

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

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,]
- ^[F2]variant 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.