



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

AMBU Australia Pty Ltd

for approval to supply

AMBU Australia Pty Ltd - Airway pressure monitor, non-powered

ARTG Identifier	295414
ARTG Start date	23/10/2017
Product Category	Medical Device Included Class IIa
GMDN	46634
GMDN Term	Airway pressure monitor, non-powered
Intended Purpose	Manometer used with an resuscitators, hyperinflation bags, CPAP and circuit devices to provide a visual indication of a patient's airway pressure.

Manufacturer Details	Address	Certificate number(s)
Ambu AS	Baltorpbakken 13 Ballerup, , DK-2750 Denmark	DV-2009-MC-13176-3

ARTG Standard Conditions

The above Medical Device Included Class IIa 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. Airway pressure monitor, non-powered

Product Specific Conditions

No specific conditions have been recorded against this entry.

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