



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)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	