regulation, provided that the appropriate legislation for medical devices is issued by the relevant competent authorities.

如果相关主管部门颁布了有关医疗器械的相应的法规，则所有的医疗器械都不属于本技术法规的管辖范围。

## 2) Technical requirements 技术要求

To fulfill the requirements of this regulation, the supplier shall comply with the basic characteristics of electrical and electronic equipment, as follows:

**为满足本法规的要求，供应商应遵守以下电子电气设备的基本要求：**

- A. Electrical and electronic equipment shall not contain the following hazardous substances with the limits provided:

电气电子设备不得含有不符合以下限量的下列有害物质



Hazardous substances 有害物质	Maximum concentration values by weight 按重量计算的最大浓度值
Lead 铅(Pb)	0.1%
Mercury 汞(Hg)	0.1%
Cadmium 镉(Cd)	0.01%
Hexavalent chromium 六价铬(CrVI)	0.1%
Polybrominated biphenyls 多溴联苯(PBB)	0.1%
Polybrominated biphenyls ethers 多溴联苯醚(PBDE)	0.1%
Bis (2-ethylhexyl) phthalate 邻苯二甲酸二 (2-乙基己基) 酯 (DEHP)	0.1%
Butyl benzyl phthalate 邻苯二甲酸丁苄酯 (BBP)	0.1%
Dibutyl phthalate 邻苯二甲酸二丁酯 (DBP)	0.1%
Diisobutyl phthalate 邻苯二甲酸二异丁酯 (DIBP)	0.1%

- B. Electrical and electronic equipment shall meet the technical requirements specified in the standard specifications in the following table. When the Saudi or Gulf standard standards are not available, they shall meet the international standards:

电子电气设备应符合下表中标准所规定的技术要求。当没有沙特或海湾标准标准时，应符合国际标准：



No.	Reference No. of the Standard 标准编号	Title of the Standard 标准名称
1	IEC 63000:2016	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances 关于限制有害物质的电气和电子产品评估的技术文件
2	SASO IEC 62321:2010	Electrotechnical products – Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers) 电子电气产品-六种限制物质(铅、汞、镉、六价铬、多溴联苯和多溴联苯醚)的含量测定
3	IEC 62321-1:2013	Determination of certain substances in electrotechnical products – Part 1: Introduction and overview 电工产品中某些物质的测定 第 1 部分：简介和概述
4	IEC 62321-2:2013	Determination of certain substances in electrotechnical products – Part 2: Disassembly, disjointment and mechanical sample preparation 电工产品中某些物质的测定 第 2 部分：拆卸、解体和机械样品制备
5	IEC 62321-3-1:2013	Determination of certain substances in electrotechnical products – Part 3-1: Screening - Lead, mercury, cadmium, total chromium and total bromine by Xray fluorescence spectrometry 电工产品中某些物质的测定 第 3-1 部分：筛选-采用 X 射线荧光光谱法测定铅、汞、镉、总铬和总溴
6	IEC 62321-3-2:2020 RLV	Determination of certain substances in electrotechnical products – Part 3-2: Screening - Fluorine, bromine and chlorine in polymer and electronics by combustion-ion chromatography (C-IC) 电工产品中某些物质的测定 第 3-2 部分：筛选-采用燃烧离子色谱法 (C-IC) 测定聚合物和电子器件中的氟、溴和氯
7	IEC 62321-4:2013+AMD1:2017 CSV	Determination of certain substances in electrotechnical products – Part 4: Mercury in polymers, metals and electronics by CV-AAS, CV-AFS, ICPOES and ICP-MS 电工产品中某些物质的测定 第 4 部分：采用 CV-AAS、CV-AFS、ICPOES 和 ICP-MS 测定聚合物、金属和电子器件中的汞
8	IEC 62321-5:2013	Determination of certain substances in electrotechnical products – Part 5: Cadmium, lead and chromium in polymers and electronics



		and cadmium and lead in metals by AAS, AFS, ICP-OES and ICP-MS 电工产品中某些物质的测定 第 5 部分：采用 AAS，AFS，ICP-OES 和 ICP-MS 聚合物和电子器件中的镉、铅和铬以及测定金属中的铅和镉
9	SASO IEC 62321-6:2015	Determination of certain substances in electrotechnical products - Part 6: Polybrominated biphenyls and polybrominated diphenyl ethers in polymers by gas chromatography-mass spectrometry (GC-MS) 电工产品中某些物质的测定 第 6 部分：采用气相色谱-质谱法 (GC-MS) 测定聚合物中的多溴联苯和多溴联苯醚
10	SASO IEC 62321-7-1:2015	Determination of certain substances in electrotechnical products - Part 7-1: Hexavalent chromium - Presence of hexavalent chromium (Cr(VI)) in colourless and coloured corrosion-protected coatings on metals by the colorimetric method 电工产品中某些物质的测定 第 7-1 部分：六价铬-采用比色法测定金属上无色和有色防腐涂层中存在的六价铬(Cr(VI))
11	IEC 62321-7-2:2017	Determination of certain substances in electrotechnical products - Part 7-2: Hexavalent chromium - Determination of hexavalent chromium (Cr(VI)) in polymers and electronics by the colorimetric method 电工产品中某些物质的测定 第 7-2 部分：六价铬-采用比色法测定聚合物和电子产品中的六价铬(Cr(VI))
12	IEC 62321-8:2017	Determination of certain substances in electrotechnical products - Part 8: Phthalates in polymers by gas chromatography-mass spectrometry (GCMS), gas chromatography-mass spectrometry using a pyrolyzer/thermal desorption accessory (Py-TD-GC-MS) 电工产品中某些物质的测定 第 8 部分：采用气相色谱-质谱联用仪(GCMS)及使用带热裂解/热脱附附件的气相色谱-质谱联用仪(Py-TD-GC-MS)测定聚合物中的邻苯二甲酸酯
13	IEC 62474:2018 RLV	Material declaration for products of and for the electrotechnical industry 电工行业产品的材料声明
14	IEC TR 62474-1:2015	Material declaration for products of and for the electrotechnical industry - Part 1: Guidance for the implementation of IEC 62474 电工行业产品的材料声明-第 1 部分：IEC 62474 的实施指南



15	SASO IEC TR 62476:2011	Guidance for evaluation of product with respect to substance-use restrictions in electrical and electronic products 关于电子电气产品中物质使用限制的产品评估指南
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- C. The electrical and electronic equipment shall pass the conformity assessment, and shall accompany a technical file that includes all documents and information that can prove the product's compliance with the requirements of this regulation.

电子电气设备应通过合格评定，并应附有技术文件，其中应包括可证明产品符合本法规要求的所有文件和信息。

- D. The factory shall have an effective quality management system (a factory that has obtained a management system certificate in accordance with the special requirements for the application of ISO 9001 in the scope of related electrical and electronic equipment products - or its equivalent - is deemed to fulfill the requirements of this clause).

工厂应具有有效的质量管理体系（已按照 ISO 9001（或等同标准）对于相关的电子电气设备产品的特殊要求获得了管理体系证书的工厂，以证明符合本条款的要求）。

### 3) Conformity assessment 符合性评估

- A. Only the requirements of conformity assessment procedures mentioned in this technical regulation shall be adhered to, instead of those mentioned in any standard specification.

仅应遵守本技术法规中提到的合格评定程序的要求，而不是任何其它标准规范中提到的要求。





- B. The supplier shall obtain a Certificate of Conformity (Type 1a) and the relevant test report from the Manufacturing company, and submit them to the Authority (SASO) for acquiring a Certificate of Conformity.

供应商应从制造公司获得符合性证书(1a 型)和相关的测试报告，并将其提交给权威机构(SASO)获得符合性证书。

#### 4) Technical File 技术文件

A technical file shall accompany the product that includes the following:

产品随附的技术文件应包括以下内容：

- Supplier (manufacturer / importer) Declaration of Conformity according to the form attached in Annex 4 of this regulation  
供应商（制造商/进口商）符合性声明，按照本法规附件 4 中的表格填写。
- Risk assessment document  
风险评估文件
- Essential warnings and cautions and manuals for the safe and proper use of the product  
基本警告、注意事项以及安全和正确使用产品的说明书。

#### Note 注释

*This technical regulation contains the following annexes:*

本技术法规包含以下附件：

- 1) Annex 1: List of standards for electrical and electronic equipment  
附件 1：电子电气设备标准清单
- 2) Annex 2: List of hazardous substances restricted in electrical and electronic products  
附件 2：电子电气产品中限制使用的有害物质清单
- 3) Annex 3: Sample of conformity assessment form (Type 1a) according to ISO/IEC 17067  
附件 3：符合 ISO / IEC 17067 的合格评定表（类型 1a）的样本
- 4) Annex 4: Sample of Supplier Declaration of Conformity  
附件 4：供应商符合性声明样本



## 10 Australia-Approved Consumer Goods (Products Containing Button/Coin Batteries) Safety and Information Standard (12/23/2020)

### 澳大利亚-批准消费品（含有纽扣电池的产品）安全和信息标准

The Australia Government has published approved Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard and Consumer Goods (Products Containing Button/Coin Batteries) Information Standard. On and after 22 June 2022, consumer goods containing button/coin batteries shall comply with the Regulations.

澳大利亚政府发布已被批准的《消费品（含有纽扣电池的产品）安全标准和消费品（含有纽扣电池的产品）信息标准》。自 2022 年 6 月 22 日起，含有纽扣电池的消费品都必须符合该法规的规定。

## 11 Australia - Approved Consumer Goods (Button/Coin Batteries) Safety and Information Standard (12/24/2020)

### 澳大利亚-批准消费品（纽扣电池）安全和信息标准

The Australia Government has published approved Consumer Goods (Button/Coin Batteries) Safety Standard and Consumer Goods (Button/Coin Batteries) Information Standard. On and after 22 June 2022, an applicable button/coin battery shall comply with the Regulations.

澳大利亚政府发布已被批准的《消费品（纽扣电池）安全标准和消费品（纽扣电池）信息标准》。自 2022 年 6 月 22 日起，适用的纽扣电池都必须符合该法规的规定。



## 12 EU - RoHS renewal assessment for 9 exemptions regarding lead in alloys, lead in high temperature molten solder, lead in glass ceramics of electronic components and others (12/15/2020)

### 欧盟 RoHS 关于合金中的铅、高温焊料中的铅、电子元器件玻璃陶瓷中的铅等 9 项豁免条款的展期评估

On December 15, 2020, the EU RoHS exemption Pack 22 evaluation project was launched. Pack 22 evaluation project covers nine items in RoHS Annex III (6(a), 6(a)-I, 6(b), 6(b)-I, 6(b)-II, 6(c), 7(a), 7(c)-I and 7(c)-II). The evaluation period is 10 months.

2020 年 12 月 15 日，欧盟 RoHS 豁免 Pack 22 评估项目启动，涵盖 RoHS 附件 III 中的 6(a)、6(a)-I、6(b)、6(b)-I、6(b)-II、6(c)、7(a)、7(c)-I 和 7(c)-II 这九个条款。评估为期 10 个月。

Item 条款	Exemptions 豁免内容
6(a)	Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0.35 % lead by weight. 用于加工的钢和镀锌钢中的铅含量不超过 0.35% (Wt)
6(a)-I	Lead as an alloying element in steel for machining purposes containing up to 0.35 % lead by weight and in batch hot dip galvanised steel components containing up to 0.2 % lead by weight. 用于加工的钢，铅含量不超过 0.35% (Wt) ，用于批量热浸镀锌钢中的铅含量不超过 0.2% (Wt)
6(b)	Lead as an alloying element in aluminium containing up to 0.4 % lead by weight. 铝合金中的铅含量不超过 0.4% (Wt)
6(b)-I	Lead as an alloying element in aluminium containing up to 0.4 % lead by weight, provided it stems from lead-bearing aluminium scrap recycling.



	来源于回收的含铅铝废料，铅作为合金元素在铝合金中的含量不超过 0.4% (Wt)
6(b)-II	Lead as an alloying element in aluminium for machining purposes with a lead content up to 0.4 % by weight. 用于加工目的的铝，铅作为合金元素含量不超过 0.4% (Wt)
6(c)	Copper alloy containing up to 4 % lead by weight. 铜合金中的铅含量不应该超过 4% (Wt)
7(a)	Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead). 高温熔融焊料中的铅（即：锡铅焊料合金中铅含量≥85% (Wt) ）
7(c)-I	Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound. 电子元器件的玻璃或陶瓷（电容中介电陶瓷除外）中的铅，或玻璃或陶瓷复合材料中的铅（例如：压电陶瓷器件）
7(c)-II	Lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher. 额定电压为 125V 交流电或 250V 直流电或以上的电容器的介电陶瓷中的铅

The online stakeholder consultation shall run for ten weeks from 23 December 2020 to 03 March 2021.

本次评估活动的在线公众咨询于 2020 年 12 月 23 日开通，为期 10 周至 2021 年 3 月 3 日。

These exemptions will be effective until the assessment results are announced. If the exemption is revoked after the assessment, a transition period of 12 to 18 months will be set for the industry to replace materials.

在公布评估结果前，这些豁免将继续有效。如果评估后豁免被撤销，则会设定 12 个月到 18 个月的过渡期用于业界替换材料。



## PART 4 Chemical 化学类

### 13 EU - Approved Amendment to Annex XVII to REACH Regulation (EC) No 1907/2006 Regard Tattoo Inks and Permanent Make-up (12/16/2020)

**欧盟-批准对于 REACH 法规(EC) No 1907/2006 的附录 XVII 的修订，修订涉及纹身产品或永久性化妆品**

The European Commission has published Commission Regulation (EU) 2020/2081 to amend Annex XVII to REACH Regulation (EC) No 1907/2006. The amendment aimed to restrict the substances used in tattoo inks or permanent make-up, which are mentioned in Regulation (EC) No 1272/2008, Regulation (EC) No 1223/2009. Therefore, regarding this issue entry 75 shall be newly added to Annex XVII:

欧盟委员会发布法规(EU) 2020/2081，对 REACH 的附件 XVII 进行修订。该修订针对在法规(EC) No 1272/2008 和法规 (EC) No 1223/2009 提到的，用于纹身产品或永久性化妆品中的物质的限制。因此，相关的新条款 75 将被添加到附录 XVII。

#### 1) Restriction 限制

After 4 January 2022, the following substances in mixtures for use for tattooing purposes shall not be used for tattooing purposes shall not be placed on the market unless they fulfil the following restrictions:

2022 年 1 月 4 日之后，以下混合物中用于纹身用途的物质不得用于纹身，除非它们满足以下限制，否则不得投放市场：



- A. Substances classified as any of the following in Part 3 of Annex VI to Regulation (EC) No 1272/2008:

分类在法规(EC) No 1272/2008 附录 VI 第三部分中的物质：

- a. carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, but excluding any such substances classified due to effects only following exposure by inhalation

Restriction: Concentration < 0.00005% by weight

致癌物类别 1A、1B 或 2，或生殖细胞诱变剂类别 1A、1B 或 2，但不包括任何仅因吸入暴露而影响而归入此类的物质。

限制：浓度<0.00005%（质量百分比）。

- b. reproductive toxicant category 1A, 1B or 2 but excluding any such substances classified due to effects only following exposure by inhalation

Restriction: concentration < 0.001% by weight

生殖毒性类别 1A、1B 或 2，但不包括任何仅由于吸入后会产生影响而归入此类的物质。

限制：浓度<0.001%（质量百分比）。

- c. skin sensitiser category 1, 1A or 1B

Restriction: concentration < 0.001% by weight

皮肤致敏剂 1、1A 或 1B 类

限制：浓度<0.001%（质量百分比）。

- d. skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2 or serious eye damage category 1 or eye irritant category 2

皮肤腐蚀 1、1A、1B 或 1C 类或皮肤刺激 2 类或严重眼损伤 1 类或眼睛刺激性 2 类



Restriction 限制:

- Concentration < 0.1% by weight, if the substance is used solely as a pH regulator.

浓度<0.1%（质量百分比），如果该物质仅用作 pH 调节剂。

- Concentration < 0.01% by weight in all other cases.

浓度<0.01%（质量百分比），用于其它场合时。

B. Substances listed in Annex II to Regulation (EC) No 1223/2009.

Restriction: concentration < 0.00005% by weight

法规(EC) No 1223/2009 附录 II 中列出的物质。

限制：浓度<0.00005%（质量百分比）。

C. Substances listed in Annex IV to Regulation (EC) No 1223/2009 having the following product type or body parts:

属于以下产品类型或身体部位的法规(EC) No 1223/2009 附录 VI 中列出的物质。

- Rinse-off products 清洗产品.
- Not to be used in products applied on mucous membranes  
不用于粘膜的产品.
- Not to be used in eye products 不用于眼部的产品.

Restriction: concentration < 0.00005% by weight.

限制：浓度<0.00005%（质量百分比）。

D. Substances that meet the conditions of maximum concentration in ready for use preparation and other mentioned in Annex VI to Regulation (EC) No 1223/2009.



不符合法规 (EC) No. 1223/2009 号附件 VI 中所述条件 (即用型制剂及其他制剂中的最大浓度) 的物质。

- E. Substances listed in Appendix 13, which shall be less than the concentration limit (by weight). Please refer to the document for the detail.
- 附录 13 中列出的物质, 其应小于浓度极限 (以重量计)。请参阅文件以获得有关详细信息。

The following two substances shall not apply to the above restrictions until 4 January 2023:

2023 年 1 月 4 日前, 以下两种物质不适用于上述限制:

- Pigment Blue 15:3 颜料蓝 15:3 (CAS No 147-14-8);
- Pigment Green 7 颜料绿 7 (CAS No 1328-53-6).

## 2) Labelling requirement 标签要求

- A. After 4 January 2022, the mixture for use for tattooing purpose shall be marked with the following information:

2022 年 1 月 4 日后, 用于纹身用途的混合物应标示以下信息:

- a. the statement "Mixture for use in tattoos or permanent make-up";  
"用于纹身或永久性化妆的混合物"的声明;
- b. a reference number to uniquely identify the batch;  
标识批次的唯一参考号码;
- c. the list of ingredients; 成分表;
- d. the additional statement "pH regulator" for substances falling under the restriction of point (1)(d)(i).

对于属于第(1)(d)(i)项中限制的物质, 需要加上附加的声明说明 "pH 调节剂"。





- e. the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13.

如果混合物中镍的含量低于附录 13 规定的浓度限值，声明“含镍。可引起过敏反应。”；

- f. the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13.

如果混合物中的铬（VI）低于附录 13 规定的浓度限值，声明“含六价铬。可引起过敏反应。”；

- g. safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

法规（EC）No 1272/2008 未规定的在标签上标明的安全使用说明。

- B. The information shall be clearly visible, easily legible and marked in a way that is indelible on the packaging.

信息应清晰可见，易读易懂并在包装上以不可磨灭的方式标记。

- C. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes.

不含“用于纹身或永久性化妆的混合物”声明的混合物不得用于纹身目的。

### 3) Exception 豁免

- A. Substances that are gases at temperature of 20 °C and pressure of 101.3 kPa, or generate a vapor pressure of more than 300 kPa at temperature of 50 °C, but not include formaldehyde (CAS No 50-00-0).

在温度为 20°C 以及压力为 101.3 kPa 下的气体，或在温度为 50°C 下产生蒸气压大于 300 kPa 的物质，但不包括甲醛（CAS 编号 50-00-0）。

- B. A mixture for use for tattooing purposes exclusively for medical purposes.

用于医疗目的的纹身用混合物。



#### 14 EU - Approved Commission Regulation to Amend Annex XVII to REACH Regulation (EC) No 1907/2006 Regarding the Entries and the Testing Methods of Azocolourants (12/16/2020)

##### 欧盟批准修订 REACH 法规附录 XVII 多个项目及更新偶氮染色剂的测试方法

The European Commission has published Commission Regulation (EU) 2020/2096 to amend Annex XVII to REACH Regulation (EC) No 1907/2006. The amendments shall enter in force on 5 January 2021, unless specified in individual substance. The following are the highlight of the amendments:

欧盟委员会发布了法规(EU) 2020/2096，修订 REACH 法规(EC) No 1907/2006 附录 XVII。除个别物质另有规定外，此修订将于 2021 年 1 月 5 日生效。以下是修订的要点：

##### 1) Amendments to Entry 3 (Liquid substances or mixtures which are regarded as dangerous)

###### 修订第 3 项（被认为是危险的液体物质或混合物）

A. The Risk Phrase "R65" shall be deleted in this entry (point 3 and 5 of the restrictions).

将删除此项中的“R65”危险警语（限制的第 3 点和第 5 点）。

B. The restrictions in point 6 and 7 shall be deleted.

将删除第 6 点和第 7 点。



- 2) Amendments to Entries 28, 29 and 30 (Substances which are classified as carcinogen category 1A or 1B, germ cell mutagen category 1A or 1B and reproductive toxicant category 1A or 1B)

修订第 28、29 和 30 项（被分类为第 1A 类或第 1B 类的致癌物质、第 1A 类或第 1B 类的致基因突变的物质以及第 1A 类或第 1B 类的生殖毒性物质）

The devices covered by Regulation (EU) 2017/45 shall not apply to the restrictions of these entries.

此三项限制将不适用于欧盟法规(EU) 2017/45 所涵盖的设备。

(注释：欧盟法规(EU) 2017/45 为关于医疗器械的法规)

- 3) Amendments to Appendix 2 (Entry 28 – Carcinogens: Category 1B)

修订附件 2（第 28 项 - 致癌物质：第 1B 类）

The following entries shall be added in the table 下表将添加以下条目：

Substances 物质	Index No 索引号	EC No EC 号	CAS No CAS 号	Effective date 生效日期
Cobalt 钴	027-001-00-9	231-158-0	7440-48-4	1 October 2021 2021 年 10 月 1 日
benzo[ <i>rst</i> ]pentaphene 二苯并(A,I)芘	601-090-00-X	205-877-5	189-55-9	1 October 2021 2021 年 10 月 1 日
dibenzo[ <i>b,def</i> ]chrysene 二苯并[ <i>b,def</i> ]芘; dibenzo[ <i>a,h</i> ]pyrene 二苯并[ <i>a,h</i> ]芘	601-091-00-5	205-878-0	189-64-0	1 October 2021 2021 年 10 月 1 日
1,2-dihydroxybenzene; pyrocatechol 邻苯二酚	604-016-00-4	204-427-5	120-80-9	5 July 2021 2021 年 7 月 5 日



acetaldehyde; ethanal 乙醛	605-003-00-6	200-836-8	75-07-0	5 July 2021 2021 年 7 月 5 日
spirodiclofen (ISO); 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate 螺螨酯	607-730-00-4	-	148477-71-8	5 July 2021 2021 年 7 月 5 日

#### 4) Amendments to Appendix 5 (Entry 30 – Reproductive toxicants: Category 1A) 修订附件 5 (第 30 项 - 生殖毒性物质: 第 1A 类)

The following entry shall be added in the table 下表中将添加以下条目:

Substances 物质	Index No 索引号	EC No EC 号	CAS No CAS 号	Effective date 生效日期
methylmercuric chloride 甲基氯化汞	080-012-00-0	204-064-2	115-09-3	1 October 2021 2021 年 10 月 1 日

#### 5) Amendments to Appendix 6 (Entry 30 – Reproductive toxicants: Category 1B) 修订附件 6 (第 30 项 - 生殖毒性物质: 第 1B 类)

The following entry shall be added in the table 下表中将添加以下条目:

Substances 物质	Index No 索引号	EC No EC 号	CAS No CAS 号	Effective date 生效日期
cobalt 钴	027-001-00-9	231-158-0	7440-48-4	1 October 2021 2021 年 10 月 1 日
ethylene oxide; oxirane 环氧乙烷	603-023-00-X	200-849-9	75-21-8	1 October 2021 2021 年 10 月 1 日
ethanol, 2,2'-iminobis-, N-(C13-15 branched and linear alkyl) derivs. 二氨基乙醇, N-(C13-15 分支和线性烷基)的衍生物	603-236-00-8	308-208-6	97925-95-6	1 October 2021 2021 年 10 月 1 日



2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone 2-苄基-2-(二甲氨基)-1-(4-吗啉代苯基)-1-丁酮	606-047-00-9	404-360-3	119313-12-1	5 July 2021 2021 年 7 月 5 日
diisohexyl phthalate 邻苯二甲酸二异己酯	607-737-00-2	276-090-2	71850-09-4	1 October 2021 2021 年 10 月 1 日
propiconazole (ISO); (2RS,4RS;2RS,4SR)-1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole 丙环唑	613-205-00-0	262-104-4	60207-90-1	5 July 2021 2021 年 7 月 5 日
1-vinylimidazole 1-乙烯基咪唑	613-328-00-X	214-012-0	1072-63-5	5 July 2021 2021 年 7 月 5 日
halosulfuron-methyl (ISO); methyl 3-chloro-5-[[[4,6dimethoxypyrimidin-2-yl]carbamoyl]sulfamoyl]-1-methyl-1H-pyrazole-4-carboxylate 氯吡嘧磺隆	613-329-00-5	-	100784-20-1	1 October 2021 2021 年 10 月 1 日
2-methylimidazole 2-甲基咪唑	613-330-00-0	211-765-7	693-98-1	1 October 2021
dibutylbis(pentane-2,4-dionato-O,O')tin 二正丁基双(乙酰丙酮基)锡	650-056-00-0	245-152-0	22673-19-4	1 October 2021

6) Amendments to Appendix 10 (Entry 43 – Azocolourants – List of testing methods) 修订附件 10 (第 43 项 - 偶氮着色剂 - 测试方法列表)

The following testing standards shall be updated: 将更新以下测试标准:



Current testing standard 现行的协调标准	Proposed updated testing standard 将执行的协调标准
<p>EN ISO 17234-1:2010</p> <p>Leather - Chemical tests for the determination of certain azo colorants in dyed leathers - Part 1: Determination of certain aromatic amines derived from azo colorants</p> <p>皮革-测定染色皮革中某些偶氮着色剂的化学试验-第 1 部分：来自偶氮着色剂的某些芳香胺的测定</p>	<p>EN ISO 17234-1:2015</p> <p>Leather - Chemical tests for the determination of certain azo colorants in dyed leathers - Part 1: Determination of certain aromatic amines derived from azo colorants</p> <p>皮革-测定染色皮革中某些偶氮着色剂的化学试验-第 1 部分：来自偶氮着色剂的某些芳香胺的测定</p>
<p>EN 14362-1:2012</p> <p>Textiles - Methods for determination of certain aromatic amines derived from azo colorants - Part 1: Detection of the use of certain azo colorants accessible with and without extracting the fibres</p> <p>纺织品-来自偶氮着色剂的某些芳香胺的测定方法-第 1 部分：经过萃取纤维和没有经过萃取纤维取得的某些偶氮着色剂使用的检测</p>	<p>EN ISO 14362-1:2017</p> <p>Textiles - Methods for determination of certain aromatic amines derived from azo colorants - Part 1: Detection of the use of certain azo colorants accessible with and without extracting the fibres</p> <p>纺织品-来自偶氮着色剂的某些芳香胺的测定方法-第 1 部分：经过萃取纤维和没有经过萃取纤维取得的某些偶氮着色剂使用的检测</p>
<p>EN 14362-3:2012</p> <p>Textiles - Methods for determination of certain aromatic amines derived from azo colorants - Part 3: Detection of the use of certain azo colorants, which may release 4-aminoazobenzene</p> <p>纺织品-来自偶氮着色剂的某些芳香胺的测定方法-第 3 部分：可能释放 4-氨基偶氮苯的偶氮着色剂使用的检测</p>	<p>EN ISO 14362-3:2017</p> <p>Textiles - Methods for determination of certain aromatic amines derived from azo colorants - Part 3: Detection of the use of certain azo colorants, which may release 4-aminoazobenzene</p> <p>纺织品-来自偶氮着色剂的某些芳香胺的测定方法-第 3 部分：可能释放 4-氨基偶氮苯的偶氮着色剂使用的检测</p>

## 7) Amendments to Entry 46 ((a) Nonylphenol, (b) Nonylphenol ethoxylates)

### 修订第 46 项 ((a)壬基酚, (b)壬基酚聚氧乙烯醚)

The references to CAS number and EC number in paragraph (a) of column 1 are deleted.

第 1 列(a)点中的 CAS 号和 EC 号将被删除。

Besides, the following entries shall be deleted:

此外，以下项目将被删除：



- Entry 22 (Pentachlorophenol)  
第 22 项 (五氯苯酚)
- Entry 67 (Bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE))  
第 67 项 (十溴联苯醚(decaBDE))
- Entry 68 (Perfluorooctanoic acid (PFOA) and its salts) from 4 July 2020  
第 68 项 (全氟辛酸(PFOA)及其盐类) (从 2020 年 7 月 4 日起执行)



## PART 5 Others 其它

### 15 United Kingdom - Approved Designating UK(NI) as Conformity Mark for Products in Northern Ireland Market (12/18/2020)

#### 英国-批准指定 UK(NI)为进入北爱尔兰市场的产品符合性标志

The Secretary of State of the United Kingdom has published S.I. No. 1460 of 2020 *The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020*, which introduces the UK(NI) Mark for products to be marketed in Northern Ireland, and provides transitional provisions for placing products based on the EU law on the UK market.

英国国务大臣发布了法规 S.I. No. 1460/2020 《产品安全和计量等（修订等）（UK(NI)标示）（退出欧盟）法规 2020》。该法规介绍了针对在北爱尔兰销售的产品的 UK(NI)标志，并基于欧盟法规对投放英国市场的产品进行了过渡性规定。

#### 1) UK(NI) Mark

##### UK(NI)标志

According to the Protocol on Ireland/Northern Ireland to the Withdrawal Agreement, the provisions of certain EU law related to consumer products like toys, personal protective equipment and RoHS shall apply to Northern Ireland. As a result, the conformity mark used in Northern Ireland (i.e. CE Mark) will be deviated from that used in Great Britain (England, Wales and Scotland) (i.e. UKCA Mark).

根据《退出协议》中的《爱尔兰/北爱尔兰议定书》，某些欧盟法规中有关玩具、个人防护装备和 RoHS 等消费品的规定将适用于北爱尔兰。因此，在北爱尔兰使用的符合性标志（即 CE 标志）将不同于在大不列颠（英格兰、威尔士和苏格兰）使用的符合性标志（即 UKCA 标志）。





According to the new regulations, for products to be placed on the market of Northern Ireland, if a CE Mark is affixed based on an assessment or a certificate issued by a UK notified body, the UK(NI) Mark shall be affixed as well.

根据新法规，对于投放北爱尔兰市场的产品，如果其 CE 标志的使用是基于由英国公告机构进行的评定或基于由英国公告机构出具的证书，则需同时使用 UK(NI)标志。

The UK(NI) Mark will be in the form as shown below. Unless specified by other regulations, it shall be at least 5 mm high. It can be reduced or enlarged, but the proportions shall be respected.

UK(NI)标志为如下所示。除其他法规另有规定外，标志的高度应至少为 5 mm。此标志可被缩小或放大，但比例需保持不变。



In short, when placing products which require conformity mark by law on the Northern Ireland market,

简而言之，在将法规规定需使用符合性标志的产品投放北爱尔兰市场时，

- Both CE Mark and UK(NI) Mark are required, if using a UK conformity assessment body;  
如果使用了英国符合性评定机构，则需同时使用 CE 标志和 UK(NI)标志
- Only CE Mark is required, if using an EU conformity assessment body.  
如果使用了欧盟符合性评定机构，则仅需使用 CE 标志。



Only products that are classified as “qualifying Northern Ireland goods” and labelled with the appropriate conformity mark(s) as mentioned above, can be placed on the Great Britain market.

只有被归类为“合格的北爱尔兰货物”并标有上述合适的符合性标志的产品，才可以投放到大不列颠市场。

**Note 备注:**

“Qualifying Northern Ireland goods” means goods which are:

“合格的北爱尔兰货物”是指以下货物：

- a) Present in Northern Ireland and are not subject to any customs supervision, restriction or control which does not arise from the goods being taken out of the territory of Northern Ireland or the European Union; or  
出现在北爱尔兰，且没有被海关监管、限制或管控，而这些海关监管、限制或管控并非是由于将货物从北爱尔兰或欧盟的领土中带出而产生的；或
- b) NI processed products  
北爱尔兰加工产品

Details can be referred to SI 2020 No. 1454 The Definition of Qualifying Northern Ireland Goods (EU Exit) Regulations 2020.

详情可参阅法规 SI 2020 No. 1454 《合格的北爱尔兰货物的定义（退出欧盟）法规 2020》。

## 2) Summary on CE, UKCA and UK(NI) Marks CE, UKCA 和 UK(NI)标志总结

The UK Government has published guidance on conformity mark labelling. Here is a summary table extracted from the official information:

英国政府发布了符合性标志标签的指引。以下是对官方信息的汇总表：



	Type of goods 货物类型	Accepted marking or combination of markings 接受的标志或标志组合
Placing goods on the market in Northern Ireland 将货物投放北爱尔兰市场	Manufactured goods being placed on the market in NI using an EU conformity assessment body 投放北爱尔兰市场的制成品使用 欧盟符合性评定机构	CE
	Manufactured goods being placed on the market in NI using a UK-based body 投放北爱尔兰市场的制成品使用 英国符合性评定机构	CE and UKNI CE 和 UKNI
Placing goods on the market in Great Britain 将货物投放大不列颠市场	Manufactured goods being placed on the GB market until the end of 2021 投放大不列颠市场的制成品直至 2021 年底	UKCA or CE UKCA 或 CE
	Manufactured goods placed on the GB market from 1 Jan 2022 投放大不列颠市场的制成品从 2022 年 1 月 1 日起	UKCA
Placing qualifying Northern Ireland goods on the market in Great Britain (unfettered access) 将合格的北爱尔兰货物投放大不列颠市场 (不受限制地进入)	Qualifying Northern Ireland goods being placed on the GB market under unfettered access 合格的北爱尔兰货物不受限制地 进入和投放大不列颠市场	CE or CE and UKNI CE 或 CE 和 UKNI
Placing goods on the EU market 将货物投放欧盟市场	Manufactured goods being placed on the EU market 投放欧盟市场的制成品	CE

The Department for Business, Energy and Industry Strategy. (2020). Guidance – Using the UKNI marking from 1 January 2021 [Online]. Available at: <https://www.gov.uk/guidance/using-the-ukni-marking-from-1-january-2021>.

详见商业、能源和工业战略部(2020). 指引-从 2021 年 1 月 1 日起使用 UKNI 标志。指引在线网址: <https://www.gov.uk/guidance/using-the-ukni-marking-from-1-january-2021>.



### 3) Transitional arrangements 过渡性规定

- A. The UKCA Mark may be affixed to a label on the product or an accompanying document instead of locations as required by the respective regulations until 31 December 2022.

UKCA 标志可以使用于产品的标签或随附文档上，而不是相应法规所要求的位置，直至 2022 年 12 月 31 日。

- B. For products imported from an EEA state and placed on the UK market, the exemption from labelling the importer's name and address will be extended to 31 January 2022.

对于进口自欧洲经济区(EEA)国家而投放英国市场的产品，关于进口商名称和地址的标签豁免将延长至 2022 年 1 月 31 日。

- C. Products which comply with the EU requirements and are placed on the UK market on or before 31 December 2021 may continue to be made available on the market after the same date. Any obligation originated from the EU requirements continues to have effect.

符合欧盟要求并于 2021 年 12 月 31 日或之前在英国市场投放产品的产品可能会在 2021 年 12 月 31 日之后继续在市场上销售。源自欧盟要求的义务继续有效。

### 4) Additional information on UK product safety regulations

#### 有关英国产品安全法规的附加信息

Since the UK shall amend all related legislations for the new situations and their implementations for the Brexit. The Secretary of State has published "The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019" and cited it as SI No. 696 of 2019 to amend the existing Acts and Regulations relating to product safety and metrology for the purposes. The affected regulations are shown below, here is the highlight:



由于英国将针对脱欧后出现的新情况及法规的实施修订所有相关的法规。国务大臣发布了法规 SI No. 696/2019 《产品安全和计量等（修订等）（退出欧盟）法规 2019》，修订现有的与产品安全和计量相关的法案和法规。受影响的法规见文末，以下是重点：

**A. General 一般性规定：**

- a. The EU no longer recognises UK based Notified Bodies, so they become **UK Approved Bodies** to provide conformity assessments.

欧盟不再承认英国的公告机构，因此它们成为**英国认可机构**提供符合性评定。

- b. A new **UKCA conformity mark** (see below) replaces the CE marking for products placed on the UK market which have been assessed by a UK Approved Body (or by non-EU 3rd country CABs, where an agreement exists).

新的 **UKCA 符合性标志**（见下）取代了 CE 标志，用于那些已由英国认可机构（或具有协议的非欧盟的第三国的符合性评定机构）评定的投放英国市场的产品。

- c. The enforcement authority has been changed from the EU Commission to **UK Department for Business, Energy and Industrial Strategy (BEIS)** under the Secretary of State.

执法机构从欧盟委员会改为英国国务大臣下属的**商业、能源和工业战略部(BEIS)**。

- d. BEIS has to establish and operate a database with information on market surveillance and product safety. An enforcement authority receiving a notification of risk is required to notify the BEIS through that database instead of EU Rapex database.



BEIS 需建立和运行一个包含市场监督和产品安全的数据库。接收风险通报的执法官方机构需通过该数据库通报 BEIS，而不是通过欧盟 RAPEX 数据库。

- e. The EU term 'placing on the market' will mean the first making available of a product on the UK Market. "Making available" will refer to supply on the UK market.

欧盟术语“投放市场”指首次在英国市场上投放产品。“提供”指供应英国市场。

- f. To place products on the UK market, manufacturers must meet the requirements of the UK legislations.

将产品投放英国市场，制造商需符合英国法规要求。

- g. The UK **Designated Standards** replace EU Harmonised Standards. Designated standards are standards which have been adopted by any of the following recognized standardization bodies and designated by the BEIS publishing a reference to them:

英国**指定标准**取代欧盟协调标准。指定标准是下列任一认可的标准化机构所采用的通过 BEIS 发布的标准号指定的标准：

- the European Committee for Standardization (CEN);  
欧洲标准化委员会(CEN);
- the European Committee for Electrotechnical Standardization (CENELEC);  
欧洲电工标准化委员会(CENELEC);
- the European Telecommunications Standards Institute (ETSI);  
欧洲电信标准组织(ETSI);
- the British Standards Institution (BSI).  
国标准协会(BSI)。



B. UKCA Conformity Mark:

UKCA 符合性标志:

Products that comply with the requirements of relevant legislations shall affix UKCA Mark, e.g., toys. You may refer to the [guidance](#) of using UKCA Mark.

符合相关法规要求的产品应附上 UKCA 标志，例如玩具。可参考使用 UKCA 标志的指引。

a. UKCA Marking is needed when the product:

需附上 UKCA 标志，当产品：

- Is for the market in Great Britain; 投放大不列颠市场；
- Is covered by legislation which required the UKCA Marking;  
被要求 UKCA 标志的法规所覆盖；
- Requires mandatory third-party conformity assessment;  
要求强制性第三方符合性评定；
- Conformity assessment has been carried out by a UK conformity assessment body and the conformity assessment files have not been transferred from UK assessment body to an EU recognized body before 1 January 2021.

符合性评定已由英国符合性评定机构进行，且符合性评定文件在 2021 年 1 月 1 日之前尚未从英国评定机构转移至欧盟认可机构。



b. Requirements of the UKCA Mark:

UKCA 标志的要求：

- The illustration of UKCA Mark is

UKCA 标志的图示如下：



- The height of the UKCA Mark shall be at least 5 mm. The reduction or enlargement of the UKCA Mark shall follow the proportion of the illustration.

UKCA 标志的高度应至少为 5 mm。对 UKCA 标志进行缩小或放大时，标志的比例需保持不变。

- The UKCA Mark shall be visible and legible (from 1 January 2023 it must be permanently attached).

UKCA 标志应清晰可见和易读（从 2023 年 1 月 1 日起，标志需永久附着）。

c. When the products bear the UKCA Mark, the UK Declaration of Conformity shall be drawn up. Technical documentation shall also be prepared and kept for 10 years. Please note that the Technical documentation shall demonstrate that the product conforms with the regulatory requirements.

当产品带有 UKCA 标志时，应出具英国符合性声明。应编制技术文件并保存 10 年。请注意：技术文档应证明产品符合法规要求。





d. Some specific terms currently used in EU Regulations or Directive shall be changed in UK Regulations. Here are some examples:

欧盟法规或指令中目前使用的某些特定术语将在英国法规中被更改。以下是一些示例：

EU 欧盟	UK 英国
Harmonised standards 协调标准	Designated standards 指定标准
EC Declaration of Conformity EC 符合性声明	Declaration of Conformity 符合性声明
EC Type Examination EC 型式试验	Type Examination 型式试验
UK Notified Body 英国公告机构	UK Approved Body 英国认可机构

5) Amendments to the Acts and Regulations are depicted in different Schedule 对法案和法规的修订在不同的附表中进行描述：

- Schedule 1 Hallmarking Act 1973  
附表 1- 《纯度印记法 1973》
- Schedule 2 Weights and Measures Act 1985  
附表 2- 《称量和计量法 1985》
- Schedule 3 Consumer Protection Act 1987  
附表 3- 《消费者保护法 1987》
- Schedule 4 Measuring Container Bottles (EEC Requirements) Regulations 1977



附表 4 - 《计量用容器瓶（EEC 要求）法规 1977》

- Schedule 5 Measuring Instruments (EEC Requirements) Regulations 1988

附表 5- 《计量用仪器（EEC 要求）法规 1988》

- Schedule 6 Weights and Measures (Intoxicating Liquor) Order 1988

附表 6- 《称量和计量（致醉液体）法令 1988》

- Schedule 7 Lifting Operations and Lifting Equipment Regulations 1998

附表 7- 《起重作业和起重设备法规 1998》

- Schedule 8 Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001

附表 8- 《户外环境使用设备噪声排放法规 2001》

- Schedule 9 General Product Safety Regulations 2005

附表 9- 《一般产品安全法规 2005》

- Schedule 10 Offshore Installations (Safety Case) Regulations 2005

附表 10- 《离岸设施（安全案例）法规 2005》

- Schedule 11 Weights and Measures (Packaged Goods) Regulations 2006

附表 11- 《称量和计量（包装货物）法规 2006》

- Schedule 12 Supply of Machinery (Safety) Regulations 2008

附表 12- 《机械（安全）法规 2008》

- Schedule 13 Aerosol Dispensers Regulations 2009

附表 13 - 《气溶胶喷散器法规 2009》

- Schedule 14 Accreditation Regulations 2009

附表 14- 《认可法规 2009》

- Schedule 15 Toys (Safety) Regulations 2011

附表 15- 《玩具（安全）法规 2011》



- Schedule 16 Explosives Regulations 2014 and associated provision relating to retained direct EU legislation  
附表 16-《爆炸物法规 2014》以及与保留的直接欧盟法规有关的规定
- Schedule 17 Weights and Measures (Revocations) Regulations 2015  
附表 17-《称量和计量（废除）法规 2015》
- Schedule 18 Offshore Installations (Offshore Safety Directive) (Safety Case etc.) Regulations 2015  
附表 18-《离岸设施（离岸安全指令）（安全案例等）法规 2015》
- Schedule 19 Pyrotechnic Articles (Safety) Regulations 2015  
附表 19-《烟火物品（安全）法规 2015》
- Schedule 20 Electromagnetic Compatibility Regulations 2016  
附表 20-《电磁兼容性法规 2016》
- Schedule 21 Simple Pressure Vessels (Safety) Regulations 2016  
附表 21-《简单压力容器（安全）法规 2016》
- Schedule 22 Lifts Regulations 2016  
附表 22-《电梯指令 2016》
- Schedule 23 Electrical Equipment (Safety) Regulations 2016  
附表 23-《电气设备（安全）法规 2016》
- Schedule 24 Pressure Equipment (Safety) Regulations 2016  
附表 24-《压力设备（安全）法规 2016》
- Schedule 25 Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016  
附表 25-《用于潜在爆炸性环境的设备和防护系统法规 2016》
- Schedule 26 Non-automatic Weighing Instruments Regulations 2016  
附表 26-《非自动称量用仪器法规 2016》



- Schedule 27 Measuring Instruments Regulations 2016  
附表 27-《计量用仪器法规 2016》
- Schedule 28 Recreational Craft Regulations 2017 and related amendment  
附表 28-《游艇法规 2017》及相关修订
- Schedule 29 Radio Equipment Regulations 2017 and related amendment  
附表 29-《无线电设备法规 2017》及相关修订
- Schedule 30 Identification and Traceability of Explosives Regulations (Northern Ireland) 2013  
附表 30-《爆炸物的识别与可追溯性法规（北爱尔兰）2013》
- Schedule 31 Making Available on the Market and Supervision of Transfers of Explosives Regulations (Northern Ireland) 2016  
附表 31-《爆炸物投放市场和转移监管法规（北爱尔兰）2016》
- Schedule 32 Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 2017  
附表 32 -《用于潜在爆炸性环境的设备和防护系统法规（北爱尔兰）2017》
- Schedule 33 Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93  
附表 33 - 法规(EC) No 765/2008《欧洲议会和理事会关于产品销售的认可和市场监管要求，及废除法规(EEC) No 339/93 的法规》



- Schedule 34 Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, and amendment of the Cosmetic Products Enforcement Regulations 2013, and amendment of related direct EU tertiary legislation

附表 34 - 法规(EC) No 1223/2009 《欧洲议会和理事会关于化妆品的法规》，以及对《化妆品执行法规 2013》的修订，以及对相关的直接欧盟三级法规的修订

- Schedule 35 Regulation (EU) 2016/425 of the European Parliament and of the Council of on personal protective equipment and repealing Council Directive 89/686/EEC, and amendment of the Personal Protective Equipment (Enforcement) Regulations 2018

附表 35 - 法规(EU) 2016/425 《欧洲议会和理事会关于个人防护装备，及废除理事会指令 89/686/EEC 的法规》，以及对《个人防护装备（执行）法规 2018》的修订

- Schedule 36 Regulation (EU) 2016/426 of the European Parliament and of the Council on appliances burning gaseous fuels and repealing Directive 2009/142/EC, and amendment of the Gas Appliances (Enforcement) and Miscellaneous Amendments Regulations 2018

附表 36 - 法规(EU) 2016/426 《欧洲议会和理事会关于燃烧气体燃料的器具，及废除指令 2009/142/EC 的法规》，以及对《燃气器具（执行）和各种修订法规 2018》的修订

- Schedule 37 contains revocation of retained direct EU and EEA legislation

附表 37 包含对保留的直接欧盟和欧洲经济区立法的废除



Other certain affected Regulations (Not within SI No. 696 of 2019 *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019*):

**其他某些受影响的法规**（不在法规 S.I. No. 696/2019 《产品安全和计量等（修订等）（退出欧盟）法规 2019》）：

- The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019  
《REACH 等（修订等）（退出欧盟）法规 2019》
- The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019  
《医疗器械（修订等）（退出欧盟）法规 2019》
- The Persistent Organic Pollutants (Amendment) (EU Exit) Regulations 2019  
《持久性有机污染物（修订）（退出欧盟）法规 2019》
- The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019  
《食品接触材料和物品（修订）（退出欧盟）法规 2019》



## 16 Brazil - Approved Amendment to the Transition Period of the Conformity Assessment Requirements for Party Articles (12/14/2020)

### 巴西-批准对于派对用品合格评定要求过渡期的修订

The National Institute of Metrology, Quality and Technology (INMETRO) of Brazil has published Ordinance No.343/2020 for amendments on transition period of Ordinance No. 507/2019, Changes the mandatory nature of the Conformity Assessment Requirements for Party Items and makes other provisions. The amendments of the transition period shall enter into force immediately.

巴西国家计量、质量和技术研究所（INMETRO）发布了第 343/2020 号条例，对第 507/2019 号条例的过渡期进行了修订，更改了对派对用品的合格评定要求的强制性，并做出了其他规定。关于过渡期的修正案应立即生效。

Because of impact of the Coronavirus pandemic (COVID - 19), party articles products already manufactured or imported with Conformity Identification Seal can be placed in the market until further noticed (the original deadline was 10 December 2022). Besides, there is no time limit for manufacturers and importers to market the party articles in stock with the Compulsory Conformity Identification Seal in Brazil market, provided party articles are produced within the validity period of compulsory certification.

因为冠状病毒（COVID-19）的影响，已经制造或进口且带有合格识别标志的派对用品产品可以投放市场，直到另行通知为止（原截止日期为 2022 年 12 月 10 日）。此外，只要是在强制性认证有效期内生产的，制造商和进口商就可以无时间限制的在巴西市场销售具有强制性合格识别标志的库存产品。



## 17 EU - Approved Marking Specifications for Certain Single-use Plastic Products (12/22/2020)

### 欧盟-发布特定一次性塑料制品标签规范

The European Commission has published Implementing Regulation (EU) 2020/2151 on harmonised marking specifications on certain single-use plastic products. The specifications shall apply from 3 July 2021.

欧盟委员会发布了关于特定一次性塑料制品标签规范的实施法规（EU）2020/2151。本规范自 2021 年 7 月 3 日起实施。

As required by Directive (EU) 2019/904, the marking specifications for four product groups are established. The markings shall be labelled to inform consumers on inappropriate waste disposal means and the negative impact of littering. The detailed requirements are found in the Annexes of the Regulation (*please refer to the attachment for the full text*):

根据指令（EU）2019/904 的要求，制定了四类产品的标签规范。标签上应附有告知消费者不适当废物处理和乱扔垃圾所导致负面影响的相关内容。

- **Annex I:** Sanitary towel (pads), tampons and tampon applicators

**附件一：**卫生巾（垫）、卫生棉条和卫生棉条充填器

- **Annex II:** Wet wipes, i.e. pre-wetted personal care and domestic wipes

**附件二：**湿巾，即湿性个人护理用品和家用湿巾

- **Annex III:** Tobacco products with filters and filters marketed for use in combination with tobacco products

**附件三：**带过滤嘴的烟草产品和单独销售的用于与烟草产品结合使用的过滤烟嘴





- **Annex IV:** Single-use beverage cups (which are partly or wholly made from plastic)

**附件四：一次性饮料杯（部分或全部由塑料制成）**

The information text of the marking shall be written in the official language or languages of the Member State(s) where the products are placed on the market.

标签信息应以产品投放市场国的官方语言表述。

## 18 France- Published Reference Standards for Ladders and Step Stools (12/17/2020)

### 法国法国法国法国---发布梯子和踏凳参考标准

On December 17, 2020, The Ministry of Economy, Finance and Recovery of France has published a notice on the latest list of reference standards for the enforcement of Decree No. 96-333 on safety of ladders and step stools. The notice shall supersede the one on the same subject dated 10 November 2019 with immediate effect.

2020 年 12 月 17 日，法国经济、财政和复兴部公布了一份关于执行第 96-333 号法令的最新参考标准清单的通知，该法令涉及梯子和踏凳的安全。该通知应取代日期为 2019 年 11 月 10 日的同一主题的通知，并立即生效。



The notice contains two lists of reference standards for demonstration of compliance with Decree No. 96-333. One is for the presumption of compliance with the safety requirements, the other one is for providing the necessary information for the intended use of products.

该通知包含两份证明符合第 96-333 号法令的参考标准清单。一种是假定产品符合安全要求，另一种是为产品的预期用途提供必要的信息。

#### Standards for compliance with safety requirements defined in Decree No. 96-333

##### 符合第 96-333 号法令规定的安全要求的标准

Standard Index 标准目录	Standard Title 标准名称
NF EN 131-1 + A1 (September 2019)	Ladders - Part 1: Terms, types, functional sizes 梯子-第 1 部分：术语，类型，功能尺寸
NF EN 131-2 + A2 (March 2017)	Ladders - Part 2: Requirements, testing, marking 梯子-第 2 部分：要求，测试，标志
<b>NF EN 131-4 (March 2020)</b> (updated from August 2007 version 更新自 2007 年 8 月版本)	Ladders - Part 4: Single or multiple hinge-joint ladders 梯子-第 4 部分：单铰链或多铰链接合梯
NF EN 131-6 (February 2019)	Ladders - Part 6: Telescopic ladders 梯子-第 6 部分：伸缩梯
NF EN 14183 (June 2004)	Step stools 踏凳



Standards for providing the necessary information for the intended use of products

为产品的预期用途提供必要信息的标准

Standard Index 标准目录	Standard Title 标准名称
NF EN 131-3 (January 2018)	Ladders - Part 3: Marking and user instructions 梯子-第 3 部分：标签和说明书
<b>NF EN 131-4 (March 2020)</b> (updated from August 2007 version 更新自 2007 年 8 月版本)	Ladders - Part 4: Single or multiple hinge-joint ladders 梯子-第 4 部分：单铰链或多铰链接合梯
NF EN 131-6 (February 2019)	Ladders - Part 6: Telescopic ladders 梯子-第 6 部分：伸缩梯
NF EN 14183 (June 2004)	Step stools 踏凳

Products conforming to the reference standards listed on the notice dated 10 November 2019 can be placed on the market on or before 15 June 2021 and sold until stock depletion.

符合 2019 年 11 月 10 日通告所列参考标准的产品可于 2021 年 6 月 15 日或之前投放市场，直至售罄。



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