

# UL International (UK) Ltd

An affiliate of Underwriters Laboratories Inc.

## EC Certificate - Full Quality Assurance System Approval Certificate

(Annex IV, section 3 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

### Manufacturer

Biokit S.A.  
Can Malé  
08186 Lliçà d'Amunt  
Barcelona  
Spain

### Authorised Representative

### Scope of Certificate:

The design, manufacture and distribution of in vitro diagnostic reagent kits for detection of:

1. Antibodies to rubella, toxoplasma and cytomegalovirus by enzyme immunoassay and agglutination.
2. Antibodies or antigen to hepatitis B virus by enzyme immunoassay.

### Device Classifications:

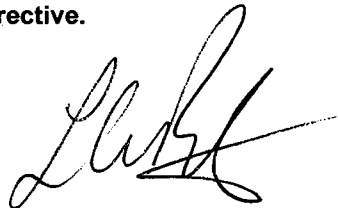
Annex IV, List A and B Devices

### Device descriptions:

As further detailed in attachment(s)

**We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.**

### Certificate issued by:



**Certification Manager**  
For UL International (UK) Ltd

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Certificate no: 302  
Original certificate: 5 November 2003  
Current certificate: 9 October 2006  
Certificate expiry: 5 November 2009

