Medicines & Healthcare products Regulatory Agency

UL International (UK) Ltd
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RG24 8AH

Approved Body: UL International (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 – AB0 system	EC declaration of conformity; Full quality assurance system	Annex III; Annex IV	
IVD 0102 – Rhesus (C, c, D, E, e)	EC declaration of conformity; Full quality assurance system	Annex III; Annex IV	

IVD 0103 – Anti-Kell	EC declaration of conformity; Full quality assurance system	Annex III; 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 III; Annex IV	
IVD 0202 – HTLV I and II	EC declaration of conformity; Full quality assurance system	Annex III; Annex IV	
IVD 0203 – Hepatitis B, C and D	EC declaration of conformity; Full quality assurance system	Annex III; 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 III; Annex IV	
IVD 0302 – Irregular anti-erythrocytic antibodies	EC declaration of conformity; Full quality assurance system	Annex III; Annex IV	
IVD 0303 – Congenital infections: rubella, toxoplasmosis	EC declaration of conformity; Full quality assurance system	Annex III; Annex IV	
IVD 0305 – Human infections: cytomegalovirus, chlamydia	EC declaration of conformity; Full quality assurance system	Annex III; Annex IV	

IVD 0307 – Tumoral marker: PSA	EC declaration of conformity; Full quality assurance system	Annex III; Annex IV	
IVD 0308 – Risk of trisomy 21 (incl. software)	EC declaration of conformity; Full quality assurance system	Annex III; Annex IV	
IVD 0309 – Device for self-diagnosis: device for the measurement of blood sugar	EC declaration of conformity; Full quality assurance system	Annex III; Annex IV	
IVD 0400 – Devices for self-testing			
IVD 0401 – Clinical chemistry	EC declaration of conformity; Full quality assurance system	Annex III; Annex IV	
IVD 0403 – Immunology	EC declaration of conformity; Full quality assurance system	Annex III; Annex IV	
IVD 0404 – Molecular Biology	EC declaration of conformity; Full quality assurance system	Annex III; Annex IV	
IVD 0405 – Pregnancy and ovulation	EC declaration of conformity; Full quality assurance system	Annex III; Annex IV	
IVD 0406 – Specimen receptacles	EC declaration of conformity; Full quality assurance system	Annex III; Annex IV	

Horizontal technical competence	Limitations
MDS 7205 – IVDs incorporating software / utilising software / controlled by software and Standalone IVD 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 in 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	