

Commission Delegated Directive (EU) 2020/366 of 17 December 2019 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabiliser in polyvinyl chloride used in certain in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases (Text with EEA relevance)

- Article 1 Annex IV to Directive 2011/65/EU is amended as set out...
Article 2 (1) Member States shall adopt and publish, by 31 March...
Article 3 This Directive shall enter into force on the twentieth day...
Article 4 This Directive is addressed to the Member States.
Signature

ANNEX

In Annex IV to Directive 2011/65/EU, entry 41 is replaced...
41. Lead as a thermal stabiliser in polyvinyl chloride (PVC)...

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

- (1) [OJ L 174, 1.7.2011, p. 88.](#)
- (2) Commission Delegated Directive (EU) 2015/573 of 30 January 2015 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in polyvinyl chloride sensors in in-vitro diagnostic medical devices ([OJ L 94, 10.4.2015, p. 4.](#))
- (3) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices ([OJ L 331, 7.12.1998, p. 1.](#))
- (4) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency ([OJ L 396, 30.12.2006, p. 1.](#))