



EC CERTIFICATE

National Health Service Blood & Transplant (NHSBT)

14 Estuary Banks
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 Description:

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

Device Classifications:

Annex II List A

Model Type:

Please refer to Attachment: 1

We hereby declare that a design examination has been carried out on the device(s) listed, 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 product references.

File Number	A18088	Cycle Start Date	December 12, 2018
Certificate Number	309.181212	Effective Date	December 12, 2018
Initial Issue Date	December 11, 2003	Expiry Date	December 11, 2023

Authorised by

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



Check Certificate
Status: [here](#)

Notified Body
0843

IVDD A4 S4 DE
00-MB-A0043 Issue: 15.0

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:

Model/Type	Classification	G/UMDN Code
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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 Guildford, Surrey, GU3 1LR, United Kingdom