

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

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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) Mobile medical devices are medical devices which are designed and approved by a notified body according to Council Directive 93/42/EEC⁽²⁾ 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:

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