



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 duodenoscope, single-use

ARTG Identifier	375476
ARTG Start Date	29/09/2021
Product Category	Medical Device Included Class IIa
GMDN	64067
GMDN Term	Flexible video duodenoscope, single-use
Intended Purpose	The aScope™ Duodeno is designed to be used with the aBox™ Duodeno, endoscopic accessories (e.g. biopsy forceps) and other ancillary equipment (e.g. medical grade video monitor) for endoscopy and endoscopic surgery within the duodenum.

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 duodenoscope, single-use

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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