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

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

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 13485:2012, EN ISO 14971:2012, EN ISO 18113-2:2009, EN ISO 15223-1: 2012, EN 13612:2002, EN 23640:2013 and EN 13641:2002.

Signed: 
Name: Norman Hawkes
Position: Technical Manager
Place: Omega Diagnostics, Omega House, Hillfoots Business Village, Alva, Clackmannanshire, FK12 5DQ, Scotland, United Kingdom.
Date: 01st June 2016

EDMA Classification	Description	Product Product Code - Test Size
Chlamydia (15 01 01)		
15 01 01 01	CHLAMYDIA ANTIGEN KIT	Fluorotect® Chlamydia OD019 – 50 Tests OD019Z – 50 Tests