



Medicines & Healthcare products  
Regulatory Agency

BSI Assurance UK Ltd  
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Milton Keynes  
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United Kingdom

**Approved Body:** BSI Assurance UK Ltd 0086

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

**Reference:** In-Vitro Diagnostics 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 - ABO system	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	
IVD 0102 - Rhesus (C, c, D, E, e)	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	
IVD 0103 - Anti-Kell	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	

<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 EC verification	Annex III Annex IV Annex VI	
IVD 0202 - HTLV I and II	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	
IVD 0203 - Hepatitis B, C and D	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	
IVD 0204 - Variant Creutzfeldt-Jakob disease (vCJD)	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	
<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 EC verification	Annex III Annex IV Annex VI	
IVD 0302 - Irregular anti-erythrocytic antibodies	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	
IVD 0303 - Congenital infections: rubella, toxoplasmosis	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	
IVD 0304 - Hereditary disease: phenylketonuria	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	
IVD 0305 - Human infections: cytomegalovirus, chlamydia	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	
IVD 0306 - HLA tissue groups: DR, A, B	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	
IVD 0307 - Tumoral marker: PSA	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	
IVD 0308 - Risk of trisomy 21 (incl. software)	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	
IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	
<b>IVD 0400 - Devices for self-testing</b>			
IVD 0401 - Clinical chemistry	EC declaration of conformity Full quality assurance system	Annex III Annex IV	

	EC verification	Annex VI	
IVD 0402 - Haematology	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	
IVD 0403 - Immunology	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	
IVD 0404 - Molecular biology	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	
IVD 0405 - Pregnancy and ovulation	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	
IVD 0406 - Specimen receptacles	EC declaration of conformity Full quality assurance system EC verification	Annex III Annex IV Annex VI	

Horizontal technical competence	Limitations
<b>MDS 7200 - IVD Specifics</b>	
MDS 7205 - IVDs incorporating software / utilising software / controlled by 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), sterilisation with hydrogen peroxide, sterilisation with liquid chemical sterilising agents, thermic sterilisation with dry heat, sterilisation with supercritical carbon dioxide, sterilisation with nitrogen dioxide, sterilisation with chlorine dioxide
MDS 7207 - IVDs utilising micromechanics	
MDS 7208 - IVDs utilising nanomaterials	
MDS 7209 - IVDs utilising biological active coating and/or material	
MDS 7210 - IVDs utilising material of human origin	