Commission Directive 2011/100/EU of 20 December 2011 amending Directive 98/79/EC of the European Parliament and of the Council on in-vitro diagnostic medical devices (Text with EEA relevance)

Article 1

Annex II to Directive 98/79/EC is amended in accordance with the Annex to this Directive.

Article 2

1 Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive by 30 June 2012 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

Member States shall apply those provisions from 1 July 2012.

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 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 20 December 2011.

For the Commission

The President

José Manuel BARROSO