

**COMMISSION DELEGATED DIRECTIVE 2014/71/EU
of 13 March 2014**

**amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU
of the European Parliament and of the Council as regards an exemption for lead in solder in one
interface of large area stacked die elements**

(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) SDE (stacked die elements) detector technology is used in X-ray detectors of computed tomography (CT) and X-ray systems. It offers advantages for patients as it reduces the necessary X-ray dose exposure. Large area SDE detectors cannot yet be produced with lead-free solders. The substitution and the elimination of lead are therefore scientifically and technically impracticable for the above-mentioned applications.
- (3) The use of lead in large area stacked die elements with more than 500 interconnects per interface used in X-ray detectors of CT and X-ray systems should therefore be exempted from the prohibition until 31 December 2019. In view of the innovation cycles of the medical devices and monitoring and control instruments sectors this is a relatively short transition period which is unlikely to have adverse impacts on innovation.
- (4) In accordance with the repair-as-produced principle of Directive 2011/65/EU, which is meant to extend the life-time of compliant products once placed on the market, spare parts shall benefit from this exemption past its end date without time limitations.
- (5) 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.

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.

⁽¹⁾ OJ L 174, 1.7.2011, p. 88.

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, 13 March 2014.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Annex IV to Directive 2011/65/EU the following point 38 is added:

‘38. Lead in solder in one interface of large area stacked die elements with more than 500 interconnects per interface which are used in X-ray detectors of computed tomography and X-ray systems.

Expires on 31 December 2019. May be used after that date in spare parts for CT and X-ray systems placed on the market before 1 January 2020.’
