

Commission Delegated Directive 2014/12/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders on printed circuit boards of detectors and data acquisition units for Positron Emission Tomographs which are integrated into Magnetic Resonance Imaging equipment (Text with EEA relevance)

COMMISSION DELEGATED DIRECTIVE 2014/12/EU

of 18 October 2013

amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders on printed circuit boards of detectors and data acquisition units for Positron Emission Tomographs which are integrated into Magnetic Resonance Imaging equipment

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment⁽¹⁾, and in particular Article 5(1)(a) thereof,

Whereas:

- (1) Directive 2011/65/EU prohibits the use of lead in electrical and electronic equipment placed on the market.
- (2) Strong vibrations occur in Positron Emission Tomographs which are integrated into Magnetic Resonance Imaging. Research has shown that lead-free solders that have been investigated for vibration susceptibility are more vulnerable to early failure under the severe vibration conditions than bonds made with tin/lead solder. The specific conditions and geometrical restrictions of the equipment restrict the applicability of mechanical measures that could eliminate or sufficiently mitigate the effects of the intense vibration.
- (3) Substitution or elimination of lead is currently scientifically and technically impracticable. A temporary exemption is needed to allow manufacturers sufficient time for research to identify suitable lead-free materials and designs.
- (4) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

*Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After
IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.*

Article 2

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by the last day of the sixth month after entry into force at the latest. They shall forthwith communicate to the Commission the text of those provisions.

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.

Done at Brussels, 18 October 2013.

For the Commission

The President

José Manuel BARROSO

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

ANNEX

In Annex IV to Directive 2011/65/EU the following point 32 is added:

32. Lead in solders on printed circuit boards of detectors and data acquisition units for Positron Emission Tomographs which are integrated into Magnetic Resonance Imaging equipment. Expires on 31 December 2019.

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After
IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

- (1) [OJ L 174, 1.7.2011, p. 88.](#)