Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Geoff Acton
Managing Director
Antaria Pty Ltd
Unit 1 & 2 /81 Shettleston Street
Rocklea QLD 4106
AUSTRALIA

TGA Reference: E23-540199

Subject: Issue of GMP certificate MI-2023-LI-07756-1

Dear Mr Acton,

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

Katherine Clark
Director, GMP Operations and Strategy
Manufacturing Quality Branch

19 June 2023

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

Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2023-LI-07756-1

Issued to:

Antaria Pty Ltd
ABN: 36 092 404 727

Manufacturing Site Address:

Unit 1 & 2 /81 Shettleston Street
Rocklea QLD 4106
AUSTRALIA

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a licence with number **MI-2019-LI-02603-1** 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 16 to 19 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 July 2018.

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: **19 June 2023** **Expiry Date:** **19 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

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Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2023-LI-07756-1

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
Active Pharmaceutical Ingredient manufacture	Non Sterile	API - Not Defined	Not Applicable	Active material manufacture
Sunscreen manufacture	Non Sterile	Topical Sunscreen Forms	Listed Therapeutic Good	Testing chemical and physical
Sunscreen manufacture	Non Sterile	Topical Sunscreen Forms, Liquids Group	Listed Therapeutic Good	Manufacture of dosage form
Sunscreen manufacture	Non Sterile	Topical Sunscreen Forms, Semi Solids	Listed Therapeutic Good	Manufacture of dosage form

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 APIs is limited to non-sterile APIs and Proprietary Ingredient containing zinc oxide.

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