



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 - Flexible video gastroscope, single-use

<b>ARTG Identifier</b>	388998
<b>ARTG Start Date</b>	24/05/2022
<b>Product Category</b>	Medical Device Included Class IIa
<b>GMDN</b>	65299
<b>GMDN Term</b>	Flexible video gastroscope, single-use
<b>Intended Purpose</b>	The aScope Gastro is a sterile, single use flexible gastroscope intended to be used for endoscopic access to and examination of the upper gastrointestinal anatomy. It provides visualisation via a compatible Ambu display unit and to be used with endo-therapy accessories and other ancillary equipment.

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 gastroscope, single-use

### Product Specific Conditions

No specific conditions have been recorded against this entry.

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