Draft

COMMISSION DIRECTIVE ../…/EC

of […]

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 of the European Parliament and of the Council on *in vitro* diagnostic medical devices, the United Kingdom has requested that the European Commission take the necessary measures to add "Variant Creutzfeldt-Jakob disease" (vCJD) assays to List A of Annex II to this 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 Directive 90/385/EEC[2] and referred to in Article 7(1) of Directive 98/79/EC,

HAS ADOPTED THIS DIRECTIVE:

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, by […] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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1 OJ L 331, 7.12.1998, p. 1.

2 OJ L 189, 20.7.1990, p. 17.

They shall apply those provisions from […].

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, […]

For the Commission
The President
[…]

ANNEX

The following indent is added at the end of List A of Annex II to Directive 98/79/EC:

"- Variant Creutzfeldt-Jakob disease (vCJD) assays for blood screening, diagnosis and confirmation."