Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Mr Fergus O'Connell
Head of Quality
Eurofins BioPharma Product Testing Australia Pty Ltd
6 Monterey Road
DANDENONG SOUTH VIC 3175

TGA Reference: E19-639088

Subject: Issue of GMP certificate MI-2026-LI-00517-1

Dear Mr O'Connell,

Please find enclosed the GMP certificate for your manufacturing premises as requested. Please do not hesitate to contact the Manufacturing Quality Branch if you require any further information.

Yours sincerely,

Signed and authorised by

Scott Pearce
Assistant Director
Licensing, Certification and Engagement Section
Manufacturing Quality Branch

16 February 2026

Contact: GMP@health.gov.au, Phone: 1800 020 653

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2026-LI-00517-1

Issued to:

Eurofins BioPharma Product Testing Australia Pty Ltd
ABN: 63 114 804 572

Manufacturing Site Address:

6 Monterey Road
DANDENONG SOUTH VIC 3175
AUSTRALIA

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a licence with number **MI-2019-LI-10319-1** to manufacture therapeutic goods under Section 38 of the *Therapeutic Goods Act 1989* and is included in the national inspection program following Section 40(4)(b) of the *Therapeutic Goods Act 1989.*

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 18 to 20 June 2024, it is considered that the manufacturer complies with the Good Manufacturing Practice requirements of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 01 February 2022.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status after the expiry date. This certificate should also not be relied upon where the status of the licence to manufacture therapeutic goods is not current. Where required, the Therapeutic Goods Administration as the issuing authority should be consulted.

Issue Date: **16 February 2026** **Expiry Date:** **20 June 2027**

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.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2026-LI-00517-1

MANUFACTURING OPERATIONS

The manufacturer above is authorised under Section 38 of the *Therapeutic Goods Act 1989* to carry out the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Testing chemical and physical
Medicine manufacture	Sterile & Non Sterile	All Dosage Forms	Therapeutic Goods for Clinical Trials	Testing chemical and physical
Medicine manufacture	Sterile & Non Sterile	All Dosage Forms	Not Applicable	Testing chemical and physical
Medicine manufacture	Non Sterile	All Dosage Forms	Registered Therapeutic Good	Testing microbial
Medicine manufacture	Non Sterile	All Dosage Forms	Therapeutic Goods for Clinical Trials	Testing microbial
Medicine manufacture	Non Sterile	All Dosage Forms	Not Applicable	Testing microbial
Medicine manufacture	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Endotoxin Testing
Medicine manufacture	Sterile & Non Sterile	All Dosage Forms	Therapeutic Goods for Clinical Trials	Endotoxin Testing
Medicine manufacture	Sterile & Non Sterile	All Dosage Forms	Not Applicable	Endotoxin Testing

In addition to the statutory conditions that apply to all licences granted under Section 38 of the *Therapeutic Goods Act 1989,* the following specific conditions have been imposed on the licence under Sections 40(1) and/or 40(2) of the *Therapeutic Goods Act 1989*:

No further conditions are applicable.

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TGA Health Safety Regulation