



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 - Endoscopic video image processor

ARTG Identifier	375475
ARTG Start Date	29/09/2021
Product Category	Medical Device Included Class IIa
GMDN	18034
GMDN Term	Endoscopic video image processor
Intended Purpose	The aBox™ Duodeno is designed to be used with the aScope™ Duodeno, 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. Endoscopic video image processor

Product Specific Conditions

No specific conditions have been recorded against this entry.

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ARTG Identifier: 375475
ARTG Start Date: 29/09/2021