



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 - Pressure monitor, tube cuff

ARTG Identifier	319421
ARTG Start date	28/06/2019
Product Category	Medical Device Included Class Im
GMDN	36877
GMDN Term	Pressure monitor, tube cuff
Intended Purpose	A hand held non electronic manometer intended to measure the pressure of an endotracheal and laryngeal cuff. This device is not an inflator.

Manufacturer Details	Address	Certificate number(s)
Vbm Medizintechnik GmbH	Einsteinstr 1 , Sulz a N, 72172 Germany	DV-2018-MC-21676-1

ARTG Standard Conditions

The above Medical Device Included Class Im 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. Pressure monitor, tube cuff

Product Specific Conditions

No specific conditions have been recorded against this entry.

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