

Commission Delegated Directive 2014/13/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 populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices other than portable emergency defibrillators (Text with EEA relevance)

COMMISSION DELEGATED DIRECTIVE 2014/13/EU

of 18 October 2013

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(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<sup>(1)</sup>, 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) Mobile medical devices are medical devices which are designed and approved by a notified body according to Council Directive 93/42/EEC<sup>(2)</sup> to be hand carried, or to be transported on own wheels, on a cart or trolley or in a vehicle, aircraft or vessel during and/or between operations.
- (3) Substitution or elimination of lead in the populated printed circuit boards of mobile medical devices is currently technically impracticable. A temporary exemption to allow the continued use of lead solders is needed until further research has been carried out to identify alloys that are reliable for the normal life of mobile medical devices.
- (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.

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### *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

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## ANNEX

In Annex IV to Directive 2011/65/EU the following point 33 is added:

33. Lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices other than portable emergency defibrillators. Expires on 30 June 2016 for class IIa and on 31 December 2020 for class IIb.

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- (1) [OJ L 174, 1.7.2011, p. 88.](#)
- (2) [OJ L 169, 12.7.1993, p. 1.](#)