



Australian Register of Therapeutic Goods Certificate

Issued to

Rapp Australia Pty Ltd

for approval to supply

Rapp Australia Pty Ltd - Intensive-care ventilator, general-purpose

ARTG Identifier	333747
ARTG Start date	8/04/2020
Product Category	Medical Device Included Class IIb
GMDN	47244
GMDN Term	Intensive-care ventilator, general-purpose
Intended Purpose	The critical care ventilator is an electronically controlled, electronically powered machine, which is used in ICU for the critical care, in Respiratory Department or Emergency Department for the rescue and therapy of the patient with respiratory insufficiency, and in other departments for providing respiratory support for the patient. The ventilator is applicable for patients weighing at least 3 kg (7 lbs.), who require the following types of ventilatory support: Positive Pressure Ventilation, delivered invasively (by ET or Tracheotomy tube) or non-invasively (by mask) via Assist/Control, SIMV, CPAP and other modes of ventilation. The ventilator is intended for use in hospital and hospital-type facilities. It may be used during intra-hospital transport provided that electrical power is supplied.

Manufacturer Details	Address	Certificate number(s)
Beijing Aeonmed Co Ltd	Room 405 Basement 1 to 4th Floor of 901 Unit Building 9 No 26 Outer Ring West Rd Fengtai District, Beijing, 100070 China	DV-2020-MC-04707-1

ARTG Standard Conditions

The above Medical Device Included Class IIb has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. Intensive-care ventilator, general-purpose

Product Specific Conditions

No specific conditions have been recorded against this entry.

