



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2022-CE-08447-1

Issued to:

Eurofins Donor & Product Testing LLC

Manufacturing Site Address:

401 N 3rd Street, Suite 279
Philadelphia Pennsylvania 19123
United States of America

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer has been inspected following Section 32EA(1) of the *Therapeutic Goods Act 1989* in connection with manufacturers of Biologicals (items made from or containing human cells or human tissues) located outside Australia.

From the knowledge gained during inspection of this manufacturer, the latest of, that was conducted on 03 to 05 June 2024, it is considered that the manufacturer complies with the Good Manufacturing Practice (GMP) requirements of the Australian Code of Good Manufacturing Practice for Human Blood and Blood Components, Human Tissues and Human Cellular Therapy Products (2013).

This certificate reflects the status of the manufacturing site at the time of the inspection noted above. This certificate remains valid until the expiry date provided that re-inspections are conducted as determined by the Therapeutic Goods Administration as the issuing Authority. This certificate should not be relied upon to reflect the compliance status after the expiry date.

Issue Date: 06 June 2025

Expiry Date: 05 May 2026

This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration. The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.



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MANUFACTURING OPERATIONS

This certificate covers the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Manufacturing Step
Testing Laboratory - Blood Tissue Cellular	Virology Screening and Syphilis Testing NAT Testing

The following limitations are applicable to these manufacturing operations:

NAT Testing is restricted to HIV-I/II, HCV, HBV and West Nile Virus (WNV)

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The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.