

## 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.

**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.
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