Certificate Number
AU Q00557

Australian Government
Department of Health, Disability and Ageing
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:** Dongguan Medica Technology Co Ltd

**Manufacturer Address:** Room 408, Building No.1
No.136 Gang Jian Road,
Chang Ping Town, Dongguan,
GUANGDONG 523781
China

**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:** 12 May 2026

**Certificate Expiry Date:** 12 May 2031

**Additional Conditions:**

The following additional conditions have been imposed by the Delegate to the Secretary under Section 41EK or 41EL of the Act:

1. The manufacturer must submit the evidence of device-level venting verification testing that is consistent with UL 8139 Section 31 or a higher safety standard. The testing results must demonstrate that during a Li-ion cell venting event, the device effectively relieves internal pressure, such that the mouthpiece remains intact and the pressure wave is directed away from the mouthpiece along the longitudinal axis.

   The evidence must be submitted to devices@tga.gov.au within six (6) months of the date of issuing of this certificate and no later than 12 November 2026.

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

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# Scope of Certificate

## Manufacturer Facilities

| | Name and Address | Scope |
|---|---|---|
| 1 | Dongguan Medica Technology Co., Ltd<br>Room 408, Building No.1<br>No. 136 Gang Jian Road<br>Chang Ping Town, Dongguan<br>GUANGDONG 523781<br>China | Develop and manufacture vaporizers |

## Design and Manufacture of Device Categories

| | Description | Limitations (if applicable) |
|---|---|---|
| 1 | Ambulatory nebulizer - heated | Class IIb |

## Critical Suppliers

| | Name and Address | Scope |
|---|---|---|
| 1 | Shenzhen Lingtai Electronic Technology Co., Ltd<br>B701, 1978 Longhai International<br>Tongsheng Community, Dalang Street<br>Longhua District, Shenzhen<br>GUANGDONG 518110<br>China | Supply of the lithium battery |
| 2 | Dongguan Guoyan Electric Heating Material Co., Ltd<br>Sima village industrial zone<br>Chang ping Town, Dongguan City<br>GUANGDONG 523570<br>China | Supply of the ceramic furnace |

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# Certificate History

| Version | Details | Issue Date | File Reference |
|---|---|---|---|
| 1.1 | Initial Certification | 12 May 2026 | E25-558643 |
| Certificate Location (Manufacturer Root File Number): | | | E25-558647 |

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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.