

# UKCA Certificate

**Certificate number**

188048.250522

**File number**

A18088

**Initial issue date**

2025-05-22

**Cycle start date**

2025-05-22

**Effective date**

2025-05-22

**Expiry date**

2030-05-21

**UK Approved  
Body  
0843**

**National Health Service Blood & Transplant  
(NHSBT)**

14 Estuary Banks  
Liverpool L24 8RB UNITED KINGDOM

**UKCA Design Examination Certificate**

Part IV of The Medical Devices Regulations 2002, Annex IV Section 4  
[as modified by Part 3 of Schedule 2A to The Medical Devices Regulations 2002]

Scope of Certificate:

EC Design-examination for in vitro diagnostic medical devices List A

**See Attachment(s) for devices referenced. Certificate with Attachment(s)  
totals 2 pages.**

Authorized by:



Paul Daysh  
Operations manager – Medical Regulatory



Check certificate status: [here](#)

We hereby declare that a design examination has been carried out on the device(s) listed, following the requirements of Part IV of the UK Medical Device Regulations as specified above. We certify that the design of the device(s) listed conforms with the requirements of the aforementioned regulation with respect to the relevant provisions of Annex IV section 4 of the associated regulation as referenced in Schedule 2A, Part 3.

UL International (UK) Limited  
Units 1-4 Horizon, Kingsland Business Park, Wade Road  
Basingstoke, RG24 8AH, United Kingdom

## Attachment 1 of 1

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	-