Medicines & Healthcare products Regulatory Agency

MHRA

SGS United Kingdom Limited
Rossmore Business Park
Ellesmere Port
Cheshire
CH65 3EN
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 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	

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 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