



EC CERTIFICATE

Omega Diagnostics Ltd

Hillfoots Business Village
Alva
Clackmannanshire
Scotland FK12 5DQ
United Kingdom

EC Certificate - Full Quality Assurance System Approval Certificate

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

Scope of Certificate:

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

Device Classification:

Annex II List B

Device Descriptions:

Fluorotect Chlamydia

Model:

OD019

File Number	A17881	Cycle Start Date	15 August 2016
Certificate No.	618.160818	Effective Date	18 August 2016
		Expiry Date	14 August 2019

Authorised by

Brian Rodgers
Certification Manager

For and on Behalf of UL International (UK) Ltd

We hereby declare that an examination of the full quality assurance system has been carried out per report 11260817, 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 Council 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 and is subject to periodic surveillance as required by 98/79/EC, Annex IV, Section 5. For Annex II, List A devices where they are covered by this certificate, an EC Design Examination certificate according to 98/79/EC, Annex IV, Section 4 is required.

Notified Body

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