

# 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

Not applicable

### Scope of Certificate:

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

1. Antibodies to rubella, toxoplasma and cytomegalovirus by enzyme immunoassay, chemiluminescent immunoassay and agglutination.
2. Antibodies or antigens to Hepatitis B Virus by enzyme immunoassay.

### Device Classifications:

Annex II, List A and B Devices

### Device descriptions:

As further detailed in attachment 1-2

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

UL International (UK) Ltd  
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Certificate no: 302  
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Current certificate: 4 May 2010  
Certificate expiry: 22 October 2012

