



EC CERTIFICATE

National Institute for Biological Standards and Control (NIBSC)

Blanche Lane South Mimms
Potters Bar Hertfordshire EN6 3QG UK

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:

The design and manufacture of biological standards and controls used for the control of anti-blood group quantitation, HLA tissue typing and markers for Hepatitis B Virus, Hepatitis C Virus, Human Immunodeficiency Virus, Human Cytomegalovirus, Rubella virus and Toxoplasma gondii

Device Classification:

Annex II List A and List B

Device Descriptions:

See Attachments 1-5

Model Type:

See Attachments 1-5

We hereby declare that an examination of the full quality assurance system has been carried out per report 4787579443, 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. This certificate is issued with 5 attachments listing model numbers listing additional locations covered by this certificate.

File Number A17562
Certificate No. 329.170524

Cycle Start Date 19 February 2016
Effective Date 24 May 2017
Expiry Date 18 February 2019
Authorised by

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

Notified Body
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Attachment 1 of 5

The products detailed below are covered under the scope of this certificate

Device Description	Model	Classification
British Working Standard for HBsAg 0.2 IU/mL	07/288-xxx	Annex II List A
NIBSC Monitor Sample for HBsAg 0.051 IU/mL	07/286-xxx	Annex II List A
British Working Standard for Anti-HIV-1	99/750-xxx	Annex II List A
British Working Standard for Anti-HIV-1 1 in 5 Dilution	99/710-xxx	Annex II List A
Monitor Sample for Anti-HIV-2	99/674-xxx	Annex II List A
Monitor Sample for Anti-HTLV-1	03/104-xxx	Annex II List A
British Working Standard for Anti-HCV	14/240-xxx	Annex II List A
British Working Standard for Anti-HCV 1 in 8 Dilution	10/154-xxx	Annex II List A
British Working Standard for Anti-HCV 1 in 8 Dilution	14/242-xxx	Annex II List A
The British Standard for Anti-D antibodies	73/515 and 73/517	Annex II List B
The British Standard for Anti-c antibodies	84/628	Annex II List B
2nd British Standard for Anti-Rubella Serum, Human	67/182	Annex II List B
HLA-A Genotyping Panel	05/208-xxx	Annex II List B
HLA-DRB1 Genotyping Reference Panel	10/136-xxx	Annex II List B

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Attachment 2 of 5

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Device Description	Model	Classification
HCV RNA Working Reagent for Nucleic Acid Amplification Techniques (genotype 3)	02/264-xxx	Annex II List A
Hepatitis B Virus DNA Working Reagent for Nucleic Acid Amplification Techniques	11/182-xxx	Annex II List A
HIV-1 RNA Working Reagent	99/634-xxx	Annex II List A
HIV-1 RNA Working Reagent	99/636-xxx	Annex II List A
HBV, HCV and HIV Triplex Reagent (NAT)	14/198-xxx	Annex II List A
Human Cytomegalovirus for Nucleic Acid Amplification Techniques	08/314-xxx	Annex II List B
Clinical Virology Multiplex: Immunodeficiency panel working reagent for Nucleic Acid Amplification Tests (NAT)	15/130-xxx	Annex II List B

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Attachment 3 of 5

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Device Description	Model	Classification
Anti-HIV-1: Quality Control Serum: Sample 1	QCRHIV1QC1	Annex II List A
Anti-HIV-1: Quality Control Serum: Sample 2	QCRHIV1QC2	Annex II List A
Anti-HIV-1: Quality Control Serum: Sample 3	QCRHIV1QC3	Annex II List A
Anti-HIV-1: Quality Control Serum: Sample 5	QCRHIV1QC5	Annex II List A
HIV1 p24 Antigen: Quality Control Serum: Sample 1	QCRHIV1P24QC1	Annex II List A
HIV1 p24 Antigen: Quality Control Serum: Sample 2	QCRHIV1P24QC2	Annex II List A
Anti-HIV-2: Quality Control Serum: Sample 2	QCRHIV2QC2	Annex II List A
Anti-HIV-2: Quality Control Serum: Sample 3	QCRHIV2QC3	Annex II List A
Anti-HCV Quality Control Serum: Sample 1	QCRHCVQC1	Annex II List A
Anti-HBs Quality Control Serum: Sample 1	QCRHBsQC1	Annex II List A
HBsAg Quality Control Serum: Sample 1	QCRHBsGQC1	Annex II List A
HBsAg Quality Control Serum: Sample 2	QCRHBsGQC2	Annex II List A

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Attachment 4 of 5

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Device Description	Model	Classification
Anti-HBe Quality Control Serum: Sample 1	QCRHBeQC1	Annex II List A
Total Anti-HBc Quality Control Serum: Sample 1	QCRTHBcQC1	Annex II List A
Total Anti-HBc Quality Control Serum: Sample 2	QCRTHBcQC2	Annex II List A
IgM Anti-HBc Quality Control Serum: Sample 1	QCRHBcIgMQC1	Annex II List A
HIV-1 Rapid Test Device: Quality Control Serum: Sample 1	QCRHIVRTDQC1	Annex II List A
Anti-CMV Quality Control Serum Sample 1: Sample 1	QCRCMVQC1	Annex II List B
IgM Anti-CMV Quality Control Reagent 1	QCRCMVlgMQC1	Annex II List B
Anti-Rubella Quality Control Serum: Sample 1	QCRRUBQC1	Annex II List B
Anti-Toxoplasma Quality Control Serum: Sample 1	QCRTOXOQC1	Annex II List B
Anti-Rubella Quality Control Serum Sample 2	QCRRUBQC2	Annex II List B
Anti-Rubella IgM Quality Control Serum Sample 1	QCRRUBlgMQC1	Annex II List B

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Attachment 5 of 5

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Device Description	Model	Classification
IgM Anti-Toxoplasma gondii Quality Control Reagent 1	QCRTOXOIgMQC1	Annex II List B

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