



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 cystoscope, single-use

ARTG Identifier	409510
ARTG Start Date	24/05/2023
Product Category	Medical Device Included Class IIa
GMDN	61728
GMDN Term	Flexible video cystoscope, single-use
Intended Purpose	A sterile endoscope with a flexible inserted portion intended for the visual examination and treatment of the bladder and the urinary tract by introduction through the urethra. This device offers consistent quality without any deterioration of image or bending quality for both outpatient clinic and inpatient consult procedures. This is a single-use device.

Manufacturer Details	Address	Certificate number(s)
Ambu AS	Baltorpbakken 13 Ballerup , , DK-2750 Denmark	DV-2009-MC-13176-3

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 cystoscope, 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

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