

新版欧盟 RoHS 指令 2011/65/EU

2011 年 7 月 1 日欧盟官方发布了新版的 RoHS 指令 2011/65/EU, 新指令于 2011 年 7 月 21 日生效。2013 年 1 月 2 日新指令正式实施后, 现行 RoHS 指令 2002/95/EC 将同时废除。

新 RoHS 指令 2011/65/EU 主要有以下修订内容:

1, 扩大适用产品范围

新增第 8 类医疗器械、第 9 类监视和控制仪器(包括工业监控仪器)、第 11 类其他电子电器产品。

- 过度期:
- 1) 医疗器械, 2014 年 7 月 22 日
 - 2) 体外诊断医疗器械, 2016 年 7 月 22 日
 - 3) 监测和控制仪器, 2014 年 7 月 22 日
 - 4) 工业监测和控制仪器, 2017 年 7 月 22 日

2, 理清部分定义

理清了“电子电气设备(或者 EEE)”、“大型固定工业工具”、“大型固定装置”、“电缆”、“制造商”、“授权代表”等 28 个术语的定义, 详见 2011/65/EU 第 3 条

3, 删除了其中的生产商(producer)规定

而添入了“制造商”(manufacturer)、“授权代表”(authorised representative)、“进口商”(importer)、“经销商”(distributor)的定义, 并对其职责进行了明确的界定。详见 2011/65/EU 第 3、7、8、9、10 条。

4, 规定了产品需贴附 CE 标志及 CE 标志的相关事宜

将电子电气产品 RoHS 符合性纳入 CE 标志的要求, 并对符合性声明、技术文件等作出了具体规定。2011/65/EU 第 14 条规定了加贴 CE 标志的一般原则, 必须符合条例 (EC) No 765/2008 第 30 条所规定的一般原则。2011/65/EU 第 15 条规定了 CE 标志的加贴规则和要求。

5, 管控的有害物质的范围未扩大

还是维持了原有的六种物质的原限量要求, 但是提出了今后的审查过程中, 要对包括 HBCDD、DEHP、BBP、DBP 四种物质优先进行考察, 为指令今后扩大管控物质的范围铺路。同时考虑与 REACH 的兼容。

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Eurofins 提供 RoHS 完整测试服务, 包含化学湿式分析、XRF 筛选、RoHS 产品符合性评估、IECQ QC080000 系统认证、RoHS 法规咨询与培训等服务。



更多信息, 欢迎联系我们

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New RoHS Directive 2011/65/EU

On July 1, 2011 EU official released new version of RoHS directive 2011/65/EU, which will be taken into effect on July 21, 2011. Old RoHS directive 2002/95/EC will be abolished after the official implementation of new directive 2011/65/EU on January 2, 2013.

Main amendments on New RoHS Directive 2011/65/EU

1, Categories of EEE covered by this Directive

Medical devices, Monitoring and control instruments including industrial monitoring and control instruments and other EEE not covered by any of the category above were added in scope.

Transition period:

- 1) Medical devices July-22-2014
- 2) Diagnostic medical devices July-22-2016
- 3) Monitoring and control instrument July-22-2014
- 4) Industrial monitoring and control instruments July-22-2017

2, New definition

“Electrical and electronic equipment or EEE”, “Large-scale stationary industrial tools”, “large-scale fix installation”, “Cables”, “Manufacturer”, “Authorised representative” etc. New definition of 28 phrases. Article 3, 2011/65/EU.

3, Remove of producer

New definition of “Manufacturer”, “Authorised representative”, “importer”, “distributor” and their obligations. Article 3, 7, 8, 9, 10, 2011/65/EU.

4, Rules and conditions for affixing the CE marking.

The CE marking shall be affixed before the EEE is placed on the market
The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

5, Maintain the restricted substances

Continued to reduce the problems of heavy metals and flame retardants concerned. In particular, the risks to human health and the environment arising from the use of HBCDD, DEHP, BBP, DBP should be considered as a priority, and compatible to REACH.

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For more information, please contact us

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