EC CERTIFICATE

Diagnostics for the Real World Ltd

845 Embedded Way, Suite 150
San Jose, CA 95138 United States

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV (excluding sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Scope of Certificate:
Design and manufacture of in vitro diagnostic reagent kits

1. **Immunochromatography devices for rapid detection of Chlamydia**
2. **Nucleic acid based amplification assays for HIV-1**

Device Classification:
Annex II List A and B

Device Descriptions:

Chlamydia Rapid Test (Professional Use)	**P/N 1100-20**	**– List B**
Chlamydia Rapid Test (Professional Use)	**P/N 1200-20**	**– List B**
SAMBA HIV-1 Semi-Q Test	**P/N 4100-12**	**– List A**
SAMBA I HIV-1 Qual Whole blood Test	**P/N 4200-12**	**– List A**
SAMBA II HIV-1 Qual Whole Blood Test	**P/N 4500-12**	**– List A**
SAMBA II HIV-1 Semi-Q Test	**P/N 4400-12**	**– List A**

We hereby declare that an examination of the full quality assurance system has been carried out per report 11658655, 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.

File Number	A13801	Cycle Start Date	02 June 2017
Certificate No.	593.170531	Effective Date	02 June 2017
		Expiry Date	01 June 2022

Authorised by

C.H. Tonkin
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body

0843

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