



Title: European Commission publishes Directive (EU) 2016/585 amending Annex IV to RoHS 2.0

Date: 19 April 2016

Abstract: On 16 April 2016, the *Official Journal of the European Union* officially published Directive (EU) 2016/585 to amend point 31 of Annex IV to Directive 2011/65/EU (RoHS 2.0) as regards an exemption for lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices or electron microscopes.

On 16 April 2016, the *Official Journal of the European Union* officially published Directive (EU) 2016/585 to amend point 31 of Annex IV to Directive 2011/65/EU (RoHS 2.0) as regards an exemption for lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices or electron microscopes.

In last October, EU used to submit notification concerning such amendment, which has been reported by C&K Testing. The highlights for the amendment are as the following:

1. Different expiry dates for the exemption are set for in vitro diagnostic medical devices, medical devices other than in vitro diagnostic medical devices and electron microscopes and their accessories.
2. Polybrominated diphenyl ethers (PBDE) are included in exemption.

Annex IV to Directive 2011/65/EU is amended as follows:

(1) point 31 is deleted; (2) the following point 31a is added:

31(a).	Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer.	Expires on: (a) 21 July 2021 for the use in medical devices other than in vitro diagnostic medical devices; (b) 21 July 2023 for the use in in vitro diagnostic medical devices; (c) 21 July 2024 for the use in electron microscopes and their accessories.
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This Directive (EU) 2016/585 shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. Member States shall publish laws, regulations and administrative norms as per the Directive before 28 February 2017. It is noted that the Directive shall apply on 6 November 2017

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C&K Testing advises manufacturers to pay prompt attention to any change to the exemption list so as to ensure products to the EU market comply with the latest requirements. Meanwhile, technicians of C&K Testing also provide interpretation and Q&A for RoHS exemptions to be expiry on 21 July 2016 aiming to facilitate the understanding on RoHS 2.0.

Further information[Directive \(EU\) 2016/585](#)[FAQs on RoHS exemptions to be expired on 21 July 2016 \(Newsletter\)](#)[RoHS 2.0 exempts polybrominated diphenyl ethers \(PBDE\)—News from C&K Testing in Nov. 2015](#)[中文阅读](#)

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