



Medicines & Healthcare products  
Regulatory Agency

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United Kingdom

**Approved Body:** TUV SUD BABT Unlimited AB 0168

**Legislation:** Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002).

**Reference:** In-Vitro Diagnostic Medical Devices

**The body is formally accredited against:**  
EN ISO/IEC 17021 - Certification of management systems

**Name of National Accreditation Body (NAB):** UKAS - United Kingdom Accreditation Service

**The accreditation covers the product categories and conformity assessment procedures concerned by this notification:** Yes

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives [as modified by Part III of Schedule 2A to the Medical Devices Regulations 2002]	Limitations
<b>IVD 0100 - List A: Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups</b>			
IVD 0101 - AB0 system	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
IVD 0102 - Rhesus (C, c, D, E, e)	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
IVD 0103 - Anti-Kell	EC declaration of conformity Full quality assurance system	Annex III Annex IV	

<b>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</b>			
IVD 0201 - HIV infection (HIV 1 and 2)	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
IVD 0202 - HTLV I and II	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
IVD 0203 - Hepatitis B, C and D	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
IVD 0204 - Variant Creutzfeldt-Jakob disease (vCJD)	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
<b>IVD 0300 - List B: Reagents, reagent products and devices for self - diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating</b>			
IVD 0301 - Anti-Duffy and anti-Kidd	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
IVD 0302 - Irregular anti-erythrocytic antibodies	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
IVD 0303 - Congenital infections: rubella, toxoplasmosis	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
IVD 0304 - Hereditary disease: phenylketonuria	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
IVD 0305 - Human infections: cytomegalovirus, chlamydia	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
IVD 0306 - HLA tissue groups: DR, A, B	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
IVD 0307 - Tumoral marker: PSA	EC declaration of conformity Full quality assurance system	Annex III Annex IV	

IVD 0308 - Risk of trisomy 21 (incl. software)	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
<b>IVD 0400 - Devices for self-testing</b>			
IVD 0401 - Clinical chemistry	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
IVD 0402 - Haematology	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
IVD 0403 - Immunology	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
IVD 0404 - Molecular biology	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
IVD 0405 - Pregnancy and ovulation	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
IVD 0406 - Specimen receptacles	EC declaration of conformity Full quality assurance system	Annex III Annex IV	

<b>Horizontal technical competence</b>	<b>Limitations</b>
MDS 7205 - IVDs incorporating software / utilising software / controlled by software & Standalone IVD Software	
MDS 7206 - IVDs in sterile condition	Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), others (need to be specified)
MDS 7208 - IVDs utilising nanomaterials	
MDS 7209 - IVDs utilising biological active coating and/or material	
MDS 7210 - IVDs utilising material of human origin	