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► **B**

COMMISSION DELEGATED DIRECTIVE (EU) 2023/1526

of 16 May 2023

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

(Text with EEA relevance)

(OJ L 185, 24.7.2023, p. 26)

Corrected by:

► **C1** Corrigendum, OJ L 188, 27.7.2023, p. 59 (2023/1526)

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Annex IV to Directive 2011/65/EU is amended as set out in the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by ►**C1** 31 January 2024 ◄ at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate the text of those provisions to the Commission.

They shall apply those provisions from ►**C1** 1 February 2024 ◄.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

▼B*ANNEX*

In Annex IV to Directive 2011/65/EU, 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.’.