

ANNEX

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.