



EC CERTIFICATE

National Health Service Blood & Transplant

14 Estuary Banks
Speke, Liverpool L24 8RB
United Kingdom

EC Design - Examination Certificate

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

Device Descriptions:

Control red blood cell preparations for determining ABO status of patients prior to the receipt of donated blood

Models:

As further detailed in Attachment 1

File Number	A18088	Cycle Start Date	12 December 2013
Certificate No.	309.160801	Effective Date	01 August 2016
		Expiry Date	11 December 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 SR3214122, 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. 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



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Attachment 1 of 1

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% suspension)	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 (10 mL 0.8% suspension)	PR015	Annex II List A
Brr cells in CellStab (10 mL 0.8% suspension)	PR035	Annex II List A
Brr cells in CellMedia (10 mL 0.8% suspension)	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 (10 mL 0.8% suspension)	PR046	Annex II List A

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