EC CERTIFICATE

National Institute for Biological Standards and Control (NIBSC)

Blanche Lane
South Mimms
Potters Bar
Hertfordshire EN6 3QG UNITED KINGDOM

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 infectious disease including Hepatitis B Virus, Hepatitis C Virus, Human Immunodeficiency Virus, Human Cytomegalovirus, Rubella virus and Toxoplasma gondii

Device Classifications:

Annex II List A
Annex II List B

Device Descriptions and Model Type:

Please refer to Attachments: 1, 2, 3

We hereby declare that an examination of the full quality assurance system has been carried out 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 3 attachments listing product references covered by this certificate.

File Number	A17562	Cycle Start Date	February 19, 2016
Certificate Number	329.180406	Effective Date	April 6, 2018
Initial Issue Date	February 19, 2016	Expiry Date	February 18, 2019

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

Check Certificate Status: here

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

EC CERTIFICATE

National Institute for Biological Standards and Control (NIBSC)

Blanche Lane
South Mimms
Potters Bar
Hertfordshire EN6 3QG UNITED KINGDOM

Attachment 1 of 3

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

Model/Type	Classification	G/UMDN Code
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	-
Human Cytomegalovirus for Nucleic Acid Amplification Techniques 08/314-xxx	Annex II List B	-
Clinical Virology Multiplex I: Immunodeficiency panel working reagent for Nucleic Acid Amplification Tests (NAT) 15/130-xxx	Annex II List B	-
Total Anti-HBc Quality Control Serum: Sample 2 QCRTHBcQC2	Annex II List A	-
Anti-CMV Quality Control Serum Sample 1: Sample 1 QCRCMVQC1	Annex II List A	-
IgM Anti-CMV Quality Control Reagent 1 QCRCMVIgMQC1	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 QCRRUBIgMQC1	Annex II List B	-
IgM Anti-Toxoplasma gondii Quality Control Reagent 1 QCRTOXOIgMQC1	Annex II List B	-
NIBSC Monitor Sample for HBsAg 0.05IU/mL 07/286-xxx	Annex II List A	-
British Working Standard for HBsAg 0.2IU/mL 07/288-xxx	Annex II List A	-
Monitor Sample for Anti-HTLV-1 03/104-xxx	Annex II List A	-
Monitor Sample for Anti-HIV-2 99/674-xxx	Annex II List A	-
British Working Standard for Anti-HIV-1 99/750-xxx	Annex II List A	-

File Number	A17562	Cycle Start Date	February 19, 2016
Certificate Number	329.180406	Effective Date	April 6, 2018
Initial Issue Date	February 19, 2016	Expiry Date	February 18, 2019

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

Check Certificate Status: here

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

EC CERTIFICATE

National Institute for Biological Standards and Control (NIBSC)

Blanche Lane
South Mimms
Potters Bar
Hertfordshire EN6 3QG UNITED KINGDOM

Attachment 2 of 3

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

Model/Type	Classification	G/UMDN Code
British Working Standard for Anti-HCV 14/240-xxx	Annex II List A	-
British Working Standard for Anti-HCV 1 in 8 Dilution 14/242-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-HIV-1 1 in 5 Dilution 99/710-xxx	Annex II List A	-
HBsAg Quality Control Serum: Sample 2 QCRHBsGQC2	Annex II List A	-
Total Anti-HBc: Quality Control Serum: Sample 1 QCRTHBcQC1	Annex II List A	-
HIV-1 Rapid Test Device: Quality Control Serum: Sample 1 QCRHIVRTDQC1	Annex II List A	-
Anti-HIV-2: Quality Control Serum: Sample 3 QCRHIV2QC3	Annex II List A	-
Anti-HIV-2: Quality Control Serum: Sample 2 QCRHIV2QC2	Annex II List A	-
Anti-HIV-1: Quality Control Serum: Sample 5 QCRHIV1QC5	Annex II List A	-
Anti-HIV-1: Quality Control Serum: Sample 3 QCRHIV1QC3	Annex II List A	-
Anti-HIV-1: Quality Control Serum: Sample 2 QCRHIV1QC2	Annex II List A	-
Anti-HIV-1: Quality Control Serum: Sample 1 QCRHIV1QC1	Annex II List A	-
HIV-1 p24 Antigen: Quality Control Serum: Sample 2 QCRHIV1P24QC2	Annex II List A	-
HIV-1 p24 Antigen: Quality Control Serum: Sample 1 QCRHIV1P24QC1	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	-
Anti-HBe: Quality Control Serum: Sample 1 QCRHBEQC1	Annex II List A	-
IgM Anti-HBc: Quality Control Serum: Sample 1 QCRHBcIgMQC1	Annex II List A	-

File Number	A17562	Cycle Start Date	February 19, 2016
Certificate Number	329.180406	Effective Date	April 6, 2018
Initial Issue Date	February 19, 2016	Expiry Date	February 18, 2019

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

Check Certificate Status: here

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

EC CERTIFICATE

National Institute for Biological Standards and Control (NIBSC)

Blanche Lane
South Mimms
Potters Bar
Hertfordshire EN6 3QG UNITED KINGDOM

Attachment 3 of 3

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

Model/Type	Classification	G/UMDN Code
HBV, HCV and HIV Triplex Reagent (NAT) 14/198-xxx	Annex II List A	-
HIV-1 RNA Working Reagent 99/636-xxx	Annex II List A	-
HIV-1 RNA Working Reagent 99/634-xxx	Annex II List A	-
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	-
Hepatitis A, Hepatitis B, Hepatitis C, Hepatitis E, Human Immunodeficiency Virus-1 and Parvovirus B19 Blood Virology Multiplex II reagent for Nucleic Acid Amplification Testing (Blood Virology Multiplex II) 16/154-XXX	Annex II List A	-

File Number	A17562	Cycle Start Date	February 19, 2016
Certificate Number	329.180406	Effective Date	April 6, 2018
Initial Issue Date	February 19, 2016	Expiry Date	February 18, 2019

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

Check Certificate Status: here

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom