



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 - Anaesthesia face mask, non-scavenging,
single-use**

ARTG Identifier	330227
ARTG Start date	20/02/2020
Product Category	Medical Device Included Class IIa
GMDN	46232
GMDN Term	Anaesthesia face mask, non-scavenging, single-use
Intended Purpose	The Ambu® UltraSeal™ II is a disposable face mask developed specifically for anaesthesia departments and designed for use with manual and automatic ventilators and anaesthesia machines.

Manufacturer Details	Address	Certificate number(s)
Besmed Health Business Corp	No 5 Lane 116 Wu-Kong 2nd Road Wu-Ku District New Taipei City, Taiwan, 24888 Taiwan	DV-2019-MC-14315-1

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. Anaesthesia face mask, non-scavenging, 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

ARTG Identifier: 330227
ARTG Start Date: 20/02/2020