Medicines & Healthcare products Regulatory Agency

DEKRA Certification UK Ltd
Stokenchurch House
Oxford Road
Stokenchurch
High Wycombe
HP14 3SX

Approved Body: DEKRA Certification UK Ltd

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 II 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)	Annex IV	
*IVD 0102 - Rhesus (C, c, D, E, e)	EC declaration of conformity (full quality assurance system)	Annex IV	
*IVD 0103 - Anti-Kell	EC declaration of conformity (full quality assurance system))	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 (full quality assurance system)	Annex IV	
*IVD 0203 - Hepatitis B, C and D	EC declaration of conformity (full quality assurance system)	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 (full quality assurance system)	Annex IV	
*IVD 0302 - Irregular anti-erythrocytic antibodies	EC declaration of conformity (full quality assurance system)	Annex IV	
*IVD 0303 - Congenital infections: rubella, toxoplasmosis	EC declaration of conformity (full quality assurance system)	Annex IV	
*IVD 0304 - Hereditary disease: phenylketonuria	EC declaration of conformity (full quality assurance system)	Annex IV	
*IVD 0305 - Human infections: cytomegalovirus, chlamydia	EC declaration of conformity (full quality assurance system)	Annex IV	
*IVD 0306 - HLA tissue groups: DR, A, B	EC declaration of conformity (full quality assurance system)	Annex IV	
*IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar	EC declaration of conformity (full quality assurance system)	Annex IV	
IVD 0400 - Devices for self-testing			
*IVD 0401 - Clinical chemistry	EC declaration of conformity (full quality assurance system)	Annex IV	
*IVD 0403 - Immunology	EC declaration of conformity (full quality assurance system)	Annex IV	

Horizontal technical competence	**Limitations**
*MDS 7205 - IVDs incorporating software / utilising software / controlled by software	
*MDS 7206 - IVDs in sterile condition	
*MDS 7209 - IVDs utilising biological active coating and/or material	