



Australian Government

Department of Health and Aged Care
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	416098
ARTG Start Date	2/08/2023
Product Category	Medical Device Included Class IIb
GMDN	46232
GMDN Term	Anaesthesia face mask, non-scavenging, single-use
Intended Purpose	The Ambu face masks (Ambu Disposable Face Mask and Ambu King Mask) are disposable face masks intended for oxygenating and ventilating the airways and/or to direct anaesthesia to the upper airways. The device is for use in hospital and pre-hospital (EMS) environments. For use by CPR and/or medical professionals trained in airway management only.

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 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. 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: 416098
ARTG Start Date: 2/08/2023