



EUROPEAN
COMMISSION

Brussels, XXX
[...] (2022) XXX draft

ANNEX

ANNEX

to

Commission Delegated Directive

amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabilizer in polyvinyl chloride used as base materials in sensors used in in-vitro diagnostic medical devices

ANNEX

In Annex IV, the following entry 41a is added:

‘41a. Lead as a thermal stabilizer 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 creatinine and blood urea nitrogen in whole blood.

Applies to category 8 and expires on 31 December 2023.’.