Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2023-LI-09493-1

Issued to:

Delta Laboratories Pty Ltd
ABN: 29 050 324 742

Manufacturing Site Address:

8 Warringah Close
SOMERSBY NSW 2250
Australia

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a licence with number **MI-25102004-LI-000050-1** 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 26 to 30 August 2022, 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 – 1 May 2021.

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: **4 August 2023** **Expiry Date:** **30 August 2025**

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

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2023-LI-09493-1

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	Non Sterile	Liquids Group	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Semi Solids	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Sunscreen manufacture	Non Sterile	Topical Sunscreen Forms, Liquids	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological 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*:

The authorisations described in Part 1 of the Licence are restricted as follows:

This licence does not authorise the manufacture of preparations containing:

a) penicillins, cephalosporins, antineoplastic drugs; or

b) steroids, except semi-solid preparations for topical use containing <1% hydrocortisone or <1% prednisolone; or

c) hormones, excepting preparations containing steroid hormones permitted in b) and adrenocorticotrophic hormone.

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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Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2023-LI-09492-1

Issued to:

Delta Laboratories Pty Ltd
ABN: 29 050 324 742

Manufacturing Site Address:

9 Chivers Road
Somersby NSW 2250
Australia

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a licence with number **MI-2017-LI-11602-1** 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 31 August 2022, 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 – 1 May 2021.

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: **4 August 2023** **Expiry Date:** **31 August 2025**

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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Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2023-LI-09492-1

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	Non Sterile	All Dosage Forms	Registered Therapeutic Good	Manufacture of dosage form
Medicine manufacture	Non Sterile	All Dosage Forms	Registered Therapeutic Good	Secondary packaging
Medicine manufacture	Non Sterile	Semi Solids	Registered Therapeutic Good	Testing chemical and physical
Medicine manufacture	Non Sterile	Liquids Group	Registered Therapeutic Good	Testing chemical and physical
Medicine manufacture	Non Sterile	Topical Sunscreen Forms, Liquids Group	Listed Therapeutic Good	Testing chemical and physical

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*:

The Manufacture of Dosage Form is restricted to storage, sampling and dispensing of starting materials. This application does not authorise the manufacture of preparations containing:

a) penicillins, cephalosporins, antineoplastic drugs; or

b) steroids, except semi-solid preparations for topical use containing <1% hydrocortisone or <1% prednisolone; or

c) hormones, excepting preparations containing steroid hormones permitted in b) and adrenocorticotrophic hormone.

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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