

Appendix A ?

Details on product groups and categories (conformity assessment procedure in accordance with Directive 98/79/EC (IVDD))



Product Service



Manufacturer:



Application identification:

Product details

Group

Please tick and list the devices of the following codes in ascending order

IVD 0100 List A

Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups

- IVD 0101 ABO system
- IVD 0102 Rhesus (C, c, D, E, e)
- IVD 0103 Anti-Kell

IVD 0200 List A

Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of

- IVD 0201 HIV infection (HIV 1 and 2)
- IVD 0202 HTLV I and II
- IVD 0203 Hepatitis B, C and D

IVD 0300 List B

Reagents, reagent products and devices for self - diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating

- IVD 0301 Anti-Duffy and anti-Kidd
- IVD 0302 Irregular anti-erythrocytic antibodies
- IVD 0303 Congenital infections: rubella, toxoplasmosis
- IVD 0304 Hereditary disease: phenylketonuria
- IVD 0305 Human infections: cytomegalovirus, chlamydia
- IVD 0306 HLA tissue groups: DR, A, B
- IVD 0307 Tumoral marker: PSA
- IVD 0308 Risk of trisomy 21 (incl. software)
- IVD 0309 Device for self-diagnosis: device for the measurement of blood sugar

IVD 0400 Devices for self-testing

- IVD 0401 Clinical chemistry
- IVD 0402 Haematology
- IVD 0403 Immunology
- IVD 0404 Molecular biology
- IVD 0405 Pregnancy and ovulation
- IVD 0406 Specimen receptacles



	Name of model	Trade name	Model (number(s))	Intended use	EDMS Code	OEM supplier	Classification
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							