

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 display monitor

ARTG Identifier 337704

ARTG Start Date 11/06/2020

Product Category Medical Device Included Class 1

GMDN 56654

GMDN Term Endoscopic video image display monitor

Intended Purpose The aView 2 advance monitor is intended to display images from

endoscopic procedures It compatible with DICOM and PACS systems for use with various scopes including aScope 4 RhinoLaryngo, aScope 4

Broncho and aScope 4 Cysto.

Manufacturer Details	Address	Certificate number(s)
	Baltorpbakken 13 Ballerup , , DK-2750 Denmark	

ARTG Standard Conditions

The above Medical Device Included Class 1 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 display monitor

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: 337704 ARTG Start Date: 11/06/2020