



CERTIFICATE

EC No 1434-IVDD-351/2019
Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

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

for the design, manufacture and final inspection of in vitro diagnostic medical devices
List A

List of devices covered by this certificate is given in the Annex no. 1

complies with requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended)
implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 18.07.2019 to 11.12.2023

The date of issue of the Certificate: 18.07.2019



Application No: 660/2019
Module: H7


mgr Anna Wyroba
Vice-President



Certificate No **1434-IVDD-351/2019**
Issued under the Contract No **MD-112/2019**
Bears the PCBC hologram.
Warsaw, 18.07.2019



ANNEX 1 TO CERTIFICATE
VALID ONLY WITH CERTIFICATE
No 1434-IVDD-351/2019

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

A1rr cells in Alsevers (10 mL 2.8% suspension) PR012

A2rr cells in Alsevers (10 mL 2.8% suspension) PR022

Brr cells in Alsevers (10 mL 2.8% suspension) PR033

OR1r cells in Alsevers (10 mL 2.8% suspension) PR044

A1rr cells in CellStab (10 mL 0.8% suspension) PR014

A1rr cells in CellMedia (10 mL 0.8% suspension) PR015

Brr cells in CellStab (10 mL 0.8% suspension) PR035

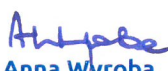
Brr cells in CellMedia (10 mL 0.8% suspension) PR036

BR1r cells in Alsevers (10 mL 2.8% suspension) PR034

OR1r cells in CellStab (10 mL 0.8% suspension) PR045

OR1r cells in CellMedia (10 mL 0.8% suspension) PR046




mgr Anna Wyroba
Vice-President



Annex 1 to certificate No. **1434-IVDD-351/2019**
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