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United Kingdom

**Approved Body:** SGS United Kingdom Limited 0120

**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 (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
- *IVD 0102 - Rhesus (C, c, D, E, e)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
- *IVD 0103 - Anti-Kell	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	

*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 (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
- *IVD 0202 - HTLV I and II	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
- *IVD 0203 - Hepatitis B, C and D	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
*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	Full quality assurance system Production quality assurance	Annex IV Annex VII	
- *IVD 0302 - Irregular anti-erythrocytic antibodies	Full quality assurance system Production quality assurance	Annex IV Annex VII	
- *IVD 0303 - Congenital infections: rubella, toxoplasmosis	Full quality assurance system Production quality assurance	Annex IV Annex VII	
- *IVD 0304 - Hereditary disease: phenylketonuria	Full quality assurance system Production quality assurance	Annex IV Annex VII	
- *IVD 0305 - Human infections: cytomegalovirus, chlamydia	Full quality assurance system Production quality assurance	Annex IV Annex VII	
- *IVD 0306 - HLA tissue groups: DR, A, B	Full quality assurance system Production quality assurance	Annex IV Annex VII	
- *IVD 0307 - Tumoral marker: PSA	Full quality assurance system Production quality assurance	Annex IV Annex VII	Restricted to PSA controls
- *IVD 0308 - Risk of trisomy 21 (incl. software)	Full quality assurance system Production quality assurance	Annex IV Annex VII	
- *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar	Full quality assurance system Production quality assurance	Annex IV Annex VII	
*IVD 0400 - Devices for self-testing			
- *IVD 0401 - Clinical chemistry	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII	
- *IVD 0402 - Haematology	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII	
- *IVD 0403 - Immunology	EC declaration of conformity	Annex III	

<b>Product family, product /Intended use/Product range</b>	<b>Procedure/Modules</b>	<b>Annexes or articles of the directives [as modified by Part III of Schedule 2A to the Medical Devices</b>	<b>Limitations</b>
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		Regulations 2002]	
	Full quality assurance system Production quality assurance	Annex IV Annex VII	
- *IVD 0404 - Molecular biology	EC declaration of conformity EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex VII	
- *IVD 0405 - Pregnancy and ovulation	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII	
- *IVD 0406 - Specimen receptacles	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII	
Horizontal technical competence		Limitations	
*MDS 7205 - IVDs incorporating software / utilising software / controlled by software			
*MDS 7206 - IVDs in sterile condition		EC declaration of conformity Annex III Full quality assurance system Annex IV Production quality assurance Annex VII	
*MDS 7209 - IVDs utilising biological active coating and/or material		EC declaration of conformity Annex III Full quality assurance system Annex IV Production quality assurance Annex VII	
*MDS 7210 - IVDs utilising material of human origin		EC declaration of conformity Annex III Full quality assurance system Annex IV Production quality assurance Annex VII	