EC CERTIFICATE

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate,
Danehill, Lower Earley, Berkshire, RG6 4UT, UK

EC Design - Examination Certificate

Annex IV, section 4 of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Device Classification:
Annex II, list A

Device Descriptions:
In vitro diagnostic monoclonal antibody reagents for identification of blood groups

Model:	Anti-A	Product Code 600005/600010/600000
	Anti-B	Product Code 610005/610010/610000
	Anti-A,B	Product Code 620005/620010/620000
	Anti-C	Product Code 690005
	Anti-E	Product Code 691005
	Anti-c	Product Code 692005
	Anti-e	Product Code 693005
	Anti-D Clone 1	Product Code 730010/730000
	Anti-D Clone 2	Product Code 710010/710000
	Anti-D Duoclone	Product Code 740010/740000
	Anti-K	Product Code 760005/760010
	Anti C+D+E	Product Code 700005/700010/700000

File Number	A12241	Cycle Start Date	23 May 2013
Certificate No.	355.130523	Effective Date	23 May 2013
		Expiry Date	23 May 2018

Authorised by

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

We hereby declare that a design examination has been carried out on the device(s) listed per report 13CA18998, following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV section 4 of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the design of the device(s) listed conforms with the relevant provisions of Annex IV section 4 of the aforementioned directive as transposed into national legislation.

Notified Body

0843

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

EC CERTIFICATE

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate,
Danehill, Lower Earley, Berkshire RG6 4UT, UK

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV, section 3 of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Scope of Certificate:
The design and manufacture of in vitro diagnostic reagents for identification of blood groups

Device Classification:
Annex II, List A and B

Device Descriptions:
Please refer to Attachment 1

Model:
Please refer to Attachment 1

File Number	A12241	Cycle Start Date	22 May 2011
Certificate No.	354.110725	Effective Date	25 July 2011
		Expiry Date	22 May 2014

Authorised by

Ivor Barrett
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 SR9839550, 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 1 attachment 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

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate,
Danehill, Lower Earley, Berkshire RG6 4UT, UK

Attachment 1 of 1

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

Device Description	Model	Classification
Anti-A	600005/600010/600000	Annex II List A
Anti-B	610005/610010/610000	Annex II List A
Anti-A,B	620005/620010/620000	Annex II List A
Anti-C	690005	Annex II List A
Anti-E	691005	Annex II List A
Anti-c	692005	Annex II List A
Anti-e	693005	Annex II List A
Anti-K	760005/760010	Annex II List A
Anti-D Clone 2	710010/710000	Annex II List A
Anti-D Clone 1	730010/730000	Annex II List A
Anti-D Duoclone	740010/740000	Annex II List A
Anti-Jka	323002/323000	Annex II List B
Anti-Jkb	324002/324000	Annex II List B
Anti-Fya	316002/316000	Annex II List B
Anti-Fyb	317002/317000	Annex II List B
Anti-Human Globulin Clear (Elite Clear)	415010/415100/415000	Annex II List B
Anti-Human Globulin Green (Elite Green)	435010/435100/435000	Annex II List B
Monoclonal Anti-Fy^a Blood Grouping Reagent	774000/774002	Annex II List B
Monoclonal Anti-C+D+E	700005/700010/700000	Annex II List A
Anti-IgG Clear	401010/401000	Annex II List B
Anti-IgG Green	402010/402000	Annex II List B

File Number A12241
Certificate No. 354.110725

Cycle Start Date 22 May 2011
Effective Date 25 July 2011
Expiry Date 22 May 2014

Authorised by

Ivor Barrett
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
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