



Certificate Number
AU Q00224

Australian Government

Department of Health
Therapeutic Goods Administration

Conformity Assessment Certificate **Full Quality Assurance Procedures**

Schedule 3, Part 1 (excluding clause 1.6) of the *Therapeutic Goods (Medical Devices) Regulations 2002*

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 manufacturer's quality management system complies with the relevant provisions of Schedule 3, Part 1 (excluding clause 1.6) of the *Therapeutic Goods (Medical Devices) Regulations 2002*. Certification is based on an assessment of the Full Quality Management System, applied at each stage of medical device manufacture, from the design of a device until its final inspection before being supplied.

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

This certificate is issued under Section 41EE of the *Therapeutic Goods Act 1989* 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	



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Certificate History

Version	Details	Issue Date	File Reference
1.1	Initial certification	31 March 2009	2009/003407
2.1	Recertification certificate format change	01 April 2014	2014/004481
3.1	Recertification Update to include manufacturing facility scope 'Design development and manufacture of dermatological lasers (Copper bromide)' Update to the certificate version numbers as per internal TGA modification	28 March 2019	E18-353244
Certificate Location (Manufacturer Root File Number):			2010/010714



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Conditions

The following conditions apply automatically under Section 41EJ of the *Therapeutic Goods Act 1989*:

Entry and inspection powers

- (1) A conformity assessment certificate is subject to the conditions that the manufacturer in respect of whom the certificate is issued will:
 - (a) allow an authorised person:
 - (i) to enter, at any reasonable time, premises (including premises outside Australia) at which the person or any other person deals with medical devices of a kind covered by the certificate; and
 - (ii) while on those premises, to inspect those premises and medical devices of any kind on those premises and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of medical devices of any kind on those premises or any thing on those premises that relates to medical devices of any kind; and
 - (iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises; and
 - (b) if requested to do so by an authorised person:
 - (i) produce to the person such documents relating to devices of a kind covered by the certificate, or to the manufacturer's quality management system, as the person requires; and
 - (ii) allow the person to copy the documents.

Review

- (2) A conformity assessment certificate is subject to the condition that the manufacturer in respect of whom the certificate is issued will cooperate in any review by the Secretary of the certificate to determine whether the conformity assessment procedures relating to the following matters have been applied to the kinds of medical devices covered by the certificate:
 - (a) the application of quality management systems for the manufacture of medical devices;
 - (b) the certification of compliance with the essential principles;
 - (c) any other requirement of the conformity assessment procedures specified in the regulations made for the purposes of subsection 41EC(2).

Notification of substantial changes

- (3) A conformity assessment certificate is subject to the condition that the person in respect of whom the certificate is issued will notify the Secretary, in writing, of any plan for substantial changes to:
 - (a) quality management systems; or
 - (b) the product range covered by those systems; or
 - (c) the product design of kinds of medical devices;in respect of which the certificate is issued.

Fees

- (4) A conformity assessment certificate is subject to the condition that the applicant for the certificate will pay a fee, prescribed in the regulations, for a review under subsection (2), when the fee becomes due and payable.
- (5) The regulations may prescribe different levels of fees for different kinds of manufacturers and medical devices.

Conditions in regulations

- (5A) A conformity assessment certificate is subject to any conditions prescribed by the regulations for the purposes of this subsection.

Conditions do not limit other conditions

- (6) A condition imposed under this section is in addition to any conditions imposed under this Division.