

EC Declaration of Conformity (Directive 98/79/EC)

Manufacturer Omega Diagnostics, Omega House, Hillfoots Business Village, Alva,
Scotland, United Kingdom
FK12 5DQ

Manufacturer Identification Code: GB / 000072

Competent Authority: Medicines and Healthcare Products Regulatory Agency,
Competent Authority Number: GB / CA 01

Notified Body: UL International (UK) Ltd
Notified Body Number: 0843

Product Details: See EC Declaration of Conformity List (below)

Classification: IVDD, Annex II List B

Conformity Assessment Route: Annex IV IVDD, Full Quality Assurance

We hereby declare the devices named in the EC Declaration of Conformity List (below) comply with the requirements of DIRECTIVE 98/79/EC, on in vitro diagnostic medical devices.

Standards Applied: EN ISO 9001:2008, EN ISO 13485:2003, EN ISO 14971:2007,
EN 375:2001, EN 591:2001, EN 980:2008, EN 13612:2002, EN
13640:2002, & EN 13641:2002.

Signed:



Name: Norman Hawkes
Position: Technical Manager
Place: Omega Diagnostics, Omega House, Hillfoots Business Village, Alva, Scotland,
United Kingdom, FK12 5DQ
Date: 12th November 2009

EDMA Classification	Description	Product Product Code - Test Size
Chlamydia (15 01 01)		
15 01 01 01	CHLAMYDIA ANTIGEN KIT	Fluorotect Chlamydia OD019 – 50 Tests

OMEGA DIAGNOSTICS LTD

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AN ISO 9001 : 2000 AND ISO 13485 : 2003 CERTIFIED COMPANY

Registered in Scotland No. 107178
Registered Office: Omega House, Hillfoots Business Village, Alva, FK12 5DQ