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 - Endobronchial tube

ARTG Identifier	413733
ARTG Start Date	19/07/2023
Product Category	Medical Device Included Class IIb
GMDN	31328
GMDN Term	Endobronchial tube
Intended Purpose	A kit intended for the visual guidance and positioning of the VivaSight Endobronchial 2 DLT and SDL. The introduction of the endobronchial tube enables one lung ventilation (OLV). The kit consists of, the VivaSight Endobronchial Tube (sterile), Adaptor Cable (non-sterile) and 2 suction catheters (sterile). The kit is supplied non-sterile.

Manufacturer Details	Address	Certificate number(s)
Ambu AS	Baltorpbakken 13 Ballerup , , DK-2750 Denmark	DV-2021-MC-17322-1

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. Endobronchial tube

Product Specific Conditions

No specific conditions have been recorded against this entry.