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## **ANNEX**

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

- (1) point 31 is deleted;
- (2) the following point 31a is added:
  - Lead, cadmium, hexavalent chromium, and polybrominated diphenyl 31a. 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:

- 21 July 2021 for the use in medical devices other than in vitro diagnostic (a) medical devices;
- 21 July 2023 for the use in *in vitro* diagnostic medical devices; (b)
- (c) 21 July 2024 for the use in electron microscopes and their accessories.