



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 - Flexible video bronchoscope, single-use

<b>ARTG Identifier</b>	378052
<b>ARTG Start Date</b>	16/11/2021
<b>Product Category</b>	Medical Device Included Class IIa
<b>GMDN</b>	60963
<b>GMDN Term</b>	Flexible video bronchoscope, single-use
<b>Intended Purpose</b>	A set that contains an aScope Bronchoscope and a aScope Bronchosampler. It is intended to be used for Broncho Alveolar Lavage (BAL) or Bronchial Wash (BW) procedure and enable aspiration and collection of a fluid sample(s) from the bronchial or alveolar part of the lung.

Manufacturer Details	Address	Certificate number(s)
Ambu AS	Baltorpbakken 13 Ballerup , , DK-2750 Denmark	DV-2021-MC-16940-1

### 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. Flexible video bronchoscope, 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: 378052  
ARTG Start Date: 16/11/2021