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)

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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in-vitro diagnostic medical devices[(1)], and in particular Article 14 thereof,

Whereas:

(1) In accordance with Article 14(1)(a) of Directive 98/79/EC, the United Kingdom has requested that the Commission take the necessary measures to add 'Variant Creutzfeldt-Jakob disease' (vCJD) assays to List A of Annex II to that Directive.

(2) In order to ensure the highest level of health protection and ensure that the conformity of vCJD assays with the essential requirements set out in Annex I to Directive 98/79/EC is verified by notified bodies, vCJD assays for blood screening, diagnosis and confirmation should be added to List A of Annex II to Directive 98/79/EC.

(3) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Article 6(2) of Council Directive 90/385/EEC[(2)] and referred to in Article 7(1) of Directive 98/79/EC,

HAS ADOPTED THIS DIRECTIVE:

(**1**) OJ L 331, 7.12.1998, p. 1.

(**2**) OJ L 189, 20.7.1990, p. 17.