Certificate Number
MRA Q00064

Australian Government

Department of Health
Therapeutic Goods Administration

# EC Certificate

## Full Quality Assurance Procedures

This is to certify that the Full Quality Assurance System described below conforms to the relevant provisions of Annex II, section 3 with the exemption of 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.

| | |
|---|---|
| **Manufacturer Name:** | Norseld Pty Ltd |
| **Manufacturer Address:** | 18 Lowe Street<br>Adelaide SA 5000<br>Australia |
| **Commencement Date:** | 29 April 2014 |
| **Certificate Expiry Date:** | 28 April 2019 |
| **Associated CA Cerificate** | AU Q00224 |

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. Its validity is dependent on the currency of the associated CA Certificate listed above.

This certificate is issued by:

**Maria Yang**
*Signed electronically*
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606
Australia

**Notified Body Identification Number**

0805

Australian Government
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Therapeutic Goods Administration

# Scope of Certificate

## Device Categories

| | Description | Limitations (if applicable) |
|---|---|---|
| 1. | Laser, Copper Bromide, Class IIb | |

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# Certificate History

| Version | Details | Issue Date | File Reference |
|---|---|---|---|
| 1 | Initial certification | 25 March 2009 | 2009/003407 |
| 2 | Recertification, certificate format change | 29 April 2014 | 2014/004481 |
| Certificate Location (Manufacturer Root File Number): | | | 2010/010714 |