ANNEX II

LIST OF DEVICES REFERRED TO IN ARTICLE 9(2) AND (3)

List A

— Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: ABO system, rhesus (C, c, D, E, e) anti-Kell,

— reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D**[**F1**,]**

— **[**F2variant Creutzfeldt-Jakob disease (vCJD) assays for blood screening, diagnosis and confirmation.**]**

Textual Amendments

F1 Substituted by 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).

F2 Inserted by 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).

List B

— Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: anti-Duffy and anti-Kidd,

— reagents and reagent products, including related calibrators and control materials, for determining irregular anti-erythrocytic antibodies,

— reagents and reagent products, including related calibrators and control materials, for the detection and quantification in human samples of the following congenital infections: rubella, toxoplasmosis,

— reagents and reagent products, including related calibrators and control materials, for diagnosing the following hereditary disease: phenylketonuria,

— reagents and reagent products, including related calibrators and control materials, for determining the following human infections: cytomegalovirus, chlamydia,

— reagents and reagent products, including related calibrators and control materials, for determining the following HLA tissue groups: DR, A, B,

— reagents and reagent products, including related calibrators and control materials, for determining the following tumoral marker: PSA,

— reagents and reagent products, including related calibrators, control materials and software, designed specifically for evaluating the risk of trisomy 21,

— the following device for self-diagnosis, including its related calibrators and control materials: device for the measurement of blood sugar.