

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)...

- (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.](#)).