



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|--|
| Summary for ARTG Entry: | 371189 | Lycopodium Process Industries Pty Ltd - Intensive-care ventilator, general-purpose |
| ARTG entry for | Medical Device Included (Export Only) Class 1 | |
| Sponsor | Lycopodium Process Industries Pty Ltd | |
| Postal Address | Level 5 1 Adelaide Terrace, East Perth, WA, 6004 Australia | |
| ARTG Start Date | 16/07/2021 | |
| Product Category | Medical Device Class 1 | |
| Status | Active | |
| Approval Area | Medical Devices | |

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

| Name | Address |
|---------------------------------------|---|
| Lycopodium Process Industries Pty Ltd | Upper Level 253 - 269 Wellington Road Mulgrave, VIC, 3179 Australia |

Products

1 . Intensive-care ventilator, general-purpose

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|-------------------------|--|-----------------------|------------|
| Product Type | Single Device Product | Effective Date | 16/07/2021 |
| GMDN | 47244 Intensive-care ventilator, general-purpose | | |
| Intended Purpose | Intended to be used by health care professionals in a critical care environment to provide mechanical ventilation for children and adult patients (+30 kg to 120 kg) as a temporising measure while they are not otherwise able to support independent breathing | | |

Specific Conditions

No Specific Conditions included on Record

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