

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 - Electrode, electromyograph

ARTG Identifier	108391	
ARTG Start date	9/09/2004	
Product Category	Medical Device Included Class IIa	
GMDN	11441	
GMDN Term	Electrode, electromyograph	
Intended Purpose	For recording bioelectrical signals during an electromyograph	

Manufacturer Details	Address	Certificate number(s)
Ambu AS	Baltorpbakken 13 Ballerup, , DK-2750 Denmark	DV-2010-MC-03829-3

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. Electrode, electromyograph

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: 108391 ARTG Start Date: 9/09/2004