According to IVDD
Annex II [98/79/EC]

IVD devices according to 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,
for the detection, confirmation and quantification in human specimens of markers of
- HIV infection (HIV 1 and 2),
- HTLV I and II
- hepatitis B, C and D.

IVD devices according to list B:
Reagents and reagent products, including related calibrators and control materials, for determining the following
- blood groups: anti-Duffy and anti-Kidd,
- irregular anti-erythrocytic antibodies,
- HLA tissue groups: DR, A, B,
for the detection and quantification in human samples of
- congenital infections: rubella, toxoplasmosis,
- for diagnoses of
- hereditary disease: phenylketonuria,
- human infections: Cytomegalovirus, Chlamydia,
- tumoral marker: PSA,
designed specifically for evaluating the risk of
- trisomy 21 (also software),
- Device for self-diagnosis, including its related calibrators and control materials:
  - device for the measurement of blood sugar.
IVD devices for self-testing:
Art.1(2)d [98/79/EC]: ‘device for self-testing’ means any device intended by the manufacturer to be able to be used by lay persons in a home environment;

IVD devices for performance evaluation:
Art.1(2)e [98/79/EC]: ‘device for performance evaluation’ means any device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside his own premises;

Other in vitro diagnostic medical devices