

# 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

Omega Diagnostics Ltd  
Hillfoots Business Village  
Alva  
Clackmannanshire  
FK12 5DQ

### Authorised Representative

Not Applicable

**Scope of Certificate:** The Manufacture and Distribution of In Vitro Diagnostic Reagent kits for detection of Chlamydia SPP by immunofluorescence

**Device Classifications:** Annex II List B

**Device descriptions:** Fluorotect Chlamydia product code OD019

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: 618  
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Current certificate: 2 February 2010  
Attachments: N/A  
Certificate expiry: 13 April 2010

