



Certificate Number  
AU Q00345

**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:** Malmot Australia Pty Ltd  
**Manufacturer Address:** 9-11 McKay Avenue  
LEETON NSW 2705  
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:** 25 November 2019  
**Certificate Expiry Date:** 25 November 2024

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

**Dr Ying Huang**  
*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	Malmet Australia Pty Ltd 9-11 Mckay Avenue LEETON NSW 2705 Australia	Design, product identification, manufacture, labelling, testing, final release, warehousing and dispatch

### Design and Manufacture of Device Categories

Description	Limitations (if applicable)
1 Decontamination sanitising washers	



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## Certificate History

Version	Details	Issue Date	File Reference
1.1	Initial certification	27 November 2014	2013/021697
2.1	Recertification Addition of scope of activities undertaken at the manufacturer's facility Update to certificate version number as part of TGA internal modification	25 November 2019	E19-638278
Certificate Location (Manufacturer Root File Number):			2014/047792



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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.