Medicines & Healthcare products Regulatory Agency

MHRA

BSI Assurance UK Ltd
Kitemark Court
Davy Avenue
Milton Keynes
MK5 8PP

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**
*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups			
- *IVD 0101 - ABO system	EC declaration of conformity EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex VI Annex IV	
- *IVD 0102 - Rhesus (C, c, D, E, e)	EC declaration of conformity EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex VI Annex IV	
- *IVD 0103 - Anti-Kell	EC declaration of conformity EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex VI Annex IV	
*IVD 0200 - 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)	EC declaration of conformity EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex VI Annex IV	
- *IVD 0202 - HTLV I and II	EC declaration of conformity EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex VI Annex IV	
- *IVD 0203 - Hepatitis B, C and D	EC declaration of conformity EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex VI Annex IV	
- *IVD 0204 - Variant Creutzfeldt-Jakob disease (vCJD)	EC declaration of conformity EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex VI Annex IV	
*IVD 0300 - 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	EC declaration of conformity EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex VI Annex IV	
- *IVD 0302 - Irregular anti-erythrocytic antibodies	EC declaration of conformity EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex VI Annex IV	
- *IVD 0303 - Congenital infections: rubella, toxoplasmosis	EC declaration of conformity EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex VI Annex IV	
- *IVD 0304 - Hereditary disease: phenylketonuria	EC declaration of conformity EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex VI Annex IV	
- *IVD 0305 - Human infections: cytomegalovirus, chlamydia	EC declaration of conformity EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex VI Annex IV	
- *IVD 0306 - HLA tissue groups: DR, A, B	EC declaration of conformity EC verification EC declaration of conformity	Annex III Annex VI Annex IV	

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**
	(full quality assurance system)		
- *IVD 0307 - Tumoral marker: PSA	EC declaration of conformity EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex VI Annex IV	

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

Horizontal technical competence	**Limitations**
*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), others (need to be specified)
*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	