Australian Register of Therapeutic Goods Certificate

Issued to

AMBU Australia Pty Ltd

for approval to supply

AMBU Australia Pty Ltd - PEEP valve, single-use

ARTG Identifier	141016
ARTG Start Date	26/06/2007
Product Category	Medical Device Included Class IIa
GMDN	46823
GMDN Term	PEEP valve, single-use
Intended Purpose	The Ambu Disposable PEEP Valve is suitable for use with resuscitators, portable ventilators, and CPAP systems which have airtight connections and can operate with a positive pressure in the patient connection throughout the entire expiratory phase and is adjustable for the selection of positive end expiratory pressures between 1.5 and 20 centimeters of water (cmH2O)

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. PEEP valve, single-use

Product Specific Conditions

· No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

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