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From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 16 May 2023

To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

No. Cion doc.: C(2023) 3138 final - Annex

Subject: ANNEXES to the 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 material in sensors used in in-vitro diagnostic medical devices

Delegations will find attached document C(2023) 3138 final - Annex.

Encl.: C(2023) 3138 final - Annex



Brussels, 16.5.2023
C(2023) 3138 final

ANNEX

ANNEXES

to the

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 material 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.’