Certificate Number
AU Q00196

Australian Government
Department of Health and Aged Care
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: Cigweld Pty Ltd

Manufacturer Address: 71 Gower Street
PRESTON VIC 3072
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: 07 December 2023

Certificate Expiry Date: 16 November 2028

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

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

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Scope of Certificate

Manufacturer Facilities

	Name and Address	Scope
1	Cigweld Pty Ltd 71 Gower Street PRESTON VIC 3072 Australia	Design, assembly, testing, packaging, labelling, final release, warehousing and dispatch

Design and Manufacture of Device Categories

	Description	Limitations (if applicable)
1	Resuscitator pulmonary gas-powered	
2	Humidifier non-heated	
3	Mask air/oxygen	
4	Regulator gas high-pressure	
5	Suction unit gas powered	
6	Suction unit vacuum	
7	Flowmeter oxygen therapy	