



Council of the  
European Union

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## COVER NOTE

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From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	12 February 2016
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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No. Cion doc.:	C(2016) 748 final - Annex 1
Subject:	Annex to Commission Delegated Directive amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council 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

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Delegations will find attached document C(2016) 748 final - Annex 1.

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Encl.: C(2016) 748 final - Annex 1



Brussels, 12.2.2016  
C(2016) 748 final

ANNEX 1

**ANNEX**

**to**

**COMMISSION DELEGATED DIRECTIVE**

**amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council 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**

## ANNEX

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### COMMISSION DELEGATED DIRECTIVE

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

- (1) Point 31 is deleted.
- (2) The following point 31a is added:

"31a. 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."