Commission Delegated Directive (EU) 2015/574 of 30 January 2015 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 mercury in intravascular ultrasound imaging systems (Text with EEA relevance)

COMMISSION DELEGATED DIRECTIVE (EU) 2015/574

of 30 January 2015

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 mercury in intravascular ultrasound imaging systems

(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 mercury in electrical and electronic equipment placed on the market.

(2) Mercury is used in electric rotating connectors in medical devices for intravascular ultrasound imaging. Substitution of mercury or of the specific component would shorten product life or impair performance significantly.

(3) Both the substitution of mercury in the connector and the elimination of mercury via substitution of the connector or the device are technically impracticable or have negative overall impacts due to an impact on patients' health.

(4) The use of mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency modes of operation (> 50 MHz) should therefore be exempted until 30 June 2019. In view of the innovation cycles for medical devices this is a short transition period which is unlikely to have adverse impacts on innovation.

(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.

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After exit day 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 ninth 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, 30 January 2015.

For the Commission

The President

Jean-Claude JUNCKER