EC CERTIFICATE

National Health Service Blood & Transplant

14 Estuary Banks
Speke, Liverpool L24 8RB
United Kingdom

EC Certificate - Full Quality Assurance System Approval Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)

Scope of Certificate:
The design and manufacture of in vitro diagnostic medical devices for determining blood groups

Device Classification:
Annex II List A and List B

Device Descriptions:
As further detailed in Attachments 1,2,3

Model:
As further detailed in Attachments 1,2,3

File Number	A18088	Cycle Start Date	12 December 2015
Certificate No.	308.160801	Effective Date	01 August 2016
		Expiry Date	11 December 2018

Authorised by

Brian Rodgers
Certification Manager
For and on Behalf of UL International (UK) Ltd

We hereby declare that an examination of the full quality assurance system has been carried out per report SR3214122, 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 model numbers.

Notified Body

0843

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

EC CERTIFICATE

National Health Service Blood & Transplant

14 Estuary Banks
Speke, Liverpool L24 8RB
United Kingdom

Attachment 1 of 3

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

Product Name	Model/Type	Classification
A1rr cells in Alsevers (10 mL 2.8%suspension)	PR012	Annex II List A
A2rr cells in Alsevers (10 mL 2.8%suspenion)	PR022	Annex II List A
Brr cells in Alsevers (10 mL 2.8%suspension)	PR033	Annex II List A
OR1r cells in Alsevers (10 mL 2.8%suspension)	PR044	Annex II List A
A1rr cells in CellStab (10 mL 0.8%suspension)	PR014	Annex II List A
A1rr cells in CellMedia	PR015	Annex II, list A
Brr cells in CellStab (10 mL 0.8%suspension)	PR035	Annex II List A
Brr cells in CellMedia	PR036	Annex II, list A
BR1r cells in Alsevers (10 mL 2.8%suspension)	PR034	Annex II List A
OR1r cells in CellStab (10 mL 0.8%suspension)	PR045	Annex II List A
OR1r cells in CellMedia	PR046	Annex II, list A
2 Cell antibody screen	PR101	Annex II List B
2 Cell antibody screen in CellStab	PR102	Annex II List B
2 Cell antibody screen in CellMedia	PR103	Annex II List B
rr Cell antibody screen in CellStab	PR106	Annex II List B
rr Cell antibody screen in CellMedia	PR108	Annex II List B

File Number A18088
Certificate No. 308.160801

Cycle Start Date 12 December 2015
Effective Date 01 August 2016
Expiry Date 11 December 2018

Authorised by

Brian Rodgers
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

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

EC CERTIFICATE

National Health Service Blood & Transplant

14 Estuary Banks
Speke, Liverpool L24 8RB
United Kingdom

Attachment 2 of 3

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

Product Name	Model/Type	Classification
r'r and r''r Cell antibody screen in CellStab	PR107	Annex II List B
r'r and r''r Cell antibody screen in Cell Media	PR109	Annex II List B
3 Cell antibody screen	PR121	Annex II List B
3 Cell antibody screen papainised in Alsevers	PR124	Annex II List B
3 Cell antibody screen in CellStab	PR122	Annex II List B
3 Cell antibody screen in CellMedia	PR123	Annex II List B
Antibody ID panel products in Alsevers	PR141/144/201/211	Annex II List B
Antibody ID panel products in CellStab	PR142/143	Annex II List B
Antibody ID panel products in CellMedia	PR162/163	Annex II List B
Antibody ID panel products in LISP	PR146	Annex II List B
Antibody ID panel products papainised in Alsevers	PR154	Annex II List B
Antibody ID panel products papainised in CellStab	PR152/153	Annex II List B
Antibody ID panel products papainised in CellMedia	PR172/173	Annex II List B
IgG coated cells	PR092	Annex II List B
ZZAP Kit	PN161	Annex II List B

File Number A18088
Certificate No. 308.160801

Cycle Start Date 12 December 2015
Effective Date 01 August 2016
Expiry Date 11 December 2018

Authorised by

Brian Rodgers
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

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

EC CERTIFICATE

National Health Service Blood & Transplant

14 Estuary Banks
Speke, Liverpool L24 8RB
United Kingdom

Attachment 3 of 3

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

Product Name	Model/Type	Classification
Weak Anti-K Control	PN043	Annex II List B
Weak Anti-c Control	PN042	Annex II List B
Weak Anti-Fya Control	PN044	Annex II List B
Weak Anti-D control	PN046	Annex II List B
AB Serum	PN061	Annex II List B

File Number A18088
Certificate No. 308.160801

Cycle Start Date 12 December 2015
Effective Date 01 August 2016
Expiry Date 11 December 2018

Authorised by

Brian Rodgers
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

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