



Brussels, **XXX**  
[...] (2019) **XXX** draft

ANNEX

ANNEX

to

**Commission Delegated Directive**

**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**

## ANNEX

In Annex IV to Directive 2011/65/EU, entry 41 is replaced by the following:

- "41. Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases.

Expires on [the last day of the 24<sup>th</sup> month after the publication of the Delegated Directive in the Official Journal]."