



Medicines & Healthcare products Regulatory Agency

UL International (UK) Ltd
Unit 1-3 Horizon Kingsland Business Park Wade Road
Basingstoke
RG24 8AH
United Kingdom

Approved Body: UL International (UK) Ltd 0843

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 0308 - Risk of trisomy 21 (incl. software)	Full quality assurance system	Annex IV	