

Notified Body
Identification number

0805



Australian Government

Department of Health
Therapeutic Goods Administration

Certificate Number
MRA Q00064

EC Certificate

Full Quality Assurance Procedures

Annex II, excluding section 4, of the Council Directive 93/42/EEC on Medical Devices

Issued to

Manufacturer Name: Norseld Pty Ltd
Manufacturer Address: 18 Lowe Street
ADELAIDE SA 5000
Australia

For the Design and Manufacture of device categories listed on page 2 of this certificate.

This is to certify that the Full Quality Assurance System described below conforms to the relevant provisions of Annex II, excluding section 4, of the Council Directive 93/42/EEC on medical devices. Certification is based on an examination of the Full Quality Assurance System which applies at every stage from design to final controls.

This certificate has effect at all times from the commencement date, until the end of the period specified in the certificate (expiry date), or unless it has been suspended or revoked.

Commencement Date: 28 March 2019
Certificate Expiry Date: 27 March 2024
Associated CA Certificate: AU Q00224

This certificate is issued by:

ZHOU, Jie
Signed electronically
Delegate of the Secretary
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia

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Scope of Certificate

Manufacturer Facilities

Name and Address		Scope
1	Norseld Pty Ltd 18 Lowe Street ADELAIDE SA 5000 Australia	Design development and manufacture of dermatological lasers (Copper bromide)

Design and Manufacture of Device Categories

Description		Limitations (if applicable)
1	Skin Surface Treatment System Applicator, Laser	Class IIb

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Certificate History

Version	Details	Issue Date	File Reference
1.1	Initial certification	25 March 2009	2009/003407
2.1	Recertification certificate format change	29 April 2014	2014/004481
3.1	Recertification Update to device category from 'Laser, Copper Bromide, Class IIb' to 'Skin Surface Treatment System Applicator, Laser' with limitations Update to include manufacturing facility scope 'Design development and manufacture of dermatological lasers (Copper bromide)' Update to the certificate version numbers as internal TGA modification	28 March 2019	E18-353244
Certificate Location (Manufacturer Root File Number):			2010/010714