



Australian Register of Therapeutic Goods Certificate

Issued to

Rapp Australia Pty Ltd

for approval to supply

Rapp Australia Pty Ltd - Transport electric ventilator

ARTG Identifier	333748
ARTG Start date	8/04/2020
Product Category	Medical Device Included Class IIb
GMDN	36289
GMDN Term	Transport electric ventilator
Intended Purpose	The emergency ventilator is a pneumatically driven electrically controlled machine. It can provide patients with mechanical ventilation, and also can monitor and display of ventilation parameters. The ventilator is mainly used in the emergency rooms of hospitals, transfer after operations, field and occasions where first-aid or transfer is needed for care of adult, paediatric, infant patients weighting at least 3.5 kg.

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. Transport electric ventilator

Product Specific Conditions

No specific conditions have been recorded against this entry.