CERTIFICATE

EC Certificate No. 1434-IVDD-131/2022

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

National Health Service
Blood & Transplant (NHSBT)
14 Estuary Banks, Liverpool L24 SRB
United Kingdom

i.e. *in vitro* diagnostic medical devices
List A

The list of medical devices covered by this certificate is provided in the annex 1

in terms of design documentation, comply with requirements
of Annex IV (Section 4) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 02.05.2022 to 27.05.2025
The date of issue of the Certificate: 02.05.2022

The date of the first issue of the Certificate: 18.07.2019

CE 1434

Issued under the Contract No. MD-008/2022
Application No: 595/2021
Certificate bears the qualified signature.
Warsaw, 02/05/2022
Module H6/V1

Aleksandra Kostrzewa
Digitally signed by Aleksandra Kostrzewa
President

ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-131/2022

List of medical devices covered by the certificate:

A1rr cells in Alsevers (10 ml 2.8%suspension) PR012
A2rr cells in Alsevers (10 ml 2.8%suspenion) PR022
Brr cells in Alsevers (10 ml 2.8%suspension) PR033
OR1r cells in Alsevers (10 ml 2.8%suspension) PR044
A1 rr cells in CellStab (10 ml 0.8%suspension) PR014
A1 rr cells in CellMedia (10 ml 0.8%suspension) PR015
Brr cells in CellStab (10 ml 0.8%suspension) PR035
Brr cells in CellMedia (10 ml 0.8%suspension) PR036
BR1 r cells in Alsevers (10 ml 2.8%suspension) PR034
OR1r cells in CellStab (10 ml 0.8%suspension) PR045
OR1 r cells in CellMedia (10 ml 0.8%suspension) PR046

CE 1434

Issued under the Contract No. MD-008/2022
Application No: 595/2021
Certificate bears the qualified signature.
Warsaw, 02/05/2022

Aleksandra Kostrzewa
President

Digitally signed by Aleksandra Kostrzewa

By Royal Charter

Supplementary information to AR120 834769 - Non-significant changes approved after the 26th May 2022 as per the Transitional Provisions of IVDR Article 110.3

Issued to: National Health Service
Blood & Transplant (NHSBT)
14 Estuary Banks, Liverpool L24 8RB
United Kingdom

Date: 22 September 2025

Changes Approved:

Date	Reference Number	Action
22 September 2025	30535773	Transfer of appropriate surveillance to BSI per Regulation EU 2024/1860 of devices referenced in the Certificate Letter. Original NB Certificate Number: 1434-IVDD-131/2022.

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Inspiring trust for a more resilient world.

22 September 2025

NHSBT Reagents
14 Estuary Banks
Speke
Liverpool
L24 SRB
United Kingdom

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

The transitional provisions specified in IVDR Article 110(3) (as amended by (EU) 2024/1860) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing IVDD certificates from 26th May 2022.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) or under IVDR Article 110(3), as applicable, and as per the guidance provided in MDCG 2020-3/MDCG 2022-6.

The related certificate specified below continues to remain valid and devices can be placed on the market based on this certificate as long as the manufacturer complies with the conditions specified in Section 3c of Article 120 of MDR or in Section 3c of Article 110 of IVDR, as applicable.

Original certificate number	**BSI reference number**	**Directive and Annex**	**Reference Number**	**Changes approved**
1434-IVDD-131/2022	AR120 834769	98/79/EC Annex IV Section 4	30535773	Transfer of appropriate surveillance to BSI per Regulation EU 2024/1860 of devices: A1rr cells in Alsevers (10 ml 2.8%suspension) PR012 A2rr cells in Alsevers (10 ml 2.8%suspenion) PR022 Brr cells in Alsevers (10 ml 2.8%suspension) PR033 OR1r cells in Alsevers (10 ml 2.8%suspension) PR044 A1 rr cells in CellStab (10 ml 0.8%suspension) PR014

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Original certificate number	BSI reference number	Directive and Annex	Reference Number	Changes approved
1434-IVDD-131/2022	AR120 834769	98/79/EC Annex IV Section 4	30535773	A1 rr cells in CellMedia (10 ml 0.8%suspension) PR015 Brr cells in CellStab (10 ml 0.8%suspension) PR035 Brr cells in CellMedia (10 ml 0.8%suspension) PR036 BR1 r cells in Alsevers (10 ml 2.8%suspension) PR034 OR1r cells in CellStab (10 ml 0.8%suspension) PR045 OR1 r cells in CellMedia (10 ml 0.8%suspension) PR046 Original NB Certificate Number: 1434-IVDD-131/2022

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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